FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/CPD 300SL

Product name(s):

Major 300SL, Cloe 300SL, ProSto 300SL

Chemical active substance(s):
Clopyralid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: INNVIGO Sp. z o.o.

Submission date: 12.2021

MS Finalisation date: 09.2022; 03.2023;10.2024; 11.2024

Version history

When	What
December 2021	New data for CHR/H/CPD based on the renewal of active substance - clopyralid. New data is highlighted in yellow.
September 2022	ZRMs evaluated submitted by Applicant dRR
March 2023	The final Registration Report
October 2024	Corrected PECgw
October 2024	Correction made by the Fate section
November 2024	Corrections made by the Fate section

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8 Fate and behaviour in the environment (KCP 9)

In the following document, data for active substance clopyralid was described during its renewal. Data matching and equivalent matching studies have been evaluated by RMS. Therefore, Applicant is allowed to refer to the endpoints and input parameters determined at the European level.

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. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion** **PECgw**
					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/hL a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL, CZ, RO, SLO, HU, SK, LT, LV	Winter oilseed rape Brassica napus, (BRSNW)	F	broadleaf weeds	Spray, medium sprayer	Spring BBCH 30–51	a) 1 b) 1	n/a	a) 0.4 b) 0.4	**a) 0.12** b) **0.12**	200-300	n/a		R**
2	PL, CZ, RO	Winter oilseed rape Brassica napus, (BRSNW)	F	annual and perennial broadleaf weeds	Spray, medium sprayer	Spring BBCH 30–50	a) 1 b) 1	n/a	a) 0.078+0.3 b) 0.078+0.3 CHR/H/PCR* + CHR/H/CPD*	**a)** 0.0234+**0.09** b) 0.0234 +**0.09** CHR/H/PCR* + CHR/H/CPD*	200-300	n/a		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion** **PECgw**
					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/hL 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			
3	PL, CZ, RO	Winter oilseed rape Brassica napus, (BRSNW)	F	broadleaf weeds	Spray, medium sprayer	Autumn BBCH 20–21	a) 1 b) 1	n/a	a) 0.2 b) 0.2	**a) 0.06** b) **0.06**	200-300	n/a		A
4	PL, CZ, RO	Winter oilseed rape Brassica napus, (BRSNW)	F	annual and perennial broadleaf weeds	Spray, medium sprayer	Autumn BBCH ~~13-14~~ 20–21	a) 1 b) 1	n/a	a) 0.078+0.3 b) 0.078+0.3 CHR/H/PCR* + CHR/H/CPD*	a) 0.0234+**0.09** b) 0.0234 +**0.09** CHR/H/PCR* + **CHR/H/CPD***	200-300	n/a		R**
~~5~~	~~PL, CZ, RO~~	~~Winter oilseed rape Brassica napus, (BRSNW)~~	~~F~~	~~annual and perennial broadleaf weeds~~	~~Spray medium sprayer~~	~~Autumn BBCH 13-14~~	~~a) 1 a) 1~~	~~n/a~~	~~a) 0,078+0,3+1.5 b) 0,078+0,3+1.5 CHR/H/PCR* + CHR/H/CPD* + CHR/H/MTC*~~	~~a) 0.0234+**0.09**+0.750 b) 0.0234+**0.09**+0.750 CHR/H/PCR* + **CHR/H/CPD*** + CHR/H/MTC*~~	~~200-300~~	~~n/a~~		~~C~~
6	PL, CZ, RO, SLO	Winter wheat Triticum aestivum (TRZAW);	F	broadleaf weeds	Spray medium sprayer	Spring BBCH 20-29 CZ: BBCH 21-29	a) 1 b) 1	n/a	a) 0.4 b) 0.4	**a) 0.12** b) **0.12**	200-300	n/a		R**
7	PL, CZ, RO, SLO, LT, LV	Sugar beet Beta vulgaris (BEAVP)	F	broadleaf weeds	Spray medium sprayer	BBCH 12 - 14	a) 1 a) 1	n/a	a) 0.4 b) 0.4	**a) 0.12** **b) 0.12**	200-300	n/a		R**
8	PL, CZ, RO, SLO,	Sugar beet Beta vulgaris	F	broadleaf weeds	Spray medium sprayer	BBCH 12-14	b) 3 c) 3	6-10	a) 0.2 b) 0.6	**a) 0.06** **b) 0.18**	200-300	n/a		R**

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion** **PECgw**
					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/hL 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			
	LT, LV	(BEAVP)												
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)														
7														
8														
Minor uses according to Article 51 (zonal uses)														
9														
10														
Minor uses according to Article 51 (interzonal uses)														
11														
12														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

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

*The risk assessment for CHR/H/PCR and CHR/H/MTC was covered by the individual registration process. CHR/H/PCR and CHR/H/MTC was evaluated and registered in Poland.

** The risk mitigation measures are required

Table 8.1-2: Assessed (critical) uses during approval of Clopyralid concerning the Section Environmental Fate (EFSA Journal 2018;16(7):5389)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Winter cereal (wheat, barley oat, rye, triticale, spelt)	CEU/SEU	GF-1374	F	Broad-leaf weeds	EC	80 g/L Clopyralid + 2.5 g/L florasulam + 144.1 g/L fluroxypyr meptyl (equivalent to 100 g/L fluroxypyr)	Over all broad cast foliar spray	BBCH 13-39 (1st Feb to 30th of June)	1	n/a	Clopyralid: 0.02 to 0.1 kg as/hL + Florasulam 0.0000625 to 0.0003125 kg as/hL + Fluroxypyr meptyl: 0.036 to 0.18 kg as/hL (0.025 to 0.125 kg ae/hL)	80-400	Clopyralid 0.08 kg as/ha + Florasulam 0.0025 kg as/ha + Fluroxypyr-meptyl 0.144 kg as/ha (0.100 kg ae/ha)	n/a	Dose: 1L GF-1374/ha Due to clopyralid content, straw treated with GF-1374 must not be used for compost production (for cultivating susceptible vegetables).
Established permanent pasture	CEU/SEU	GF-1374	F	Broadleaf weeds	EC	80 g/L Clopyralid + 2.5 g/L florasulam + 144.1 g/L fluroxypyr meptyl (equivalent to 100 g/L	Over all broad cast foliar spray	1st Feb to 30th September	1	n/a	Clopyralid: 0.03 to 0.15 kg as/hL + Florasulam 0.00009375 to 0.00046875 kg as/hL + Fluroxypyr	100-400	Clopyralid 0.12 kg as/ha + Florasulam 0.00375 kg as/ha + Fluroxypyr-meptyl 0.216	7 to 14 days (see note 1)	Dose: 1.5L GF-1374/ha. Note 1: PHI: 7 days for CEU and 14 days for SEU is the interval before any crop cutting or grazing. Fluroxypyr is the limiting factor.

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Clopyralid potentially relevant for exposure assessment

No metabolites. No relevant metabolites of clopyralid were identified during the EU peer review of the active substance (EFSA Journal 2018; 16(7):5389).

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 Clopyralid and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Clopyralid - laboratory studies (EFSA Journal 2018;16(7):5389)

Parent	Dark aerobic conditions						
Soil type	Biomass mgC/100 g	pH[a)]	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Parabraunerde (silt loam)	47	7.7	20 / 18.63 [c]	44.4 / 147.3	34.2	6.796	SFO
Marcham (sandy clay loam)	170	8.3	20 / 20.19 [c]	34.5 / 114.7	32.4	5.478	SFO
Castle Rising (sandy loam)	313	8	20 / 65.13 [c]	26.3 / 87.3	26.3	8.284	SFO
Speyer 2.1 (sand)	NA	6.5	20 / 12.58 [c]	64.6 / 214.6	64.6	5.466	SFO
Speyer 2.2 (sand)	110	6.3	20 / 18.56 [c]	16.2 / 53.8	16.2	7.78	SFO
Marshall county (silt loam)	11.92	6	25 / 23.42 [d]	8.6 / 28.5	11.6	6.49	SFO
A (sandy loam)	33.2	6.2	20 / 24.28 [e]	16.5 / 54.8	16.5	4.856	SFO
B (clay loam)	78.2	7.6	20 / 28.05 [e]	23 / 76.4	23.0	6.767	SFO
C (clay loam)	48.5	5.6	20 / 48.17 [e]	4.9 / 16.2	4.9	12.73	SFO
D (loam)	70.9	7.5	20 / 35.30 [e]	9.8 / 32.4	9.8	10.17	SFO
Geometric mean (if not pH dependent)					19.1		
pH dependence					No		

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] Reported soil moisture: 40% of maximum WHC
[d)] Reported soil moisture: 75% of 1/3 bar WHC
[e)] Reported soil moisture: 45% WHC

ZRMS comments:
Laboratory data on aerobic soil degradation of clopyralid and metabolites are in accordance with the LoEP (EFSA Journal 2018; 16 (8):5389).

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3-2: Summary of anaerobic degradation rates for Clopyralid - laboratory studies (EFSA Journal 2018;16(7):5389)

Parent	**Dark anaerobic conditions**						
Soil type	Biomass mgC/100 g	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Sandy loam	8.9	7.4	20 / flooded	>1 year	> 1year	n/a	First-order
Geometric mean (if not pH dependent)							

[a)] Measured in 0.01M CaCl2
[b)] Normalised using a Q10 of 2.58

8.4 Field studies (KCP 9.1.1.2)

In satisfactory field dissipation studies carried out at four sites in France, three in Germany, and one each in the UK, Denmark and Spain (spray application to the soil surface on bare soil plots in late spring or in autumn), clopyralid exhibited low to moderate persistence. Field study DegT50 values were derived following normalisation to FOCUS reference conditions (20°C and pF2 soil moisture) following the EFSA (2014) DegT50 guidance (EFSA Journal 2018;16(7):5389).

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

8.4.1.1 Clopyralid and its metabolites

Table 8.3-3: Summary of soil dissipation for Clopyralid - field studies (EFSA Journal 2018;16(7):5389)

Parent								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm [b)]	Method of calculation
Loamy sand (bare)	Bargstedt, Germany	4.3	0-100	21	69.6	23.9	13	SFO
Loam (bare)	Wilson, UK	6.2	0-100	16.7	55.6	22.6	13.5	SFO
Silty clay loam (bare)	Sermaises, France	7	0-100	16.3	54	19.3	7.5	SFO
Silty clay loam (bare)	Ansonville, France	8.2	0-20	0.16	12.1	5.36	2.07	DFOP / SFO Norm
Clay loam (bare)	Mainbervilliers, France	7.1	0-20	6.04	28.3	7.22	2.7	DFOP / SFO Norm
Silty clay loam (bare)	Oederquart, Germany	7.5	0-20	16.2	53.9	12	5.69	SFO
Sandy clay loam (bare)	Middlefart, Denmark	7.5	0-20	23.7	78.7	13.1	8.46	SFO
Clay loam (bare)	Canals, Spain	8.0	0-100	13.7	45.5	19.2	12.3	SFO
Silty clay loam (bare)	B. Württemberg, Germany	7.4[c]	0-100	10.2	33.9	7.94	9.34	SFO
Silt loam (bare)	B. d'Islemade, France	7.3[c]	0-100	9.11	30.3	17.6	7.41	SFO
Geometric mean (if not pH dependent)							7.05	
pH dependence				No				

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[c)] 0-30 cm

ZRMS comments:
Aerobic degradation data on clopyralid from field studies are in accordance with the LoEP (EFSA Journal 2018; 16 (8):5389).

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

No accumulation observed in the field studies (EFSA Journal 2018;16(7):5389).

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 and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for Clopyralid (EFSA Journal 2018;16(7):5389)

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Merzenhausen	1.00	7.19	0.051	Not Calculated	0.0057	0.57[b]	0.9[c]
Kaldenkirchen	0.98	5.34	0.048		0.0267	2.72[b]	0.9[c]
Lanna	2.06	6.62	0.151		0.0054	0.26[b]	0.9[c]
Overhetfeld	0.93	6.49	0.032		0.0125	1.34[b]	0.9[c]
Calke sandy loam	3.15	5.7	0.139[b]	Not Calculated	0.01	0.5	0.489
Longwoods sandy loam	3.13	7.4	0.069[b]		0.08	2.5	0.9[c]
LUFA 2.1 loamy sand	0.68	4.9	0.040[b]		0.03	4.1	0.9[c]
Quilen loam	4.02	6.9	0.356[b]		0.16	3.9	0.804
DU-L-PF clay loam	6.47	6.3	0.282[b]		0.14	2.1	0.829
Geometric mean (if not pH dependent)*					0.026	1.41	
Arithmetic mean (if not pH dependent)							0.836
pH dependence			No				

a) Measured calcium chloride solution
b) Calculated and reported in M-CA, not in the study report
c) For modelling each soil was checked against OECD 106 reliability criterion (Kd > 0.1 for direct method and Kd > 0.3 for indirect method). Freundlich coefficient of soils not meeting the criterios was set to 0.9.
* Only relevant after implementation of the published EFSA guidance.

ZRMS comments:
The adsorption/desorption endpoints of clopyralid reflect the outcome of the EU peer-review and are in accordance with EFSA Conclusion 2018.

8.5.2 Column leaching (KCP 9.1.2.1)

Not relevant (EFSA Journal 2018;16(7):5389)

8.5.3 Lysimeter studies (KCP 9.1.2.2)

No new lysimeter studies were performed for the product formulation.

Four lysimeter studies were evaluated and reported in the EFSA conclusion for clopyralid (EFSA, 2018). Occasional exceedances of 0.1 µg/L were detected in leachate samples, but the annual average concentrations of clopyralid were below 0.1 µg/L in all studies. In one lysimeter, the annual average concentration of unidentified radioactivity was 0.113 µg/L in one year.

According to EFSA Journal 2018;16(7):5389, the following Lysimeter/ field leaching study is available:
1) Germany, spring application of 150 or 200 g clopyralid/ha on oilseed rape + partly a second application of 125 g a.s./ha on winter wheat 1 year later:
A total of 935 mm of precipitation was received in year 1 and 895.5 mm in year 2. 438 – 478 L of leachate was collected in year 1 and 411-437 L in year 2.
In the first year of application the annual average concentration in leachate was < 0.050 µg/L ai equivalent, however occasional exceedings of 0.10 µg/L were detected.
In the second year the annual average concentration in leachate was < 0.055 µg/L. In the soil cores the majority of radioactivity remained in the top layers of 0 – 40 cm. 11.49 – 12.38 % of AR was found in soil 2 years after the single application.
In the third year the annual average concentration in leachate was 0.001 – 0.019 µg/L. Maximum concentration of ai equivalents in leachate of the third year was 0.043 µg/L in the lysimeter which received two applications. In the soil cores 9.82 – 10.11 % of RA was found 2 years after the second application. The total recovery of RA in the three year monitoring period was 12.81 – 17.53 % of the applied RA, considering the both applications.
2) Germany, winter oilseed rape, 120 or 141 g clopyralid/ha, 847 and 1011 mm rain in years 1 and 204 – 417 mm of leachate was collected in two lysimeters in years 1 and 2. In the lysimeter with higher application rate the annual average concentration of unidentified radioactivity was 0.127 µg/L equivalent in year 1, but taken over the whole study period of two years, the average concentration was 0.064 – 0.078 µg/L equivalent. Occasional exceedings of 0.1 µg/L were detected soon after the application in both lysimeters.
3) Germany, sugar beet, spring application of 118 g clopyralid/ha, 754 and 871 mm rainfall in years 1 and 2:113 and 196 mm of leachate was collected in years 1 and 2. Annual average concentrations of clopyralid were 0.010 and 0.002 µg/L in years 1 and 2. Unidentified radioactivity was present in the leachate at annual average concentrations of 0.113 and 0.031 µg/L equivalent in years 1 and 2, respectively. Dissolved CO_2 was the major metabolite observed in the leachate. 24.6 % of AR was measured in soil after 111 days, and after 2 years 13.2 % of AR was recovered. (It was considered very unlikely that a single unknown substance would exceed an annual concentration of 0.1 µg/L.)
4) Germany, sugar beet, spring application of 99 or 185 g clopyralid/ha, ca 700 mm rainfall/year: In year 1 the leachate volume was 180 and 248 mm, and in year 2 70 to 79 mm. Annual average concentrations in the leachate were not calculated, but in individual samples the clopyralid concentrations up to 0.135 µg/L were detected occasionally. 26 months after application 20 % of AR was recovered from the soil, majority of it in tillage layer (0 – 30 cm).

8.5.4 Field leaching studies (KCP 9.1.2.3)

See 8.5.3.

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 Clopyralid and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of 8.6.2 Clopyralid (EFSA Journal 2018;16(7):5389)

Parent Clopyralid	**Distribution: max in water 100.13 % at 0d, 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 / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Loamy sand	6.5	5.5	20	>500 days	n/a	128	n/a	>500 days	n/a	First-order
Sandy silt loam	8.16	7.7	20	>500 days	n/a	167	n/a	>500 days	n/a	First-order
Geometric mean at 20°C[b]						148				

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58

Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d
Loamy sand	6.5	5.5	2% after 100 d	5% at 100 d
Sandy silt loam	8.1	7.7	5% after 100 d	5% at 100 d

(Hall & al. 2002)

- **Hydrolytic degradation**

Hydrolytic degradation of the active substance and metabolites > 10 %

pH 4, 50 °C: DT_{50} >1 year (Smith 2000)
pH 7: 50 °C: DT_{50} >1 year
pH 9: 50 °C: DT_{50} >1 year

- **Aqueous photochemical degradation**

Photolytic degradation of active substance and metabolites above 10 %

Xenon lamp for an equivalent of 41.6 days of summer sunlight at 40 ºN, DT50 ca 38000 days, no photolytic degradation products in aqueous sterile buffer could be observed. Photolysis is not a significant route of degradation of clopyralid in waters

Quantum yield of direct phototransformation in water at > 290 nm
1.01 x· 10 –6 mol · Einstein -1 (Ponte 2014)

- **Ready biodegradability**

Clopyralid isn't readily biodegradable.

In the Modified Sturm Test the cumulative CO2 production of clopyralid was 5-10% of the theoretical maximum after 27 days. (Jenkins 1991)

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

8.7.1 Justification for new endpoints

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

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

Use No.	1, 2	3,4,5	6	7	8
Crop	Winter oilseed rape	Winter oilseed rape	Winter wheat	Sugar beet	Sugar beet
Application rate (g as/ha)	120	90	120	120	60
Number of applications/interval	1	1	1	1	3/ 6d
Crop interception (%)	40	40	20	20	20
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm	5cm	5cm	5cm	5cm

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Clopyralid	191.96	-	23.7 d representative worst case from field studies	(EFSA Journal 2018;16(7):5389)

8.7.2.1 Clopyralid and its metabolites

Table 8.7-3: PECsoil for Clopyralid

		PECsoil (mg/kg):									
		Sugar beet (120ga.s/ha)		Sugar beet (3 x 60 g a.s/ha)		Winter wheat (120 g a.s/ha)		Winter oilseed (90g a.s/ha)		Winter oilseed (120g a.s/ha)	
Initial (CHR/H/CPD):		0.1280		0.1628		0.1280		0.0720		0.0320	
		Clopyralid		Clopyralid		Clopyralid		Clopyralid		Clopyralid	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial (active substance):		0.1280	-	0.1628	-	0.1280	-	0.0720	-	0.0320	-
Short term	24 h	0.1243	0.1262	0.1581	0.1604	0.1243	0.1262	0.0699	0.0710	0.0311	0.0315
	2 d	0.1207	0.1243	0.1535	0.1581	0.1207	0.1243	0.0679	0.0699	0.0302	0.0311
	4 d	0.1139	0.1208	0.1448	0.1536	0.1139	0.1208	0.0641	0.0680	0.0285	0.0302
Long term	7d	0.1043	0.1158	0.1326	0.1472	0.1043	0.1158	0.0587	0.0651	0.0261	0.0289
	14 d	0.0850	0.1050	0.1081	0.1352	0.0850	0.1050	0.0478	0.0591	0.0212	0.0263
	21 d	0.0693	0.0956	0.0881	0.1265	0.0693	0.0956	0.0390	0.0538	0.0173	0.0239
	28 d	0.0564	0.0874	0.0718	0.1186	0.0564	0.0874	0.0317	0.0492	0.0141	0.0218
	42 d	0.0375	0.0737	0.0477	0.1031	0.0375	0.0737	0.0211	0.0415	0.0094	0.0184
	50 d	0.0297	0.0673	0.0377	0.0960	0.0297	0.0673	0.0167	0.0378	0.0074	0.0168
	100d	0.0069	0.0414	0.0087	0.0620	0.0069	0.0414	0.0039	0.0233	0.0017	0.0104

PECsoil (mg/kg):										
	Sugar beet (120ga.s/ha)		**Sugar beet (3 x 60 g a.s/ha)**		**Winter wheat (120 g a.s/ha)**		**Winter oilseed (90g a.s/ha)**		**Winter oilseed (120g a.s/ha)**	
Initial (CHR/H/CPD):	**0.1280**		**0.1628**		**0.1280**		**0.0720**		**0.0320**	
	Clopyralid		Clopyralid		Clopyralid		Clopyralid		Clopyralid	
	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Plateau concentration (5 cm) after year 10	<0.0001	-	<0.0001	-	<0.0001	-	<0.0001	-	<0.0001	-
PECaccumulation (PECact +PECsoil plateau)	**0.1280**	-	**0.1628**	-	**0.1280**	-	**0.0720**	-	**0.0320**	-

8.7.2.2 PEC$_{soil}$ of formulation

Table 8.7-4: PEC$_{soil}$ for CHR/H/CPD

Crop	**Active substance/ reparation**	**Application rate* (g/ha)**	**PECact (mg/kg)**	**PEC$_{twa}$21 d (mg/kg)**	**Tillage depth (cm)**	**PEC$_{soil,plateau}$ (mg/kg)**	**PECaccu = PECact + PEC$_{soil,plateau}$ (mg/kg)**
Winter oilseed rape(spring)	Clopyralid	459.2	0.367	-	-	-	-
Winter oilseed rape(autumn)	Clopyralid	344.4	0.275	-	-	-	-
Winter wheat	Clopyralid	459.2	0.4898	-	-	-	-
Sugar beet	Clopyralid	459.2	0.4898	-	-	-	-
Sugar beet	Clopyralid	3 x 229.6	0.735	-	-	-	-

*d=1.148g/ml

ZRMS comments:

The calculations of PEC$_{soil}$ submitted by Applicant were accepted.
The degradation endpoint DT50 used for clopyralid corresponds to field studies in accordance with the LoEP (EFSA, 2018).
The intended uses are covered by the presented PECsoil calculations.

	Sugar beet (120ga.s/ha)	Sugar beet (3 x 60 g a.s/ha)	Winter wheat (120 g a.s/ha)	Winter oilseed (90g a.s/ha)	Winter oilseed (120g a.s/ha)
Initial PECsoil (mg/kg)	0.1280	0.1628	0.1280	0.0720	0.0320
PECs accumulation	0.1280	0.1628	0.1280	0.0720	0.0320

The acceptable predicted environmental concentrations of clopyralid in soil are appropriate to be used for the subsequent risk assessment

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

8.8.1 Justification for new endpoints

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

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

Use No.	1, 2	3, 4, 5	6	7	8
Crop	Winter oilseed (spring)	Winter oilseed (autumn)	Winter wheat (spring)	Sugar beet	Sugar beet
Application rate (g as/ha)	Clopyralid: 120	Clopyralid: 90	Clopyralid: 120	Clopyralid: 60	Clopyralid: 120
Number of applications/interval (d)	1/ NA	1/NA	1/NA	3/6d	1/NA
Relative application date	+191(emergence)/	+5(emergence)/	04.04*	+10(emergence)/	+10(emergence)/
Crop interception (%)	80	40	20	20	20
Frequency of application	annual	annual	annual	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,

*The absolute date (4th April) was included in the calculation, since AppDate generated the autumn date which is not in compliance with label.

Table 8.8-2: Input parameters related to Clopyralid and metabolite(s) for PEC_{gw} calculations

Compound	**Clopyralid**	**Value in accordance with EU endpoint y/n/ Reference***
Molecular weight (g/mol)	191.96	(EFSA Journal 2018;16(7):5389)
Water solubility (mg/L):	1.43 x 105 at pH 7 and 20°C	(EFSA Journal 2018;16(7):5389)
Saturated vapour pressure (Pa):	set to 0 Pa as worst case	(EFSA Journal 2018;16(7):5389)
DT_{50} in soil (d)	Geometric mean parent DT50 field 7.05 d (n = 10) (normalisation to pF2, 20°C with Q10 of 2.58)	(EFSA Journal 2018;16(7):5389)
DT_{50} in soil (d) lab/field	7.05	(EFSA Journal 2018;16(7):5389)
Transformation rate	-	
K_{foc} (mL/g)/K_{fom}	geometric mean 1.41 mL/g (n = 9), arithmetic mean	(EFSA Journal 2018;16(7):5389)

Compound	**Clopyralid**	**Value in accordance with EU endpoint y/n/ Reference***
1/n	1/n= 0.836 (n = 9)	(EFSA Journal 2018;16(7):5389)
Plant uptake factor	0 / 0.0002711/ 0.5[1]	(EFSA Journal 2018;16(7):5389)
Formation fraction	-	

* Delete row in case of no pH dependency

[1] Tier 1 / Tier 2; Tier 2 value according to Briggs equation (Briggs et al., 1982) with log(KOW) = -2.63 TSCF = 0.774 exp -[(log KOW - 1.78)2/2.44] / Tier 3

8.8.2.1 Clopyralid and its metabolites

Only scenarios relevant for MS according to GAP were taken into account – Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, Porto.

Table 8.8-4: PEC_{gw} for Clopyralid (with FOCUS PEARL 4.4.4) – Tier 1 – every year

Scenario	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L⁻¹ **Sugar beet, 60 g a.s/ha, 3 applications**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Sugar beet, 120 g a.s/ha, 1 application**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter wheat, Spring Appn 120 g a.s/ha**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter oilrappe, Autumn Appn., 90 g a.s/ha**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter oilrappe, Spring Appn., 120 g a.s/ha**
Châteaudun	**0.250265**	**0.134030**	0.005026	**0.116898**	0.003750
Hamburg	**0.158848**	0.086146	**0.123394**	**0.999440**	0.045209
Kremsmünster	0.081318	0.048724	**0.113612**	**0.227777**	0.052700
Okehampton	0.093791	0.048899	**0.125210**	**0.181367**	0.044807
Piacenza	0.033238	0.024000	0.060766	**0.620778**	0.007771
Porto	0.053042	0.038555	0.011612	**0.420980**	0.002096

Table 8.8-5: PEC_{gw} for Clopyralid (with FOCUS PELMO 5.5.3) – Tier 1 – every year

Scenario	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Sugar beet, 60 g a.s/ha, 3 applications**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Sugar beet, 120 g a.s/ha, 1 application**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter wheat, 120 g a.s/ha**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter oilseed rappe, Autumn Appn., 90 g a.s/ha**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter oilseed rappe, Spring Appn., 120 g a.s/ha**
Châteaudun	0.065	0.035	0.004	**0.249**	0.011
Hamburg	0.063	0.039	**0.138**	**1.340**	**0.223**
Kremsmünster	**0.128**	0.077	**0.181**	**0.482**	**0.140**
Okehampton	**0.230**	**0.123**	**0.242**	**0.348**	**0.624**
Piacenza	**0.360**	**0.241**	0.090	**1.687**	0.015
Porto	**0.460**	**0.454**	0.012	**0.497**	**0.122**

In the tables above bolded values exceeded the trigger value of 0.1µg/L. Both PELMO and PEARL simulations indicate exceedance in most scenarios. Therefore higher tier calculations taking into account PUF 0.0002711 and application every other year were performed.

Table 8.8-6: PEC_{gw} for Clopyralid (with FOCUS PEARL 4.4.4) – Tier 2 – every other year

Scenario	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Sugar beet, 60 g a.s/ha, 3 applications**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Sugar beet, 120 g a.s/ha, 1 application**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter wheat, Spring Appn 120 g a.s/ha**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter oilrappe, Autumn Appn., 90 g a.s/ha**	**Clopyralid** 80th Percentile PEC_{GW} at 1 m soil depth µg L^{-1} **Winter oilrappe, Spring Appn., 120 g a.s/ha**

Châteaudun	**0.127408**	0.062980	0.002469	0.040461	There was no exceedance in Tier 1. Therefore no further calculation were presented.
Hamburg	0.088424	0.044529	0.065073	**0.473117**	
Kremsmünster	0.038960	0.021492	0.062958	0.095600	
Okehampton	0.057338	0.034459	0.063116	0.099135	
Piacenza	0.019276	0.014745	0.034921	**0.394661**	
Porto	0.025677	0.016839	0.006356	**0.201231**	

Table 8.8-7: PEC$_{gw}$ for Clopyralid (with FOCUS PELMO 5.5.3) – Tier 2 – every other year

Scenario	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Sugar beet, 60 g a.s/ha, 3 applications**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Sugar beet, 120 g a.s/ha, 1 application**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter wheat, 120 g a.s/ha**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter oilseed rappe, Autumn Appn., 90 g a.s/ha**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter oilseed rappe, Spring Appn., 120 g a.s/ha**
Châteaudun	0.042	0.023	0.002	**0.106**	0.006
Hamburg	0.034	0.020	0.064	**0.615**	**0.142**
Kremsmünster	0.059	0.033	0.083	**0.239**	0.073
Okehampton	**0.127**	0.077	**0.102**	**0.209**	**0.350**
Piacenza	**0.199**	**0.203**	0.044	**1.148**	0.009
Porto	**0.179**	**0.174**	0.007	**0.262**	0.064

In the tables above bolded values still exceeds the trigger value of 0.1µg/L. Both PELMO and PEARL simulations indicate exceedance in most scenarios. Therefore further risk refinement is required. Updated calculations include application every third year. Additional comments to application are described below:

1. Triple application on sugar beet – exceedance in both PELMO and PEARL calculations. Further data available below.
2. Single application on sugar beet – exceedance only in PELMO calculations. **The predicted environmental concentration of clopyralid for scenarios relevant in Poland are considered acceptable.**
3. Application on winter wheat – exceedance only in PELMO calculations. **The predicted environmental concentration of clopyralid for scenarios relevant in Poland are considered acceptable.**
4. Autumn application on winter oilseed rape - both PELMO and PEARL calculations indicate exceedance of concentration of clopyralid in groundwater. Therefore further risk assessment is provided.
5. Spring application on winter oilseed rape – PEARL calculations indicate an acceptable risk. Only PELMO calculations were refined

Table 8.8-8: PEC$_{gw}$ for Clopyralid (with FOCUS PEARL 4.4.4) – Tier 2 – every third year

Scenario	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Sugar beet, 60 g a.s/ha, 3**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Sugar beet, 120 g a.s/ha, 1 application**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter wheat, Spring Appn 120 g a.s/ha**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter oilrappe, Autumn Appn., 90**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter oilrappe, Spring Appn., 120**

	applications			g a.s/ha	g a.s/ha
Châteaudun	0.091538	There was no exceedance in Tier 2. Therefore no further calculation were presented.	There was no exceedance in Tier 2. Therefore no further calculation were presented.	0.041622	There was no exceedance in Tier 1. Therefore no further calculation were presented.
Hamburg	0.057502			**0.360425**	
Kremsmünster	0.028743			0.065033	
Okehampton	0.037556			0.073500	
Piacenza	0.017033			**0.277940**	
Porto	0.015083			**0.127977**	

Table 8.8-9: PEC$_{gw}$ for Clopyralid (with FOCUS PELMO 5.5.3) – Tier 2 – every third year

Scenario	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Sugar beet, 60 g a.s/ha, 3 applications**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Sugar beet, 120 g a.s/ha, 1 application**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter wheat, 120 g a.s/ha**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter oilseed rappe, Autumn Appn., 90 g a.s/ha**	**Clopyralid** 80th Percentile PEC$_{GW}$ at 1 m soil depth µg L^{-1} **Winter oilseed rappe, Spring Appn., 120 g a.s/ha**
Châteaudun	0.036	There was no exceedance in Tier 2. Therefore no further calculation were presented.	There was no exceedance in Tier 2. Therefore no further calculation were presented.	0.097	0.004
Hamburg	0.026			**0.486**	0.091
Kremsmünster	0.045			**0.158**	0.054
Okehampton	0.092		0.073	**0.147**	**0.214**
Piacenza	**0.145**	0.096	There was no exceedance in Tier 2. Therefore no further calculation were presented.	**0.777**	0.005
Porto	**0.124**	**0.109**		**0.120**	0.045

In the tables above bolded values still exceeds the trigger value of 0.1µg/L. Both PELMO and PEARL simulations indicate exceedance in most scenarios. Therefore further risk refinement is required.
The EFSA has interpreted that if residues of the parent compound are found on the aerial part of the plants cultivated in soil treated with the substance, it is generally accepted that the substance is uptaken by the roots and that a TSCF of 0.5 can be used as plant uptake factor for groundwater modelling. That is why PUF=0.5 was chosen as a risk refinement for clopyralid.
For all application (except from autumn application on winter oilseed rape) the risk for scenarios relevant in Poland is considered acceptable.
For spring application on winter oilseed rape, the exceedance of concentration in Okehampton was recalculated taking into account the date from AppDate (238 days after emergence), PUF has not been changed in the calculation.

Table 8.8-10: PEC_{gw} for Clopyralid and metabolite(s) (with FOCUS PEARL 4.4.4) – Tier 3 – every third year

Scenario	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Sugar beet, 60 g a.s/ha, 3 applications	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Sugar beet, 120 g a.s/ha, 1 application	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Winter wheat, Spring Appn 120 g a.s/ha	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Winter oilrappe, Autumn Appn., 90 g a.s/ha	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Winter oilrappe, Spring Appn., 120 g a.s/ha
Châteaudun	There was no exceedance in Tier 3. Therefore no further calculation were presented.	There was no exceedance in Tier 2. Therefore no further calculation were presented.	There was no exceedance in Tier 2/3. Therefore no further calculation were presented.	0.039999	There was no exceedance in Tier 1. Therefore no further calculation were presented.
Hamburg				**0.355714**	
Kremsmünster				0.063207	
Okehampton				0.073159	
Piacenza				**0.277887**	
Porto				**0.123890**	

Table 8.8-11: PEC_{gw} for Clopyralid (with FOCUS PELMO 5.5.3) – Tier 3 – every third year

Scenario	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Sugar beet, 60 g a.s/ha, 3 applications	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Sugar beet, 120 g a.s/ha, 1 application	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Winter wheat, 120 g a.s/ha	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Winter oilseed rappe, Autumn Appn., 90 g a.s/ha	Clopyralid 80^{th} Percentile PEC_{GW} at 1 m soil depth µg L^{-1} Winter oilseed rappe, Spring Appn., 120 g a.s/ha
Châteaudun	There was no exceedance in Tier 3. Therefore no further calculation were presented.	There was no exceedance in Tier 2. Therefore no further calculation were presented.	There was no exceedance in Tier 2/3. Therefore no further calculation were presented.	0.082	There was no exceedance in Tier 3. Therefore no further calculation were presented.
Hamburg				**0.405**	
Kremsmünster				**0.126**	
Okehampton				**0.103**	0.055*
Piacenza	0.089			**0.735**	There was no exceedance in Tier 3. Therefore no further calculation were presented.
Porto	0.095	0.075		**0.109**	

* Tier 2 PUF was used.

The predicted environmental concentration of clopyralid in groundwater is below 0.1µg/L. Therefore is poses no unacceptable risk.
In the case of **oilseed rape (autumn), it is necessary to reduce the application rate from 0.09kg/ha to 0,06kg/ha and BBCH stage from 13-14 to 20-21**. Additionally, it was necessary to use the absolute date of 23.08 (plant update factor of 0.0002711 was used in the calculation) to obtain acceptable results below 0.1µ/L.

Table 8.8-12: PEC$_{gw}$ for Clopyralid (with FOCUS PEARL 4.4.4) – Tier 2– every third year

Scenario	**Clopyralid** 80[th] Percentile PEC$_{GW}$ at 1 m soil depth µg L-1 **Winter oilseed rappe, Autumn Appn., 60 g a.s/ha** **Every third year**
Châteaudun	0.002169
Hamburg	0.035215
Kremsmünster	0.012866
Okehampton	0.017216
Piacenza	0.012349
Porto	0.006981

Table 8.8-13: PEC$_{gw}$ for Clopyralid (with FOCUS PELMO 5.5.3) – Tier 2– every third year

Scenario	**Clopyralid** 80[th] Percentile PEC$_{GW}$ at 1 m soil depth µg L-1 **Winter oilseed rappe, Autumn Appn., 60 g a.s/ha** **Every third year**
Châteaudun	0.009
Hamburg	0.094
Kremsmünster	0.063
Okehampton	0.077
Piacenza	0.041
Porto	0.012

The predicted environmental concentration of clopyralid in groundwater is below 0.1µg/L. Therefore is poses no unacceptable risk for all intended uses.

ZRMS comments:

The PECgw calculated for proposed uses were accepted. The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO.
All input parameters for clopyralid were considered acceptable as they followed the LoEP EFSA 2018;16(7):5389. Simulations PUF value of 0 was assumed in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

The results of the PECgw with FOCUS PELMO and PEARL indicate that PECgw of clopyralid were less than 0.1 µg/L. For some uses risk mitigations should be used at National Level.
In the case of oilseed rape (autumn), was necessary to reduce the application rate from 0.09 kg/ha to 0,06 kg/ha and BBCH stage from 13-14 to 20-21.

PL: PECgw calculations were performed with the FOCUS scenarios relevant for Poland using the FOCUS PELMO (5.5.3) and FOCUS PEARL 4.4.4 model Châteaudun, Hamburg, Kremsmünster. For some uses following risk mitigations are proposed by RMS:
Use every third year - Winter oilseed rape; Spring Appl. 120 g a.s/ha (BBCH 30–50) (0.4L product/ha)
- Winter oilseed rape; Autum . 60 g a.s/ha (BBCH20-21) (0.2L product/ha)
- Sugar beet, Appl. 3 x 60 g a.s/ha (BBCH 12-14) (0,2L product/ha)

Use every other year - Sugar beet, Appl. 120 g a.s/ha, (BBCH 12-14) (0.4L product/ha)
- Winter wheat Appl. 120 g a.s/ha (BBCH 20-29), (0.4L product/ha)

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

8.9.1 Justification for new endpoints

8.9.2 Active substance(s), relevant metabolite(s) and the CHR/H/CPD (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	CHR/H/CPD				
Use No.	1, 2, 3	4, 5	6	7	8
Crop	Winter oilseed rape(spring)	Winter oilseed rape(autumn)	Winter wheat	Sugar beet	Sugar beet
Application rate (kg as/ha)	Clopyralid: 0.12	Clopyralid: 0.09	Clopyralid: 0.12	Clopyralid: 0.12	Clopyralid: 0.06
Number of applications/interval (d)	1	1	1	1	3/6d
Application method	spray	spray	spray	spray	spray
Soil depth (cm)	5	5	5	5	5
Models used for calculation	Step 1-2 in FOCUS	Step 1-2 in FOCUS	Step 1-2 in FOCUS	Step 1-2 in FOCUS	Step 1-2 in FOCUS

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

Crop	Scenario	Application window used in modelling
Winter oilseed rape(spring)	-	FOCUS 3 not provided. Not necessary.
Winter oilseed rape(autumn)	-	FOCUS 3 not provided. Not necessary.
Winter wheat	-	FOCUS 3 not provided. Not necessary.
Sugar beet	-	FOCUS 3 not provided. Not necessary.

8.9.2.1 Clopyralid and its metabolites

Table 8.9-3: Input parameters related to Clopyralid and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Clopyralid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	191.96	EFSA Journal 2018;16(7):5389
Saturated vapour pressure (Pa)	1.36 × 10-3 Pa at 20°C	EFSA Journal 2018;16(7):5389
Water solubility (mg/L)	1.43 × 105	EFSA Journal 2018;16(7):5389

Compound	Clopyralid	Value in accordance to EU endpoint y/n/ Reference
Diffusion coefficient in water (m^2/d)	not required for Step 1+2	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2	default
K_{foc} (mL/g)	1.41	EFSA Journal 2018;16(7):5389
Freundlich Exponent 1/n	0.836	EFSA Journal 2018;16(7):5389
Plant Uptake	0	EFSA Journal 2018;16(7):5389
$DT_{50,soil}$ (d)	7.05	EFSA Journal 2018;16(7):5389
$DT_{50,water}$ (d)	1000	EFSA Journal 2018;16(7):5389
$DT_{50,sed}$ (d)	1000	EFSA Journal 2018;16(7):5389
$DT_{50,whole\ system}$ (d)	1000	EFSA Journal 2018;16(7):5389
Maximum occurrence observed (% molar basis with respect to the parent)	-	-
Formation fraction in soil:	-	-

Table 8.9-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Clopyralid following single application of CHR/H/CPD on winter oilseed rape

Winter oilseed rape (spring)						Winter oilseed rape (autumn)				
Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d-$PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	-	41.03	-	40.73	0.58	-	30.77	-	30.55	0.43
Step 2	-	2.45	-	2.43	0.03	-	1.83	-	1.82	0.03
Northern Europe	-	2.45	-	2.43	0.03	-	1.83		1.82	0.03

Table 8.9-5: FOCUS Step 1,2 ~~and 3~~ PECsw and PECsed for Clopyralid following single application of CHR/H/CPD on sugar beet

Sugar beet (60x3g/ha)						Sugar beet (120g/ha)				
Scenario FOCUS	**Waterbody**	**Max PEC sw (µg/L)***	**Dominant entry route**	**21 d-PECsw,twa (µg/L)****	**Max PECsed (µg/kg)***	**Waterbody**	**Max PEC sw (µg/L)***	**Dominant entry route**	**21 d-PECsw,twa (µg/L)****	**Max PECsed (µg/kg)***
Step 1	-	61.54	drainage/run off	61.09	0.87	-	41.03	drainage/run off	40.73	0.58
Step 2	-	2.71	drainage/run off	2.69	0.04	-	2.72	drainage/run off	2.70	0.04
Northern Europe	-	2.71	drainage/run off	2.69	0.04	-	2.72	drainage/run off	2.70	0.04

Table 8.9-6: FOCUS Step 1,2 PECsw and PECsed for Clopyralid following single application of CHR/H/CPD on winter wheat

Winter wheat					
Scenario FOCUS	**Waterbody**	**Max PECsw (µg/L)***	**Dominant entry route**	**21 d- PECsw,twa (µg/L)****	**Max PECsed (µg/kg)***
Step 1	-	41.03	drainage/run off	40.73	0.58
Step 2	-	2.72	drainage/run off	2.70	0.04
Northern Europe		2.72	drainage/run off	2.70	0.04

* single applications should be marked.
** twa-time as required by ecotox

Conclusion:
For steps FOCUS 1 PEC_{SW} for Clopyralid in all crops and applications < RAC* (3 mg/l - 300 µg/l), triggering the not necessity to carry out risk refinement in the form of FOCUS 3 and Focus Step 4 PEC_{SW} calculations.
*RAC is regulatory acceptable concentration, set by Myriophyllum spicatum E_rC_{50}>3.0mg/l

ZRMS calculations:

The PECsw calculations at Step 1-2 and 3 were accepted. The PEC of clopyralid in surface water and sediment (PECsw and PECsed) has been assessed with the FOCUS surface water model FOCUS STEPS 1-2. All input parameters for clopyralid were considered acceptable as they followed the LoEP (2018).

Obtained PECsw and PECsed values are suitable for subsequent ecotoxicological risk assessment.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour for Clopyralid (EFSA Journal 2018;16(7):5389)

Compound	Clopyralid
Direct photolysis in air	No data submitted nor required
Quantum yield of direct phototransformation	Not determined

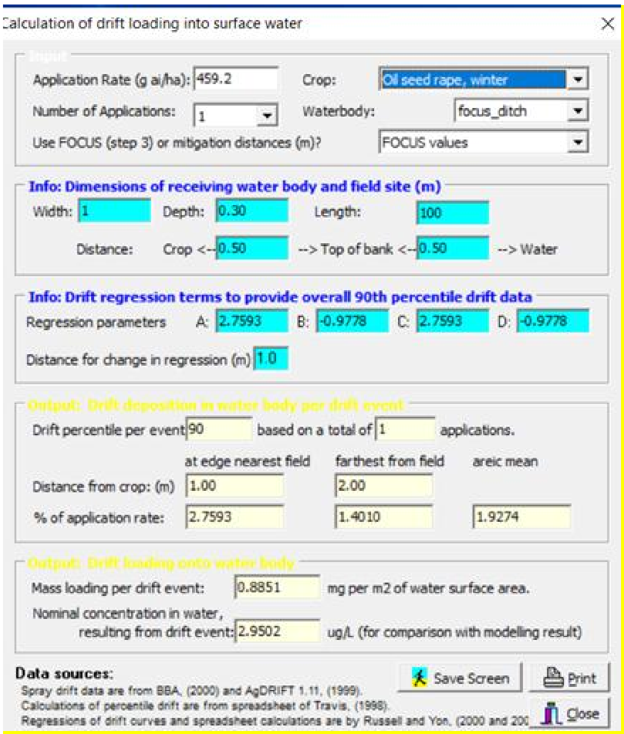
Photochemical oxidative degradation in air	Atkinson calculation using AOPWIN v.1.90 DT50 = 19.5 days (Madsen 2002)
Volatilisation	BBA guideline: from plant surfaces: ≤4 % in 24 hours (Day & Rudel 1994) BBA guideline: from soil: <2 % in 24 hours (Day & Rudel 1994)
Metabolites	Not examined

The vapour pressure at 20 °C of the Clopyralid is 1.36 × 10-3 Pa. Clopyralid is regarded as low-volatile (volatilisation from soil and from plant surface). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the Clopyralid due to volatilization with subsequent deposition is not considered.

ZRMS comments:
Accepted.

$PEC_{sw/sed}$ of CHR/H/CPD 300 SL

Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate winter oilseed rape (spring)	1 x 459.2 g [prod]/ha equivalent to 1 x 120 g a.s/ha
Resulting PECsw sugar beets	2.9502 µg[prod]/L


Calculation of drift loading into surface water
Application Rate (g ai/ha): 459.2
Crop: Oil seed rape, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? FOCUS values
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 0.50 --> Top of bank <-- 0.50 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 1.00 2.00
% of application rate: 2.7593 1.4010 1.9274
Mass loading per drift event: 0.8851 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 2.9502 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 200
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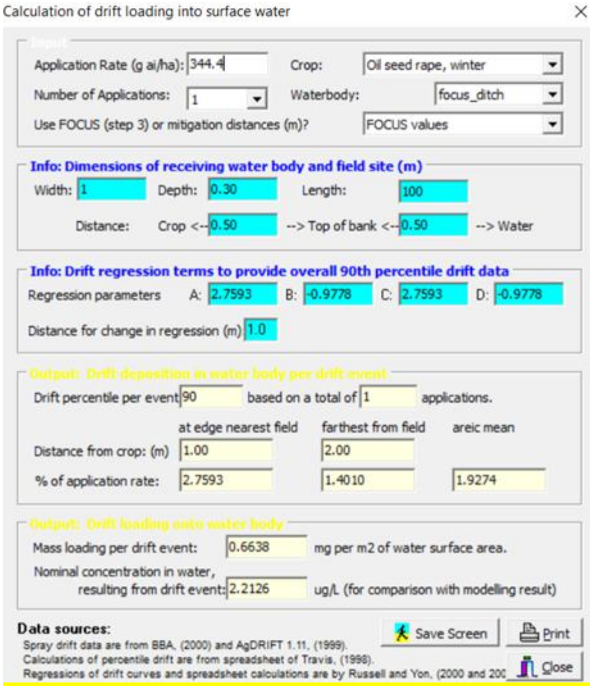
Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate winter oilseed rape (autumn)	1 x 344.4 g [prod]/ha equivalent to 1 x 90 g a.s/ha
Resulting PECsw sugar beets	2.2126 µg[prod]/L


Calculation of drift loading into surface water
Application Rate (g ai/ha): 344.4
Crop: Oil seed rape, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? FOCUS values
Info: Dimensions of receiving water body and field site (m)
Width: 1 Depth: 0.30 Length: 100
Distance: Crop <-- 0.50 --> Top of bank <-- 0.50 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 1.00 2.00
% of application rate: 2.7593 1.4010 1.9274
Mass loading per drift event: 0.6638 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 2.2126 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 200
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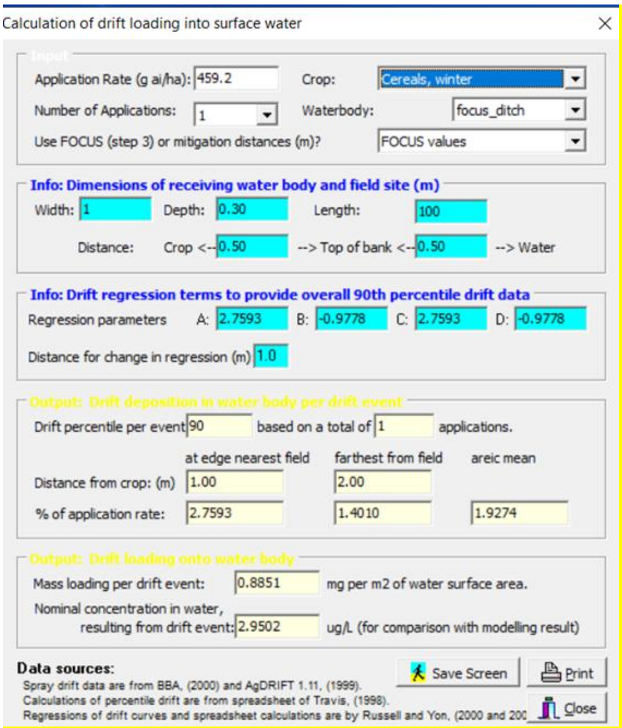
Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate winter wheat	1 x 459.2 g [prod]/ha equivalent to 1 x 120 g a.s/ha
Resulting PECsw sugar beets	2.9502 µg[prod]/L


Calculation of drift loading into surface water
Input
Application Rate (g ai/ha): 459.2
Crop: Cereals, winter
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? FOCUS values
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 0.50 --> Top of bank <-- 0.50 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Output: Drift deposition in water body per drift event
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 1.00 2.00
% of application rate: 2.7593 1.4010 1.9274
Output: Drift loading onto water body
Mass loading per drift event: 0.8851 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 2.9502 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 200
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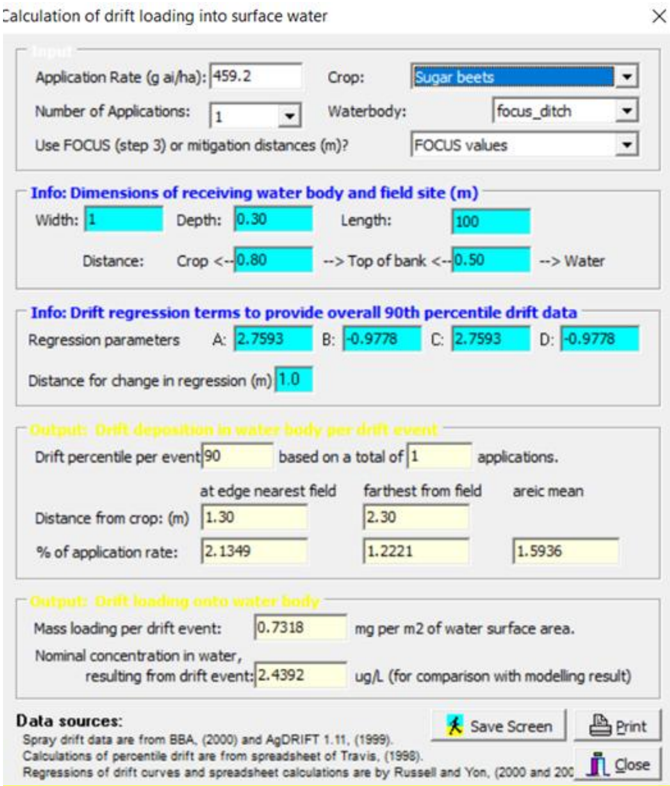
Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate sugar beets	1 x 459.2 g [prod]/ha equivalent to 1 x 120 g a.s/ha
Resulting PECsw sugar beets	2.4392 µg[prod]/L


Calculation of drift loading into surface water
Application Rate (g ai/ha): 459.2
Crop: Sugar beets
Number of Applications: 1
Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? FOCUS values
Info: Dimensions of receiving water body and field site (m)
Width: 1
Depth: 0.30
Length: 100
Distance: Crop <-- 0.80 --> Top of bank <-- 0.50 --> Water
Info: Drift regression terms to provide overall 90th percentile drift data
Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0
Output: Drift deposition in water body per drift event
Drift percentile per event 90 based on a total of 1 applications.
at edge nearest field
farthest from field
areic mean
Distance from crop: (m) 1.30 2.30
% of application rate: 2.1349 1.2221 1.5936
Output: Drift loading onto water body
Mass loading per drift event: 0.7318 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 2.4392 ug/L (for comparison with modelling result)
Data sources:
Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 200
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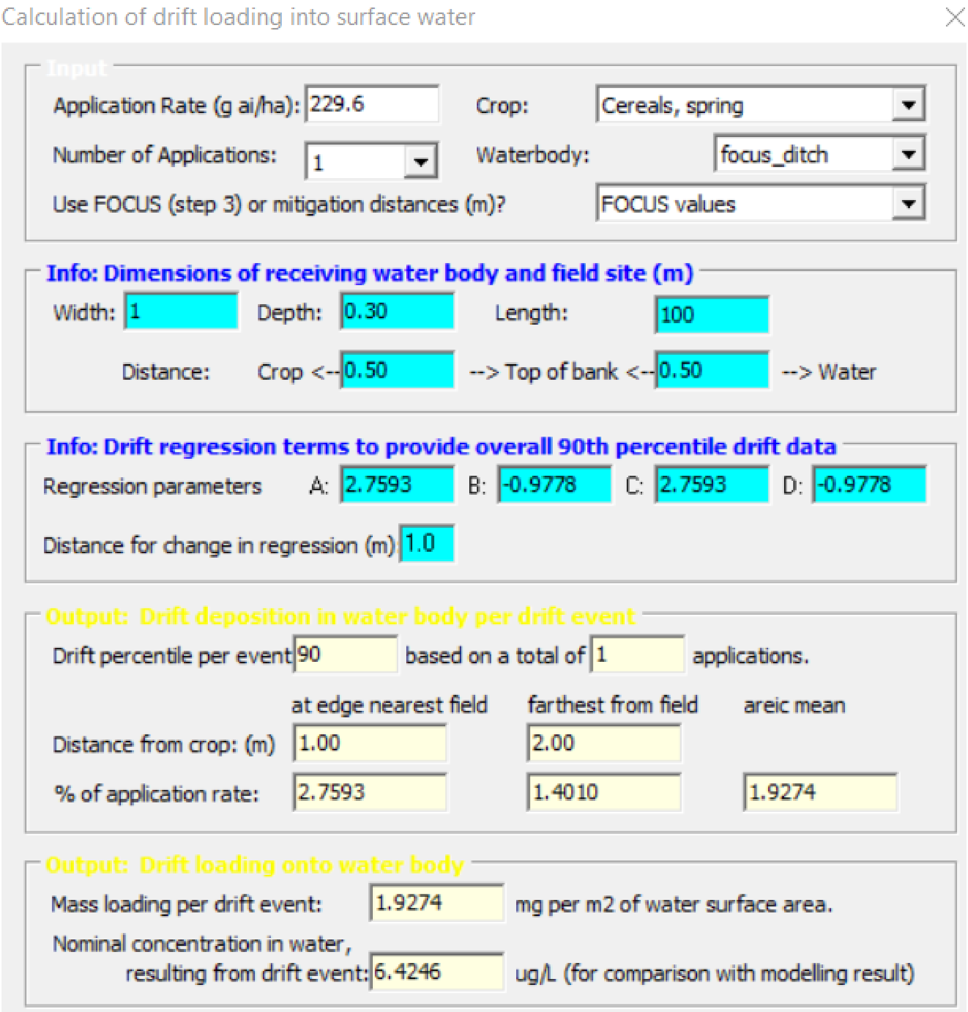
Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate sugar beets	1 x 229.6g [prod]/ha equivalent to 1 x 120 g a.s/ha
Resulting PECsw sugar beets	6.4246 µg[prod]/L



Calculation of drift loading into surface water

Input

Application Rate (g ai/ha): 229.6 Crop: Cereals, spring
Number of Applications: 1 Waterbody: focus_ditch
Use FOCUS (step 3) or mitigation distances (m)? FOCUS values

Info: Dimensions of receiving water body and field site (m)

Width: 1 Depth: 0.30 Length: 100
Distance: Crop <-- 0.50 --> Top of bank <-- 0.50 --> Water

Info: Drift regression terms to provide overall 90th percentile drift data

Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778
Distance for change in regression (m) 1.0

Output: Drift deposition in water body per drift event

Drift percentile per event 90 based on a total of 1 applications.

	at edge nearest field	farthest from field	areic mean
Distance from crop: (m)	1.00	2.00	
% of application rate:	2.7593	1.4010	1.9274

Output: Drift loading onto water body

Mass loading per drift event: 1.9274 mg per m2 of water surface area.
Nominal concentration in water, resulting from drift event: 6.4246 ug/L (for comparison with modelling result)

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	M.Zielinska	2021	PEC soil calculations.	N	Chemirol
KCP 9.2.4	M.Zielinska	2021	PECgw calculations.	N	Chemirol
KCP 9.2.5	M.Zielinska	2021	PECsw calculations.	N	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1	Baloch, R.;Grant, R.	1991	Degradation and metabolism of Clopyralid in Soil under Aerobic Conditions DAS Report No.GHE-P-2398R Agricultural Research and Development Center, DowElanco Limited, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, U.K. GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Skinner, W.; Jao, N.; Smith, J. K.	1995	Aerobic Soil Metabolism of [14C]Clopyralid DAS Report No.GHE-C-3598 PTRL West, Inc. 4123-B Lakeside Drive, Richmond, CA 94806 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Wardrope, L.	2009	The Degradation of (14C)-Clopyralid in Soil Under Aerobic Conditions DAS Report No.808711 Charles River Laboratories, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.1	Allan, J.; Lowrie, C. ; Hall, B. E.	2002	The Degradation of C14 Clopyralid in Soil Under Anaerobic Conditions DAS Report No.GHE-P-9563 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS

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 9.1.1	Schubert, S.	2015	Evaluation of kinetic endpoints for clopyralid from laboratory soil degradation studies DAS Report No. 151039 Dow AgroSciences, Milton Park, UK GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Rawle, N.; Yon, D.	2002	The dissipation of clopyralid in soil following a single application of LONTREL (EF-1136), Denmark and the UK – 2000 DAS Report No. GHE-P-9370 CEMAS GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Rawle, N.; Yon, D.	2002	The dissipation of clopyralid in soil following a single application of LONTREL (EF-1136), Germany and Northern France – 2000 DAS Report No. GHE-P-9371 CEMAS GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Kröger, F.	2015	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at three sites to bare soil in Europe in 2013-2015 Eurofins Agroscience Services, Stade, Germany Eurofins Study S13-00312 DAS Study No. 130673 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Robinson, P.	2015	Estimation of kinetic endpoints for clopyralid from soil dissipation studies. Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 150296 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Kröger, F.	2016	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site to bare soil in South Europe in 2015. Eurofins Agroscience Services, Stade, Germany Eurofins Study S15-02991 DAS Study No. 150672 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Kröger, F.	2016	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site to bare soil in South Europe in 2015. Eurofins Agroscience Services, Stade, Germany	N	DAS

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
			Eurofins Study S15-02992 DAS Study No. 150673 GLP/GEP (Y/N): Yes Published (Y/N): No		
KCP 9.1.2	Robinson, P.	2016	Estimation of kinetic endpoints for clopyralid from field soil dissipation studies (Southern Europe). Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 160486 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Ahrens, C. & Kröger, F.	2017	Final report – Field soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site in North EU and one site in South EU to bare soil in 2016 - 2017. Eurofins Agroscience Services, Stade, Germany; Eurofins Study S16-01795 DAS Study No. 160394 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Robinson, P.	2017	Estimation of kinetic endpoints for clopyralid from soil dissipation studies (North and South Europe). Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 170481 GLP/GEP (Y/N): No Published (Y/N): No	N	DAS
KCP 9.1.2	Reeves, G. L. & Mittelstaedt, W.	2002	Adsorption/Desorption of Clopyralid in Soil: Corrections to Final Report of Study DW 2/92 from August 1993 DAS Report No.GHE-P-9762 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Buntain, I., Simmonds, M.	2015	[14C]-Clopyralid: Adsorption to and Desorption from Five Soils DAS Report No.130699 Battelle UK Ltd., Chelmsford, Essex, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Schnöder, F.	2004	[14C] Clopyralid: Leaching in outdoor lysimeters following spring application to oilseed rape – Final report DAS Report No.000136 Covarance Laboratories, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Dust, M., Führ, F.	1994	Degradation and leaching of clopyralid monoethylamine salt after post emergence application of LONTREL 100 to winter rape in German lysimeters DAS Report No.GHE-P-4037 Forschungszentrum Julich GmbH, Julich, Germany	N	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/GEP (Y/N): Yes Published (Y/N): No		
KCP 9.1.2	Brumhard, B., Führ, F., Baloch, R.	1994	Behaviour of [2,6 14C] Clopyralid (LONTREL*) in a sandy Pseudogley Braunerde after post-emergence application to sugar beet DAS Report No.GHE-P-2908 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Brumhard, B., Baloch, R., Führ, F.	1994	Behaviour of [2,6 14C] clopyralid formulated as LONTREL 100 in Parabraunerde (Orthic Luvisol) after post emergence application to sugar beet lysimeters DAS Report No.GHE-P-2580 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Smith-Drake, J. K.	2000	Hydrolysis of 14C Clopyralid in Natural Water And Buffered Water as a Function of pH DAS Report No.000132 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.1.2	Hall B.E.; Allen, J.; Clements B.	2002	The Aerobic Degradation of [14]-Clopyralid in Natural Waters and their Associated Sediments DAS Report No.GHE-P-9564 Inveresk Research International, Tranet, East Lothian, UK Published (Y/N): No	N	DAS
KCP 9.1.2	Ponte, M.	2014	Direct Aqueous Photodegradation of [14C]Clopyralid in pH 7 Buffer DAS Report No.140077 PTRL West, Hercules, California, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.2	Jenkins, W. R.	1991	LONTREL T: Assessment of its Biodegradability - Modified Sturm Test Life Science Research, Eye, Suffolk, UK DAS Report No. GHE-P-2522 GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCP 9.3	Day, S. R.; Rudel, H.	1994	The evaporation of Clopyralid acid from soil and leaf surfaces following application of LONTREL 100 DAS Report No. GHE-P-3507 Fraunhofer Institute, D-57392 Schmallenberg,	N	DAS

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
			Grafschaft/Hochsauerland, Germany GLP/GEP (Y/N): Yes Published (Y/N): No		
KCP 9.3	Madsen, S.	2002	Calculation of the Stability in Air of Clopyralid - Photochemical Degradation. DAS Report No. LLC NAFST GLP/GEP (Y/N): No Published (Y/N): No	N	DAS

Appendix 2 Detailed evaluation of the new Annex II studies

No new studies provided.