FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: K-300 SL-RR

Product name(s): FAWORYT 300 SL

Chemical active substance:

Clopyralid, 300 g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT – Art. 43

(Renewal of authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2021

Correction: 06/2022

MS Finalisation date: 06/2022; 10/2022

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 2 /38
Template for chemical PPP
Version ~~December 2021~~
<mark>June 2022</mark>.

Version history

When	What
December 2021	dRR version 1 submitted by applicant
<mark>June 2022</mark>	<mark>First correction for product authorization</mark>
June 2022	zRMS first assessment
October 2022	Final Registration Report

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 3 /38
Template for chemical PPP
Version ~~December 2021~~
<mark>June 2022</mark>

Table of Contents

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 4 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

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 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)	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			
1	PL	Winter wheat	F	Dicotyledonous weeds (from cotyledon stage to the rosette stage)	Spraying, broadcast-foliar	BBCH 21-29 (Spring)	a) 1 an bi-annual application b) 1	N/A	a) 0.3-0.4 b) 0.3-0.4	a) 90-120 b) 90-120	200/300	N/A	none	R Acceptable with an bi-annual application
2	PL	Winter rape	F	Dicotyledonous weeds (from cotyledon stage to the rosette stage)	Spraying, broadcast-foliar	BBCH 10-50 (Spring)	a) 1 an bi-annual application b) 1	N/A	a) 0.3-0.4 b) 0.3-0.4	a) 90-120 b) 90-120	200/300	N/A	none	R Acceptable with an bi-annual application
3	PL	Sugar beet	F	Dicotyledonous weeds (from cotyledon stage to the rosette stage)	Spraying, broadcast-foliar	BBCH 12-14 (Spring)	a) 1 b) 1	N/A	a) 0.3 b) 0.3	a) 90 b) 90	200/300	N/A	none	A

* 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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 5 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

C	To be confirmed by cMS
N	No safe use

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

Crop and/or situation (crop destination / purpose of crop)	Member state(s)	Product name	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	number min-max	Min. interval between applications (days)	kg a.s /hL min-max	kg a.s./ha min-max	Water L/ha min/max		
Winter cereal (wheat, barley oat, rye, triticale, spelt)	CEU/SEU	GF-1374 (80 g/L Clopyralid + 2.5 g/L florasulam + 144.1 g/L fluroxypyr meptyl (equivalent to 100 g/L fluroxypyr)	F	Broad-leaf weeds	Overall broadcast 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)	Clopyralid 0.08 kg as/ha + Florasulam 0.0025 kg as/ha + Fluroxypyr-meptyl 0.144 kg as/ha (0.100 kg ae/ha)	80-400	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 (80 g/L Clopyralid + 2.5 g/L florasulam + 144.1 g/L fluroxypyr meptyl (equivalent to 100 g/L fluroxypyr)	F	Broad-leaf weeds	Overall broadcast 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 meptyl: 0.054 to 0.27 kg as/hL (0.0375 to 0.1875 kg ae/hL)	Clopyralid 0.12 kg as/ha + Florasulam 0.00375 kg as/ha + Fluroxypyr-meptyl 0.216 kg as/ha (0.15kg ae/ha)	100-400		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. Clopyralid residues in plant tissue (including manure) which has not completely decayed may affect succeeding susceptible crops. Do not use any plant material treated with GF-1374 for composting. Do not use manure from animals fed on crops treated with GF-1374 for composting or mulching.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 6 /38
Template for chemical PPP
Version ~~December 2021~~
<mark>June 2022</mark>

													Manure produced from animals fed on grass or forage treated with clopyralid can be used on or before the planting of crops such as grass, cereals and maize.

*   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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 7 /38
Template for chemical PPP
Version ~~December 2021~~
<mark>June 2022</mark>.

> **zRMS comments:**
>
> The dRR was prepared by applicant. All comments and conclusions of the zRMS are presented in grey.
> Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency. New calculations of PECgw are presented in yellow.

8.2 Metabolites considered in the assessment

No metabolites of clopyralid were assessed at EU level during the substance

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)

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

8.3.1.1 Clopyralid

Data on aerobic degradation in soil of the active substance is presented in the following table.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 8 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

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

clopyralid, Laboratory studies, 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

8.3.2   Anaerobic degradation in soil (KCP 9.1.1.1)

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

Table 8.3-2:   **Rate of degradation in soil (anaerobic) laboratory studies Clopyralid**

Clopyralid, Dark anaerobic conditions							
Soil type / Location	pH[a]	t. °C / % MWHC	DT50 / DT90 (d)	DT50 (d) 20 °C[b]	St. (χ^2)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy loam	7.4	20 / flooded	>1 year	>1 year	n/a	First-order	EFSA Journal 2018;16(7):5389
Geometric mean (if not pH dependent)							

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 9 /38
Template for chemical PPP
Version December 2021
June 2022

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

8.4 Field studies (KCP 9.1.1.2)

Field studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

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

Data on soil dissipation of the active substance is presented in the following table.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 10 /38
Template for chemical PPP
Version December 2021
June 2022

8.4.1.1 Clopyralid

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

Clopyralid, Field studies								
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. (x^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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 11 /38
Template for chemical PPP
Version December 2021
June 2022

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not relevant since trigger is not exceeded. For calculated PEC,plateau see section on PECsoil (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 as presented in the following table.

8.5.1 Clopyralid

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

Clopyralid							
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.

8.5.2 Column leaching (KCP 9.1.2.1)

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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 12 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

According to EFSA Journal 2018;16(7):5389, the following Lysimeter/ field leaching study is available:

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. The data have however been attached as additional information, as evaluated during the first approval of clopyralid.	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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 13 /38
Template for chemical PPP
Version December 2021
June 2022

	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 point 8.5.2

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

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

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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 14 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

8.7 Predicted Environmental Concentrations in soil (PEC$_{soil}$) (KCP 9.1.3)

8.7.1 Justification for new endpoints

No new endpoints are presented in the current submission.

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

Predicted environmental concentrations in soil for clopyralid and formulation were calculated for the use on winter cereal (*winter wheat*), winter rape and sugar beet.

The interception rates were estimated to be 20% for winter cereal & sugar beet and 40% for winter rape. Crop interception at these growth stages was derived according to recommendations of FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014).

The initial PECsoil values of clopyralid were calculated the software tool ESCAPE 2.0 (26 November 2019). The results are presented in the below Tables.

Table 8.7-1: Input parameters related to application for PEC$_{soil}$ calculations

Use No.	1	2	3
Crop	Winter wheat	Winter rape	Sugar beet
Application rate (g as/ha)	Clopyralid; 120 g as/ha		Clopyralid; 90 g as/ha
Number of applications/interval	1/n.a.		
Crop interception (%)	20%	40%	20%
BBCH	BBCH 21-29	BBCH 10-50	BBCH 12-14
Depth of soil layer	5 cm		

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	EFSA Journal 2018;16(7):5389

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 15 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

8.7.2.1 Clopyralid

Table 8.7-3: **PEC$_{soil}$ for clopyralid on crop winter wheat**

PEC$_{soil}$ (mg/kg)		Winter wheat			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1280	-		-
Short term	24h	0.1243	0.1262		
	2d	0.1207	0.1243		
	4d	0.1139	0.1208		
Long term	7d	0.1043	0.1158		
	14d	0.0850	0.1050		
	21d	0.0693	0.0956		
	28d	0.0564	0.0874		
	42d	0.0375	0.0737		
	50d	0.0297	0.0673		
	100d	0.0069	0.0414		
Plateau concentration 5 cm		<0.0001	-		-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not required			

Table 8.7-4: **PEC$_{soil}$ for clopyralid on crop winter rape**

PEC$_{soil}$ (mg/kg)		Winter rape			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0960	-		-
Short term	24h	0.0932	0.0946		
	2d	0.0905	0.0933		
	4d	0.0854	0.0906		
Long term	7d	0.0782	0.0868		
	14d	0.0637	0.0788		
	21d	0.0519	0.0717		
	28d	0.0423	0.0655		
	42d	0.0281	0.0553		
	50d	0.0222	0.0504		
	100d	0.0052	0.0311		
Plateau concentration 5 cm		<0.0001	-		-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not required			

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 16 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Table 8.7-5: **PEC$_{soil}$ for clopyralid on crop sugar beet**

PEC$_{soil}$ (mg/kg)		Sugar beet			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0960	-		-
Short term	24h	0.0932	0.0946		
	2d	0.0905	0.0933		
	4d	0.0854	0.0906		
Long term	7d	0.0782	0.0868		
	14d	0.0637	0.0788		
	21d	0.0519	0.0717		
	28d	0.0423	0.0655		
	42d	0.0281	0.0553		
	50d	0.0222	0.0504		
	100d	0.0052	0.0311		
Plateau concentration 5 cm		<0.0001	-		-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not required			

8.7.2.2 PEC$_{soil}$ of Faworyt 300 SL

Table 8.7-6: **PEC$_{soil}$ for Faworyt 300 SL on crops winter wheat and winter rape**

Active substance/ reparation	Max. application rate (L/ha)	Amount of the product (g/ha)*	Crop inter-ception (%)	PEC$_{act}$ (mg formu-lation /kg soil)**	PEC$_{twa}$21 d (mg/kg)	Tillage depth (cm)	PEC$_{soil,plateau}$ (mg/kg)	PEC$_{accu}$ = PEC$_{act}$ + PEC$_{soil,plateau}$ (mg/kg)
Faworyt 300 SL *(Winter wheat)*	0.4	465.6	20	0.4966	n/a	5 cm	not required	not required
Faworyt 300 SL *(Winter rape)*	0.4	465.6	40	0.3725				
Faworyt 300 SL *(Sugar beet)*	0.3	349.2	20	0.3725				

* rate after taking into account of formulation density equal to 1.164 g/mL
** based on the recommended crop interception, soil density of 1.5 g/cm^3 and soil depth of 5 cm

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 17 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

> **ZRMS comments:**
> The calculations of PEC$_{soil}$ submitted by Applicant have been accepted.
> The degradation endpoint used for clopyralid corresponds to the worst case lab. DT50, normalised to 20 ºC and pF 2 in accordance with the LoEP (EFSA, 2018).
> All intended uses are covered by the presented PECsoil calculations.
> The PECsoil values for clopyralid that can be used for the risk assessment are presented in Tables 8.7-3 8.7.5.

8.8 Predicted Environmental Concentrations in groundwater (PEC$_{gw}$) (KCP 9.2.4)

8.8.1 Justification for new endpoints

PEC$_{gw}$ modelling for clopyralid was performed using the EU agreed endpoints from the EFSA Conclusion for clopyralid (EFSA Journal 2018; 16(7):5389). Modelling was first performed using the agreed endpoints for sorption, which is the geometric mean K$_{fOC}$ value of 1.41 mL/g and mean 1/n of 0.836. The modelling was repeated for corrected sorption endpoints.

EFSA derived the mean values after rejecting part the data that did not comply with the reliability criteria from the OECD 106 guideline. However, they rejected the 1/n values, but not the Kfoc values, which is not in line with the guideline. New sorption endpoints were derived here using the correct procedure from the OECD 106 guideline. The modelling was repeated using the corrected sorption parameters.

Table 8.8-1: New sorption endpoints proposed for clopyralid

	Mean values before applying OECD criteria	EFSA agreed endpoint (EFSA, 2018 [a])	Corrected endpoint
K$_{foc}$ (mL/g)	1.41 (geometric mean, n = 9)	1.41 (geometric mean, n = 9)	3.18 (geometric mean, n = 9)
1/n	0.739 (arithmetic mean, n = 9)	0.836 (arithmetic mean, n = 9)	0.836 (arithmetic mean, n = 9)

a) EFSA Journal 2018; 16(7):5389

Corrected sorption endpoints for clopyralid

Błąd! Nie można odnaleźć źródła odwołania. shows the sorption data that was evaluated by EFSA (2018). According to the OECD 106 test guideline (point 71), accurate determination of the Freundlich isotherm is possible if the Kd multiplied with the soil/solution rate is > 0.3 (indirect method) or > 0.1 (direct method). When failing this criterion, no Freundlich parameters should be derived (K$_{F,OC}$ and 1/n).

EFSA rejected the first four soils (Kd < 0.3, indirect method), and for the Longwoods and LUFA 2.1 soils (Kd <0.1, direct method). EFSA rejected the sorption exponent 1/n for these six soils, but failed to reject the corresponding K$_{F,OC}$ measurements. In our opinion it is incorrect to use the K$_{F,OC}$ values from nonlinear fits in combination with the default 1/n value. The small K$_{F,OC}$ values derived from nonlinear fits would underestimate the amount of sorption. Also, it is not in line with the OECD 106 guideline, which states that no K$_{F,OC}$ values should be derived for these soils.

The more recent EFSA report on the OECD 106 checklist (EFSA, 2017[1]; p.9-10) clarifies that the "estimate of sorption can be derived from the geometric mean of the individual distribution coefficient (Kd) values at each tested concentration. The organic carbon normalised adsorption coefficient (Koc) for each soil should be derived from the geometric mean Kd. These Koc values should be combined with a default 1/n value of 0.9 for inclusion in the regulatory database." Note that this refers to the Kdoc. So according to the EFSA report, one would use the Kdoc in combination with the default 1/n value, not the (rejected) Freundlich

---

[1] EFSA, 2017. Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326. 17 pp.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 18 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Kfoc values.

Table 8.8-2 shows the sorption data evaluated by EFSA (2018), but selecting the Kdoc instead of the Kfoc for the soils for which EFSA rejected the Freundlich exponent. The Kdoc was calculated from the Kd (Kd x 100/OC) and used in combination with the default 1/n of 0.9[2]. The new geometric mean Koc from combining the Kdoc and Kfoc values is 3.18 mL/g (n=9).

Table 8.8-2:   **Summary of soil adsorption/desorption for clopyralid**

Clopyralid								
Soil name	**OC (%)**	**pH (CaCl₂)**	**Kd (mL/g)**	**Kf (mL/g)**	**Kdoc (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Merzenhausen	1	7.19	0.051	- [a]	5.1	- [a]	0.9 [a]	y/ EFSA, 2018
Kaldenkirchen	0.98	5.34	0.048	- [a]	4.9	- [a]	0.9 [a]	y/ EFSA, 2018
Lanna	2.06	6.62	0.151	- [a]	7.33	- [a]	0.9 [a]	y/ EFSA, 2018
Overhetfeld	0.93	6.49	0.032	- [a]	3.4	- [a]	0.9 [a]	y/ EFSA, 2018
Calke sandy loam	3.15	5.7	0.139	0.01	-	0.5	0.489	y/ EFSA, 2018
Longwoods sandy loam	3.13	7.4	0.069	- [a]	2.2	- [a]	0.9 [a]	y/ EFSA, 2018
LUFA 2.1 loamy sand	0.68	4.9	0.040	- [a]	5.9	- [a]	0.9 [a]	y/ EFSA, 2018
Quilen loam	4.02	6.9	0.356	0.14	-	3.9	0.804	y/ EFSA, 2018
DU-L-PF clay loam	6.47	6.3	0.282	0.16	-	2.1	0.829	y/ EFSA, 2018
Geometric mean (n=9)					**3.18** [b]		-	y/ EFSA, 2018
Arithmetic mean (n=9)					-		0.836	y/ EFSA, 2018
pH-dependency y/n	No							

b) The amount of sorption during these tests was deemed too small to derived reliable Freundlich fits. (EFSA used criteria Kd < 0.1 for direct method and Kd < 0.3 for indirect method). Freundlich Kfoc and 1/n were rejected and replaced by the Kdoc and default 1/n of 0.9.

c) Geometric mean of combined Kdoc and Kfoc values

d) EFSA Journal 2018; 16(7):5389

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

The calculation of the predicted environmental concentrations in ground waters (PEC$_{GW}$) of clopyralid has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL v.4.4.4, FOCUS PELMO v.5.5.3 and MACRO in FOCUS v5.5.4. Calculation were performed for FOCUS scenarios relevant for Poland (*Hamburg, Kremsmünster & Chateaudun*) and Romania (*Hamburg & Okehampton).* Application scenarios which were considered for the simulations are summarised in belowTables.

The application dates for the individual crop were selected using the tool "AppDate Version 2.03" (current system version 2.03).

Table 8.8-3:   **Input parameters related to application for PEC$_{gw}$ calculations**

Use No.	1	2	3

---

[2] The default 1/n value of 0.9 is acceptable when the Koc value is derived from on a range of test concentrations. When derived from a single concentration, then according to the latest EFSA guidance, the default 1/n value is 1.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 19 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Crop	Winter wheat	Winter rape	Sugar beet
Application rate (g as/ha)	Clopyralid; 120 g as/ha		Clopyralid; 90 g as/ha
Calculated amount of active reaching soil (kg a.s./ha)	~~0.06~~ 0.096	0.072	0.072
Number of applications/interval (d)	1/n.a.		
Crop interception (%)	~~50%~~ 20 %	40%	20%
BBCH	BBCH 21-29	BBCH 10-50	BBCH 12-14
Relative application date	-	-	-
Frequency of application	~~Annual~~ biennial	biennial	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4		

Table 8.8-4:   **Application dates used for groundwater risk assessment**

Scenario	Application dates (absolute)		
	Crop		
	winter cereal (*winter wheat*)	Winter rape	Sugar beet
Châteaudun			
Hamburg	1 April	1 April	1 April
Kremsmünster			20 April
Okehampton			

8.8.2.1   Clopyralid and its metabolites

Table 8.8-5:   **Input parameters related to active substance Clopyralid 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 (g/mol):	1.43×10^5 and 20°C	EFSA Journal 2018;16(7):5389
Saturated vapour pressure (Pa):	set to 0 Pa as worst case and 20°C	EFSA Journal 2018;16(7):5389
DT_{50} in soil (d)	7.05 d (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58/2.2, n =10)	EFSA Journal 2018;16(7):5389
K_{foc} (mL/g)	1.41 mL/g (geometric mean, n = 9)	EFSA Journal 2018;16(7):5389
K_{fom} (mL/g)	0.82 mL/g	calculated from Kfoc; Kfom = Kfoc/1.724
1/n	0.836 (arithmetic mean/, n = 9)	EFSA Journal 2018;16(7):5389
Plant uptake factor	0*/ 0.000271**	EFSA Journal 2018;16(7):5389
Revised sorption coefficient (Table 8.8-2)		
K_{foc} (mL/g)	3.18 (geometric mean, n = 9)	See Table 8.8-2
K_{fom} (mL/g)	1.821	$K_{fOC}/1.724$

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 20 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

*Tier 1

** 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]

Table 8.8-6: **PEC$_{gw}$ for Clopyralid on crops winter cereal, winter rape and sugar beet (with FOCUS PEARL v. 4.4.4)**

Application date	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)				
		annual app. Agreed endpoints (EFSA, 2018)		annual app. Clopyralid Revised sorption K$_{foc}$		bi-annual app. Agreed endpoints (EFSA, 2018)
		Tier 1 (PUF = 0)	*Tier 2 (PUF =0.000271)*	*Tier 1 (PUF = 0)*	*Tier 2 (PUF =0.000271)*	*Tier 1 (PUF = 0)*
winter cereal; Max. app. rate: 120 g a.s./ha with ~~50~~ 20 %; BBCH (21-29)						
1 April	Châteaudun	~~0.004028~~ 0.006804	~~0.004027~~	0.003796	-	-
	Hamburg	~~0.086568~~ 0.144155	~~0.086542~~	0.080010	-	-
	Kremsmünster	~~0.087719~~ 0.145283	~~0.087701~~	0.085765	-	-
	Okehampton	~~0.084744~~ **0.139491**	~~0.084716~~	0.090394	-	-
winter rape; Max. app. rate: 120 g a.s./ha with 40 %; BBCH (10-50)						
1April	Châteaudun	0.015452	0.015449	0.007596	0.007594	-
	Hamburg	**0.142703**	**0.142661**	0.076808	0.076792	-
	Kremsmünster	**0.169002**	**0.168974**	0.098859	0.098844	-
	Okehampton	**0.130806**	**0.130776**	0.080447	0.080431	-
Sugar beet; Max. app. rate: 90 g a.s./ha with 20 %; BBCH (12-14)						
20 April	Châteaudun	0.087199	0.087167	-	-	-
	Hamburg	0.061421	0.061390	-	-	-
	Kremsmünster	0.043550	0.043538	-	-	-
	Okehampton	0.049027	0.049021	-	-	-
Sugar beet; Max. app. rate: 90 g a.s./ha with 20 %; BBCH (12-14)						
1April	Châteaudun	0.072472	0.072448	-	-	-
	Hamburg	0.044140	0.044119	-	-	-
	Kremsmünster	0.037282	0.037275	-	-	-
	Okehampton	0.043982	0.043976	-	-	-

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 21 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Table 8.8-5: **PEC$_{gw}$ for Clopyralid on crops winter cereal, winter rape and sugar beet (with FOCUS PELMO v.5.5.3)**

Applica-tion date	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)						
		annual app. Agreed endpoints (EFSA, 2018)		annual app. Clopyralid Revised sorption K$_{foc}$		bi-annual app. Agreed endpoints (EFSA, 2018)		bi-annual app. Revised sorption K$_{foc}$
		Tier 1 (PUF = 0)	*Tier 2 (PUF =0.000271)*	*Tier 1 (PUF = 0)*	*Tier 2 (PUF =0.000271)*	*Tier 1 (PUF = 0)*	*Tier 2 (PUF =0.000271)*	*Tier 1 (PUF = 0)*
winter cereal; Max. app. rate: 120 g a.s./ha with ~~50~~ 20 %; BBCH (21-29)								
1 April	Châteaudun	~~0.003~~-**0.005**	~~0.003~~	~~0.001~~-**0.002**	~~0.001~~	**0.003**	-	0.001
	Hamburg	~~0.091~~-**0.155**	~~0.091~~	~~0.043~~-**0.076**	~~0.043~~	0.073	-	0.035
	Kremsmünster	~~0.105~~-**0.179**	~~0.105~~	~~0.059~~-**0.102**	~~0.059~~	**0.107**	-	0.061
	Okehampton	~~0.121~~-**0.205**	~~0.121~~	~~0.070~~-**0.123**	~~0.070~~	0.086	-	0.057
winter rape; Max. app. rate: 120 g a.s./ha with 40 %; BBCH (10-50)								
1April	Châteaudun	0.008	0.008	0.004	0.004	0.005	0.005	-
	Hamburg	**0.106**	**0.106**	0.057	0.057	0.053	0.053	-
	Kremsmünster	**0.181**	**0.181**	**0.101**	**0.101**	0.098	0.098	-
	Okehampton	**0.160**	**0.160**	**0.106**	**0.106**	0.089	0.089	-
sugar beet; Max. app. rate: 90 g a.s./ha with 20 %; BBCH (12-14)								
20 April	Châteaudun	0.018	0.018	-	-	-	-	-
	Hamburg	0.024	0.024	-	-	-	-	-
	Kremsmünster	0.048	0.048	-	-	-	-	-
	Okehampton	0.081	0.081	-	-	-	-	-
sugar beet; Max. app. rate: 90 g a.s./ha with 20 %; BBCH (12-14)								
1April	Châteaudun	0.014	0.014	-	-	-	-	-
	Hamburg	0.037	0.037	-	-	-	-	-
	Kremsmünster	0.042	0.042	-	-	-	-	-
	Okehampton	0.071	0.071	-	-	-	-	-

Applications were considered for the FOCUS scenarios *Chateaudun, Hamburg, Kremsmunster and Oakhampton* defined for the FOCUS crops winter oilseed rape, winter cereal and sugar beet in PEARL and PELMO. For FOCUS MACRO, only the scenario 'Chateaudun' is defined. Application dates are presented in Table 8.8.2. The dates were selected with the tool AppDate (current system version 2.03).

In the first instance runs were simulated with annual application of FAWORYT 300 SL on winter oilseed rape. The results of modelling with PELMO studies show that the active substance clopyralid exceeding of the trigger value of 0.1 µg/L for two scenarios (*Kremsmunster and Oakhampton*), therefore a second calculation was performed with bi-annual application. The results of the PECgw calculation with FOCUS PELMO with a bi-annual application indicate that PECgw of clopyralid were less than 0.1 µg/L for all relevant scenarios in uses in winter oilseed rape.

The predicted environmental concentration (PEC_gw) of clopyralid obtained from models FOCUS PEARL and FOCUS PELMO for winter cereal and sugar beet, indicate the PECgw values were below the trigger of 0.1 µg/L for all model scenarios with an annual application.

Table 8.8-6:   **80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth follow-ing the <u>annual application</u> to <u>winter cereals</u>, 1 × 120 g a.s./ha; CI 50% (FOCUS MACRO)**

Application date	Julian Days	Scenario	80th percentile PECgw (µg/L)
			Tier 1 *(PUF = 0)*
1 April	91	Châteaudun	0.00218

Table 8.8-7:   **80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth follow-ing the <u>annual application</u> to <u>winter rape</u>, 1 × 120 g a.s./ha; CI 40% (FOCUS MACRO)**

Application date	Julian Days	Scenario	80th percentile PECgw (µg/L)
			Tier 1 *(PUF = 0)*
1 April	91	Châteaudun	0.0029

Table 8.8-8:   **80th percentile leachate concentrations of clopyralid in groundwater at 1 m soil depth follow-ing the <u>annual application</u> to <u>sugar beet</u>, 1 × 90 g a.s./ha; CI 20% (FOCUS MAC-RO)**

Application date	Julian Days	Scenario	80th percentile PECgw (µg/L)
			Tier 1 *(PUF = 0)*
1 April	91	Châteaudun	0.025
20 April	110		0.0215

All PEC_gw values obtained using MACRO model (Châteaudun scenario) were less than 0.1 µg/L in the intended for uses in winter cereals, winter rape and sugar beet.

ZRMS comments:

PECgw calculations were performed with the FOCUS scenarios relevant for Poland using the FOCUS PELMO (5.5.3) and FOCUS PEARL model Châteaudun, Hamburg, Kremsmünster, Okehampton.
All input parameters for clopyralid were considered acceptable as they followed the LoEP (2018).
The predicted environmental concentration (PECgw) of clopyralid obtained from models FOCUS PEARL and FOCUS PELMO for sugar beet indicate the PECgw values were below the trigger of 0.1 µg/L for all model scenarios with an annual application.
All PECgw values obtained using MACRO model (Châteaudun scenario) were less than 0.1 µg/L in the intended for uses in winter cereals, winter rape and sugar beet.

After re-calculation by Applicant the predicted environmental concentration (PECgw) of clopyralid obtained from models FOCUS PEARL and FOCUS PELMO for winter cereal and winter rape with bi-annual application were below the trigger of 0.1 µg/L.
Based on the assessment, the use of clopyralid is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern:
-       Winter cereals and winter rape with an bi-annual application
-       Sugar beet with an annual application

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 23 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

8.9 Predicted Environmental Concentrations in surface water (PEC$_{SW}$) (KCP 9.2.5)

8.9.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints

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

The calculation of the predicted environmental concentrations in surface waters and water sediments (PEC$_{SW}$ and PEC$_{SED}$) of clopyralid and the formulation have been assessed.

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

Plant protection product	Faworyt 300 SL		
Use No.	1	2	3
Crop	Winter wheat	Winter rape	Sugar beet
Application rate (kg as/ha)	Clopyralid; 120 g as/ha		Clopyralid; 90 g as/ha
Number of applications/interval (d)	1/n.a.		
Application window	March - May (relevant for STEP 1 and 2 only)		
Interception	average crop cover - (Step2)	minimal crop cover - (Step2)	
Application method	Sprying		
Models used for calculation	STEPS 1-2 in FOCUS v.3.2		

8.9.2.1 Clopyralid

Table 8.9-2: Input parameters related to active substance clopyralid for PEC$_{sw/sed}$ calculations STEP 1/2

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)	not required for Step 1+2	-
Water solubility (mg/L)	1.43×10^5 and 20°C	EFSA Journal 2018;16(7):5389
Diffusion coefficient in water (m²/d)	not required for Step 1+2	-
Diffusion coefficient in air (m²/d)	not required for Step 1+2	-
K$_{foc}$ (mL/g)	1.41 mL/g (geometric mean, n	EFSA Journal 2018;16(7):5389

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 24 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Compound	Clopyralid	Value in accordance to EU end-point y/n/ Reference
	= 9)	
Freundlich Exponent 1/n	not required for Step 1+2	-
Plant Uptake	not required for Step 1+2	-
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	-
$DT_{50,soil}$ (d)	7.05 d (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58/2.2, n =10)	EFSA Journal 2018;16(7):5389
$DT_{50,water}$ (d)	0	EFSA Journal 2018;16(7):5389
$DT_{50,sed}$ (d)	0	EFSA Journal 2018;16(7):5389
$DT_{50,whole\ system}$ (d)	0	EFSA Journal 2018;16(7):5389
Maximum occurrence observed (% molar basis with respect to the parent)	-	
Formation fraction in soil:	-	

PECsw/sed

Table 8.9-3: **FOCUS Step 1,2 and 3 PECsw and PECsed for clopyralid following single/ multiple application(s) of Fawort 300 SL to winter cereals and winter oilseed rape**

Scenario FOCUS	Waterbody	Max PECsw (µg/L)*	Dominant entry route	7 d- PECsw,twa (µg/L)**	Max PECsed (µg/kg)*
Step 1	---	41.0285		40.9272	0.5629
Step 2 - Winter cereals	ditch	5.4101	spray drift, runoff, drainage	5.3963	0.0762
Step 2- Winter oilseed rape	ditch	4.3323		4.3212	0.0610
Northern Europe	March-May, spring sprying				

** twa-time as required by ecotox

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 25 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Table 8.9-5: **FOCUS Step 1,2 and 3 PEC$_{sw}$ and PEC$_{sed}$ for clopyralid following single/ multiple application(s) of Fawort 300 SL to sugar beets**

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)*	Dominant entry route	7 d- PEC$_{sw,twa}$ (µg/L)**	Max PEC$_{sed}$ (µg/kg)*
Step 1	---	30.7714	spray drift, runoff, drainage	30.6954	0.4222
Step 2	dirch	5.4101		5.3963	0.0762

During degradation studies in soil no significant metabolites were found. Thus, no predicted environmental concentrations in surface water and sediment for metabolites were calculated.

Relevant outputs from calculation are included in appendix 3.

8.9.2.2 PEC$_{sw/sed}$ of Faworyt 300 SL

The PEC values of Faworyt 300 SL in surface water have been assessed with the FOCUS SWASH model. The PEC$_{SW}$ for single application and for the highest application rate (0.4L/ha x 1.161 g/ml = 464.4 g/ha) recommended for use in winter wheat.

Table 8.9-7: **The PEC$_{SW}$ values for MEDALISTA 60 SG on winter cereals**

Mitigation distances from crop (m)	Water-body	Drift values (%)	Mass loading per drift event (mg/m² of water surface area)	PECsw (µg/L)
1		2.76	0.895	2.984
5		0.57	0.243	0.809
10		0.29	0.129	0.429
20		0.15	0.067	0.223

---

zRMS comments:

The PECsw calculations at Step 1-2 are acceptable. 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

Compound	clopyralid
Direct photolysis in air	No data
Quantum yield of direct phototransformation	1.01 x· 10 –6 mol · Einstein -1
Photochemical oxidative degradation in air	DT50 = 19.5 days (Atkinson calculation using AOPWIN v.1.90)
Volatilisation	BBA guideline: from plant surfaces: ≤4 % in 24 hours BBA guideline: from soil

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 26 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

	Vapour pressure (Pa): 1.36×10^{-3} kPa at 25°C
	Henry's Law Constant (Pa.m3/mol): 3.28×10^{-10}

The fate and behaviour in air of clopyralid was evaluated during the Annex I Inclusion. No additional studies have been performed.

There was no need to calculate PEC_A due to low volatility of clopyralid.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 27 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

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 9.2.4	Łożuk I.	2021	Calculation of the predicted environmental concentrations of clopyralid in groundwater after application of Faworyt 300 SL (FOCUS PEARL, FOCUS PELMO, MACRO in FOCUS) CIECH Sarzyna S.A., Poland RR/14/21 non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 9.2.5	Siwiec I.	2021	Calculation of the predicted environmental concentrations of clopyralid in surface water after application of Faworyt 300 SL (FOCUS Step 1 and 2) CIECH Sarzyna S.A., Poland RR/15/21 non GLP Unpublished	N	CIECH Sarzyna S.A.

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 28 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 29 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

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

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 30 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Appendix 2   Detailed evaluation of the new Annex II studies

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

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 1

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 08.07.2021, 09:57:44

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: winter cereals, North Europe, spring, 1 app/season

Active substance:	Clopyralid
Application rate (g/ha) of a.i.:	120.00
Application/crop type:	cereals, winter
Number of applications per season:	1.00
Water solubility (mg/L):	143000.00
KOC compound(L/kg):	1.41
DT50 water/sediment (d):	1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Equilvalent app. rate for drift (g/ha):	120.00
Equilvalent app. rate for runoff/drainage(g/ha):	120.00
Equilvalent app. rate for runoff/drainage(g/ha) of parent:	0.00E+00
Loading to water body via drift (mg/m2):	0.3311
Loading to water body via runoff/drainage(mg/m2):	12.0000

fraction of substance entering water body in water phase: 0.9981
fraction of substance entering water body in sediment phase: 0.0019

Table: Calculated Concentrations in the water body

	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA
0	41.0285		0.5629	
1	40.9980	41.0133	0.5781	0.5705
2	40.9696	40.9986	0.5777	0.5742
4	40.9129	40.9699	0.5769	0.5757
7	40.8279	40.9272	0.5757	0.5760
14	40.6303	40.8281	0.5729	0.5751
21	40.4336	40.7294	0.5701	0.5739
28	40.2379	40.6309	0.5674	0.5726
42	39.8493	40.4351	0.5619	0.5699
50	39.6290	40.3237	0.5588	0.5684
100	38.2791	39.6369	0.5397	0.5588

Maximum PECsw values in water and sediment are calculated from single application.
Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Preditions Step 2

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 08.07.2021, 09:57:47

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: winter cereals, North Europe, spring, 1 app/season

Active substance: Clopyralid
Application rate (g/ha) of a.i.:   120.00
Crop Interception: average crop cover (20 %)
Application/crop type: cereals, winter
Number of applications per season: 1
Region and season of application: North Europe, Mar. - May
Water solubility (mg/L):   143000.00
KOC assessed compound(L/kg):   1.41
KOC parent compound(L/kg):   0.00E+00
DT50 water(d):   1000.00
DT50 sediment (d):   1000.00
DT50 soil (d):   7.05

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):   1.00
Spraydrift (% of application):   2.7590
Runoff + drainage(% of application):   2.00

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 32 /38
Template for chemical PPP
Version ~~December 2021~~
June 2022

Ratio of field to water body: 10.00

Water depth (cm):   30.00
Sediment depth (cm):   5.00
Effective sediment depth for sorption (cm):   1.00
Sediment OC (%):   5.00
Sed. bulk density (kg/L):   0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run: 1

Equilvalent application rate for drift (g/ha):   120.00
Equilvalent application rate for runoff/drainage(g/ha):   96.00

Loading to water body per drift event(mg/m2):   0.3311
Loading to water body via runoff/drainage (mg/m2):   1.2957
   fraction of substance entering water body in water phase: 0.9981
   fraction of substance entering water body in sediment: 0.0019

Total Loading to water body via drift (mg/m2):   0.3311 (20.3519%)
Total Loading to water body via water phase(mg/m2):   1.2933 (79.4987%)
Total Loading to water body via sediment phase (mg/m2):   0.0024 (0.1495%)
Maximum PECSW (µg/L):   5.4101
Maximum PECSW occuring on day: 4
Maximum PECsed (µg/kg dry sediment):   0.0762
Maximum PECsed occuring on day: 5

Table: Calculated Concentrations in the water body

	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
Time after max. peak(d)	Actual	TWA	Actual	
0	5.4101	---	0.0762	---
1	5.4056	5.4078	0.0762	0.0762
2	5.4019	5.4058	0.0761	0.0762
4	5.3944	5.4020	0.0760	0.0761
7	5.3832	5.3963	0.0759	0.0760
14	5.3571	5.3832	0.0755	0.0759
21	5.3312	5.3702	0.0751	0.0757
28	5.3054	5.3572	0.0748	0.0755
42	5.2542	5.3314	0.0740	0.0751
50	5.2251	5.3167	0.0736	0.0749
100	5.0471	5.2262	0.0711	0.0736

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 1

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 08.07.2021, 10:31:01

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 33 /38
Template for chemical PPP
Version ~~December 2021~~
<mark>June 2022</mark>

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: winter rape, North Europe, spring, 1 app/season

Active substance:	Clopyralid
Application rate (g/ha) of a.i.:	120.00
Application/crop type:	oil seed rape, winter
Number of applications per season:	1.00
Water solubility (mg/L):	143000.00
KOC compound(L/kg):	1.41
DT50 water/sediment (d):	1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):	1.00
Spraydrift (% of application):	2.7590
Runoff + drainage(% of application):	10.00
Ratio of field to water body:	10.00
Water depth (cm):	30.00
Sediment depth (cm):	5.00
Effective sediment depth for sorption (cm):	1.00
Sediment OC (%):	5.00
Sed. bulk density (kg/L):	0.80

RESULTS OF THE CALCULATION

Equilvalent app. rate for drift (g/ha):	120.00
Equilvalent app. rate for runoff/drainage(g/ha):	120.00
Equilvalent app. rate for runoff/drainage(g/ha) of parent:	0.00E+00
Loading to water body via drift (mg/m2):	0.3311
Loading to water body via runoff/drainage(mg/m2):	12.0000
fraction of substance entering water body in water phase:	0.9981
fraction of substance entering water body in sediment phase:	0.0019

Table: Calculated Concentrations in the water body

	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA
0	41.0285		0.5629	
1	40.9980	41.0133	0.5781	0.5705
2	40.9696	40.9986	0.5777	0.5742
4	40.9129	40.9699	0.5769	0.5757
7	40.8279	40.9272	0.5757	0.5760
14	40.6303	40.8281	0.5729	0.5751
21	40.4336	40.7294	0.5701	0.5739
28	40.2379	40.6309	0.5674	0.5726
42	39.8493	40.4351	0.5619	0.5699
50	39.6290	40.3237	0.5588	0.5684
100	38.2791	39.6369	0.5397	0.5588

Maximum PECsw values in water and sediment are calculated from single application.
Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 34 /38
Template for chemical PPP
Version December 2021
June 2022

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Preditions Step 2

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 08.07.2021, 10:31:03

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: winter rape, North Europe, spring, 1 app/season

Active substance: Clopyralid
Application rate (g/ha) of a.i.:   120.00
Crop Interception: minimal crop cover (40 %)
Application/crop type: oil seed rape, winter
Number of applications per season: 1
Region and season of application: North Europe, Mar. - May
Water solubility (mg/L):   143000.00
KOC assessed compound(L/kg):   1.41
KOC parent compound(L/kg):   0.00E+00
DT50 water(d):   1000.00
DT50 sediment (d):   1000.00
DT50 soil (d):   7.05

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):   1.00
Spraydrift (% of application):   2.7590
Runoff + drainage(% of application):   2.00
Ratio of field to water body: 10.00

Water depth (cm):   30.00
Sediment depth (cm):   5.00
Effective sediment depth for sorption (cm):   1.00
Sediment OC (%):   5.00
Sed. bulk density (kg/L):   0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run: 1

Equilvalent application rate for drift (g/ha):   120.00
Equilvalent application rate for runoff/drainage(g/ha):   72.00

Loading to water body per drift event(mg/m2):   0.3311
Loading to water body via runoff/drainage (mg/m2):   0.9718
      fraction of substance entering water body in water phase: 0.9981
      fraction of substance entering water body in sediment: 0.0019

Total Loading to water body via drift (mg/m2):   0.3311 (25.4119%)

Total Loading to water body via water phase(mg/m2):   0.9700 (74.4481%)
Total Loading to water body via sediment phase (mg/m2): 0.0018 (0.1400%)
Maximum PECSW (µg/L):   4.3323
Maximum PECSW occuring on day: 4
Maximum PECsed (µg/kg dry sediment):   0.0610
Maximum PECsed occuring on day: 5

Table: Calculated Concentrations in the water body

	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
Time after max. peak(d)		Actual	TWA	Actual
0	4.3323	---	0.0610	---
1	4.3286	4.3305	0.0610	0.0610
2	4.3256	4.3288	0.0609	0.0610
4	4.3197	4.3257	0.0609	0.0609
7	4.3107	4.3212	0.0607	0.0609
14	4.2898	4.3107	0.0604	0.0607
21	4.2691	4.3003	0.0602	0.0606
28	4.2484	4.2899	0.0599	0.0604
42	4.2074	4.2692	0.0593	0.0602
50	4.1841	4.2575	0.0590	0.0600
100	4.0416	4.1849	0.0569	0.0590

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Predictions Step 1

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 08.07.2021, 10:35:03

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: sugar beet, North Europe, spring, 1 app/season

Active substance: Clopyralid
Application rate (g/ha) of a.i.:   90.00
Application/crop type: sugar beets
Number of applications per season: 1.00
Water solubility (mg/L):   143000.00
KOC compound(L/kg):   1.41
DT50 water/sediment (d):   1000.00

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):   1.00
Spraydrift (% of application):   2.7590
Runoff + drainage(% of application): 10.00
Ratio of field to water body: 10.00

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 36 /38
Template for chemical PPP
Version December 2021
June 2022

Water depth (cm):   30.00
Sediment depth (cm):   5.00
Effective sediment depth for sorption (cm):   1.00
Sediment OC (%):   5.00
Sed. bulk density (kg/L):   0.80

RESULTS OF THE CALCULATION

Equilvalent app. rate for drift (g/ha):   90.00
Equilvalent app. rate for runoff/drainage(g/ha):   90.00
Equilvalent app. rate for runoff/drainage(g/ha) of parent: 0.00E+00
Loading to water body via drift (mg/m2):   0.2483
Loading to water body via runoff/drainage(mg/m2):   9.0000
      fraction of substance entering water body in water phase: 0.9981
      fraction of substance entering water body in sediment phase: 0.0019

Table: Calculated Concentrations in the water body

	PECsw (µg/L)		PECsed(µg/kg dry sediment)	
Time (d)	Actual	TWA	Actual	TWA
0	30.7714		0.4222	
1	30.7485	30.7600	0.4336	0.4279
2	30.7272	30.7489	0.4333	0.4306
4	30.6847	30.7274	0.4327	0.4318
7	30.6209	30.6954	0.4318	0.4320
14	30.4727	30.6211	0.4297	0.4313
21	30.3252	30.5470	0.4276	0.4304
28	30.1784	30.4732	0.4255	0.4295
42	29.8870	30.3263	0.4214	0.4275
50	29.7217	30.2428	0.4191	0.4263
100	28.7093	29.7277	0.4048	0.4191

Maximum PECsw values in water and sediment are calculated from single application.
Compare with ecotox endpoints. If TER values are less than regulatory triggers, then go to Step 2

STEPS 1-2 in FOCUS

FOCUS Surface water Tool for Exposure Preditions Step 2

developed by Michael Klein

Program version: Version 3.2
Date of this simulation: 08.07.2021, 10:35:06

OVERVIEW ON THE SUBSTANCE SPECIFIC INPUT DATA USED IN THE CALCULATION

Comments: sugar beet, North Europe, spring, 1 app/season

Active substance: Clopyralid
Application rate (g/ha) of a.i.:   90.00
Crop Interception: minimal crop cover (20 %)
Application/crop type: sugar beets
Number of applications per season: 1

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 37 /38
Template for chemical PPP
Version ~~December 2021~~
<mark>June 2022</mark>

Region and season of application: North Europe, Mar. - May
Water solubility (mg/L):   143000.00
KOC assessed compound(L/kg):   1.41
KOC parent compound(L/kg):   0.00E+00
DT50 water(d):   1000.00
DT50 sediment (d):   1000.00
DT50 soil (d):   7.05

SCENARIO DATA USED IN THE CALCULATION

Distance to the water body (m):   1.00
Spraydrift (% of application):   2.7590
Runoff + drainage(% of application):   2.00
Ratio of field to water body: 10.00

Water depth (cm):   30.00
Sediment depth (cm):   5.00
Effective sediment depth for sorption (cm):   1.00
Sediment OC (%):   5.00
Sed. bulk density (kg/L):   0.80

RESULTS OF THE CALCULATION

Number of application per season considered for this run: 1

Equilvalent application rate for drift (g/ha):   90.00
Equilvalent application rate for runoff/drainage(g/ha):   72.00

Loading to water body per drift event(mg/m2):   0.2483
Loading to water body via runoff/drainage (mg/m2):   0.9718
    fraction of substance entering water body in water phase: 0.9981
    fraction of substance entering water body in sediment: 0.0019

Total Loading to water body via drift (mg/m2):   0.2483 (20.3519%)
Total Loading to water body via water phase(mg/m2):   0.9700 (79.4987%)
Total Loading to water body via sediment phase (mg/m2):   0.0018 (0.1495%)
Maximum PECSW (µg/L):   4.0575
Maximum PECSW occuring on day: 4
Maximum PECsed (µg/kg dry sediment):   0.0572
Maximum PECsed occuring on day: 5

Table: Calculated Concentrations in the water body

Time after max. peak(d)	PECsw (µg/L) Actual	PECsw (µg/L) TWA	PECsed(µg/kg dry sediment) Actual	PECsed(µg/kg dry sediment) TWA
0	4.0575	---	0.0572	---
1	4.0542	4.0559	0.0571	0.0571
2	4.0514	4.0543	0.0571	0.0571
4	4.0458	4.0515	0.0570	0.0571
7	4.0374	4.0472	0.0569	0.0570
14	4.0178	4.0374	0.0566	0.0569
21	3.9984	4.0277	0.0563	0.0568
28	3.9790	4.0179	0.0561	0.0566
42	3.9406	3.9985	0.0555	0.0563

K-300 SL-RR/FAWORYT 300 SL
Part B – Section 8 - Core Assessment
Applicant/ version

Page 38 /38
Template for chemical PPP
Version December 2021
June 2022

50	3.9188	3.9875	0.0552	0.0562
100	3.7853	3.9196	0.0533	0.0552