FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: PP-113H

Product name(s): BARILOCHE

Chemical active substance:

Clopyralid 100 g/L (10% w/v) SL

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: PROPLAN Plant Protection Company, S.L.

Submission date: December 2021

MS Finalisation date: July 2022; corrected 04.2023; corrected II_06.2023

Version history

When	What
February 2019	Initial version
December 2021	Version 2, Update for the renewal.
July 2022	Assessment dRR art.43
April 2023	The final version of RR after commenting period.
June 2023	The final version of RR after II commenting period.

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8 Fate and behaviour in the environment (KCP 9)

The product BARILOCHE (Clopyralid 10% w/v SL), is currently registered in Italy (16096), Spain (ES-00493), UK (Re. No. 17577), Poland (Reg. No. R-26/2018wu), Germany (Reg. No. 008865-00), Czech Republic (Reg. No. 5583-0) and Romania (Reg. No. 466PC) in Sugar beet.

This new dossier has been carried out to support the renewal of the approval of the active substance Clopyralid.

All the changes that have been made in this section, with respect to the original dossier, have been highlighted in yellow. It must be taken into account that the format of the dossier has changed.

8.1 Critical GAP and overall conclusions

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

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

1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	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			PECgw
1	C. EU (CZ, DE, PL, RO)	Sugar beet	F	CIRAR and COMPOSITAE	Tractor boom sprayer	BBCH 10-39	1	1.2	120	80-400	-	Do not use between the 31st August and 1st March	Do not use between the 31st August and 1st March Further refinement for scenarios Piacenza and Okehampton is required on national level For others scenarios risk mitigation measures are required: application every two years

* 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

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

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

zRMS comments:

The dRR was prepared by applicant. All comments and conclusions of the zRMS are presented in grey or yellow post RR.
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.

8.2 Metabolites considered in the assessment

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 substances. The degradation endpoints for the active substance clopyralid in the following sections were taken from the EFSA conclusion for clopyralid (EFSA Journal 2018; 16(7):5389).

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Clopyralid

Laboratory studies of clopyralid degradation in aerobic soils are reported in the EFSA conclusion of clopyralid (EFSA Journal 2018; 16(7):5389).

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

clopyralid, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH (H_2O)**	**t.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C, pF2 [a]**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Para-braunerde	silt loam	7.7	20	18.63 [b]	44.4	147.3	34.2	6.796	SFO	y/ EFSA, 2018[e]
Marcham	sandy clay loam	8.3	20	20.19 [b]	34.5	114.7	32.4	5.478	SFO	y/ EFSA, 2018[e]
Castle Rising	sandy loam	8	20	65.13 [b]	26.3	87.3	26.3	8.284	SFO	y/ EFSA, 2018[e]
Speyer 2.1	sand	6.5	20	12.58 [b]	64.6	214.6	64.6	5.466	SFO	y/ EFSA, 2018[e]
Speyer 2.2	sand	6.3	20	18.56 [b]	16.2	53.8	16.2	7.78	SFO	y/ EFSA, 2018[e]
Marshall county	silt loam	6	25	23.42 [c]	8.6	28.5	11.6	6.49	SFO	y/ EFSA, 2018[e]
A (sandy loam)	sandy loam	6.2	20	24.28 [d]	16.5	54.8	16.5	4.856	SFO	y/ EFSA, 2018[e]
B (clay loam)	clay loam	7.6	20	28.05 [d]	23	76.4	23.0	6.767	SFO	y/ EFSA, 2018[e]
C (clay loam)	clay loam	5.6	20	48.17 [d]	4.9	16.2	4.9	12.73	SFO	y/ EFSA, 2018[e]
D (loam)	loam	7.5	20	35.30 [d]	9.8	32.4	9.8	10.17	SFO	y/ EFSA, 2018[e]
						Geometric mean (n=10)	**19.1**			
						pH-dependency: y/n	No			

a) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
b) Reported soil moisture: 40% of maximum WHC

c) Reported soil moisture: 75% of 1/3 bar WHC
d) Reported soil moisture: 45% WHC
e) EFSA Journal 2018; 16(7):5389

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)

Anaerobic degradation of clopyralid in soil were evaluated during the EU peer review. No anaerobic degradation or photolysis in soil was observed for clopyralid (DT50 > 1 year).

8.4 Field studies (KCP 9.1.1.2)

No field studies were performed with the formulation, 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)

8.4.1.1 Clopyralid

Field dissipation studies with clopyralid were evaluated at EU level and reported in the EFSA conclusion on clopyralid (EFSA Journal 2018; 16(7):5389). The field dissipation DT50 are shown in Table 8.4-1. The longest non-normalised field DT50 of 23.7 days is selected for PEC_{soil} calculations.

The field DegT50 derived by normalisation of the field dissipation endpoints are shown in Table 8.4-2. The geometric mean vale of 7.05 days was selected as agreed endpoint for use in modelling for surface water and groundwater.

Triggering endpoints

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

Clopyralid, Field studies – Triggering endpoints									
Soil type	**Location**	**pH (H_2O)**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Loamy sand (bare)	Bargstedt, Germany	4.3	0-100	21	69.6	-	13	SFO	y/ EFSA, 2018 [a]
Loam (bare)	Wilson, UK	6.2	0-100	16.7	55.6	-	13.5	SFO	y/ EFSA, 2018 [a]
Silty clay loam (bare)	Sermaises, France	7	0-100	16.3	54	-	7.5	SFO	y/ EFSA, 2018 [a]
Silty clay loam (bare)	Ansonville, France	8.2	0-20	0.16	12.1	-	2.07	DFOP	y/ EFSA, 2018 [a]

Clopyralid, Field studies – Triggering endpoints									
Soil type	**Location**	**pH (H_2O)**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (x^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Clay loam (bare)	Mainbervilliers, France	7.1	0-20	6.04	28.3	-	2.7	DFOP	y/ EFSA, 2018 [a]
Silty clay loam (bare)	Oederquart, Germany	7.5	0-20	16.2	53.9	-	5.69	SFO	y/ EFSA, 2018 [a]
Sandy clay loam (bare)	Middlefart, Denmark	7.5	0-20	23.7	78.7	-	8.46	SFO	y/ EFSA, 2018 [a]
Clay loam (bare)	Canals, Spain	8.0	0-100	13.7	45.5	-	12.3	SFO	y/ EFSA, 2018 [a]
Silty clay loam (bare)	B.Württemberg, Germany	7.4	0-100	10.2	33.9	-	9.34	SFO	y/ EFSA, 2018 [a]
Silt loam (bare)	B. d'Islemade, France	7.3	0-100	9.11	30.3	-	7.41	SFO	y/ EFSA, 2018 [a]
			Maximum (n=10)	23.7					

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

Modelling endpoints

Table 8.4-2: Summary of aerobic degradation rates for clopyralid - field studies: Modelling endpoints

Clopyralid, Field studies – Modelling endpoints						
Soil type	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT50 (d) [a] 20°C, pF2**	**Fit, Kinetic**	**Evaluated on EU level y/n/ Reference**
Loamy sand (bare)	Bargstedt, Germany	4.3	0-100	23.9	SFO	y/ EFSA, 2018 [b]
Loam (bare)	Wilson, UK	6.2	0-100	22.6	SFO	y/ EFSA, 2018 [b]
Silty clay loam (bare)	Sermaises, France	7	0-100	19.3	SFO	y/ EFSA, 2018 [b]
Silty clay loam (bare)	Ansonville, France	8.2	0-20	5.36	SFO	y/ EFSA, 2018 [b]
Clay loam (bare)	Mainbervilliers, France	7.1	0-20	~~7.22~~ 6.04	DFOP /SFO	y/ EFSA, 2018 [b]
Silty clay loam (bare)	Oederquart, Germany	7.5	0-20	12	SFO	y/ EFSA, 2018 [b]
Sandy clay loam (bare)	Middlefart, Denmark	7.5	0-20	13.1	SFO	y/ EFSA, 2018 [b]
Clay loam (bare)	Canals, Spain	8.0	0-100	19.2	SFO	y/ EFSA, 2018 [b]
Silty clay loam (bare)	B. Württemberg, Germany	7.4	0-100	7.94	SFO	y/ EFSA, 2018 [b]
Silt loam	B. d'Islemade,	7.3	0-100	17.6	SFO	y/ EFSA, 2018 [b]

Clopyralid, Field studies – Modelling endpoints						
Soil type	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT50 (d) [a] 20°C, pF2**	**Fit, Kinetic**	**Evaluated on EU level y/n/ Reference**
(bare)	France					
				Geometric mean (n=10)	**7.05**		y/ EFSA, 2018 [b]
			pH-dependency y/n	No		

[a)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
[b)] EFSA Journal 2018; 16(7):5389

Based on statistical analysis of the laboratory and field kinetic endpoints for modelling using the EFSA spreadsheet tool (EFSA Journal 2014;12(5):3662), EFSA concluded that the laboratory and field data are from different populations. Therefore the geometric mean from the field data was selected for modelling clopyralid (EFSA Journal 2018; 16(7):5389).

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)

Soil accumulation testing was not required.

8.5 Mobility in soil (KCP 9.1.2)

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

8.5.1 Clopyralid

Soil sorption studies for clopyralid were evaluated during the EU peer review (EFSA, 2018). The agreed endpoints are listed in Table 8.5-2. The first four soils (Merzenhausen, Kaldenkirchen, Lanna and Overhetfeld) are from a study by Reeves and Mittelstaedt (2002), and were originally included in the original DAR for clopyralid (2003). The additional five soils listed in the table are from a new study by Buntain and Simmonds (2015) that was submitted during the renewal of clopyralid (AIR dossier M-CA).

According to the OECD 106 test guideline for sorption studies[1], 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). Based on these criteria, EFSA applied a quality check on the sorption data for clopyralid. The Kd values measured on the first four soils were <0.3 (indirect method), and the Kd values for the Longwoods and LUFA 2.1 soils were <0.1 (direct method). EFSA set the Freundlich coefficients (1/n) of these soils to the default value of 0.9. The geometric mean values of $K_{F,OC}$ and 1/n were selected for use in modelling.

[1] OECD (2000), Test No. 106: Adsorption -- Desorption Using a Batch Equilibrium Method, OECD Guidelines for the Testing of Chemicals, Section 1, OECD Publishing, Paris

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

Clopyralid								
Soil name	**OC (%)**	**pH ($CaCl_2$)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Merzenhausen	1	7.19	0.051	- [a]	0.0057	0.57	0.9 [b]	y/EFSA, 2018 [c]
Kaldenkirchen	0.98	5.34	0.048	- [a]	0.0267	2.72	0.9 [b]	y/EFSA, 2018 [c]
Lanna	2.06	6.62	0.151	- [a]	0.0054	0.26	0.9 [b]	y/EFSA, 2018 [c]
Overhetfeld	0.93	6.49	0.032	- [a]	0.0125	1.34	0.9 [b]	y/EFSA, 2018 [c]
Calke sandy loam	3.15	5.7	0.139	- [a]	0.01	0.5	0.489	y/EFSA, 2018 [c]
Longwoods sandy loam	3.13	7.4	0.069	- [a]	0.08	2.5	0.9 [b]	y/EFSA, 2018 [c]
LUFA 2.1 loamy sand	0.68	4.9	0.040	- [a]	0.03	4.1	0.9 [b]	y/EFSA, 2018 [c]
Quilen loam	4.02	6.9	0.356	- [a]	0.16	3.9	0.804	y/EFSA, 2018 [c]
DU-L-PF clay loam	6.47	6.3	0.282	- [a]	0.14	2.1	0.829	y/EFSA, 2018 [c]
Geometric mean (n=9)					0.026	**1.41**		y/EFSA, 2018 [c]
Arithmetic mean (n=9)							0.836	y/EFSA, 2018 [c]
pH-dependency y/n			No					

a) Not calculated
b) 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 coefficients of soils not meeting the criteria were set to 0.9
c) EFSA Journal 2018; 16(7):5389

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)

No column leaching studies were reported for clopyralid.

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:

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	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:

have however been attached as additional information, as evaluated during the first approval of clopyralid.	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 CO2 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)

No field leaching studies were reported for clopyralid.

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

Water-sediment studies with clopyralid were reported in EFSA, 2018 (EFSA Journal 2018; 16(7):5389).

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

Clopyralid Distribution (max. sediment 26% after 100 days)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**DegT90 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Loamy sand	6.5/5.5	>500	>500	First-order	128	n.a.		>500	First-order	y/ EFSA, 2018 [a]
Sandy silt loam	8.16/7.7	>500	>500	First-order	167	n.a.		>500	First-order	y/ EFSA, 2018 [a]
Geometric mean (n=2)					148					

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

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

8.7.1 Justification for new endpoints

Here the corresponding normalised DT50 of 23.7 days was used.

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

PEC_{soil} clopyralid were calculated according to the FOCUS guidance document on persistence in soil[2] for their maximum application rates, corrected for crop interception, and assuming mixing into a 5 cm soil layer and a soil density of 1.5 g/cm^3.

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

Crop	Sugar beet BBCH 10-39
Application rate (g as/ha)	clopyralid: 125 (Worse case southern zone)
Number of applications/interval	1

[2] FOCUS (2000). Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (9188/VI/97 rev. 8, 12.07.2000).

Crop interception (%)	20
Depth of soil layer (relevant for plateau concentration) (cm)	5 (no tillage)

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 (SFO, Maximum, field studies, non-normalised (n=10)	y/ EFSA, 2018 [a]

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

8.7.2.1 Clopyralid

Table 8.7-3: PEC_{soil} for clopyralid on sugar beet

PEC_{soil} (mg/kg)		Sugar beet			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0,1333		-	-
Short term	24h	0,1295	0,1314	-	-
	2d	0,1258	0,1295	-	-
	4d	0,1186	0,1258	-	-
Long term	7d	0,1087	0,1206	-	-
	14d	0,0885	0,1094	-	-
	21d	0,0722	0,0996	-	-
	28d	0,0588	0,0910	-	-
	50d	0,0309	0,0701	-	-
	100d	0,0072	0,0431	-	-
Plateau concentration (5/20 cm) after year x		Not required	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not required	Not required	-	

8.7.2.2 PEC_{soil} of PP-113H

Predicted environmental concentrations of the formulated product in soil (PEC_{soil}) were calculated for a maximum single spray application rate of 1.25 L/ha. The product formulation is expected to disperse quickly after application to the soil. Therefore, only the initial concentration after single application is required for the risk assessment. The PEC_{soil} was calculated from the application rate corrected for crop interception, and assuming mixing into a 5 cm soil layer and a soil density of 1.5 g/cm^3.

Table 8.7-4: PEC$_{soil}$ for PP-113H on sugar beet

~~Active substance/ reparation~~	~~Application rate (g/ha)~~	~~PECact (mg formula-tion/kg)~~	~~PEC$_{twa}$21 d (mg/kg)~~	~~Tillage depth (cm)~~	~~PEC$_{soil,plateau}$ (mg/kg)~~	~~PECaccu = PECact + PEC$_{soil,plateau}$ (mg/kg)~~
~~PP-113H~~	~~1051.6 a)~~	~~1.1217~~	~~-~~	~~5~~	~~-~~	~~-~~

a) Based on an application rate of 1250 L/ha and a formulation density of 1.0516 g/ml and 20% crop interception

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).
The intended is covered by the presented PECsoil calculations, however zRMS performed new calculations PECsoil (mg/kg) for proposed use in GAP 120 g/ha

PECsoil for clopyralid on sugar beet

	Single application	Multiple applications
	Actual	TWA
Initial	**0.1280**	-
24h	0.1243	0.1262
2d	0.1207	0.1243
4d	0.1139	0.1208
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	-	-
(PECact +PECsoil plateau)	Not required	

PECsoil for PP-113H on sugar beet
Based on an application rate of 1200 L/ha and a formulation density of 1.0516 g/ml and 20% crop interception calculated by zRMS **PECs was 1.345 formulation/kg**.

The PECsoil values for clopyralid and formulation presented in Tables 8.7-4 and 8.7.5. can be used for the risk assessment.

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**~~

~~Table 8.5- 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[3]; 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 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[4]. The new geometric mean Koc from combining the Kdoc and Kfoc values is 3.18 mL/g (n=9).~~

[3] 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.
[4] 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.

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

Clopyralid								
Soil name	**OC (%)**	**pH ($CaCl_2$)**	**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)

PEC_{gw} values were calculated for clopyralid, following application of PP-113H to sugar beet at BBCH 10-39. Calculations were performed using the standard FOCUS procedures.
The model has been performed for BBCH 10-19 and BBCH 20-39. And for the refinements it has been done using an application every two years.

Table 8.8-3: Input parameters related to application for PEC_{gw} calculations

Crop	Sugar beet BBCH 10-39
Application rate (g as/ha)	clopyralid: 125 (Worse case southern zone)
Number of applications	1
Application date	April/June
Crop interception (%)	20/70
Frequency of application	Annual/ Bi-annual
Models used for calculation	FOCUS PEARL v 4.4.4, FOCUS PELMO v 5.5.3

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

Crop	Scenario	Application dates (absolute)
Sugar beet BBCH 10-39	BBCH 10-19	April (20 April)
	BBCH 20-39	May (6 May)

8.8.2.1 Clopyralid

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	y/ EFSA, 2018 [a]
Water solubility (g/mol):	143000 (pH 7, 20°C)	y/ EFSA, 2018 [a]
Saturated vapour pressure (Pa):	1.36×10^{-3} (25°C)	y/ EFSA, 2018 [a]
DT_{50} in soil (d)	~~7.05~~ (6.04 geometric mean field data, normalised to pF2, 20 °C with Q_{10} of 2.58, n =10)	y/ EFSA, 2018 [a]
Transformation rate	0.0983	ln(2)/DT50
K_{foc} (mL/g)	1.41 (geometric mean, n = 9)	y/ EFSA, 2018 [a]
K_{fom} (mL/g):	0.818	K_{fOC}/1.724
1/n	0.836 (arithmetic mean, n = 9)	y/ EFSA, 2018 [a]
Plant uptake factor	0.000271	y/ EFSA, 2018 [a]
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~~

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

Table 8.8-6: PEC_{gw} for clopyralid on sugar beet 1 x 125g s.a./ha BBCH 10-19 (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		Clopyralid Agreed endpoints (EFSA, 2018)	~~**Clopyralid Revised sorption K_{foc}**~~
Sugar beet (BBCH 10-19)	Châteaudun	0.026	~~0.016~~
	Hamburg	0.036	~~0.018~~
	Jokioinen	**0.263**	~~**0.113**~~
	Kremsmünster	0.079	~~0.048~~
	Okehampton	**0.133**	~~0.076~~

	Piacenza	**0.229**	~~0.152~~
	Porto	**0.152**	~~0.063~~
	Sevilla	0.003	~~0.002~~
	Thiva	0.000	~~0.000~~

Table 8.8-7: PEC$_{gw}$ for clopyralid on sugar beet 1 x 125 g s.a./ha BBCH 10-19 bi-annual application (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Clopyralid Agreed endpoints (EFSA, 2018)	~~Clopyralid Revised sorption K$_{foc}$~~
Sugar beet (BBCH 10-19) (bi-annual	Châteaudun	0.016	~~0.009~~
	Hamburg	0.018	~~0.009~~
	Jokioinen	**0.156**	~~0.068~~
	Kremsmünster	0.035	~~0.018~~
	Okehampton	0.065	~~0.036~~
	Piacenza	**0.128**	~~0.084~~
	Porto	0.077	~~0.029~~
	Sevilla	0.002	~~0.001~~
	Thiva	0.000	~~0.000~~

Table 8.8-8: PEC$_{gw}$ for clopyralid on sugar beet 1 x 125 g s.a./ha BBCH 20-39 application (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Clopyralid Agreed endpoints (EFSA, 2018)	~~Clopyralid Revised sorption K$_{foc}$~~
Sugar beet (BBCH 20-39)	Châteaudun	0.047	~~0.029~~
	Hamburg	0.046	~~0.023~~
	Jokioinen	**0.220**	~~0.088~~
	Kremsmünster	0.079	~~0.049~~
	Okehampton	**0.142**	~~0.088~~
	Piacenza	**0.117**	~~0.059~~
	Porto	0.061	~~0.033~~
	Sevilla	0.000	~~0.000~~
	Thiva	0.001	~~0.000~~

Table 8.8-9: PEC$_{gw}$ for clopyralid on sugar beet 1 x 125g s.a./ha BBCH 10-19 (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Clopyralid Agreed endpoints (EFSA, 2018)	~~**Clopyralid Revised sorption K_{foc}**~~
sugar beet (BBCH 10-19)	Châteaudun	**0.193701**	~~**0.123890**~~
	Hamburg	**0.122790**	~~0.071472~~
	Jokioinen	**0.115182**	~~0.059173~~
	Kremsmünster	0.061190	~~0.042207~~
	Okehampton	0.059871	~~0.036715~~
	Piacenza	0.024152	~~0.015499~~
	Porto	0.010200	~~0.006439~~
	Sevilla	0.000023	~~0.000010~~
	Thiva	0.001036	~~0.000533~~

Table 8.8-10: PEC$_{gw}$ for clopyralid on sugar beet 1 x 125 g s.a./ha <u>BBCH 10-19 bi-annual</u> application (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Clopyralid Agreed endpoints (EFSA, 2018)	~~**Clopyralid Revised sorption K_{foc}**~~
sugar beet (BBCH 10-19) bi-annual	Châteaudun	0.091100	~~0.030773~~
	Hamburg	0.065459	~~0.023832~~
	Jokioinen	0.069940	~~0.031465~~
	Kremsmünster	0.028025	~~0.014211~~
	Okehampton	0.040749	~~0.021581~~
	Piacenza	0.011690	~~0.008603~~
	Porto	0.004152	~~0.008454~~
	Sevilla	0.000016	~~0.000027~~
	Thiva	0.000448	~~0.000079~~

Table 8.8-11: PEC$_{gw}$ for clopyralid on sugar beet 1 x 125 g s.a./ha BBCH 20-39 application (with FOCUS PEARL 4.4.4)

Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**	
		Clopyralid Agreed endpoints (EFSA, 2018)	~~**Clopyralid Revised sorption K$_{foc}$**~~
Sugar beet (BBCH 20-39)	Châteaudun	0.068272	~~0.040135~~
	Hamburg	0.042762	~~0.022381~~
	Jokioinen	0.038558	~~0.018744~~
	Kremsmünster	0.021439	~~0.014249~~
	Okehampton	0.020983	~~0.011729~~
	Piacenza	0.008516	~~0.005025~~
	Porto	0.003500	~~0.002116~~
	Sevilla	0.000008	~~0.000003~~
	Thiva	0.000355	~~0.000160~~

For sugar beet a BBCH 10-29 application, all calculated PECgw values were less than 0.1 µg/L in all scenarios using both models when the product is used an application every two years.

For BBCH 20-39 application all calculated PECgw values were less than 0.1 µg/L in all scenarios using both models.

Therefore, the use of the formulated product PP-113H can be considered to be safe with respect to leaching to groundwater and contamination of drinking water.

ZRMS comments:

The PECgw values were calculated for clopyralid, following application of PP-113H to sugar beet at BBCH 10-39. Calculations were performed using the standard FOCUS procedures.
The model has been performed for BBCH 10-19 and BBCH 20-39. And for the refinements it has been done using an application every two years.
The PECgw calculated for 125 g/ha were accepted as worst case.
All input parameters for clopyralid were considered acceptable as they followed the LoEP (2018).
The input parameters for clopyralid are shown Table 8.8-5:The input parameters were taken from the agreed list of endpoints in the EFSA Conclusion (EFSA, 2018). Modelling was 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 results of the simulations indicated that the 80th percentile annual average concentrations in leachate at 1 m depth for clopyralid is below the trigger of 0.1 µg/l for modelling conducted using FOCUS PEARL for application every two years on sugar beet (BBCH 10-19) and every year for BBCH (20-39) in all FOCUS scenarios.
The results of the simulations indicated that the 80th percentile annual average concentrations in leachate at 1 m depth for clopyralid are below the trigger of 0.1 µg/l for modelling conducted using FOCUS PELMO for application every two years on sugar beet (BBCH 10-19), except Jokioinen and Piacenza scenarios.
For application every year BBCH (20-39) clopyralid is below the trigger of 0.1 µg/l for except scenarios

Jokioinen, Piacenza and Okehampton.
For this scenarios are required refined. Applicant performed modeling with new revised $K_{FOC.}$ However, the new revised sorption endpoint K_{FOC} had not been assessed by zRMS for used in PECgw modeling. The decision to use the revised K_{FOC} should be taken at the national level

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.
General, the results of the PECgw with FOCUS PELMO and PEARL with application every two years **indicate that PECgw of clopyralid were less than 0.1 µg/L** for all relevant in PL scenarios in uses in sugar beet.
The following conclusion of the evaluation is published in EFSA Journal 2018; 16(7):5389):
the potential for groundwater exposure from the representative uses by clopyralid above the parametric drinking water limit of 0.1 lg/L (as estimated by annual average recharge concentrations in water moving below 1 m soil depth) was concluded to be high in geoclimatic situations that are represented by varying proportions of the FOCUS groundwater scenarios depending on the month of the year that applications are made in the simulations. For the representative use on winter cereals: with application on 1 February and 1 March, six out of nine FOCUS scenarios were above the parametric drinking water limit. When applications were simulated on 1 April, this reduced to five out of nine. When applications were simulated on 1 May and 1 June, this reduced again to four out of nine FOCUS scenarios being above the parametric drinking water limit. For the representative use on grassland: with application on 1 February, three out of nine FOCUS scenarios were above the parametric drinking water limit.
When applications were simulated on 1 March and 1 August this reduced to two out of nine. When applications were simulated on 1 April, May, June and July, no FOCUS scenario was indicated to have concentrations above the parametric drinking water limit.

Considering the effect of application dates on the concentration of the substance in groundwater, the following limitation should be applied: **Do not use between the 31st August and 1st March.**

However, the mitigation measures of risk for ground water should be considered at national level of MS.

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

8.9.1 Justification for new endpoints

PEC_{sw} modelling for clopyralid was performed using the EU agreed endpoints from the EFSA Conclusion for clopyralid (EFSA Journal 2018; 16(7):5389).

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

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

Plant protection product	PP-113H
Crop	Sugar beet

	BBCH 10-39
Application rate (g as/ha)	clopyralid: 125 (Worse case southern zone)
Number of applications/interval (d)	1
Application window	Mar-May (STEP 1-2)
Application method	Ground spray
CAM (Chemical application method) in PRZM	1 (appln foliar linear)
Soil depth (cm) in PRZM	4
Models used for calculation	FOCUS STEPS1-2 v3.2 FOCUS SWASH v5.3 FOCUS PRZM v4.3.1 FOCUS MACRO v5.5.4 FOCUS TOXWA v5.5.3

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of PP-113H

Crop	Scenario	Application window used in modelling
Sugar beet	D3	11 May – 10 Jun
	D4	20 May – 19 Jun
	D4	20 May – 19 Jun
	R1	02 May – 01 Jun
	R1	02 May – 01 Jun
	R3	05 Apr -05 May

8.9.2.1 Clopyralid

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

Compound	Clopyralid	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	191.96	y/ EFSA, 2018 [a]
Saturated vapour pressure (Pa)	1.36×10^{-3} (25°C)	y/ EFSA, 2018 [a]
Water solubility (mg/L)	143000 (pH 7, 20°C)	y/ EFSA, 2018 [a]
Diffusion coefficient in water (m²/d)	not required for Step 1+2/ 4.3×10^{-5}	default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/ 0.43	default
K_{foc} (mL/g)	1.41 (geometric mean, n=9)	y/ EFSA, 2018 [a]
Freundlich Exponent 1/n	0.836 (arithmetic mean, n=9)	y/ EFSA, 2018 [a]
Plant Uptake	0.000271	y/ EFSA, 2018 [a]
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05	default

Compound	**Clopyralid**	**Value in accordance to EU end-point y/n/ Reference**
$DT_{50,soil}$ (d)	7.05 (geometric mean from field studies, normalised to pF2, 20 °C with Q_{10} of 2.58, n =10)	y/ EFSA, 2018 [a]
$DT_{50,water}$ (d)	1000	default
$DT_{50,sed}$ (d)	1000	default
$DT_{50,whole\ system}$ (d)	1000	default

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for clopyralid following single application of PP-113H to sugar beet

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	---	42,7381	-	42,6326	0,5864
Step 2					
Northern Europe	Mar-May	5,6355	Runoff/drainflow	5,6212	0,0794
Southern Europe	Mar-May	10,1061	Runoff/drainflow	10,0812	0,1010
Step 3					
D3	ditch	0.6652	Drift	0.1234	0.05843
D4	pond	0.04972	Drift	0.04904	0.03807
D4	stream	0.5602	Drift	0.03693	0.02160
R1	pond	0.02700	Runoff	0.02629	0.01431
R1	stream	0.6150	Runoff	0.04277	0.03554
R3	stream	4.470	Runoff	0.6275	0.3769

ZRMS calculations:

The PECsw calculations at Step 1-2 and 3 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 of clopyralid (EFSA, 2018 [a])

Compound	Clopyralid
Direct photolysis in air	Not available, no data required
Quantum yield of direct phototransformation	Not available, no data required

Photochemical oxidative degradation in air	DT50: 19.5 days derived by the Atkinson model (AOPWIN v. 1.90). OH (12h) concentration not reported [a]
Volatilisation	Vapour pressure (Pa): 1.36×10^{-6} kPa at 25°C Equivalent to 7.07×10^{-4} Pa at 20°C Henry's Law Constant ($Pa.m^3/mol$): 3.28×10^{-10} at 20°C. Measured volatilisation in 24 hours: <4% from plant surfaces, and <2% from soil [a)]
Metabolites	None

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

The vapour pressure at 20 °C of the active substance clopyralid is > 10^{-4} Pa. Hence the active substance is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance clopyralid due to volatilization with subsequent deposition should be considered.

According to FOCUS Air guidance [SANCO/10553/2006 Rev 2 June 2008], deposition onto adjacent surface waters and terrestrial ecosystems due to volatilisation is small in comparison to spray drift. Hence, deposition from volatilisation only needs to be considered if spray drift mitigations are considered in the risk assessment. No drift mitigations were required for clopyralid for the proposed use of PP-113H.

The photochemical oxidative degradation in air for clopyralid is slow, with a calculated half-life of 19.5 days (Atkinson method, AOPWIN v1.90. However, the risk for long-range aerial transport of clopyralid was assessed as minimal in the first EU evaluation of clopyralid in 2005 (EFSA Scientific Report (2005) 50, 1–65) based on the low vapour pressure, Henry's law constant and experimental data on volatilization from plants and soil. During the renewal (Draft Renewal Assessment Report, RMS Finland, March 2018), the data on the fate and behaviour of clopyralid in air was considered still valid and acceptable, and no further studies were required to support the renewal for the approval of clopyralid.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.3 KCP 9.2.4 KCP 9.2.5	Domingo J.	2021	Predicted environmental concentrations of clopyralid following use of BARILOCHE (PP-113-H) on sugar beet Proplan Report PP113-011221 Non GLP Unpublished	N	PROPLAN

Appendix 2 Detailed evaluation of the new Annex II studies

No new Annex II fate studies were performed for this submission.