REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **AMINO 30 SL**

Product name(s): El Camino 30 SL, Ranchero 30 SL

Chemical active substance(s):

Aminopyralid, 30 g/L

Central Zone

Zonal Rapporteur Member State: PL

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 01/2025

zRMS Assessment: 18/04/2025

Following commenting period/Verification of reference list: 01/07/2025

Version history

When	What
April 2025	zRMs evaluated dRR submitted by Applicant
July 2025	Following commenting period Verification of reference list

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8 Fate and behaviour in the environment (KCP 9)

The document was prepared in order to describe the environmental fate for authorisation of AMINO 30 SL containing aminopyralid of application on winter oilseed rape (use no. 1 in GAP Table).

General comment
This document presents the environmental fate summary and exposure calculations for the plant protection product AMINO 30 SL (El Camino 30 SL/ Ranchero 30 SL), a soluble concentrate type formulation (SL) containing 30 g/L aminopyralid for use as a herbicide for winter oilseed rape. The following data and information were provided by the applicant Innvigo Sp. z o.o. as a dRR. All comments of the evaluator there are in the “greyboxes”.

8.1 Critical GAP and overall conclusions

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

GAP rev. , date: year-month-day

PPP (product name/code):	El Camino 30 SL, Ranchero 30 SL/AMINO 30 SL	Formulation type:	SL
Active substance 1:	aminopyralid	Conc. of as 1:	30 g/l (c)
Active substance 2:	n/a	Conc. of as 2:	-
Active substance….:	n/a	Conc. of as ….:	-
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: 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 a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter oilseed rape (BRSNW)	F	Dicotyledonous weeds	Spray, medium spray	Autumn BBCH 10-18	a) 1 b) 1	n/a	a) 0.2-0.267 L/ha b) 0.2-0.267 L/ha	a) 6-8.01 g a.s/ha b) 6-8.01 g a.s/ha	200-300	-	-	**R** PL and other MS where Piacenza scenario is not relevant: - the acceptable dose of aminopyralid

														is **8.01 g a.s/ha every other year.** MS where Piacenza scenario is relevant: - the acceptable dose of aminopyralid is **6.0 g a.s/ha every other year** or **8.01 g a.s/ha every third year.**
2														
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
3														
4														
Minor uses according to Article 51 (zonal uses)														
5														
6														
Minor uses according to Article 51 (interzonal uses)														
7														
8														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

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

(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

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

* 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

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

Summary of representative uses evaluated (*aminopyralid*)

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s.g/l (i)	Method Kind (f-h)	Growth stage & season (j)	Number min-max (k)	Interval between apps	g a.s. /hL min-max	water (L/ha) min-max	g a.s./ha min-max		
Grassland established and rotational pasture	EU BE, DE, FR, IE NL, LU, UK	GF-839	F	Broad-leaved weeds	EO	Aminopyralid (A): 30 Fluroxypyr (F): 100	Broadcast Foliar Tractor mounted boom sprayer	Established grassland* Spring/ Summer	1 per year	N/A	A: 15-30 F: 50-100	200-400	A: 60 F: 200	7	A gun sprayer or knapsack with hand lance may be used in some countries
Amenity grassland	EU UK, BE,FR, ES, IT, LU	GF-839	F	Broad-leaved weeds	EO	Aminopyralid (A): 30 Fluroxypyr (F):100	Broadcast Foliar Tractor/van mounted boom or gun sprayer Knapsack with handlance	Established grassland Spring/ Summer	1 per year	N/A	A: 10-30 F: 33-100	200-600	A: 60 F: 200	7	

* GF-839 may be used on established grassland intended for grazing in the calendar year of application. GF-839 may NOT be used on fields intended for hay, haylage or silage production in the calendar year of application.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

General comment zRMS
AMINO 30 SL a soluble concentrate type formulation (SL) containing 30 g/L aminopyralid for use as a herbicide for winter oilseed rape. Aminopyralid (4-amino-3,6-dichloropyridine-2-carboxylic acid): CAS No 150114-71-9 is recognised as approved for use in plant protection products under Regulation (EC) No 1107/2009 in Annex of Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 with the expiration of approval on 31

May 2027.

In this assessment used endpoints evaluated on EU level in accordance with EFSA documents:
- The SANCO report for Aminopyralid (SANCO/11423/2014 rev 1 - final 11 July 2014);
- “Conclusion on the peer review of the pesticide risk assessment of the active substance aminopyralid” - EFSA Journal 2013;11(9):3352.

8.2 Metabolites considered in the assessment

According to the EFSA Journal 2013;11(9):3352 no relevant metabolites occur.

zRMS comment
Information relating to no aminopyralid metabolites is in line with EFSA Journal 2013;11(9):3352.

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.

Evaluation by zRMS	Rate of degradation in soil (KCP 9.1.1)
Comments	No new data. Information in Section 8.3 is available in dossiers of active substance: aminopyralid and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

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. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Aminopyralid - EFSA Journal 2013;11(9):3352.

8.3.1.1 Aminopyralid

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type (USDA)	O.C. %	pHa	t. oC / % MWHC	DT50 /DT90 (d)	DT50 (d) 20 °C pF2/10kPa	chi2	Method of calculation
Thessaloniki, loam	1.5	7.7	20°C / 40% MWHC	26.2 / 86.9	26.2	10.8	SFO
Cuckney, sand	1.5	5.6	20°C / 40% MWHC	144.7 / 480.8	144.7	1.3	SFO
Charentilly, loam	1.0	5.8	20°C / 40% MWHC	28.4 / 94.4	28.0	7.2	SFO
Parabraun Erde, silt loam	1.0	7.7	20°C / 40% MWHC	84.9 / 282.0	84.9	1.1	SFO
Geometric mean			-	-	54.8	-	-

[a]in 0.01M $CaCl_2$

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Since the DT_{90}(field) values were clearly < 1 year, then aminopyralid is not expected to accumulate in soil.

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. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Aminopyralid - EFSA Journal 2013;11(9):3352.

8.3.2.1 Aminopyralid

Table 8.3-2: Summary of anaerobic degradation rates for aminopyralid - laboratory studies

Supplementary laboratory studies ‡

Parent	Anaerobic conditions: essentially stable
	Soil photolysis: DT50 = 121.2 d (under test conditions; degradation in dark control subtracted); summer sunlight at 40°N DT50 = 78.8 d; DT50 in irradiated samples prior to subtraction of degradation in dark control = 59.4 d assuming summer sunlight at 40°N.

pH dependence (yes / no) (if yes type of dependence) ‡	No
Soil accumulation and plateau concentration ‡	Since the DT_{90}(field) values were clearly < 1 year, then aminopyralid is not expected to accumulate in soil.

8.4 Field studies (KCP 9.1.1.2)

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

Studies on dissipation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Aminopyralid - EFSA Journal 2013;11(9):3352.

8.4.1.1 Aminopyralid

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

Field studies ‡

Parent	Aerobic conditions								
Soil type (USDA) (indicate if bare or cropped soil was used).	Location (country or USA state).	pHa	Depth (cm)	DT50 (d) actual	DT90 (d) actual	Chi2 error %	DT50 (d) Norm.	Chi2 error %	Method of calculation
Clay loam (bare)	UK	6.6	0-20	34.9	116.1	11.1	16.6	4.0	SFO after exclusion of data points prior to 10mm rainfall
Silt loam (bare)	Germany (2008)	6.4	0-50	22.0	73.0	6.9	17.2	8.34	
Loam (bare)	S France (2008)	6.2	0-50	15.4	51.0	16.4	10.9	18.0	
Sandy clay loam	N France (2011)	7.8	0-100	-	-	-	12.8	18.7	
Geometric mean					-	-	14.1	-	-

[a]in water

pH dependence (yes / no) (if yes type of dependence) ‡	No
Soil accumulation and plateau concentration ‡	Since the DT_{90}(field) values were clearly < 1 year, then aminopyralid is not expected to accumulate in soil.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil dissipation trials have shown that the estimated $DT_{90(field)}$ for aminopyralid was clearly <1 year, and so the potential for aminopyralid to accumulate in soil following successive applications is not required and has not been investigated.

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. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Aminopyralid - EFSA Journal 2013;11(9):3352.

Evaluation by zRMS	**Mobility in soil (KCP 9.1.2)**
Comments	No new data. Information in Section 8.5 is available in dossiers of active substance: aminopyralid and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

8.5.1 Aminopyralid

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡						
Soil Type	OC %	Soil pH[a]	Kf (mL/g)	Kfoc (mL/g)	1/n	R2
Thessaloniki (silty clay loam)	1.0	7.8	0.039	3.91	0.860	0.991
Faringdon (clay)	3.2	7.5	0.079	2.45	0.919	0.999
Ryerson (silty clay)	3.9	7.8	0.232	5.94	0.887	0.996
Cuckney (sand)	1.6	6.6	0.063	3.92	0.888	0.994
Charentilly (clay loam)	1.0	6.1	0.043	4.35	0.824	0.988
Dowling (clay)	1.5	6.9	0.043	2.85	0.793	0.993
Barnes (clay loam)	3.6	4.8	0.625	17.36	0.903	1.000
Norfolk (loamy sand)	0.6	4.5	0.147	24.46	0.881	0.996
Altlußheim (loam)	1.7	7.5	0.203	11.92	0.95	0.998
Barrow on Trent (sandy loam)	4.6	6.3	0.184	4.01	0.87	0.999
Hertfordshire (clay loam)	2.2	7.6	0.193	8.77	0.96	1.000
Römenberg/Rheinland-Pfalz (sandy loam)	0.7	7.4	0.099	14.18	0.92	0.999
Arithmetic mean, excluding acid soils (n=12)				6.84	0.899	-
Median, excluding acid soils (n=12)				5.14[1]	0.899[1,2]	-
Arithmetic mean, acidic soils (n=2, shaded rows)				20.91	0.892	-
pH dependence, Yes or No			Yes; stronger sorption in acid soils (pH 4.5-4.8)			

[a] in $CaCl_2$

[1] The median Kfoc and 1/n, excluding acidic soils, were used in the FOCUS modelling.

[2] The 1/n accompanying the median K_{foc} has been derived as the arithmetic mean of the 1/n values from the same non-acidic soils (n=12)

8.5.2 Column leaching (KCP 9.1.2.1)

Column leaching ‡	No data submitted, none required.
Aged residues leaching ‡	No data submitted, none required.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Lysimeter/ field leaching studies ‡	No data submitted, none required.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Lysimeter/ field leaching studies ‡	No data submitted, none required.

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

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Aminopyralid - EFSA Journal 2013;11(9):3352.

Evaluation by zRMS	**Degradation in the water/sediment systems (KCP 9.2)**
Comments	No new data. Information in Section 8.6 is available in dossiers of active substance: aminopyralid and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

8.6.1 Aminopyralid

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

Degradation in water / sediment

Parent	Distribution (Max. sed 39.9% AR after 62 d; French system); no major metabolites)			
First order non linear regression				
Test system	Compartment			DT_{50} (days), r^2
French; sand (water pH: 5.9 Sediment pH: 6.1)	Water + sediment (degradation)			809.5, 0.605
First order biphasic nonlinear regression hockey stick				
Test system	Compartment	1st phase DT_{50} (days), r^2	Inflection point (days)	2nd phase DT_{50} (days), r^2
French	Water (dissipation)	23.3, 0.980	11.4	187.8, 0.741
Italian; sandy silt loam (water pH: 8.2 Sediment pH: 7.9)	Water (dissipation)	31, 0.995	10.8	490.6, 0.893
	Water + sediment (degradation)	83.2, 0.987	12.9	828.5, 0.795
US; sandy loam (water pH: 7.9 Sediment pH: 8.1)	Water (dissipation)	36, 0.996	8.1	918.7, 0.963
	Water + sediment (degradation)	104.3, 0.903	7	1495.3, 0.790
Arithmetic mean (2^{nd} phase DT_{50} for biphasic fit)		Water		532.4
		Water + sediment		1044.4
Geometric mean (2^{nd} phase DT_{50} for biphasic fit)		Water		439.1
		Water + sediment		1000.9

The kinetic assessment of the water:sediment systems was not conducted in line with the FOCUS kinetics guidance. For FOCUSsw modelling a default 1000 d DT_{50} was used for all compartments.

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

8.7.1 Justification for new endpoints

All endpoints used for PEC soil calculations are EU approved and were evaluated on EU level and presented in:

- Aminopyralid - EFSA Journal 2013;11(9):3352.

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

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

Use No.	1
Crop	Winter oilseed rape (BRSNW)
Application rate (g as/ha)	aminopyralid: 8.01
Number of applications/interval	1
Crop interception (%)	40
Depth of soil layer (relevant for plateau concentration) (cm)	5 (20 cm (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
aminopyralid	207.026	-	35 d (Kinetics: SFO Field or Lab: representative worst case from field studies (spring application).	EFSA Journal 2013;11(9):3352

8.7.2.1 Aminopyralid

Table 8.7-3: PEC_{soil} for aminopyralid on winter oilseed rape

PEC_{soil} (mg/kg)		Single application	
		Actual	TWA
Initial		0.0064	-
Short term	24h	0.0063	0.0063
	2d	0.0062	0.0063
	4d	0.0059	0.0062
Long term	7d	0.0056	0.0060
	14d	0.0049	0.0056
	21d	0.0042	0.0052
	28d	0.0037	0.0049
	42d	0.0028	0.0044
	50d	0.0024	0.0041
	100d	0.0009	0.0028
Plateau concentration (~~5~~ 20cm) after 10 years		<0.0001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.0064	-

8.7.2.2 PEC_{soil} of AMINO 30 SL

The PEC_{soil} of the formulation AMINO 30 SL was calculated using the following formula based on the crop interception: 40% and maximum application rate that is 272.79 ~~87~~ g/ha (worse case scenario covers all intended uses)

PEC_{soil} = application rate$_{of\ formualtion}$ [g/ha] · (1 – (crop interception [%]/100)) / 100 · d [g/cm^3] · l [cm]

if:

Application rate $_{of\ formulation}$: 272.79 g/ha (application rate [L/ha] x density of formulation)

Density of formulation: 1.0217 g/ml
d – soil density: 1.5 g/cm^3
l – soil depth: 5 cm

Table 8.7-4: PEC_{soil} for AMINO 30 SL on winter oilseed rape

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
AMINO 30 SL	272.79	0.218	-	5	<0.0001	0.218

Evaluation by zRMS PL	**PECsoil (KCP 9.1.3)**
Modelling	The assumptions of calculations are acceptable. The predicted environmental concentrations in soil (PECsoil) of aminopyralid were calculated according to recommendations of the FOCUS workgroup on degradation kinetics using: - the maximum application rate: 0.267l of AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL /ha/per season i.e. 8.01 g aminopyralid /ha, considering 40% interception for winter oilseed rape. It was assumed that the active substance were distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL. The calculated PECs values are presented in Tables 8.7-3. The applicant correctly calculated the PECsoil for aminopyralid. The results of PECsoil calculations provided by the Applicant are properly calculated for the formulation AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL. They are shown in the Table 8.7-4. The calculated PECsoil values for AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL and aminopyralid are appropriate to be used for the subsequent risk assessment for soil organisms.
Agreed Endpoints	**Aminopyralid:** Initial PEC_{soil}: 0.0064 mg/kg **Formulation: AMINO 30 SL/ El Camino 30 SL, Ranchero 30 SL** PECact = 0.218 mg/kg

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

8.8.1 Justification for new endpoints

All endpoints used for PEC soil calculations are EU approved and were evaluated on EU level and presented in:

- Aminopyralid - EFSA Journal 2013;11(9):3352.

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

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

Use No.	1
Crop	Winter oilseed rape
Application rate (g as/ha)	aminopyralid: 8.01
Number of applications/interval (d)	1
Relative application date	1 day after emergence
Crop interception (%)	40
Frequency of application	every other year
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Comments	The Applicant did not provide detailed information on application dates used for groundwater exposure assessment so the evaluator supplemented this data in the table below.

Crop	Scenario	Application dates
Winter oilseed rape	Châteaudun	08 September (251)
	Hamburg	03 September (246)
	Kremsmünster	03 September (246)
	Okehampton	15 August (227)
	Piacenza	06 October (279)
	Porto	08 September (251)

8.8.2.1 Aminopyralid

Table 8.8-2: Input parameters related to active substance aminopyralid for PEC_{gw} calculations

Compound	aminopyralid	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	207.026	EFSA Journal 2013;11(9):3352
Water solubility (mg/L):	205000 (at 20°C)	EFSA Journal 2013;11(9):3352
Saturated vapour pressure (Pa):	9.50E-09 (at 20°C) 2.60E-08 (at 25°C)	EFSA Journal 2013;11(9):3352
DT_{50} in soil (d)	14.1 d (geomean normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	EFSA Journal 2013;11(9):3352
K_{foc} (mL/g)/K_{fom}	5.27/3.06 (geomean)	EFSA Journal 2013;11(9):3352
1/n	0.8876 (arithmetic ~~geomean~~)	EFSA Journal 2013;11(9):3352
Plant uptake factor	0	EFSA Journal 2013;11(9):3352
Formation fraction	-	-

* Delete row in case of no pH dependency

Table 8.8-3: PEC_{gw} for aminopyralid for use 1 (included in GAP table)- winter oilseed rape (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
		Aminopyralid 8.01 g a.s/ha every year	Aminopyralid 8.01 g a.s/ha every other year
Winter oilseed rape	Châteaudun	0.039	0.018
	Hamburg	**0.178**	0.094
	Kremsmünster	0.070	0.036
	Okehampton	0.060	0.036
	Piacenza	**0.115**	0.066
	Porto	0.092	0.064

Table 8.8-4: PEC_{gw} for aminopyralid for use 1 (included in GAP table)- winter oilseed rape (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		Aminopyralid 8.01 g a.s/ha every year	Aminopyralid 8.01 g a.s/ha every other year	Aminopyralid 6.0 g a.s/ha every other year	Aminopyralid 8.01 g a.s/ha every third year
Winter oilseed rape	Châteaudun	0.034	0.015	-	-
	Hamburg	**0.209**	0.097	-	-
	Kremsmünster	**0.106**	0.057	-	-
	Okehampton	0.092	0.055	-	-
	Piacenza	**0.252**	**0.128**	0.094	0.087
	Porto	**0.117**	0.058	-	-

The acceptable dose of aminopyralid in Poland is 8.01 g a.s/ha every other year.
The acceptable dose of aminopyralid in MS for which Piacenza is a relevant scenario is 6.0 g a.s/ha every other year or 8.01 g a.s/ha every third year.

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Modelling	For the active substance aminopyralid the calculations presented here are accepted. Input parameters used in FOCUS ground water modelling are correct. According to EU guidance [EFSA 2014] the Applicant used geomean K_{foc} values for model input together with the arithmetic mean 1/n. Both FOCUS models were used FOCUS-PEARL 5.5.5 and FOCUS-PELMO 6.6.4. Additionally, zRMS calculated PECgw by means of FOCUS MACRO 5.5.4. for Châteaudun scenario for the every year application. **PECgw for aminopyralid (FOCUS MACRO 5.5.4) – winter oilseed rape, (BBCH 10) – 1× 8.01 g/ha**

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)
		Aminopyralid
Annual application		
Winter oilseed rape	Châteaudun	0.0271

The application every year, every second and third year were taken into consideration. PEC_{GW} values were calculated for intended use on winter oilseed rape.
PECgw	Results of modelling with FOCUS PELMO 6.6.4 and PEARL 5.5.5 show that PECgw for active substance are below the trigger value of 0.1 µg/L for Central Zone relevant scenarios apart Piacenza scenario if formulation is used every other

	year. For Member States where Piacenza scenario is relevant the acceptable dose of aminopyralid is 6.0 g a.s/ha every other year or 8.01 g a.s/ha every third year. Moreover, PECgw values for active substance aminopyralid calculated by means the FOCUS MACRO 5.5.4. are below 0.1 µg/L for Châteaudun scenario for annual application.
Conclusion	PL and other MS where Piacenza scenario is not relevant: - the acceptable dose of aminopyralid is **8.01 g a.s/ha every other year.** MS where Piacenza scenario is relevant: - the acceptable dose of aminopyralid is **6.0 g a.s/ha every other year or 8.01 g a.s/ha every third year.**

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

8.9.1 Justification for new endpoints

All endpoints used for PEC soil calculations are EU approved and were evaluated on EU level and presented in:

- Aminopyralid - EFSA Journal 2013;11(9):3352.

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	AMINO 30 SL
Use No.	1
Crop	Winter oilseed rape
Application rate (kg as/ha)	aminopyralid: 0.00801
Number of applications/interval (d)	1
Application window	June – Sep. Oct. – Feb. (relevant for STEP 1 and 2 only)
Application method	Spray, medium spray
CAM (Chemical application method)	foliar linear application
Soil depth (cm)	5
Models used for calculation	STEP 1-2 in FOCUS

8.9.2.1 Aminopyralid

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

Compound	aminopyralid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	207.026	EFSA Journal 2013;11(9):3352
Water solubility (mg/L)	205,000 (at 20°C and buffered at pH 7)	EFSA Journal 2013;11(9):3352
K_{foc} (mL/g)	5.27 (geomean)	EFSA Journal 2013;11(9):3352
Freundlich Exponent 1/n	0.8876 (arithmetic geomean)	EFSA Journal 2013;11(9):3352
$DT_{50,soil}$ (d)	14.1 d (geomean field; normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	EFSA Journal 2013;11(9):3352
$DT_{50,water}$ (d)	1000	EFSA Journal 2013;11(9):3352
$DT_{50,sed}$ (d)	1000	EFSA Journal 2013;11(9):3352
$DT_{50,whole\ system}$ (d)	1000	EFSA Journal 2013;11(9):3352
Maximum occurrence observed (% molar basis with respect to the parent)	-	-
Formation fraction in soil:	-	-

$PEC_{sw/sed}$

Table 8.9-3: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for aminopyralid following single application(s) of AMINO 30 SL to Winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.73	Runoff/drainage	2.70	0.14
Step 2					
Northern Europe	June-Sep.**	0.33	Runoff/drainage	0.33	0.02
	Oct.-Feb.**	0.73	Runoff/drainage	0.72	0.04

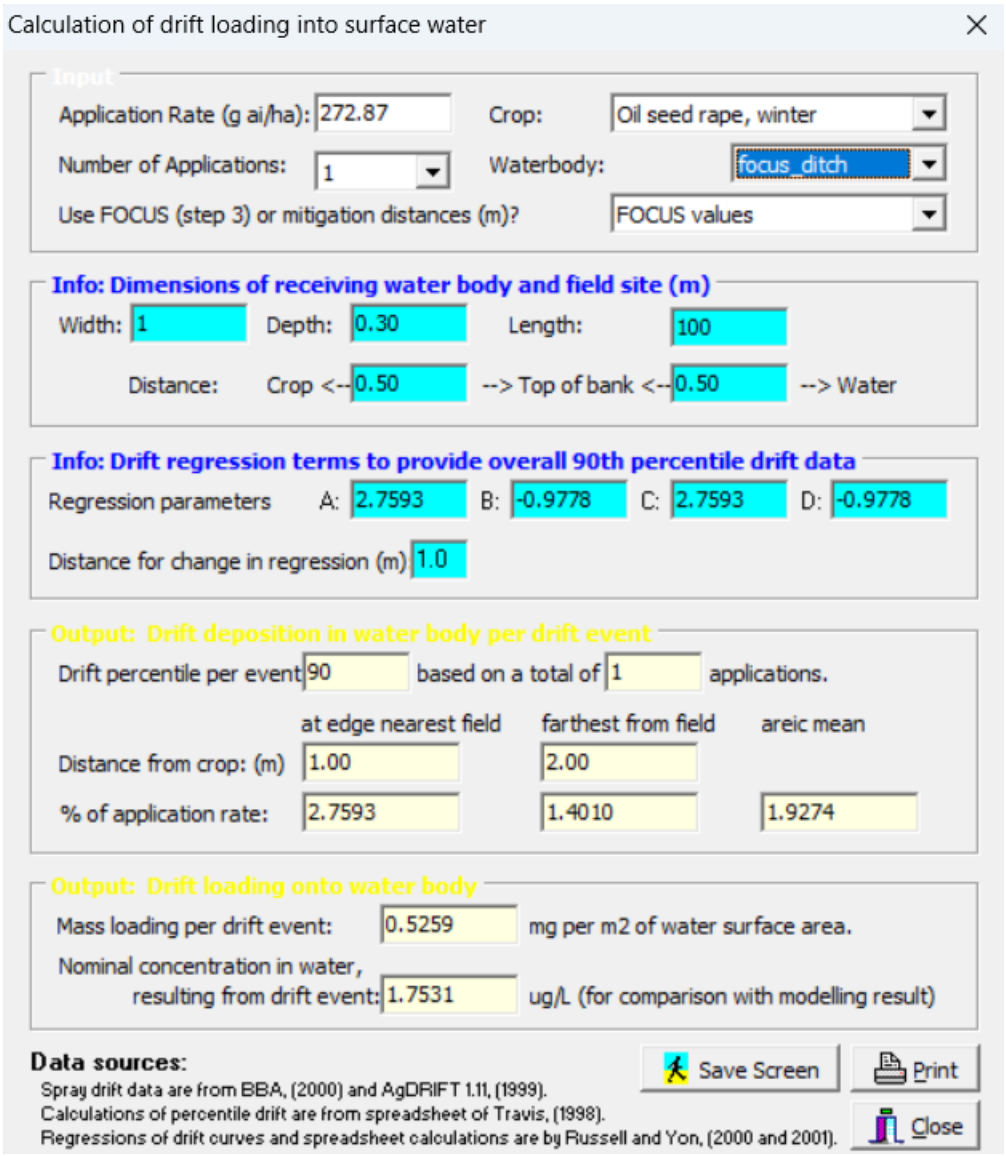
* single applications should be marked.
** twa-time as required by ecotox

8.9.2.2 $PEC_{sw/sed}$ of AMINO 30 SL

Pec_{sw} of AMINO 30 SL for winter oil seed rape was calculated using the Drift calculator into surface water from SWASH ver. 5.3.

Table 8.9-~~4~~ ~~3~~: PECsw of AMINO 30 SL for winter oil seed rape in Drift calculator into surface water from SWASH ver. 5.3

Intended use	Winter oil seed rape
Formulation	AMINO 30 SL
Application rate (g[prod]/ha)	1 × 8.01 g
Entry into surface water via spraydrift (Drift alculator from SWASH)	
Buffer zone (m)	no buffer zone no drift reduction
PECsw [µg prod/L]	~~1.7531~~ 1.7526 (focus ditch) 0.0598 (focus pond) 1.3006 (focus stream)



Evaluation by zRMS	PECsw (KCP 9.2.5)
Inputs for Modelling	For the active substance aminopyralid the calculations presented here are accepted. Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for aminopyralid after the application of the product AMINO 30 SL / El Camino 30 SL, Ranchero 30 SL to winter oilseed rape: - 1x 0.267l product AMINO 30 SL / El Camino 30 SL, Ranchero 30 SL /ha. Input parameters used in FOCUS surface water/sediment modelling for active substance are correct. The PEC_{SW} and PEC_{sed} were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2). The calculations were carried out at Step 1 and Step 2 for aminopyralid. **AMINO 30 SL / El Camino 30 SL, Ranchero 30 SL** Calculations of PEC_{SW} values for formulation has been provided by Applicant

	only for FOCUS ditch. zRMS completed this calculation with waterbodies: FOCUS pond and FOCUS stream. For calculations Applicant used incorrect application rate 272.87 instead of 272.79g a.i./ha. The evaluator recalculated PEC_{SW} of formulation submitted by Applicant. The results was presented in Tables above. Presented calculations of $PEC_{sw/sed}$ may be used for risk assessment.
Agreed endpoints	Please refer to Tables from 8.9-3 to 8.9-4.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

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	Aminopyralid
Direct photolysis in air	Not required since aminopyralid is not volatile
Quantum yield of direct phototransformation	Not required since aminopyralid is not volatile
Photochemical oxidative degradation in air	DT_{50} of 6.4 days derived by the Atkinson model (version 1.90), OH (12h) concentration assumed = 1.5 x 10^6 molecules/cm^3
Volatilisation	from plant surfaces: negligible in 24 hours from soil: up to 2.6% AR in 24 hours Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil. Aminopyralid has a very low vapour pressure of 9.5 x 10^{-9} Pa at 20ºC. As such, it is considered that significant amounts of aminopyralid will not be present in air.
Metabolites	None

The vapour pressure at 20 °C of the active substance aminopyralid is < 10^{-5} Pa. Hence the active substance aminopyralid is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance aminopyralid due to volatilization with subsequent deposition should not be considered.

Evaluation by zRMS	**Fate and behaviour in air (KCP 9.3)**
Comments	The data on the atmospheric degradation and behaviour for the active substance of AMINO 30 SL / El Camino 30 SL, Ranchero 30 SL follow the EU assessment and is therefore agreed by the zRMS.
Conclusion for exposure assessment	The vapour pressure at 20°C of the active substance: aminopyralid is 9.5 x10^{-9} Pa. Hence active substance is regarded as non-volatile and the environmental concentrations in air and the transport through air are considered negligible.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1.1	Yoder, R. N. and Smith, K.P.	2003a	Aerobic Soil Degradation of XDE-750 in Four European Soils DAS, Indiana, USA Report No.: 020054 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 9.1.1.1	Rutherford, L.A. and	2004	Anaerobic aquatic metabolism of XDE-750.	N	DAS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Owner**
	Meitl, T.J.		DAS, Indiana, USA Report No.: 020052 GLP/GEP (Y/N): Y Published (Y/N): N		
KCP 9.1.1.2.1	Anon	2004a	Further comments on environmental fate and behaviour following the outcome of the completeness check. Submitted to the UK on 18/06/2004 Dow AgroSciences Ltd, Hitchin, UK Report No.: - GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
KCP 9.1.1.2.1	Havens, P.	2004	The Normalisation Procedure Dow AgroSciences LLC, Idianapolis, USA Report No.: - GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
KCP 9.1.1.2.1	Anon	2004b	Further comments on the Normalisation Procedure. Submitted to the UK on 20/05/2005 Dow AgroSciences Ltd, Hitchin, UK Report No.: - GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
KCP 9.1.2	Rutherford, L. A.	2002	Soil Batch Equilibrium Adsorption/Desorption of XDE-750 DAS, Indiana, USA Report No.: GH-C 5552 010064 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3	Yoder, R. N. & Smith, K.P.	2003b	Degradation of XDE-750 in 2 European and 1 US Sediment and Pond Water Systems DAS, Indiana, USA Report No.: 020062 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS

Data point	Author(s)	Year	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	Owner
KCP 9.1.1.1	Rutherford, L.A.	2004	Photodegradation of XDE-750 on soil DAS Indiana, USA Report No.: 020080 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 9.1.1.2.1	Unsworth, C., Scrimshaw, O., Balluff, M., Lagrasse, S., Morgan, A.J. and Schelle, G.	2003	A one year field study to determine the dissipation of XDE-750 through soil following a single application of GF-819, Europe – 2002-2003. Covance Laboratories Ltd, Yorkshire, UK Report No.: 295/154 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 9.1.2	Rutherford, L. A.	2002	Soil Batch Equilibrium Adsorption/Desorption of XDE-750 DAS, Indiana, USA Report No.: GH-C 5552 010064 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCP 9.3, KCP 9.3.1	Knoch, E. and Heim, L.	2003	XDE-750 volatilisation – Atkinson calculation and volatilisation from soil and dwarf runner bean when formulated as 30 g ae/L EO (BBA Guideline Part IV, Section 6-1, 1990) Institut Fresenius, Herten, Germany Report No.: 010051 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS

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

Appendix 2 Detailed evaluation of the new Annex II studies

No new studies provided.

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