FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: Diflufenikan 500 SC

Product name(s): -

Chemical active substance:

Diflufenican, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o. / ProAgri International Sp. z o.o.

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Version history

When	What
07.2023	Initial assessment by zRMS
01.2024	The final Registration Report
06.2024	Corrections in line to MRiRW comments were made

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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

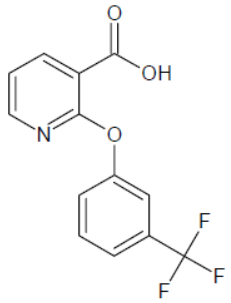
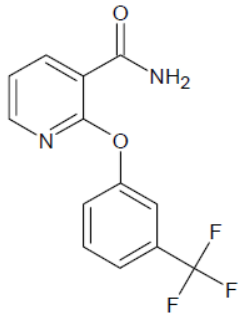
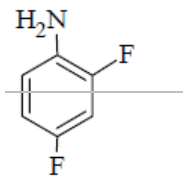
1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures**	**Conclusion** **PECgw**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**kg, L product / ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g, kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**			
1	Poland	~~Winter wheat,~~ ~~Winter barley~~ Winter wheat, Winter triticale Winter rye	F	weeds (for details please refer to dRR Part B0 and B3)	broadcast spraying	BBCH 00-29 Autumn application pre & post emergence	1 a) 1 b) 1	0,2 – 0,3 L/ha a) 0,3 L/ha b) 0,3 L/ha	100-150 g diflufenican a) 150g diflufenican b) 150g diflufenican	100-400 L/ha	N/A	N/A	A

* F: professional field use, G: professional greenhouse use, I: indoor application

zRMS comments:
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.

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments relevant for PEC calculation	Exposure assessment required due to
AE BI07137	283		Soil: 16.8% Water/sediment: 35.7 %	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
AE 0542291	282		Soil: 26.3% Water/sediment: 0.01 %	PEC_{soil} PEC_{gw} $PEC_{sw/sed}$
~~AE C522392~~	~~129.11~~		~~NR~~	~~PEC_{air}~~

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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

Table 8.3.1-1: Summary of aerobic degradation rates for diflufenican - laboratory studies

Diflufenican	Aerobic conditions					
Soil type	**pH ($CaCl_2$)**	**t.ºC / % MWHC**	**DT_{50}/DT_{90} (d)**	**DT_{50} (d) 20ºC pF2/10kPa**	**St. (r^2)**	**Method of calculation**
Sandy loam	7.7 [(a)]	22ºC/ 75 % of 0.33 bar	248.5/825.5	237.9	0.9980	SFO
Clay loam	6.6 [(a)]	22ºC/ 75 % of 0.33 bar	139.5/463.4	119.9	0.9967	SFO
Clay loam	6.5	20ºC/45 %	232.6/772.7	193.5	0.9954	SFO
Clay loam	6.5	20ºC/45 %	206.0/684.3	172.1	0.9975	SFO
Clay loam	6.5	20ºC/45 %	176.3/585.8	147.3	0.9967	SFO
Silty clay loam	7.5	20ºC/45 %	44.3/147.2	44.3	0.9819	SFO
Sandy loam 1	5.5	20ºC/45 %	129.3/429.5	129.3	0.9836	SFO
Sandy loam 2	6.9	20ºC/45 %	89.8/298.3	89.8	0.9890	SFO
Sandy loam 2	6.9	10°C/45 %	204.4/679.0 [(b)]			SFO
Geometric mean/median				**128 /** 138.3		
Arithmetic mean				141.8		

[a]pH calculation method not stated
[b]Calculated by the Rapporteur

Table 8.3.1-2: Summary of aerobic degradation rates for AEB107137 - laboratory studies

AE B107137	Aerobic conditions						
Soil type	**pH ($CaCl_2$)**	**t.ºC / % MWHC**	**DT_{50}/ DT_{90} (d)**	**f. f. kdp/ kf (a)**	**DT_{50} (d) 20ºC pF2/10kPa**	**St. (r^2)**	**Method of calculation**
Silt loam 1	7.0	20ºC/45 %	9.1/30.2	1	7.5	0.9919	SFO
Sandy loam	6.2	20ºC/45 %	17.9/59.5	1	13.9	0.9868	SFO
Silt loam 2	7.4	20ºC/45 %	14.5/48.1	1	10.4	0.9959	SFO
Geometric mean/median					**10.3** / 10.4		

Arithmetic mean	10.6

[a] The Rapporteur could not verify the lower formation fractions of 33 and 37% provided by Notifier for AE B107137 and AE 0542291 respectively and therefore a formation fraction of 1 (i.e. 100%) was additionally assumed as a worst case in FOCUS groundwater modelling

Table 8.3.1-3: Summary of aerobic degradation rates for AE0542291 - laboratory studies

AE 0542291	Aerobic conditions						
Soil type	**pH ($CaCl_2$)**	**t. °C / % MWHC**	**DT_{50}/ DT_{90} (d)**	**f. f. kdp/kf (a)**	**DT_{50} (d) 20°C pF2/10kPa**	**St. (r^2)**	**Method of calculation**
Silt loam 1	7.0	20°C/45 %	13.6/45.2	1	11.1	0.987	SFO
Sandy loam	6.2	20°C/45 %	58.7/194.9	1	45.7	0.999	SFO
Silt loam 2	7.4	20°C/45 %	33.2/110.2	1	23.8	0.991	SFO
Geometric mean/median					**22.9** / 23.8		
Arithmetic mean					26.9		

[a] The Rapporteur could not verify the lower formation fractions of 33 and 37% provided by Notifier for AE B107137 and AE 0542291 respectively and therefore a formation fraction of 1 (i.e. 100%) was additionally assumed as a worst case in FOCUS groundwater modelling

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant. No significant degradation of parent and no specific metabolites under anaerobic conditions.

Anaerobic degradation in soil is not relevant for exposure assessment of the product Diflufenican 500 SC for the intended uses in winter cereals,

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)

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

Table 8.4.1-1: Summary of aerobic degradation rates for diflufenican – field studies

Diflufenican	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used)	**Location (country or USA state).**	**pH**	**Depth (cm)**	**DT_{50} (d) actual**	**DT_{90}(d) actual**	**St. (r^2)**	**DT_{50} (d) 20°C / pF2**	**Method of calculation**
Loamy sand (b)	UK	5.8	30	**621**	2063	0.493	282.0	SFO
Sandy silt loam I	France	7.1	30	241	801	0.796	130.0	SFO
Sandy loam (b)	Netherlands	6.3	30	389	1292	0.495	199.5	SFO
Clay (b)	Spain	7.6	30	236	784	0.728	122.2	SFO
Clay loam (b)	Italy	6.9	30	224	744	0.748	103.4	SFO

Geometric mean/median Maximum (n=5)	315/241 **621**			156/130*	

*Note a Q10 of 2.2 was assumed during the normalization.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not relevant. See point 8.4.1.1.

The accumulation potential of diflufenican was evaluated during the Annex I Inclusion and was accepted by the European Commission (SANCO/3782/08 – rev. 1 – 14. March 2008). No additional studies have been performed.
It is concluded in the EFSA conclusion (EFSA Scientific Report (2007) 122, 1-84) that the soil an accumulation factor of 2.53 should be used on MS level.

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 Laboratory studies (KCP 9.1.2.1)

Table 8.5.1-1: Summary of soil adsorption/desorption for diflufenican

Diflufenican						
Soil Type	**OC %**	**Soil pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**R^2**
Sandy loam	2.09	7.7	33.9	1622	0.875	>0.988
Loamy sand	0.75	6.6	13.5	1800	0.917	>0.988
Clay loam	1.68	6.6	39.8	2369	0.934	>0.988
Silty clay loam	2.26	6.8	48.9	2164	0.923	>0.988
Clay loam (Shelley Field)	2.4	6.2	98.82	4118	0.901	0.998
Silt loam (Kissendorf)	1.4	6.7	46.28	3306	0.897	1.000
Sandy loam (Manningtree)	3.6	5.3	267.51	7431	0.991	0.998
Loam (Santilly)	0.9	7.0	39.86	4428	0.940	0.999
Clay loam (Lleida)	2.9	8.0	88.91	3066	0.917	0.999
Clay loam (Chazay)	1.9	6.6	73.49	3868	0.879	0.998
Geometric mean			55.6	**3090.6**	0.9	
Arithmetic mean			75.1	3417	**0.917**	
Median			47.6	3186	0.917	
pH dependence, Yes or No			No			

Table 8.5.1-2: Summary of soil adsorption/desorption for AEB107137

Soil Type	OC %	Soil pH	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	1.9	7.0	0.22	12	0.72
Sand	1.6	5.8	0.11	7	0.99
Clay loam	4.7	7.6	0.38	8	0.54
Sandy loam	1.8	6.0	0.42	23	0.68
Geometric mean				**11.1**	
Arithmetic mean/median				13/10	**0.73**/0.70
pH dependence (yes or no)				No	

Table 8.5.1-3: Summary of soil adsorption/desorption for AE0542291

Soil Type	OC %	Soil pH	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	0.8	6.0	1.3	160	0.80
Sand	1.2	5.3	1.5	127	0.84
Clay loam	2.6	7.0	3.6	137	0.77
Sandy loam	3.9	6.0[a]	4.0	103	0.85
Geometric mean				**131.1**	
Arithmetic mean/median				132/132	**0.81**/0.82
pH dependence (yes or no)				No	

[a] pH in CaCl2

8.5.2 Column leaching (KCP 9.1.2.1)

None required.

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.

A two years lysimeter study was conducted in Germany with radiolabelled diflufenican. All the lysimeter were cropped with winter wheat in the first year, with winter barley in the second year and green mustard on the final year. Applications were made at 185 g a.s./ha, pre-emergent. Analysis of the leachate in the lysimeter study showed that annual average concentration of diflufenican at first year was 0.003 and at second year <0.003 µg /L. Annual average concentrations of metabolites AE B107137 and AE 0542291 were <0.003 µg /L.

Table 8.5-1: Summary of lysimeter / field leaching studies for diflufenican and metabolites

Lysimeter/ field leach-	Location: Germany (Bruhl, Schwemmlob) Study type (e.g. lysimeter, field): lysimeter	Yes, EF-SA Sci-

ing studies	Soil properties: pH = 7.2, OC= 1.05 Dates of application: 3rd December 1990 Crop: 1st year winter wheat, 2nd year winter barley, final green mustard Interception estimated: None (application pre-emergent) Number of applications: lysimeter 219 1 application each year, lysimeter 220 1 application 1st year Duration: 2 years Application rate: 185 g a.s./ha/year (nominal) Average annual rainfall and irrigation (mm): 853 mm Average annual leachate volume (mm): 325 mm %radioactivity in leachate (maximum/year): 0.014 % AR 1st year, 0.117 % AR 2nd year Individual annual average concentrations: 1st year 0.003 µg /L and 2nd year <0.003 µg /L active substance, <0.003 µg /L metabolites AE B107137 and AE 0542291. Unidentified radioactivity: total max 0.01 µg /L parent equivalents.	entific Report (2007) 122, 1-84

8.5.4 Field leaching studies (KCP 9.1.2.3)

Not relevant. No studies submitted.

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.

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

Diflufenican	Distribution (Max. in sed 74.4 % after 14 d)									
Water / sediment system	**pH water phase**	**pH sed**	**t.°C**	**DT_{50}-DT_{90} whole sys.**	**St. (r2)**	**DT_{50}-DT_{90} water**	**St. (r2)**	**DT_{50}- DT_{90} sed**	**St. (r2)**	**Method of calculation**
Unter Widdersheim	8.2	7.5	20	90	0.76	n.a.	n.a.	n.a.	n.a.	SFO
Bickenbach	8.2	7.8	20	154	0.77	n.a.	n.a.	n.a.	n.a.	SFO
Clay, UK	7.8	6.3	20	345	0.82	n.a.	n.a.	n.a.	n.a.	SFO
Sand, UK	6.8	5.4	20	195	0.96	n.a.	n.a.	n.a.	n.a.	SFO
Arithmetic mean (DT_{50})				196		n.a.		n.a.		
Geometric mean (n=4)				**175**		n.a.		n.a.		

n.a. no reliable value available

Table 8.6-2: Summary of observed metabolites

AE B107137	Distribution (max in water 32.6 % after 30 d, max in sed 13.3 % after 30 d)	Yes, EFSA Scientific Report (2007) 122, 1-84
AE C522392	Distribution (max in water 6.1 % after 30 d, max in sed 1.0 % after 59 d)	

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

8.7.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

8.7.2 Active substance and relevant metabolites

The predicted environmental concentrations in soil PECs of nicosulfuron and its metabolites were calculated using single formulas in FOCUS guidance – FOCUS (1997): Soil persistence models and EU registration. The final report of the work of the Soil Modelling Work group of FOCUS (Forum for the Coordination of pesticide fate models and their Use). Input parameters related to application and active substances/metabolites data for PECs calculation are summarized below.

Table 8.7.2-1: Input parameters related to application for PECsoil calculations

Use No.	1, 2
Crop	winter cereals
Application rate (g as/ha)	150
Number of applications/interval	1/-
Crop interception (%)	0
Depth of soil layer (relevant for plateau concentration) (cm)	5 (no tillage)
Soil density (g/cm3)	1.5
Models used for calculation	single formula in FOCUS guidance

Table 8.7.2-2: Input parameter for active substance and relevant metabolites for PECsoil calculation

Compound	Molecular weight (g/mol)	Max. observed in soil (%)	DT_{50} (days)	Koc (ml/kg)	Value in accordance to EU endpoint y/n/ Reference
Diflufenican	394	-	**621** (highest non-normalized field DT_{50} in soil)	3090.6 (geomean laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=10)	Yes, EFSA Scientific Report (2007) 122, 1-84
AE B107137	283	16.8	**17.9** (highest non-normalized field DT_{50} in soil)	11.1 (geomean laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=4)	
AE 0542291	282	26.3	**58.7** (highest non-normalized field DT_{50} in soil)	130.1 (geomean laboratory studies,	

Compound	Molecular weight (g/mol)	Max. observed in soil (%)	DT_{50} (days)	Koc (ml/kg)	Value in accordance to EU endpoint y/n/ Reference
				normalisation to 10 kPa or pF2, 20°C, n=4)	

Table 8.7.2-3: PECs of diflufenican in soil after application to winter cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.2000	-	-	-
Short term	24h	0.1998	0.1999	-	-
	2d	0.1996	0.1998	-	-
	4d	0.1991	0.1996	-	-
Long term	7d	0.1984	0.1992	-	-
	14d	0.1969	0.1984	-	-
	21d	0.1954	0.1977	-	-
	28d	0.1938	0.1969	-	-
	50d	0.1891	0.1945	-	-
	100d	0.1789	0.1892	-	-
Average plateau concentration		**0.5980**	-	-	-
Background concentration		0.3980	-	-	-

PEC_{soil} of metabolites

Table 8.7.2-4: PECs of metabolite AEB107137 after application to winter cereals

PEC_{soil} (mg/kg)		Winter cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0241	-	-	-
Short term	24h	0.0232	0.0237	-	-
	2d	0.0223	0.0232	-	-
	4d	0.0207	0.0224	-	-
Long term	7d	0.0184	0.0211	-	-
	14d	0.0140	0.0186	-	-
	21d	0.0107	0.0165	-	-
	28d	0.0082	0.0147	-	-
	50d	0.0035	0.0107	-	-

	100d	0.0005	0.0061	-	-
Average plateau concentration		0.0240	-	-	-
Background concentration		0.0000	-	-	-

Table 8.7.2-5: PECs of metabolite AE0542291 after application to winter cereals

PEC_{soil} (mg/kg)		**Winter cereals**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		0.0376	-	-	-
Short term	24h	0.0372	0.0374	-	-
	2d	0.0368	0.0372	-	-
	4d	0.0359	0.0368	-	-
Long term	7d	0.0347	0.0361	-	-
	14d	0.0319	0.0347	-	-
	21d	0.0294	0.0333	-	-
	28d	0.0270	0.0321	-	-
	50d	0.0209	0.0284	-	-
	100d	0.0116	0.0221	-	-
Average plateau concentration		0.0380	-	-	-
Background concentration		0.0010	-	-	-

8.7.2.1 PEC_s of formulation

PECs for formulation was obtained from PECs for diflufenican taking into account content of active substance and density of the formulation Diflufenikan 500 SC. TWA PECs, $_{background}$ PECs and accumulation PECs are not relevant for formulation.

Table 8.7.2.1-6: PECs for formulation after application to winter cereals

Active substance/ preparation	**Application rate (L/ha)**	**PECact (mg as/kg)**	**PECact * (mg formulation/kg)**
Diflufenikan 500 SC	0.3 L/ha	0.2000	0.4776

* calculated on the basis of density value of 1.194 g/mL

zRMS comment:

The calculations were accepted. The EU agreed endpoints were used for calculations. Calculations were performed with consideration of the critical use pattern proposed in GAP.
The interception values based on the FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014) was considered.
The PECs accum of active substances/metabolites, if relevant, was assessed.
The presented PEC_{soil} values are suitable for ecotoxicological risk assessment.

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

8.7.3 Justification for new endpoints

Not relevant. No new endpoints proposed.

8.7.4 Active substance and relevant metabolites (KCP 9.2.4)

PECgw for active substance and its metabolites after application to winter cereals were calculated with FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4 for FOCUS groundwater scenarios. Application timing for each crop/scenario was settled with AppDate 3.06. Input parameters related to application and active substance and metabolites data for PECgw calculation are summarized below.

Table 0.2-1: Input parameters related to application for PECgw calculations

Use No.	1, 2
Crop	Winter cereals
Application rate (g as/ha)	150
Number of applications/interval (d)	1/-
Relative application date	7 days before emergence & 21 days after emergence
Crop interception (%)	0
Frequency of application	annual
Models used for calculation	FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4

Table 0.2-2: Input parameters related to active substance diflufenican and metabolites for PECgw calculations

Compound	**Diflufenican**	**AE B107137**	**AE 0542291**	**Value in accordance with EU endpoint y/n/ Reference***
Molecular weight (g/mol)	394	283	282	Yes, EFSA Scientific Report (2007) 122, 1-84
Water solubility (mg/mol):	0.05	410	100	Yes, EFSA Scientific Report (2007) 122, 1-84
Saturated vapour pressure (Pa):	$4.25 \cdot 10^{-6}$ at 25°C	0 at 20°C (default value)	0 at 20°C (default value)	Yes, EFSA Scientific Report (2007) 122, 1-84
DT_{50} in soil (d)	128 (geomean laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=8)	10.3 (geomean from laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=3)	22.9 (geomean from laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=3)	Yes, EFSA Scientific Report (2007) 122, 1-84
Transformation rate	0.00542	0.06730	0.003027	Calculated for PELMO; $(\ln(2)/DT_{50})$ x FFm

Kfoc (mL/g)	3090.6 (geometric mean, normalisation to 10 kPa or pF2, 20°C, n=10)	11.1 (geometric mean, normalisation to 10 kPa or pF2, 20°C, n=4)	130.1 (geometric mean, normalisation to 10 kPa or pF2, 20°C, n=4)	Yes, EFSA Scientific Report (2007) 122, 1-84
1/n	0.917 (arithmetic mean, n=10)	0.73 (arithmetic mean, n=4)	0.81 (arithmetic mean, n=4)	Yes, EFSA Scientific Report (2007) 122, 1-84
Plant uptake factor	0 (default value)	0 (default value)	0 (default value)	Yes, EFSA Scientific Report (2007) 122, 1-84
Formation fraction	-	1 from parent	l from parent	Yes, EFSA Scientific Report (2007) 122, 1-84

Table 0.2-3: PECgw for diflufenican and metabolites on winter cereals (7 days before emergence; PELMO 6.6.4)

Crop	Scenario	Diflufenican	AE B107137	AE 0542291
Winter cereals	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 0.2-4: PECgw for diflufenican and metabolites on winter cereals (21 days after emergence; PELMO 6.6.4)

Crop	Scenario	Diflufenican	AE B107137	AE 0542291
Winter cereals	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 0.2-5: PECgw for diflufenican and metabolites on winter cereals, 7 days before emergence; PEARL 5.5.5)

Crop	Scenario	diflufenican	AEB107137	AE0542291
Winter cereals	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.006	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	0.011	< 0.001
	Piacenza	< 0.001	0.001	< 0.001
	Porto	< 0.001	0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

Table 0.2-6: PECgw for diflufenican and metabolites on winter cereals (21 days after emergence; PEARL 5.5.5)

Crop	Scenario	diflufenican	AEB107137	AE0542291
Winter cereals	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.004	< 0.001
	Kremsmünster	< 0.001	0.001	< 0.001
	Okehampton	< 0.001	0.007	< 0.001
	Piacenza	< 0.001	0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

For all scenarios PECgw values for diflufenican and its metabolites are below the trigger value of 0.1 µg/L.

zRMS comment:

The PECgw calculations provided by the Applicant for difufenican and its metabolites are considered acceptable.
All used endpoints were agreed at the EU level.
Calculations of PECgw for all active substances and its relevant metabolite were provided with PUF = 0.
The recommended FOCUS models were used: FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5. The autumn application was taken into consideration. MACRO simulations were not required, since PECgw values calculated using FOCUS PEARL and FOCUS PELMO were <0.001 µg/L.

Results of FOCUS groundwater modelling show that the active substance and its metabolites are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L through direct leaching in the intended uses of Diflufenican 500 SC in winter cereals (winter wheat and winter barley) in all FOCUS groundwater scenarios.

PECgw:
Diflufenican: < 0.001 µg/L
AE B107137: < 0.01 µg/L
AE 0542291: < 0.001 µg/L

The additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

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

8.8.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

8.8.2 Active substance, relevant metabolites and the formulation (KCP 9.2.5)

PECsw for diflufenican and its metabolites after application to winter cereals were calculated with STEPS 1-2 in FOCUS v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS

TOXSWA v5.5.3, SWAN v5.0.1 Application timing for each crop/scenario was settled with AppDate 3.06. Input parameters related to application and active substance/metabolites data for $PEC_{sw/sed}$ calculation are summarized below.

Table 8.8.2-1: Input parameters related to application for PECSW/SED calculations

Use No.	1, 2
Crop	winter cereals
Application rate (g as/ha)	150
Number of applications/interval (d)	1/-
Application window	Oct-Feb (relevant for STEP 1 and 2 only)
Interception (%)	0
Application method	ground spray
CAM (Chemical application method)	foliar linear
Soil depth (cm)	4
Models used for calculation	STEPS 1-2 in FOCUS v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.0.1

Table 8.8.2-2: FOCUS Step 3 and 4 scenario related input parameters for PECsw/sed calculations

Crop	**Application window used in modelling**		
Winter cereals	**Scenario**	**1st possible appl at BBCH 00**	**last possible appl at BBCH 29**
	D1	15.09 (258)	09.11 (313)
	D2	15.10 (288)	09.12 (343)
	D3	11.11 (315)	05.01 (5)
	D4	12.09 (255)	06.11 (310)
	D5	31.10 (304)	25.12 (359)
	D6	20.11 (324)	14.01 (14)
	R1	02.11 (306)	27.12 (361)
	R3	21.11 (325)	15.01 (15)
	R4	31.10 (304)	17.01 (17)

Table 8.8.2-3: Input parameters related to active substance diflufenican and metabolites for PECsw/sed calculations STEP 1, 2, 3 and 4

Compound	**diflufenican**	**AE B107137**	**AE 0542291**	**Value in accordance with EU endpoint y/n/ Reference***
Molecular weight (g/mol)	394	283	282	Yes, EFSA Scientific Report (2007) 122, 1-84
Saturated vapour pressure (Pa)	not required for Step 1+2/ $4.25 \cdot 10^{-6}$ at 25°C	not required for Step 1+2/ 0 at 20°C (default	not required for Step 1+2/ 0 at 20°C (default	Yes, EFSA Scientific Report (2007) 122, 1-84

Compound	diflufenican	AE B107137	AE 0542291	Value in accordance with EU endpoint y/n/ Reference*
	Step 3+4	value) Step 3+4	value) Step 3+4	
Water solubility (mg/L)	0.05 at 20°C	410 at 20°C	100 at 20°C	Yes, EFSA Scientific Report (2007) 122, 1-84
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5} Step 3+4	not required for Step 1+2	not required for Step 1+2	Yes, EFSA Scientific Report (2007) 122, 1-84
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43 Step 3+4	not required for Step 1+2	not required for Step 1+2	Yes, EFSA Scientific Report (2007) 122, 1-84
K_{foc} (mL/g)	3090.6 (geometric mean, normalisation to 10 kPa or pF2, 20°C, n=10)	11.1 (geometric mean, normalisation to 10 kPa or pF2, 20°C, n=4)	130.1 (geometric mean, normalisation to 10 kPa or pF2, 20°C, n=4)	Yes, EFSA Scientific Report (2007) 122, 1-84
Freundlich Exponent 1/n	0.917 (arithmetic mean, n=10)	0.917 (arithmetic mean, n=10)	0.81 (arithmetic mean, n=4)	Yes, EFSA Scientific Report (2007) 122, 1-84
Plant Uptake	not required for Step 1+2/ 0 Step 3+4	not required for Step 1+2/ 0 Step 3+4	not required for Step 1+2/ 0 Step 3+4	Yes, EFSA Scientific Report (2007) 122, 1-84
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05(MACRO) 0.50 (PRZM) Step 3+4	not required for Step 1+2	not required for Step 1+2	Yes, EFSA Scientific Report (2007) 122, 1-84
$DT_{50,soil}$ (d)	128 (geomean laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=8)	10.3 (geomean from laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=3)	22.9 (geomean from laboratory studies, normalisation to 10 kPa or pF2, 20°C, n=3)	Yes, EFSA Scientific Report (2007) 122, 1-84
$DT_{50,water}$ (d)	1000* (worst case)	76.2[a]	730[b] (worst case)	Yes, EFSA Scientific Report (2007) 122, 1-84
$DT_{50,sed}$ (d)	175* (geomean, n=4)	730[b] (worst case)	730[b] (worst case)	Yes, EFSA Scientific Report (2007) 122, 1-84
$DT_{50,whole\ system}$ (d)	175* (geomean, n=4)	730[b] (worst case)	730[b] (worst case)	Yes, EFSA Scientific Report (2007) 122, 1-84
Maximum occurrence observed (% molar basis with	-	Soil: 16.8% Total system: 35.7%	Soil: 26.3% Total system: 0.01 % (not found in wa-	Yes, EFSA Scientific Report (2007) 122, 1-84

Compound	diflufenican	AE B107137	AE 0542291	Value in accordance with EU endpoint y/n/ Reference*
respect to the parent)			ter/sediment)	

[a] Arithmetic mean DT_{50} in water phase of two from four systems for AE B107137 (DAR, 2006)
[b] worst case assumption of two years from four test systems for parent (DAR,2006)
* in line with EFSA (2011) interpretation of FOCUS surface water recommendations, as the Koc of diflufenican is greater than 2000, the geometric mean DT_{50} for the total water sediment systems was used for the sediment phase and a conservative default value was used for the water phase.

$PEC_{sw/sed}$

Table 8.8.2-4: FOCUS Step 1, 2 and 3 PECsw and PECsed for diflufenican following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21d TWA PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1	NR	11.144	9.6540	NR	301.7693
Step 2 Northern Europe	NR	5.148	4.8868	NR	155.266
Step 2 Southern Europe	NR	4.192	3.9615	NR	125.8525
Step 3					
D1	ditch	0.9800	0.5645	drainage	6.804
D1	stream	0.8417	0.1672	drainage	3.317
D2	ditch	1.064	0.3285	drainage	5.327
D2	stream	0.8931	0.2096	drainage	3.087
D3	ditch	0.9482	0.03599	drainage	0.5024
D4	pond	0.03818	0.03044	drainage	0.4584
D4	stream	0.8223	0.01127	drainage	0.1745
D5	pond	0.03305	0.02638	drainage	0.2877
D5	stream	0.8872	0.01616	drainage	0.2449
D6	ditch	0.9589	0.2691	drainage	2.412
R1	pond	0.08077	0.06542	runoff and erosion	1.030
R1	stream	0.6251	0.02390	runoff and erosion	0.9975
R3	stream	0.8678	0.06582	runoff and erosion	44.32
R4	stream	0.6290	0.02733	runoff and erosion	0.7582

Table 8.8.2-5: Global maximum PECsw Step 4 values for diflufenican following single application to winter cereals

		Mitigation options								
Vegetative strip (m)		**-**	**-**	**5**	**-**	**10**	**10-12**	**-**	**20**	**18-20**
No spray buffer (m)		**-**	**5**	**5** VFS	**10**	**10** VFS	**10**	**20**	**20** VFS	**20**
Nozzle reduction (%)		**-**	**-**	**-**	-	-	-	-	-	-
Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**
D1	ditch	0.9800	0.3381	0.3381	0.3381	0.3381	0.3381	0.3381	0.3381	0.3381
D1	stream	0.8417	0.3076	0.3076	0.2122	0.2122	0.2122	0.2122	0.2122	0.2122
D2	ditch	1.064	0.6678	0.6678	0.6678	0.6678	0.6678	0.6678	0.6678	0.6678
D2	stream	0.8931	0.4213	0.4213	0.4213	0.4213	0.4213	0.4213	0.4213	0.4213
D3	ditch	0.9482	0.2571	0.2571	0.1363	0.1363	0.1363	0.07082	0.07082	0.07082
D4	pond	0.03818	0.03672	0.03672	0.03409	0.03409	0.03409	0.03186	0.03186	0.03186
D4	stream	0.8223	0.3004	0.3004	0.1593	0.1593	0.1593	0.1307	0.1307	0.1307
D5	pond	0.03305	0.02862	0.02862	0.02064	0.02064	0.02064	0.01385	0.01385	0.01385
D5	stream	0.8872	0.3241	0.3241	0.1719	0.1719	0.1719	0.08930	0.08930	0.08930
D6	ditch	0.9589	0.4453	0.4453	0.4453	0.4453	0.4453	0.4453	0.4453	0.4453
R1	pond	0.08077	0.07881	0.02838	0.07531	0.02040	0.03591	0.07234	0.01362	0.01951
R1	stream	0.6251	0.4292	0.2284	0.4292	0.1211	0.1922	0.4292	0.06293	0.1001
R3	stream	0.8678	0.5038	0.3171	0.5038	0.1887	0.2299	0.5038	0.1246	0.1206
R4	stream	0.6290	0.6166	0.2298	0.6166	0.1219	0.2783	0.6166	0.06331	0.1454

Metabolites of diflufenican

Table 8.8.2-6: FOCUS Step 1 and 2 PECsw and PECsed for AEB107137 following single application to winter cereals

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**Max PEC_{sed} (µg/kg)**
Step 1	NR	18.9335	NR	2.0990
Step 2 Northern Europe	NR	8.7908	NR	0.9747
Step 2 Southern Europe	NR	7.1002	NR	0.7872

Table 8.8.2-7: FOCUS Step 1 and 2 PECsw and PECsed for AE 0542291 following single application to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
Step 1	NR	8.0238	NR	10.4388
Step 2 Northern Europe	NR	3.5546	NR	4.6245
Step 2 Southern Europe	NR	2.8437	NR	3.6996

zRMS comment:

The PEC_{sw} calculations for diflufenican and its metabolites were provided by Applicant and are considered acceptable. The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. The autumn application was taken into consideration. All used endpoints for active substance and its metabolites are in line EFSA Scientific Report (2007) 122, 1-84.
The relevant metabolites AEB107137 and AE 0542291 were taken into consideration; the Step 1 & 2 were used in PEC assessment. In the table above the higher values of PECsw and PECsed are presented

zRMS is of the opinion, that relevant mitigation measures will be proposed at the Member State level.

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

Table 8.9-1 Summary of atmospheric degradation and behaviour

Compound	diflufenican
Direct photolysis in air	not studied – no data requested
Quantum yield of direct phototransformation	not studied – no data requested
Photochemical oxidative degradation in air	DT_{50} of 5.0 d (EU), 3.3 d (USA) derived by the Atkinson method of calculation
Volatilisation	Vapour pressure: $4.25 \cdot 10^{-6}$ Pa at 25°C Henry's Law Constant: $>1.18 \cdot 10^{-2}$ Pa·m³/mol at 20°C From plant surfaces (BBA guideline): negligible (max. 0.3 %) after 24 hours
Metabolites	Metabolite AE C522392 was found to be volatile in an anaerobic soil degradation study (peak of 28.11% AR in volatile traps). However, because its DT_{50} in air is 10.5 hours (via Atkinson calculation), it is unlikely to persist in the troposphere or be subject to long range transport.

In accordance with EFSA Scientific Report (2007) 122, 1-84, diflufenican has a vapour pressure of 4.25 10^{-6} Pa at 25 ºC and a Henry's Law constant of > 1.18 · 10^{-2} Pa·m³/mol at 20 ºC and could be considered slightly volatile. Volatilization of diflufenican from plant surface and soil was negligible (plants: 0.3 AR % after 24 h, soil: 0.0 – 0.005% AR after 24 h). A theoretical calculation of the potential for photo-oxidation resulted in a half-life of 3.3 d based on an OH radical concentration of 1.5 10^6 cm^{-3} on a 12h day basis. Based on the negligible potential for volatilization form plant and soil surface it is considered that exposure to air and therefore long range transport thought air is insignificant for diflufenican. However, during expert's meeting soil anaerobic metabolite 2,4-difluroaniline was found to be very volatile and may need to be assessed for the air compartment and for transport through air when prolonged anaerobic conditions are expected to occur in soil. The meeting agreed that at any case exposure is expected to

be “very low”.

zRMS comment:

The data on the atmospheric degradation and behaviour for diflufenican as listed in the table follow the EU assessment and are agreed by zRMS.

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
KCP 9.2.4/01	Hara-Skrzypiec A.	2022	Diflufenikan 500 SC Calculation of predicted environmental concentrations of diflufenican and its metabolites in groundwater using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/22/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	Pestila* ProAgri**
KCP 9.2.5/01	Hara-Skrzypiec A.	2022	Diflufenikan 500 SC Calculation of Predicted Environmental Concentrations of diflufenican and its metabolites in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/21/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	Pestila* ProAgri**

*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)
**ProAgri Spółka z ograniczoną odpowiedzialnością or ProAgri International Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o. or ProAgri International Sp. z o.o.)

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
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the new Annex II studies

Not relevant.

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

Not relevant.