==FINAL== REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GLOB2106cF

Product name: Revus Pro

Chemical active substances:

Propamocarb-HCl, 450 g/L
Mandipropamid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: March 2023

==MS Finalisation date: 06/03/2024==

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Version history

When	What
March 2023	Initial dossier submission by applicant for approval of new product
July 2023	Dossier sent for evaluation
November 2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

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8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	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 saf-ener/ 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	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, BE, CZ, DE, NL	Seed, ware and starch potato (SOLTU)	F	*Phytophthora infestans* (PHYTIN)	Normal downward spraying	After emergence to shortly before harvest (BBCH 21-89)	a) 3 b) 3	7	a) 1.9 b) 5.7	a) Propamocarb-HCl: 0.855 + Mandipropamid: 0.1425 b) Propamocarb-HCl: 2.565 + Mandipropamid: 0.4275	150-300	14	/	A

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 "Conclusion"

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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
					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		
1	N & S	Potatoes	F	Mildew: *Phytophtora infestans*	Foliar spray	As 1st symptoms occur	6 max	Repeat each 7 days	a) 1.5 L/ha b) 9 L/ha	a) 1.083 b) 6.498	500	14	Proplant

* 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

Table 8.1-3: **Assessed (critical) uses during approval of Mandipropamid concerning the Section Environmental Fate**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	N & S	Potatoes	F	Mildew: *Phytophtora infestans*	Foliar spray	From beginning of infection (BBCH 51) up to BBCH 90	6 max	Repeat each 7 days	a) 0.6 L/ha b) 3.6 L/ha	a) 0.150 b) 0.900	200-800	3	Revus

* 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

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8.2 Metabolites considered in the assessment

There are no relevant metabolites for Propamocarb-HCl.

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposue assessment required due to
SYN 500003	224.7 g/mol		Soil: <10% Water/sediment systems: - water: 9.2%, - sediment: 3.5%	PECsw/sed: risk to aquatic organisms
SYN 504851	226.7 g/mol		Soil: <10% Water/sediment systems: - water: 21.0%, - sediment: 24.3%	PECsw/sed: risk to aquatic organisms
SYN 521195	397.9 g/mol		Water/sediment systems: - water: 3.4%, - sediment: 15.6%	PECsw/sed: risk to aquatic organisms
SYN 539678	399.9 g/mol		Water/sediment systems: - water: 1.9%, - sediment: 11.2%	PECsw/sed: risk to aquatic organisms
CGA 380778	373.8 g/mol		Soil: 6.0% Water/sediment systems: - total system: 0.001%	PECsoil: risk to soil organisms PECsw/sed: risk to aquatic organisms
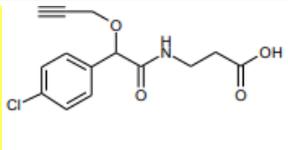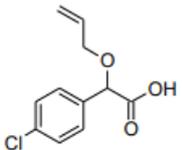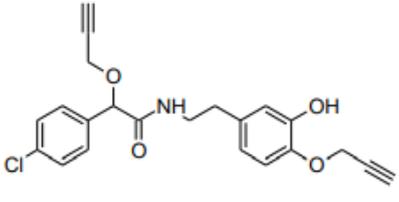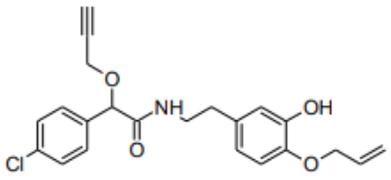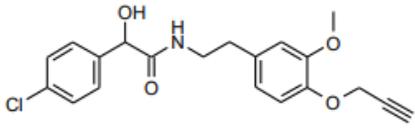
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8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Propamocarb-HCl and its metabolites

The rate of degradation in soil of propamocarb-HCl was evaluated during the Annex I Inclusion. No additional studies have been performed.

The fate and behaviour of propamocarb-HCl in soil is discussed in detail in the corresponding document of the EU review dossier where the study references can be found (EFSA, 2006).

The geometric mean DT_{50} value of laboratory aerobic topsoil values normalized to 20°C and pF2 moisture content reported in the EFSA conclusions 2006 is 13.91 days (n= 17 values). This degradation rate includes temperature-normalized data with Q_{10} value of 2.2. Although the normalization could be updated considering a Q_{10} value of 2.58, no significant impact is expected on the PEC results.

For the full datasets, reference is made to the DAR of propamocarb-HCl, Vol. 3 B8.

8.3.1.2 Mandipropamid and its metabolites

In soil laboratory incubations under aerobic conditions in the dark, mandipropamid exhibited low to medium persistence, forming the minor (<10% applied radioactivity (AR)) metabolite CGA 380778 (max. 6% AR) which exhibited very low to low persistence.

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

Mandipropamid, Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**T (°C)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Silt loam, sandy loam	7.3 (KCl)	19	pF2	26.1	86.7	23.7	0.985	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
		7.1 (KCl)	20	40	19.2	63.7	14.0	0.988	SFO	
		7.3 (w)	20	75% pF2	79.1	263	64.7	0.985	SFO	
		7.3 (KCl)	20	40	12.6	41.7	8.6	0.991	SFO	
		7.3 (KCl)	20	40	23.6	78.5	16.1	0.986	SFO	
		7.3 (KCl)	20	40	25.1	83.4	17.2	0.993	SFO	
		7.3 (KCl)	20	40	28.2	93.8	19.3	0.994	SFO	
		7.3 (KCl)	20	40	33.7	112	23.0	0.990	SFO	
		7.3	20	40	36.5	121	25.0	0.968	SFO	

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Soil name	Soil type	pH	T (°C)	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	r²	Kinetic model	Evaluated on EU level y/n/ Reference
Mandipropamid, Laboratory studies, aerobic conditions										
		(KCl)								
		-	Geometric mean		27.9	92.7	20.2	-	-	
Borstel	Silt loam, loamy sand	6.5 (w)	20	pF2	80.6	268	80.2	0.986	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
		5.6 (KCl)	20	40	38.6	128	26.5	0.947	SFO	
		5.6 (KCl)	20	40	60.8	202	41.4	0.993	SFO	
		5.6 (KCl)	20	40	80.0	266	54.5	0.981	SFO	
		5.6 (KCl)	20	40	93.1	309	63.4	0.980	SFO	
		5.6 (KCl)	20	40	107	355	72.9	0.963	SFO	
		5.6 (KCl)	20	40	131	434	89.3	0.959	SFO	
		-	Geometric mean		79.3	263	57.1	-	-	
18 Acres	Sandy clay loam	6.2 (w)	20	pF2	43.9	146	43.7	0.966	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
Marsillargues	Loam	8.5 (w)	20	pF2	85.7	285	83.9	0.984	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
Visalia	Sandy loam	6.6 (w)	25	75% 1/3 bar	34.4	114	38.4	0.980	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
Geometric mean (n=19)							43.9			
pH-dependency: y/n							No			

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Table 8.3-2:   **Summary of aerobic degradation rates for CGA 380778 - laboratory studies**

CGA 380778, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T (°C)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Silt loam, sandy loam	7.3 (KCl)	19	pF2	7.0	23.2	6.4	0.985	$P_{SFO} \rightarrow M_{SFO}$	Y EFSA Scientific Report (2012) 10(11), 2935
		7.1 (KCl)	20	40	10.3	34.2	7.5	0.988	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (w)	20	75% pF2	22.5	74.7	18.4	0.985	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (KCl)	20	40	5.2	17.3	3.6	0.991	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (KCl)	20	40	9.4	31.2	6.4	0.986	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (KCl)	20	40	5.0	16.6	3.4	0.993	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (KCl)	20	40	4.9	16.3	3.4	0.994	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (KCl)	20	40	6.2	20.6	4.2	0.990	$P_{SFO} \rightarrow M_{SFO}$	
		7.3 (KCl)	20	40	6.3	20.9	4.3	0.968	$P_{SFO} \rightarrow M_{SFO}$	
		7.4 (w)	20	pF2	3.5	11.6	3.58	0.982	SFO	
		-	Geometric mean		7.0	23.2	5.2	-	-	
Borstel	Silt loam, loamy sand	6.5 (w)	20	pF2	29.2	96.9	29.0	0.986	$P_{SFO} \rightarrow M_{SFO}$	Y EFSA Scientific Report (2012) 10(11), 2935
		5.6 (KCl)	20	40	11.8	39.2	8.0	0.947	$P_{SFO} \rightarrow M_{SFO}$	
		5.6 (KCl)	20	40	29.0	96.3	19.8	0.993	$P_{SFO} \rightarrow M_{SFO}$	
		5.6 (KCl)	20	40	37.0	122.8	25.2	0.981	$P_{SFO} \rightarrow M_{SFO}$	
		5.6 (KCl)	20	40	26.0	86.3	17.7	0.980	$P_{SFO} \rightarrow M_{SFO}$	
		5.6 (KCl)	20	40	40.0	133	27.3	0.963	$P_{SFO} \rightarrow M_{SFO}$	
		5.6 (KCl)	20	40	31.0	103	21.1	0.959	$P_{SFO} \rightarrow M_{SFO}$	
		-	Geometric mean		27.5	91.3	19.8	-	-	
18 Acres	Sandy clay loam	6.2 (w)	20	pF2	25.0	83.0	24.9	0.966	$P_{SFO} \rightarrow M_{SFO}$	Y EFSA Scientific Report
		6.0	20	pF2	3.1	10.3	3.1	0.976	SFO	

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CGA 380778, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T (°C)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
		(w)								(2012) 10(11), 2935
		-	Geometric mean		8.8	29.2	8.8	-	-	
Marsillargues	Loam	8.5 (w)	20	pF2	22.7	75.4	22.2	0.984	P_{SFO} → M_{SFO}	Y EFSA Scientific Report (2012) 10(11), 2935
Visalia	Sandy loam	6.6 (w)	25	75% 1/3 bar	37.7	125	42.1	0.980	P_{SFO} → M_{SFO}	Y EFSA Scientific Report (2012) 10(11), 2935
		6.0 (w)	20	pF2	35.7	119	35.7	0.906	SFO	
		-	Geometric mean		36.7	122	38.8	-	-	
Geometric mean (n=22)							15.1			
pH-dependency: y/n							No			

Table 8.3-3: **Summary of aerobic degradation rates for SYN 500003 - laboratory studies**

SYN 500003, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T (°C)**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**r²**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Sandy loam	7.1 (K)	20	pF2	1.5	5.0	1.5	0.981	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
18 Acres	Sandy loam	7.1 5.8 (K)	20	pF2	1.2	4.0	1.2	0.974	SFO	
Marsillargues	Silt loam	7.3 1 (K)	20	pF2	4.0	13.3	4.0	0.997	SFO	
Geometric mean (n=3)							1.9			
pH-dependency: y/n							No			

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 for the active substance.

The fate and behaviour of propamocarb-HCl in soil is discussed in detail in the corresponding document of the EU review dossier where the study references can be found. Reference is made to the EFSA peer review (2006) and the DAR of propamocarb-HCl.

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In anaerobic soil incubations mandipropamid was essentially stable (EFSA peer review (2012) and DAR).

8.4 Field studies (KCP 9.1.1.2)

Studies on field dissipation rates with the formulation were not performed since it is possible to extrapolate from data obtained with the active substance.

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

8.4.1.1 Propamocarb-HCl and its metabolites

Please refer to EFSA Scientific Report (2006) 78, 1-80. No additional studies have been performed. EU data from field studies are not reported here as not used for risk assessment.

8.4.1.2 Mandipropamid and its metabolites

Triggering endpoints

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

Mandipropamid, Field studies – Triggering endpoints									
Soil type	Location	pH (CaCl$_2$)	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	Kinetic parameters	R^2 (%)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy loam, bare	Switzerland	7.5	0-10	12.8	42.5	n.a.	0.910	SFO	Y EFSA Scientific Report (2012) 10(11), 2935
Sandy loam, bare	Switzerland	7.5	0-10	12.7	42.1	n.a.	0.908	SFO	
Silt loam, bare	Germany	6.7	0-30	5.6	199	n.a.	0.958	FOMC	
Loamy sand, bare	Germany	5.5	0-30	29.2	240	n.a.	0.837	FOMC	
Silt loam (grass)	France North	7.4	0-30	19.6	65.1	n.a.	0.873	FOMC	
Silt clay loam (grass)	France North	7.4	0-30	20.7	128	n.a.	0.875	FOMC	
Sandy loam (grass)	France South	7.6	0-30	12.5	67.3	n.a.	0.951	FOMC	
Loam (grass)	France South	7.4	0-30	20.5	68.1	n.a.	0.916	SFO	
Sandy loam (grass)	Spain	7.7	0-30	22.3	147	n.a.	0.908	FOMC	
Loamy sand (grass)	Spain	7.2	0-30	2.0	47.9	n.a.	0.988	FOMC	
Maximum (n=10)				29.2	240				
Median (n=10)				16.2	67.7				

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Propamocarb-HCl:
Soil accumulation tests were not performed. Not required.

Mandipropamid:

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In a soil accumulation study (6 years, 6 x 150 g as/ha per year, potatoes, lettuce, GAP) no accumulation observed. Residual amounts at the time of the 1st application of the new year (22 – 50 g as/ha) indicate at least a limited potential for accumulation if applied several times in a year.

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 Propamocarb-HCl and its metabolites

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

propamocarb-HCl							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level Y Reference**
Minnesota	Clay loam	3.15	5.80	77.2	2451	0.77	Y EFSA Scientific Report (2006) 78, 1-80
Sarotti	Loamy silt	1.30	7.38	2.63	202	0.90	
Abington	Loamy sand	1.86	7.4	2.49	134	0.90	
Borstel	Silty sand	1.04	5.81	1.29	124	0.84	
Ptungstadt	Loamy clay	1.57	6.4	9.70	618	0.87	
German 2.1	Sand	0.48	6.0	0.671	140	0.926	
German 2.2	Loamy sand	2.06	6.0	0.849	41	0.910	
Schering 170	Sandy loam	1.45	5.2	5.200	359	0.822	
Speyer 2.2	Loamy sand	2.26	6.1	1.28	56.63	0.925	
Cranfield 249	Sandy clay loam	3.48	6.5	6.26	179.88	0.854	
Midwest 1	Sandy loam	1.05	5.7	13.82	1321.22	0.827	
Midwest 2	Loamy sand	0.58	5.9	4.64	800	0.862	
Geometric mean (n=12)					**263.65**		
Arithmetic mean (n=12)						**0.867**	
pH-dependency					No		

8.5.2 Mandipropamid and its metabolites

Table 8.5-2: Summary of soil adsorption/desorption for Mandipropamid

Mandipropamid							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Loam	2.6	7.1	-	782	0.839	Y EFSA Scientific Report (2012) 10(11), 2935
Borstel	Loamy sand	1.0	5.1	-	1294	0.876	
Marsillargues	Silt clay loam	1.2	7.3	-	1067	0.803	
Vetroz	Silt loam	5.0	7.2	-	1064	0.916	

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Mandipropamid							
Soil name	Soil type	OC (%)	pH (-)	Kd (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Sanger	Sandy loam	0.5	6.6	-	694	0.860	
Chula	Loamy sand	0.7	4.9	-	405	0.780	
North Rose	Loamy sand	1.2	6.7	-	624	0.840	
Geometric mean (n=7)					**795.4**		
Arithmetic mean (n=7)					**847**	**0.85**	
pH-dependency y/n					No		

Table 8.5-3:   **Summary of soil adsorption/desorption for CGA 380778**

CGA 380778							
Soil name	Soil type	OC (%)	pH (-)	Kd (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	3.3	5.6	-	482	0.88	Y EFSA Scientific Report (2012) 10(11), 2935
Gartenacker	Loam	2.1	7.2	-	501	0.88	
Visalia	Sandy loam	0.53	6.3	-	361	0.79	
Geometric mean (n=3)					**443.4**		
Arithmetic mean (n=3)					**448**	**0.85**	
pH-dependency y/n					No		

Table 8.5-4:   **Summary of soil adsorption/desorption for SYN 504851**

SYN 504851							
Soil name	Soil type	OC (%)	pH (-)	Kd (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	3.3	5.6	-	3	0.91	Y EFSA Scientific Report (2012) 10(11), 2935
Gartenacker	Loam	2.0	7.2	-	4	0.89	
Visalia	Sandy loam	0.5	6.2	-	8	0.59	
Marsillargues	Loam	0.6	7.8	-	5	0.66	
Geometric mean (n=4)					**4.7***		
Arithmetic mean (n=4)					**5**	**0.76**	
pH-dependency y/n					No		

* In modelling, **4.6 mL/g** is used (taking into account the geomean of replicate values)

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Table 8.5-5:   **Summary of soil adsorption/desorption for SYN 521195**

SYN 521195							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
18 Acres	Sandy clay loam	3.3	5.6	-	1437	0.98	Y EFSA Scientific Report (2012) 10(11), 2935
Gartenacker	Loam	2.1	7.4	-	1414	0.80	
Visalia	Sandy loam	0.5	6.2	-	1109	0.82	
Marsillargues	Silt loam	0.8	7.9	-	1145	0.83	
Geometric mean (n=4)					**1267.4***		
Arithmetic mean (n=4)					**1276**	**0.86**	
pH-dependency y/n					No		

* In modelling, **1224 mL/g** is used (taking into account the geomean of replicate values).

Table 8.5-6:   **Summary of soil adsorption/desorption for SYN 539678**

SYN 539678							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Loam	2.0	7.1	-	430	0.96	Y EFSA Scientific Report (2012) 10(11), 2935
Marsillargues	Loam	0.6	7.8	-	2100	0.99	
Visalia	Sandy loam	0.5	6.0	-	2000	1.12	
Geometric mean (n=3)					**1217.8**		
Arithmetic mean (n=3)					**1510**	**1.02**	
pH-dependency y/n					No		

Table 8.5-7:   **Summary of soil adsorption/desorption for SYN 500003**

SYN 500003							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
18 Acres	Sandy clay loam	3.3	5.4	-	10	0.75	Y EFSA Scientific Report (2012) 10(11), 2935
Gartenacker	Loam	2.0	7.2	-	7	1.05	
Visalia	Sandy loam	0.5	6.2	-	8	0.66	
Marsillargues	Silt loam	0.8	7.9	-	20	0.93	
Geometric mean (n=4)					**10.3***		
Arithmetic mean (n=4)					**11**	**0.85**	

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SYN 500003							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
pH-dependency y/n	No						

* In modelling, **9 mL/g** is used (taking into account the geomean of replicate values).

zRMS Comments:	In EFSA Scientific Report (2012) 10(11), 2935 for Kfoc the only arithmetic mean is available. The geometric Kfoc values were calculated by the Applicant based on presented data presented in EFSA, 2012. The arithmetic mean was added for consistence with EFSA, 2012.

8.5.3 Column leaching (KCP 9.1.2.1)

Propamocarb-HCl:
Column leaching data for propamocarb-HCl are reported in EFSA Scientific Report (2006) 78, 1-80. No additional studies have been performed.

Mandipropamid:
Not studied - no data requested.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Propamocarb-HCl:

Lysimeter studies were not required for propamocarb-HCl (EFSA Scientific Report (2006) 78, 1-80).

Mandipropamid:

Not studied - no data requested.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Propamocarb-HCl:

Field leaching studies were not required for propamocarb-HCl (EFSA Scientific Report (2006) 78, 1-80).

Mandipropamid:

Not studied - no data requested.

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 Propamocarb-HCl and its metabolites

The degradation of propamocarb-HCl in water/sediment systems has been evaluated during the EU review. No additional studies have been performed.

The first order DT_{50} values of propamocarb hydrochloride in the water phase and in the whole system were calculated to be (geometric mean of 2 values): $DT_{50water}$ = 12.2 days, $DT_{50sediment}$ = 24.5 days, and $DT_{50whole\_system}$ = 18.3 days (EFSA Scientific Report (2006) 78, 1-80).

For the full datasets, reference is made to the DAR of propamocarb-HCl, Vol. 3 B8.

8.6.2 Mandipropamid and its metabolites

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

Water/sediment system[a)]	pH (H₂O) sed.	DegT$_{50}$ whole syst. (d$^)$)	DegT$_{90}$ whole syst. (d)	Kinetic, Fit	DissT$_{50}$ water (d)	DissT$_{90}$ water (d)	Kinetic, Fit	DissT$_{50}$ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Mandipropamid Distribution (max. sediment 62.5%AR after 1 day)
Calwich Abbey	7.6	10.3	28.7	SFO	Stable		SFO	4.4	SFO	Y
Calwich Abbey	7.5	5.9	17.2	SFO	Stable		SFO	4.9	SFO	EFSA Scientific
Swiss Lake	6.0	14.1	41.3	SFO	234	777	SFO	5.7	SFO	Report (2012) 10(11), 2935
Swiss Lake	5.0	25.9	61.9	SFO	Stable		SFO	7.7	SFO	
Geometric mean (n=4)		**12.2**	**33.5**		**Stable**			**5.5**		

Table 8.6-2:   **Summary of observed metabolites**

SYN 504851 Water/sediment system	Max. in water 21.0% AR Max. in sediment 24.3% AR Max. in total system: 33.3% AR Worst-case assumption: Max. DT$_{50}$ in water: 1000 days Max. DT$_{50}$ in sediment: 1000 days Max. DT$_{50}$ in water/sediment system: 1000 days	Y EFSA Scientific Report (2012) 10(11), 2935
SYN 521195 Water/sediment system	Max. in water 3.4% AR Max. in sediment 15.6% AR Max. in total system: 17.7% AR DT$_{50}$ in water: 9 days (geometric mean from 4 aerobic water/sediment studies) DT$_{50}$ in sediment: 9 days DT$_{50}$ in water/sediment system: 9 days	
SYN 539678 Water/sediment system	Max. in water 1.9% AR Max. in sediment 11.2% AR Max. in total system: 12.6% AR DT$_{50}$ in water: 28.5 days (geometric mean from 4 aerobic water/sediment studies) DT$_{50}$ in sediment: 28.5 days DT$_{50}$ in water/sediment system: 28.5 days	
SYN 500003 Water/sediment system	Max. in water 9.2% AR Max. in sediment 3.5% AR Max. in total system: 9.2% AR DT$_{50}$ in water: 31.3 days (geometric mean from 2 aerobic water/sediment studies) DT$_{50}$ in sediment: 31.3 days DT$_{50}$ in water/sediment system: 31.3 days	
CGA 380778 Non-transient soil metabolite	Max. in total system: 0.001% AR Worst-case assumption: Max. DT$_{50}$ in water: 1000 days Max. DT$_{50}$ in sediment: 1000 days Max. DT$_{50}$ in water/sediment system: 1000 days	

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

zRMS Comments:	Calculations of PEC$_{SOIL}$ for active substances, metabolites and formulation were submitted.

Calculations of PEC$_{SOIL}$ for active substances, metabolites and formulation were submitted.

The endpoints used for soil exposure assessment are consistent with the list of endpoints for active substances and its metabolites.

The crop interception of 60% was taken into consideration.

Propamocarb-HCl:

The DT$_{50}$ value for active substance used for PEC$_{SOIL}$ assessment was accepted as it represents the worst case.

Calculations of PEC$_{SOIL}$ for propamocarb-HCl were recalculated by evaluator with the Calculator (Excel).

The PEC$_{SOIL}$ values for active substance at single and multiple applications are presented in the table below:

Crop	Propamocarb-HCl	
	PEC$_{SOIL}$, ini [mg/kg]	
	Single application	Multiple applications
Potatoes	0.456 0.540*	1.321 1.582*

*PEC$_{SOIL}$ accum

Mandipropamid:

The DT$_{50}$ value for active substance used for PEC$_{SOIL}$ assessment was accepted at the EU level (EFSA, 2012). For its relevant metabolite CGA 380778 the maximum DT$_{50}$ value from laboratory study is 42.1 d. The PEC$_{SOIL}$ for metabolite was recalculated with the Calculator (Excel).

The PEC$_{SOIL}$ values for active substance and its metabolite at single and multiple applications are presented in the table below:

	Mandipropamid		CGA 380778	
Crop	PECs [mg/kg soil]			
	Single application	Multiple applications	Single application	Multiple applications
Potatoes	0.076	0.209	0.004	0.011

Given the DT$_{50}$ and DT$_{90}$ of mandipropamid and metabolite CGA 380778 are < 100 d and 365 d respectively, calculations PEC$_{SOIL}$ to estimate potential accumulation were not undertaken.

Formulation:

Calculations of PEC$_{SOIL}$ for formulation was recalculated by evaluator with the Calculator (Excel). For formulation PEC$_{SOIL}$= 1.0943 mg/kg soil.

These values will be used in further risk assessment.

8.7.1 Justification for new endpoints

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

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

Use No.	1

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Crop	Potatoes
Application rate (g as/ha)	Propamocarb-HCl: 855 g/ha Mandipropamid: 142.5 g/ha CGA 380778: 7.76 g/ha
Number of applications/interval	3/7 d
Crop interception (%)	60
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)/20 (tillage ; plateau conc.)

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
Propamocarb-HCl	224.7	-	136 (worst case first order laboratory value, undertaken at 40-50% MWHC and a temperature of 20°C)	Y/EFSA, 2006
Mandipropamid	411.9	-	72.3 (pseudo-SFO, representative worst case from field studies)	Y/EFSA, 2012
CGA 380778	373.8	6	~~15.1~~ 42.1	Y/EFSA, 2012

8.7.2.1 Propamocarb-HCl

Table 8.7-3: **PEC$_{soil}$ for Propamocarb-HCl on potatoes**

PEC$_{soil}$ (mg/kg)	Potatoes			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.4560	-	~~1.3057~~ 1.321	-
Plateau concentration (5 cm) after year 10	~~Not required~~ 0.084	-	~~Not required~~ 0.261	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)	~~Not required~~ 0.540	-	~~Not required~~ 1.582	-

8.7.2.2 Mandipropamid and its metabolites

Table 8.7-4: **PEC$_{soil}$ for Mandipropamid on potatoes**

PEC$_{soil}$ (mg/kg)	Potatoes			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.0760	-	0.2092	-

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Short term	24h	0.0753	0.0756	0.2072	0.2082
	2d	0.0746	0.0753	0.2052	0.2072
	4d	0.0731	0.0746	0.2013	0.2052
Long term	7d	0.0711	0.0735	0.1956	0.2023
	14d	0.0665	0.0711	0.1829	0.1958
	21d	0.0621	0.0688	0.1711	0.1895
	28d	0.0581	0.0667	0.1600	0.1835
	50d	0.0471	0.0604	0.1295	0.1662
	100d	0.0291	0.0489	0.0802	0.1346
Plateau concentration (20 cm)		Not required	-	Not required	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		Not required	-	Not required	-

PEC_{soil} of metabolites

Table 8.7-5:   **PEC_{soil} for CGA 380778 on potatoes**

PEC_{soil} (mg/kg)		Potatoes			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0041	-	0.0087	-
Short term	24h	0.0040	0.0040	0.0083	0.0085
	2d	0.0038	0.0040	0.0080	0.0083
	4d	0.0034	0.0038	0.0073	0.0080
Long term	7d	0.0030	0.0035	0.0063	0.0075
	14d	0.0022	0.0031	0.0046	0.0064
	21d	0.0016	0.0027	0.0033	0.0056
	28d	0.0011	0.0023	0.0024	0.0049
	50d	0.0004	0.0016	0.0009	0.0034
	100d	0.0000	0.0009	0.0001	0.0019

8.7.2.3 PEC_{soil} of GLOB2106cF

Table 8.7-6:   **PEC_{soil} for GLOB2106cF on potatoes**

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)
GLOB2106cF	2051.81	~~3.1697~~ 1.0943	3.0068	20	0.1477	3.3175

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8.8 Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4)

zRMS Comments:	The PECgw assessment for active substance mandipropamid, its metabolite CGA 380778 and active substance propamocarb-HCl was accepted. Modelling was performed using FOCUS-PEARL and FOCUS-PELMO models for a threefold application to potatoes. In the list of endpoints for active substances and its metabolites for Kfoc the only arithmetic mean is available, but for calculations of PECgw for active substances and its metabolites the geometric Kfoc values were used, following the current EU guidance [EFSA (2014)]. The geometric Kfoc values were calculated by the Applicant. This approach was accepted as it represents a worse case. Calculations of PECgw for active substance were provided in with PUF = 0.0. The maximum PECgw values for active substance mandipropamid, its metabolite CGA 380778 and active substance propamocarb-HCl are below the trigger value of 0.1 µg/L in all tested scenarios and models.

8.8.1 Justification for new endpoints

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

Table 8.8-1: Input parameters related to application for PECgw calculations

Use No.	1
Crop	Potatoes
Application rate (g as/ha)	Propamocarb-HCl: 855 g/ha Mandipropamid: 142.5 g/ha
Number of applications/interval (d)	3/7 d
Relative application date	**"Early" set relative to emergence (Table 8.8-2)** 1st application: at BBCH21 2nd application: 7 days after the 1st (corresponding to BBCH 25-27) 3rd application: 7 days after the 2nd (corresponding to BBCH 29-34) **"Late" set relative to harvest** 1st application: 28 days before harvest 2nd application: 21 days before harvest 3rd application: 14 days before harvest
Crop interception (%)	60
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5 FOCUS PELMO v6.6.4

Table 8.8-2: Application dates used for groundwater risk assess: "early" set

Crop	Scenario	BBCH21 relative to emergence*	Input for first application	Input for second application	Input for third application
Potatoes	Châteaudun	13	12	19	26

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Crop	Scenario	BBCH21 relative to emergence*	Input for first application	Input for second application	Input for third application
- early	Hamburg	20	20	27	34
	Jokioinen	24	24	31	38
	Kremsmünster	20	20	27	34
	Okehampton	22	20	27	34
	Piacenza	12	12	19	26
	Porto	22	20	27	34
	Sevilla	17	17	24	31
	Thiva	17	17	24	31

*proposed in AppDate v 3.06 at BBCH21. Four groups of scenarios were modelled: (Châteaudun and Piacenza), (Jokioinen), (Hamburg, Kremsmünster, Okehampton and Porto) and (Sevilla and Thiva) using the same application dates.

8.8.2.1 Propamocarb-HCl and its metabolites

Table 8.8-3: Input parameters related to active substance Propamocarb-HCl for PEC_{gw} calculations

Compound	Propamocarb-HCl	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	224.7	Y EFSA Scientific Report (2006) 78, 1-80
Water solubility (mg/L):	935000 (at 20°C) 1870000 (at 30°C)	Y EFSA Scientific Report (2006) 78, 1-80
Saturated vapour pressure (Pa):	8.1×10^{-5} Pa at 25ºC Recalculation using EVA 3.0 rev2h: 4.21×10^{-5} Pa at 20°C 16.84×10^{-5} Pa at 30°C	Y EFSA Scientific Report (2006) 78, 1-80
DT_{50} in soil (d)	13.91*	Y EFSA Scientific Report (2006) 78, 1-80 (geometric mean DT_{50} value of laboratory aerobic topsoil values normalised to 20 °C and pF2 moisture content [n= 17 values])
Transformation rate	-	
K_{foc} (mL/g)	263.65	**N** EFSA Scientific Report (2006) 78, 1-80 (geomean Kfoc value from 12 soils, in accordance to current guidance)
1/n	0.867	Y EFSA Scientific Report (2006) 78, 1-80
Plant uptake factor	0	Default
Formation fraction	Not applicable	

*Applicant indicates the DT_{50} of 13.91 is the EU recommended value (EFSA 2006) which includes temperature-normalized data with Q_{10} of 2.2. The normalization should have been updated considering a Q_{10} value of 2.58. However, no significant impact is expected on the PEC results.

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Table 8.8-4:   **PEC$_{gw}$ for Propamocarb-HCl on potato (with FOCUS PEARL 5.5.5)**

FOCUS crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1})
		Propamocarb-HCl
Potato, early First application: at BBCH21	Châteaudun	<0.001
	Hamburg	<0.001
	Jokioinen	<0.001
	Kremsmünster	<0.001
	Okehampton	<0.001
	Piacenza	<0.001
	Porto	<0.001
	Sevilla	<0.001
	Thiva	<0.001
Potato, late Last application: 14 days before harvest	Châteaudun	<0.001
	Hamburg	<0.001
	Jokioinen	<0.001
	Kremsmünster	<0.001
	Okehampton	<0.001
	Piacenza	<0.001
	Porto	<0.001
	Sevilla	<0.001
	Thiva	<0.001

Table 8.8-5:   **PEC$_{gw}$ for Propamocarb-HCl on potato (with FOCUS PELMO 6.6.4)**

FOCUS crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1})
		Propamocarb-HCl
Potato, early First application: at BBCH21	Châteaudun	~~0.000~~ <0.001
	Hamburg	~~0.000~~ <0.001
	Jokioinen	~~0.000~~ <0.001
	Kremsmünster	~~0.000~~ <0.001
	Okehampton	~~0.000~~ <0.001
	Piacenza	~~0.000~~ <0.001
	Porto	~~0.000~~ <0.001
	Sevilla	~~0.000~~ <0.001
	Thiva	~~0.000~~ <0.001
Potato, late Last application: 14 days before harvest	Châteaudun	~~0.000~~ <0.001
	Hamburg	~~0.000~~ <0.001
	Jokioinen	~~0.000~~ <0.001
	Kremsmünster	~~0.000~~ <0.001
	Okehampton	~~0.000~~ <0.001
	Piacenza	~~0.000~~ <0.001
	Porto	~~0.000~~ <0.001
	Sevilla	~~0.000~~ <0.001
	Thiva	~~0.000~~ <0.001

The PECgw of Propamocarb-HCl is below the drinking water limit of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected following the application of Propamocarb-HCl according to the intended uses.

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8.8.2.2 Mandipropamid and its metabolites

Table 8.8-6: **Input parameters related to Mandipropamid and its metabolites for PEC$_{gw}$ calculations**

Compound	Mandipropamid	CGA 380778	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	411.9	373.9	Y EFSA Scientific Report (2012) 10(11), 2935
Water solubility (mg/L):	4.2 (25°C) 8.4 (35°C)	100 (25°C)	Y EFSA Scientific Report (2012) 10(11), 2935
Saturated vapour pressure (Pa):	$<9.4 \times 10^{-7}$ Pa at 25 ℃ $<37.6 \times 10^{-7}$ Pa at 35 ℃	$<9.4 \times 10^{-7}$ Pa at 25 ℃ (parent value as surrogate)	Y EFSA Scientific Report (2012) 10(11), 2935
DT$_{50}$ in soil (d)	43.9 (geometric mean value of laboratory normalised to 20 °C and pF2 moisture content, Q10=2.58, n=5 values)	15.1 (geometric mean value of laboratory normalised to 20 °C and pF2 moisture content, Q10=2.58 n=5 values)	Y EFSA Scientific Report (2012) 10(11), 2935
Kfoc (mL/g)*	795.4 (geomean, n = 7)	443.4 (geomean, n = 3)	Y EFSA Scientific Report (2012) 10(11), 2935 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
1/n	0.85 (arithmetic mean)	0.85 (arithmetic mean)	Y EFSA Scientific Report (2012) 10(11), 2935
Plant uptake factor	0	0	Default
Formation fraction (PEARL)	Not applicable	0.218 (21.8% from Mandipropamid)	Y EFSA Scientific Report (2012) 10(11), 2935
Transformation rate (PELMO)	From parent to sink: 0.012347	From parent to metabolite: 0.003442 From metabolite to sink: 0.0459	Calculated (ln2/DT50*f.f.)

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Table 8.8-7: **PECgw for Mandipropamid and CGA 380778 on potato (with FOCUS PEARL 5.5.5)**

FOCUS crop	Scenario	80th Percentile PECGW at 1 m Soil Depth (µg L-1)	
		Mandipropamid	**CGA 380778**
Potato, early First application: at BBCH21	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
Potato, late Last application: 14 days before harvest	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

Table 8.8-8: **PECgw for Mandipropamid and CGA 380778 on potato (with FOCUS PELMO 6.6.4)**

FOCUS crop	Scenario	80th Percentile PECGW at 1 m Soil Depth (µg L-1)	
		Mandipropamid	**CGA 380778**
Potato, early First application: at BBCH21	Châteaudun	~~0.000~~ <0.001	~~0.000~~ <0.001
	Hamburg	~~0.000~~ <0.001	~~0.000~~ <0.001
	Jokioinen	~~0.000~~ <0.001	~~0.000~~ <0.001
	Kremsmünster	~~0.000~~ <0.001	~~0.000~~ <0.001
	Okehampton	~~0.000~~ <0.001	~~0.000~~ <0.001
	Piacenza	~~0.000~~ <0.001	~~0.000~~ <0.001
	Porto	~~0.000~~ <0.001	~~0.000~~ <0.001
	Sevilla	~~0.000~~ <0.001	~~0.000~~ <0.001
	Thiva	~~0.000~~ <0.001	~~0.000~~ <0.001
Potato, late Last application: 14 days before harvest	Châteaudun	~~0.000~~ <0.001	~~0.000~~ <0.001
	Hamburg	~~0.000~~ <0.001	~~0.000~~ <0.001
	Jokioinen	~~0.000~~ <0.001	~~0.000~~ <0.001
	Kremsmünster	~~0.000~~ <0.001	~~0.000~~ <0.001
	Okehampton	~~0.000~~ <0.001	~~0.000~~ <0.001
	Piacenza	~~0.000~~ <0.001	~~0.000~~ <0.001
	Porto	~~0.000~~ <0.001	~~0.000~~ <0.001
	Sevilla	~~0.000~~ <0.001	~~0.000~~ <0.001
	Thiva	~~0.000~~ <0.001	~~0.000~~ <0.001

The PECgw of Mandipropamid is below the drinking water limit of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected following the application of Mandipropamid according to the intended uses.

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

zRMS Comments:	The PECsw/sed assessment for active substances and their metabolites was accepted. STEP 1 & 2 and STEP 3 were used for PECsw and PECsed assessment. All used endpoints for active substances and their metabolites were agreed at the EU level. In the list of endpoints for active substances and its metabolites for Kfoc the only arithmetic mean is available, but for calculations of PECsw for active substances and its metabolites the geometric Kfoc values were used. The geometric Kfoc values were calculated by the Applicant. This approach was accepted as it represents a worse case.

Propamocarb-HCl:

The Applicant submitted calculations PECsw/sed carried out using for the STEP 1 & 2 for a threefold application to potatoes:

Crop	Substance	Max PECsw (µg/L)	Max PECsed (µg/kg)
potatoes	Propamocarb-HCl (3 x 855 g/ha)	171.2359	443.1489

Mandipropamid:

The Applicant submitted calculations PECsw/sed carried out using for the STEP 1 & 2 for a threefold application to potatoes for active substance and their metabolites. For mandipropamid the Applicant submitted calculations PECsw/sed for the STEP 3 for two scenarios Set 1 and Set 2 presented in Table 8.9-6.

The max PECsw for Central Zone considering D3, D4, ~~D5,~~ R1, R3 ~~and R4~~ scenarios are presented in the tables below:

		early	late
Mandipropamid (3 x 142.5 g/ha)	Set 1	1.594 R3 stream	2.470 R3 stream
	Set 2	2.033 R1 stream	2.468 R3 stream

The max PECsw for metabolites are presented in the table below:

Crop	SYN 504851	SYN 500003	SYN 521195	SYN 539678	CGA 380778
potatoes	Max PEC$_{SW}$ (µg/L)				
	Step 1				
	26.6781	7.4179	9.9295	7.1249	4.8771
	Max PECsed (µg/L)				
	1.1940	0.6499	113.3094	80.9098	21.6250
	Step 2				
	9.8333	2.6538	3.4320	2.5142	1.2945

Formulation. The PECsw for the formulation GLOB2106cF for single application of

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2051.81 g prod./ha in potatoes was recalculated by the evaluator and is of 10.899 µg/L.

Cropping scenario	FOCUS scenario	Max. PECsw (µg/L)
Potatoes	Ditch	10.899
	Pond	0.4353
	Stream	8.4893

The relevant mitigation measure will be recommended in ecotoxicological section.

8.9.1 Justification for new endpoints

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	GLOB2106cF
Use No.	1
Crop	Potatoes
Application rate (kg as/ha)	Propamocarb-HCl: 855 g/ha Mandipropamid: 142.5 g/ha
Number of applications/interval (d)	3/7*
Application window	Oct-Feb March-May June-Sept (relevant for STEP 1 and 2 only)
Application method	Ground spray
CAM (Chemical application method)	CAM2
Soil depth (cm)	4
Crop interception (relevant for STEP 1 and 2 only)	Minimal crop cover
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v3.1, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN-v5.0.0

*for each application scheme an additional PECsw simulation is performed based on a single application

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC$_{sw/sed}$ calculations for the application of GLOB2106cF

Crop	Scenario	Application window used in modelling*
		Single** or multiple (3) applications
Potatoes – Early	D3 Ditch	30-May (150) - 13-Jul (194=BBCH55)
	D4 Pond/Stream	17-Jun (168) -31-Jul (212=BBCH51)
	D6 Ditch (1)	24-Apr (114) - 7-Jun (158=BBCH 6539 51)
	D6 Ditch (2)	21-Aug (233) - 4-Oct (277=BBCH62)

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Crop	Scenario	Application window used in modelling*
	R1 Pond/Stream	20-May (140) - 3-Jul (184=BBCH63)
	R2 Stream	6-Apr (96) - 20-May (140=BBCH55)
	R3 Stream	24-Apr (114) - 7-Jun (158=BBCH63)
Potatoes – Late	D3 Ditch	19-Jul (200=BBCH59) - 1-Sep (244=BBCH81)
	D4 Pond/Stream	27-Jul (208=BBCH39) -9-Sep (252=BBCH77)
	D6 Ditch (1)	18-May (138=BBCH51) - 1-Jul (182=BBCH81)
	D6 Ditch (2)	28-Sept (271=BBCH59) - 11-Nov (315=BBCH85)
	R1 Pond/Stream	12-Jul (193=BBCH67) – 25-Aug (237=BBCH85)
	R2 Stream	18-Apr (108=BBCH28) - 1-Jun (152=BBCH64)
	R3 Stream	5-Jul (186=BBCH72) – 18-Aug (230=BBCH85)

* Corresponding BBCH stage from AppDate v 3.06 tool. Window proposed in AppDate starting at at BBCH 21 for "early" set (+44d) and finishing 14 days before harvest for "late" set (and starting 44 d before). For sake of clarity, the applicant mentions in the above table the corresponding BBCH stages. Both sets are covering the entire period of the intended GAP.
** Date of application is always within 30 days of the first day of the application window.

8.9.2.1 Propamocarb-HCl and its metabolites

Table 8.9-3: Input parameters related to active substance propamocarb-HCl for PEC$_{sw/sed}$ calculations STEP 1/2

Compound	Propamocarb-HCl	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	224.7	Y EFSA Scientific Report (2006) 78, 1-80
Saturated vapour pressure (Pa)	not required for Step 1-2	
Water solubility (mg/L)	935 g/L (20°C, pH 7)	Y EFSA Scientific Report (2006) 78, 1-80
Diffusion coefficient in water (m²/d)	not required for Step 1-2	
Diffusion coefficient in air (m²/d)	not required for Step 1-2	
K$_{foc}$ (mL/g)	Koc (L/kg): 263.65 (geomean Kfoc value from 12 soils using both datasets)	N / EFSA Scientific Report (2006) 78, 1-80
Freundlich Exponent 1/n	not required for Step 1-2	
Plant Uptake	not required for Step 1-2	
Wash-Off factor from Crop (1/mm)	not required for Step 1-2	
DT$_{50,soil}$ (d)	DT50 soil (d): 13.91* (geometric mean DT50 value of laboratory aerobic topsoil vaues normalised to 20 °C and pF2 moisture content from both datasets)	Y EFSA Scientific Report (2006) 78, 1-80

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Compound	Propamocarb-HCl	Value in accordance to EU endpoint y/n/ Reference
$DT_{50,water}$ (d)	18.3 d (whole system, geometric mean of 2 values)	N / **
$DT_{50,sed}$ (d)	18.3 d (whole system, geometric mean of 2 values)	N / **
$DT_{50,whole\ system}$ (d)	18.3 d (whole system, geometric mean of 2 values)	N / **
Maximum occurrence observed (% molar basis with respect to the parent)	-	
Formation fraction in soil:	-	

*Applicant indicates the DT_{50} of 13.91 is the EU recommended value (EFSA 2006) which includes temperature-normalized data with Q_{10} of 2.2. The normalization should have been updated considering a Q_{10} value of 2.58. However, no significant impact is expected on the PEC results.

**Applicant notes that since DT_{50} values in water and sediment are level P-I data, only DT_{50} from whole system (18.3 days) should be used in STEP 1-2 modelling for both compartments.

PECsw/sed

Table 8.9-4: **FOCUS Step 1,2 PECsw and PECsed for Propamocarb-HCl following 3 applications of GLOB2106cF to potato with 7 days interval**

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
Step 1	---	656.2043	runoff/drainage	448.5090	1.67E+03
Step 2					
Northern Europe	March-May	74.1706	runoff/drainage	50.6161	187.2362
	June-Sept	74.1706	runoff/drainage	50.6161	187.2362
	Oct-Feb	171.2359	runoff/drainage	117.5711	443.1489
Southern Europe	March-May	138.8808	runoff/drainage	95.2527	357.8446
	June-Sept	106.5257	runoff/drainage	72.9344	272.5404
	Oct-Feb	138.8808	runoff/drainage	95.2527	357.8446

Table 8.9-5: **FOCUS Step 2 PECsw and PECsed for Propamocarb-HCl following single application of GLOB2106cF to potato**

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
Step 2					
Northern	March-May	34.8446	runoff	23.7194	87.2481

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Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
Europe	June-Sept	34.8446	runoff	*23.7194*	*87.2481*
	Oct-Feb	78.8994	runoff	*54.1081*	*203.2062*
Southern Europe	March-May	64.2145	runoff	*43.9785*	*164.4894*
	June-Sept	49.5295	runoff	*33.8490*	*125.7726*
	Oct-Feb	64.2145	runoff	*43.9785*	*164.4894*

The aquatic risk assessment for Propamocarb-HCl is driven by the chronic toxicity to *Lepomis macrochirus* with a NOEC of >6300 µg/L (see dRR Section B9). Taking into account an Annex VI TER trigger value of 10, PECsw values should be lower than **630 µg/L** (the regulatory acceptable concentration, **RAC**). PECsw calculated with FOCUS STEP 2 were below this threshold and therefore, no further calculations were required.

8.9.2.2 Mandipropamid and its metabolites

Table 8.9-6: Input parameters related to active substance Mandipropamid and metabolites for PECsw/sed calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Mandipropamid	SYN 504851	SYN 500003	SYN 521195	SYN 539678	CGA 380778	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	411.9	226.7	224.7	397.9	399.9	373.8	Y EFSA Scientific Report (2012) 10(11), 2935
Saturated vapour pressure (Pa)	<9.4 x 10-7 Pa at 25 ℃	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	Y EFSA Scientific Report (2012) 10(11), 2935
Water solubility (mg/L)	4.2 (at 25°C)	500000 (at 25°C)	45000 (at 25°C)	1000	1000	100 (at 25°C)	Y EFSA Scientific Report (2012) 10(11), 2935
Diffusion coefficient in water (m²/d)	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	default
Diffusion coefficient in air (m²/d)	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	default
K_{foc} (mL/g)	795.4 (geometric mean, n=7)	4.6 (worst-case for PECsw, geometric mean, n = 4)	9 (geometric mean, n=4)	1224 (geometric mean, n=4)	1217.8 (geometric mean, n=3)	443.4 (geometric mean, n = 3)	Y EFSA Scientific Report (2012) 10(11), 2935 Geometric mean used in accordance with EFSA Journal 2014;12(5):3662.
Freundlich Exponent	0.85 (arithmetic mean)	0.76 (arithmetic	0.85 (arithmetic	0.86 (arithmetic	1.02 (arithmetic	0.85 (arithmetic	Y EFSA Scientific

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Compound	Mandipropamid	SYN 504851	SYN 500003	SYN 521195	SYN 539678	CGA 380778	Value in accordance to EU endpoint y/n/ Reference
1/n		mean, n=4) Not required for Step1-2	mean, n=4) Not required for Step1-2	mean, n=4) Not required for Step1-2	mean, n=3) Not required for Step1-2	mean, n=3) Not required for Step1-2	Report (2012) 10(11), 2935
Plant Uptake	0	0	0	0	0	0	Worst-case
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	default
$DT_{50,soil}$ (d)	43.9 (geometric mean value of laboratory normalised to 20 °C and pF2 moisture content, Q10=2.58, n=5 values)	1000 (default)	1.9 (geometric mean value of laboratory normalised to 20 °C and pF2 moisture content, Q10=2.58, n=3 values)	1000 (default)	1000 (default)	15.1 (geometric mean, lab, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58, n = 4)	Y EFSA Scientific Report (2012) 10(11), 2935
$DT_{50,water}$ (d)	**Steps 1 & 2:** 12.2 (geometric mean, whole system, n = 4) **Steps 3 & 4:** Set 1: 1000 Set 2: 12.2	1000	31.3	9	28.5	1000	Y EFSA Scientific Report (2012) 10(11), 2935
$DT_{50,sed}$ (d)	**Steps 1 & 2:** 12.2 (geometric mean, whole system, n = 4) **Steps 3 & 4:** Set 1: 12.2 Set 2: 1000	1000	31.3	9	28.5	1000	Y EFSA Scientific Report (2012) 10(11), 2935
$DT_{50,whole\ system}$ (d)	12.2	1000	31.3	9	28.5	1000	Y EFSA Scientific Report (2012) 10(11), 2935
Maximum occurrence observed (% molar basis with respect to the parent)	Not applicable	Soil: 0% Water/ Sediment (whole system): 33.3%	Soil: 0.2% Water/ Sediment (whole system): 9.2	Soil: 0% Water/ Sediment (whole system): 17.7%	Soil: 0% Water/ Sediment (whole system): 12.6%	Soil: 6.0 Total system: 0.001%	Y EFSA Scientific Report (2012) 10(11), 2935
Formation fraction in soil:	Not applicable	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	not required for Step1-2	-

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PEC$_{sw/sed}$

Table 8.9-7: **FOCUS Step 1,2 and Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Mandipropamid following 3 applications of GLOB2106cF to potato with 7 days interval – early application**

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	---	73.0884	runoff/drainage	41.5476	550.0736
Step 2					
Northern Europe	March-May	10.8755	runoff/drainage	6.2608	83.9736
	June-Sept	10.8755	runoff/drainage	6.2608	83.9736
	Oct-Feb	25.7593	runoff/drainage	14.9545	202.3592
Southern Europe	March-May	20.7980	runoff/drainage	12.0566	162.8973
	June-Sept	15.8368	runoff/drainage	9.1587	123.4355
	Oct-Feb	20.7980	runoff/drainage	12.0566	162.8973
Step 3*					
D3	ditch	0.5423	Drift	0.05466	0.4114
D4	pond	0.1346	Drainage	0.1176	0.7153
D4	stream	0.4355	Drift	0.06134	0.4355
D6$_1$	ditch	0.5401	Drift	0.02781	0.2726
D6$_2$	ditch	1.893	Drainage	0.1814	1.266
R1	pond	0.1675	Run-off	0.1525	0.8488
R1	stream	1.538	Run-off	0.06875	1.803
R2	stream	0.7669	Run-off	0.04003	2.524
R3	stream	1.594	Run-off	0.1538	1.584

*Modelled with input parameters of Set 1 (see Table 8.9-6)

Table 8.9-8: **FOCUS Step 1,2 and Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Mandipropamid following single application of GLOB2106cF to potato – early application**

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
Step 2					
Northern Europe	March-May	4.2911	runoff	2.4474	32.5037
	June-Sept	4.2911	runoff	2.4474	32.5037
	Oct-Feb	9.8096	runoff	5.6709	76.3983
Southern Europe	March-May	7.9701	runoff	4.5964	61.7667
	June-Sept	6.1306	runoff	3.5219	47.1352
	Oct-Feb	7.9701	runoff	4.5964	61.7667
Step 3*					

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Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
D3	ditch	0.7457	Drift	0.03677	0.4251
D4	pond	0.03009	Drift	0.02369	0.1590
D4	stream	0.5824	Drift	0.01084	0.09520
D6$_1$	ditch	0.7374	Drift	0.01629	0.2219
D6$_2$	ditch	0.7352	Drift	0.02905	0.2737
R1	pond	0.09205	Run-off	0.07535	0.3671
R1	stream	1.034	Run-off	0.04614	1.415
R2	stream	0.6830	Drift	0.01445	0.9718
R3	stream	0.7346	Run-off	0.04861	0.3824

*Modelled with input parameters of Set 1 (see Table 8.9-6)

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Table 8.9-9: FOCUS Step 1,2 and Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Mandipropamid following 3 applications of GLOB2106cF to potato with 7 days interval – <u>late</u> application

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	---	73.0884	runoff/drainage	41.5476	550.0736
Step 2					
Northern Europe	March-May	10.8755	runoff/drainage	6.2608	83.9736
	June-Sept	10.8755	runoff/drainage	6.2608	83.9736
	Oct-Feb	25.7593	runoff/drainage	14.9545	202.3592
Southern Europe	March-May	20.7980	runoff/drainage	12.0566	162.8973
	June-Sept	15.8368	runoff/drainage	9.1587	123.4355
	Oct-Feb	20.7980	runoff/drainage	12.0566	162.8973
Step 3*					
D3	ditch	0.5431	Drift	0.0638	0.4450
D4	pond	0.1095	Drainage	0.09337	0.6043
D4	stream	0.4468	Drift	0.04057	0.3170
D6$_1$	ditch	0.5395	Drift	0.03316	0.2311
D6$_2$	ditch	2.764	Drainage	0.3333	2.357
R1	pond	0.3556	Run-off	0.3045	2.184
R1	stream	1.422	Run-off	0.06904	0.9022
R2	stream	0.9918	Run-off	0.05026	2.913
R3	stream	2.470	Run-off	0.2680	3.899

*Modelled with input parameters of Set 1 (see Table 8.9-6)

Table 8.9-10: FOCUS Step 1,2 and Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Mandipropamid following <u>single</u> application of GLOB2106cF to potato – <u>late</u> application

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
Step 2					
Northern Europe	March-May	4.2911	runoff	2.4474	32.5037
	June-Sept	4.2911	runoff	2.4474	32.5037
	Oct-Feb	9.8096	runoff	5.6709	76.3983
Southern Europe	March-May	7.9701	runoff	4.5964	61.7667
	June-Sept	6.1306	runoff	3.5219	47.1352
	Oct-Feb	7.9701	runoff	4.5964	61.7667
Step 3*					
D3	ditch	0.7460	Drift	0.03898	0.4394
D4	pond	0.03008	Drift	0.02372	0.1436

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Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
D4	stream	0.5606	Drift	0.005162	0.04548
D6$_1$	ditch	0.7420	Drift	0.02405	0.3056
D6$_2$	ditch	0.7415	Drift	0.05869	0.4713
R1	pond	0.07824	Run-off	0.06652	0.5500
R1	stream	1.035	Run-off	0.03114	0.8952
R2	stream	0.6830	Drift	0.01446	0.9719
R3	stream	1.047	Run-off	0.1048	1.646

*Modelled with input parameters of Set 1 (see Table 8.9-6)

Table 8.9-11: **FOCUS Step 1,2 and Step 3 PECsw and PECsed for Mandipropamid following 3 applications of GLOB2106cF to potato with 7 days interval – early application**

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
Step 1	---	73.0884	runoff/drainage	41.5476	550.0736
Step 2					
Northern Europe	March-May	10.8755	runoff/drainage	6.2608	83.9736
	June-Sept	10.8755	runoff/drainage	6.2608	83.9736
	Oct-Feb	25.7593	runoff/drainage	14.9545	202.3592
Southern Europe	March-May	20.7980	runoff/drainage	12.0566	162.8973
	June-Sept	15.8368	runoff/drainage	9.1587	123.4355
	Oct-Feb	20.7980	runoff/drainage	12.0566	162.8973
Step 3*					
D3	ditch	0.5426	Drift	0.05344	0.5203
D4	pond	0.1258	Drainage	0.1026	0.7337
D4	stream	0.4355	Drift	0.06133	0.4538
D6$_1$	ditch	0.5402	Drift	0.02745	0.3421
D6$_2$	ditch	1.891	Drainage	0.1814	1.853
R1	pond	0.1507	Run-off	0.1016	1.031
R1	stream	2.033	Run-off	0.09001	2.351
R2	stream	0.9905	Run-off	0.05021	3.374
R3	stream	2.023	Run-off	0.1908	2.58

*Modelled with input parameters of Set 2 (see Table 8.9-6)

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Table 8.9-12: **FOCUS Step 1,2 and Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Mandipropamid following <u>single</u> application of GLOB2106cF to potato – <u>early</u> application**

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
Step 2					
Northern Europe	March-May	4.2911	runoff	2.4474	32.5037
	June-Sept	4.2911	runoff	2.4474	32.5037
	Oct-Feb	9.8096	runoff	5.6709	76.3983
Southern Europe	March-May	7.9701	runoff	4.5964	61.7667
	June-Sept	6.1306	runoff	3.5219	47.1352
	Oct-Feb	7.9701	runoff	4.5964	61.7667
Step 3*					
D3	ditch	0.7457	Drift	0.03601	0.4306
D4	pond	0.03009	Drift	0.02001	0.1759
D4	stream	0.5824	Drift	0.01084	0.09988
D6$_1$	ditch	0.7374	Drift	0.01619	0.227
D6$_2$	ditch	0.7352	Drift	0.02906	0.3678
R1	pond	0.08477	Run-off	0.05104	0.4119
R1	stream	1.034	Run-off	0.04614	1.451
R2	stream	0.683	Drift	0.01446	1.146
R3	stream	0.7339	Run-off	0.04851	0.4431

*Modelled with input parameters of Set 2 (see Table 8.9-6)

Table 8.9-13: **FOCUS Step 1,2 and Step 3 PEC$_{sw}$ and PEC$_{sed}$ for Mandipropamid following 3 applications of GLOB2106cF to potato with 7 days interval – <u>late</u> application**

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	---	73.0884	runoff/drainage	41.5476	550.0736
Step 2					
Northern Europe	March-May	10.8755	runoff/drainage	6.2608	83.9736
	June-Sept	10.8755	runoff/drainage	6.2608	83.9736
	Oct-Feb	25.7593	runoff/drainage	14.9545	202.3592
Southern Europe	March-May	20.7980	runoff/drainage	12.0566	162.8973
	June-Sept	15.8368	runoff/drainage	9.1587	123.4355
	Oct-Feb	20.7980	runoff/drainage	12.0566	162.8973
Step 3*					
D3	ditch	0.5435	Drift	0.06195	0.5693
D4	pond	0.09612	Drainage	0.07631	0.5962

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Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
D4	stream	0.4468	Drift	0.04057	0.3312
D6₁	ditch	0.5395	Drift	0.0325	0.3367
D6₂	ditch	2.761	Drainage	0.3328	3.324
R1	pond	0.3131	Run-off	0.242	2.215
R1	stream	1.419	Run-off	0.06905	1.421
R2	stream	0.9911	Run-off	0.05024	3.375
R3	stream	2.468	Run-off	0.2679	5.567

*Modelled with input parameters of Set 2 (see Table 8.9-6)

Table 8.9-14: **FOCUS Step 1,2 and Step 3 PECsw and PECsed for Mandipropamid following <u>single</u> application of GLOB2106cF to potato – <u>late</u> application**

Scenario FOCUS	Waterbody	Max PECsw (µg/L)	Dominant entry route	21 d- PECsw,twa (µg/L)	Max PECsed (µg/kg)
Step 2					
Northern Europe	March-May	4.2911	runoff	2.4474	32.5037
	June-Sept	4.2911	runoff	2.4474	32.5037
	Oct-Feb	9.8096	runoff	5.6709	76.3983
Southern Europe	March-May	7.9701	runoff	4.5964	61.7667
	June-Sept	6.1306	runoff	3.5219	47.1352
	Oct-Feb	7.9701	runoff	4.5964	61.7667
Step 3*					
D3	ditch	0.746	Drift	0.03798	0.446
D4	pond	0.03008	Drift	0.01788	0.1382
D4	stream	0.5606	Drift	0.005161	0.04849
D6₁	ditch	0.742	Drift	0.02368	0.3136
D6₂	ditch	0.7415	Drift	0.05861	0.6464
R1	pond	0.0666	Run-off	0.05102	0.5895
R1	stream	1.034	Run-off	0.03111	0.9175
R2	stream	0.683	Drift	0.01446	1.147
R3	stream	1.047	Run-off	0.1046	2.052

*Modelled with input parameters of Set 2 (see Table 8.9-6)

The aquatic risk assessment for Mandipropamid is driven by the chronic toxicity to *Daphnia magna* with a NOEC of 76 µg/L (see dRR Section B9). Taking into account an Annex VI TER trigger value of 10, PECsw values should be lower than **<u>7.6 µg/L</u>** (the regulatory acceptable concentration, **<u>RAC</u>**). PECsw calculated with FOCUS STEP 1 & 2 were above this threshold, therefore further step 3 calculations were carried out using the FOCUS SWASH model version 5.3 (MACRO 5.5.4, PRZM 4.3.1 and TOXSWA 4.4.3). PECsw calculated with FOCUS STEP 3 were below the threshold of 7.6 µg/L and therefore, no further calculations were required.

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Table 8.9-15: **FOCUS Step 1,2 PEC_sw and PEC_sed for SYN 504851 following 3 applications of GLOB2106cF to potato with 7 days interval**

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	---	26.6781	runoff/drainage	26.4806	1.1940
Step 2					
Northern Europe	March-May	4.2468	runoff/drainage	4.2150	0.1952
	June-Sept	4.2468	runoff/drainage	4.2150	0.1952
	Oct-Feb	9.8333	runoff/drainage	9.7611	0.4520
Southern Europe	March-May	7.9711	runoff/drainage	7.9124	0.3664
	June-Sept	6.1090	runoff/drainage	6.0637	0.2808
	Oct-Feb	7.9711	runoff/drainage	7.9124	0.3664

Table 8.9-16: **FOCUS Step 1,2 PEC_sw and PEC_sed for SYN 504851 following single application of GLOB2106cF to potato**

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
Step 2					
Northern Europe	March-May	1.6194	runoff	1.6072	0.0744
	June-Sept	1.6194	runoff	1.6072	0.0744
	Oct-Feb	3.6908	runoff	3.6636	0.1696
Southern Europe	March-May	3.0003	runoff	2.9781	0.1379
	June-Sept	2.3099	runoff	2.2927	0.1062
	Oct-Feb	3.0003	runoff	2.9781	0.1379

Table 8.9-17: **FOCUS Step 1,2 PEC_sw and PEC_sed for SYN 500003 following 3 applications of GLOB2106cF to potato with 7 days interval**

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	---	7.4179	runoff/drainage	5.9302	0.6499
Step 2					
Northern Europe	March-May	1.1296	runoff/drainage	0.9030	0.0994
	June-Sept	1.1296	runoff/drainage	0.9030	0.0994
	Oct-Feb	2.6538	runoff/drainage	2.1220	0.2354
Southern Europe	March-May	2.1458	runoff/drainage	1.7157	0.1897
	June-Sept	1.6377	runoff/drainage	1.3093	0.1441
	Oct-Feb	2.1458	runoff/drainage	1.7157	0.1897

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Table 8.9-18: **FOCUS Step 1,2 PECsw and PECsed for SYN 500003 following single application of GLOB2106cF to potato**

Scenario FOCUS	Waterbody	Max PECsw (μg/L)	Dominant entry route	21 d- PECsw,twa (μg/L)	Max PECsed (μg/kg)
Step 2					
Northern Europe	March-May	0.4377	runoff	0.3499	0.0385
	June-Sept	0.4377	runoff	0.3499	0.0385
	Oct-Feb	1.0047	runoff	0.8033	0.0886
Southern Europe	March-May	0.8157	runoff	0.6521	0.0718
	June-Sept	0.6267	runoff	0.5010	0.0551
	Oct-Feb	0.8157	runoff	0.6521	0.0718

Table 8.9-19: **FOCUS Step 1,2 PECsw and PECsed for SYN 521195 following 3 applications of GLOB2106cF to potato with 7 days interval**

Scenario FOCUS	Waterbody	Max PECsw (μg/L)	Dominant entry route	21 d- PECsw,twa (μg/L)	Max PECsed (μg/kg)
Step 1	---	9.9295	runoff/drainage	4.7248	113.3094
Step 2					
Northern Europe	March-May	1.4396	runoff/drainage	0.7029	17.1646
	June-Sept	1.4396	runoff/drainage	0.7029	17.1646
	Oct-Feb	3.4320	runoff/drainage	1.6908	41.5508
Southern Europe	March-May	2.7678	runoff/drainage	1.3615	33.4221
	June-Sept	2.1037	runoff/drainage	1.0322	25.2934
	Oct-Feb	2.7678	runoff/drainage	1.3615	33.4221

Table 8.9-20: **FOCUS Step 1,2 PECsw and PECsed for SYN 521195 following single application of GLOB2106cF to potato**

Scenario FOCUS	Waterbody	Max PECsw (μg/L)	Dominant entry route	21 d- PECsw,twa (μg/L)	Max PECsed (μg/kg)
Step 2					
Northern Europe	March-May	0.5715	runoff	0.2756	6.6702
	June-Sept	0.5715	runoff	0.2756	6.6702
	Oct-Feb	1.3102	runoff	0.6419	15.7121
Southern Europe	March-May	1.0640	runoff	0.5198	12.6981
	June-Sept	0.8177	runoff	0.3977	9.6842
	Oct-Feb	1.0640	runoff	0.5198	12.6981

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Table 8.9-21: **FOCUS Step 1,2 PEC$_{sw}$ and PEC$_{sed}$ for SYN 539678 following 3 applications of GLOB2106cF to potato with 7 days interval**

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	---	7.1249	runoff/drainage	5.3534	80.9098
Step 2					
Northern Europe	March-May	1.0843	runoff/drainage	0.8285	12.6709
	June-Sept	1.0843	runoff/drainage	0.8285	12.6709
	Oct-Feb	2.5142	runoff/drainage	1.9483	30.0841
Southern Europe	March-May	2.0375	runoff/drainage	1.5750	24.2797
	June-Sept	1.5609	runoff/drainage	1.2018	18.4753
	Oct-Feb	2.0375	runoff/drainage	1.5750	24.2797

Table 8.9-22: **FOCUS Step 1,2 PEC$_{sw}$ and PEC$_{sed}$ for SYN 539678 following single application of GLOB2106cF to potato**

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
Step 2					
Northern Europe	March-May	0.4234	runoff	0.3206	4.8703
	June-Sept	0.4234	runoff	0.3206	4.8703
	Oct-Feb	0.9536	runoff	0.7357	11.3267
Southern Europe	March-May	0.7769	runoff	0.5973	9.1746
	June-Sept	0.6002	runoff	0.4589	7.0224
	Oct-Feb	0.7769	runoff	0.5973	9.1746

Table 8.9-23: **FOCUS Step 1,2 PEC$_{sw}$ and PEC$_{sed}$ for CGA 380778 following 3 applications of GLOB2106cF to potato with 7 days interval**

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	---	4.8771	runoff/drainage	4.8418	21.6250
Step 2					
Northern Europe	March-May	0.5178	runoff/drainage	0.5141	2.2960
	June-Sept	0.5178	runoff/drainage	0.5141	2.2960
	Oct-Feb	1.2945	runoff/drainage	1.2851	5.7399
Southern Europe	March-May	1.0356	runoff/drainage	1.0281	4.5919
	June-Sept	0.7767	runoff/drainage	0.7711	3.4439
	Oct-Feb	1.0356	runoff/drainage	1.0281	4.5919

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Table 8.9-24: **FOCUS Step 1,2 PEC$_{sw}$ and PEC$_{sed}$ for CGA 380778 following single application of GLOB2106cF to potato**

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	*21 d- PEC$_{sw,twa}$ (µg/L)*	*Max PEC$_{sed}$ (µg/kg)*
Step 2					
Northern Europe	March-May	0.2300	runoff	*0.2284*	*1.0199*
	June-Sept	0.2300	runoff	*0.2284*	*1.0199*
	Oct-Feb	0.5750	runoff	*0.5709*	*2.5497*
Southern Europe	March-May	0.4600	runoff	*0.4567*	*2.0398*
	June-Sept	0.3450	runoff	*0.3425*	*1.5299*
	Oct-Feb	0.4600	runoff	*0.4567*	*2.0398*

PEC$_{sw/sed}$ of GLOB2106cF

The PEC$_{sw}$ of the formulation GLOB2106cF was also calculated, based on a relative density of 1.0799 kg/L for the product and 3 applications at 1.9 L/ha. The calculator tool from the FOCUS SWASH model was used for this purpose. These PEC$_{sw}$ were calculated for the ditch, pond and stream scenarios. On top, to allow for the 20% spray drift contribution from the upstream catchment in the case of streams, the drift values of the calculator have been multiplied with a factor 1.2 for the stream scenario. The results of these calculations are provided in the table below.

Table 8.9-25: **Maximum PECsw for GLOB2106cF**

Cropping scenario	FOCUS scenario	1 m	
		% drift	Max. PECsw (µg/L)
Potatoes	Ditch	1.1578	7.9186
	Pond	0.1491	0.3058
	Stream	0.8976	6.1393
		-	7.3672*

*taking into account the 20% contribution from the upstream catchment

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	Propamocarb-HCl
Direct photolysis in air	Not determined – no data requested
Quantum yield of direct phototransformation	Not determined in air
Photochemical oxidative degradation in air	DT$_{50}$ = 4.03 and 13.4 hours (Atkinson method)
Volatilisation	<u>From plant surfaces:</u> Propamocarb hydrochloride was found to volatilise from plant surfaces (French beans) <10.0%, this value is less than the BBA trigger value of 20.0% in volatilisation studies conducted over a 24 hour period. <u>From soil:</u> Volatilisation loss of Propamocarb hydrochloride is estimated to be <0.0001% of the applied amount within 24 hours after treatment (Dow method) and was found to

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	evaporate <15.0% in volatilisation studies conducted over a 24 hour period, which is less than the BBA trigger value of 20.0%.
Metabolites	Not applicable.

Based on its vapour pressure ($3.1 – 4.7 * 10^{-5}$ Pa at 20 ºC and $<1.7 * 10^{-3}$ Pa at 25 ºC) and its Henry's Law constant ($<1.7 * 10^{-8}$ Pa m^3 mol^{-1} at 20 ºC and $3.54 * 10^{-7}$ Pa m^3 mol^{-1} at 25 ºC), the volatility of propamocarb hydrochloride can be considered low. This suggestion was further supported following investigation of the volatility of propamocarb hydrochloride from soil (loss <0.001% of the applied amount, calculated with the Dow method) and leaf surfaces.

Bimolecular rate constants for atmospheric reactions with photo-generated hydroxyl radicals were calculated to be $9.54 * 10^{-11}$ cm^3 molecule^{-1} s^{-1} and $2.878322 * 10^{-11}$ cm^3 molecule^{-1} s^{-1} in two oxidative studies, corresponding to atmospheric DT$_{50}$ values estimated to be 4.03 hours and 13.4 hours, respectively. All these factors suggested that levels of propamocarb hydrochloride in air following normal agricultural use of the formulated product will be low.

Table 8.10-2:   Summary of atmospheric degradation and behaviour

Compound	Mandipropamid
Direct photolysis in air	No data provided, data not required
Quantum yield of direct phototransformation	290 nm: 0.492 300 nm: 0.370
Photochemical oxidative degradation in air	DT$_{50}$ = 1.36 (Atkinson method) OH$^-$ concentration (12 h) assumed = 1.5×10^6 cm^{-3}
Volatilisation	From plant surfaces (BBA guideline): Negligible after 24 hrs From soil surfaces (BBA guideline): < 8.9 % AR after 24 hrs
Metabolites	None

Mandipropamid has a low vapour pressure of $< 9.4 \times 10^{-7}$ Pa at 20 5°C. Volatilisation of mandipropamid from soil and leaf surface is negligible. In the eventuality that some Mandipropamid should reach the air e.g. by drift, Mandipropamid would be rapidly degraded by hydroxyl radicals. The estimated half-life (Atkinson method) of Mandipropamid in the atmosphere is 1.36 hrs.

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Appendix 1   Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Keunen E.	2023	Estimation of the PECgw of Propamocarb-HCl, Mandipropamid and relevant metabolites GLOB2106cFGWC Globachem NV non GLP Unpublished	N	Globachem NV
KCP 9.2.5	Keunen E.	2023	Estimation of the PECsw and PECsed of Propamocarb-HCl, Mandipropamid and relevant metabolites GLOB2106cFSWC Globachem NV non GLP Unpublished	N	Globachem NV

Appendix 2   Detailed evaluation of the new Annex II studies

No new studies were submitted.