FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 076127 A

Product name(s): PROSIM

Chemical active substances:

Propamocarb hydrochloride, 400 g/L
Cymoxanil, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 08.2021 ; updated 12.2022 ; 03.2023

Version history

When	What
10.2020	Submission by Applicant
08.2021	Assesment dRR by zRMS for commenting
06.12.2022	Assesment dRR_update by zRMS for commenting
March 2023	The final version of RR

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

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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	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Potato**	F	*Phytophthora infestans*	Foliar spray	BBCH 21-95	a) 1 b) 6	7-10	a) 2.5 b) 15	a) 1 propamocarb + 0.125 cymoxanil b) 6 propamocarb + 0.75 cymoxanil	200-400			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

Table 8.1-2: Assessed (critical) uses during approval of Propamocarb 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 Min-max	Min. interval between applications (days)	kg as/hL min-max	g or kg as/ha min-max	Water L/ha Min-max		
1	North and South	Lettuce	F/G	*Bremia lactucae*	Drench	-	2	T1: after seedling T2: before transplanting	T1: 0.360 T2: 0.18	T1: 72.2 (10 mL/m²) T2: 36.1 (5mL/m²)	20000	21	[1] [3}
					Foliar spray	-	2	T3: just after transplanting T4: 12-16d after transplanting	T3&T4: 0.072-0.415	T3&T4: 1.44-1.66	400-200		
2	North and South	Tomato rock-wool	G	*Phytophthora spp. Pythium spp.*	Drench	-	1	T1: 0-10 d after seeding	T1: 0.058-0.144	T1: 28.9 (4mL/m²)	20000-50000	3	[1]
					Nutrient solution	-	4	T2: just after transplanting T3: T2 + 7 d T4: maturing T5: T4 +7-10 d	T2, T3, T4&T5: 0.024-0.12	T2, T3, T4&T5: 0.722-2.166	3000		
3	Indoor & outdoor in South	Tomato (soil grown crop)	G&F	*Phytophthora spp. Pythium spp.*	Drench	-	2	T1: 0-10 d after seeding T2: 7-10 d before transplanting	T1: 0.36 T2: 0.18	T1&T2: 72.2 (10 mL/m²)	20000-40000	3	Protected in field (plastic tunnel) Outdoor only in Southern Europe [1] [2] [3]
					Nutrient solution	-	2	T3: maturing T4: T3 + 7-10 d	T3&T4: 0.0722	T3&T4: 2.166	3000		
4	N & S	Lettuce	G	*Damping off: Phytophthora spp./Pythium spp.*	Drench in nurseries	-	2	T1: at sowing T2: before transplanting	T1&T2: 0.06-0.24	T1&T2: 36.1-72.2 (5-10 mL/m²)	30000-60000 (3-6 L/m²)	n.a.	5-10 mL Proplant/m²: 3-6 L of 0.15% solution (15 mL Proplant in 10 L water)/m² USED IN NURSERIE

			F&G	*Bremia lactucae*	Foliar spray	-	3	T3: after transplanting T4/T5: repeat after 10 days	T3-T5 : 0.072	T3-T5 : 1.083	1500	21	1.5 L Proplant/ha [1] [2] [3]
5	N & S	Potatoes	D	*Mildew: Phytophthora infestans*	Foliar spray	As 1st symp-tom occur	6	Repeat each 7 days	T1-T6 : 0.216	T1-T6 : 1.083	500	14	1.5 L Proplant/ha in associ-ation with half rate of applic. of any contact fungicide e.g. 1.6 kg/ha mancozeb or 1.0 kg/ha chlorothalonil [1]

* 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

[1] The risk assessment for operators, workers and bystanders is inconclusive

[2] The risk assessment has revealed data gaps in section 4

[3] The risk assessment has revealed data gaps in section 5

Table 8.1-3: Assessed (critical) uses during approval of Cymoxanil 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: develop-mental 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 as/hL min-max	g or kg as/ha min-max	Water L/ha min/max		
1	South	Lettuce	F	*Bremica lactucae*	Spray	BBCH 40-49	3-4	7	0.03-0.048	0.240	500-800	10	Oxon
2	North	Lettuce	F	*Bremica lactucae*	Spray	BBCH 21-95	4	7-10	0.026-0.060	0.120	200-450	7	Oxon
3	South	Potato	F	*Phytophthora infestans*	Spray	BBCH 21-95	5	7	0.012-0.024	0.120	500-1000	7	Oxon
4	North	Potato	F	*Phytophthora infestans*	Spray	BBCH 21-95	6-8	7-10	0.029-0.058	0.175	300-600	7	DuPont
5	South	Potato	F	*Phytophthora infestans*	Spray	BBCH 21-95	6-8	7-10	0.029-.058	0.175	300-600	14	DuPont

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

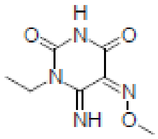
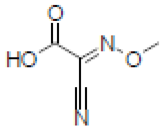
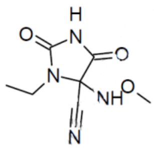
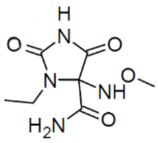
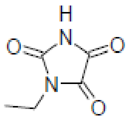
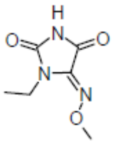
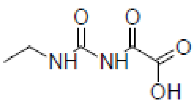
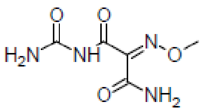
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

Metabolites of Propamocarb potentially relevant for exposure assessment

The aerobic and anaerobic soil metabolism and soil photolysis studies indicated that no metabolites or degradation products were observed to form at levels greater than 10%.

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IN-U3204 1-ethyl-6-iminodihydropyrimidine-2,4,5(3H)-trione 5-(O-methyloxime) (E-configuration)	198.5 g/mol		Soil: 24.7 Water:24.7 Sediment: 0.5 Total: 24.7	PEC_{gw}: leaching potential to groundwater PEC_{soil}: not covered by EU assessment $PEC_{sw/sed}$: not covered by EU assessment
IN-W3595 Cyano(methoxyimino)acetic acid (E-configuration)	128.2 g/mol		Soil: 10.1 Water: 26.1 Sediment: 2.3 Total: 27.5	PEC_{gw}: leaching potential to groundwater PEC_{soil}: not covered by EU assessment $PEC_{sw/sed}$: not covered by EU assessment
IN-JX915 3-ethyl-4-(methoxyamino)-2,5-dioxoimidazolidine-4-carbonitrile (stereomer racemate)	198.2 g/mol		Soil: 10.9 Water: 7.2 Sediment: 1.2 Total: 8.5	PEC_{gw}: leaching potential to groundwater PEC_{soil}: not covered by EU assessment $PEC_{sw/sed}$: not covered by EU assessment
IN-KQ960 3-ethyl-4-(methoxyamino)-2,5-dioxoimidazolidine-4-carboxamide (stereomer racemate)	216.2 g/mol		Soil: 6.3 Water: 13.0 Sediment: 5.5 Total: 14.3	PEC_{gw}: leaching potential to groundwater $PEC_{sw/sed}$: not covered by EU assessment
IN-T4226 1-ethylimidazolidine-2,4,5-trione	142.1 g/mol		Soil: 1.7 Water: 11.1 Sediment: 1.0 Total: 12.0	$PEC_{sw/sed}$: not covered by EU assessment
IN-R3273 1-ethylimidazolidine-2,4,5-trione 5-(O-methyloxime) (E-configuration)	171.2 g/mol		Soil: 2.4 Water: 5.0 Sediment: 0.5 Total: 5.0	$PEC_{sw/sed}$: not covered by EU assessment
IN-KP533 {[(ethylamino)carbonyl]amino}(oxo)acetic acid	160.1 g/mol		Soil: 2.7 Water: 20.5 Sediment: 6.5 Total: 26.0	$PEC_{sw/sed}$: not covered by EU assessment
Metabolite fraction M5 N-(aminocarbonyl)-2-(methoxymino)maloamide (E-configuration)	198.2 g/mol		Soil: 0.0 Water: 22.9 Sediment: 0.0 Total: 22.9	PECsw/sed: not covered by EU assessment

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 and its metabolites

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

Propamocarb hydrochloride, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Minnesota	Clay loam	5.80[c]	20	56.92	136.0	452.0	90.3	-	1st order	EFSA Scientific Report (2006) 78, 1-80, DAR, 2005 and Addendum, 2005
Sarotti	Loamy silt	7.38[c]	20	40.57	11.7	38.9	9.55	-		
Abington	Loamy sand	7.4[c]	20	49.43	10.9	36.1	10.9	-		
Borstel	Silty sand	5.81[c]	20	30.53	29.7	98.8	21.4	-		
B6	Sandy loam 1*	7.1[d]	20	27	22.4	74.3	16.38	0.98		
B7	Clay loam 1*	6.7[d]	20	32	23.4	77.6	14.69	0.97		
B8	Clay loam 2**	8.0[d]	20	32	17.8	59.0	11.18	0.95		
B9	Sandy loam 2*	5.5[d]	20	27	87.7	291.5	64.13	0.91		
B6	Sandy loam 1**	7.1[d]	20	-	14.4	46.8	-	0.98		
Sarotti	Loamy silt	7.38[c]	10	-	25.3	84.1	10.2	-		
Borstel, 20 cm	Silty sand[a]	6.29[c]	10	-	73.7	245.0	-	-		
B6	Sandy loam *	7.1[d]	10	-	47.2	156.9	-	0.93		
LS 2.2	Loamy sand 1	6.6	25	36	14	27.7[b]	12.4	-		
California	Loamy sand	5.2	25	30	28	72.4[b]	32.3	-		
German	Loamy sand 2	6.6	25	45.5	10	17[b]	7.59	-		
LS 2.2[e]	Loamy sand 1	6.6	25	36	13	24.7[b]	11.0	-		

Propamocarb hydrochloride, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
	Loamy sand 1	6.6	25	-	12	21.1[b]	9.43	-		
LS 2.2	Loamy sand	5.6	22	36	17.7	27.8[b]	9.81	-		
LS 2.2	Loamy sand	6.6	15	36	22.0	29.7[b]	6.04	-		
SL 2.3	Sandy loam	6.6	15	36	24.0	20.4[b]	4.13	-		
Geometric mean (n=17)							**13.91** 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: 13.91 days [n = 17 values])				
pH-dependency:							No			

*** Dose rate = 250 mg/kg**
**** Dose rate = 10 mg/kg**
a: Half-life values determined for 20 cm
b: recalculated DT_{50} (RMS) values from original data
c: Determination in $CaCl_2$
d: Determined in H_2O
e: DT_{50} is based on 2 applications 4000 mg/kg
Q_{10} 2.2

8.3.1.2 Cymoxanil and its metabolites

Table 8.3-2: Summary of aerobic degradation rates for Cymoxanil - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH[a]**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} [b](d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model[c]**	**Evaluated on EU level y/n/ Reference**
Arrow, UK	Sandy loam	6.0 uk	20	40	0.1	0.5	0.2	1.4	FOMC	EFSA Scientific Report (2008) 167, 1-116
Sassafras, US	Sandy loam	6.4 uk	25	75% 1/3 bar	1.2	18.8	5.8	17.6		
Black Andosol, J	Sandy clay loam	6.8 uk	25	50	0.2	0.8	0.4	5.9		
Probstei, DE	Sandy loam	6.5 uk	20	50	2.3	13.1	3.1	6.9		
Sermoise, F	Sandy loam	7.8 uk	20	50	0.7	2.3	0.6	16.7		
Evensham, UK	Sandy clay loam	5.7 uk	20	50	2.5	33.3	7.3	6.5		
Cranfield 230, UK	Silt loam	4.3 ca	20	40	4.3	23.7	6.1	4.3		

Cymoxanil, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH[a]**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} [b](d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model[c]**	**Evaluated on EU level y/n/ Reference**
Cranfield 164, UK	Silt loam	6.4 ca	20	40	0.9	3.1	0.8	2.6	SFO	
Cranfield, 115, UK	Clay loam	7.5 ca	20	40	0.2	0.8	0.2	5.7		
Geometric mean (n=9)							**1.2**			
pH-dependency:							Soil DT_{50} significantly (p < 0.05) depending on soil pH (lower under acidic conditions)			
UK	Silt loam	6.5 ca	10	40	1.4	4.7	-	2.8	SFO	

a: Matrix of pH measurement (uk denotes unknown and ca denotes $CaCl_2$)
b: SDO-DT_{50} re-calculated from FOMC-DT_{90} by division with 3.32
c: Best fit

Table 8.3-3: Summary of aerobic degradation rates for IN-U3204 - laboratory studies

IN-U3204, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH[a]**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Black Andosol, J	Sandy clay loam	6.8 uk	25	50	0.6	1.9	0.9	11.0	P_{SFO} → M_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Cranfield 164, UK	Silt loam	6.4 ca	20	40	0.4	1.3	0.3	26.2	P_{SFO} → M_{SFO}	
Cranfield 115, UK	Clay loam	7.5 ca	20	40	0.2	0.6	0.2	12.2	P_{SFO} → M_{SFO}	
Geometric mean (n=3)							**0.4**			
pH-dependency:							No			

a: Matrix of pH measurement (uk denotes unknown and ca denotes $CaCl_2$)

Table 8.3-4: Summary of aerobic degradation rates for IN-W3595 - laboratory studies

IN-W3595, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Black Andosol, J	Sandy clay loam	6.8	25	50	1.7	5.5	2.5	14.5	P_{SFO} → M_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Semoise, F	Sandy loam	7.8	20	50	2.8	9.4	2.2	69.3	P_{SFO} → M_{SFO}	
Max (n=2)							**2.5**			

IN-W3595, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
						pH-dependency:	No			

Table 8.3-5: Summary of aerobic degradation rates for IN-KQ960 - laboratory studies

IN-KQ960, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Black Andosol, J	Sandy clay loam	6.8	25	50	7.6	25.2	11.2	19.2	P_{SFO}→$M1_{SFO}$ →$M2_{SFO}$[a]	EFSA Scientific Report (2008) 167, 1-116

a: M1 = IN-U3204, M2 = IN-KQ960

Table 8.3-6: Summary of aerobic degradation rates for IN-JX915 - laboratory studies

IN-JX915, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Black Andosol, J	Sandy clay loam	6.8	25	50	0.6	1.9	1.0	27	P_{SFO}→M_{SFO}	EFSA Scientific Report (2008) 167, 1-116

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Propamocarb hydrochloride and its metabolites

Table 8.3-7: Summary of aerobic degradation rates for Propamocarb hydrochloride - laboratory studies

Propamocarb hydrochloride, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
B6	Sandy	7.1	20	-	308.16	1023.69	-	0.9838	1st order	EFSA

Propamocarb hydrochloride, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
	loam[ts]*									Scientific Report (2006) 78, 1-80, DAR, 2005
B6	Sandy loam[ts]*	7.1	20	-	65.68	218.18	-	0.9815		
B6	Sandy loam[wp]*	7.1	20	-	14.70	318.91	-	0.9873	1st order 2P	
B6	Sandy loam[wp]*	7.1	20	-	7.03	53.11	-	0.9797		
German standard soil 2.2	Sandy loam[ts]*	-	25	-	459.0	1524.9	-	0.76	1st order	
				Geometric mean (n=5)	**62.58**					
				pH-dependency:	No					

ts/wp: Half-life values determined for total system and the water phase respectively
*** Dose rate = 250 mg/kg**
**** Dose rate = 10 mg/kg**

8.3.2.2 Cymoxanil and its metabolites

The anaerobic degradation in soil of Cymoxanil was not evaluated during the EU review of Cymoxanil. However, no additional studies have been performed. According to the DAR, Cymoxanil does not have autumn application and will not be used in crops where anaerobic conditions will persist. In the case of partial/local anaerobic conditions in soil, Cymoxanil is likely to extensively degrade during aerobic phases and is not considered to be persistent long enough to move into the saturated zone.

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)

8.4.1.1 Propamocarb hydrochloride and its metabolites

Triggering endpoints

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

Propamocarb hydrochloride, Field studies – Triggering endpoints									
Soil type	**Location**	**pH* (NaCl)**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**Kinetic parameters**	**St. (r^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Loamy sand	USA, GEorgia	5.7	0-15	17.6	58.6	-	0.76	1st order	EFSA Scientific Report (2006) 78, 1-80, DAR, 2005
Loamy sand	USA, Georgia	5.9	0-15	17.4	57.7	-	0.78		
Sandy loam	USA, California	9.0	0-15	22.1	73.3	-	0.99		
Sandy loam	USA, California	8.6	0-15	23.7	78.6	-	0.92		
Maximum (n=4)				23.7	78.6				

*** pH values at 15 cm deep.**

8.4.1.2 Cymoxanil and its metabolites

Field studies are not required because Cymoxanil consistently showed DT_{50} values at both 10 and 20°C very much shorter than 60 days under laboratory conditions.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not applicable for Propamocarb hydrochloride.
Owing to the fast degradation of Cymoxanil observed in laboratory degradation studies, the potential of accumulation is considered to be negligible even after multiple application.

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 hydrochloride and its metabolites

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

Propamocarb hydrochloride							
Soil name	**Soil type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Minnesota[a]	Clay loam	3.15	5.80	77.2	2451	0.77	EFSA Scientific Report (2006) 78, 1-80, DAR, 2005
Sarotti[a]	Loamy silt	1.30	7.38	2.63	202	0.90	
Abington[a]	Loamy sand	1.86	7.4	2.49	134	0.90	
Borstel[a]	Silty sand	1.04	5.81	1.29	124	0.84	
Ptungstadt[a]	Loamys clay	1.57	6.4	9.70	618	0.87	
Borstel (20 cm)[b]	Loamy sand	0.56	6.29	0.96*	171*	0.86*	
Borstel (40 cm)[b]	Loamy sand	0.24	6.34	1.04*	433*	0.91*	
Borstel (60 cm)[b]	Clay sand	0.18	6.37	1.00*	556*	0.86*	
Borstel (90 cm)[b]	Sand	0.02	3.40	0.72*	3600*	0.86*	
German 2.1[a]	Sand	0.48	6.0	0.671	140	0.926	
German 2.2[a]	Loamy sand	2.06	6.0	0.849	41	0.910	
Schering 170[a]	Sandy loam	1.45	5.2	5.20	359	0.822	
Speyer 2.2[a]	Loamy sand	2.26	6.1	1.28	56.63	0.925	
Cranfield 249[a]	Sandy clay loam	3.48	6.5	6.26	179.88	0.854	
Midwest 1[a]	Sandy loam	1.05	5.7	13.82	1321.22	0.827	
Midwest 2[a]	Loamy sand	0.58	5.9	4.64	800	0.862	
Geometric mean (n=12)					-	-	
Arithmetic mean (n=12)					**535** EFSA Scientific Report (2006) 78, 1-80 (arithmetic mean Kfoc value from 12 soils, in accordance to current guidance)	0.867	
pH-dependency					No obvious pH dependance for Propamocarb hydrochloride. However, there is a possibility that adsorption to soil may depen on the clay content of the soil.		

*** values not taken into account for the geomean and arithmetic mean calculation.**
a: Topsoil
b: Subsoil horizons

8.5.2 Cymoxanil and its metabolites

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

Cymoxanil							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Speyer 2.1, DE	Silt loam	0.59	6.9	0.090	15.1	0.88	EFSA Scientific Report (2008) 167, 1-116
Midwest 1, US	Sandy loam	1.0	5.7	0.910	87.1	0.87	
Cranfield 115, UK	Loamy sand	1.6	8.1	0.462	28.9	0.81	
Cranfield 164, UK	Clay	2.0	7.2	0.856	43.4	0.87	
Geometric mean (n=4)					35.8	-	
Arithmetic mean (n=4)					-	0.86	
pH-dependency					No		

Table 8.5-3: Summary of soil adsorption/desorption for IN-W3595

IN-W3595							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Bayboro, US	Loamy sand	2.3	4.6	0.63	27.4	-	EFSA Scientific Report (2008) 167, 1-116
Chino, US	Sandy loam	0.99	7.6	0.026	2.6	-	
Fargo, US	Silt loam	3.2	7.8	0.074	2.3	-	
Sassafras, US	Sandy loam	0.45	6.4	0.020	4.3	-	
Geometric mean (n=4)					5.15	-	
Arithmetic mean (n=4)					-	1.0[a]	
$K_{oc\ acid}$ $K_{oc\ base}$ pK_a					**33.3** **2.3** **5.2**		
pH-dependency					Yes		

a: PRAPeR 32 agreed default value

Table 8.5-4: Summary of soil adsorption/desorption for IN-R3273

IN-R3273							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Bayboro, US	Loamy sand	2.3	4.6	0.59	25.7	-	EFSA Scientific Report (2008) 167, 1-116
Chino, US	Sandy loam	0.99	7.6	0.49	49.5	-	
Fargo, US	Silt loam	3.2	7.8	1.5	46.9	-	

IN-R3273							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Sassafras, US	Sandy loam	0.43	6.4	0.21	45.7	-	
Geometric mean (n=4)					40.64	-	
Arithmetic mean (n=4)					-	1.0[a]	
pH-dependency					Yes		

a: PRAPeR 32 agreed default value

Table 8.5-5: Summary of soil adsorption/desorption for IN-JX915

IN-JX915							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
Bayboro, US	Loamy sand	2.3	4.6	0.13	5.4	-	EFSA Scientific Report (2008) 167, 1-116
Chino, US	Sandy loam	0.99	7.6	0.34	34.3	-	
Fargo, US	Silt loam	3.2	7.8	0.66	20.6	-	
Sassafras, US	Sandy loam	0.43	6.4	0.021	4.4	-	
Geometric mean (n=4)					11.38	-	
Arithmetic mean (n=4)					-	1.0[a]	
pH-dependency					No		

a: PRAPeR 32 agreed default value

Table 8.5-6: Summary of soil adsorption/desorption for IN-U3204

IN-U3204						
Soil Type	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
HPLC method	-	-	-	27.9	1.0[a]	EFSA Scientific Report (2008) 167, 1-116
pH-dependency				Not applicable		

a: PRAPeR 32 agreed default value

Table 8.5-7: Summary of soil adsorption/desorption for IN-KQ960

IN-KQ960						
Soil Type	**OC (%)**	**pH**	**Kd (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
HPLC method	-	-	-	21.6	1.0[a]	EFSA Scientific Report (2008) 167, 1-116
pH-dependency				Not applicable		

a: PRAPeR 32 agreed default value

Table 8.5-8: Summary of soil adsorption/desorption for IN-T4226

IN-T4226						
Soil Type	**OC (%)**	**pH**	**Kf (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
HPLC method	-	-	-	17.7	1.0[a]	EFSA Scientific Report (2008) 167, 1-116
pH-dependency				Not applicable		

a: PRAPeR 32 agreed default value

Table 8.5-9: Summary of soil adsorption/desorption for IN-KP533

IN-KP533						
Soil Type	**OC (%)**	**pH**	**Kf (mL/g)**	**Koc (mL/g)**	**1/n**	**Evaluated on EU level y/n/ Reference**
HPLC method	-	-	-	12.9	1.0[a]	EFSA Scientific Report (2008) 167, 1-116
pH-dependency				Not applicable		

a: PRAPeR 32 agreed default value

8.5.3 Column leaching (KCP 9.1.2.1)

Propamocarb hydrochloride	Column leaching; Guideline: BBA Part IV, Section 4-2 (1986) Precipitation: 200 mm Time period: 5 days Leachate: 0.043-0.260% total residues in leachate, 37.0-92.8% radioactivity retained in top 5 cm, 0.5-41.62% radioactivity retained in 5-10 cm column segment, 0.5-13.1% radioactivity retained in 10-15 cm column segment, <0.1-0.2% radioactivity retained in 15-20 cm column segment, <0.1% radioactivity retained in the remaining segments 20-25 cm and 25-30 cm Aged residues leaching: Guideline: SETAC (1995), Part 1, Section 6 Aged for: 12 days (Midwest 3), 23 days (Speyer2.3) Time period: 2 days Precipitation: 200 mm Leachate: 0.67-0.90% radioactivity in leachate, 27.88-44.49% radioactivity retained in top 6 cm, 6.21-14.86% radioactivity retained in 6-12 cm column segment, 1.60-10.90% radioactivity retained in 12-18 cm column segment, 0.28-3.90% radioactivity retained in 18-24 cm column segment, 0.07-1.06% radioactivity retained in 24-30 cm column segment
Cymoxanil	According to the DAR: Reliable sorption data have been generated for the active substance and metabolites. Therefore, column leaching and aged residues studies on Cymoxanil and any degradation product are not required.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Propamocarb hydrochloride	Not required.
Cymoxanil	One lysimeter study conducted in Lower Saxony, Germany Two soil monoliths (1 m², 1.2 m soil depth): 0 – 30 cm: sand 75.2 %, silt 21.2 %, clay 3.6 %, Corg 1.29 %, pH ($CaCl_2$) 5.4 Application (as Curzate 50 WP) onto potatoes: Lys1: 3 x 320 g ai/ha, June 30, July 6, July 14, 1993 3 x 320 g ai/ha, June 30, July 7, July 14, 1994 Lys2: 3 x 320 g ai/ha, June 30, July 6, July 14, 1993 Crop cover: potatoes, winter rye (1st year), potatoes, winter barley (2nd year) Precipitation: 1171 mm (1st year), 1176 mm (2nd year), 850 mm (3rd year) Mean annual temperature: 11.9 °C (1st year), 9.9 °C (2nd year), 8.5 °C (3rd year) Leachate (mean of both lysimeter): 894 mm (1st year), 738 mm (2nd year), 497 mm (3rd year) **Annual mean concentrations in leachates:** Total radioactivity in leachates: Lys1: 0.27, 0.56 and 0.19 µg ai equiv./L (1st, 2nd, 3rd year) Lys2: 0.26, 0.11 µg ai equiv./L (1st, 2nd year) Unidentified radioactivity in leachates (owing to loss during work-up, unidentified radioactivity of RP-C8 HPLC, unidentified polars): Lys1: 0.23, 0.46 and 0.16 µg ai equiv./L (1st, 2nd, 3rd year) Lys2: 0.21, 0.10 µg ai equiv./L (1st, 2nd year) **Maximum annual mean concentration in leachates:** Cymoxanil: < LOQ IN-U3204: < 0.01 µg L^{-1} (Lys2, 2nd year) IN-T4226: 0.02 µg L^{-1} (Lys1, 2nd year) IN-R3273: 0.01 µg L^{-1} (Lys1, 2nd year) IN-R3274: 0.02 µg L^{-1} (Lys1, 2nd year) Oxamic acid (IN-18474): < LOQ Oxalic acid: 0.03 µg L^{-1} (Lys1, 2nd year) LOQ = 0.01 µg L^{-1}

8.5.5 Field leaching studies (KCP 9.1.2.3)

Propamocarb hydrochloride	Not required.
Cymoxanil	Please refer to point 8.5.4 Lysimeter studies

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 hydrochloride and its metabolites

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

Propamocarb hydrochloride Distribution (max. water 102.3% after 0 days and max. sediment 36.9% after 14 days)										
Water/sediment system	**pH water/ 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**
Oostvaardersplassen	8.2/-	15.5	51.5	1st order	11.6	38.4	1st order	-	1st order	EFSA Scientific Report (2006) 78, 1-80, DAR, 2005
Schoonrewoerdse Wiel	9.3/-	15.9	52.7		12	39.9		-		
Mill Stream Pond	7.4/7.7	21.0	69		10.0	34		26		
Iron Hatch Steam	8.0/8.2	16.0	53		15.0	49		23		
Geometric mean (n=4)		16.96	56.13		12.02	39.97		24.46		
Pikeville	5.49/4.75	100.0	332.3	1st order	12.1	40.1	1st order	93.0	1st order	

8.6.2 Cymoxanil and its metabolites

Table 8.6-2: Summary of degradation in water/sediment of Cymoxanil

Cymoxanil Distribution (max. in sediment 3.9% after 1 days)										
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	0.5	1.7	1.00	0.5	1.7	1.00	Nc	P_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Sand	5.3/5.1	1.6	5.3	0.99	1.5	5.0	0.99	Nc	P_{SFO}	
Silty clay loam	8.3/7.5	0.1	0.2	1.00	0.1	0.2	1.00	Nc	P_{SFO}	
Silt loam	8.3/7.5	0.2	0.5	1.00	0.2	0.5	1.00	Nc	P_{SFO}	
Geometric mean (n=4)		0.3	1.0		0.3	1.0				

Table 8.6-3: Summary of degradation in water/sediment of IN-U3204

IN-U3204 Distribution (max. in water 24.7% after 0.13 d and max. in sediment 0.5% after 3 d)									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r²**	**$DissT_{50/90}$ water (d)**	**r²**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	0.6	2.0	0.92	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	EFSA Scientific Report (2008) 167, 1-116
Silty clay loam	8.3/7.5	0.2	0.5	0.98	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Silt loam	8.3/7.5	0.5	1.7	0.96	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Geometric mean (n=3)		0.4	1.2						

Table 8.6-4: Summary of degradation in water/sediment of IN-W3595

IN-W3595 Distribution (max. in water 26.1% after 0.25 d and max. in sediment 2.3% after 1 d)									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r²**	**$DissT_{50/90}$ water (d)**	**r²**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	3.6	12.1	0.95	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	EFSA Scientific Report (2008) 167, 1-116
Silty clay loam	8.3/7.5	2.7	9.0	0.99	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Silt loam	8.3/7.5	2.7	8.9	0.98	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Geometric mean (n=3)		3.0	9.9						

Table 8.6-5: Summary of degradation in water/sediment of IN-KQ960

IN-KQ960 Distribution (max. in water 13.0% after 1 d and max. in sediment 5.5% after 30 d)									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r²**	**$DissT_{50/90}$ water (d)**	**r²**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	154	521	0.76	Nc	-	Nc	M_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Silty clay loam	8.3/7.5	45.4	151	0.97	Nc	-	Nc	M_{SFO}	
Silt loam	8.3/7.5	15.2	50.5	0.98	Nc	-	Nc	M_{SFO}	
Geometric mean (n=3)		47.4	158						

Table 8.6-6: Summary of degradation in water/sediment of IN-T4226

IN-T4226 Distribution (max. in water 11.1% after 3 d and max. in sediment 1.0% after 8 d)									
Water/ sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50/90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	3.9	12.9	0.99	Nc	-	Nc	M_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Sand	5.3/5.1	5.4	17.9	0.91	Nc	-	Nc	M_{SFO}	
Geometric mean (n=2)		4.6	15.2						

Table 8.6-7: Summary of degradation in water/sediment of IN-JX915

IN-JX915 Distribution (max. in water 7.2% after 1 d and max. in sediment 1.2% after 1 d)									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50/90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	2.5	8.3	0.79	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	EFSA Scientific Report (2008) 167, 1-116
Sand	5.3/5.1	1.1	3.7	0.96	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Silty clay loam	8.3/7.5	2.1	7.1	0.88	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Silt loam	8.3/7.5	1.5	5.1	0.97	Nc	-	Nc	$P_{SFO} \rightarrow M_{SFO}$	
Geometric mean (n=4)		1.7	5.8						

Table 8.6-8: Summary of degradation in water/sediment of IN-R3273

IN-3273 Distribution (max. in water 5.0% after 3 d and max. in sediment 0.5% after 3 d)									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50/90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	6.0	19.9	0.93	Nc	-	Nc	M_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Sand	5.3/5.1	6.7	22.2	0.98	Nc	-	Nc	M_{SFO}	
Geometric mean (n=2)		6.3	21.0						

Table 8.6-9: Summary of degradation in water/sediment of IN-KP533

IN-KP533 Distribution (max. in water 20.5% after 10 d and max. in sediment 6.5% after 1 d)[a]									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50/90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	7.4/7.0	2.3	7.5	0.96	Nc	-	Nc	M_{SFO}	EFSA Scientific

IN-KP533 Distribution (max. in water 20.5% after 10 d and max. in sediment 6.5% after 1 d)[a]									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50/90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Sand	5.3/5.1	3.0	10.0	0.97	Nc	-	Nc	M_{SFO}	Report (2008) 167, 1-116
Geometric mean (n=2)		2.6	8.7						

a: Worst-case assessment, individual amounts of IN-KP533 in two of four water/sediment systems not known (in two systems maximal 8.0% of AR in the entire system)

Table 8.6-10: Summary of degradation in water/sediment of Metabolite fraction M5

Metabolite fraction M5 Distribution (max. in water 22.9% after 1 d and max. in sediment 0%)									
Water/sediment system	**pH water/ sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**r^2**	**$DissT_{50/90}$ water (d)**	**r^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Silty clay loam	8.3/7.5	1.2	4.0	1.00	Nc	-	Nc	M_{SFO}	EFSA Scientific Report (2008) 167, 1-116
Silt loam	8.3/7.5	1.6	5.2	1.00	Nc	-	Nc	M_{SFO}	
Geometric mean (n=2)		1.4	4.6						

Table 8.6-11: Summary of observed metabolites in water/sediment system

IN-U3204	Max. in water 24.7% after 0.13 d and max. in sediment 0.5% after 3 d	EFSA Scientific Report (2008) 167, 1-116
IN-W3595	Max. in water 26.1% after 0.25 d and max. in sediment 2.3% after 1 d	
IN-KQ960	Max. in water 13.0% after 1 d and max. in sediment 5.5% after 30 d	
IN-T4226	Max. in water 11.1% after 3 d and max. in sediment 1.0% after 8 d	
IN-JX915	Max. in water 7.2% after 1 d and max. in sediment 1.2% after 1 d	
IN-R3273	Max. in water 5.0% after 3 d and max. in sediment 0.5% after 3 d	
IN-KP 533	Max. in water 20.5% after 10 d and max. in sediment 6.5% after 1 d	
Metabolite fraction M5	Max. in water 22.9% after 1 d and max. in sediment 0%	

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

8.7.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.7.2 Active substances and relevant metabolites

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

Use No.	1
Crop	**Potato**
Application rate (g as/ha)	Propamocarb: 1000 Cymoxanil: 125
Number of applications/interval	6/7
Crop interception (%)	60 (for all applications)
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)

Table 8.7-2: Input parameter for active substances and relevant metabolites for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Max. occur-rence (%)**	**DT_{50} (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Propamocarb	224.7	-	136.0 days (worst case first order laboratory value, undertaken at 40-50% MWHC and a temperature of 20°C)	EFSA Scientific Report (2006) 78, 1-80
Cymoxanil	198.2	-	7.3 (worst case of normalised laboratory value, 10 kPa or pF2, 20°C with Q_{10} of 2.2)	EFSA Scientific Report (2008) 167, 1-116)
IN-U3204	198.2	24.7	0.9 (worst case of normalised laboratory value, 10 kPa or pF2, 20°C with Q_{10} of 2.2)	
IN-W3595	128.2	10.1	2.5 (worst case of normalised laboratory value, 10 kPa or pF2, 20°C with Q_{10} of 2.2)	
IN-JX915	198.2	10.9	1.0 (normalised laboratory value, 10 kPa or pF2, 20°C with Q_{10} of 2.2)	

8.7.2.1 Propamocarb hydrochloride

Table 8.7-3: PEC_{soil} for Propamocarb hydrochloride in potato

PEC_{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.533	-	2.932	-
Short term	24h	0.531	0.532	2.917	2.925
	2d	0.528	0.531	2.903	2.917
	4d	0.523	0.528	2.873	2.903
Long term	7d	0.515	0.524	2.830	2.881
	14d	0.497	0.515	2.730	2.830
	21d	0.479	0.506	2.635	2.781
	28d	0.462	0.497	2.542	2.733
	50d	0.413	0.471	2.273	2.589
	100d	0.320	0.418	1.761	2.297
Plateau concentration (20 cm) after year 7		-	-	0.162	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		-	-	**3.094**	-

8.7.2.2 Cymoxanil and its metabolites

Table 8.7-4: PEC_{soil} for Cymoxanil in potato

PEC_{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.067	-	0.135	-
Short term	24h	0.061	0.064	0.123	0.129
	2d	0.055	0.061	0.111	0.123
	4d	0.046	0.055	0.092	0.112
Long term	7d	0.034	0.049	0.069	0.098
	14d	0.018	0.037	0.036	0.075
	21d	0.009	0.029	0.018	0.058
	28d	0.005	0.023	0.009	0.047
	50d	0.001	0.014	0.001	0.028
	100d	<0.001	0.007	<0.001	0.014
Plateau concentration (20 cm) after year		-	-	-	-
$PEC_{accumulation}$		-	-	-	-

(PEC_{act} +$PEC_{soil\ plateau}$)				

PEC_{soil} of metabolites

PEC_{soil} values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application $rate_{metabolite}$ = ($MW_{metabolite}$/ MW_{parent}) x (% maximum occurrence/100) x application $rate_{parent}$

The corresponding application rates for each metabolite are summarized in the table below.

Table 8.7-5: Corrected application rates for the metabolites

Metabolite	Application rate of the parent (g/ha)	MW_{parent}	$MW_{metabolite}$	Maximum occurrence in soil (%)	Corrected application rate (g/ha)
IN-U3204	125	198.2	198.2	24.7	30.875
IN-W3595			128.2	10.1	8.166
IN-JX915			198.2	10.9	13.625

The results of PEC_{soil} calculations are presented in the tables below.

Table 8.7-6: PEC_{soil} for IN-U3204 on potato

PEC_{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.016	-	0.017	-
Short term	24h	0.008	0.011	0.008	0.012
	2d	0.004	0.008	0.004	0.008
	4d	0.001	0.005	0.001	0.005
Long term	7d	<0.001	0.003	<0.001	0.003
	14d	<0.001	0.002	<0.001	0.002
	21d	<0.001	0.001	<0.001	0.001
	28d	<0.001	0.001	<0.001	0.001
	50d	<0.001	<0.001	<0.001	<0.001
	100d	<0.001	<0.001	<0.001	<0.001
Plateau concentration (20 cm) after year		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-7: PEC_{soil} for IN-W3595 on potato

PEC_{soil} (mg/kg)	Potato			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.004	-	0.005	-

Short term	24h	0.003	0.004	0.004	0.004
	2d	0.003	0.003	0.003	0.004
	4d	0.001	0.003	0.002	0.003
Long term	7d	0.001	0.002	0.001	0.002
	14d	<0.001	0.001	<0.001	0.001
	21d	<0.001	0.001	<0.001	0.001
	28d	<0.001	0.001	<0.001	0.001
	50d	<0.001	<0.001	<0.001	<0.001
	100d	<0.001	<0.001	<0.001	<0.001
Plateau concentration (20 cm) after year		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-8: PEC_{soil} for IN-JX915 on potato

PEC_{soil} (mg/kg)		Potato			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.007	-	0.007	-
Short term	24h	0.004	0.005	0.004	0.005
	2d	0.002	0.004	0.002	0.004
	4d	<0.001	0.002	<0.001	0.002
Long term	7d	<0.001	0.001	<0.001	0.001
	14d	<0.001	0.001	<0.001	0.001
	21d	<0.001	<0.001	<0.001	<0.001
	28d	<0.001	<0.001	<0.001	<0.001
	50d	<0.001	<0.001	<0.001	<0.001
	100d	<0.001	<0.001	<0.001	<0.001
Plateau concentration (20 cm) after year		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

8.7.2.3 PEC_{soil} of Propamocarb 40% + Cymoxanil 5% SC

Since Propamocarb 40% + Cymoxanil 5% SC is rapidly broken down into its constituent parts on contact with soil and/or crop material, it is appropriate to calculate the PEC_S following a single application only, using the following equation:

$$PEC_S(\text{mg/kg}) = \frac{\text{Application rate (g/ha)} \times \text{(1-F)}}{100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3\text{)}}$$

Table 8.7-9: PEC$_{soil}$ for Propamocarb 40% + Cymoxanil 5% SC on potato

Preparation	Application rate (g/ha)	Crop interception (%)	PEC$_{act}$ (mg/kg)
Propamocarb + Cymoxanil / Propamocarb 40% + Cymoxanil 5% SC	6 x 2659*	60	8.509

*** Based on density value of 1.0636 g/cm^3**

zRMS comments:

PECs values were calculated by Applicant for application rate 6 x 2.5 L product ha^{-1} with crop interception 60 % (BBCH 21 – 95) for potatoes.

PEC values for propamocarb was calculated with agreed LoEP (EFSA Scientific Report Scientific Report (2006) 78, 1-80.
PEC values for cymoxanil and its metabolites was calculated with agreed LoEP (EFSA Scientific Report (2008) 167, 1).
zRMS agrees with calculations of PECs.

The acceptable predicted environmental concentrations of propamocarb and cymoxanil and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

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

8.8.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC$_{gw}$ calculations

Use No.	1
Crop	**Potato**
Application rate (g as/ha)	Propamocarb: 1000 Cymoxanil: 125
Number of applications/interval (d)	6/7
Crop interception (%)	60/85
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

It should be noted that as recommended in the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (FOCUS 2011), a corrected application rate is calculated taking into account the interception by the crop canopy. Therefore, the substance is applied directly to the ground in the models, thus avoiding the internal interception routines in the models.

Table 8.8-2: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)*	Interception (%) from BBCH 21
Châteaudun	13/05	60/60/60/85/85/85
Hamburg	30/05	60/60/60/60/60/85
Jokioinen	29/06	60/60/60/60/60/60
Kremsmünster	30/05	60/60/60/60/60/85
Okehampton	22/05	60/60/60/60/60/85
Piacenza	02/05	60/60/60/85/85/85
Porto	06/04	60/60/60/60/60/85
Sevilla	17/02	60/60/60/60/85/85
Thiva	18/03	60/60/60/60/85/85

8.8.2.1 Propamocarb hydrochloride

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

Compound	Propamocarb hydrochloride	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	224.7	EFSA Scientific Report (2006) 78, 1-80
Water solubility (mg/L):	1005000 (max. values for PEARL: 1000000)	
Saturated vapour pressure (Pa):	1.358 x 10^{-3} at 20°C (worst case)	
DT_{50} in soil (d)	13.91 (geomean of lab. study, normalised to 10 kPa, 20°C, Q_{10} 2.2, n=17)	
K_{foc} (mL/g)/K_{fom}	263.65 (geomean, n=12) / 152.93	
1/n	0.867 (arithmetic mean, n=12)	
Plant uptake factor	0	

Table 8.8-4: PEC_{gw} for Propamocarb hydrochloride on potato (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)	
	PEARL	PELMO
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

8.8.2.2 Cymoxanil and its metabolites

Table 8.8-5: Input parameters related to active substance Cymoxanil and metabolites for PEC_{gw} calculations

Compound	Cymoxanil	IN-U3204	IN-W3595	IN-JX915	IN-KQ960	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	198.2	198.2	128.1	198.2	216.2	EFSA Scientific Report (2008) 167, 1-116
Water solubility (mg/L):	783 at pH7, 20ºC					
Saturated vapour pressure (Pa):	1.5 x 10^{-4} (at 20°C)	0 (default)				
DT_{50} in soil (d)	7.3 worst case Q10 = 2.2 1.2 (geomean, n=9) Q10 = 2.2	0.4 (geomean, n=3) Q10 = 2.2	2.5 (worst case, n=2) Q10 = 2.2	1.0 (n=1)	11.2 (n=1)	
K_{foc}/K_{fom} (mL/g)	35.8/20.8 (geomean, n=4)	27.9/16.2 (n=1)	Acid: 33.3/19.3* Base: 2.3/1.3* pKa 5.2* PELMO scenario specific, top soil pH **	11.38/6.6 (geomean, n=4)	21.6/12.5 (n=1)	
1/n	0.86 (arithmetic mean, n=4)	1.0 (default)				
Plant uptake factor	0					
Formation fraction	-	0.36 from parent	0.15 from parent	0.10 from parent	0.16 from IN-U3204	

*** For PEARL calculations**
**** The $CaCl_2$ top soil pH scenarios**

Table 8.8-6: FOCUS scenarios top soil pH and IN-W3595 Kfoc used for PELMO calculations

FOCUS scenario	Soil pH (H_2O)	Soil pH (KCl)	Soil pH ($CaCl_2$)*	Kfoc**
Châteaudun	8	7.3	7.5	2.3
Hamburg	6.4	5.7	5.8	33.3
Jokioinen	6.2	5.5	5.6	33.3
Kremsmünster	7.7	7	7.2	2.3
Okehampton	5.8	5.1	5.2	33.3
Piacenza	7	6.3	6.5	33.3
Porto	4.9	4.2	4.3	33.3
Sevilla	7.3	6.6	6.8	33.3
Thiva	7.7	7	7.2	2.3

*** According to UBA Excel spreadsheet Input Decision v3.02**
**** Kfoc according to $CaCl_2$ pH since the Kfoc was calculated in $CaCl_2$ media**

Table 8.8-7: PEC$_{gw}$ for Cymoxanil and metabolites on potato (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) at DT$_{50}$ 7.3 d worst case

Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)									
	Cymoxanil		IN-U3204		IN-W3595		IN-JX915		IN-KQ960	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.015	0.012
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.091	0.074
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	**0.166**	**0.175**
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.047	0.051
Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.044	0.053
Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.006	0.006
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.003	0.007
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.001
Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	0.002

Table 8.8-8: PEC$_{gw}$ for Cymoxanil and metabolites on potato (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) at geomean DT$_{50}$ 1.2d

Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)									
	Cymoxanil		IN-U3204		IN-W3595		IN-JX915		IN-KQ960	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	**0.110**	**0.117**

According to Addendum to the DAR, 2008, the metabolite IN-KQ960 was predicted to exceed the groundwater trigger of 0.1 µg/L in the FOCUS scenario Jokioinen. Taking into account the conservative assumptions for groundwater modelling and results of representative lysimeter study conducted on the Borstel soil in Germany, IN-KQ960 is not expected to exceed the groundwater trigger of 0.1 µg/L.

Indeed, the IN-KQ960 PEC$_{gw}$ exceeded the groundwater trigger of 0.1 µg/L in Hamburg and Jokioinen scenarios being the maximum PEC_{gw} is equal to 0.175 µg/L for Jokioinen PELMO scenario at DT_{50} 7.3 d worst case, but when calculations are made with the DT_{50} geomean of 1.2 d, the maximum PEC_{gw} value of equal to 0.117 µg/L for Jokionen PEARL scenario. These values are close to the trigger of 0.1 µg/L.

However, according to EFSA Scientific Report (2008) 167, 1-116, due to the toxicological profile of Cymoxanil, the assessment of IN-KQ960 relevance should be considered. The assessment of relevance of metabolite IN-KQ960 in groundwater according to SANCO/221/2000 guidance document (relevant for all uses evaluated in geoclimatic conditions represented by Jokionen FOCUS groundwater scenario, data gap identified by EFSA).

However, the RMS point out, that IN-KQ960 is not likely to exceed the trigger of 0.1 µg/L under ‘real outdoor conditions’ of intended use owing to the following reasons:

- *IN-KQ960 was only observed in the Japanese ‘Black Andosol’ > 5 % of AR (from which the only valid DegT50 and valid formation fraction used for modelling derive from). IN-KQ960 was never detected > 5 % of AR in any of the eight European or US lab soil studies (maximum confirmed occurrence of IN-KQ960 in these soils 0.6 % of AR). Andosols are considered to represent only a very minor area of soils in Europe (including formally active and still active volcanic areas).*
- *Groundwater modelling of IN-KQ960 is extremely sensitive to the 1/n value used. Since no valid 1/n value is available for INKQ960 (KOC determined by means of HPLC), the PRAPeR 32 agreed default value of 1.0 was used for revised modelling for conservative reasons. However, the great majority of organic compounds exhibit a 1/n value about 0.9 (as indicated by the FOCUS default value).*
- *In the available lysimeter study, representing worst case conditions in terms of precipitation, amount of leachate, degradation rate of cymoxanil (acidic lysimeter soil) and application rate (3 x 320 g ai ha-1), no individual leachate compound is considered to exceed 0.1 µg L-1. Taking into account, that (i) the lysimeter soil used (‘Borstel’ soil) is more or less identical to the soil implemented in the Hamburg groundwater scenario (which resulted in an exceedance of the 0.1 µg L-1 trigger based on the worst case DegT50 of cymoxanil) and that (ii) total precipitation (1170 mm) and the amount of leachate (820 L m-2) in the lysimeter study were distinct higher than modelled in the Hamburg scenario (average precipitation 650 mm, average amount of leachate 183 L m-2), it seems evident that the modelling overpredicts the leaching behaviour of IN-KQ960 or, more likely, modelling input data for INKQ960 are too conservative.*

Concluding, the RMS does not expect IN-KQ960 to exceed 0.1 µg/L in shallow groundwater even under more vulnerable conditions.

Furthermore the *PRAPeR 32* decision was agreed under the assumption that the adsorption is lineal since the Kfoc was determined only at one concentration, but for metabolites IN-U3402 and IN-KQ960 due to technical problems in the OECD 106 study no Kfoc nor 1/n reliable values were determined and Koc value was determined using the HPLC method according to OECD 121 guidance. Besides, the IN-KQ960 Koc value from OECD 121 is practically the same than the Koc value calculated by the RMS from water/sediment study, so at 2 different concentrations. Therefore, according to the Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.2 May 2014:

“….When there is no data, a default value of 0.9 should be used. If a linear relation for sorption has been determined the value may be set to 1[2].”

“[2] The origin of the last sentence in this paragraph is the FOCUS Surface Water Scenarios workgroup report. Applicants should be aware that with the aim of harmonising regulatory exposure assessments, Member State fate and behaviour experts from the competent authorities have agreed the following as a practical way of applying,” If a linear relation for sorption has been determined the value may be set to 1". They have interpreted this sentence to mean that where an applicant has chosen to carry out a batch adsorption experiment investigating only a single concentration (i.e. just screening experiments in the OECD 106 test guideline), that the applicant has started with the assumption (i.e. text from section 2.4.3 “has determined”) that a linear relation for sorption in that soil is reasonable, so a 1/n of 1 should be ascribed for that soil. In the situation where the available experiments investigated the relationship between soil solution concentration and sorption, but it was not possible to determine a reliable 1/n

value, (i.e. text from section 2.4.3 "where there is no data") the default value of 0.9 has been ascribed to the pertinent soils."

The 1/n value of 1 is not justifiable for metabolite IN-U3402 nor for metabolite IN-KQ960, below the results using 0.9 instead of 1 for 1/n.

Table 8.8-9: PEC$_{gw}$ for Cymoxanil and metabolites on potato (with FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) at geomean DT$_{50}$ 1.2d and 1/n 0.9 for metabolites IN-U3204 and IN-KQ960

Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)									
	Cymoxanil		IN-U3204		IN-W3595		IN-JX915		IN-KQ960	
	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.005	0.006

Conclusions

After the refinements the PECgw for cymoxanil and its metabolites were below of 0.1 µg/L in all scenarios. Therefore, the relevance assessment according to SANCO/221/2000 –rev.10 is not necessary.

zRMS comments:

The zRMS accepted the calculation of PECgw values for active substances presented by the Applicant.
In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. The geomean of the DT$_{50}$ and Koc a values were used in modelling.

PECgw values were calculated by Applicant for application rate 6 x 2.5 L product ha^{-1} with crop interception 60 % (BBCH 21 – 95) for potatoes.
PECgw values for propamocarb was calculated EFSA with agreed LoEP (EFSA Scientific Report Scientific Report (2006) 78, 1-80.
PECgw values for cymoxanil and its metabolites was calculated with agreed LoEP (EFSA Scientific Report (2008) 167, 1).
The 80th percentile groundwater concentrations PECgw for propamocarb and cymoxanil and its metabolites are less than trigger value 0.1 µg/L.

The use of PROSIM doesn't pose a risk for ground water and the relevance assessment of the metabolite is not necessary.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

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

8.9.1 Justification for new endpoints

Not relevant as there is no deviation to EU agreed endpoints.

8.9.2 Active substances, relevant metabolites and the formulation (KCP 9.2.5)

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

Plant protection product	Propamocarb 40% + Cymoxanil 5% SC
Use No.	1
Crop	Potato
Application rate (kg as/ha)	Propamocarb: 1000 Cymoxanil: 125
Number of applications/interval (d)	6/7
Application window	March-May (average crop cover)
Application method	Foliar spray
CAM (Chemical application method)	CAM 2
Soil depth (cm)	4 cm
Models used for calculation	FOCUS STEPS 1-2 v3.2

8.9.2.1 Propamocarb hydrochloride

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

Compound	Propamocarb hydrochloride	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	224.7	EFSA Scientific Report (2006) 78, 1-80
Water solubility (mg/L)	1005000 (max. value in FOCUS SWASH 1000000)	
K_{foc} (mL/g)	263.65 (geomean, n=12)	
$DT_{50,soil}$ (d)	13.91 (geomean of lab. study, normalised to 10 kPa, 20°C, Q_{10} 2.2, n=17)	
$DT_{50,water}$ (d)	16.96 (geomean, n=4)	
$DT_{50,sed}$ (d)	1000 (defaut)	
$DT_{50,whole\ system}$ (d)	16.96 (geomean, n=4)	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 36.9	

$PEC_{sw/sed}$

Table 8.9-3: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Propamocarb hydrochloride following single/multiple applications of Propamocarb 40% + Cymoxanil 5% SC in 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 1	---	255.830 / 1530.000	Drainage / runoff	170.177 / 1020.000	650.249 / 3900.000
Step 2					
N-Europe	March-May	26.673 / 74.037	Drainage / runoff	19.179 / 53.462	68.930 / 192.179
S-Europe		46.879 / 134.192	Drainage / runoff	33.981 / 97.531	122.167 / 350.668

8.9.2.2 Cymoxanil and its metabolites

Table 8.9-4: Input parameters related to active substance Cymoxanil and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	**Cymoxanil**	**IN-U3204**	**IN-W3595**	**IN-KQ960**	**IN-T4226**	**IN-JX915**	**IN-R3273**	**IN-KP533**	**Fraction M5**	**Value in accordance to EU end-point y/n/ Reference**
Molecular weight (g/mol)	198.2	198.2	128.1	216.2	142.1	198.2	171.2	160.1	198.2	EFSA Scientific Report (2008) 167, 1-116
Saturated vapour pressure (Pa)	1.5×10^{-4} at 20°C	not required for Step 1+2								
Water solubility (mg/L)	783 at pH 7, 20ºC									
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	not required for Step 1+2								
Diffusion coefficient in air (m²/d)	0.43									
K_{foc}/K_{fom} (mL/g)	35.8/20.8 (geomean, n=4)	27.9 (n=1)	2.3 (worst case for basic soil)	21.6 (n=1)	17.7 (n=1)	11.38 (geomean, n=4)	40.64 (geomean, n=4)	12.9 (n=1)	2.3 (worst case for basic soil)	
Freundlich Exponent 1/n	0.86 (arithmetic mean, n=4)	not required for Step 1+2								
Plant Uptake	0									
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)									
$DT_{50,soil}$ (d)	1.2 (geomean,	0.4	2.5 (worst	11.2 (n=1)	1000	1.0 (n=1)	1000 (default)			

Compound	**Cymoxanil**	**IN-U3204**	**IN-W3595**	**IN-KQ960**	**IN-T4226**	**IN-JX915**	**IN-R3273**	**IN-KP533**	**Fraction M5**	**Value in accord-ance to EU end-point y/n/ Reference**
	n=9) Q10 = 2.2	(geomean, n=3) Q10 = 2.2	case, n=2) Q10 = 2.2		(default)					
$DT_{50,water}$ (d)	0.3 (geomean, n=4)	0.4 (geomean, n=3)	3.0 (geomean, n=3)	47.4 (geomean, n=3)	4.6 (geomean, n=2)	1.7 (geomean, n=4)	6.3 (geomean, n=2)	2.6 (geomean, n=2)	1.4 (geomean, n=2)	
$DT_{50,sed}$ (d)	1000 (default)									
$DT_{50,whole\ system}$ (d)	0.3 (geomean, n=4)	0.4 (geomean, n=3)	3.0 (geomean, n=3)	47.4 (geomean, n=3)	4.6 (geomean, n=2)	1.7 (geomean, n=4)	6.3 (geomean, n=2)	2.6 (geomean, n=2)	1.4 (geomean, n=2)	
Maximum occurrence observed (% molar basis with respect to the parent)	3.9	Soil: 24.7 Water: 24.7 Sediment: 0.5 Total system: 24.7	Soil: 10.1 Water: 26.1 Sediment: 2.3 Total system: 27.5	Soil: 6.3 Water: 13.0 Sediment: 5.5 Total system: 14.3	Soil: 1.7 Water: 11.1 Sediment: 1.0 Total system: 12.0	Soil: 7.2 Water: 1.2 Sediment: 8.5 Total system: 52.6	Soil: 2.4 Water: 5.0 Sediment: 0.5 Total system: 5.0	Soil: 2.7 Water: 20.5 Sediment: 6.5 Total system:26.0	Soil: 1×10^{-5} Water: 22.9 Sediment: 0.0 Total system:22.9	

$PEC_{sw/sed}$

Table 8.9-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for Cymoxanil following <u>single/multiple</u> applications of Propamocarb 40% + Cymoxanil 5% SC on 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 1	---	40.918 / 40.918	Drainage / runoff	1.154 / 1.154	14.237 / 14.237
Step 2					
Northern Europe	March-May	1.149 / 0.680	Drainage / runoff	0.054 / 0.041	0.262 / 0.155
Southern Europe		1.149 / 0.803	Drainage / runoff	0.075 / 0.024	0.283 / 0.288

Metabolites of Cymoxanil

Table 8.9-6: FOCUS Step 1 and 2 PECsw and PECsed for IN-U3204 following <u>single/multiple</u> applications 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 1	---	20.129 / 20.129	Drainage / runoff	0.662 / 0.662	5.537 / 5.537
Step 2					
Northern Europe	March-May	0.284 / 0.168	Drainage / runoff	0.016 / 0.012	0.051 / 0.030
Southern Europe		0.284 / 0.203	Drainage / runoff	0.021 / 0.007	0.056 / 0.057

Table 8.9-7: FOCUS Step 1 and 2 PECsw and PECsed for IN-W3595 following <u>single/multiple</u> applications 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 1	---	10.299 / 61.794	Drainage / runoff	2.108 / 12.647	0.232 / 1.393
Step 2					
Northern Europe	March-May	0.244 / 0.239	Drainage / runoff	0.050 / 0.049	0.006 / 0.006
Southern Europe		0.406 / 0.418	Drainage / runoff	0.084 / 0.086	0.009 / 0.010

Table 8.9-8: FOCUS Step 1 and 2 PECsw and PECsed for IN-KQ960 following <u>single/multiple</u> applications 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 1	---	9.284 / 55.706	Drainage / runoff	7.990 / 47.940	1.975 / 11.851
Step 2					
Northern Europe	March-May	0.446 / 1.101	Drainage / runoff	0.384 / 0.948	0.096 / 0.237

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	21 d- PEC$_{sw,twa}$ (µg/L)	Max PEC$_{sed}$ (µg/kg)
Southern Europe		0.726 / 1.738	Drainage / runoff	0.626 / 1.498	0.157 / 0.374

Table 8.9-2: FOCUS Step 1 and 2 PECsw and PECsed for IN-T4226 following <u>single/multiple</u> applications 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 1	---	4.097 / 24.583	Drainage / runoff	1.240 / 7.439	0.708 / 4.246
Step 2					
Northern Europe	March-May	0.138 / 0.378	Drainage / runoff	0.043 / 0.117	0.024 / 0.067
Southern Europe		0.222 / 0.706	Drainage / runoff	0.069 / 0.218	0.039 / 0.125

Table 8.9-3: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for IN-JX915 following <u>single/multiple</u> applications 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 1	---	25.149 / 25.148	Drainage / runoff	2.949 / 2.949	2.793 / 2.793
Step 2					
Northern Europe	March-May	0.605 / 0.380	Drainage / runoff	0.105 / 0.079	0.045 / 0.036
Southern Europe		0.605 / 0.548	Drainage / runoff	0.138 / 0.066	0.067 / 0.062

Table 8.9-4: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for IN-R3273 following <u>single/multiple</u> applications 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 1	---	2.576 / 15.456	Drainage / runoff	1.004 / 6.021	1.027 / 6.160
Step 2					
Northern Europe	March-May	0.130 / 0.536	Drainage / runoff	0.052 / 0.217	0.053 / 0.218
Southern Europe		0.229 / 1.038	Drainage / runoff	0.092 / 0.419	0.093 / 0.421

Table 8.9-5: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for IN-KP533 following <u>single/multiple</u> applications 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 1	---	9.738 / 58.426	Drainage / runoff	1.735 / 10.408	1.225 / 7.350

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	0.258 / 0.673	Drainage / runoff	0.047 / 0.122	0.033 / 0.087
Southern Europe		0.432 / 1.288	Drainage / runoff	0.078 / 0.234	0.056 / 0.166

Table 8.9-6: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for Fraction M5 following single/multiple applications 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 1	---	9.791 / 9.791	Drainage / runoff	0.949 / 0.949	0.219 / 0.219
Step 2					
Northern Europe	March-May	0.264 / 0.161	Drainage / runoff	0.037 / 0.028	0.004 / 0.003
Southern Europe		0.264 / 0.215	Drainage / runoff	0.049 / 0.021	0.005 / 0.005

8.9.2.3 PEC$_{sw/sed}$ of Propamocarb 40% + Cymoxanil 5% SC

The PEC$_{SW}$ for Propamocarb 40% + Cymoxanil 5% SC was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%Drift_{90th\,\%ile} \times Application\,rate\,(g/ha)}{Water\ depth\,(cm) \times 10}$$

The application of Propamocarb 40% + Cymoxanil 5% SC is 2.5 L/ha, corresponding to 6 x 2659 g/ha (taking into account a density of 1.0636 g/cm^3) for potato. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC$_{SW}$ value is presented in the table 8.9-14.

Table 8.9-14: PEC$_{sw}$ for Propamocarb 40% + Cymoxanil 5% SC following single/multiple applications to potato

Crop	Distance (m)	Drift (%)	Max PEC$_{sw}$ (µg/L)
potato	1	2.77/1.64	24.551/87.215

The PEC$_{sed}$ for Propamocarb 40% + Cymoxanil 5% SC was calculated using the following equation:

$$PEC_{sed}\,(\mu g/kg\,dw) = \frac{\%Drift_{90th\,\%ile} \times Application\ rate\ (g/ha) \times \%Active\ substance\ in\ sediment}{1000 \times sediment\ density\ (g/cm^3) \times sediment\ height\ (cm)}$$

The application of Propamocarb 40% + Cymoxanil 5% SC is 2.5 L/ha, corresponding to 6 x 2659 g/ha (taking into account a density of 1.0636 g/cm^3) for potato. The maximum percentage of Propamocarb in the sediment is 36.9% and of Cymoxanil in the sediment is 3.9%. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC$_{sed}$ value is presented in the table 8.9-15.

Table 8.9-15: PEC_{sed} for Propamocarb 40% + Cymoxanil 5% SC following single/multiple applications to potato

Crop	Distance (m)	Drift (%)	Active substance	% in the sediment	Max PEC_{sed} (µg/kg) (based on maximum occurrence)
Potato	1	2.77/1.64	Propamocarb	36.9	41.813/148.534
			Cymoxanil	3.9	4.419/15.699

zRMS comments:

Evaluator agrees with modelling carried out by Applicant.
Predicted concentrations of propamocarb and cymoxanil and their metabolites in surface water were calculated by the Applicant at Steps 1to 2.

PECgw values were calculated by Applicant for application rate 6 x 2.5 L product ha^{-1} with crop interception 60 % (BBCH 21 – 95) for potatoes.

PECgw values for propamocarb was calculated EFSA with agreed LoEP (EFSA Scientific Report Scientific Report (2006) 78, 1-80.

PECgw values for cymoxanil and its metabolites was calculated with agreed LoEP (EFSA Scientific Report (2008) 167, 1).

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

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

Table 8.10-1: Summary of Propamocarb atmospheric degradation and behaviour

Compound	Propamocarb
Direct photolysis in air	Not determined – no data requested
Quantum yield of direct phototransformation	Not determind in air
Photochemical oxidative degradation in air	DT50 (h): 4.03 and 13.4 hrs derived by the Atkinson model
Volatilisation	From plant surfaces: Propamocarb hydrochloride was found to volatilise from plant surface (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. From soil: 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 evaporate <15.0% in volatilisation studies conducted over a 24 hour period, which is less than the BBA trigger value of 20.0%.

	Vapour pressure (Pa): 8.1×10^{-5} Pa at 25°C [97.7% purity] 1.66×10^{-3} at 25°C [99.1% purity] Henry's Law Constant (Pa.m3/mol): 8.5×10^{-9} Pa.m^3.mol^{-1}
Metabolites	

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

Table 8.10-2: Summary of Cymoxanil atmospheric degradation and behaviour

Compound	Cymoxanil
Direct photolysis in air	Not studies – no data requested
Quantum yield of direct phototransformation	0.0052 / 0.00058 (n=2)
Photochemical oxidative degradation in air	DT50 (h): 21.3 hrs derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 cm^{-3}
Volatilisation	Not stidues – no data requested Vapour pressure (Pa): 1.5×10^{-4} Pa (20°C, 99.9%) Henry's Law Constant (Pa.m3/mol): 3.3×10^{-5} Pa.m^3.mol^{-1} at pH 5 3.8×10^{-5} Pa.m^3.mol^{-1} at pH 7
Metabolites	Not studies – no data requested

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

ZRMS comments:

The data on atmospheric degradation and behaviour in air for Propamocarb provided by the Applicant are considered acceptable. The cymoxanil is regarded as non-volatile and, consequently, exposure of adjacent surface waters and terrestrial ecosystems due to volatilization with subsequent deposition is not expected.

Appendix 1 Lists of data considered in support of the evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
K-CP 9.2.4/01	-	2020	Propamocarb: Predicted Environmental Concentrations in Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO – output pilk Non-GLP Unpublished		
K-CP 9.2.4/02	-	2020	Cymoxanil: Predicted Environmental Concentrations in Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO – output plik Non-GLP Unpublished		
K-CP 9.2.5/01	-	2020	Propamocarb: Predicted Environmental Concentrations in Surface, Using FOCUS STEPS 1-2 - summary Non-GLP Unpublished		
K-CP 9.2.5/02	-	2020	Cymoxanil: Predicted Environmental Concentrations in Surface, Using FOCUS STEPS 1-2 - summary Non-GLP Unpublished		

Appendix 2 Detailed evaluation of the new Annex II studies

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