FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **ORKAN 350 SL**

Product name(s): **ORKAN 350 SL, SPRINTE 350 SL**

Chemical active substance(s):

Glyphosate, 240 g/L

MCPA, 90 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(renewal of authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 04/2020

MS Finalisation date: 26/10/2021

Version history

When	What
06/2020	Dossier sent for evaluation to Merit Mark (PL)
01.2021	Changes in sections 8.8 and 8.9
01/2021	zRMS finalised evaluation
10/2021	Evaluation after commenting period - RR

Table of Contents

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

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, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	**zRMS Conclusion** ~~**(efficacy)**~~
					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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Apple	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Po-lygonum aviculare* *Malva neglecta* **susceptible weeds in dose 8,0 l/ha:** *Taraxacum officinale* *Epilobium ciliatum* *Lamium purpureum* *Elymus repens* *Equisetum arvense*	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 8,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8L/ha: 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	300 L/ha	n.a.		

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, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	**zRMS Conclusion ~~(efficacy)~~**
					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			
Minor uses according to Article 51 (field uses)														
2	Poland	Cherry	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Poa annua* *Vicia cracca* *Chenopodium album* ***susceptible weeds in dose 7,0 l/ha:*** *Taraxacum officinale* *Epilobium ciliatum*	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7 L/ha: 0,63 kg/ha (MCPA) 1,82 kg/ha (glyphosate)	300 L/ha	n.a.		
3	Poland	Pear, quince, medlar	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Po-lygonum aviculare* *Malva neglecta* **susceptible weeds in dose 8,0 l/ha:** *Taraxacum officinale* *Epilobium ciliatum* *Lamium purpureum* *Elymus repens* *Equisetum arvense*	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 8,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8L/ha: 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	300 L/ha	n.a.		

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, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	**zRMS Conclusion** ~~**(efficacy)**~~
					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			
4	Poland	Sweet cherry, plum, peach, apricot, nectarine	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Poa annua* *Vicia cracca* *Chenopodium album* ***susceptible weeds in dose 7,0 l/ha:*** *Taraxacum officinale* *Epilobium ciliatum*	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 7,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7 L/ha: 0,63 kg/ha (MCPA) 1,82 kg/ha (glyphosate)	300 L/ha	n.a.		
5	Poland	Hazelnuts, Walnuts	F	**susceptible weeds in dose 5,0 l/ha:** *Senecio vulgaris* *Stellaria media* *Capsella-bursa-pastoris* *Galium aparine* *Poa annua* *Echinochloa crus-galli* **susceptible weeds in dose 7,0 l/ha:** *Chenopodium album* *Geranium pusillum* *Convolvulus arvensis* *Po-lygonum aviculare* *Malva neglecta* **susceptible weeds in dose 8,0 l/ha:** *Taraxacum officinale* *Epilobium ciliatum* *Lamium purpureum* *Elymus repens* *Equisetum arvense*	Foliar spraying; medium drops.	Product used in period intensive growth weeds in dose needed to destruction occurring species weeds	1	-	5,0- 8,0 L/ha	In dose 5L/ha: 0,45 kg/ha (MCPA) 1,30 kg/ha (glyphosate) In dose 7-8L/ha: 0,63-0,72 kg/ha (MCPA) 1,82-2,08 kg/ha (glyphosate)	300 L/ha	n.a.		

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

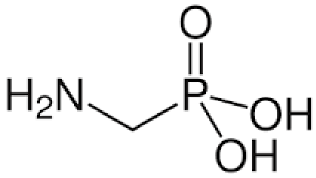
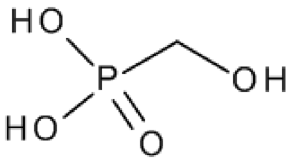
1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional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

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

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
AMPA (aminomethyl-phosphonic acid)	111.04		Soil 53.8% Water/Sediment: 27.1%	Soil Groundwater Surface water
HMPA 2-Hydroxy-3-methylpentanoic acid	112.02		Surface water 10%	Surface water

There are no relevant metabolites of MCPA.

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)

Reference to:

- Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302);

  Report and proposed decision of Italy, made to the European Commision under 91/414/EEC (2001) for MCPA

8.3.1.1 Glyphosate and its metabolites

Glyphosate exhibits low to very high persistence in soil. The principal soil metabolite was aminomethylphosphonic acid (AMPA). The maximum amount of AMPA detected ranged from 13.3 to 50.1% AR. This metabolite exhibits moderate to high persistence.

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

Glyphosate, Laboratory studies, aerobic conditions							
Soil type	**pH (H2O)**	**T (oC) / soil moisture**	**recalculated SFO DT_{50} (days) actual**	**Normalised SFO DT_{50}(days) 20 °C, pF2**	**Fit χ2 error (%)**	**Method of calculation**	**Evaluated on EU level / Reference**
Gartenacker, loam	7.1	20/ pF2.5	16.95	15.2	3.0	DFOP, DT_{90}/3.32	Y/ EFSA Journal 2015;13(11):4302)
Arrow, sandy loam	6.5[a]	20/ 40% MWHC	500.3	427.8	2.31	FOMC DT90/3.32	
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	6.27	6.7	6.9	FOMC DT90/3.32	
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	25.28	22.6	5.93	DFOP, DT_{90}/3.32	
Maasdjik, sandy loam	7.5[a]	20/ 1/3 bar	18.7	14.1	0.84	DFOP, DT_{90}/3.32	
Drusenheim,	7.4	20/	4.63	3.6	2.4	DFOP,	

loam		pF2.5				DT_{90}/3.32	
Pappelacker, loamy sand	7.0	20/ pF2.5	13.09	12.0	4.1	FOMC DT90/3.32	
18-Acres, clay loam	5.7	20/ pF2.5	141.9	133.8	2.9	DFOP, DT_{90}/3.32	
Speyer 2.3, Loamy Sand	6.9	20/40% MWHC	6.6	6.6	2.41	DFOP, DT_{90}/3.32	
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	15.45	15.45	2.45	DFOP, DT_{90}/3.32	
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	129	129	4.04	FOMC DT90/3.32	
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	3.93	3.93	7.45	DFOP, DT_{90}/3.32	
Dupo, silt loam	7.3[b]	25/ 75% FC	2.80	3.70	3.8	FOMC DT90/3.32	
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	43.06$	43.06	3.91	FOMC DT90/3.32 $	
Maximum (n = 15)				427.8	according to EFSA DG SANCO working document on evidence needed to identify POP, PBT and vPvB properties for pesticides from 25.09.2012- rev.3		
Geometric mean (n = 15)				19.74			

[a] converted from given pH in CaCl2 or KCl in order to allow pH dependency tests of the degradation
[b] buffer solution unknown
$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium

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

AMPA, Laboratory studies, aerobic conditions							
Soil type	**pH (H2O)**	**T (°C) / % soil moisture**	**DT50 (d)**	**DT90 (d)**	**Fit χ2 error (%)**	**Method of calculation**	**Evaluated on EU level / Reference**
Gartenacker, loam	7.1	20/ pF2.5	120.07	398.9	9.2	DFOP (par) – SFO (met)	Y/ EFSA Journal 2015;13(11):4302)
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	99.1	329	6.98	FOMC (par) – SFO (met)	
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	300.71	998.9	16.06	DFOP (par) – SFO (met)	
Drusenheim, loam	7.4	20/ pF2.5	38.98	129.5	3.3	DFOP (par) – SFO (met)	
Pappelacker, loamy sand	7.0	20/ pF2.5	126.57	420.5	6.2	FOMC (par) – SFO (met)	
Speyer 2.3, loamy sand	6.9	20/ 40% MWHC	77.50	257.43	10.18	DFOP (par) – SFO (met)	
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	41.87	139.10	16.23	DFOP (par) – SFO (met)	
Dupo, silt loam	7.3[b]	25/ 75% FC	48.32	160.5	7.57	FOMC (par) – SFO (met)	
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	230.7	766	4.29	FOMC (par) – SFO (met)	
Maximum (n = 9)			300.71	998.9		SFO	

[a] converted from given pH in $CaCl_2$ or KCl
[b] buffer solution unknown

Modelling endpoints

Table 8.3-3: Summary of aerobic degradation rates for glyphosate - laboratory studies: Modelling endpoints

Glyphosate, Laboratory studies – Modelling endpoints						
Soil type	**pH (H2O)**	**T (oC) / % soil moisture**	**DT_{50} (d) 20°C pF2**	**Fit χ2 error (%)**	**Method of calculation**	**Evaluated on EU level / Reference**
Gartenacker, loam	7.1	20/ pF2.5	16.0	4.6	DT90 FOMC/ 3.32	Y/ EFSA Journal 2015;13(11):4302)
Arrow, sandy loam	6.5[a]	20/ 40% MWHC	159.6	3.52	DFOP slow phase	
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	6.6	6.92	DT90 FOMC/ 3.32	
Les Evouettes, Silt Loam	6.1[b]	20/ 40% MWHC	93.3	6.17	DT90 FOMC/ 3.32	
Maasdjik, sandy loam	7.5[a]	20/ 1/3 bar	15.2	3.79	DT90 FOMC/ 3.32	
Drusenheim, loam	7.4	20/ pF2.5	4.2	3.5	DT90 FOMC/ 3.32	
Pappelacker, loamy sand	7.0	20/ pF2.5	12.0	4.1	DT90 FOMC/ 3.32	
18-Acres, clay loam	5.7	20/ pF2.5	160.5	2.9	DFOP slow phase	
Speyer 2.3, Lomay Sand	6.9	20/40% MWHC	7.2	3.84	DT90 FOMC/ 3.32	
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	19.5	5.72	DT90 FOMC/ 3.32	
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	72.2	4.97	DFOP slow phase	
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	3.76	7.67	DT90 FOMC/ 3.32	
Dupo, silt loam	7.3[b]	25/ 75% FC	3.70	3.80	DT90 FOMC/ 3.32	
2.2, loamy sand	6.0	20/ 40% MWHC	40.6	6.95	SFO	
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	43.06$	3.91$	DT90 FOMC/ 3.32	
Geometric mean (n = 15)			**20.51**	-	**Endpoint for modelling of PEC_{GW} and PEC_{SW}/ PEC_{Sed}**	
pH dependency			No			

[a] converted from given pH in $CaCl_2$ or KCl
[b] buffer solution unknown
$ labelled in the phosphonomethyl-glycine anion of glyphosate-trimesium

Table 8.3-4: Summary of aerobic degradation rates for AMPA- laboratory studies: Modelling endpoints

AMPA, Laboratory studies – Modelling endpoints							
Soil type	**pH (H2O)**	**T (oC) / % soil moisture**	**f. f. (kpar → kmet)**	**DT50 (d) 20 °C F2/10kPa**	**Fit χ2 error (%)**	**Method of calculation**	**Evaluated on EU level / Reference**
Gartenacker, loam	7.1	20/pF2.5	0.1817	119.9	8.9	FOMC (par) – SFO (met)	Y/ EFSA Journal 2015;13(11):4302)
Soil B,	6.7	25/75% of 1/3	0.2646	106.2	6.98	FOMC (par) –	

Sandy loam		bar				SFO (met)	
Les Evouettes, Silt Loam	6.1	20/ 40% MWHC	0.3618	300.9	14.00	FOMC (par) – SFO (met)	
Drusenheim, loam	7.4	20/ pF2.5	0.2578	36.8	2.1	FOMC (par) – SFO (met)	
Pappelacker, loamy sand	7.0	20/ pF2.5	0.1835	116.3	6.2	FOMC (par) – SFO (met)	
18-Acres, clay loam	5.7	20/ pF2.5	0.2169[1)]	-[1)]	-[1)]	FOMC (par) – SFO (met)	
Speyer 2.3, loamy sand	6.9	20/ 40% MWHC	0.3435	70.92	11.41	FOMC (par) – SFO (met)	
Speyer 2.1, sand	6.5[a]	20/ 45% MWHC	0.520[1)]	-[1)]	-[1)]	DFOP (par) – SFO (met)	
Speyer 2.2, loamy sand	6.2[a]	20/ 45% MWHC	0.6076[1)]	-[1)]	-[1)]	FOMC (par) – SFO (met)	
Speyer 2.3, loamy sand	6.9[a]	20/ 45% MWHC	0.4283	42.14	16.48	FOMC (par) – SFO (met)	
Dupo, silt loam	7.3[b]	25/ 75% FC	0.3637	30.5	7.57	FOMC (par) – SFO (met)	
Speyer 2.1, sand	6.9[b]	20/ 40% MWHC	0.5851	230.7	4.29	FOMC (par) – SFO (met)	
Geometric mean (n = 9)			-	**88.84**			
pH dependency			-	No			
Arithmetic mean (n = 12)			**0.3595**				

[a] converted from given pH in $CaCl_2$ or KCl
[b] buffer solution unknown
1) Acceptable visual fit for formation phase of AMPA, however no statistically acceptable fit for AMPA could be obtained in this pathway

8.3.1.2 MCPA

Agreed EU End-points used in the Evaluation (SANCO/4062/2001 - final – 11/07/2008)

End-Point	**MCPA**
$DT_{50\ lab}$ (20°C, aerobic)	Range from 7 to 41 days (n = 14, data from literature); DT_{50} of 24 days (25 °C). MCPA SANCO 4062/2001-final, 11 July 2008,
$DT_{90\ lab}$ (25°C, aerobic)	79 – from the rout of degradation study (n=1)
$DT_{50\ lab}$ (10°C, aerobic)	78 days - calculated
$DT_{50\ lab}$ (20°C, anaerobic)	No degradation

Summary

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

The fate and behaviour of MCPA in soil is discussed in detail in the corresponding document of the EU review dossier where the study references can be found. Degradation rate of MCPA under aerobic and anaerobic condition was investigated in the same studies used to establish the route of degradation in soil. MCPA is rapidly degraded in soil under aerobic condition by microbial action. Half-life values were reported to be in the range of 7 to 41 days, the calculated degradation half-life under aerobic conditions were 24 days while under anaerobic condition MCPA did not degrade. A calculated DT_{90} was 79 days – such results have been confirmed in the published literature.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Glyphosate and its metabolites

Degradation of glyphosate in soil under anaerobic conditions was investigated in three soils. Glyphosate exhibits high to very high persistence under these conditions (DT50 anaerobic = 135 →1000 d). The same major metabolite AMPA, as identified under aerobic conditions, was also formed under anaerobic conditions.

Mineralisation after 100 days	0.87 - 45.42 % after 66 - 120 d (n = 3)
Non-extractable residues after 100 days	20.88 - 24.6 % 66 - 120 d (n = 3)
Metabolites requiring further consideration	AMPA: max. 30.2 % after 84 days (n = 3)
DT50	DT50 = 142 d (n = 1), no significant degradation (n = 1), no DT50 calculated (n = 1)

Table 8.3-5: Summary of anaerobic degradation rates for glyphosate - laboratory studies

Glyphosate, Laboratory studies, anaerobic conditions						
Soil type	**Application rate (µg/g)**	**pH**	**t.ºC**	**OC %**	**Remarks**	**Evaluated on EU level / Reference**
Loamy sand	5	5.8	20	1.7	No significant degradation	RAR Glyphosate-Annex B.8: Environmental fate and behaviour (2013)
Loamy sand	30	6.9	23	1.3	No DT50 value was calculted	
Silt loam	5.8	5.1	20	1.2	DT50: 31 days (anaerobic)	
Snady loam	20	6.5	20	1.0	DT50: 19.3 days (anaerobic)	
Sandy loam	5.22	5.9	20	1.8	DT50: 142 days (anaerobic)	

8.3.2.2 MCPA and its metabolites

MCPA did not degrade under anaerobic condition.

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)

Reference to:

- Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302);
- RAR Glyphosate - Volume 3. Annex B.8: Environmental fate and behaviour (2013);
- Report and proposed decision of Italy, made to the European Commision under 91/414/EEC (2001) for MCPA

8.4.1.1 Glyphosate and its metabolites

Triggering endpoints

AMPA exhibited higher persistence in the field dissipation studies than in the laboratory aerobic degradation experiments. AMPA was also captured as being formed at a comparable (but numerically higher) proportion of the precursor glyphosate (53.8 % on a molar basis) to that which was observed in the available laboratory soil incubations.

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

Glyphosate, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**Kinetic parameters**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level Reference**
Sandy clay	Diegten Switzerland	7.1	0-30	6.1	116.1	k1 0.1437 k2 0.0033 g 0.854	4.96	DFOP	Y/ EFSA Journal 2015;13(11):4302)
Sandy loam	Menslage Germany	4.7	0-30	5.7	200.8	K1 0.1786 k2 0.0041 g 0.771	9.4	DFOP	
Loamy sand	Buchen Germany	6.4	0-30	40.9	187.3	K1 0.019 k2 2.3E-14 g 0.927	6.6	DFOP	
Sandy loam	Kleinzecher Germany	7.0	0-30	38.3	386.6	K1 0.0384 k2 0.0037 g 0.575	11.7	DFOP	
Loam	Unzhurst, Germany	6.7	0-30	27.7	122.3	k1 0.0280 k2 8.9E-4 g 0.922	8.4	DFOP	
Silt loam	Rohrbach Germany	8.5	0-30	20.1	66.9	k 0.0344	3.8	SFO Top down	
Clay loam	Herrngiers-dorf Germany	8.0	0-30	33.7	111.9	k 0.0206	10.6	SFO	
Sily loam	Wang-Inzkofen Germany	7.2	0-30	17.8	165.5	alpha 0.975 beta 17.207	8.7	FOMC	
Worst case kinetics for PEC$_{Soil}$ and as trigger for higher tier studies (n = 8)				**38.3**	**386.6**	k1 0.0384 k2 0.0037 g 0.575	DFOP Kleinzecher, Germany		
Maximum with regard to P-criterion (n = 8)				116.4	386.6	maximum overall DT$_{90}$ (DFOP)/3.32** trial Kleinzecher			
Geomean with regard to P-criterion (n = 8)				45.2	149.96	based on overall DT90/3.32**			

* Glyphosat-trimesium as test substance
****** according to EFSA DG SANCO working document on evidence needed to identify POP, PBT and vPvB properties for pesticides from 25.09.2012- rev.3

Table 8.4-2: Summary of aerobic degradation rates for AMPA - field studies: Triggering endpoints

AMPA, Field studies – Triggering endpoints									
Soil type	**Location**	**pH**	**Depth (cm)**	**DissT50 (d) actual**	**DT90 (d) actual**	**f.f.**	**St. (χ^2)**	**Method of calc.**	**Evaluated on EU level/ Reference**
Sandy loam	Kleinzecher, Germany	7.0	0-30	514.9	>1000	0.508	15.9	DFOP-SFO	Y/ EFSA Journal 2015;13(11):4302)
Loam	Unzhurst, Germany	6.7	0-30	633.1	>1000	0.332	13.3	DFOP-SFO	

Silt loam	Rohrbach, Germany	8.5	0-30	374.9	>1000	n.d.	8.6	SFO Top down	
Clay loam	Herrngiers-dorf, Germany	8.0	0-30	288.4	958.1	n.d.	10.9	SFO Top down	
Silt loam	Wang-Inzkofen, Germany	7.2	0-30	283.6	942.3	0.547	15.6	FOMC-SFO	
Maximum (n=5)				**633.1**	**>1000**		SFO Unzhorst, Germany		
Arithmetic mean (n = 3)						0.462			

Soil accumulation and plateau concentration: no experimental data; calculation of plateau concentration see $PEC_{Soil.}$

8.4.1.2 MCPA

No reliable data available.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Glyphosate:

Maximum DT90 value of 386 days exceeds the trigger of 365 days and justifies the consideration of an accumulation potential of glyphosate in soil.

MCPA:

DT_{90lab} value are below of 365 days, no soil accumulation testing is required.

8.5 Mobility in soil (KCP 9.1.2)

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

Reference to:

- Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302);
- RAR Glyphosate- Annex B.8: Environmental fate and behaviour (2013);
- Report and proposed decision of Italy, made to the European Commision under 91/414/EEC (2001) for MCPA

8.5.1 Glyphosate and its metabolites

Glyphosate and AMPA exhibit low mobility or be immobile in soil.

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

Glyphosate								
Soil Type	**OC %**	**Soil pH (H2O)**	**Kd (mL/g)**	**Koc (mL/g)**	**Kf (mL/g)**	**Kfoc/Kdoc (mL/g)**	**1/n**	**Evaluated on EU level / Reference**
Drummer, silty clay loam	1.45	6.5			324.0	22300	0.92	Y/ EFSA Journal 2015;13(11):4302)
Dupo, silt loam	0.87	7.4			33.0	3800	0.80	
Spinks, loamy sand	1.10	5.2			660.0	60000	1.16	
Greenan sand, sand	0.80	5.7	263	32838	-	32838	1.00	
Auchincruive, sand loam	1.60	7.1	811	50660	-	50660	1.00	
Headley Hall,	1.40	7.8	50	3598	-	3598	1.00	

sandy clay loam								
Californian sandy soil, loamy sand	0.60	8.3	5	884	-	884	1.00	
Les Evouettes II, silt loam	1.40	6.1	48	3404	-	3404	1.00	
Darnconner sediment, loam (Sediment)	3.00	7.1	510	17010	-	17010	1.00	
Lilly Field, sand	0.29	5.7			64.0	22000	0.75	
Visalia, sandy loam	0.58	8.4			9.4	1600	0.72	
Wisborough Green, silty clay loam	2.26	5.7			470.0	21000	0.93	
Champaign, silty clay loam	2.15	6.2			700.0	33000	0.94	
18 Acres, sandy loam	1.80	7.4			90.0	5000	0.76	
Speyer 2.1, sand	0.62	6.5			29.5	4762	0.84	
Speyer 2.2, loamy sand	2.32	6.2			71.7	3091	0.84	
Speyer 2.3, loamy sand	1.22	6.9			37.7	3092	0.84	
Soil 2.1, sand	0.70	5.9	66.4	9486	-	9486	1.00	
Soil 2.3, loamy sand	1.34	6.3	76.5	5709	-	5709	1.00	
Soil F3, sandy loam	1.20	7.3	54.4	4533	-	4533	1.00	
Arithmetic mean (n = 20)						**15388**	**0.93**	
pH dependency						No	-	

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

AMPA						
Type	**OC %**	**Soil pH (H2O)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n**	**Evaluated on EU level / Reference**
SLI Soil #1, clay loam	2.09	7.7	77.1	3640	0.79	Y/ EFSA Journal 2015;13(11):4302)
SLI Soil #2, sand	18.68[1)]	4.7[1)]	1570.0[1)]	8310[1)]	0.9[1)]	
SLI Soil #4, sand	1.33	7.4	15.7	1160	0.75	
SLI Soil #5, clay loam	0.93	7.6	53.9	5650	0.79	
SLI Soil #9, loamy sand	1.57	6.3	110.0	6920	0.77	
SLI Soil #11, sand	0.29	4.6	73.0	24800	0.79	
Lilly Field, sand	0.29	5.7	133.0	45900	0.86	
Visalia, sandy loam	0.58	8.4	10.0	1720	0.78	
Wisborough Green, silty clay loam	2.26	5.7	509.0	22500	0.91	
Champaign, silty clay loam	2.15	6.2	237.0	11100	0.86	
18 Acres, sandy loam	1.80	7.4	74.2	4130	0.84	
Schwalbach, silt loam	1.59	6.1	137.4	8642	0.98	
Hofheim, silt loam	1.24	6.1	87.9	7089	0.92	
Bergen-Enkheim, silty clay	2.25	8.3	33.9	1507	0.91	
Soil 2.1, sand	0.90	5.8	16.7	1861	0.6650	
Soil 2.2, loamy sand	2.30	6.2	189.7	8248	0.5506	
Soil 3A, sandy silty loam	2.60	7.6	29.1	1119	0.67109	
Arithmetic mean (n = 16)				**9749**	**0.81**	
pH dependency				No	-	

1) Not included for calculation of statistics (mean values, correlations) due to high OC - content

8.5.2 MCPA

Agreed EU End-points used in the Evaluation

- SANCO/4062/2001 - final – 11/07/2008
- Draft Assessment Report for MCPA

End-Point	**MCPA**
Column leaching	No data available
Aged residues leaching	The radioactivity of aged MCPA residues was concentrated in the top soil layer. Leachate contamination: less than 1% of TAR.
Lysimetr studies	Less than 0.5% of MCPA residues were detected in the percolate in a 2 year period. Most of the residue (about 80% of the total found) was detected in the top soil layer 0-10 cm after 735 d

Summary

The mobility in soil of MCPA was evaluated during the Annex I Inclusion. No additional studies have been performed.

Conclusion/endpoint:

Table 8.5-3 K_{foc} and 1/n (Freundlich exponent) values for MCPA in different sets of soils

Soil Selection	K_{foc} [mL/g]			1/n		
	range	mean	median	range	mean	median
American soils (n=8)	10-157	74	-	0.50-0.72	0.68	-

The results of soil adsorption / desorption studies indicate that MCPA is not strongly absorbed to the soil and has a potential to migrate through light soils of low organic matter content if rain or irrigation occurs shortly after application of the chemical. Potential for migration at later times will depend on the rate of MCPA application, rate of MCPA degradation by the soil and the extent to which MCPA is stabilized by soil and made unavailable to the leaching process.

This possible potential to migrate through light soils has been examined more precisely in aged soil leaching columns and lysimeter studies., the results showed that MCPA residues are concentrated in the top 10 cm soil layer. No parent compounds were found in the leachate. Although MCPA has been characterized as potentially mobile in soil in laboratory adsorption studies, the lysimeter results indicate that MCPA degrades more rapidly in the soil than it moves downwards.

pH dependence: yes. less adsorption with pH increase. This effect is likely to be significant only at pH values, about 4.

The adsorption depends on soil pH. Koc and 1/n separately from soils of pH < 7 and pH ≥ 7 are presented in table below.

Table 8.5-4 K_{foc} and 1/n (Freundlich exponent) values for MCPA in different sets of soils

Soil Selection	pH	K_{foc} [mL/g]		1/n	
		range	mean	range	mean
American soils n =4	< 7	33-157	80.25	0.70-0.721	0.72
American soils n =4	≥ 7	9.6-60	38.4	0.50-0.72	0.65

8.5.3 Column leaching (KCP 9.1.2.1)

- Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302);
- RAR Glyphosate- Annex B.8: Environmental fate and behaviour (2013);
- Report and proposed decision of Italy, made to the European Commision under 91/414/EEC (2001) for MCPA

A. Glyphosate and its metabolite

Reliable adsorption coefficients of the active substance were obtained by adsorption/desorption studies and, consequently, no column leaching studies are to be conducted.
During the 2001 EU evaluation of glyphosate, acceptable column leaching studies, soil thin layer chromatography study and column leaching study were submitted. Based on these studies, glyphosate possesses very low potential for leaching.

Column leaching	**1st study (glyphosate):** 7 soils, Eluation : 508 mm water Leachate: 0.03 - 6.56% of applied radioactivity in leachate **2nd study (glyphosate):** 3 soils, Eluation: 200 mm water Leachate: 0.12 - 1.45% of applied radioactivity in leachate **3rd study (glyphosate):** 3 soils Leachate: <1 µg/L - 2.6 µg/L glyphosate derivatives **4th study (glyphosate trimesium):** 3 soils, Eluation: 200 mm water Leachate: <2% of applied glyphosate-trimesium	
Aged residues leaching	**1st study (glyphosate):** 1 sand soil Aged for (d): 8 days Eluation (mm): 380mm over 48 h ^{14}C distribution after 8 days: Glyphosate: 48.6% of applied radioactivity, AMPA: 21.45% of applied radioactivity, non-extractable: 1.65% of applied radioactivity, CO2: 2.35% of applied radioactivity **2nd study (glyphosate-trimesium):** 1 sand soil Aged for (d): 30 d Eluation (mm): 200 mm water over 48 h ^{14}C distribution after 30 days: Glyphosate-14C: 52 % extractable (AMPA 26 %), 12 % unextractable, 33 % CO2; TMS-14C: 10 % extractable, 21 % unextractable, 57 % CO2 0.1% / 0.5% (Glyphosate /TMS) of applied radioactivity in leachate	Y/ EFSA Journal 2015;13(11):4302)

B. MCPA

No reliable data available.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

No reliable data available

8.5.5 Field leaching studies (KCP 9.1.2.3)

No reliable data available

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.

Reference to:

- Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302);
- Addendum to RAR Glyphosate- Annex B.8: Environmental fate and behaviour (2015);
- Report and proposed decision of Italy, made to the European Commision under 91/414/EEC (2001) for MCPA

8.6.1 Glyphosate and its metabolites

Glyphosate partitioned in the sediment to a substantial extent (max 61.4 % AR after 14 d). The persistence of glyphosate in these systems was relatively variable going from moderate to high persistence (DT50 whole system (SFO) = 13.82 d to > 301 d). Two major metabolites were found in the water phase: AMPA (max. 15.7 % AR after 14 d) and HMPA (max. 10.0 % AR after 61 d). Only the metabolite AMPA exceeded 10 % AR in the sediment (max. 18.7 % AR after 58 d).

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

Glyphosate, Distribution (max. sediment 61.4 % after 14 days)							
System	**Persistence endpoints at Level P-I**				**Modelling endpoints at Level P-I**		**Evaluated on EU level / Reference**
	Model	**DT50[4)] (days)**	**DT90[4)] (days)**	**SFO DT50[4)] (days)**	**Model**	**SFO DT50[4)] (days)**	
Total system							
Cache	FOMC	8.47	45.89	13.82[5)]	FOMC	13.82[1)]	Y/ EFSA Journal 2015;13(11):4302)
Putah	DFOP	210.66	976.54	294.14[5)]	DFOP	329.85[2)]	
Loamy Sediment	FOMC	70.48	∞	-[6)]	-[3)]	-[3)]	
Sandy Sediment	HS	16.03	346.81	104.465)	HS	154.19[2)]	
Creek	SFO	16.78	55.74	16.78	SFO	16.78	
Pond	HS	67.45	281.39	84.76[5)]	HS	92.42[2)]	
TNO	FOMC	93.06	> 1000	>301.20[5)]	-[3)]	-[3)]	
Kromme Rijn	DFOP	28.86	232.92	70.16[5)]	DFOP	88.67[2)]	
	Minimum	-	-	13.82	13.82	13.82	
	Maximum	-	-	301.20	329.85	301.20	
Geometric mean (n = 7/6[8)])		-	-	74.52		**67.74**	
Water phase							
Cache	HS	4.98	26.84	8.08[5)]	SFO	6.94	Y/ EFSA Journal 2015;13(11):4302)
Putah	FOMC	8.25	72.40	21.81[5)]	FOMC	21.81[1)]	
Loamy Sediment	FOMC	1.06	24.11	7.26[5)]	FOMC	7.26[1)]	
Sandy Sediment	DFOP	22.63	6.82[5)]	DFOP	6.821	22.63	
Creek	SFO	43.67	13.15	SFO	13.15	43.67	
Pond	HS	26.89	8.105)	HS	8.101)	26.89	
TNO	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
Kromme Rijn	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
	Minimum	-	-	6.82		6.82	
	Maximum	-	-	21.81		21.81	
Geometric mean (n =6)		-	-	9.88		**9.63**	
Sediment phase							
Cache	SFO						Y/

Glyphosate, Distribution (max. sediment 61.4 % after 14 days)							
Putah	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	EFSA Journal 2015;13(11):4302)
Loamy Sediment	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
Sandy Sediment	FOMC	383.86	∞	-[3)]	-[3)]	-[3)]	
Creek	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
Pond	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
TNO	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
Kromme Rijn	SFO	75.61	251.16	75.61	SFO	75.61	
Minimum		-	-	34.05		34.05	
Maximum		-	-	75.61		75.61	
Geometric mean (n = 2)		-	-	-[7)]		-[7)]	

1) Back-calculated from DT90 of bi-phasic model (DT90/3.32)
2) Calculated from slower k-rate
3) no reliable fit achieved
4) DT50 = degradation DT50 for total system, Dissipation DT50 for water and sediment phase
5) Back-calculated SFO to derive endpoints for P criteria (SFO DT50 = DT90/3.32)
6) Back-calculation of SFO DT50 not possible
7) Not calculated, since a sufficient number of DT50 values were not available
8) Number of values for deriving persistence endpoint (SFO DT50) and the modelling endpoint

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

AMPA, Distribution (max. 15.7 % AR in water after 14 days, max. 18.7 % AR in sediment after 58 days							
System	**Persistence endpoints at Level P-I**				**Modelling endpoints at Level P-I**		**Evaluated on EU level / Reference**
	Model	**DT50[4)] (days)**	**DT90[4)] (days)**	**SFO DT50[4)] (days)**	**Model**	**SFO DT50[4)] (days)**	
Total system							
Rückhaltebecken	FOMC	13.80	1513.00	455.72[5)]	DFOP	102.87[2)]	Y/ EFSA Journal 2015;13(11):4302)
Schäphysen	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
Bickenbach	HS	10.54	191.25	57.61[5)]	HS	77.83[2)]	
Unter-Widdersheim	HS	77.36	307.19	92.53[5)]	HS	98.98[2)]	
Bickenbach	HS	44.53	205.21	61.81[5)]	HS	69.31[2)]	
Unter-Widdersheim	FOMC	20.13	885.03	266.58[5)]	-[3)]	-[3)]	
A	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	-[3)]	
B	-[6)]	-[6)]	-[6)]	-[6)]	-[6)]	-[6)]	
Minimum		-	-	57.61		69.31	
Maximum		-	-	455.72		102.87	
Geometric mean (n = 5/4[7)])		-	-	131.97		**86.09**	
Water phase							
Rückhaltebecken	FOMC	2.20	22.50	6.78[5)]	FOMC	6.78[1)]	Y/ EFSA Journal 2015;13(11):4302)
Schäphysen	FOMC	1.00	7.80	2.35[5)]	FOMC	2.35[1)]	
Bickenbach	DFOP	2.54	47.57	14.33[5)]	DFOP	14.33[1)]	
Unter-Widdersheim	FOMC	2.13	26.31	7.92[5)]	FOMC	7.92[1)]	
Bickenbach	DFOP	6.59	51.47	15.50[5)]	DFOP	15.50[1)]	
Unter-Widdersheim	HS	2.02	17.15	5.17[5)]	HS	5.17[1)]	

AMPA, Distribution (max. 15.7 % AR in water after 14 days, max. 18.7 % AR in sediment after 58 days							
A	FOMC	0.69	8.87	2.67[5]	FOMC	2.67[1]	
B	DFOP	1.28	6.87	2.07[5]	DFOP	2.07[1]	
Minimum		-	-	2.07		2.07	
Maximum		-	-	15.50		15.50	
Geometric mean (n = 8)		-	-	5.47		**5.47**	
Sediment phase							
Rückhaltebecken	-[3]	-[3]	-[3]	-[3]	-[3]	-[3]	Y/ EFSA Journal 2015;13(11):4302)
Schäphysen	-[3]	-[3]	-[3]	-[3]	-[3]	-[3]	
Bickenbach	-[8]	-[8]	-[8]	-[8]	-[8]	-[8]	
Unter-Widdersheim	-[8]	-[8]	-[8]	-[8]	-[8]	-[8]	
Bickenbach	-[3]	-[3]	-[3]	-[3]	-[3]	-[3]	
Unter-Widdersheim	-[3]	-[3]	-[3]	-[3]	-[3]	-[3]	
A	-[3]	-[3]	-[3]	-[3]	-[3]	-[3]	
B	-[6]	-[6]	-[6]	-[6]	-[6]	-[6]	

1) Back-calculated from DT90 of bi-phasic model (DT90/3.32)
2) Calculated from slower k-rate
3) no reliable fit achieved
4) DT50 = DegT50 for total system but DT50 for water and sediment phase
5) Back-calculated SFO to derive endpoints for P criteria (SFO DT50 = DT90/3.32)
6) excluded from kinetic evaluation due to analytical problems
7) Number of values for deriving persistence endpoint (SFO DT50) and the modelling endpoint
8) excluded from kinetic evaluation due to different amounts of AMPA in the sediment reported in the study

Table 8.6-3: Summary of observed metabolites - Water/sediment system

AMPA	Distribution: max. 15.7 % AR in water after 14 days max. 18.7 % AR in sediment after 58 days	Y/ EFSA Journal 2015;13(11):4302)
HMPA	Distribution: 10.0 % & 7.5 % max. in water after 61 and 100 days (consecutive data points)	

8.6.2 MCPA

Show that MCPA is stable in aqueous buffered solutions at pH between 5 to 9. No significant degradation of MCPA acid was observed and no degradation products were detected.

Photolysis is a major route of degradation for MCPA in a sterile aqueous buffer system at pH 5 and 25°C. Half-life is 25.3 days.

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

RMS comments

The submitted calculations were accepted.
The used endpoints for both active substance and metabolites were agreed at the EU level.

The risk envelope approach was considered for proposed pattern use (No 1, 3 and 5); the maximum application rates of 720 g MCPA/ha and 2080 g glyphosate/ha were taken for PECsoil assessment. It covers the lower rates of 450 g/ha and 630 g/ha of MCPA and 1300 g/ha and 1820 g/ha of glyphosate, use No 2 and 4.
The interception of 40% was taken for PECs assessment. This approach was accepted.

Glyphosate. The relevant metabolite of glyphosate, AMPA, was considered in accordance with EFSA conclusion (2015). The application rate of metabolite AMPA based on max dose of glyphosate (2080 g a.s./ha) and max occurrence (58.3%) should be 728 g/ha, not 735 g/ha as it was assumed by Applicant, but this higher value represents a worse case and was accepted.

MCPA. The submitted calculations for active substance were accepted. No metabolites of MCPA was considered (SANCO/4062/2001 - final – 11/07/2008). The metabolite 4C2M need not to be considered as the maximum observed occurrence in soil is 3.9%. and no PECsoil calculations were performed.

The formulation was considered too.

The maximum PEC_S values are presented below:

Crop group	Glyphosate	AMPA	MCPA	Formulation
	PEC_S [mg ai/kg]			
Cereals	1.664	0.588 1.784*	0.576	7.315

* $PEC_{accumulation}$ after 20 years

These values will be used in further risk assessment.

8.7.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.
ORKAN 350 SL was not assessed as representative formulation. PEC_{soil} was calculated according to endpoints for Glyphosate and MCPA and submitted for ORKAN 350 SL.

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	Orchards
Application rate (g as/ha)	8 L/ha Glyphosate 2.08 kg/ha: MCPA: 0.72 kg/ha
Number of applications/interval	1/0
Crop interception (%)	40

Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)

PEC_{soil} of metabolites

For the metabolites initial PEC_{soil} was calculated according to the following equation:

PECs (initial) = (Max. PECs (parent) x Max. metabolite occurence x Molar weight fraction)/100

$$A_{metabolite} = A_{perent} \times (\text{Max. metabolite occurence} \times \text{Molar weight fraction})/100$$

Where:

A_{perent} - Application rate of the parent
$A_{metabolite}$ - Equivalent application rate of the metabolite [g/ha]

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

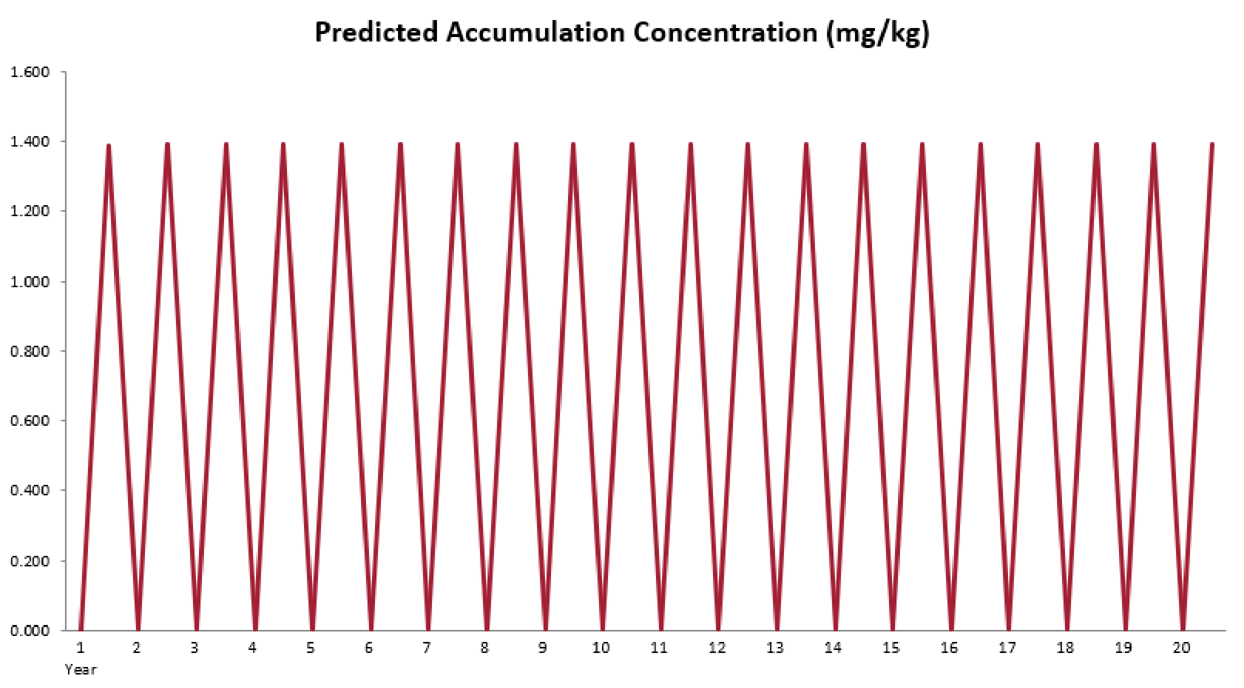
Compound	Molecular weight (g/mol)		Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Glyphosate	169.07	1	100 %	38.3	EFSA Journal 2015;13(11):4302
AMPA	111.04	0.657	53.8 %	633	
MCPA	200.6	1	100%	24	SANCO/4062/2001-final

8.7.2.1 Glyphosate and its metabolite

Table 8.7-3: PEC_{soil} for glyphosate on orchards

PEC_{soil} (mg/kg)		Orchards	
		Single application	
		Actual	TWA
Initial		1.664	1.664
Short term	24h	1.634	1.649
	2d	1.605	1.634
	4d	1.548	1.605
Long term	7d	1.466	1.563
	14d	1.292	1.470
	21d	1.138	1.384
	28d	1.002	1.305
	50d	0.673	1.095
	100d	0.272	0.769
Plateau concentration (5cm) after year 20		0.002	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		1.666	-

Figure 1 Saw-teeth curve showing PEC_S concentrations of glyphosate following subsequently single annual applications of ORKAN 350 SL on Orchards.

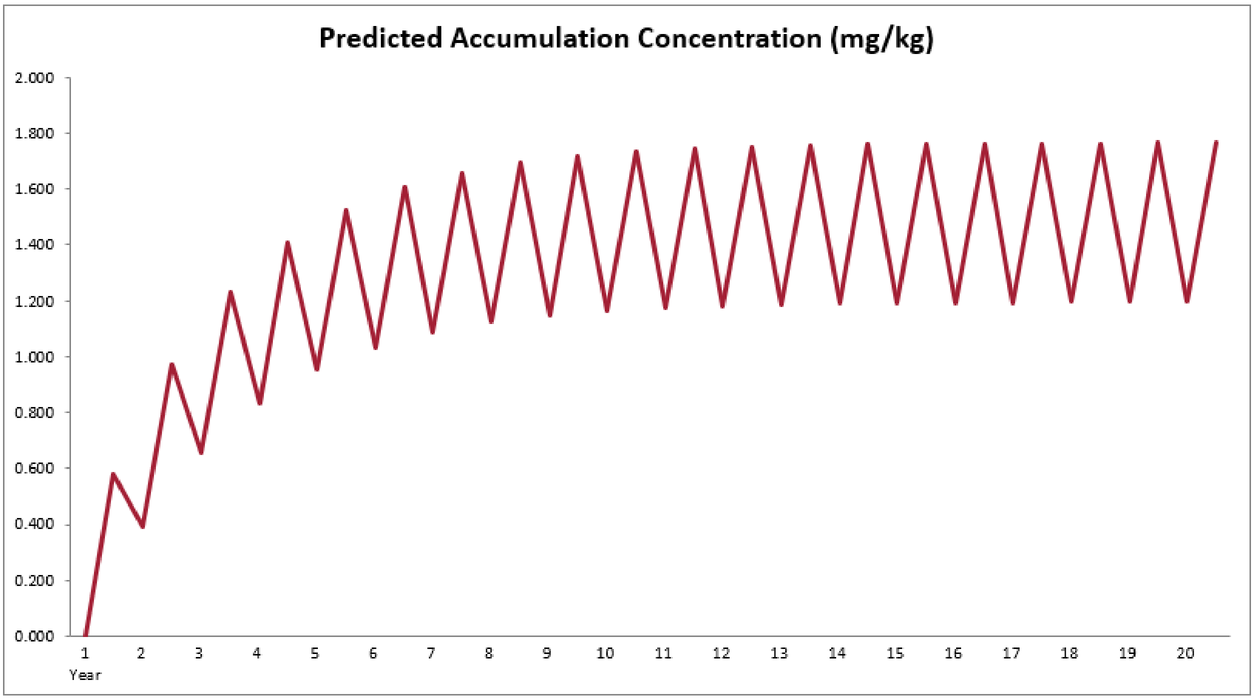


PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for AMPA on orchards

PEC_{soil} (mg/kg) Application 735 g/ha		Orchards	
		Single application	
		Actual	TWA
Initial		0.588	0.588
Short term	24h	0.587	0.588
	2d	0.587	0.587
	4d	0.585	0.587
Long term	7d	0.584	0.586
	14d	0.579	0.584
	21d	0.575	0.581
	28d	0.570	0.579
	50d	0.557	0.572
	100d	0.527	0.557
Plateau concentration (5cm) after year 20		1.196	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)		1.784	-

Figure 2 Saw-teeth curve showing PEC_S concentrations of AMPA following subsequently single annual applications of ORKAN 350 SL on Orchards.



8.7.2.2 MCPA

Table 8.7-5: PEC_{soil} for MCPA on orchards

PEC_{soil} (mg/kg) Application 735 g/ha		Orchards	
		Single application	
		Actual	TWA
Initial		0.576	0.576
Short term	24h	0.560	0.568
	2d	0.544	0.560
	4d	0.513	0.544
Long term	7d	0.471	0.522
	14d	0.384	0.474
	21d	0.314	0.432
	28d	0.257	0.395
	50d	0.136	0.305
	100d	0.032	0.188
Plateau concentration (5cm) after year 20		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		0.576	-

8.7.2.3 PEC_{soil} of ORKAN 350 SL

Table 8.7-6: PEC_{soil} for ORKAN 350 SL on Orchards

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
ORKAN 350 SL	~~8000~~ 9144	~~6.4~~ 7.315*	---	---	~~6.4~~
Glyphosate	2080	1.664	1.384	0.002	1.666
MCPA	720	0.576	0.432	---	0.576

* density of 1.143 g/mL based on data presented in Section 1

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

Evaluator's Comments:	The calculations have been done in accordance with FOCUS Groundwater guidelines. Models FOCUS-PEARL and FOCUS-PELMO have been used. For formulation application in orchards the winter cereals with relevant interception were taken into consideration. For winter cereals spring application was considered. **Glyphosate**. The relevant parameters have been taken according to List of Endpoints. An active substance and its metabolite AMPA were taken into consideration. For glyphosate the PECgw values were < 0.001 µg a.s./L, below the trigger value of 0.1 µg/L. **AMPA**: The PECgw values are below the trigger value 0.1 µg/L; **MCPA**. The Applicant has proposed to consider the Koc dependent on pH (neutral to alkaline soils with Koc = 38.8 mL/g and acidic soil with Koc = 80.25 mL/g). In List of Endpoints agreed at the EU level (2003) the arithmetic mean Koc value of 74 mL/g was calculated. In accordance with FOCUS GW guidance the geometric mean is recommended to use in PECgw assessment. The geometric mean value of 56.6 mL/g was calculated. The difference in Koc values does not affect the final results. This approach was accepted. The PECgw were recalculated by evaluator considering the max application rate of 0.72 kg a.s./ha. For PECgw assessment the DT_{50} in soil of 31.6 d (from route of degradation study, normalized to 20ºC, pF2, Q_{10} 2.58) was taken. The metabolite 4C2M were also taken into consideration with following input parameters:

Compound	4C2M	Value in accordance with EU endpoint Reference*
Molecular weight (g/mol)	142.6	DAR, Addendum October 2003, SANCO/4062/2001-final (11/07/2008) and 4C2M OECD SID
Water solubility (g/L):	2.3 @ 20ºC	
Saturated vapour pressure (Pa):	26.66 @ 25ºC	
DT_{50} in soil (d)	21	

K_{foc} (mL/g)/K_{fom}	400/232	
1/n	1 (worst case)	
Plant uptake factor	0	
Formation fraction	1 (default)	

The PECgw values for MCPA on winter cereals are presented in following table

pH < 7; Koc = 80.25 mL/g

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		MCPA		4C2M	
		PEARL	PELMO	PEARL	PELMO
Winter cereals	Châteaudun	<0.001	<0.001	<0.001	0.006
	Hamburg	<0.001	<0.001	<0.001	0.003
	Jokioinen	<0.001	<0.001	0.176	0.003
	Kremsmünster	<0.001	< 0.001	<0.001	0.003
	Okehampton	<0.001	<0.001	<0.001	0.004
	Piacenza	<0.001	<0.001	<0.001	0.003
	Porto	<0.001	<0.001	<0.001	0.002
	Sevilla	<0.001	<0.001	0.0935	0.026
	Thiva	<0.001	<0.001	<0.001	0.016

pH ≥ 7; Koc = 38.4 mL/g

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)			
		MCPA		4C2M	
		PEARL	PELMO	PEARL	PELMO
Winter cereals	Châteaudun	<0.001	<0.001	<0.001	0.006
	Hamburg	<0.001	<0.001	<0.001	0.004
	Jokioinen	<0.001	<0.001	0.209	0.002
	Kremsmünster	<0.001	0.001	<0.001	0.005
	Okehampton	<0.001	<0.001	<0.001	0.002
	Piacenza	<0.001	0.001	<0.001	0.003
	Porto	<0.001	<0.001	<0.001	0.003
	Sevilla	<0.001	<0.001	0.149	0.026
	Thiva	<0.001	<0.001	<0.001	0.017

Results.

MCPA. PECgw < 0.001 µg a.s./L, are below the trigger value of 0.1 µg/L for alkaline, neutral and acidic soils. The consideration of pH dependence of Koc does not affect the final conclusion.

4C2M: The PECgw value is below the trigger value.

8.8.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.
ORKAN 350 SL was not assessed as representative formulation. PEC_{GW} was calculated, using PEARL 4.4.4 and PELMO 5.5.3, according to endpoints for Glyphosate and MCPA and their metabolites and submitted for ORKAN 350 SL.

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 - Orchards
Crop	Winter cereals*
Application rate (g as/ha)	8 L/ha Glyphosate 2.08 kg/ha: MCPA: 0.72 kg/ha
Number of applications/interval (d)	1/0
Application date used for calculations	01 June
Crop interception (%)	40
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,

*Since product is to be used as a weed killer, calculations were performed using winter cereals instead of pome fruits.

8.8.2.1 Glyphosate and its metabolite

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

Parameter	Compounds		Value in accordance with EU endpoint y/n/ Reference*
	Glyphosate	AMPA	
Physico-Chemical parameters			
Molecular weight [g mol^{-1}]	169	111	Y/ EFSA Journal 2015;13(11):4302
Water solubility [mg L^{-1}] (20°C)	10500	10500	
Molar enthalpy of dissolution [kJ mol^{-1}]	27		FOCUS default
Vapor pressure [Pa] (25°C)	1.31×10^{-5}	1.31×10^{-5}	Y/ EFSA Journal 2015;13(11):4302
Molar enthalpy of vaporization [kJ mol^{-1}]	95		FOCUS default
Diffusion coefficient in water [m² d^{-1}]	4.3×10^{-5} (20°C)		FOCUS default
Diffusion coefficient in gas [m² d^{-1}]	0.43 (20°C)		FOCUS default
Degradation in soil			
DT_{50} soil [d] (geomean)	20.51	88.84	Y/ EFSA Journal 2015;13(11):4302 Geometric mean of the DT_{50} values of all soils
Reference temperature Q10	20 2.58	20 2.58	FOCUS default
Molar activation energy [kJ mol $^{-1}$]	65.4		FOCUS default
Moisture correction function	pF 2		FOCUS default

Parameter	Compounds		Value in accordance with EU endpoint y/n/ Reference*
	Glyphosate	AMPA	
Reference moisture [-]	0.7		
Sorption to soil			
Koc (mL/g)	15388	9749	Y/ EFSA Journal 2015;13(11):4302
$K_{f,om}$ [mL g^{-1}] (mean Koc/1.724)	8925.75	5652.55	
Freundlich exponent 1/n [-]	0.93	0.81	
Method of sorption subroutine description	*No pH independent*	*No pH independent*	
Crop/ Management related parameters			
Crop uptake factor [-]	0	0	Worst case assumption; FOCUS default

Table 8.8-3: PEC$_{gw}$ for glyphosate and AMPA in Orchards (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		FOCUS PEARL 4.4.4		FOCUS PELMO 5.5.3	
		Glyphosate	AMPA	Glyphosate	AMPA
Orchards	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001

The PECgw were calculated for the highest application rate recommended for use in orchards applied for 8 L/ha ~~kg/ha~~. Obtained PECgw of glyphosate and its metabolite AMPA in each scenario and for the recommended use of ORKAN 350 SL are significant below the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.

8.8.2.2 MCPA

Table 8.8-4: Input parameters related to active substance MCPA for PEC$_{gw}$ calculations

Parameter	Compounds	Value in accordance with EU endpoint y/n/ Reference
	MCPA	
Physico-Chemical parameters		
Molecular weight [g mol^{-1}]	200.6	MCPA SANCO 4062/2001-final, 11 July 2008
Water solubility [mg L^{-1}] (20°C)	293900	
Molar enthalpy of dissolution [kJ mol^{-1}]	27	FOCUS default
Vapor pressure [Pa] (30°C)	4.0E-4	MCPA SANCO 4062/2001-final, 11 July

Parameter	Compounds		Value in accordance with EU endpoint y/n/ Reference
	MCPA		
			2008
Molar enthalpy of vaporization [kJ mol^{-1}]	95		FOCUS default
Diffusion coefficient in water [m² d^{-1}]	4.3 x 10^{-5} (20°C)		
Diffusion coefficient in gas [m² d^{-1}]	0.43 (20°C)		
Degradation in soil			
DT_{50} soil [d] (geomean)	24		MCPA SANCO 4062/2001-final, 11 July 2008
Reference temperature Q10	20 2.58		FOCUS default
Molar activation energy [kJ mol $^{-1}$]	65.4		FOCUS default
Moisture correction function Reference moisture [-]	pF 2 0.7		FOCUS default
Sorption to soil			
	pH <7	pH≥7	DAR for MCPA– average value 2008
Koc (mL/g)	80.25	38.4	
$K_{f,om}$ [mL g^{-1}] (mean Koc/1.724)	46.55	22.27	
Freundlich exponent 1/n [-]	0.72	0.65	
Crop/ Management related parameters			
Crop uptake factor [-]	0		Worst case assumption; FOCUS default

Table 8.8-5: PEC$_{gw}$ for MCPA on Orchards (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

~~Crop~~	~~Scenario~~	~~80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)~~	
		~~MCPA~~	
		~~FOCUS PEARL 4.4.4~~	~~FOCUS PELMO 5.5.3~~
~~Orchards pH <7~~	~~Châteaudun~~	~~< 0.001~~	~~< 0.001~~
	~~Hamburg~~	~~0.241~~	~~< 0.001~~
	~~Jokioinen~~	~~2.391~~	~~< 0.001~~
	~~Kremsmünster~~	~~0.085~~	~~< 0.001~~
	~~Okehampton~~	~~0.068~~	~~< 0.001~~
	~~Piacenza~~	~~< 0.001~~	~~< 0.001~~
	~~Porto~~	~~< 0.001~~	~~< 0.001~~
	~~Sevilla~~	~~< 0.001~~	~~< 0.001~~
	~~Thiva~~	~~< 0.001~~	~~< 0.001~~
~~Orchards ph>7~~	~~Châteaudun~~	~~0.002~~	~~< 0.001~~
	~~Hamburg~~	~~1.906~~	~~< 0.001~~

	Jokioinen	6.105	< 0.001
	Kremsmünster	0.462	< 0.001
	Okehampton	0.900	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

The PECgw were calculated for the highest application rate recommended for use in orchards applied for 8 kg/ha. Obtained PECgw values of MCPA for the recommended use of ORKAN 350 SL are over the trigger value of 0.1 µg/L in scenarios recommended for Poland (Chateaudun, Hamburg and Kremsmünster). However, this calculations are performed for Tier 1 representing the worst case with inappropriate conditions. According to higher tier level studies (field studies) performed with MCPA, there is no possibility to contaminate ground water using ratios as proposed in GAP.

In field study (Kubiak R., 1991) during two years, using 2000 g of MCPA/ha on both acidic and basic soil, (pH 6.1 and 7.1, respectively) most of residues was accumulate in top 10 cm of soil and no residues was detected in percolate. Therefore the groundwater concentration of MCPA in natural conditions should be much lower than calculated and pose no risk for contamination when ORKAN 350 SL is used annually according to GAP. According to this study MCPA degrades more rapidly in the soil than it moves downwards and it is no as mobile as it was shown in laboratory studies.

Additionally, according to aged residue column leaching (Zohner A., 1988) most of residues was concentrated in the top 5 cm of the soil. The leachate fraction contained 0.02% of originally applied substance, and half-life time of aerobic soil metabolism of approximately 2 weeks were reported (what is much lower than 24 days used for calculations) and is possibly connected with microflora activity.

In another studies (Goodwin P.A. and Laskowski D.A., 1988; Fernando T.R. 1992) strong correlation between rising of adsorption and decreasing concentration of MCPA was shown. Therefore, most of substance is quickly degraded in top soil layer and it adsorption rises. That prevents leaching to groundwater.

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

zRMS Comments:	The submitted PECsw/sed assessment was accepted. All used endpoints were agreed at the EU level or recalculated based on EU data. The calculations have been done in accordance with FOCUS Surface water guidelines. Models Step 1 & 2 and Step 3 and Step 4 have been used. As the herbicide formulation is used to weeds control in orchards – a surrogate crop was used in PECsw assessment. As in PECgw subsection, the winter cereals in spring use with relevant interception were taken into consideration. Drift, drainage and runoff as a main exposure route were considered. All relevant scenarios were taken into consideration and according to national requirements scenarios D3, D4 and R1. The endpoints for both active substances and their metabolite used in modelling were accepted. Relevant metabolites of both active substances were taken into consideration in Step 1 and 2. **Glyphosate.** The PECsw assessment was provided in Step 1 and was sufficient. The relevant PECsw and PECsed values for active substance and its metabolites are provided in the table below.

Substance	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
Glyphosate	51.35	5040
AMPA	29.42	2540
HMPA	20.96	202.22

MCPA. In PECsw assessment the Applicant has proposed to consider the Koc dependent on pH (neutral to alkaline soils with Koc = 38.8 mL/g and acidic soil with Koc = 80.25 mL/g) as in PECgw assessment. This approach was accepted.
Comparing the final results of PECsw assessment in Step 4 with VFSmod, the consideration of pH dependence of Koc does not affect the final conclusion.

The PECsw assessment was provided in Step 4 with mitigation measures.

Substance	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
	10m vbs with 10 m nss	
MCPA	0.5843	0.0810

4C2M. The metabolite 4C2M was taken into consideration by evaluator with following input parameters:

Compound	4C2M	Value in accordance with EU endpoint Reference*
Molecular weight (g/mol)	142.6	DAR, Addendum October 2003, SANCO/4062/2001-final (11/07/2008) and 4C2M OECD SID
Water solubility (g/L):	2.3 @ 20ºC	
Saturated vapour pressure (Pa):	26.66 @ 25ºC	
DT_{50} in soil (d)	21	
$DT_{50,water}$ (d)	21	
$DT_{50,sed}$ (d)	1000	
$DT_{50,whole\ system}$ (d)	21	
Maximum occurrence observed (% molar basis with respect to the parent)	Water: 11.6*** Sediment: - Total system: 11.6	

PECsw values of 4C2M assessed in Step 1 and Step 2 are presented in table below:

Scenario	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	17.76	68.85
Step 2	2.85	11.23

Formulation

The PEcsw for formulation was accepted. The use pattern of formulation solo (max 8 L prod/ha) was used in drift exposure assessment and 1 m of non-spray buffer strip as a mitigation measure was proposed:

- 1 m of NSB: PECsw = 58.75 µg/L.

The final mitigation measures are proposed in Section 9.
The PEC_{SW} values for active substance and its metabolites will be used for further risk assessment

8.9.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.
ORKAN 350 SL was not assessed as representative formulation. PEC_{SW} was calculated, using SWASH 5.3, according to endpoints for Glyphosate and MCPA and their metabolites and submitted for ORKAN 350 SL.

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

Use No.	1 - Orchards
Crop	Winter cereals*
Application rate (kg as/ha)	Glyphosate: 2.08 MCPA: 0.72

Number of applications/interval (d)	1/0
Application window	Mar. – May/ June – Sep.
Application method	Ground spray
Models used for calculation	STEPS1-2 ver.3.2 FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1 FOCUS SWAN 5.1

*Since product is to be used as a weed killer, calculations were performed using winter cereals instead of pome fruits.

Crop	**Scenario**	**Application window used in STEP 3 modelling**
Orchards*	D1	01.03- 30.10
	D2	01.03- 30.10
	D3	01.03- 30.10
	D4	01.03- 30.10
	D5	01.03- 30.10
	D6	01.03- 30.10
	R1	01.03- 30.10
	R2	01.03- 30.10
	R3	01.03- 30.10
	R4	01.03- 30.10

*Since the product could be used always during weeds growth period, then wide range of date was used as a possible application date

8.9.2.1 Glyphosate and its metabolites

Table 8.9-2 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration
Glyphosate	**67 µg/L**
AMPA	**1000 µg/L**
HMPA	**1000 µg/L**

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

Compound	Glyphosate	AMPA	HMPA	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	169.07	111	112	Y/EFSA Journal 2015;13(11):4302

Compound	Glyphosate	AMPA	HMPA	Value in accordance to EU endpoint y/n/ Reference
Saturated vapour pressure (Pa)	1.31 x 10^{-5} not required for Step 1+2/0			Worst case assumption.
Water solubility (mg/L) (20°C)	10500			Y/EFSA Journal 2015;13(11):4302
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3 x 10^{-5}			Default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/ 0.43			Default
K_{foc} (mL/g)/ K_{fom} (mL/g) K_{FOM} =K_{FOC} / 1.724	15388/8926	9749/5655	15388/8926	Y/EFSA Journal 2015;13(11):4302
Plant Uptake	not required for Step 1+2 0.5			Default
Wash-Off factor from Crop (m-1)	not required for Step 1+2/ 50			Default
Foliar half-life (day)	not required for Step 1+2/ 10 10			Default
$DT_{50,soil}$ (d) (Step 1, Step 2, Step 3)	20.51	88.84	1000	Y/EFSA Journal 2015;13(11):4302
$DT_{50,water}$ (d)	1000	86.09	1000	
$DT_{50,sed}$ (d)	67.74	86.09	1000	
$DT_{50,whole\ system}$ (d)	67.74	86.09	1000	
Maximum occurrence observed (% molar basis with respect to the parent)	-	Water: 27.1 Sediment: 27.1	Water: 10 Sediment: 10	

Table 8.9-4: FOCUS Step 1 PEC_{sw} and PEC_{sed} for Glyphosate following single application of ORKAN 350 SL in orchards

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	---	51.35	0	30.23	5040

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

For the intended uses of ORKAN 350 SL, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (green alga) in all FOCUS Steps 1-3 scenarios. Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies.

Table 8.9-5: FOCUS Step 1 PEC_{sw} and PEC_{sed} for AMPA following single applications of ORKAN 350 SL in orchards

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	---	29.42	0	24.24	2540

Table 8.9-6: FOCUS Step 1 PEC_{sw} and PEC_{sed} for HMPA following single applications of ORKAN 350 SL in orchards

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	---	20.96	0	20.11	202.22

8.9.2.2 MCPA

Table 8.9-7 Summary of input parameters of MCPA for PECsw and PECsed calculations

Parameter	Value	Source
Molecular weight [g/mol]	200.6	MCPA SANCO 4062/2001-final, 11 July 2008
Water solubility [mg /L]	293900 (25°C)	MCPA SANCO 4062/2001-final, 11 July 2008
Vapour pressure [Pa]	$4.0 \cdot 10^{-4}$ (30°C)	MCPA SANCO 4062/2001-final, 11 July 2008
DT_{50} soil [d]	24	MCPA SANCO 4062/2001-final, 11 July 2008
DT_{50} water [d]	13.5	MCPA SANCO 4062/2001-final, 11 July 2008
DT_{50} sediment [d]	~~16.9~~ 1000	MCPA SANCO 4062/2001-final, 11 July 2008
DT_{50} water/sediment system[d]	16.9	MCPA SANCO 4062/2001-final, 11 July 2008
K_{oc} [mL g^{-1}], soil pH<7	80.25	MCPA SANCO 4062/2001-final, 11 July 2008 and DAR for MCPA; mean of four K_{oc} values obtained in soils with pH<7
K_{om} [mL g^{-1}], soil pH<7	46.55	calculated Koc=1.724·Kom
Freundlich exponent 1/n [-], soil pH<7	0.72	MCPA SANCO 4062/2001-final, 11 July 2008 and DAR for MCPA; mean of four 1/n for K_{oc} values obtained in soils with pH<7
K_{oc} [mL g^{-1}], soil pH≥7	38.4	MCPA SANCO 4062/2001-final, 11 July 2008 and DAR for MCPA; mean of four K_{oc} values obtained in soils with pH≥7
K_{om} [mL g^{-1}], soil pH≥7	22.27	calculated Koc=1.724·Kom
Freundlich exponent 1/n [-], soil pH≥7	0.65	MCPA SANCO 4062/2001-final, 11 July 2008 and DAR for MCPA; mean of four 1/n for K_{oc} values obtained in soils with pH≥7

Table 8.9-8 Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (EFSA Journal)

Compound	Ecotoxicology lowest regulatory acceptable concentration (RAC)
MCPA	**15.2 µg/L (*Lemna gibba*)**

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for MCPA pH<7 following single application of ORKAN 350 SL to Orchards

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	---	223.42	0	149.36	173.98
Step 2					
Mar. – May/ June – Sep.	---	43.67 37.06	4	~~26.84~~ 25.56	~~33.73~~ 29.60
Step 3					
D3	ditch	4.547	~~60~~	0.1651	1.280
D4	pond	0.1594	~~60~~	0.1241	0.4051
D4	stream	3.607	~~60~~	0.06959	0.2286
R1	Pond	0.5756	~~32~~	0.4328	1.155
R1	stream	**20.96**	~~32~~	0.5493	4.857

Value above RAC, are bolded.

Since only presented scenarios are relevant for Poland, no more scenarios were calcluated

For the intended uses of ORKAN 350 SL, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (*Lemna gibba*) in one FOCUS Step 3 scenario (R1). Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies.

Table 8.9-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for MCPA pH <7 based on FOCUS Step 4 calculations and toxicity data for aquatics organisms with mitigation of spray drift and run-off for the use of ORKAN 350 SL in orchards

PEC_{sw} (µg/L)	Scenario	STEP 4 MCPA	
Nozzle reduction	Vegetative strip (m)	0	10
	No spray buffer (m)	10	10
None	D3 ditch	**0.6537**	**0.6537**
50 %		**0.3268**	---
None	D4 pond	**1.260**	**0.09991**
50 %		**0.09333**	---
None	D 4 stream	**0.6996**	**0.6996**
50 %		**0.3502**	---
None	R1 pond	**0.5350**	**0.09786**
50 %		**0.5018**	---
None	R1 stream	20.96	**0.5843**
50 %		20.96	---

RAC: Regulatory acceptable concentration

PEC/RAC ratios below the relevant trigger of 1 are shown in bold

Table 8.9-11: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for MCPA pH>7 following single application of ORKAN 350 SL to Orchards

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	---	234.93	0	157.28	87.67
Step 2					
Mar. – May/ June – Sep.	---	~~45.90~~ 38.92	~~4~~	~~28.15~~ 26.46	~~16.97~~ 14.90
Step 3					
D3	ditch	4.547	~~60~~	0.1651	1.128
D4	pond	0.1584	~~60~~	0.1235	0.3909
D4	stream	3.607	~~60~~	0.06582	0.2141
R1	pond	0.4770	~~32~~	0.3604	0.9368
R1	stream	**16.53**	~~32~~	0.4393	3.354

Since only presented scenarios are relevant for Poland, no more scenarios were calculated

For the intended uses of ORKAN 350 SL, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (*Lemna gibba*) in one FOCUS Step 3 scenario (R1). Therefore, risk mitigation assessment is necessary and PEC/RAC ratios were calculated considering reduced exposure of surface water bodies.

Table 8.9-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for MCPA pH>7 based on FOCUS Step 4 calculations and toxicity data for aquatics organisms with mitigation of spray drift and run-off for the use of ORKAN 350 SL in orchards

PEC_{sw} (µg/L)	Scenario	STEP 4 MCPA	
Nozzle reduction	Vegetative strip (m)	0	10
	No spray buffer (m)	10	10
None	D3 ditch	**0.6537**	**0.6537**
50 %		0.3268	---
None	D4 pond	**0.09892**	**0.09892**
50 %		0.08892	---
None	D 4 stream	**0.6992**	**0.6992**
50 %		0.3499	---
None	R1 pond	**0.4361**	**0.09787**
50 %		0.4027	---
None	R1 stream	16.53	**0.5843**
50 %		16.53	---

RAC: Regulatory acceptable concentration
PEC/RAC ratios below the relevant trigger of 1 are shown in bold

8.9.2.3 PECsw for formulation considering drift factor

RAC for formulation is 730 µg/L (*Pseudokirchneriella subcapitata*), whereas calculated concentration of formulation in water obtained using drift loading calculator is ~~62.5~~ 58.75 µg/L when using ~~0.75~~ 1 m mitigation distance. ~~(minimal available value)~~

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

Reference to:

- Peer review of the pesticide risk assessment of the active substance glyphosate (EFSA Journal 2015;13(11):4302);
- RAR Glyphosate - Volume 3. Annex B.8: Environmental fate and behaviour (2013);
- Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-D (EFSA Journal 2014;12(9):3812);
- Report and proposed decision of Italy, made to the European Commission under 91/414/EEC (2001) for MCPA

Table 8.10-1 Summary of atmospheric degradation and behaviour – glyphosate

Compound	Glyphosate
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	DT_{50} of 1.6 hours derived by the Atkinson model (version 1.92). OH (12h) concentration assumed = $1.5x10^{6} cm^{-3}$
Volatilisation	Volatilization from plants and soil surfaces (BBA guideline): not detectable after 24 hours (n = 2) Vapour pressure (Pa): 1.31×10^{-5} Pa at 25°C; Henry's Law Constant ($Pa.m^3/mol$): 2.1×10^{-7} Pa m^3 mol^{-1} (25 °C) Glyphosate trimesium: < 1×10^{-11} Pa (20 °C), Henry's Law Constant: < 2×10^{-9} Pa m_3 mol^{-1} No volatilisation expected from soil and plants. The calculated atmospheric life time of glyphosate is < 2 days, thus long range transport via air can be excluded
Metabolites	None

The vapour pressure at 25 °C of the active substance glyphosate is near to 10^{-5} Pa. Hence the active substance glyphosate is regarded as non-volatile.

Table 8.10-2 Summary of atmospheric degradation and behaviour – MCPA

Compound	MCPA
Direct photolysis in air	DT_{50} = 0.78 d
Quantum yield of direct phototransformation	Not determined
Photochemical oxidative degradation in air	Not determined
Volatilisation	Vapour pressure (Pa): 4×10^{-4} Pa at 32°C; Henry's Law Constant ($Pa.m^3/mol$): 5.5×10^{-5} Pa m^3 mol^{-1} (25 °C) No volatilisation expected from soil and plants. The calculated atmospheric life time of MCPA is < 1 days, thus

	long range transport via air can be excluded
Metabolites	None

The vapour pressure at 32 °C of the active substance MCPA is 4×10^{-4} Pa. Hence the accumulation of active substance MCPA in air is unlikely.

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Data protection claimed Y/N	Owner
KCP 9.1	Anon	2002	Commission Recommendation of 4th July 2002 on the results of the risk evaluation for the substances ethyl acetoate, 4- chloro-o-cresol, dimethyldioctade. (EC Recommendation on PCOC) 2002/576/EC	N	---
KCP 9.1	Concha M; Shepler K	1994	Photodegradation of (14C)-MCPA in/on Soil by Natural Sunlight MCPA DPWG PTRL West USA 436W-1 GLP, unpublished	N	---
KCP 9.1	Cremers. R.K.H., Salmon-te Rietstap F.G.Ch.	2003	Determination of the degradation of MCPA using [14C]-MCPA in two water/sediment systems. MCPA DPWG TNO Laboratories – The Netherlands V4022/01 GLP, unpublished	N	---
KCP 9.1	Dean, G. M.	1995	Rate and route of degradation of [^{14}C]glyphosate in one soil incubated under aerobic conditions Report. No.: SNY 333/951445 (study) Date: December 1, 1995 GLP: yes Not published 2310244	N	ALS

KCP 9.1	Dorn, S.	2012	Kinetic modelling analysis of the degradation behaviour of glyphosate and its metabolite AMPA from aerobic laboratory soil degradation studies Report No.: 303604-1 Date: May 3, 2012 GLP: no (kinetic evaluation: does not contain laboratory work) Not published 2315991	N	EGT
KCP 9.1	Esser, T.	1996	[P-Methylene-^{14}C]glyphosate acid: aerobic soil metabolism Report No.: PTRL548W-1 (study) RR 96-027B (sponsor) Date: July 11, 1996 GLP: yes Not published 2310248	N	SYN
KCP 9.1	Esser	1996*	P-Methylene-14C] Glyphosate Acid: Photodegradation in-on Soil by Natural Sunlight (WRC-96-066) ASF71/0159 ! RR 96-046B GLP: Yes not published 2154348	N	SYN
KCP 9.1	Feil, J.	2009*	Ready biodegradability of glyphosate in a manometric respirometry test Report No.: 53981163 Date: December 10, 2009 GLP: yes Not published	N	NUF
KCP 9.1	Fernando T.R.	1992	Sorption/Desorption of ^{14}C-MCPA Acid on Soils by the Batch Equilibrium Method GLP: yes Published	N	-

KCP 9.1	Goodwin, P.A.	1998	An Adsorption Study of MCPA GLP: yes Published	N	-
KCP 9.1	Goodyear, A	1996	(14C)-glyphosate: Aerobic Soil Metabolism Report No.: 1413/1-1015 (study) Date: July 11, 1996 GLP: yes Not published 2310246	N	NUF
KCP 9.1	Hayes, S.E.	2000	Glyphosate Acid: Calculation of Half- Life by Reaction with Atmospheric Hydroxyl Radicals 46852/01 GLP: yes Not published 2154359	N	SYN
KCP 9.1	Heintze, A.	1996*	Degradation and metabolism of glyphosate in two water/sediment systems under aerobic conditions - Laboratory test Report No.: 96138/01-CUWS (study) Date: December 16, 1996 GLP: yes Not published 1939626	N	MON
KCP 9.1	Jönsson, J., Camm, R.	2010	Removal of Glyphosate and AMPA by water treatment UC8164v2 MON GLP: N, published: N 2316003 /	N	EGT
KCP 9.1	Jönsson, J.	2012	Review of sustainable water treatment UC8408v2 MON GLP: N, published: N 2316001 /	N	EGT
KCP 9.1	Knoch, E.	2003*	Route and rate of anaerobic soil degradation of glyphosate according to SETAC, Part 1, 1.2 (March 1995) Report No.: IF-02/00005224 Date: February 7, 2003 GLP: yes Not published	N	ALS

KCP 9.1	Knoch, E.	2003	Aminomethylphosphonic acid: adsorption/desorption Report No.: IF-02/00005220 (study) Date: February 07, 2003 GLP: yes Not published 2310262	N	ALS
KCP 9.1	Kreschnak, C	2012	Kinetic modelling analysis of the degradation behaviour of glyphosate and its metabolite AMPA in field soil dissipation studies Report No.: 303604-2 Date: April 27, 2012 GLP: no (kinetic evaluation: does not contain laboratory work) Not published 2315993	N	EGT
KCP 9.1	Kubiak, R.	1991	Outdoor Lysimeter Study on ^{14}C-MCPA in 2 different soils (Final Report) GLP: no published	N	-
KCP 9.1	Lowrie, C., Clayton, M.A., Paterson K.	2003	The degradation of [14C]-glyphosate in soil under anaerobic conditions Report No.: 22581 (study); MSL-18018 (sponsor) Date: July 08, 2003 GLP: yes Not published 2310253	N	MON
KCP 9.1	Mamouni, A.	2002	First amendment (addendum) to report - Degradation of $_{14}$C-glyphosate in three soils incubated under aerobic conditions RCC Study No. : 271618 Date: June 3, 2002 GLP: No Not published 2437068	N	CHE
KCP 9.1	McEwen, A.	2004*	[14C]-Glyphosate: Anaerobic soil metabolism (rate and route of degradation in a sandy loam soil) Report No.: SNN/05 Date: July 19, 2004 GLP: yes Not published	N	SIN

KCP 9.1	McEwen, A.	2004b	[14C]-AMPA: Degradation and fate in water/sediment systems BioDynamics Research Limited, Northhamptonshire, UK Report No.: SNN/03 (study) Date: June 7, 2004 GLP: yes Not published 2310275	N	SIN
KCP 9.1	McLaughlin, S., Schanné, C.	1996	[14C]-Glyphosate: determination of soil degradation, bio-transformation and metabolism under aerobic conditions Report No.: 96-120-1020 (study) Date: June 14, 1996 GLP: yes Not published 2310250	N	SIN
KCP 9.1	McLaughlin, S.	1996	Determination of the mobility of aged[14C]- glyphosate residues in one soil Springborn Laboratories, Horn, Switzerland Report No.: 96-121-1020 (study) Date: June 14, 1996 GLP: yes Not published 2310268	N	SIN
KCP 9.1	Muller, K., Lane, M.C.G.	1996	Glyphosate acid: adsorption and desorption properties of the major metabolite, AMPA, in soil Report No: RJ2129B Date: August 27, 1996 GLP: yes Not published 2310266	N	SYN
KCP 9.1	Partsch, S.	2012	Kinetic modelling analysis of the disappearance behaviour of glyphosate and its metabolite AMPA in water-sediment studies Report No.: 303604-3 Date: April 30, 2012 GLP: no (kinetic evaluation: does not contain laboratory work) Not published 2316005	N	EGT

KCP 9.1	Ponte, M.	2010	Rate and route of degradation of [14C]-glyphosate in one soil incubated under aerobic conditions Report No.: PTRL1923W-1 (study) MSL0023070 (sponsor) Date: October 6, 2010 GLP: yes Not published 2310242	N	EGT
KCP 9.1	Ponte, M.	2010	Rate of degradation of [14C]glyphosate in three soils incubated under aerobic conditions Report No.: PTRL1946W-1 (study); MSL0023071 (sponsor) Date: October 6, 2010 GLP: yes Not published 2310255	N	EGT
KCP 9.1	Schneider, E.	1993	Glyphosate isopropylamine salt adsorption/desorption PR93/017 Date: June 17, 1993 GLP: yes Not published 1027844	N	FSG
KCP 9.1	Thomas, P.K., Lane M.C.G.6	1996	Glyphosate acid: adsorption and desorption properties in 5 soils Report No: RJ2152B Date: September 12, 1996 GLP: yes Not published 2310260	N	SYN
KCP 9.1	van der Kolk, J.	1996	Glyphosate: determination of adsorption and desorption properties based on the OECD method 106 Report No.: 95-111-1020 (study) Date: April 26, 1996 GLP: yes Not published 2310258	N	SIN

KCP 9.1	Wittig, A.	2002	Adsorption/desorption behaviour of AMPA on soil according OECD 106 (adopted January 2000) Report No.: PR02/007 (study) Date: June 24, 2002 GLP: yes Not published 2310264	N	FSG
KCP 9.1	van Noorloos, B., Slangen, P.J	2001	Adsorption/desorption of glyphosate on soil Report No.: 320164 (study) Date: December 10, 2001 GLP: yes Not published 2310257	N	AGC
KCP 9.1	Zohner, A.	1988	Determination of the Mobility of Soil-Aged Residues by Soil Column Leaching Test for ^{14}C-MCPA Acid GLP: no published	N	-
KCP 9.2	Anonymous	2012	Analysis of groundwater contamination with glyphosate/AMPA SCE Aménagement et Énvironnement, Nantes, France Report No.: - Date: February 2012 GLP: no (desk study: does not contain laboratory work) Not published 2310289	N	EGT
KCP 9.2	Anyusheva, M.	2012	Predicted environmental concentrations of glyphosate and its metabolite AMPA in soil (PEC_S) following application to various crops in the EU Report No.: 303605-1 Date: April 25, 2012 GLP: no (modelling study: does not contain laboratory work) Not published 2315997	N	EGT

KCP 9.2	Anyusheva, M.	2012	Predicted environmental concentrations of glyphosate and its metabolite AMPA in groundwater (PEC_{gw}) using FOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.3 following application to various crops in the EU Report No.: 303605-2 Date: April 25, 2012 GLP: no (modelling study: does not contain laboratory work) Not published 231599	N	EGT
KCP 9.2	Anyusheva, M.	2012	Predicted environmental concentrations of glyphosate and its metabolites AMPA and HMPA in surface water (PECsw) and sediment (PECsed) following application to various crops in the EU Report No.: 303605-3 Date: April 27, 2012 GLP: no (modelling study: does not contain laboratory work) Not published 2316007	N	EGT
KCP 9.2	Calliera, M., Ferrari, F., Lamastra, L.	2011	Investigation of the potential glyphosate groundwater contamination in Lombardia region (North Italy) Aeiforia Srl, Fidenza, Italy Report No.: - Date:20 October 2011 GLP: no (literature study: does not contain laboratory work) Published 2310280	N	LIT
KCP 9.2	Carter, A., Pepper, T.	2005	An investigation of reported borehole contamination in the Vemmenhög Catchment, Sweden ADAS UK Ltd, Nottinghamshire, England Report No.: - Date: December 2005 GLP: no (literature study: does not contain laboratory work) Not Published 2310285	N	MON

KCP 9.2	Franke, A.C., Groeneveld, R.M.W., Kempenaar, C.	2010	Evaluative van metingen van glyfosaat en AMPA in grondwater in Nederland (Evaluation of glyphosate and AMPA measurements in groundwater in The Netherlands) Plant Research International, Wageningen UR, The Netherlands Report No.: 354 / 2310284 Date: October 2010 GLP: no (literature study: does not contain laboratory work) Not Published	N	LIT
KCP 9.2	Horth, H.	2012	Survey of glyphosate and AMPA in groundwaters and surface waters in Europe HoHQ, UK Report No.: -2310291 GLP: no (desk study: does not contain laboratory work) Not published	N	EGT
KCP 9.2	Jene B	2002	Calculation of predicted environmental concentrations in groundwater (PECgw) of MCPA using FOCUS-PELMO 3.3.2 MCPA DPWG BASF Aktiengesellschaft Report CALC364 GLP, unpublished	N	---
KCP 9.2	MCPA DPWG	2003	Estimation of Concentration of MCPA in Surface Water and sediment following application to Cereals (1.8 kg.ha) and meadow (3 x 1.8 kg/ha). MCPA DPWG MCPA TF PECSW v2 /2003unpublished	N	---
KCP 9.2	Schmidt, B., Reichert N.	2006	Clarification of well-related findings of glyphosate and AMPA in groundwater SGS Institut Fresenius GmbH, Taunusstein, Germany Report No.: IF-06/00603024 (study) 2310282 Date: 14 December 2006 GLP: no (literature study: does not contain laboratory work) Not Published	N	MON
KCP 9.3	De Vries, R.	1997 *	Determination of the rate of volatilization of glyphosate from soil and plant surface (french beans) Report No.: 191071 Date: 1997 GLP: yes Not published	N	AGC
KCP 9.3	Schneider, E.	1996*	Glyphosate: Determination of volatilisation - Field study Report No.: PR94/032 (study); Date: 1996 GLP: yes Not published	N	FSG

Codes of owner	
AGC	AgriChem B.V.
ALS	Alschu-Chemie GmbH
CHE	Cheminova A/S
EGT	European Glyphosate Task Force AIR 2
FSG	Feinchemie Schwebda GmbH
LIT	Published literature
MON	Montedison (Deutschland) Chemie Handels GmbH
NUF	Nufarm GmbH & Co KG
SIN	SINON EU CORPORATION
SYN	Syntana Handelsgesellschaft

Appendix 2 Detailed evaluation of the new Annex II studies

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