Table A7_1_2_2_2-3: Summary of analytical results for fenoxycarb in microcosm water

Fenoxycarb [µg/l]					Fenoxycarb [µg/l]				
Dose D1	Study Day	Tank 64	Tank 80	Tank 82	**Dose D2**	Study Day	Tank 62	Tank 70	Tank 84
	PRE	<0.001	<0.001	<0.001		PRE	<0.001	<0.001	<0.001
	0.17	0.011	0.012	0.013		0.17	0.033	0.030	0.13
	0.5	0.0032	0.0044	0.0044		0.5	0.0095	0.0078	0.015
	1	0.0018	0.0015	0.0018		1	0.0018	0.0020	0.0027
	2	<0.001	<0.001	<0.001		2	<0.001	<0.001	<0.001
	5	<0.001	<0.001	<0.001		5	<0.001	<0.001	<0.001
	28	<0.001	<0.001	<0.001		28	<0.001	<0.001	<0.001
Dose D3	Study Day	Tank 53	Tank 71	Tank 85					
	PRE	<0.001	<0.001	<0.001					
	0.17	0.12	0.12	0.12					
	0.5	0.056	0.046	0.043					
	1	0.010	0.013	0.0086					
	2	<0.001	<0.001	<0.001					
	5	<0.001	<0.001	<0.001					
	28	<0.001	<0.001	<0.001					
Dose D4	Study Day	Tank 54	Tank 60	Tank 73	**Dose D5**	Study Day	Tank 52	Tank 61	Tank 74
	PRE	<0.001	<0.001	<0.001		PRE	<0.001	<0.001	<0.001
	0.17	0.37	0.34	0.38		0.17	1.1	1.2	1.2
	0.5	0.18	0.20	0.21		0.5	0.79	0.80	0.81
	1	0.072	0.097	0.094		1	0.51	0.52	0.53
	2	0.0039	0.0053	0.0056		2	0.11	0.10	0.13
	5	<0.001	<0.001	<0.001		5	<0.001	<0.001	<0.001
	7	<0.001	<0.001	<0.001		7	<0.001	<0.001	<0.001
	28	<0.001	<0.001	<0.001		14	<0.001	<0.001	<0.001
	28.17	0.26	0.33	0.29		28	<0.001	<0.001	<0.001
	28.5	0.11	0.26	0.19		28.17	1.2	0.90	1.3
	29	0.0041	0.16	0.054		28.5	0.63	0.69	0.77
	30	<0.001	0.096	0.0018		29	0.21	0.25	0.38
	33	<0.001	<0.001	<0.001		30	0.010	0.045	0.065
	35	<0.001	<0.001	<0.001		33	<0.001	<0.001	<0.001
	42	<0.001	<0.001	<0.001		35	<0.001	<0.001	<0.001
						42	<0.001	<0.001	<0.001
Dose D6	Study Day	Tank 50	Tank 65	Tank 72	**Dose D7**	Study Day	Tank 55	Tank 63	Tank 81
	PRE	<0.001	<0.001	<0.001		PRE	<0.001	<0.001	<0.001

Fenoxycarb [µg/l]					Fenoxycarb [µg/l]				
	0.17	3.3	3.4	3.5		0.17	12	11	11
	0.5	3.0	2.8	2.8		0.5	9.4	8.3	8.0
	1	2.4	2.5	2.4		1	8.3	9.2	9.0
	2	1.0	1.4	1.1		2	5.1	5.2	5.4
	5	0.076	0.12	0.10		5	1.9	2.7	2.7
	7	0.0031	0.0047	0.0043		7	0.78	1.3	1.6
	14	<0.001	<0.001	<0.001		14	0.0033	0.0018	0.0099
	28	<0.001	<0.001	<0.001		28	0.0013	<0.001	<0.001
	28.17	3.5	3.3	3.0		28.17	11	12	11
	28.5	2.5	2.6	2.7		28.5	8.0	8.6	8.2
	29	1.8	2.5	2.3		29	7.8	8.3	8.0
	30	0.83	1.5	1.2		30	4.3	5.4	5.3
	33	0.012	0.35	0.068		33	0.59	1.1	1.0
	35	0.0022	0.11	0.0026		35	0.17	0.27	0.046
	42	0.0015	0.0013	<0.001		42	0.089	0.0059	0.0013
	56	0.0012	<0.001	<0.001		56	0.0030	0.0020	0.0010
	70	<0.001	<0.001	<0.001		70	0.0021	0.0013	<0.001
	84	<0.001	<0.001	<0.001		84	<0.001	<0.001	<0.001

Note: The three lower doses received single applications, the higher doses (D4 to D7) received a second application 28 days later.

Table A7_1_2_2_2-4: Dissipation of fenoxycarb in microcosm water at six treatment levels

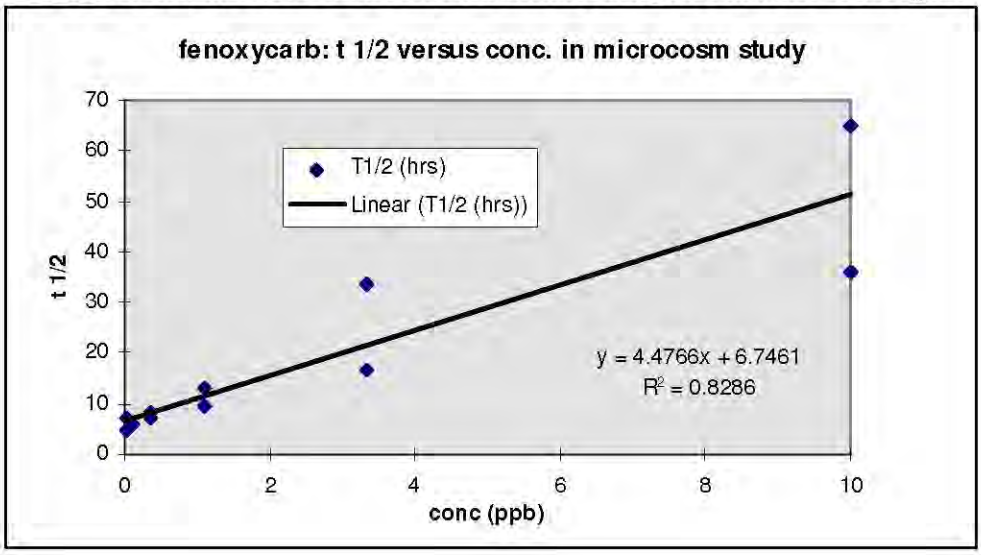
Dose Level	0.014 µg/l D1	Fenoxycarb	Dose Level	0.041 µg/l D2	Fenoxycarb	Dose Level	0.123 µg/l D3	Fenoxycarb
Tank No.	No. of Treatment	DT50 days	Tank No.	No. of Treatment	DT50 days	Tank No.	No. of Treatment	DT50 days
51	one	0.33	62	one	0.20	53	one	0.23
75	one	0.28	70	one	0.22	71	one	0.26
83	one	0.30	84	one	0.15	85	one	0.22
Mean		0.30	Mean		0.19	Mean		0.24
Dose Level	**0.37 µg/l D4**	**Fenoxycarb**	**Dose Level**	**1.11 µg/l D5**	**Fenoxycarb**	**Dose Level**	**3.33 µg/l D6**	**Fenoxycarb**
Tank No.	No. of Treatment	DT50 days	Tank No.	No. of Treatment	DT50 days	Tank No.	No. of Treatment	DT50 days
54	first	0.28	52	first	0.55	50	first	0.70
60	first	0.30	61	first	0.51	65	first	0.75
73	first	0.30	64	first	0.57	72	first	0.74
54	second	0.14	52	second	0.26	50	second	2.3
60	second	0.66	61	second	0.55	65	second	1.2
73	second	0.24	64	second	0.42	72	second	0.69
Mean		0.32	Mean		0.48	Mean		1.06

Dose Level	10.0 µg/l D7	Fenoxycarb
Tank No.	No. of Treatment	DT50 days
55	first	1.9
63	first	1.2
81	first	1.5
55	second	3.2
63	second	2.9
81	second	1.9
Mean		2.1

Table A7_1_2_2_2-5: Half-life of fenoxycarb in microcosm water at six treatment levels

Mean DT_{50} of fenoxycarb [hours]		Median	12.2
n	33	90th Percentile	45.6
Average	18.9	Minimum	3.4
STD	14.3	Maximum	76.8

Figure A7_1_2_2_2-1: Half-life versus initial concentration of fenoxycarb in water of fibreglass tanks



Section A7.1.2.2.2 Water/sediment degradation study (2)

Annex Point IIIA XII2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Nicollier, G. (2000): Degradation and Metabolism of [Phenoxy-U-^{14}C] Labelled CGA 114597 under Aerobic Laboratory Conditions in Aquatic Systems, Novartis Crop Protection AG, statement to study No. 99GN05. Study dates: November 1999 - August 2000. Issue date: 26 May, 2000 (Syngenta File No. CGA114597/0763)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; Richtlinie für die Prüfung von Pflanzenschutzmitteln, Teil IV, 5-1, Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment-System. Biologische Bundesanstalt für Land- und Forstwirtschaft Bundesrepublik Deutschland, Dezember 1990. Dutch registration Guideline, Section G.2: Behaviour in Water; Ministry of Agriculture and Fisheries, Ministry of Public Health and Environmental Hygiene, Ministry of Social Affairs, January 1987.	
2.2	**GLP**	Yes (Novartis Crop Protection AG, 4002 Basel, Switzerland)	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
		The distribution, degradation and metabolism of phenyl ring "A"-^{14}C-labelled fenoxycarb, (specific radioactivity 4.32 MBq/mg, radiochemical purity [redacted] batch no [redacted]) in equilibrated water-sediment systems was investigated. As reference material the unlabeled compound was used (purity 99.5%, batch no. AMS 593/102). The water-sediment systems from a river (Rhine) and from a pond consisted of natural water filtered through a 0.2 mm sieve, and the uppermost 5 to 10 cm of sediment sieved through a 2 mm mesh. Sediment was filled into 1 L glass metabolism flask to a height of about 2 to 2.5 cm corresponding to 270 g fresh weight for river and 220 g for pond. Afterwards, 500 mL of water were layered upon the corresponding sediment, reaching a height of about 6 cm and a surface area of 78.55 cm^2. The test systems were acclimated at laboratory conditions (20 ± 2 °C, in the dark) for about 4 weeks under aeration. After this time, pH values, redox potential and oxygen concentration in water had reached constant values. Thereafter, the labeled test substance was applied to the water surface at a target rate of 0.15 kg a.s./ha (0.05 mg/L). Incubation was at 20 °C in the dark. Samples were incubated for up to 119 days. Characteristics of the test systems are	

Section A7.1.2.2.2 Water/sediment degradation study (2)

Annex Point IIIA XII2.1

shown in Table A7_1_2_2_2-1.

For processing the water phase was decanted and centrifuged to separate suspended matter from the water phase. Sediments were extracted by shaking with acetonitrile and up to five times with acetonitrile/water at room temperature. Measurement of radioactivity was conducted by liquid scintillation counting correcting for background and for counting efficiency. HPLC was used as primary method for quantitative analysis of the combined acetonitrile/water extracts (UV detection at 235 nm, column: Nucleosil 5 µm, 250 x 4 mm, mobile phase: acetonitrile/phosphate buffer pH 9, injection volume 100-200 µL, flow rate: 1 mL/min). For selected samples the results of the HPLC analysis were confirmed by 2D-TLC.

4 RESULTS

In both systems the overall recovery ranged from 90.1% to 98.2% of the applied radioactivity. The radioactivity in the water phase decreased rapidly reaching 1.0% (river) and 0.6% (pond) of the applied radioactivity at day 119. In the sediment the amount of non-extractable radioactivity increased to a level of 56.2% after 29 days in the river system and of 54.9% after 14 days in the pond. Afterwards non-extractable radioactivity decreased to 49.5% in the river and to 52.1% in the pond by the end of the study. All volatile radioactivity was characterized as CO_2. It reached 40.4% (river) and 36.3% (pond) at day 119, indicating extensive mineralisation. The distribution and nature of radioactivity for the incubation period in the river and pond water-sediment systems are shown in Tables A7_1_2_2_2-2 and A7_1_2_2_2-3. Dissipation of the parent molecule from the water phase proceeded mainly via adsorption to the sediment matrix where the compound was further metabolised to $^{14}CO_2$ and to bound residues.

No metabolites > 5% of the applied radioactivity were found. Mainly minor metabolites, mostly of transient nature, were detected. One of them could be identified by co-chromatography as CGA 294850.

Based on the concentrations of the parent molecule in water and sediment, half-lives (DT_{50}) values were determined by applying first order one and two compartment reaction kinetics (Table A7_1_2_2_2-4). Dissipation half-lives of 1.4 and 2 days for water, 6.2 and 11.5 days for sediment and 6.0 and 6.5 days for the total system were calculated.

5 CONCLUSION

5.1 Conclusion

Short mean dissipation half-lives of 1.7 days (water) and 8.9 days (sediment) were calculated for fenoxycarb. For the total system, a mean dissipation half-life of 6.3 days was achieved.

5.1.1 Reliability 1

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09/02/11
Materials and Methods	[redacted]

Results and discussion

[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

A7_1_2_2_2-1: Water/sediment characteristics of river and pond systems

	River (Rhine) Möhlin AG / CH		Pond (Fröschweiher) Rheinfelden AG / CH	
Characteristics	**Water**	**Sediment**	**Water**	**Sediment**
Oxygen, surface [mg/L]*	10.4		7.8	
Redox potential [mV]*	+8.4		+22	
TOC [mg/L]	1.8		4.1	
Hardness [German degrees]	8.8		15.9	
pH	6.9*	7.9	6.9*	7.3
Total nitrogen [mg/L], [%]:	2.4	0.05	1.7	0.27
Phosphorous total [mg/L or kg]	0.3	372	0.3	438
Organic carbon [%]:		0.6		4.2
CEC [mVal/100 g]:		5.03		26.11
Clay [%]:		7.4		20.5
Silt [%]:		17.4		54.4
Sand [%]:		75.2		25.0
Biomass [mg C/100g dry sediment]:		18.5		105.6

* Determined at sampling site

Table A7_1_2_2_2-2: Radioactivity distribution of ^{14}C fenoxycarb in river aquatic system as percent of applied dose

	Water Layer			Sediment					
Time [days]	**Total**	**Fenoxycarb**	**CGA 294850**	**Extract-able**	**Fenoxycarb**	**CGA 294850**	**Non-extractable**	**$^{14}CO_2$**	**Recovery**
0	95.0	95.0	-	2.9	2.7	-	0.1		97.9
3	47.0	42.5	2.6	34.1	32.4	2.4	12.7	0.5	94.3
7	22.9	16.3	2.6	29.6	25.9	< LD	35.0	3.4	90.8
14	9.5	2.8	< LD	20.0	16.6	1.8	51.5	11.3	92.2
29	4.3	0.1	< LD	8.5	6.3	0.6	56.2	25.5	94.5
57	1.5	n.a.	< LD	7.7	6.2	0.2	53.0	31.4	93.5
98	1.0	n.a.	< LD	5.9	5.0	0.4	49.8	40.2	96.8
119	1.0	n.a.	< LD	5.1	4.2	0.3	49.5	40.4	95.9

LD = limit of detection
n.a.: due to very low amount of radioactivity < 1% aqueous phase from 57 days up to 119 days was not analysed

Table A7_1_2_2_2-3: Radioactivity distribution of ^{14}C fenoxycarb in pond aquatic system as percent of applied dose

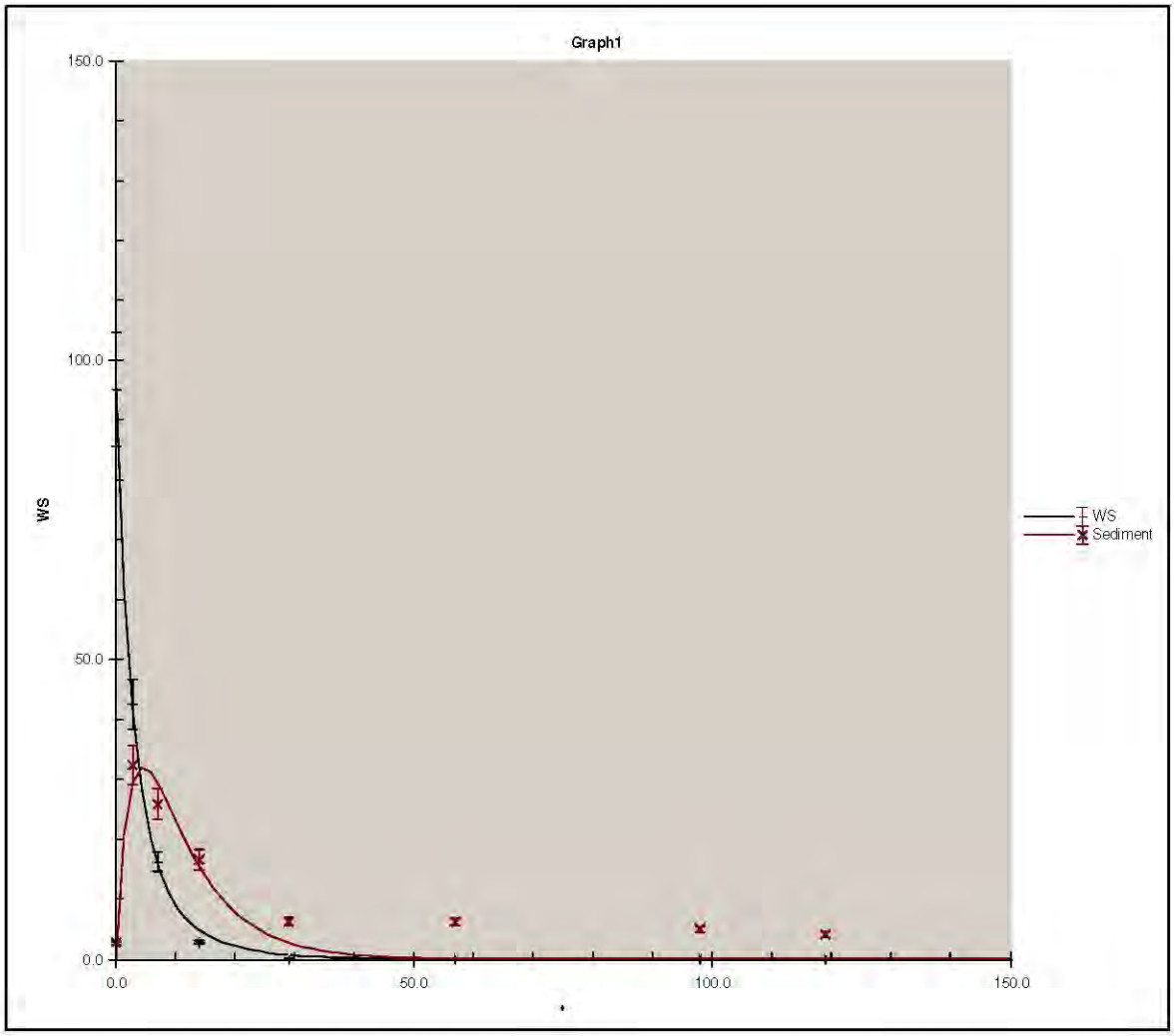
	Water Layer			Sediment					
Time [days]	Total	Fenoxycarb	CGA 294850	Extract -able	Fenoxycarb	CGA 294850	Non-extractable	$^{14}CO_2$	Recovery
0	94.4	94.5	-	3.6	3.3	-	0.1		98.2
3	29.9	19.4	3.8	41.3	37.1	3.7	20.4	0.4	92.0
7	11.9	3.8	0.0	38.9	29.9	3.5	33.3	7.3	91.4
14	6.5	0.5	0.0	15.2	10.8	1.0	54.9	13.5	90.1
28	2.7	-	< LD	14.2	9.8	0.9	53.4	20.4	90.6
57	1.5	< LD	n.a.	12.0	8.5	0.9	52.0	26.2	91.6
98	0.6	< LD	n.a.	6.2	3.8	0.6	52.6	35.4	94.8
119	0.6	< LD	n.a.	5.5	2.6	0.7	52.1	36.3	94.4

LD = limit of detection
n.a.: due to very low amount of radioactivity < 1% aqueous phase from 57 days up to 119 days was not analysed

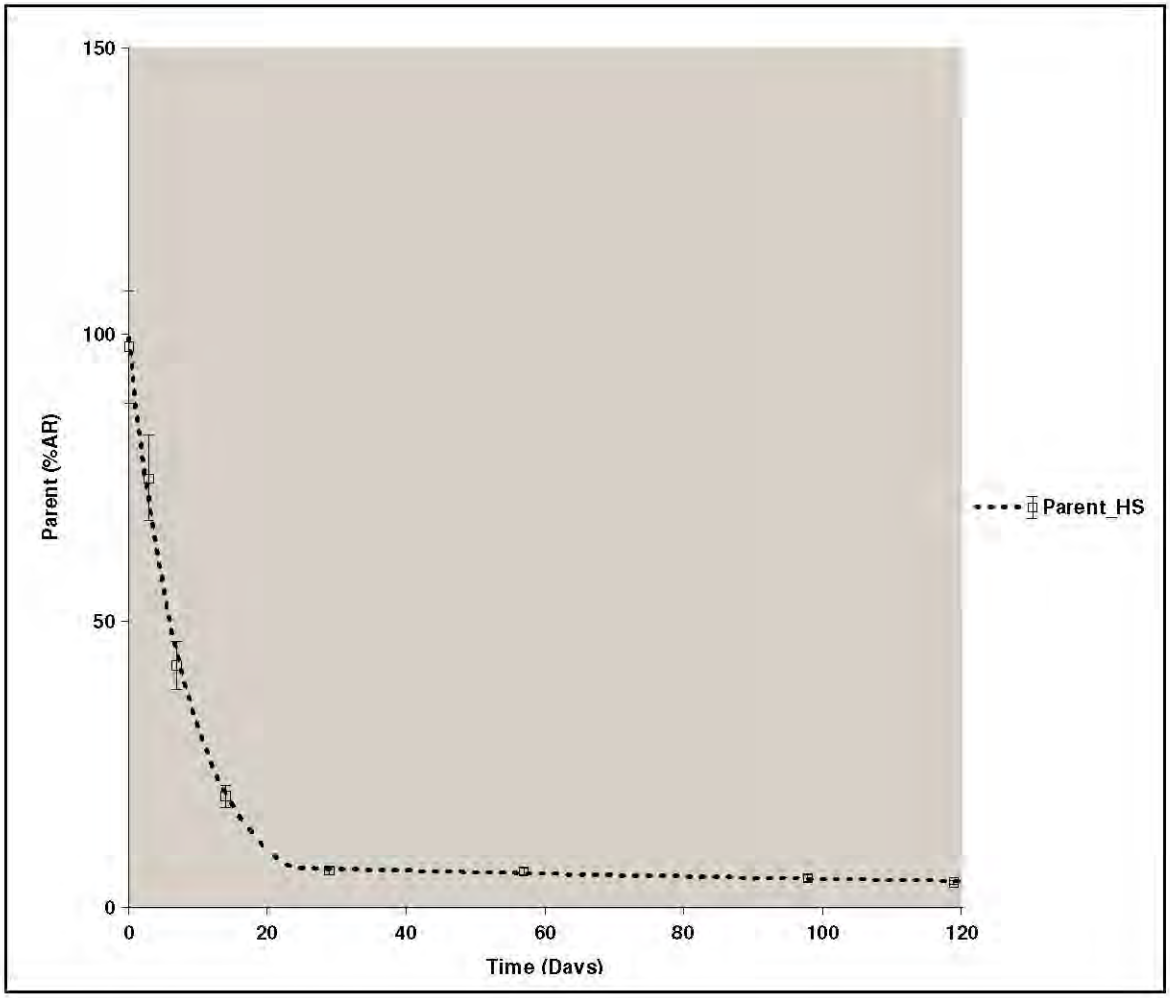
Table A7_1_2_2_2-4: Half-lives of "A"-^{14}C fenoxycarb in aquatic systems

	Total System	Water	Sediment
	DT_{50} [days]	DT_{50} [days]	DT_{50} [days]
River	6.0	2.0	6.2
Pond	6.5	1.4	11.5
Mean value	6.3	1.7	8.9

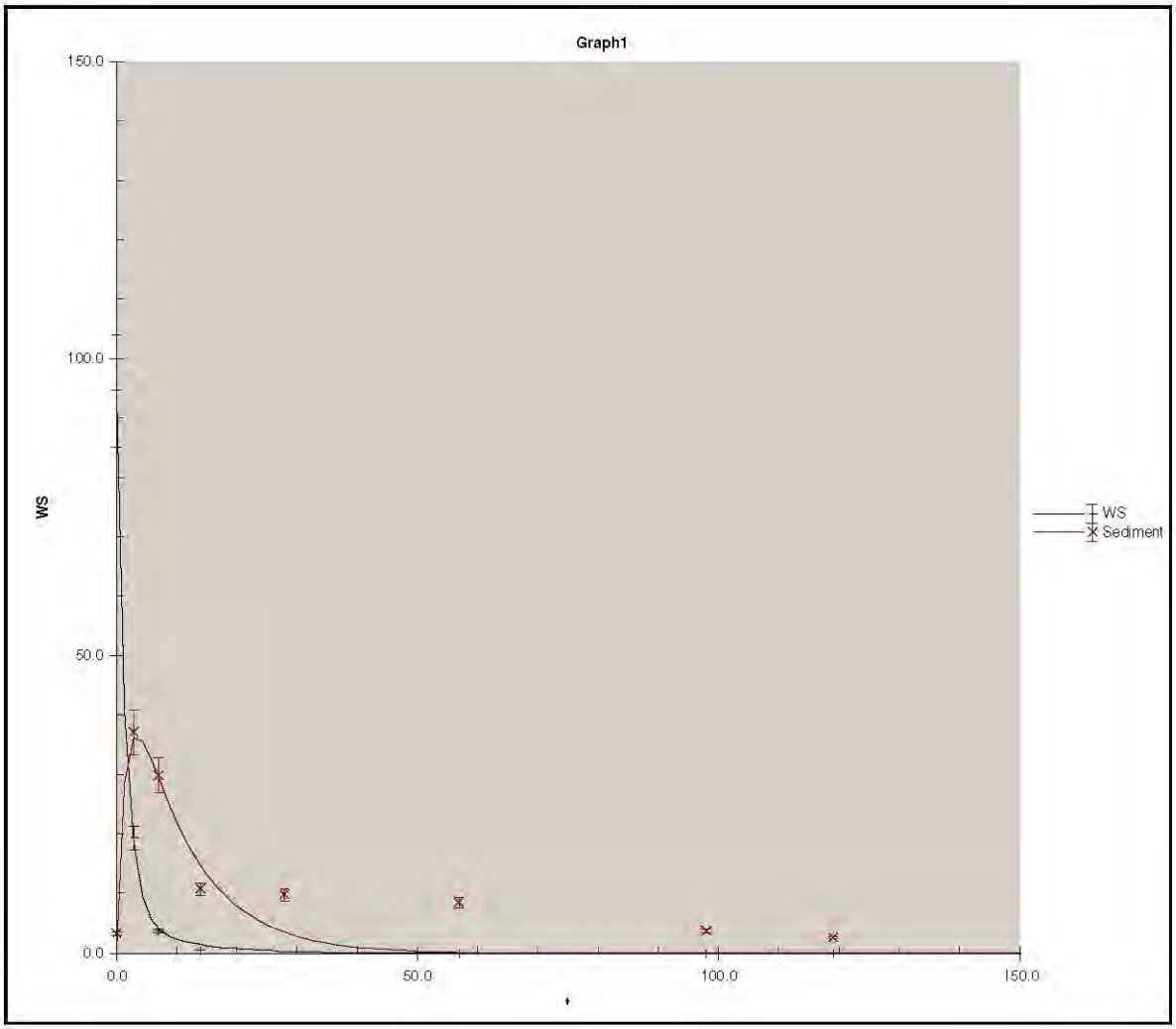
Annex 1 Evaluation by Rapporteur Member State, CA-Figures



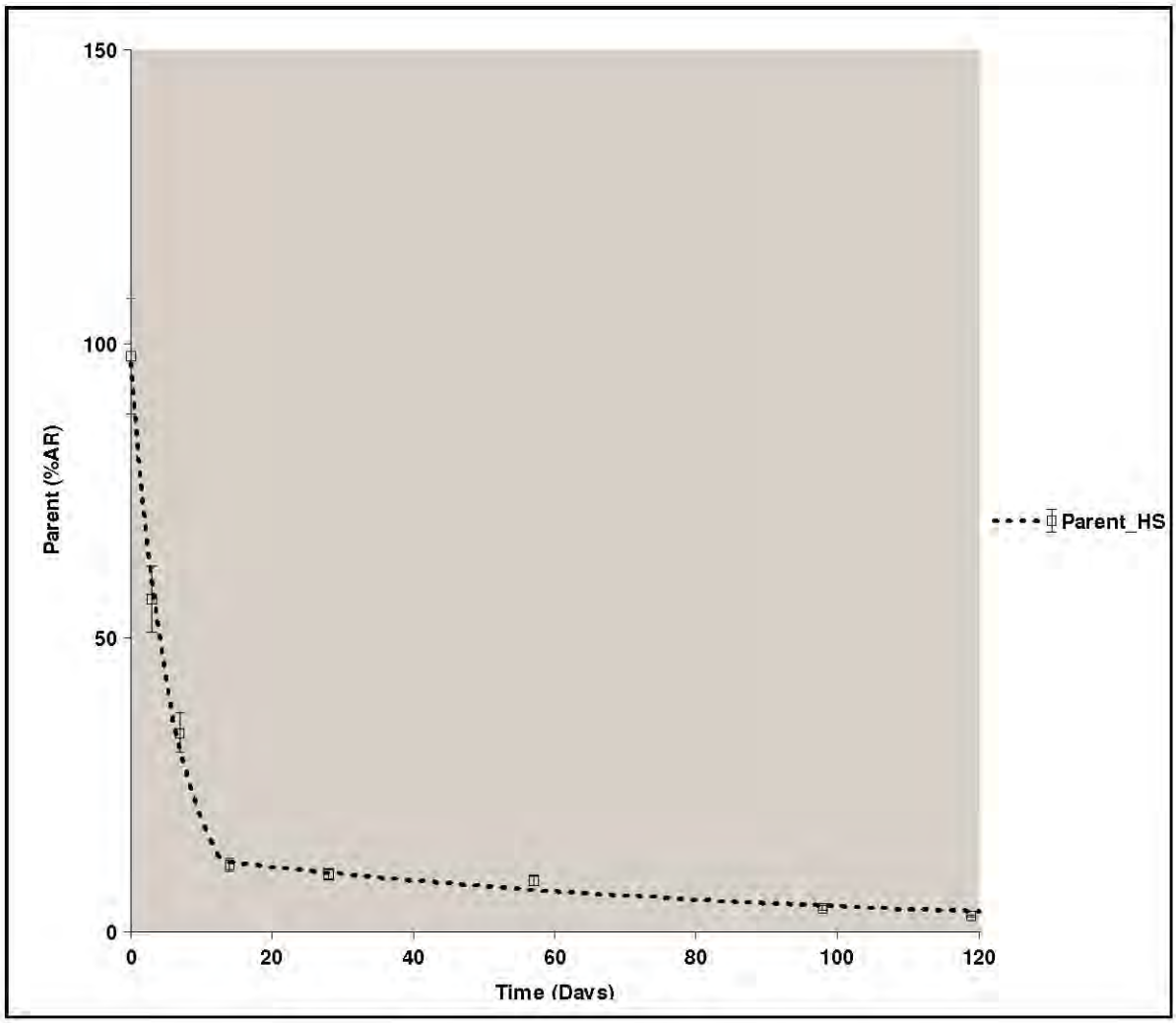
CA-Figure 1: Fenoxycarb, Nicollier (2000), water/sediment study: river, water/sediment, model: SFO



CA-Figure 2: Fenoxycarb, Nicollier (2000), water/sediment study: river, total system, model: HS



CA-Figure 3: Fenoxycarb, Nicollier (2000), water/sediment study: pond, water/sediment, model: SFO



CA-Figure 4: Fenoxycarb, Nicollier (2000), water/sediment study: pond, total system, model: HS

Section A7.1.3 Adsorption / Desorption screening test (01)

Annex Point IIA.7.7 **Fenoxycarb**

			Official use only
		1 REFERENCE	
1.1	**Reference**	Spare, W.C. (1995c): Adsorption/Desorption of ^{14}C-Fenoxycarb by the Batch Equilibrium Method on Representative Agricultural Soils. Agrisearch Inc., Frederick, United States, unpublished report, Proj. No 12213. Study dates: July 1994 - September 1994, Issue date: 25 January, 1995. (Syngenta File No. CGA114597/0526)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate: 540/9-82-021, Series 163-1, Leaching and Adsorption/Desorption Studies. US Environmental Protection Agency, October 18, 1982.	X
2.2	**GLP**	Yes (Agrisearch Inc, Frederick, USA)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: phenyl ring "B"-1,4-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 7.2 MBq/mg	
3.1.3	Purity	Radiochemical purity: [redacted]	
3.1.4	Further relevant properties	Water solubility of fenoxycarb: 7.9 mg/l at 25 °C (Stulz, 1993)	
3.1.5	Method of analysis	Methods were conducted according to US EPA-guideline § 163-1 of October 18, 1982 (see data point 2.1)	
3.2	**Degradation products**	No degradation products detected	
3.2.1	Method of analysis for degradation products	TLC analysis with two solvent systems and HPLC analysis (Shimadzu SCL-6A HPLC System) demonstrated no degradation of fenoxycarb	

Section A7.1.3 Adsorption / Desorption screening test (01)

Annex Point IIA.7.7 **Fenoxycarb**

3.3	**Reference substance**	Unlabeled fenoxycarb, Lot No.: S91-1536 from Ciba-Geigy Corporation, May 13, 1994, purity 99.0%	
3.3.1	Method of analysis for reference substance	TLC and HPLC analysis	
3.4	**Testing procedure**		
3.4.1	Test system	The adsorption/desorption characteristics of fenoxycarb have been investigated on five soils, using a batch equilibrium method (the study was performed in USA) according to US EPA-guideline § 163-1 of October 18, 1982. The soils used varied in texture and represented a range of organic carbon content of < 0.5% to 1.9% and a pH range of 6.0 to 7.7. The characteristics of the soils used are shown in table A7_1_3-1. The test system was each capped Oak Ridge Teflon® centrifuge with soil, 0.01M calcium ion solution and ^{14}C-fenoxycarb.	
3.4.2	Test solution and Test conditions	Aqueous test solutions of phenyl ring "B"1,4-^{14}C labelled fenoxycarb in 0.01 M calcium chloride was sterilized by filtration; pH after preparation was 5.44 and 5.77 (prepared twice). Test was conducted with five final concentrations of 0.099, 0.203, 0.474, 0.947 and 1.841 mg/l. The study was conducted by shaking 2 g soil and 40 ml test solution for 8 hours (equilibrium time) in the dark at 25 ± 1 °C. For the sand, 4 g soil with 20 ml solution was used. Desorption was done as above with fresh 0.01M calcium chloride solution. After centrifugation and decanting the supernatants, concentrations were determined by LSC. Additionally, desorption soil concentration was determined by combustion of the residential soil (after extraction with 1:1 solution of 80:20 MeOH:0.1N NaOH (aq, pH≈13)).	
3.5	**Calculations**	**K_f:** Freundlich adsorption coefficient (ml/g). **K_{OC}:** Freundlich adsorption coefficient (K_f) normalised to the organic carbon content (foc) of a sorbent (ml/g). **K_{des}:** Apparent desorption coefficient is the ratio between the content of the substance remaining in the soil phase and the mass concentration of the desorbed substance in the aqueous solution, when desorption equilibrium is reached (ml/g). **K_{OCdes}:** Apparent desorption coefficient (K_{des}) normalised to the organic carbon content (foc) of a sorbent (ml/g).	
		4 RESULTS	
4.1	**Measurements**	Overall recoveries during the tests comprising adsorption and desorption steps ranged from 92.1% to 100.3% for each soil type. The Freundlich adsorption coefficient K_F varied between 4.4 ml/g for the sand and 46.7 ml/g for the clay. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 1251 to 2599 ml/g. The Freundlich exponents (adsorption), 1/n, were < 1 and ranged from	X

		0.839 to 0.910. The desorption K_{OC} values were higher than the adsorption K_{OC} values with an average of 2473 ml/g. This indicates that adsorption was not fully reversible. The data are presented in table A7_1 _3-2.	
4.2	**Calculations**	Calculated adsorption/desorption parameters for fenoxycarb are given in table A7_1_3-2.	
4.3	**Degradation product(s)**	The stability of fenoxycarb during the process was confirmed by TLC and HPLC.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Five different test soils, comprising a clay, a sand, a sandy loam, a silt loam and a loam, were used for investigation of adsorption/desorption of radiolabelled fenoxycarb, applying Pesticide Assessment Guidelines, US EPA.	
5.2	**Results and discussion**	The average K_{OC} value for the adsorption is 1816 ml/g and the average K_{OC} for the desorption (after the first desorption) is 2473 ml/g. The compound is hence found to be of very strongly adsorbed to soil.	
5.3	**Conclusion**	According to Briggs (Proc. 7th British Insecticide and Fungicide Conference, Nottingham, UK, 83-86, 1973), the active substance can be classified as immobile (K_{OC} values for the adsorption varied between 1251 and 2599 mg/L; n = 5) due to a strong and irreversible binding to soil.	X
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE (*)

Date	2009/08/07
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_3-1: Classification and physico-chemical properties of soils used for adsorption/desorption

	Soil				
Name / origin	**Leland Mississippi**	**Burtonsville Maryland**	**Lime Kiln Maryland**	**Middletown Maryland**	**Yakima Washington**
Date collected	6/2/94	5/30/94	12/3/93	5/31/94	5/3/94
Classification	Clay	Sand	Sandy loam	Silt loam	Loam
Particle size: sand [%] silt [%] clay [%]	21 32 47	89 8 3	65 24 11	25 60 15	45 44 11
pH	6.6	6.0	7.7	6.7	6.8
FMC [%] at 33 kPa	35.9	4.7	15.5	27.1	24.3
Organic carbon [%]	1.8	0.2	1.8	1.0	1.9
CEC [meq/ 100 g soil]	33.4	3.5	14.9	14.1	21.4

Table A7_1_3-2: Adsorption and desorption constants of fenoxycarb in five US soils

Soil texture	**Adsorption (ml/g)**			**1st Desorption (ml/g)**		
	K_f	**K_{OC}**	**N**	**K_f**	**K_{OC}**	**N**
MS-Clay	46.7	2599	0.839	59.4	3304	0.771
MD-Sand	4.4	1883	0.910	5.5	2368	0.824
MD-Silt loam	16.2	1639	0.962	23.4	2376	0.814
MD-Sandy loam	22.5	1251	0.867	31.8	1769	0.743
WA-Loam	32.7	1710	0.873	48.7	2546	0.871
Average	24.5	1816	0.890	33.8	2473	0.805

Section A7.1.3 Adsorption / Desorption screening test (02)

Annex Point IIA.7.7 **Fenoxycarb**

			Official use only
		1 REFERENCE	
1.1	**Reference**	Pryde, A. (1982): CGA 114597 (RO 13-5223), Freundlich adsorption and desorption constants of ^{14}C-RO 13-5223/024 in four soils, Dr. R. Maag Ltd., Dielsdorf, Switzerland, unpublished report, Proj. No 041-2674, 04 March, 1982. (Syngenta File No. CGA114597/0080)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; OECD Guideline for Testing of Chemicals, 'Adsorption / Desorption', 106, adopted: 12 May, 1981.	X
2.2	**GLP**	No	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: Phenyl ring "B"-1,4-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 1.33 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	Water solubility of fenoxycarb: 7.9 mg/l at 25 °C (Stulz, 1993)	
3.1.5	Method of analysis	See data point 2.1	
3.2	**Degradation products**	No degradation products detected	
3.2.1	Method of analysis for degradation products	Not applicable	
3.3	**Reference substance**	Not reported	
3.3.1	Method of analysis for reference	Not reported	

	substance	
3.4	**Testing procedure**	
3.4.1	Test system	Adsorption and desorption of fenoxycarb were measured using a batch equilibrium procedure to determine the K_F values of phenyl ring "B"1,4-^{14}C-labelled fenoxycarb. The four soil types used are characterised in Table A7_1_3-1. All data were evaluated using the Freundlich equation and values for K_f (sorption constant), K_{OC} (sorption coefficient) and N were determined.
3.4.2	Test solution and Test conditions	Analytical grade ^{14}C-labelled fenoxycarb was prepared in distilled water at 4 concentrations between 0.099 and 1.304 mg/l. The solutions were added to soil and allowed to equilibrate while shaking at 20 °C for 24 hours. After equilibration soil/water phases were separated by centrifugation and fenoxycarb concentrations determined by liquid scintillation counting (LSC) of the aqueous phases and by difference for the soil phases. The soil phases were next desorbed first with distilled water and then with saturated $CaSO_4$ solution and concentrations determined by LSC of the aqueous phases following centrifugation.
3.5	**Calculations**	**K_f:** Freundlich adsorption coefficient (ml/g). **K_{OC}:** Freundlich adsorption coefficient (K_f) normalised to the organic carbon content (foc) of a sorbent (ml/g). **K_{des}:** Apparent desorption coefficient is the ratio between the content of the substance remaining in the soil phase and the mass concentration of the desorbed substance in the aqueous solution, when desorption equilibrium is reached (ml/g). **K_{OCdes}:** Apparent desorption coefficient (K_{des}) normalised to the organic carbon content (foc) of a sorbent (ml/g).
		4 RESULTS
4.1	**Measurements**	The Freundlich adsorption coefficient K_f varied between 18 ml/g for the Wallis sandy loam and 77 ml/g for both the Steinmaur loam and the Commugny sandy loam. Fenoxycarb is a compound with a very strong adsorption capacity to most soils. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 1960 to 6410 ml/g with an average K_{OC} value of 3238 ml/g. The first desorption of fenoxycarb from the soils with water was nearly equal to adsorption as shown by the similar desorption coefficients (2700 to 10410 ml/g) calculated after the first desorption step.
4.2	**Calculations**	Calculated adsorption/desorption parameters for fenoxycarb are given in table A7_1_3-2.
4.3	**Degradation product(s)**	None

Section A7.1.3 **Adsorption / Desorption screening test (02)**

Annex Point IIA.7.7 **Fenoxycarb**

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Four different test soils, comprising sandy loam and loam, were used for investigation of adsorption/desorption of radiolabelled fenoxycarb applying OECD Guideline for Testing of Chemicals, 'Adsorption / Desorption', 106.
5.2	**Results and discussion**	The average K_{OC} value for the adsorption is 3238 ml/g and the average K_{OC} for the desorption (after the first desorption) is 4758 ml/g. The compound is hence found to be very strongly adsorbed to soil.
5.3	**Conclusion**	According to Briggs (Proc. 7th British Insecticide and Fungicide Conference, Nottingham, UK, 83-86, 1973), the active substance can be classified as immobile (K_{OC} values for the adsorption varied between 1960 and 6410 mg/L; n = 4) due to a strong and irreversible binding to soil.
5.3.1	Reliability	2
5.3.2	Deficiencies	No GLP

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	2009/08/07
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_3-1: Classification and physico-chemical properties of soils used for adsorption/desorption

		Soil			
Name		**Dielsdorf**	**Steinmaur**	**Commugny**	**Wallis**
Classification		Sandy loam	loam	Sandy loam	Sandy loam
Particle size:	clay [%]	14.7	24.6	15.6	7.1
	silt [%]	30.8	36.2	43.6	41.4
pH		6.9	7.5	7.2	7.9
OC (%)		2.5	3.3	1.2	0.8
CEC (meq/100 g soil)		16.1	24.4	9.4	8.0

Table A7_1_3-2: Adsorption and desorption constants of fenoxycarb in four soils

Soil texture	**Adsorption (ml/g)**			**1st Desorption (ml/g)**			**2nd Desorption (ml/g)**		
	K_F	K_{OC}*	N	K_F	K_{OC}*	N	K_F	K_{OC}*	N
Dielsdorf sandy loam	49	1960	0.873	73	2920	0.978	53	2122	0.999
Steinmaur loam	77	2330	0.924	98	2700	0.999	95	2880	0.998
Commugny sandy loam	77	6410	0.990	125	10410	0.992	86	7100	0.999
Wallis sandy loam	18	2250	0.941	24	3000	0.981	26	3250	0.980
Average	55	3238	0.932	80	4758	0.9875	65	3838	0.994

* $K_{OC} = 100 \times K_F / \%OC$

Section A7.1.3 Adsorption / Desorption screening test (03)

Annex Point IIA.7.7 **CGA 294847 (aqueous photolysis metabolite)**

			Official use only
		1 REFERENCE	
1.1	**Reference**	Spare, W.C. (1995d): Adsorption/Desorption of ^{14}C-CGA 294847 by the Batch Equilibrium Method on Representative Agricultural Soils. Agrisearch Inc., Frederick, United States, unpublished report, Proj. No. 12214. Study dates: August 1994 - November 1994. Issue date: 21 July, 1995. (Syngenta File No. CGA294847/0001) Spare, W.C. (1995e): Analytical phase report: adsorption/desorption of ^{14}C-CGA 294847 by the batch equilibrium method on representative agricultural soils. Ciba-Geigy Corp., Greensboro, United States, unpublished report No. ABR-95044. Study dates: November 1994 - July 1995. Issue date: 19 July 1995. (Syngenta File No. CGA294847/0002)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes; Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate: 540/9-82-021, Series 163-1, Leaching and Adsorption/Desorption Studies. US Environmental Protection Agency, October 18, 1982.	X
2.2	**GLP**	Yes (Agrisearch Inc, Frederick, USA)	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: Company Code: CGA 294847 Chemical name: [2-(4-hydroxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: U-^{14}C-labelled CGA 294847	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 2.1 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	Water solubility of fenoxycarb: 7.9 mg/l at 25 °C (Stulz, 1993)	X
3.1.5	Method of analysis	Methods were conducted according to US EPA-guideline § 163-1 of October 18, 1982 (see data point 2.1)	
3.2	**Degradation**	There were a total of 17 components, many were common to both the	

	products	water phase and the soil extracts.
3.2.1	Method of analysis for degradation products	TLC analysis with two solvent systems and HPLC analysis (Shimadzu SCL-6A HPLC System) demonstrated rapid degradation of CGA-294847
3.3	**Reference substance**	Origin: CGA-294847: Analytical standard no. GB-LI-75, CAS No.: 102093-63-0, purity of 99.6% Degradates: CGA-114597: Lot No. S91-1536, purity 99.0% CGA-294850 (RO-16-8797): Lot No. GB-IL-8, purity 98.3% CGA-344891 (RO-43-4760): Lot No CAS-IV-48, purity > 99.9% Phenol: Lot No. 315284/1-293, purity > 99.5% Resorcinol: Lot No. 08307MY, purity 99.0% Catechol: Lot No. 06522MY, purity > 99.0% 1,2,4 benzentriol: Lot No. 00321AF, purity 99.0% 2,5 dihydroxy-1,4-benzoquinone: Lot No. 03930JZ, purity 98.0% Hydroquinone: Lot No. CZ 04622BX, purity 99.0% Tetrahydroxy-1,4-quinone: Lot No. PZ 09915MX, purity 99.0%
3.3.1	Method of analysis for reference substance	TLC and HPLC analysis
3.4	**Testing procedure**	
3.4.1	Test system	The adsorption/desorption characteristics of fenoxycarb have been investigated on five soils, using a batch equilibrium method (the study was performed in USA) according to US EPA-guideline § 163-1 of October 18, 1982. Additionally, the adsorption behaviour of CGA 294847 in sterile versus non-sterile soil following 24 hours of adsorption shaking is compared. The characteristics of the soils used are shown in table A7_1_3-1.
3.4.2	Test solution and Test conditions	The concentrations of the five aqueous 0.01M calcium chloride test solutions were 0.116, 0.218, 0.501, 0.990 and 2.017 mg/l. All solutions were sterilized by filtration. The pH of the 0.01M $CaCl_2$ solutions measured after preparation was 6.14 and 6.24 (prepared twice). They were added to soil and allowed to equilibrate in the dark while shaking in Oak Ridge Teflon® FEP centrifuge tube including screw cap closures at 25 °C for 4 hours (equilibrium time). After equilibration, the phases were separated by centrifugation. CGA-294847 concentrations were determined in the supernatants of adsorption solutions by LSC. The supernatant from one replicate per soil type at the highest concentration was analysed by TLC/HPLC. Desorption was done as above with fresh 0.01M calcium chloride solution. Soil concentrations were determined by combustion of the residential soil (after extraction with 1:1 solution of 80:20 MeOH:0.1N NaOH (aq, pH≈13). The desorption solutions and soil extracts were investigated for the same parameters as adsorption solutions (see above); Each experiment was performed in duplicate.
3.5	**Calculations**	**K_f:** Freundlich adsorption coefficient (ml/g). **K_{OC}:** Freundlich adsorption coefficient (K_f) normalised to the organic carbon content (foc) of a sorbent (ml/g).

Section A7.1.3	Adsorption / Desorption screening test (03)
Annex Point IIA.7.7	CGA 294847 (aqueous photolysis metabolite)

		K_{des}: Apparent desorption coefficient is the ratio between the content of the substance remaining in the soil phase and the mass concentration of the desorbed substance in the aqueous solution, when desorption equilibrium is reached (ml/g). **K_{OCdes}:** Apparent desorption coefficient (K_{des}) normalised to the organic carbon content (foc) of a sorbent (ml/g).	
		4 RESULTS	
4.1	**Measurements**	The data are presented in table A7_1 _3-2.	
4.2	**Calculations**	Calculated adsorption/desorption parameters for the metabolite CGA 294847 are given in table A7_1_3-2.	
4.3	**Degradation product(s)**	All of the 17 components including two zones (TLC) but with exception of the origin were below 7% of the total dose. Twelve of the compounds and the two zones were below 3% of total dose.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Five different test soils, comprising a clay, a sand, a sandy loam, a silt loam and a loam, were used for investigation of adsorption/desorption of the radiolabelled metabolite CGA 294847, applying Pesticide Assessment Guidelines, US EPA.	
5.2	**Results and discussion**	The average radiocarbon balance for each soil type ranged from 95.6 to 102.3% of applied radioactivity. The metabolite CGA 294847 was shown to degrade during the adsorption experiment. Up to 75% of the radioactivity in the water phase was degraded. Widely varying K_D estimates resulted from sterile soil (approximate mean K_D of 1.0 ml/g) vs. non-sterile soil (approximate mean K_D of 145 ml/g). Also extensive degradation of CGA 294847 was observed in the non-sterile experiment vs. the sterile experiment. Thus the K_D estimate for sterile soil reflects a high mobility of CGA 294847 in sterile systems vs. immobile in the non-sterile systems due to CGA 294847 metabolism.	X
5.3	**Conclusion**	CGA 294847 appears to degrade rapidly by microbial activity. It appears to be a transient product and of little cumulative concern to the environment. According to Briggs (Proc. 7th British Insecticide and Fungicide Conference, Nottingham, UK, 83-86, 1973), CGA 294847 can be classified as low mobile to immobile for four of five soils (K_{OC} values for the adsorption between 375 and 3175 mg/L, n = 4) due to a strong and irreversible binding to soil. Only in sandy soil, a low adsorption and elevated mobility of CGA 294847 was observed: A K_{OC} of 44 ml/g was determined for sand.	X
5.3.1	Reliability	1	X
5.3.2	Deficiencies	No	

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Date 2007/02/09

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*
Discuss if deviating from view of rapporteur member state

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1 _3-1: Classification and physico-chemical properties of soils used for adsorption/desorption

	Soil				
Name / origin	**Leland Mississippi**	**Burtonsville Maryland**	**Lime Kiln Maryland**	**Middletown Maryland**	**Yakima Washington**
Date collected	6/2/94	5/30/94	12/3/93	5/31/94	5/3/94
Classification	Clay	Sand	Sandy loam	Silt loam	Loam
Particle size: sand [%]	21	89	65	25	45
silt [%]	32	8	24	60	44
clay [%]	47	3	11	15	11
pH	6.6	6.0	7.7	6.7	6.8
FMC [%] at 33 kPa	35.9	4.7	15.5	27.1	24.3
Organic carbon [%]	1.8	0.2	1.8	1.0	1.9
CEC [meq/ 100 g soil]	33.4	3.5	14.9	14.1	21.4

Table A7_1 _3-2: Adsorption and desorption constants of the metabolite CGA 294847 in five US soils

Soil texture	**Adsorption (ml/g)**			**1st Desorption (ml/g)**		
	K_f	**K_{OC}**	**N**	**K_f**	**K_{OC}**	**N**
MS-Clay	6.7	375	0.855	81.1	4508	0.751
MD-Sand	0.1	44	0.632	*	*	*
MD-Sandy loam	12.8	712	0.692	$5.2x10^5$	$2.9x10^7$	2.071
MD-Silt loam	31.3	3175	0.884	882	89394	1.117
WA-Loam	7.9	414	0.828	129	6743	0.769
Average	11.8	944	0.778			

* Could not be determined (no desorption from sand soil)

Section A7.2.1 Aerobic degradation in soil, initial study (1)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Adam D, Nicollier, G (2001): Rate of Degradation of [Phenoxy-U-^{14}C]-labelled CGA 114597 in one Soil under Various Laboratory Conditions at 10 °C, 20 °C and 30 °C. Syngenta Crop Protection AG, Basel, Switzerland. Unpublished Report No. 01GN02. Study Dates: February - June 2001. Issue date: 07 December 2001 (Syngenta File No. CGA 114597/0793)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Draft OECD Guideline For Testing of Chemicals, Aerobic and Anaerobic Transformation in Soil, July, 1999. Richtlinien für die amtliche Prüfung von Pflanzenschutzmitteln Teil IV, 4 - 1: "Verbleib von Pflanzenschutzmitteln im Boden: Abbau, Umwandlung und Metabolismus": Biologische Bundesanstalt für Land- und Forstwirtschaft, Bundesrepublik Deutschland, Dezember 1986. Dutch Registration Guideline, G.1: Behaviour in soil; Ministry of Agriculture and Fisheries, Ministry of Public Health and Environmental Hygiene, Ministry of Social Affairs, January 1987.	
2.2	**GLP**	Yes (Syngenta Crop Protection AG)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: phenyl ring "A"-U-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 2.26 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	Samples were extracted with acetonitrile/water 80/20 at room temperature and with acetonitrile under reflux for 2 hours. The nature of radioactivity in the combined extracts was investigated by using 2D-TLC	

		and/or HPLC analysis. For the samples harvested after 3 and 90 days of incubation, respectively, the remaining soil residues were additionally extracted in two further steps: a neutral harsh extraction with 100 ml acetonitrile/deionised water (4:1) at 80 °C for 2 hours, followed by an acid harsh extraction with 100 ml acetonitrile/0.1 N HCL (9:1) at 80 °C for 2 hours. Thereafter the radioactivity in the extracts was determined by LSC after combustion. For sampling day 90, an organic matter fractionation was carried out. The humin fraction as well as the humic and fulvic acid fractions were determined. The radioactivity of volatile products in the trapping solutions (NaOH, ethylene glycol) was determined by LSC without further preparation.
3.2	**Reference substance**	Unlabelled fenoxycarb: Batch No. AMS 593/102, purity 99.5 ± 0.3% CGA 195935: Batch No. RV-1909/4, purity 93.0 ± 2.0% CGA 294848: Batch No. DPS-VII-27-2, purity 99.3 ± 0.1% CGA 294850: Batch No. RV-2345, purity 100.0 ± 2.0%
3.2.1	Method of analysis for reference substance	TLC and HPLC methods
3.3	**Soil types**	One soil type was used, see table A7_2_1-1
3.4	**Testing procedure**	
3.4.1	Test system	Rate of aerobic degradation in soil according to the guideline (see point 2.1).
3.4.2	Test solution and Test conditions	Soil samples were treated with [phenoxy-U-^{14}C]-labelled fenoxycarb at a concentration of 0.64 mg/kg dry soil, corresponding to a field application rate of 420 g a.i./ha. The samples were incubated in Erlenmeyer flaks with open gas flow system under aerobic conditions in the dark at 20 °C with a soil moisture content of 40% maximum water holding capacity (WHC; series 1) and of 25 % WHC (series 2). In addition soil samples were incubated with a soil moisture of 40% WHC at 10 °C (series 3) and at 30 °C (series 4). Duplicate samples were taken at regular intervals (0, 3, 7, 14, 28, 56, 90 and 120 days after treatment, for three sampling dates only one repetition) to determine the metabolism occurring.
		4 RESULTS
4.1	**Aerobic soil metabolism**	See table A7_2_1-2
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The objectives of the study were to provide information on the rate and route of degradation of [phenoxy-U-^{14}C]-labelled fenoxycarb, i.e. [2-(4-phenoxy-phenoxy)-ethyl]-carbamic ethyl ester, in Gartenacker soil (loam/silt loam) under various soil moisture and temperature conditions.
5.2	**Results and discussion**	

Section A7.2.1 Aerobic degradation in soil, initial study (1)

Annex Point: IIIA XII 1.1

5.2.1	DT50 values	Assuming first order degradation kinetics the half-lives and DT90 values of fenoxycarb were calculated as shown in table A7_2_1-3. Half-lives ranged from 1.1 to 4.5 days.
5.2.2	Degradation products (% of a.s.)	The overall recovery comprising the soil extracts, non-extractable residues and volatile products for all series was between 90.0% and 108.0% (all values given in % of the total applied radioactivity). The distribution of radioactivity is given in table A7_2_1-2. The extractable radioactivity declined from the beginning of the study up to the end from 105.0% to 2.0% (series 1, average of two replicates), 103.9% to 2.7% (series 2), 102.6% to 3.5% (series 3) and from 101.2% to 1.8% (series 4). The amount of fenoxycarb declined from 105.0% on day 0 to 1.4% on day 28 (series 1), from 103.9% to 2.3% (series 2) on day 56, from 102.6% to 3.4% on day 120 (series 3) and from 101.2% to 1.7% on day 28 (series 4). Based on chromatographic analysis besides the parent molecule several minor metabolites were found in amounts ≤ 4.5%. One of them was identified as CGA 294850, i.e. [2-4-(4-hydroxy-phenoxy)-phenoxy-ethyl]-carbamic ethyl ester, by co-chromatography using 2D-TLC analysis.
5.2.3	Bound residues	Non-extractable residues increased to 69.8% (at day 14; series 1), 70.1% (at day 56; series 2), 69.7% (at day 28; series 3) and 65.5% (at day 14; series 4) and decreased as the study progressed. At study termination the non-extractables accounted for 60.5%, 62.1%, 64.3% and 50.0% for series 1, 2, 3 and 4, respectively. When non-extractables of selected samples were submitted to harsh extraction procedures (i.e. reflux under neutral and acidic conditions), 4.0%, 2.4%, 2.3% and 4.0% were released for series 1, 2, 3 and 4, respectively, on day 3 and 1.0%, 1.1%, 1.3% and 0.7% on day 90. Subsequent fractionation of the bound residues (day 90) by the soil organic matter fractionation method showed that on average 2.1% to 2.3% of the applied radioactivity was associated with the fulvic acids, 4.7% to 5.9% with the humic acids and 46.3 to 58.4% with the humin fraction.
5.2.4	CO_2 formation	Carbon dioxide (CO_2) was continuously formed and reached a maximum of 36.4%, 31.3%, 27.2% and 46.3% for series 1, 2, 3 and 4 at day 120, respectively. Formation of organic volatiles was ≤ 1.1%.
5.3	**Conclusion**	Fenoxycarb was very rapidly degraded at 30 °C and 20 °C with a half-life of 1.1 to 1.3 days. Decreasing the temperature to 10 °C resulted in an increase of the half-life by a factor of approximately 3.5 (4.5 days). When the soil moisture content was lowered to 25% WHC at 20 °C, the half-life of fenoxycarb was 2.7 days. Only minor metabolites were found in amounts ≤ 4.5%. Under all conditions fenoxycarb was mainly degraded by mineralisation and formation of bound residues. The amount of non-extractable residues at study end ranged from 50.0% to 64.3%. Carbon dioxide accounted for up to 46.3%.
5.3.1	Reliability	1
5.3.2	Deficiencies	-

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2008/02/16

Materials and Methods

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks

COMMENTS FROM ...

Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_1-1: Classification and physico-chemical properties of soil used

Soil	Gartenacker
Source	Les Barges, Vouvry / VS, Switzerland
Batch-No	10/00
Classification (USDA)	Loam-silt loam
pH (KCl)	7.3
$CaCO_3$ [%]	6.5
Organic carbon [%]	2.1
N-tot. [%]	0.5
CEC [meq / 100 g soil]	13.9
Particle size (by pipette method):	
Clay [%]	11.8
Silt [%]	52.3
Sand [%]	35.9
Water holding cap. [WHC; g/100 g soil]	68.3
Microbial biomass [mg/100 dry soil] start	55.0
Microbial biomass [mg/100 dry soil] end 20 °C 40% WHC 132d 20 °C 25% WHC 132d 10 °C 40% WHC 128d 30 °C 40% WHC 128d	 63.2 53.4 49.6 30.7

Table A7_2_1-2: Distribution and recovery of radioactivity* in percent of applied ^{14}C -fenoxycarb in soil under aerobic laboratory conditions

Incubation time (days)	Cold Extract	Reflux	Sum*	$^{14}CO_2$	Organic Volatiles	Non-Extractables	Recovery	Fenoxy-carb	CGA 294850
Incubation at 20 °C and 40% WHC (Series 1)									
0	104.4	0.6	105	-	-	0.4	105.4	105	< LD
3	25.2	0.9	26.1	10.9	< 0.1	55.6	92.7	18.1	< LD
7	9.9	0.8	10.7	17.4	< 0.1	65.9	94	7.4	< LD
14	4.5	0.6	5.1	23	< 0.1	69.8	97.9	3.1	0.2
28	3.1	0.4	3.5	27.7	< 0.1	66.6	97.8	1.4	< LD
56	2.1	0.5	2.7	29.5	< 0.1	65.3	97.4	< LD	< LD
90	2	0.6	2.5	31.5	< 0.1	62.6	96.6	< LD	< LD
120	1.6	0.4	2	36.4	< 0.1	60.5	99	< LD	< LD
Incubation at 20 °C and 25% WHC (Series 2)									
0	103.4	0.6	103.9	-	-	0.4	104.3	103.9	< LD
3	49	0.8	49.8	7	< 0.1	40.2	97	41.4	< LQ
7	26	1	26.9	14.6	< 0.1	57.1	98.7	19.5	< LQ
14	14.4	0.7	15.1	13.8	< 0.1	63.5	92.4	10.8	0.3
28	5.6	0.6	6.1	24	< 0.1	68.3	98.4	3.9	< LQ
56	3	0.7	3.6	27	< 0.1	70.1	100.7	2.3	< LD
90	2.4	0.5	2.9	31.7	< 0.1	63.4	98	< LD	< LD
120	2.1	0.6	2.7	31.3	< 0.1	62.1	96.1	< LD	< LD
Incubation at 10 °C and 40% WHC (Series 3)									
0	102.2	0.4	102.6	-	-	0.3	102.9	102.6	< LD
3	66.5	0.8	67.4	1.9	< 0.1	25.7	94.9	59	< LD
7	42.5	0.9	43.5	5.6	< 0.1	46.2	95.3	35.8	< LD
14	14.9	0.8	15.7	15.1	< 0.1	64.7	95.5	11.1	0.2
28	6.9	0.6	7.5	22.2	< 0.1	69.7	99.5	4.4	0.3
56	3.9	0.8	4.7	23.5	1.1	65.7	95	3	< LD
90	3.3	0.7	3.9	23.5	1.1	67.9	101.2	2.9	< LD
120	2.9	0.6	3.5	27.2	< 0.1	64.3	95	3.4	< LD
Incubation at 30 °C and 40% WHC (Series 4)									
0	100.6	0.6	101.2	-	-	0.2	101.4	101.2	< LD
3	25	0.9	25.9	13.8	< 0.1	52.7	92.4	15.5	< LD
7	7.4	0.8	8.1	20.4	< 0.1	63.5	92	3.1	< LD
14	5	0.6	5.7	29.1	< 0.1	65.5	100.3	3.7	0.1
28	2.7	0.5	3.1	34.8	< 0.1	59.2	97.2	1.7	< LD
56	1.7	0.5	2.2	40.2	< 0.1	63.8	106.2	< LD	< LD
90	1.5	0.5	2	44.3	< 0.1	53.8	100	< LD	< LD
120	1.4	0.4	1.8	46.3	< 0.1	50	98.1	< LD	< LD

* Sum of cold and reflux extracts
LD: limit of detection ; LQ: limit of quantification

Table A7_2_1-3: Calculated half lives for the degradation of ^{14}C -fenoxycarb in soil under various conditions

	Series 1 20 °C 40% WHC	Series 2 20 °C 25% WHC	Series 3 10 °C 40% WHC	Series 4 30 °C 40% WHC
fenoxycarb				
Half-life [d]	1.3	2.7	4.5	1.1
DT_{90} [d]	4.3	9.0	14.8	3.8
Correlation coefficient	0.996	0.990	0.992	0.998

Section A7.2.1 Aerobic degradation in soil (02); Spare, W. (1995a)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Spare, W. (1995a): Aerobic and aerobic/anaerobic metabolism of "A" label ^{14}C-Fenoxycarb in a sandy loam soil: In-life/balance phase. Agrisearch Inc., Frederick, United States, unpublished report No. 12212, study dates: February 1994 - March 1995; issue date: 24 July, 1995. (Syngenta File No. CGA114597/0873)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Pesticide Assessment Guidelines, Subdivision N Series 162-1, 162-2, Chemistry: Environmental Fate, EPA: Aerobic Soil Metabolism Study, US Environmental Protection Agency, October 18, 1982	
2.2	**GLP**	Yes (Agrisearch Inc., Frederick, United States, Ciba-Geigy Corp., Greensboro, United States)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: Phenyl ring "A"-U-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 4.28 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	Soil samples of each sampling day were combusted and analysed by direct LSC. Anaerobic waters and volatiles trapping solutions were analysed by direct LSC. Sample extractions and confirmation and identification of fenoxycarb and metabolic products were performed at Ciba-Geigy Crop Protection, Inc. USA (please refer to report prepared by Thede, B. 1995a).	
3.2	**Reference**	Unlabelled fenoxycarb: analytical standard No. S91-1536, purity 99.0%	

Section A7.2.1 Aerobic degradation in soil (02); Spare, W. (1995a)

Annex Point: IIIA XII 1.1

	substance	Phenyl-(A)-^{14}C-CGA-114597: reference No. CL-XXXIII-87, radiochemical purity 99.4%
3.2.1	Method of analysis for reference substance	TLC and HPLC analyses were performed to qualitatively and quantitatively confirm fenoxycarb purity prior to application to the test soils.
3.3	**Soil types**	See Table A7_2_1-1
3.4	**Testing procedure**	
3.4.1	Test system	Route and rate of aerobic and anaerobic degradation in soil according to the guideline (see point 2.1). Test system was a foil wrapped, 250 mL Erlenmeyer flask containing ^{14}C-fenoxycarb dosed soil. Volatiles from each incubation flask were trapped using a series of duplicate 10% KOH (2) traps and confirmed by $BaCl_2$ precipitation as $BaCO_3$.
3.4.2	Test solution and Test conditions	Three sets of incubations were initiated for aerobic and anaerobic soil metabolism: 1) Aerobic soil metabolism: The soil was dosed at a concentration of 0.122 mg/kg (aerobic kinetic test) corresponding to a field rate of 280 g/ha assuming a homogeneous distribution in the top 15 cm soil layer and a soil density of 1.5 g/cm^3 and at 9.16 mg/kg for the identification of degradation products (degradation test). Incubation was at 25 °C and 75% field moisture capacity in the dark under aerobic conditions for 365 days. Soil samples were periodically aerated and trapped for volatiles at harvest date and/or every fourteen days. Duplicate samples were taken at regular intervals (16 for the 0.122 mg/kg and 6 for the 9.16 mg/kg incubations) up to one year to determine material balance and the metabolism occurring. 2) Anaerobic soil metabolism: The soil was dosed at a concentration of 0.127 mg/kg for kinetic and 9.9 mg/kg for degradate incubation. Samples were converted to anaerobic conditions after 3 hours (kinetic) or 6 days (degradate) aerobic incubation by flooding with 100 mL of sterilized HPLC grade water purged with nitrogen gas for 25 hours. Samples were kept at 25 °C. Soil samples were periodically trapped for volatiles. Duplicate samples were taken at regular intervals up to one year (sampling after 3 and 6 hours, day 14 and 1, 3, 6 and 12 months) to determine the kinetic rate. Duplicate samples were also taken to determine the degradation rate after 1, 6, 9 and 12 (1 Replicate) months. At the time of sampling, redox potential measurements, dissolved oxygen and pH determinations were used to confirm anaerobicity. 3) Aerobic soil metabolism: A third kinetic (0.121 mg/kg) dose level was utilized to generate additional kinetic samples to verify the half-life of fenoxycarb (sampling

Section A7.2.1 Aerobic degradation in soil (02); Spare, W. (1995a)

Annex Point: IIIA XII 1.1

times at 0, 1, 2, 3, 4, 5, 6 hours aerobic incubation).

4 RESULTS

4.1 Aerobic soil metabolism

The distribution and recovery of radioactivity of applied ^{14}C-fenoxycarb ("A"-^{14}C labelled) in Maryland sandy loam under aerobic and anaerobic laboratory conditions was summarized in the report prepared by Thede, B. (1995a).

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The route and rate of aerobic and anaerobic degradation of ^{14}C-labelled fenoxycarb was investigated in a Maryland sandy loam soil for one year.

The incubation and the balance of this soil metabolism study were performed at Agrisearch Inc., Frederick, Maryland (Spare, W. 1995a).

The characterisation of the degradation pattern was carried out at Ciba-Geigy Crop Protection, Inc. USA (please refer to report prepared by Thede, B. 1995a).

5.2 Results and discussion

5.2.1 DT50 values

Please refer to Thede, B. (1995a)

5.2.2 Degradation products (% of a.s.)

Please refer to Thede, B. (1995a)

5.2.3 Bound residues

Please refer to Thede, B. (1995a)

5.2.4 CO_2 formation

Aerobic soil metabolism:

Aerobic volatile generation of carbon dioxide increased to an average of 38.3% at day 360 indicating mineralisation of the phenyl ring "A".

Anaerobic soil metabolism:

Under anaerobic conditions the degradation of fenoxycarb was considerably slowed down. A continued production of $^{14}CO_2$ was observed under anaerobic conditions (32% after 360 days), indicating that there are multiple pathways operating in the degradation of fenoxycarb.

5.3 Conclusion

Over a twelve month period, the radiochemical balance averaged 96.4% for the aerobic kinetic incubations and 105.8% for the aerobic/anaerobic kinetic incubations.

Under aerobic/anaerobic conditions, water samples accounted for a maximum of 4.2% of dose (day 14, mean of 2 replicates).

Significant $^{14}CO_2$ was generated from all incubations.

5.3.1 Reliability

1

5.3.2 Deficiencies

-

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	08/02/11
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_1-1: Classification and physico-chemical properties of soil used for fenoxycarb metabolism studies

Test material used in study		"A"-^{14}C labelled fenoxycarb
Sample ID		Maryland Lime Kiln 0 - 6 "
pH		7.7
Organic matter [%]		2.2
CEC [meq/100 g soil]		10.9
Field moisture capacity (FMC) at 1/3 bar [%]		13.9
Classification (USDA)		Sandy loam
Particle size:	Clay [%]	10
	Silt [%]	16
	Sand [%]	74

Section A7.2.1 Aerobic degradation in soil (02); Thede, B. (1995a)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Thede, B. (1995a): Aerobic and aerobic/anaerobic metabolism of "A" label ^{14}C-Fenoxycarb in a sandy loam soil, Ciba-Geigy Corp., Greensboro, United States, unpublished report No. ABR-95019, issue date: 6 October, 1995. (Syngenta File No. CGA114597/0570)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Pesticide Assessment Guidelines, Subdivision N Series 162-1, 162-2, Chemistry: Environmental Fate, EPA: Aerobic Soil Metabolism Study, US Environmental Protection Agency, October 18, 1982	
2.2	**GLP**	Yes (Agrisearch Inc., Frederick, United States, Ciba-Geigy Corp., Greensboro, United States)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: Phenyl ring "A"-U-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 4.28 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	Soil samples from the kinetic aerobic incubation were extracted with methanol - 0.1 N sodium hydroxide 8:2 at room temperature (Extract 1) and with 0.5 N sodium hydroxide at 100 °C (Extract 2). Unextracted soil samples were combusted and analysed by direct LSC. The nature of radioactivity was investigated by using TLC, HPLC and GC/MSD. Analysis of anaerobic waters and volatiles trapping solutions is described	

Section A7.2.1 Aerobic degradation in soil (02); Thede, B. (1995a)

Annex Point: IIIA XII 1.1

		in the report prepared by Spare, W. (1995a).
3.2	**Reference substance**	Unlabelled fenoxycarb: analytical standard No. S91-1536, purity 99.0% Phenyl-(A)-^{14}C-CGA-114597: reference No. CL-XXXIII-87, radiochemical purity 99.4% CGA-026021 or 26021: Lot No. NEH-VI-59, purity 99.0% CGA-195935: Lot No. GB-XLVIII-40-1, purity 99.2% CGA-197810: Lot No. NV-XXXI-4, purity 99.2% CGA-197810-HCl Salt: Lot No. NV-XXXIII-2, purity > 99.9% CGA-197811: Lot No. DAH-IXX-34, purity 98.9% CGA-294847: Lot No. GB-LI-75, purity 99.6% CGA-294848: Lot No. DPS-VII-27-2, purity 99.3% CGA-294850 (RO-16-8797): Lot No. GB-IL-8, purity 98.3% CGA-294851 (RO-17-3192): Lot No. GB-IL-24-1, purity 98.0% CGA-344891 (RO-43-4760): Lot No. CAS-IV-48, purity > 99.9% CGA-344889 (RO-42-8109): Lot No. GB-IL-53, purity > 99.0% CGA-344890 (RO-17-3193): Lot No. DAH-XVII-9, purity > 96.9% Phenol: Lot No. 315284/1-293, purity > 99.5% Resorcinol: Lot No. 08307MY, purity 99.0% Catechol: Lot No. 06522MY, purity > 99.0% 1,2,4 benzentriol: Lot No. 00321AF, purity 99.0% 2,5 dihydroxy-1,4-benzoquinone: Lot No. 03930JZ, purity 98.0% Hydroquinone: Lot No. CZ 04622BX, purity 99.0% Tetrahydroxy-1,4-quinone: Lot No. PZ 09915MX, purity 99.0%
3.2.1	Method of analysis for reference substance	Two dimensional TLC, HPLC or GC/MS methods
3.3	**Soil types**	For soil description, please refer to report prepared by Spare, W. (1995a)
3.4	**Testing procedure**	
3.4.1	Test system	Route and rate of aerobic and anaerobic degradation in soil according to the guideline (see point 2.1). Test system is comprehensively described in the report of the biological/In-life phase of the study by Spare, W. (1995a).
3.4.2	Test solution and Test conditions	Three sets of incubations were initiated for aerobic and anaerobic soil metabolism: 1) Aerobic soil metabolism 2) Anaerobic soil metabolism 3) Aerobic soil metabolism Test solutions and test conditions are comprehensively described in the report of the biological/In-life phase of the study prepared by Spare, W. (1995a).

Section A7.2.1 Aerobic degradation in soil (02); Thede, B. (1995a)

Annex Point: IIIA XII 1.1

4 RESULTS

4.1 Aerobic soil metabolism

The results of the different phases of the study described by Spare, W. (1995a) and Thede, B. (1995a) are summarized in Tables A7_2_1-1 and A7_2_1-2.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The route and rate of aerobic and anaerobic degradation of ^{14}C-labelled fenoxycarb was investigated in a Maryland sandy loam soil for one year.

The incubation and the balance of this soil metabolism study were performed at Agrisearch Inc., Frederick, Maryland (report prepared by Spare, W. 1995a).

The characterisation of the degradation pattern was carried out at Ciba-Geigy Crop Protection, Inc. USA (Thede, B. 1995a).

5.2 Results and discussion

5.2.1 DT50 values

Aerobic soil metabolism:

Degradation of fenoxycarb was found to follow biphasic first-order kinetics. The rapid initial aerobic degradation (primary half-life) was calculated to be 6.7 hours. The secondary half-life was 237 days.

Anaerobic soil metabolism:

Degradation of fenoxycarb was found to follow biphasic first-order kinetics. The initial anaerobic degradation (primary half-life) was calculated to be 16 days. The secondary half-life was 8.5 months.

5.2.2 Degradation products (% of a.s.)

Aerobic soil metabolism:

The distribution of radioactivity after laboratory incorporation of phenyl ring "A"-^{14}C labelled fenoxycarb is shown in Table A7_2_1-1.

Extract 1 decreased rapidly in the first few hours of incubation and reached a level of below 10% after 30 days. Generally, as the percent of total dose in Extract 1 gradually decreased the amount in Extract 2 increased. Extract 2 fraction peaked at 7 days after application with 39.4% of total dose and then decreased. Of the multiple components present in the extraction fractions the only component present in significant quantities was parent fenoxycarb. There was no evidence of accumulation of any single metabolite during the 12 months incubation. The degradation pattern observed by TLC assays of Extract 1 demonstrated the presence of at least 10 metabolites at concentrations well below 10% of applied radioactivity.

Some of the metabolites were characterised by two dimensional TLC, HPLC or GC/MS as CGA 294850 (maximum 3.3%), CGA 197811 or CGA 26021 (maximum 0.2%), CGA 294848 (maximum 0.5%), CGA 344889 (maximum 0.2%), CGA 197810 (maximum 0.1%). Size exclusion HPLC of Extract 2 fractions supported the proposal that the majority of the radioactivity in Extract 2 is solubilised soil or microbial components into which the carbon-14 from fenoxycarb has been

		incorporated. Anaerobic soil metabolism: The results obtained for the anaerobic degradation are presented in Table A7_2_1-2. The water fraction of the anaerobic set-up made only a minor contribution to the material balance and showed the same pattern as in Extract 1. After initial rapid decrease the percent of total dose in Extract 1 decreased more slowly. As with the aerobic degradation, fenoxycarb was the only major component identified in Extract 1. The hydroxy-metabolite CGA294850 was found at a maximum level of 4.2% after 6 hours. The same general pattern of radiolabel distribution as in the aerobic test was observed in Extract 1 and Extract 2. Some of the multiple degradates further characterised were CGA 197811 or CGA 26021 (maximum 0.2%), CGA 294848 (maximum 0.4%), CGA 344889 (maximum 0.6%), CGA 197810 (maximum 0.6%).
5.2.3	Bound residues	Aerobic soil metabolism: The non-extractables reached a maximum of 40% at day 30 and then decreased to 18% after one year. Anaerobic soil metabolism: The non-extractables reached a maximum of 42.5% at day 180 and then decreased to 26.3% after one year.
5.2.4	CO_2 formation	Please refer to report prepared by Spare, W. (1995a)
5.3	**Conclusion**	Fenoxycarb degraded rapidly to several minor components at concentrations well below 10% of applied radioactivity, which do not accumulate over time. Compared to the aerobic degradation of fenoxycarb, a slower degradation of fenoxycarb under anaerobic conditions is observed.
5.3.1	Reliability	1
5.3.2	Deficiencies	-

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 09/07/30

Materials and Methods

[redacted]

Results and discussion

[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_1-1: Distribution and recovery of radioactivity* in percent of applied ^{14}C -fenoxycarb ("A"-^{14}C labelled) in Maryland sandy loam under aerobic laboratory conditions

Hours Days after applic.*	Volatiles (CO_2)*** [%]	Extrac-tables 1 [%]	Extrac-tables 2 [%]	Fenoxycarb** [%]	CGA 294850 [%]	Non-extrac-tables [%]	Total [%]
Aerobic kinetic 0.122 mg/kg							
3 h	0.0	70.6	12.9	53.3	2.8	15.6	98.9
6 h	2.4	49.7	17.0	32.6	2.6	26.4	95.4
0.5	4.5	38.0	27.1	26.7	1.8	23.5	93.0
1	7.7	28.9	29.7	20.6	0.8	24.4	90.7
1.25	8.6	23.8	30.0	15.4	1.5	32.2	94.5
2	10.5	15.2	31.8	11.9	0.7	30.7	88.1
3	12.4	19.0	33.8	14.7	0.5	30.0	95.1
7	14.8	13.9	39.4	8.1	1.2	25.4	93.4
14	14.2	12.1	23.5	7.7	0.2	38.9	88.6
21	19.4	11.5	25.5	7.4	0.2	37.1	93.4
30	20.8	9.0	22.3	6.5	0.2	40.2	92.3
60	24.9	7.1	20.9	4.6	0.2	36.3	89.1
90	29.0	5.7	17.1	4.0	0.2	36.4	88.7
180	36.2	4.8	16.7	3.9	0.1	30.1	87.9
270	36.3	3.8	14.6	3.0	0.1	27.2	81.9
360	38.3	4.8	23.0	4.0	0.1	18.2	84.0

* average of duplicate sample analysis
** a.s. determined by radio-TLC
*** determined in the report of the biological/In-life phase of the study prepared by Spare, W. (1995a)

Table A7_2_1-2: Distribution and recovery of radioactivity* in percent of applied ^{14}C-fenoxycarb in Maryland sandy loam under anaerobic laboratory conditions

Hours Days after applic.	Water Phase*** [%]	Volatiles (CO_2)*** [%]	Extrac-tables 1 [%]	Extrac-tables 2 [%]	Fenoxycarb** [%]	CGA 294850 [%]	Non-extrac-tables [%]	Total [%]
Anaerobic kinetic 0.127 mg/kg								
3 h	Not applic	Not meas.	69.0	6.7	56.1	2.1	18.6	94.2
6 h	3.6	11.9	55.6	8.3	35.9	4.2	28.0	107.3
14	4.2	16.9	41.0	19.5	24.6	2.9	24.5	105.9
30	1.9	21.1	30.7	15.0	21.2	1.7	35.4	104.0
90	1.4	25.3	22.5	15.9	13.4	2.9	35.8	100.8
180	2.3	19.7	18.4	16.2	14.7	0.3	42.5	100.1
360	1.9	32.0	13.6	23.8	9.8	0.5	26.3	107.4

* average of duplicate sample analysis
** a.s. determined by radio-TLC
*** determined in the report of the biological/In-life phase of the study prepared by Spare, W. (1995a)

Annex 1 Evaluation by Rapporteur Member State, CA-Tables

CA-Table 1 (revised Table A7_2_1-1):- Distribution and recovery of radioactivity* in percent of applied ^{14}C -fenoxycarb ("A"-^{14}C labelled) in Maryland sandy loam under aerobic laboratory conditions

Hours Days after applic.*	Volatiles (CO_2)*** [%]	Extractables			Unextractables			Mass balance
		Extractables 1 total [%]	CGA 294850 [%]	Fenoxycarb** [%]	0.5 n NaOH-extractables [%]	Non-extractables [%]	Total Unextractables [%]	Total [%]
Aerobic kinetic 0.122 mg/kg								
3 h	0.0	70.6	2.8	57.1	12.9	15.6	28.5	98.9
6 h	2.4	49.7	2.6	36	17.0	26.4	43..4	95.4
0.5	4.5	38.0	1.8	27.7	27.1	23.5	50.6	93.0
1	7.7	28.9	0.8	20.1	29.7	24.4	54.1	90.7
1.25	8.6	23.8	1.5	17.2	30.0	32.2	62.2	94.5
2	10.5	15.2	0.7	11.5	31.8	30.7	65.9	88.1
3	12.4	19.0	0.5	13.9	33.8	30.0	63.8	95.1
7	14.8	13.9	1.2	10.2	39.4	25.4	64.8	93.4
14	14.2	12.1	0.2	8.8	23.5	38.9	62.4	88.6
21	19.4	11.5	0.2	8.3	25.5	37.1	62.6	93.4
30	20.8	9.0	0.2	7.1	22.3	40.2	62.5	92.3
60	24.9	7.1	0.2	5.6	20.9	36.3	57.2	89.1
88	29.0	5.7	0.2	5.0	17.1	36.4	53.5	88.7
182	36.2	4.8	0.1	3.8	16.7	30.1	46.8	87.9
273	36.3	3.8	0.1	3.1	14.6	27.2	41.8	81.9
365	38.3	4.8	0.1	3.9	23.0	18.2	41.2	84.0

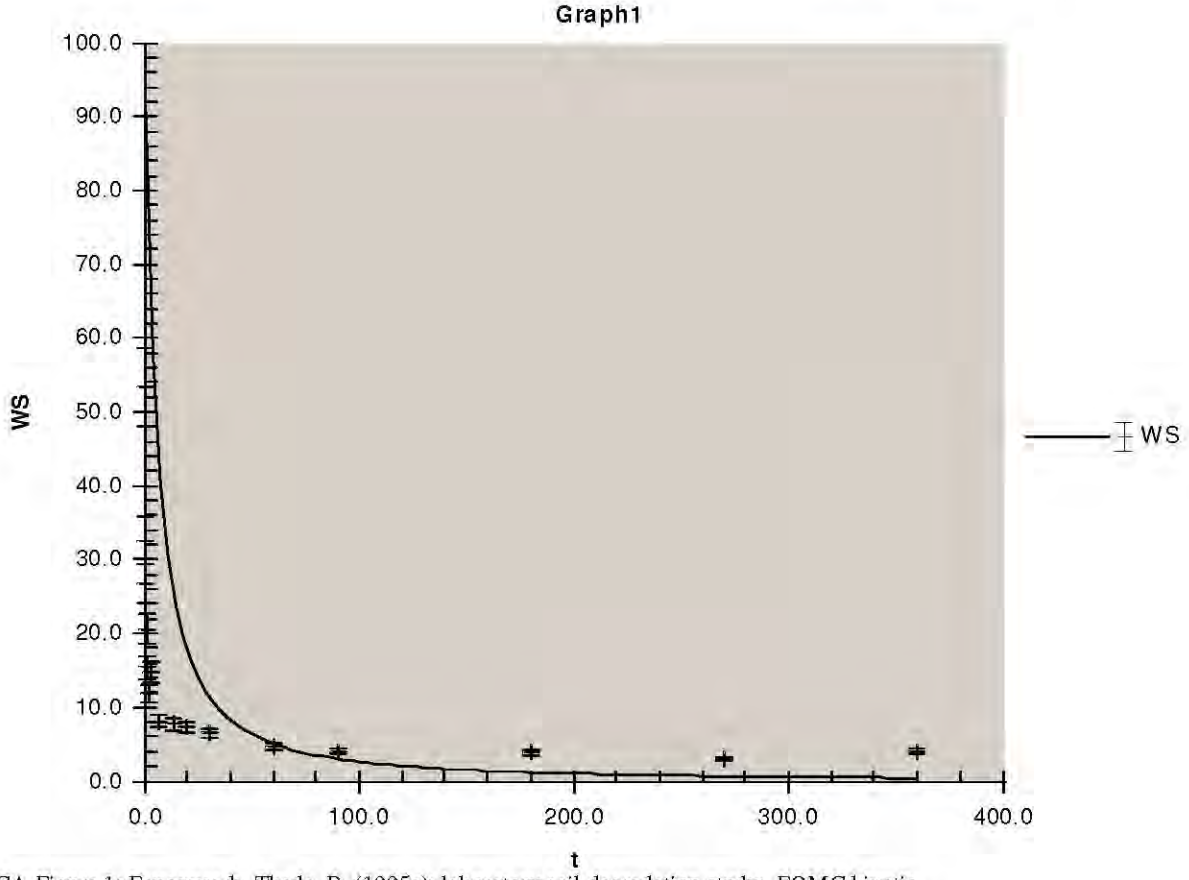
* average of duplicate sample analysis
** % total dose of fenoxycarb (HPLC assays)
*** determined in the report of the biological/In-life phase of the study prepared by Spare, W. (1995a)

CA-Table 2 (Table A7_2_1-2): Distribution and recovery of radioactivity* in percent of applied ^{14}C-fenoxycarb in Maryland sandy loam under anaerobic laboratory conditions

Hours/ Days after application	Water Phase*** [%]	Volatiles (CO_2)*** [%]	Extractables			Non-extractable residues (NER)			Total [%]
			Total Extractables 1 [%]	Fenoxycarb** [%]	CGA 294850 [%]	0.5 N NaOH-Extrac-tables 2[%]	Un-extrac-tables [%]	Total NER [%]	
3 h	Not applic	Not meas.	69.0	60	2.1	6.7	18.6	25.3	94.2
6 h	3.6	11.9	55.6	44	4.2	8.3	28.0	36.3	107.3
14	4.2	16.9	41.0	28	2.9	19.5	24.5	44	105.9
30	1.9	21.1	30.7	21	1.7	15.0	35.4	50.4	104.0
90	1.4	25.3	22.5	15	2.9	15.9	35.8	51.7	100.8
180	2.3	19.7	18.4	11.8	0.3	17.2	42.5	58.7	100.1
360	1.9	32.0	13.6	8.1	0.5	23.6	36.1	59.7	107.4

* average of duplicate sample analysis
** as % total dose of fenoxycarb (HPLC assays)
*** determined in the report of the biological/In-life phase of the study prepared by Spare, W. (1995a)

Recalculation of DT_{50} values with ModelMaker 4.0 according to FOCUS kinetics; prepared by RMS, 2008



CA-Figure 1: Fenoxycarb, Thede, B. (1995a): laboratory soil degradation study: FOMC kinetic

Values at 25°C test temperature:

DT_{50}= 5.73 d

DT_{90} = 36,6 d

$DT_{50\ modelling}$=11.01 d

r2: 0.87

Error level Chi^2 Test: >> 15

Section A7.2.1 Aerobic degradation in soil (03); Spare, W. (1995b)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Spare, W.C. (1995b): Aerobic and anaerobic metabolism of "B" label ^{14}C-Fenoxycarb in sandy loam soil: In-life/balance phase, Agrisearch Inc., Frederick, United States, unpublished report No. 12209. Study dates: February 1993 - March 1994. Issue date: 24 February, 1995. (Syngenta File No. CGA114597/0525)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Pesticide Assessment Guidelines, Subdivision N Series 162-1, 162-2, Chemistry: Environmental Fate, EPA: Aerobic Soil Metabolism Study, US Environmental Protection Agency, October 18, 1982.	
2.2	**GLP**	Yes (Agrisearch Inc., Frederick, United States, Ciba-Geigy Corp., Greensboro, United States)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: Phenyl ring "B"-U-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 1.2 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	Soil samples of each sampling day were combusted and analysed by direct LSC. Waters, extracts and volatiles trapping solutions were analysed by direct LSC. <u>Aerobic degradation:</u> The soil samples were extracted by sonication in the presence of methanol - water (sonic 1, up to day 210) and basified water (sonic 2, up to day 150).	

Section A7.2.1 Aerobic degradation in soil (03); Spare, W. (1995b)

Annex Point: IIIA XII 1.1

		Anaerobic degradation: Samples were extracted by sonication (sonic 1, up to day 180 and the 270 day sample and sonic 2, up to day 150). Non-extractable residues were quantified by combustion analysis of the residual sediment. The nature of radioactivity (fenoxycarb and metabolites) was investigated by using TLC and HPLC methods.
3.2	**Reference substance**	Unlabelled fenoxycarb: analytical standard No. S91-1536, purity 99.0% Phenyl-(A)-^{14}C-CGA-114597: reference No. GAN-XXV-74, radiochemical purity 99.1% CGA-026021 or 26021: Lot No. NEH-VI-59, purity 99.0% CGA-195935: Lot No. GB-XLVIII-40-1, purity 99.2% CGA-197810: Lot No. NV-XXXI-4, purity 99.2% CGA-294850 (RO-16-8797): Lot No. GB-IL-8, purity 98.3% CGA-294851 (RO-17-3192): Lot No. GB-IL-24-1, purity 98.0%
3.2.1	Method of analysis for reference substance	TLC and HPLC methods
3.3	**Soil types**	See Table A7_2_1-1
3.4	**Testing procedure**	
3.4.1	Test system	Route and rate of aerobic and anaerobic degradation in soil according to the guideline (see point 2.1). Test system was a foil wrapped, 500 mL Erlenmeyer flask containing ^{14}C-fenoxycarb dosed soil. Volatiles from each incubation flask were trapped using a series of polyurethane foam plugs (2), a glycol trap (1), and duplicate 10% KOH (2) traps.
3.4.2	Test solution and Test conditions	Aerobic degradation: The soil was dosed at a concentration of 10.23 mg/kg (aerobic kinetic test) corresponding to an exaggerated field rate of 23.5 kg/ha assuming a homogeneous distribution in the top 15 cm soil layer and a soil density of 1.5 g/cm^3 for the identification of degradation products. Incubation was at 25 °C and 75% field moisture capacity in the dark under aerobic conditions for 365 days. Soil samples were periodically aerated and trapped for volatiles. Duplicate samples were taken on days 0, 3, 7, 14, 21, 30, 45, 60, 90, 120, 150, 210, 270, and 360 to determine material balance and the metabolism occurring. Anaerobic degradation: The soil was dosed at a concentration of 10.23 mg/kg, and the test vessels were incubated at 25 °C and 75% field moisture capacity in the dark and converted to anaerobic conditions by flooding with nitrogen purged water after 30 days of aerobic incubation.

Section A7.2.1 Aerobic degradation in soil (03); Spare, W. (1995b)

Annex Point: IIIA XII 1.1

Soil samples were trapped for volatiles with nitrogen.

Duplicate samples were taken after 1, 2, 3, 4, 5, 6, 8, 9, and 12 months to determine material balance and the metabolism occurring.

4 RESULTS

4.1 Aerobic soil metabolism

The distribution and recovery of radioactivity of applied ^{14}C-fenoxycarb sandy loam was summarized in the report prepared by Thede, B. (1995b).

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The route and rate of aerobic and anaerobic degradation of ^{14}C-labelled fenoxycarb was investigated in a Maryland sandy loam soil for one year.

The incubation and the balance of this soil metabolism study were performed at Agrisearch Inc., Frederick, Maryland (Spare, W. 1995b).

The characterisation of the degradation pattern was carried out at Ciba-Geigy Crop Protection, Inc. USA (please refer to report prepared by Thede, B. 1995b).

5.2 Results and discussion

5.2.1 DT50 values

A recalculation of the degradation half life values has been performed at completion of analytical phase of the study. Definitive results were reported by Thede, B. (1995b).

5.2.2 Degradation products (% of a.s.)

The active substance was the only major component in all extracts. Confirmation and identification of fenoxycarb and metabolic products is performed in the report prepared by Thede, B. (1995b).

5.2.3 Bound residues

Non-extractable residues after sonication (sonic 1 and 2) without subsequent treatment are ascertained up to day 150 (max. 68.9% of applied radioactivity after 30 days).

The extraction procedures were modified during the course of the study. Results of the whole study period are summarized in the report prepared by Thede, B. (1995b).

5.2.4 CO_2 formation

Aerobic degradation:

Volatiles (carbon dioxide) were rapidly generated and accounted for nearly 20% of the total dose after 30 days. A maximum of 32.9% was reached after one year.

Anaerobic degradation:

A maximum of 26% was reached after one year.

5.3 Conclusion

The radiochemical balance averaged 93.9% for aerobic incubation period. The radioactivity in the aerobic incubation averaged 90.3% over the 12 months.

This study indicated that fenoxycarb rapidly degraded to several minor components, which do not accumulate over time.

Degradation of fenoxycarb is slower under anaerobic compared to

Section A7.2.1 Aerobic degradation in soil (03); Spare, W. (1995b)

Annex Point: IIIA XII 1.1

		aerobic conditions.
5.3.1	Reliability	1
5.3.2	Deficiencies	-

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/02/20
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]

Reliability	[redacted]
	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_1-1: Classification and physico-chemical properties of soil used for fenoxycarb metabolism studies

Test material used in study		**"B"-^{14}C labelled fenoxycarb**
Sample ID		Maryland Lime Kiln 0 - 6 "
pH		7.8
Organic matter [%]		2.6
CEC [meq/100 g soil]		10.9
Field moisture capacity (FMC) at 1/3 bar [%]		23.1
Classification (USDA)		Sandy loam
Particle size:	Clay [%]	17
	Silt [%]	12
	Sand [%]	71

Section A7.2.1 Aerobic degradation in soil (03); Thede, B. (1995b)

Annex Point: IIIA XII 1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Thede, B. (1995b): Aerobic and anaerobic metabolism of "B" label ^{14}C-Fenoxycarb in sandy loam soil, Ciba-Geigy Corp., Greensboro, United States, unpublished report No. ABR-95018. Issue date: 11 September, 1995. (Syngenta File No. CGA114597/0566)	
1.2	**Data protection**	No	
1.2.1	Data owner	Syngenta Crop Protection AG	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Pesticide Assessment Guidelines, Subdivision N Series 162-1, 162-2, Chemistry: Environmental Fate, EPA: Aerobic Soil Metabolism Study, US Environmental Protection Agency, October 18, 1982.	
2.2	**GLP**	Yes (Agrisearch Inc., Frederick, United States, Ciba-Geigy Corp., Greensboro, United States)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substance: Phenyl ring "B"-U-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 1.2 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	Aerobic degradation: The soil samples were extracted by sonication (sonic 1 and 2) as described in the report prepared by Spare, W. (1995b). The 210 day, 270 day and 360 day samples were subjected to additional extraction procedures by homogenisation with a blender/homogenise in methanol - 0.1 N sodium hydroxide (Extraction 1) and autoclaving in 0.5 N sodium hydroxide (Extraction 2) and analysed by direct LSC.	

Section A7.2.1 Aerobic degradation in soil (03); Thede, B. (1995b)

Annex Point: IIIA XII 1.1

		Anaerobic degradation: Samples were extracted by sonication as described in the report by Spare, W. (1995b). For later time, samples are additionally extracted by homogenising in methanol - 0.1 N sodium hydroxide (Extraction 1) and autoclaving in 0.5 N sodium hydroxide (Extraction 2). These extracts were analysed by direct LSC. Sonic 1 and Sonic 2 extractions were conducted by Agrisearch, Incorporated (Spare, W. 1995b). Extract 1 and Extract 2 procedures were conducted at Ciba Crop Protection, Greensboro (Thede, B. 1995b). The extraction procedures were modified during the course of the study because of the rapid rise in percent of total dose in the non-extractable fraction. The Extract 1 procedure was developed because fenoxycarb was not completely extracted from the soil by the Sonic 1 procedure. The Extract 2 procedure replaced the Sonic 2 method in order to increase the total extractability of the radiolabel. The nature of radioactivity (fenoxycarb and metabolites) was investigated by using two-dimensional TLC, HPLC and GC/MSD. Non-extractable residues of the 210 day, 270 day and 360 day samples were quantified by combustion analysis of the residual sediment.
3.2	**Reference substance**	Unlabelled fenoxycarb: analytical standard No. S91-1536, purity 99.0% Phenyl-(A)-^{14}C-CGA-114597: reference No. GAN-XXV-74, radiochemical purity 99.1% CGA-026021 or 26021: Lot No. NEH-VI-59, purity 99.0% CGA-195935: Lot No. GB-XLVIII-40-1, purity 99.2% CGA-197810: Lot No. NV-XXXI-4, purity 99.2% CGA-294850 (RO-16-8797): Lot No. GB-IL-8, purity 98.3% CGA-294851 (RO-17-3192): Lot No. GB-IL-24-1, purity 98.0%
3.2.1	Method of analysis for reference substance	Two-dimensional TLC, HPLC and GC/MSD
3.3	**Soil types**	For soil description, please refer to report prepared by Spare, W. (1995b).
3.4	**Testing procedure**	
3.4.1	Test system	Route and rate of aerobic and anaerobic degradation in soil according to the guideline (see point 2.1). Test system is comprehensively described in the report of the In-life/balance phase of the study prepared by Spare, W. (1995b).
3.4.2	Test solution and Test conditions	Test solutions and test conditions are comprehensively described in the report of the In-life/balance phase of the study prepared by Spare, W. (1995b).

Section A7.2.1 Aerobic degradation in soil (03); Thede, B. (1995b)

Annex Point: IIIA XII 1.1

4 RESULTS

4.1 Aerobic soil metabolism

The results of the different phases of the study described by Spare, W. (1995b) and Thede, B. (1995b) are summarized in Table A7_2_1-1.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The route and rate of aerobic and anaerobic degradation of ^{14}C-labelled fenoxycarb was investigated in a Maryland sandy loam soil for one year.

The incubation and the balance of this soil metabolism study were performed at Agrisearch Inc., Frederick, Maryland (Spare, W. 1995b).

The characterisation of the degradation pattern was carried out at Ciba-Geigy Crop Protection, Inc. USA (please refer to report prepared by Thede, B. 1995b).

5.2 Results and discussion

5.2.1 DT50 values

Aerobic degradation:

The half-life of fenoxycarb in aerobic soil indicated biphasic degradation kinetics. The slow secondary phase of degradation resulted from both tight binding of the components to soil and incorporation of the radiolabeled material into the carbon cycles of the soil/ microbes. A primary half-life of 7.4 days and the secondary half-life of 80 days were determined in the study.

Anaerobic degradation:

The time of conversion from aerobic to anaerobic conditions was set at 30 days. Since the primary aerobic half life of fenoxycarb was significantly shorter (7.4 days), the degradation of fenoxycarb had entered the secondary phase of degradation at the time of conversion to anaerobic conditions and the portion of unchanged fenoxycarb in the extracts amounted at Day 30 to 3.4% of the applied radioactivity.

A fenoxycarb half-life of 114 days for the anaerobic portion was calculated.

5.2.2 Degradation products (% of a.s.)

Aerobic degradation:

The distribution of radioactivity during the incubation period is given in Table A7_2_1-1.

The active substance was the only major component in all extracts.

At least eleven degradates were observed in the extracts in minor amounts with no evidence of accumulation. The distribution of radioactivity among the metabolites remained relatively constant during the one-year incubation period. There was evidence for the degradation intermediates CGA 294850, CGA 294847, CGA 344889, CGA 294848, CGA 195935, CGA 26021, CGA 197810 and CGA 197811.

Anaerobic degradation:

The aerobic/anaerobic degradation of fenoxycarb followed a similar

Section A7.2.1 Aerobic degradation in soil (03); Thede, B. (1995b)

Annex Point: IIIA XII 1.1

		pathway as was observed in the aerobic incubation. After one month at the time of conversion to anaerobicity fenoxycarb had already dissipated to a level of 2.7% of initially applied radioactivity, thus not allowing to follow the rate of dissipation after anaerobic conditions. However the study confirmed that the conversion to anaerobic conditions did not result in generation of new degradation products or accumulation of any degradation intermediates. The majority of extractable radioactivity with progressing time was found in the TLC origin fraction and was shown to be high molecular weight material that could be derivatised by alkylation and/or esterification.
5.2.3	Bound residues	Aerobic degradation: The extraction procedures were modified during the course of the study because of the rapid rise in percent of total dose in the non-extractable fraction. By applying Extraction 1 and 2, non-extractable material accounted for 31.3%, 19.5% and 25.4% of total radioactivity after 7, 9 and 12 months. Size exclusion HPLC of Extraction 2 fractions supported the assumption that the majority of the radioactivity in Extract 2 is solubilised soil or microbial components into which the carbon-14 from fenoxycarb has been incorporated.
5.2.4	CO_2 formation	Please refer to report prepared by Spare, W. (1995b).
5.3	**Conclusion**	This study indicated that fenoxycarb rapidly degraded to several minor components, which do not accumulate over time. Degradation products were not readily extractable from the soil. Degradates in turn rapidly degraded to the terminal metabolite carbon dioxide. Comparison to the aerobic incubations in the parallel test serious indicates that the rate of degradation of fenoxycarb is slower under anaerobic conditions.
5.3.1	Reliability	1
5.3.2	Deficiencies	-

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2009/07/30
Materials and Methods	[redacted]
Results and discussion	[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_1-1: Distribution and recovery of radioactivity* in percent of applied ^{14}C -fenoxycarb ("B"-^{14}C labelled) in Maryland sandy loam under aerobic laboratory conditions

Hours Days after appl ic.	Volatiles (CO_2) [%]	Sonication 1 & 2 [%]	Extraction 1 & 2 [%]	Fenoxycarb [%]	Non-extrac-table [%]	Total [%]
Aerobic, 10.23 mg/kg						
0	-**	104.0**		95.8	0.0**	104.0**
3	2.8**	72.2**		47.1	21.6**	96.5**
7	7.8**	52.3**		24.0	30.0**	90.4**
14	12.0**	42.0**		27.6	36.4**	90.4**
21	13.6**	29.0**		13.2	53.7**	96.4**
30	19.7**	15.8**		3.4	68.9**	104.3**
45	20.9**	19.8**		6.4	55.3**	95.9**
60	21.1**	15.9**		5.0	55.7**	92.6**
90	23.9**	12.2**		3.5	58.2**	94.3**
120	27.8**	12.6**		1.0	48.7**	89.1**
150	25.8**	9.6**		0.9	47.5**	82.8**
210	31.3**	1.8**	17.6	0.8	31.3	90.5**
270	31.4**		27.5	0.8	19.5	78.4
360	32.9**		23.8	0.4	25.4	82.1

* Average of duplicate sample analysis
** determined in the report of the In-life/balance phase of the study prepared by Spare, W. (1995b)

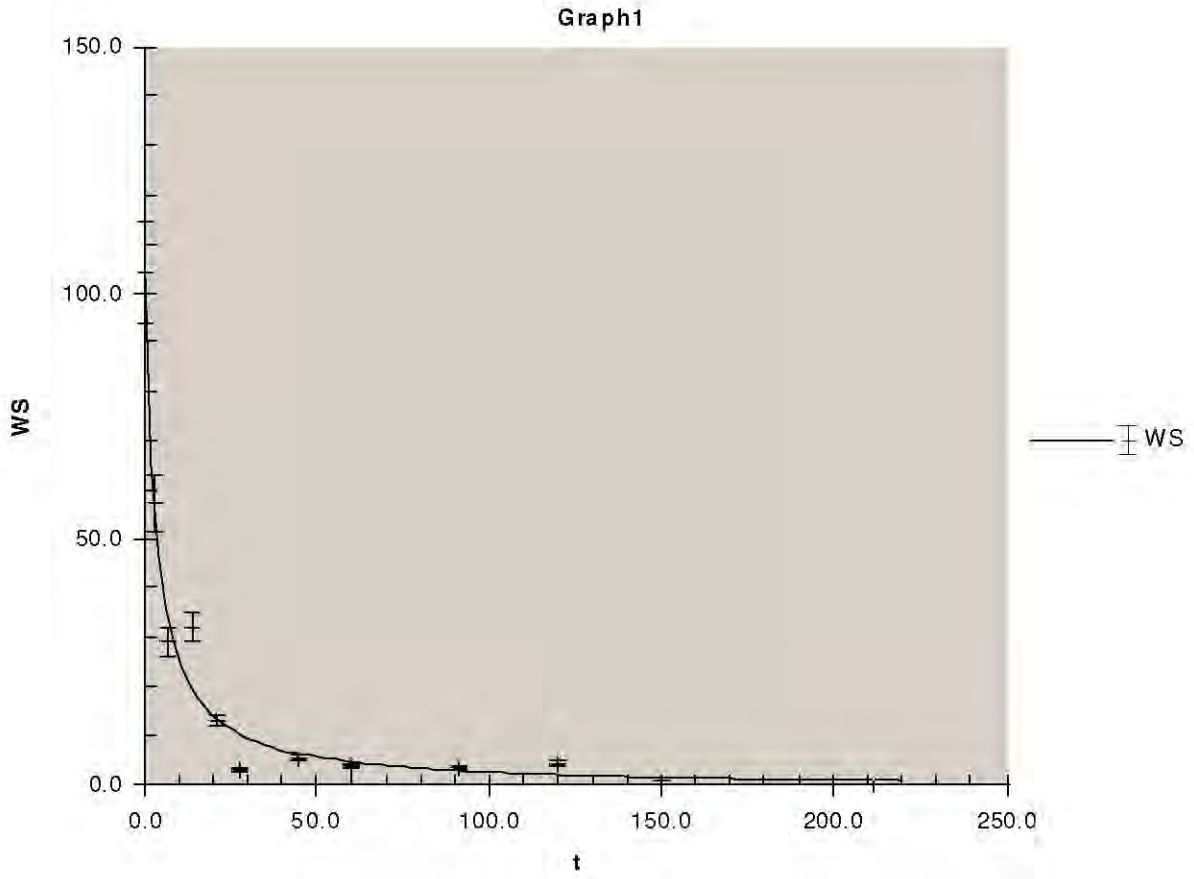
Annex 1 Evaluation by Rapporteur Member State (see next page)

CA-Table-1 (revised Table A7_2_1-1): Distribution and recovery of radioactivity* in percent of applied ^{14}C -fenoxycarb ("B"-^{14}C labelled) in Maryland sandy loam under aerobic laboratory conditions

Hours Days after applic.	Volatiles (CO_2) [%]	Extractables				Non-extrac-table [%]	Total [%]
		Sonication 1 & 2 [%] Total [1)]	0.5% NH_4OH [%]	MeOH:aq NH_4OH [%]	Fenoxycarb[2)] [%]		
Aerobic, 10.23 mg/kg							
0	-**	104.0**	n.a.	104	104	0.0**	104.0**
3	2.8**	72.2**	15	57	57	21.6**	96.5**
7	7.8**	52.3**	21	31	29	30.0**	90.4**
14	12.0**	42.0**	10	32	32	36.4**	90.4**
21	13.6**	29.0**	10	20	13	53.7**	96.4**
28	19.7**	15.8**	10	5.9	3.0	68.9**	104.3**
45	20.9**	19.8**	11	8.9	5.3	55.3**	95.9**
60	21.1**	15.9**	8.7	7.2	3.6	55.7**	92.6**
91	23.9**	12.2**	7.0	5.2	3.5	58.2**	94.3**
120	27.8**	12.6**	10	2.4	4.3	48.7**	89.1**
150	25.8**	9.6**	7.5	2.1	0.7	48**	82.8**
212	31.3**	1.8**	-	1.8	0..5	58**-	90.5**
273	31.4**	-	-	-	-	-	n.a.
365	32.9**	-	-	-	-	-	n.a.

* Average of duplicate sample analysis
** determined in the report of the In-life/balance phase of the study prepared by Spare, W. (1995b)
[1)] including metabolites (max, 2.9%AR)
[2)] sum of both extracts, the 3, 4 and 5 months 0.5% NH_4OH extracts were analysed for fenoxycarb, only after 3 month 0.4% AR was detected
n.a.: not applicable
-: no values

Recalculation of DT_{50} values with ModelMaker 4.0 according to FOCUS kinetics; prepared by RMS, 2008



CA-Figure 1: Fenoxycarb, Thede, B. (1995b): laboratory soil degradation study: FOMC kinetic

Values at 25°C test temperature:

DT_{50}= 2.93 d

DT_{90} = 28.3 d

$DT_{50\ modelling}$= 8.53 d (FOMC)

r2: 0.98

Error level Chi^2 Test: 17.8

Section A7.2.2.2 Field soil dissipation (1)

Annex Point IIIA XII 1.1

Official use only

		1 REFERENCE
1.1	**Reference**	McDonald, J. (1995): Terrestrial Field Dissipation of ^{14}C-Fenoxycarb 25WP on Bareground Soil in California, Ciba-Geigy Corp., Greensboro, United States, unpublished report, Proj. No ABR-95022, 04 May, 1995. (Syngenta File No. CGA114597/0534)
1.2	**Data protection**	No
1.2.1	Data owner	Syngenta Crop Protection AG
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Pesticide Assessment Guidelines, Subdivision N, Chemistry, Environmental Fate, Series 164-1, U.S. Environmental Protection Agency, Washington, D.C.
2.2	**GLP**	Yes (Ciba-Geigy Corp., Greensboro, United States)
2.3	**Deviations**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Radiolabeled test substances: 1) phenyl ring "A"-U-^{14}C-labelled Comply 25 WP 2) phenyl ring "B"-U-^{14}C-labelled Comply 25 WP
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	1) Specific radioactivity: 0.605 MBq/mg 2) Specific radioactivity: 0.707 MBq/mg
3.1.3	Purity	[redacted]
3.1.4	Further relevant properties	-
3.1.5	Composition of Product	25 WP formulation (w/w) Blank formulation: Tixosil 38 AB, Polyfon H, Stepanol Me Dry, Huber Clay 90 A
3.1.6	TS inhibitory to micro-organisms	No, according to the known studies with soil micro-organisms

Section A7.2.2.2 Field soil dissipation (1)

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3.2	**Reference substance**	Non-labeled fenoxycarb (purity 99.0%, lot no. S91-1536)
3.3	**Monitoring procedure**	
3.3.1	Soil properties	See Table 7_2_2_2-1
3.3.2	Test conditions	The dissipation of ^{14}C-Fenoxycarb and its metabolites in soil were studied under field conditions. Phenyl ring "A"-U-^{14}C labelled fenoxycarb and phenyl ring "B"-U-^{14}C labelled fenoxycarb formulated as a 25% w/w WP were applied to separate bare ground plots at a rate of 56 to 124 g a.s./ha at the Ciba research farm in Fresno County CA. Petri dishes were placed in the zones to determine the actual application rate. The individual plot size was 4.75 m^2.
3.3.3	Application time	2 August 1994 on bare ground plots
3.3.4	Duration of test	Last sampling was 56 days after application.
3.3.5	Analytical parameter	Samples were radioassayed for total radioactivity and those samples with greater than 5% of the applied radioactivity were further characterised qualitatively and quantitatively. Extraction was with methanol - 0.1 N sodium hydroxide (extract 1) and with 0.5 M sodium hydroxide (extract 2). LSC: Beckman Liquid Scintillation Counter (model 3801, 6000 or 6500). Counting efficiencies were determined by external standardization TLC: One (1D) and two (2D) dimensional TLC Plates: 20 x 20 cm, 0.25 mm silica gel, fluorescence visible 5 solvent systems HPLC: Detector: UV, 235 nm Column: YMC-Pack Polymer C18, PC-03-6, 4.6 x 250 mm, 6µm Mobile phase: H_2O/acetonitrile, gradient
3.3.6	Sampling	Soil core samples were taken at days 0, 1, 3, 7, 10, 13, 15, 21, 30, 42 and 56 after treatment. At each sampling time, six 4.7 cm soil cores were collected from each subplot (replicate A and B) of each plot (label A and B). The soil cores were segmented into 4 sections (0 – 7.6 cm, 7.6 – 15.2 cm, 15.2 – 22.8 cm and 22.8 – 30.4 cm, composited and homogenised.
3.3.7	Intermediates/ degradation products	CGA-294850, CGA-294847, CGA-195935, CGA-197810, CGA-197810, CGA-197810, CGA-197811, CGA-294848, CGA-294851, CGA-344891, CGA-344889, CGA-344890
3.3.8	Controls	2 replicates (replicate A and B) per ring label
3.3.9	Statistics	Rate constants and DT_{50}'s were calculated for ring A and B and both replicates using the Microsoft Excel computer software, version 5.0. A

[1] ModelMakerTM version 4.0 (Cherwell Scientific Publishing, The Magdalen Centre, Oxford OX4 4 GA).

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2-phase best fit regression line was generated.

In the study, the data obtained for the metabolite CGA-294850 were not evaluated. Therefore all data were re-evaluated using the tool ModelMaker[1] and half lives were calculated for parent and for the metabolite, taking formation and decline of the metabolite into account. The data were successfully fitted using a consecutive & competitive reaction that describes the parent disappearance via the metabolite CGA 294850 and in a parallel reaction directly to overall degradation products.

For the parent degradation, the re-evaluation with ModelMaker resulted in the same values as given in the report.

4 RESULTS

4.1	**Soil concentrations**	Ring A: 55.5 and 63.2 g a.i./ha Ring B: 115.8 and 124.2 g a.i./ha
4.1.1	Half-lives in soil	Dissipation times for fenoxycarb were calculated for each replicate as a 1st order decay with Origin 5, using the standard function "non-linear curve fit" for the formula for first order kinetics. Half-lives for fenoxycarb are given in Table 7_2_2_2-3 and half-lives for CGA 294850 are reported in Table 7_2_2_2-4.
4.1.2	Accumulation	No indication that fenoxycarb might accumulate in the soil after practical use.
4.1.3	Other observations	-
4.1.4	Controls	Not reported
4.1.5	Intermediates/ degradation products	CGA 294850 (see Table 7_2_2_2-2), CGA 294847 (< 1.6% of the total dose) and trace compounds

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Field soil dissipation studies were conducted according to the guideline (see point 2.1).
5.2	**Results and discussion**	The total radioactive residue remained essentially in the first 7.6 cm of soil. The quantification of the radioactivity for this segment is shown in Table 7_2_2_2-2. The decrease in the percent of total dose present in extracts 1 and 2 and the increase in the non-extractable residue through day 56 indicates that degradation products of fenoxycarb are tightly bound to the soil. The presence of multiple degradates was confirmed by TLC. The only significant metabolite was identified as CGA 294850 and reached a maximum of 5.7% with label "A" and of 3.8% with label "B". The aqueous photolysis degradation product CGA 294847 was present only as trace compound with the exception of a concentration < 1.6% at day 15 in a phenyl ring "B" sample. Generally there was no difference in the

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Annex Point IIIA XII 1.1

		data for the phenyl ring "A" and phenyl ring "B". The considerable decrease in total radioactivity recovered in all experiments is probably attributed to the mineralisation of the two phenyl rings of fenoxycarb and consequently to the loss of 47% to 62% of radioactivity as carbon dioxide after 56 days of incubation.
5.3	**Conclusion**	The half-lives for the degradation of fenoxycarb ranged between 6.9 and 8.9 days (n = 4) and revealed a rapid degradation of the active substance. The metabolite CGA-294850 did not exceed 10% or account for more than 5% of the amount of fenoxycarb added in soil in two sequential measurements during the respective studies. It is therefore concluded that CGA 294850 is a non-relevant soil metabolite. The DT_{50}-values of this metabolite ranged between 3.9 and 58.1 days (n = 4).
5.3.1	Reliability	Reliability indicator = 1
5.3.2	Deficiencies	No GLP

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2009/02/12

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

COMMENTS FROM ...

Date *Give date of comments submitted*

Materials and Methods *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*
Discuss if deviating from view of rapporteur member state

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 7_2_2_2-1: Field dissipation of ^{14}C-fenoxycarb: Soil characteristics

Soil characteristic	Soil depth (cm)			
	0 – 7.6	7.6 – 15.2	15.2 – 22.8	22.8 – 30.4
Texture	Sandy loam	Sandy loam	Sandy loam	Sandy loam
Sand (%)	65	63	61	63
Silt (%)	27	29	31	27
Clay (%)	8	8	8	10
Organic matter (%)	0.5	0.4	0.4	0.2
PH	6.9	6.1	5.7	6.0
Bulk density (g/cm^3)	1.38	1.32	1.37	1.38
CEC (meq/100 g)	7.2	5.7	6.6	5.8
Moisture at 1/3 bar (%)	10.4	9.9	10.0	9.9

Table 7_2_2_2-2: Field dissipation of ^{14}C-fenoxycarb: Quantification of metabolites* as a function of time (values are given in % of the total dose)

Days after application	Extract 1 [%]*	Extract 2 [%]*	Fenoxycarb [%]*	CGA-294850 [%]*	Non-extractables [%]*	Total [%]*
Phenyl ring "A" label replicate A: 63 g/ha						
0	74.6	2.6	67.5	0.3	5.8	83.0
1	86.2	6.0	69.2	1.3	7.2	99.3
3	77.6	8.5	62.8	2.2	23.4	109.4
7	44.3	10.1	26.6	4.6	18.1	72.4
10	29.8	12.6	17.6	3.4	19.3	61.6
13	35.0	24.0	20.4	2.4	30.0	88.6
15	38.2	19.5	21.7	2.4	37.8	95.5
21	18.6	16.6	11.3	1.8	32.7	67.9
30	15.5	13.5	8.6	2.9	27.0	56.0
42	1.2	14.5	6.5	1.2	32.3	58.0
56	7.3	5.1	4.0	1.0	40.4	52.7
Phenyl ring "A" label replicate B: 56 g/ha						
0	83.9	-	75.0	0.4	6.2	92.7
1	109.6	7.1	90.6	5.7	11.3	128.0
3	53.3	8.9	39.8	0.7	9.1	71.2
7	78.3	11.7	62.1	1.4	16.9	106.9
10	40.2	13.9	28.5	4.1	23.1	77.1
13	20.3	16.2	11.9	2.1	16.9	53.3
15	41.1	22.3	25.4	4.7	31.1	94.5
21	38.7	13.1	25.3	4.5	41.9	93.7
30	26.3	27.2	14.9	2.4	35.3	88.8
42	12.7	17.9	8.2	1.4	26.9	57.4
56	7.4	7.3	3.7	1.3	23.3	38.0
Phenyl ring "B" label replicate A: 115 g/ha						
0	84.7	2.4	75.6	2.5	3.6	90.6

Days after application	Extract 1 [%]*	Extract 2 [%]*	Fenoxycarb [%]*	CGA-294850 [%]*	Non-extractables [%]*	Total [%]*
1	68.6	3.9	55.3	2.6	8.2	80.7
3	81.5	10.2	69.3	3.8	18.4	110.1
7	92.6	18.4	83.1	1.6	22.6	133.6
10	31.0	15.5	11.4	2.4	21.2	67.7
13	22.9	23.7	12.7	1.7	29.4	76.0
15	22.8	25.9	12.2	2.2	30.5	79.2
21	9.0	21.7	4.0	0.4	24.6	55.3
30	13.1	16.9	6.7	1.7	35.4	65.4
42	18.6	11.6	11.3	1.9	61.7	91.9
56	6.9	4.7	4.2	1.1	40.8	52.3
Phenyl ring "B" label replicate B: 124 g/ha						
0	73.3	1.9	72.0	1.2	2.8	78.0
1	76.0	3.1	54.3	2.8	6.3	85.4
3	44.0	8.3	36.2	2.4	8.0	60.2
7	44.5	9.7	37.4	1.5	15.6	69.8
10	34.8	15.7	24.0	2.4	19.4	70.0
13	26.5	23.4	13.7	2.3	21.9	71.9
15	32.3	25.8	19.2	3.3	39.3	97.4
21	19.3	26.2	11.1	2.4	38.8	84.3
30	15.1	18.2	6.6	2.4	31.4	64.7
42	17.5	14.3	10.6	2.5	45.6	77.4
56	4.4	12.9	1.6	0.4	25.2	42.5

* Data for 0 - 7.6 cm soil segment. Lower segments contained < 5% of radioactivity.

Table 7_2_2_2-3: Field dissipation times of ^{14}C-fenoxycarb in California

Sample	Application rate [g as/ha]	DT_{50} [days]	DT_{90} [days]
	Fenoxycarb		
Phenyl ring"A"label, replicate A	63	6.9	22.9
Phenyl ring"A"label, replicate B	56	8.9	29.5
Phenyl ring"B"label, replicate A	115	7.7	25.5
Phenyl ring"B"label, replicate B	124	7.4	24.6

Table 7_2_2_2-4: Field dissipation times of CGA 294850 in California after re-evaluation of the data with ModelMaker

Sample	Applicartion rate [g as/ha]	DT_{50} [days]	DT_{90} [days]	Correlation coefficient
	CGA 294850			
Phenyl ring"A"label, replicate A	63	8.0	26.6	0.9607
Phenyl ring"A"label, replicate B	56	13.2	43.7	0.8819
Phenyl ring"B"label, replicate A	115	1.2	3.9	0.8090
Phenyl ring"B"label, replicate B	124	17.5	58.1	0.9501

Annex 1 Evaluation by Rapporteur Member State, CA-Tables

CA-Table 1 (revised 7_2_2_2-2): Field dissipation of ^{14}C-fenoxycarb: Quantification of metabolites* as a function of time (values are given in % of the total dose)

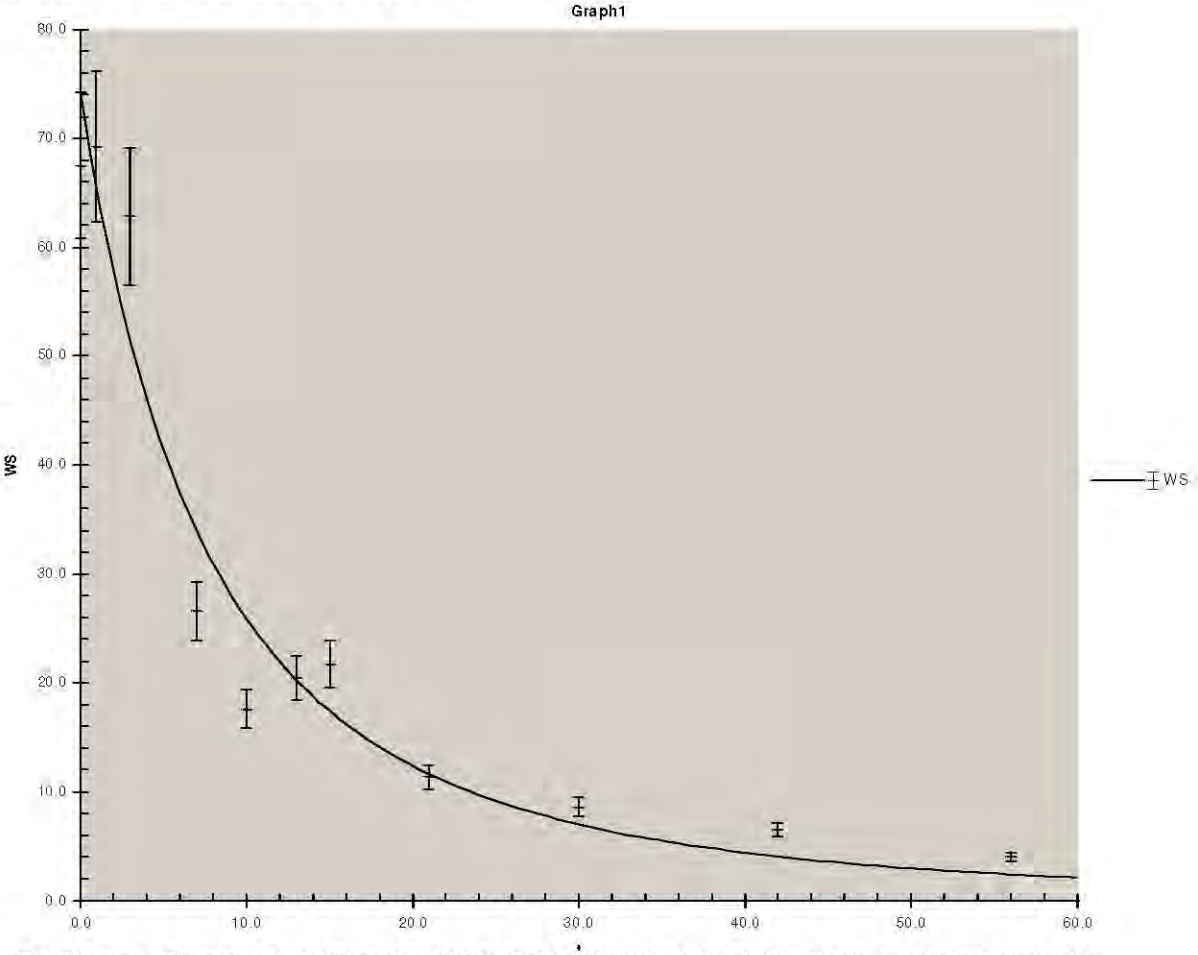
Days after application	Extract 1 [%]*	Extract 2 [%]*	Fenoxycarb [%]*	CGA-294850 [%]*	Non-extractables [%]*	Total [%]*
Phenyl ring "A" label replicate A: 63 g/ha						
0	74.6	2.6	67.5	0.3	5.8	83.0
1	86.2	6.0	69.2	1.3	7.2	99.3
3	77.6	8.5	62.8	2.2	23.4	109.4
7	44.3	10.1	26.6	4.6	18.1	72.4
10	29.8	12.6	17.6	3.4	19.3	61.6
13	35.0	24.0	20.4	2.4	30.0	88.6
15	38.2	19.5	21.7	2.4	37.8	95.5
21	18.6	16.6	11.3	1.8	32.7	67.9
30	15.5	13.5	8.6	2.9	27.0	56.0
42	1.2	14.5	6.5	1.2	32.3	58.0
56	7.3	5.1	4.0	1.0	40.4	52.7
Phenyl ring "A" label replicate B: 56 g/ha						
0	83.9	-	75.0	0.4	6.2	92.7
1	109.6	7.1	90.6	5.7	11.3	128.0
3	53.3	8.9	39.8	0.7	9.1	71.2
7	78.3	11.7	62.1	1.4	16.9	106.9
10	40.2	13.9	28.5	4.1	23.1	77.1
13	20.3	16.2	11.9	2.1	16.9	53.3
15	41.1	22.3	25.4	4.7	31.1	94.5
21	38.7	13.1	25.3	4.5	41.9	93.7
30	26.3	27.2	14.9	2.4	35.3	88.8
42	12.7	17.9	8.2	1.4	26.9	57.4
56	7.4	7.3	3.7	1.3	23.3	38.0
Phenyl ring "B" label replicate A: 115 g/ha						
0	84.7	2.4	75.6	2.5	3.6	90.6
1	68.6	3.9	55.3	2.6	8.2	80.7
3	81.5	10.2	69.3	3.8	18.4	110.1

Days after application	Extract 1 [%]*	Extract 2 [%]*	Fenoxycarb [%]*	CGA-294850 [%]*	Non-extractables [%]*	Total [%]*
7	92.6	18.4	83.1	1.6	22.6	133.6
10	31.0	15.5	11.4	12.5	21.2	67.7
13	22.9	23.7	12.7	1.7	29.4	76.0
15	22.8	25.9	12.2	2.2	30.5	79.2
21	9.0	21.7	4.0	0.4	24.6	55.3
30	13.1	16.9	6.7	1.7	35.4	65.4
42	18.6	11.6	11.3	1.9	61.7	91.9
56	6.9	4.7	4.2	1.1	40.8	52.3
Phenyl ring "B" label replicate B: 124 g/ha						
0	73.3	1.9	72.0	1.2	2.8	78.0
1	76.0	3.1	54.3	2.8	6.3	85.4
3	44.0	8.3	36.2	2.4	8.0	60.2
7	44.5	9.7	37.4	1.5	15.6	69.8
10	34.8	15.7	24.0	2.4	19.4	70.0
13	26.5	23.4	13.7	2.3	21.9	71.9
15	32.3	25.8	19.2	3.3	39.3	97.4
21	19.3	26.2	11.1	2.4	38.8	84.3
30	15.1	18.2	6.6	2.4	31.4	64.7
42	17.5	14.3	10.6	2.5	45.6	77.4
56	4.4	12.9	1.6	0.4	25.2	42.5

* in % of total dose in extract 1; Data for 0 - 7.6 cm soil segment, lower segments contained < 5% of radioactivity

Recalculation of DT_{50} values with ModelMaker 4.0 according to FOCUS kinetics; prepared by RMS, 2008

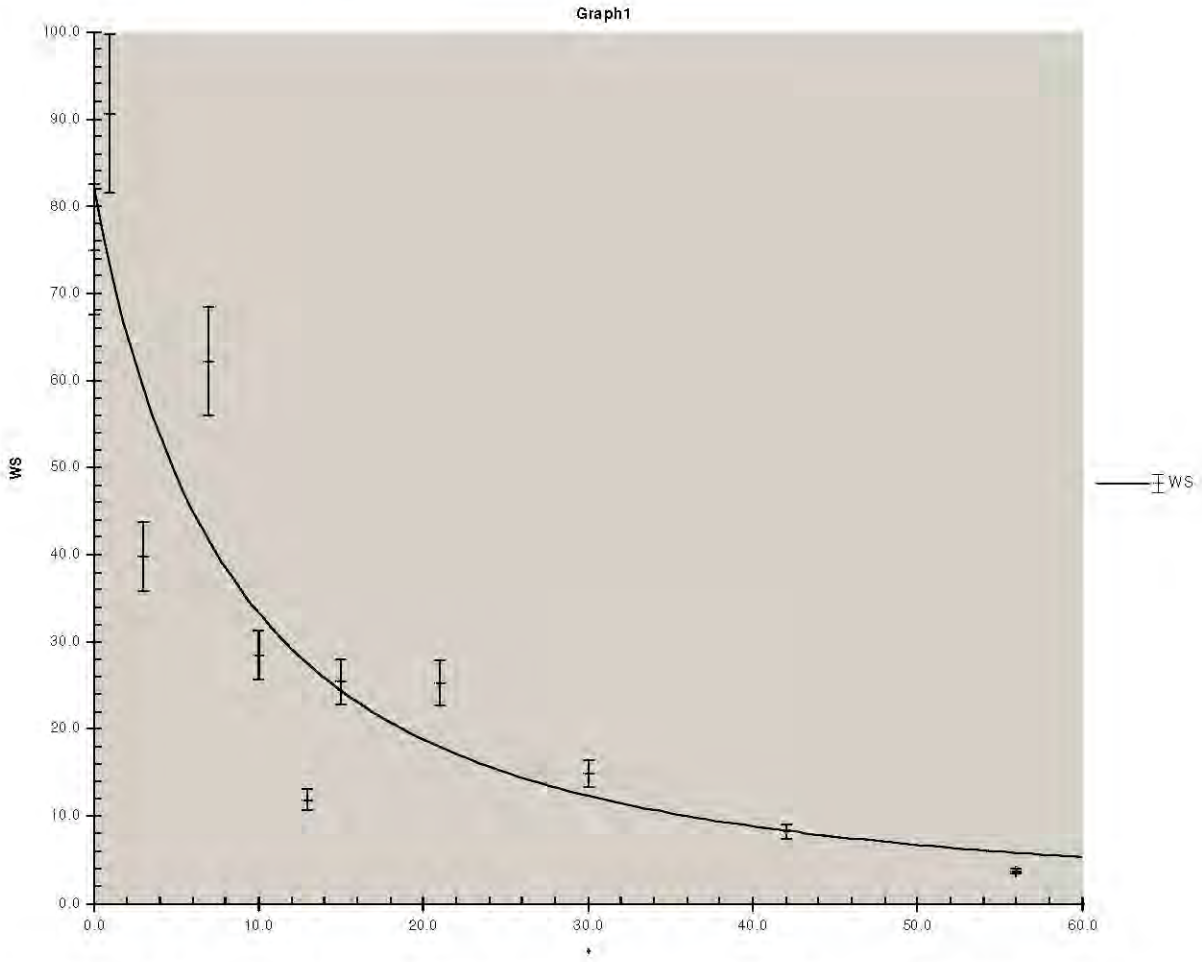
1.) Fenoxycarb, A-labelled, Replicate A



CA-Figure 1: Fenoxycarb, McDonald (1995), field soil study A-label, Replicate A, recalculation with ModelMaker 4.0; FOMC kinetic

DT50= 6.14 d
DT90 = 29.01 d
DT50modelling = 8.74 d (FOMC)
r2: 0.95
Error level Chi^2 Test: 16.3

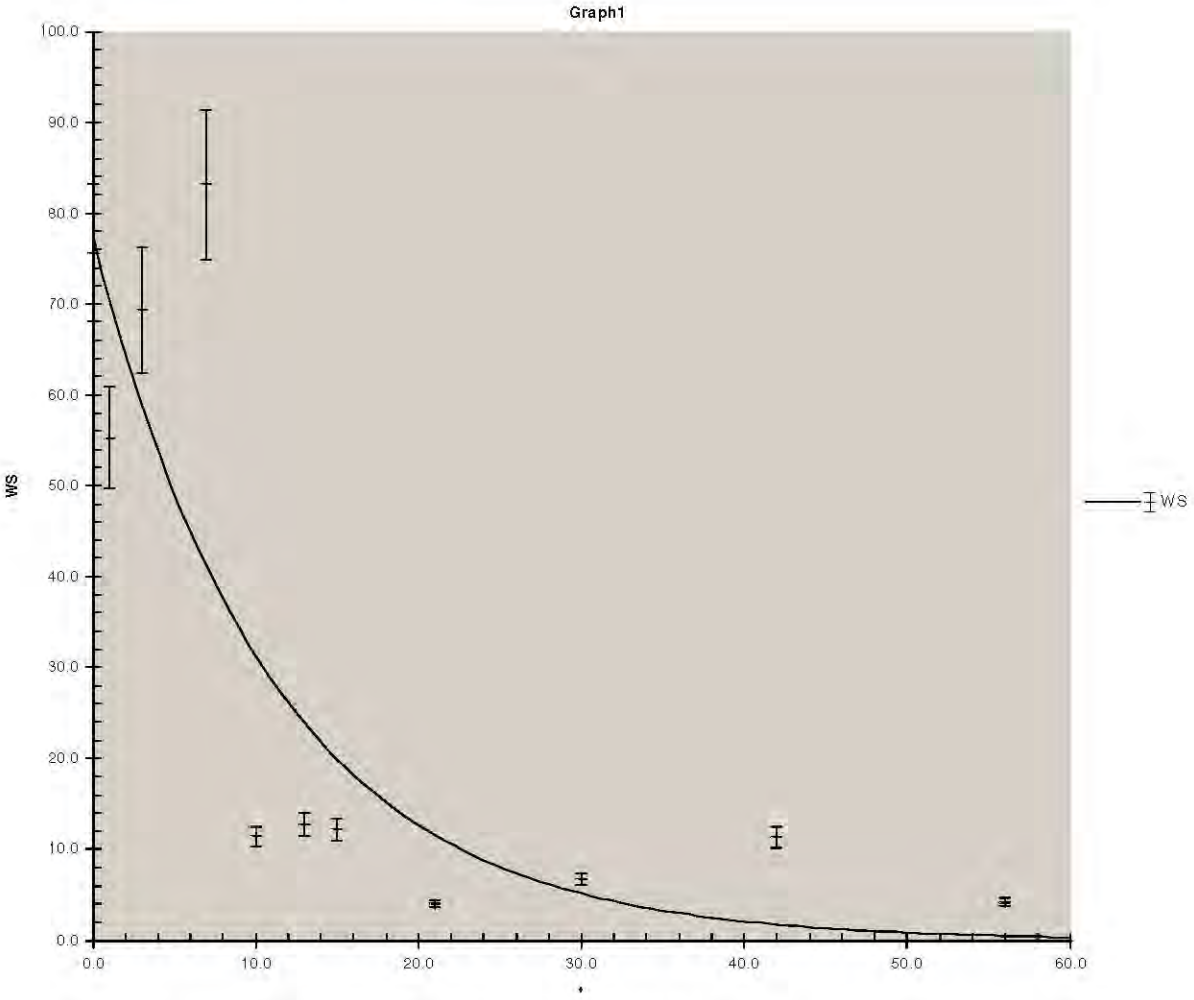
2.) Fenoxycarb, A-labelled, Replicate B



CA-Figure 2: Fenoxycarb, McDonald (1995),field soil study A-label, Replicate B, recalculation with ModelMaker 4.0; FOMC kinetic

DT50= 7.21 d
DT90 = 42.7 d
DT50modelling =12.9 d (FOMC)
r^2: 0.82
Error level Chi^2 Test: 27.9

3.) Fenoxycarb, B-labelled, Replicate A



CA-Figure 3: Fenoxycarb, McDonald (1995),field soil study B-label, Replicate A, recalculation with ModelMaker 4.0; SFO kinetic

DT50= 7.68 d
DT90 = 25.5 d
DT50modelling =7.68 d (SFO)

r^2: 0.72
Error level Chi^2 Test: 41.3