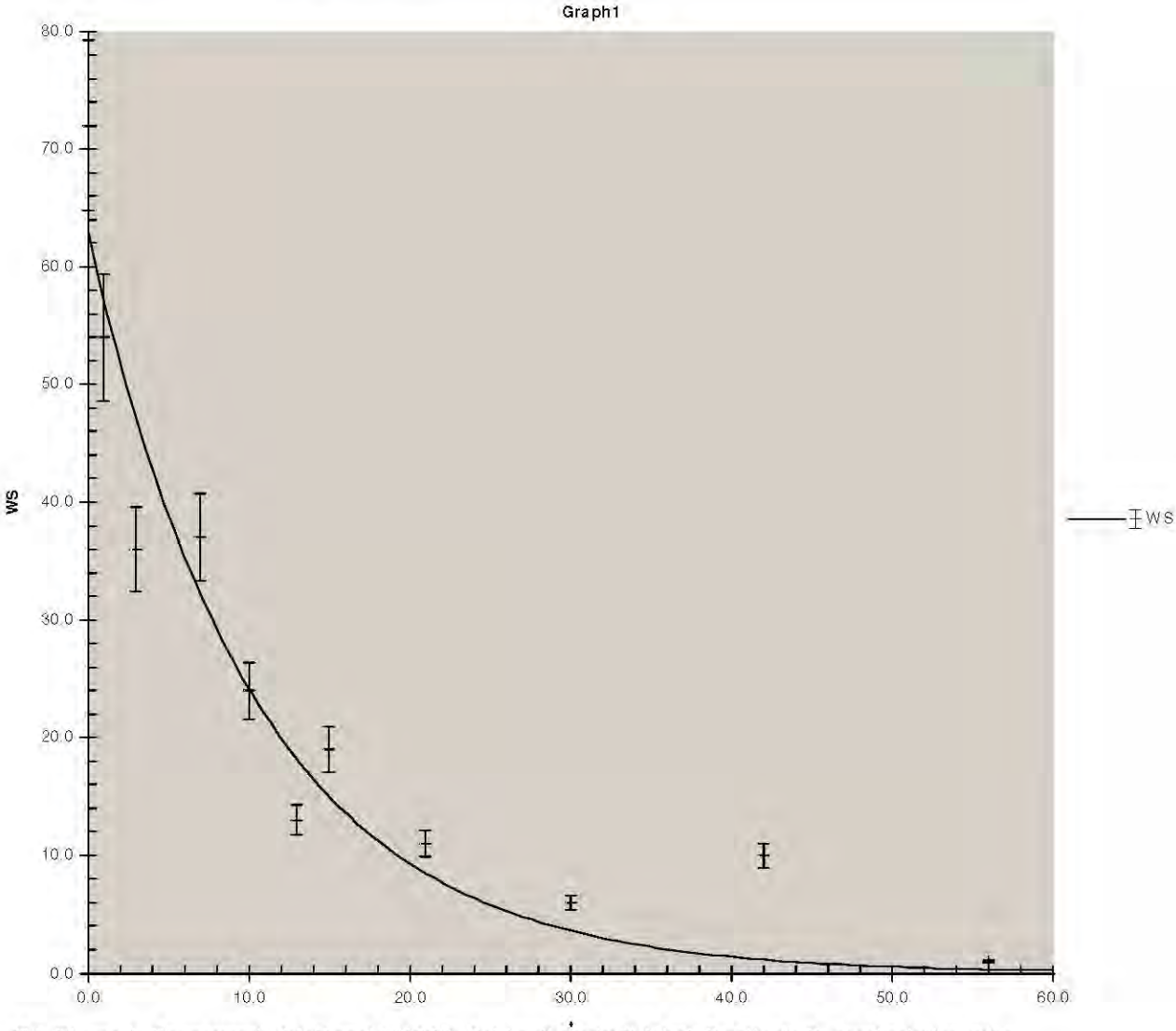
4.) Fenoxycarb, B-labelled, Replicate B



CA-Figure 4: Fenoxycarb, McDonald (1995),field soil study B-label, Replicate B, recalculation with ModelMaker 4.0; SFO kinetic

DT50= 7.28 d
DT90 = 24.2 d
DT50modelling =7.28 d (SFO)

r^2: 0.92
Error level Chi^2 Test: 18.3

Section A7.2.2.2 Field soil dissipation (2)

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		1 REFERENCE
1.1	**Reference**	1) Hänni, R. (1990): CGA 114597 (Ro13-5223), Dissipation of fenoxycarb in soil after application of Insegar (ACR 2907B) under outdoor conditions, Dr. R. Maag Ltd., Dielsdorf, Switzerland, unpublished report No. 6158-88034/88039, 20 April,1990. (Syngenta File No. CGA114597/0110) 2) Schwager, L. (1990): CGA 114597 (RO-13-5223), Dissipation in soil after application of Insegar (ACR 2907B) under outdoor conditions, Dr. R. Maag Ltd., Dielsdorf, Switzerland, unpublished report No. RES-ANA-89030/38. Study dates: May 1989 – March 1990. Issue date: 27 July, 1990. (Syngenta File No. CGA114597/0094) 3) Dorn, R. (2003): Fenoxycarb: Calculation of degradation rates for field trials in Europe. Syngenta Crop Protection AG, Basel, Switzerland. Unpublished report No. Ass03RD01. November 2003 (Syngenta File No. CGA114597/0866)
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**	1 + 2) German BBA, Teil IV, 4-1:Verbleib von Pflanzenschutzmitteln im Boden – Abbau, Umwandlung und Metabolismus. 3) No; calculation
2.2	**GLP**	No
2.3	**Deviations**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	1 + 2) Active Substance: ISO common name: fenoxycarb; Company Code: CGA 114597 Chemical name: [2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester Formulation: 25% w/w WP
3.1.1	Lot/Batch number	1 + 2) Not given 3) Not relevant, calculation
3.1.2	Specification	1 + 2) Field Dissipation Study with non-labelled fenoxycarb 3) Not relevant, calculation
3.1.3	Purity	1 + 2) Field Dissipation Study with non-labelled fenoxycarb

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		3) Not relevant, calculation
3.1.4	Further relevant properties	-
3.1.5	Composition of Product	1 + 2) Formulation: 25% w/w WP 3) Not relevant, calculation
3.1.6	TS inhibitory to micro-organisms	Not reported
3.2	**Reference substance**	None
3.3	**Monitoring procedure**	
3.3.1	Soil properties	See Table 7_2_2_2-1
3.3.2	Test conditions	Soil residues of fenoxycarb were analysed in 1) two bare ground field studies in Switzerland (Waisenhof and Ried) in 1988. 600 g of a 25% w/w WP formulation (i.e. 150 g a.s./ha) 2) two bare ground field studies in Switzerland (Steinmaur and Valesia, 1 replicate) in 1989. 3000 g of a 25% w/w WP formulation (i.e. 750 g as/ha) were applied in 500 L/ha water to the 40 m^2 bare ground plots. Rainfall total precipitation was within the normal range for the respective areas during the trial period.
3.3.3	Application time	1) 14 June 1988 (Waisenhof) 13 June 1988 (Ried) 2) 9 Mai 1989 (Steinmaur) 18 Mai 1989 (Valesia)
3.3.4	Duration of test	1) Up to 180 days 2) Up to 186 days
3.3.5	Analytical parameter	1 + 2) Extraction of the soil residues with acetone/water Clean up: gel chromatography and silica column chromatography Determination: GC, alkali flame ionization detector Detection limit: 1) 0.01 mg/kg 2) 0.02 mg/kg.
3.3.6	Sampling	1) 0, 15, 30, 90, 180 days (both locations) 2) 0, 7, 14, 21, 30, 62, 93 and 184 days (Steinmaur) 0, 6, 14, 21, 27, 61, 91 and 186 days (Valesia) Samples were taken up to a soil depth of 30 cm and were pooled in 0-5 cm, 5-15 cm and 15-30 cm segments.
3.3.7	Intermediates/ degradation products	Not analysed

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3.3.8	Controls	Not reported
3.3.9	Statistics	3) The degradation rates based on data from studies 1) and 2) were re-calculated to generate first order exponential decay rates (Dorn 2003). For the calculation of the half-life values the widely recommended tool ModelMaker[1] was used. The re-evaluation of the field data results in correlation coefficients > 0.85. In general, compared to the previous calculations, the higher r^2 values gained with the ModelMaker evaluation demonstrate that the dissipation of fenoxycarb in the field is well described by the chosen kinetic model.
		4 RESULTS
4.1	**Soil concentrations**	The soil concentrations are given in Table 7_2_2_2-2
4.1.1	Half-lives in soil	Half-lives (DT_{50} and DT_{90} values) for fenoxycarb are given in Table 7_2_2_2-2. For the Valesia trial, the day 0 value amounted only to 29% of the theoretical value. The value was also considered as an outlier due to the low recovery and replaced by the theoretical value.
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	Not analysed
		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**	Results of the analysis of fenoxycarb after application to bare ground plots in Switzerland are summarised in Table 7_2_2_2-2. For Waisenhof, Ried and Steinmaur trials, residues had reached the LOD after 30 days. In the Valesia trial the LOD was reached after 62 days. Residues were only found in the 0-5 cm soil horizon. The rate of recovery was 1) 87.8% (both trials) 2) 83.6% to 96.1%.
5.3	**Conclusion**	The half-lives for the degradation of fenoxycarb range between 5.6 and 9.0 days (n = 4) and revealed a rapid degradation of the active substance.

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

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5.3.1	Reliability	Reliability indicator = 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	2008/02/21
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 7_2_2_2-1: Relevant soil characteristics and kinetic data for soil degradation of fenoxycarb in field trials in Switzerland

Study No.	88034	88039	89038	89030
	Hänni, R. (1990)		Schwager, L. (1990)	
Location	Waisenhof	Ried	Valesia	Steinmaur
pH	7.1	6.4	8.0	7.8
C org. [%]	1.8	2.0	1.5	2.0
Clay (0 - 0.002 mm) [%]	25	20	9	18
Silt (0.002 - 0.05 mm) [%]	29	33	56	33
Soil Texture (USDA)	Sandy clay loam	Loam	Silt loam	Loam
Max. Water capacity [g water / 100 g dry soil equivalents]	-	-	51	47
Crop, stage at treatment	Bare ground	Bare ground	Bare ground	Bare ground
Treatment rate [g a.s./ha]	150	150	750	750
Application date	14 June, 1988	13 June, 1988	18 May, 1989	9 May, 1989
Total rainfall during trial period [mm]	483	483	326	535

Table 7_2_2_2-2: Fenoxycarb soil residues in Switzerland

	Residues (mg/kg)							
Trial No	**88034**		**88039**		**89030**		**89038**	
	Hänni, R. (1990)				**Schwager, L. (1990)**			
Location	**Waisenhof**		**Ried**		**Steinmaur**		**Valesia**	
Approx. day	0-5 cm	5-15 cm*	0-5 cm	5-15 cm*	0-5 cm	5-15 cm*	0-5 cm	5-15 cm*
0	0.13	< 0.01	0.10	< 0.01	0.64	< 0.02	1.15 (0.29)§	< 0.02
7	n.d.	n.d.	n.d.	n.d.	0.32	< 0.02	0.50	< 0.02
15	0.03	< 0.01	0.03	< 0.01	0.24	< 0.02	0.08	< 0.02
21	n.d.	n.d.	n.d.	n.d.	0.11	< 0.02	0.17	< 0.02
30**	0.01	0.01	0.01	0.01	< 0.02	< 0.02	0.04	< 0.02
62	n.d.	n.d.	n.d.	n.d.	< 0.02	< 0.02	< 0.02	< 0.02
90	< 0.01	< 0.01	0.01	< 0.01	< 0.02	< 0.02	< 0.02	< 0.02
180**	< 0.01	< 0.01	< 0.01	< 0.01	< 0.02	< 0.02	< 0.02	< 0.02
Kinetic results for fenoxycarb*:**								
DT_{50} (days)	7.5		9.0		8.1		5.6	
DT_{90} (days)	24.9		29.8		27.0		18.7	
r^2	0.9905		0.9848		0.9810		0.8953	

n.d. = not determined, no samples taken.

* Residues in 15 - 30 cm layer < LOQ

** 27 and 186 days for Valesia trial, 184 days for Steinmaur trial

*** Dorn (2003)

§ Theoretical value used due to low recovery

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		1 REFERENCE
1.1	**Reference**	Emburey, S.N. (2004): Dissipation Study with Fenoxycarb (CGA 114597) in or on Soil in Spain. Syngenta, Jealott's Hill International, Research Centre, Bracknell, UK, Unpublished Report No. RJ3439B, Date: 2004-01-06.
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**	Not applicable; The field test was designed to comply with Directive 91/414/EC, amended by Directive 95/36/EC.
2.2	**GLP**	Yes
2.3	**Deviations**	Not applicable
		3 MATERIALS AND METHODS
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb, Company Code: CGA 114597, IUPAC name: Ethyl-2-(4-phenoxyphenoxy)ethylcarbamate Fenoxycarb was applied as formulation A-8995 B, a 250 g/kg wettable granule
3.1.1	Lot/Batch number	No information
3.1.2	Specification	
3.1.3	Purity	Formulation A-8995 B, containing 250 g a.s./kg (wettable granule); Actual a.s. concentration in formulation according to the Analytical Certificate: 257 g/kg (i.e. within FAO Guidelines of the declared concentration).
3.1.4	Further relevant properties	-
3.1.5	Composition of Product	See Point 3.1.3
3.1.6	TS inhibitory to micro-organisms	No, according to the known studies with soil micro-organisms
3.2	**Reference substance**	Fenoxycarb (purity 99.5 %, lot no. AMS-593/3)

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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 in Spanish soil was studied under field conditions. A single application of fenoxycarb (as formulation A-8995 B, a 250 g/kg wettable granule) was applied at 225 g a.s./ha as a broadcast application to the soil surface. Soil samples from the treated plot were taken immediately after the application and on days 3, 7, 14, 31, 59 and 112 (after application). Plot size: 175 m² (14 m long by 12.5 m wide). Experimental Site: Villalba del Alcor, Huelva, Spain (detailed weather records provided in appendix of test report). Application device: Four nozzle knapsack sprayer with a boom fitted with flat fan nozzles (sprayer pressure 3 bar). Irrigation was also applied to the soil plot. Grass was sown seven days prior application, resulting in sparse grass cover.
3.3.3	Application time	The experimental phase of the study was carried out between 2002-08-06 and 2003-10-20.
3.3.4	Duration of test	Last sampling was 112 days after application.
3.3.5	Analytical parameter	Aliquots of the samples were analysed between 2003-02-18 and 2003-02-27 using procedures that were subsequently issued as RAM 406/01 (residue method for fenoxycarb in soil). At least one analysis was performed on each portion sample for the 0-10 cm and the 10-20 cm samples. The 20-30 cm samples were not analysed as the residues in each of the 10-20 cm samples were below the limit of quantification (LOQ) of the method. The LOQ of the method was 0.01 mg a.s./kg dry weight soil. Each sample residue was corrected for the mean external recovery generated in each analytical batch where the mean was <100 %. In summary, a 20 g sub-sample was wetted with dilute aqueous phosphoric acid and then shaken with acetone. After centrifugation, an aliquot of the soil extract was diluted with water and analysed by HPLC with triple quadrupole mass spectrometry detection (LC-MS/MS).
3.3.6	Sampling	Soil samples were taken using a zero contamination corer. 20 cores were taken from the treated plot and 5 cores were taken from the control plot (diameter of corer: 5 cm). Soil samples from the treated plot were taken immediately after the application and on days 3, 7, 14, 31, 59 and 112 (after application). Control samples from an untreated plot were taken before application on day 0 and 112 days after application. All samples were transferred deep frozen via a deep freezer truck to the analytical laboratory. The treated and control cores (30 cm length) were cut into three 10 cm profiles representing the soil layers 0-10 cm, 10-20 cm and 20-30 cm.

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3.3.7	Intermediates/ degradation products	Not applicable.
3.3.8	Controls	Control samples from an untreated plot were taken before application on day 0 and 112 days after application. Samples were taken from the 0-30 cm soil layer. Size of control plot: 175 m² (14 m long by 12.5 m wide), positioned 1.95 m from the treatment plot.
3.3.9	Statistics	The time taken for the initial fenoxycarb residue determined in the soil samples to decline to 50 % (DT_{50}) and 90 % (DT_{90}) of its value was calculated using the software package ModelManager (version 1.1; 2000)

4 RESULTS

4.1	**Soil concentrations**	
4.1.1	Half-lives in soil	Achieved results for degradation behaviour of fenoxycarb in field soil are given in Table 7_2_2_2-2. The half-life for fenoxycarb was calculated to be 4.0 days and the DT_{90} was determined to be 13.3 days (determined by using software ModelManager). Statistical examination of the dissipation data indicated that a simple First order Model (SFO) was an appropriate fit for the trial.
4.1.2	Accumulation	No indication that fenoxycarb might accumulate in the soil after practical use.
4.1.3	Other observations	None
4.1.4	Controls	All measured values were below the Limit of Quantification (LOQ = 0.01 mg/kg dry weight soil)
4.1.5	Intermediates/ degradation products	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A field study was carried out to investigate the dissipation of fenoxycarb in soil following a broadcast spray treatment. A single application of fenoxycarb (as formulation A-8995 B, a 250 g/kg wettable granule) was applied at 225 g a.s./ha as a broadcast application to the soil surface. Soil samples from the treated plot were taken immediately after the application and on days 3, 7, 14, 31, 59 and 112 (after application). Control samples from an untreated plot were taken before application on day 0 and 112 days after application. Samples were taken from the 0-30 cm soil layer.
5.2	**Results and discussion**	Fenoxycarb dissipated under field conditions with a half life of 4.0 days and a DT_{90} of 13.3 days, using a simple first order model. Immediately after application a fenoxycarb residue of 0.15 mg/kg dry soil was

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		determined in the 0-10 cm soil core depth. This residue in the 0-10 cm soil core depth had fallen below the limit of quantification (0.01 mg/kg) by 31 days after application. No measurable residues of fenoxycarb were determined below the 0-10 cm soil depth during the study.
5.3	**Conclusion**	The Simple First Order (SFO) model gave the best statistical fit to the data with a half life value of 4.0 days and a DT_{90} value of 13.3 days.
5.3.1	Reliability	Reliability indicator = 1
5.3.2	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/04/09
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 7_2_2_2-1: Field dissipation of ^{14}C-fenoxycarb: Soil characteristics

Soil characteristic	Soil depth (cm)		
	0 – 10	10 – 20	20 - 30
Texture (USDA)	Sandy loam	Sandy loam	Sandy loam
Sand (%)	68	66	64
Silt (%)	19	20	20
Clay (%)	13	14	15
Organic matter (%)	0.6	0.7	0.5
pH	7.9	7.8	7.8
CEC (meq/100 g)	10.4	10.7	10.4

Table 7_2_2_2-2: Field dissipation of fenoxycarb in Spanish field soil as a function of time (Limit of Quantifation (LOQ) = 0.01 mg/kg dry weight soil)

Days after Application	Fenoxycarb Residue [mg/kg dry weight soil]
0	0.15
3	0.09
7	0.04
14	0.02
31	<LOQ
59	<LOQ
112	<LOQ

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		1 REFERENCE
1.1	**Reference**	Emburey, S.N. (2004): Dissipation Study with Fenoxycarb (CGA 114597) in or on Soil in France (South). Syngenta, Jealott's Hill International, Research Centre, Bracknell, UK, Unpublished Report No. RJ3440B, Date: 2004-02-02.
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**	Not applicable; The field test was designed to comply with Directive 91/414/EC, amended by Directive 95/36/EC.
2.2	**GLP**	Yes
2.3	**Deviations**	Not applicable
		3 MATERIALS AND METHODS
3.1	**Test material**	Active Substance: ISO common name: fenoxycarb, Company Code: CGA 114597, IUPAC name: Ethyl-2-(4-phenoxyphenoxy)ethylcarbamate Fenoxycarb was applied as formulation A-8995 B, a 250 g/kg wettable granule
3.1.1	Lot/Batch number	No information
3.1.2	Specification	
3.1.3	Purity	Formulation A-8995 B, containing 250 g a.s./kg (wettable granule); Actual a.s. concentration in formulation according to the Analytical Certificate: 257 g/kg (i.e. within FAO Guidelines of the declared concentration).
3.1.4	Further relevant properties	-
3.1.5	Composition of Product	See Point 3.1.3
3.1.6	TS inhibitory to micro-organisms	No, according to the known studies with soil micro-organisms
3.2	**Reference substance**	Fenoxycarb (purity 99.5 %, lot no. AMS-593/3)

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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 in soil was studied under field conditions in southern France. A single application of fenoxycarb (as formulation A-8995 B, a 250 g/kg wettable granule) was applied at 225 g a.s./ha as a broadcast application to the soil surface. Soil samples from the treated plot were taken immediately after the application and on days 3, 7, 14, 31, 60 and 118 (after application). Plot size: 150 m² (50 m long by 3.0 m wide). Experimental Site: Grisolles, Southern France (detailed weather records provided in appendix of test report). Application device: Six nozzle knapsack sprayer with a boom fitted with flat fan nozzles (sprayer pressure 2.8 bar). Irrigation was also applied to the soil plot. Grass was sown eight days prior application, resulting in sparse grass cover.
3.3.3	Application time	The experimental phase of the study was carried out between 2002-06-28 and 2002-10-24.
3.3.4	Duration of test	Last sampling was 118 days after application.
3.3.5	Analytical parameter	Aliquots of the samples were analysed between 2003-02-24 and 2003-03-04 using procedures that were subsequently issued as RAM 406/01 (residue method for fenoxycarb in soil). At least one analysis was performed on each portion sample for the 0-10 cm and the 10-20 cm samples. The 20-30 cm samples were not analysed as the residues in each of the 10-20 cm samples were below the limit of quantification (LOQ) of the method. The LOQ of the method was 0.01 mg a.s./kg dry weight soil. Each sample residue was corrected for the mean external recovery generated in each analytical batch where the mean was <100 %. In summary, a 20 g sub-sample was wetted with dilute aqueous phosphoric acid and then shaken with acetone. After centrifugation, an aliquot of the soil extract was diluted with water and analysed by HPLC with triple quadrupole mass spectrometry detection (LC-MS/MS).
3.3.6	Sampling	Soil samples were taken using a zero contamination corer. 20 cores were taken from the treated plot and 5 cores were taken from the control plot (diameter of corer: 5 cm). Soil samples from the treated plot were taken immediately after the application and on days 3, 7, 14, 31, 60 and 118 (after application). Control samples from an untreated plot were taken before application on day 0 and 118 days after application. All samples were transferred deep frozen via a deep freezer truck to the analytical laboratory. The treated and control cores (30 cm length) were cut into three 10 cm profiles representing the soil layers 0-10 cm, 10-20 cm and 20-30 cm.

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3.3.7	Intermediates/ degradation products	Not applicable.
3.3.8	Controls	Control samples from an untreated plot were taken before application on day 0 and 118 days after application. Samples were taken from the 0-30 cm soil layer. Size of control plot: 75 m² (25 m long by 3.0 m wide), positioned 15 m from the treatment plot.
3.3.9	Statistics	The time taken for the initial fenoxycarb residue determined in the soil samples to decline to 50 % (DT_{50}) and 90 % (DT_{90}) of its value was calculated using the software package ModelManager (version 1.1; 2000)

4 RESULTS

4.1	**Soil concentrations**	
4.1.1	Half-lives in soil	Achieved results for degradation behaviour of fenoxycarb in field soil in southern France are given in Table 7_2_2_2-2. The half-life for fenoxycarb was calculated to be 9.1 days and the DT_{90} was determined to be 30.2 days (determined by using software ModelManager). Statistical examination of the dissipation data indicated that a simple First order Model (SFO) was an appropriate fit for the trial.
4.1.2	Accumulation	No indication that fenoxycarb might accumulate in the soil after practical use.
4.1.3	Other observations	None
4.1.4	Controls	All measured values were below the Limit of Quantification (LOQ = 0.01 mg/kg dry weight soil)
4.1.5	Intermediates/ degradation products	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A field study was carried out in southern France to investigate the dissipation of fenoxycarb in soil following a broadcast spray treatment. A single application of fenoxycarb (as formulation A-8995 B, a 250 g/kg wettable granule) was applied at 225 g a.s./ha as a broadcast application to the soil surface. Soil samples from the treated plot were taken immediately after the application and on days 3, 7, 14, 31, 60 and 118 (after application). Control samples from an untreated plot were taken before application on day 0 and 118 days after application. Samples were taken from the 0-30 cm soil layer.
5.2	**Results and discussion**	Fenoxycarb dissipated under field conditions with a half life of 9.1 days and a DT_{90} of 30.2 days, using a simple first order model. Immediately

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		after application a fenoxycarb residue of 0.09 mg/kg dry soil was determined in the 0-10 cm soil core depth. This residue in the 0-10 cm soil core depth had fallen below the limit of quantification (0.01 mg/kg) by 31 days after application. No measurable residues of fenoxycarb were determined below the 0-10 cm soil depth during the study.
5.3	**Conclusion**	The Simple First Order (SFO) model gave the best statistical fit to the data with a half life value of 9.1 days and a DT_{90} value of 30.2 days.
5.3.1	Reliability	Reliability indicator = 1
5.3.2	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/04/10
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 7_2_2_2-1: Field dissipation of ^{14}C-fenoxycarb: Soil characteristics

Soil characteristic	Soil depth (cm)		
	0 – 10	10 – 20	20 - 30
Texture (USDA class)	Loam	Loam	Loam
Sand (%)	42	41	42
Silt (%)	40	41	41
Clay (%)	18	18	18
Organic matter (%)	0.7	0.7	0.6
pH	7.5	7.5	7.5
CEC (meq/100 g)	10.9	10.9	11.0

Table 7_2_2_2-2: Field dissipation of fenoxycarb in field soil (Southern France) as a function of time (Limit of Quantifation (LOQ) = 0.01 mg/kg dry weight soil)

Days after Application	Fenoxycarb Residue [mg/kg dry weight soil]
0	0.09
3	0.07
7	0.07
14	0.02
31	<LOQ
60	<LOQ
118	<LOQ

Section A7.2.2.3 Aerobic degradation in soil, further studies: Extent and nature of bound residues

Annex Point: IIIA XII 1.4

			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. The radioactivity of volatile products in the trapping solutions (NaOH, ethylene glycol) was determined by LSC without further preparation. For sampling day 90, an organic matter fractionation was carried out. After harsh extractions, 10 g soil was mixed with 0.5 N aqueous NaOH solution (30 mL). The samples were shaken at room temperature for about 17 hours at 200 rpm followed by centrifugation at 2500 rpm for 10 min. HCl was added to the supernatants until a pH < 1 was reached. The resulting suspension was centrifuged, the supernatant decanted and the volume determined (fulvic acid fraction). The remaining solid (humic acid fraction) was dissolved in 25 mL of 0.5 N NaOH and radioassayed by LSC. The humic fraction was calculated by subtraction of the humic acid and the fulvic acid fractions from the bound residues of the soils after harsh extractions.
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_2_3-1
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_2_3-2 for soil metabolism and table A7_2_2_3-4 for fractionation of soil bound residues.

Section A7.2.2.3 Aerobic degradation in soil, further studies: Extent and nature of bound residues

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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

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_2_3-3. 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_2_3-2. 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 the bulk of radioactivity (46.3% to 58.4% of the applied radioactivity) being associated with the humin fraction. Minor portions of 2.1% to 2.3% as well as 4.7% to 5.9% were bound to fulvic and humic acids, respectively. The results are described in detail in table A7_2_2_3-4.

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%.

Section A7.2.2.3 Aerobic degradation in soil, further studies: Extent and nature of bound residues

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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 at amounts ≤ 4.5%. Under all experimental conditions, fenoxycarb dissipated mainly by mineralisation (up to 46.3% CO_2.) and the formation of bound residues. The amount of non-extractable residues at termination of the study ranged from 50.0% to 64.3%. A fractionation of the 90-day bound residues showed the bulk of radioactivity (46.3% to 58.4% of applied) being associated with the humin fraction. Only minor portions of 2.1% to 2.3% as well as 4.7% to 5.9% were bound to fulvic and humic acids, respectively.
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	08-02-22
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_2_2_3-1: 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_2_3-2: 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_2_3-3: 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

Table A7_2_2_3-4: Organic matter fractionation of non-extractable radioactivity in 90-day samples (in % of applied radioactivity)

Fraction	Series 1 20 °C, 40% WHC	Series 2 20 °C, 25% WHC	Series 3 10 °C, 40% WHC	Series 4 30 °C, 40% WHC
Harsh extraction				
Non-extractables after reflux extraction	62.6	63.4	67.9	53.8
Reflux with ACN/H_2O	0.7	0.8	0.5	0.5
Reflux with ACN/ 0.1 N HCL	0.4	0.3	0.8	0.3
Total extracted by harsh extraction	1.0	1.1	1.3	0.7
Radioactivity remaining in soil after harsh extraction	61.6	62.3	66.6	53.1
Organic matter fractionation				
Fulvic acids	2.3	2.3	2.3	2.1
Humic acids	5.4	5.6	5.9	4.7
Humin	53.9	54.4	58.4	46.3

Section A7.2.2.4. Anaerobic degradation in soil (1)

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) 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**	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**	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. Waters and volatiles trapping solutions were analysed by direct LSC.	

Section A7.2.2.4. Anaerobic degradation in soil (1)

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		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). The nature of radioactivity was investigated by using TLC, HPLC and GC/MSD.The nature of radioactivity was investigated by using TLC, HPLC and GC/MSD.
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**	See Table A7_2_2_4-1
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

Section A7.2.2.4. Anaerobic degradation in soil (1)

Annex Point: IIIA XII 1.1

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

4 RESULTS

4.1 Aerobic soil metabolism

See table A7_2_2_4-2

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, the characterisation of the degradation pattern was carried out at Ciba-Geigy Crop Protection, Inc. USA.

5.2 Results and discussion

5.2.1 DT50 values

Aerobic degradation:

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.

Section A7.2.2.4. Anaerobic degradation in soil (1)

Annex Point: IIIA XII 1.1

Anaerobic degradation:

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 degradation:

The distribution of radioactivity after laboratory incorporation of phenyl ring "A"-^{14}C labelled fenoxycarb is shown in Table A7_2_2_4-2.

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 degradation:

The results obtained for the anaerobic degradation are presented in Table A7_2_2_4-3.

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 degradation:

The non-extractables reached a maximum of 40% at day 30 and then decreased to 18% after one year.

Anaerobic degradation:

The non-extractables reached a maximum of 42.5% at day 180 and then decreased to 26.3% after one year.

Section A7.2.2.4. Anaerobic degradation in soil (1)

Annex Point: IIIA XII 1.1

5.2.4	CO_2 formation	Aerobic degradation: Aerobic volatile generation of carbon dioxide increased to an average of 38.3% at day 360 indicating mineralisation of the phenyl ring "A". Anaerobic degradation: Under anaerobic conditions the degradation of fenoxycarb was considerably slowed down. A continued production of ^{14}C-carbon dioxide was observed under anaerobic conditions (32% after 360 days), indicating that there are multiple pathways operating in the degradation of fenoxycarb.
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	08-02-22
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_2_4-1: 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

Table A7_2_2_4-2: 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
** as determined by radio-TLC

Table A7_2_2_4-3: 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
** As determined by radio-TLC

Annex 1 Evaluation by Rapporteur Member State, CA-Tables

CA-Table 1 (revised Table A7_2_2_4-3): Distribution and recovery of radioactivity* in percent of applied ^{14}C-fenoxycarb in Maryland sandy loam under anaerobic laboratory conditions

Hours/ Days after applica-tion	Water Phase*** [%]	Volatiles (CO_2)*** [%]	Extractables			Non-extractable residues (NER)			Total [%]
			Total Extractables 1 [%]	Fenoxy-carb** [%]	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)

CA-Table-2: Distribution and recovery of in percent of applied 14C-fenoxycarb in Maryland sandy loam under anaerobic laboratory conditions (9.9 mg a.s./kg) (degradation study)

Time (months)	1	6	9	12[A]
soil	82	77	79	64
Water layer	3.9	2.2	2.0	1.3
CO_2	7.7	14	13	15
Mass balance	94	93	94	80

[A] results of one sample

Section A7.2.2.4. Anaerobic degradation in soil (2)

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) 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	Soil samples of each sampling day were combusted and analysed by direct LSC. Waters and volatiles trapping solutions were analysed by direct LSC.	

Section A7.2.2.4. Anaerobic degradation in soil (2)

Annex Point: IIIA XII 1.1

		Aerobic degradation: 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). 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). Anaerobic degradation: Samples were extracted by sonication and for later time samples additionally by homogenising in methanol - 0.1 N sodium hydroxide (Extraction 1) and autoclaving in 0.5 N sodium hydroxide (Extraction 2). The nature of radioactivity (fenoxycarb and metabolites) was investigated by using two-dimensional TLC, HPLC and GC/MSD. Non-extractable residues 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**	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.

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

See table 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, the characterisation of the degradation pattern was carried out at Ciba-Geigy Crop Protection, Inc. USA.

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 was 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

Aerobic degradation:

Section A7.2.2.4. Anaerobic degradation in soil (2)

Annex Point: IIIA XII 1.1

	products (% of a.s.)	The distribution of radioactivity during the incubation period is given in Table A7_2_1-2. The radiochemical balance averaged 93.9% over the one-year incubation period. 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 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 to the previously sonicated samples 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	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.
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. The 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	2008/02/22
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_2_4-1: 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

Table A7_2_2_4-2: 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) [%]	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	17.7	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

Annex 1: Evaluation by Rapporteur Member State, CA-Tables

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

Months after applic.	CO_2) [%]	Extractables				Non-extrac-table [%]	Water layer [3]	Mass balance Total [%]
		Sonication 1 & 2 Total [1] [%]	0.5% NH_4OH [%]	MeOH:aq NH_4OH [%]	Fenoxycarb[2] [%]			
Anaerobic, 10.23 mg/kg								
0 [4]	20	16	10	5.9	3.0	69	n.a.	104
1	19	15	8.9	5.7	1.5	59	1.9	94
2	20	15	5.8	9.4	2.9	59	1.7	96
3	22	16	10	6.0	1.4	51	2.2	91
4	23	14	6.9	6.7	1.1	48	2.2	87
5	25	17	13	4.1	1.1	42	1.8	86
6	22	n.a.	n.a.	4.5	2.1	67	2.1	96
8	25	n.a.	n.a.	n.a.	n.a.	66	1.2	92
9	25	9.1	n.a.	9.1	n.a.	52	1.6	87
12	26	n.a.	n.a.	n.a.	n.a.	58	1.0	85

* Average of duplicate sample analysis
[1] including metabolites (max, 1.8%AR)
[2] sum of both extracts; the 2/3/4/5 months 0.5% NH_4OH extracts were analysed for fenoxycarb showing 0.2% AR in the 2 month sample.
[2] sum of both extracts, the2, 3, 4 and 5 months 0.5% NH_4OH extracts were analysed for fenoxycarb, only after 2 month 0.2% AR was detected
[3] 3/4/5/6/8 months samples were analysed and contained no detectable amount of fenoxycarb and 2 unidentified metabolites (max 1.2% AR)
[4] values at the end of 28 days aerobic incubation, beginning of anaerobic phase
n.a.: not applicable

CA-Table 2: Distribution and recovery in percent of applied ^{14}C-fenoxycarb in Maryland sandy loam under anaerobic laboratory conditions (9.9 mg a.s./ kg) (degradation study)

Time (months)	1	6	9	12[1]
Soil	82	77	79	64
Water layer	3.9	2.2	2.0	1.3
CO_2	7.7	14	13	15
Mass balance	94	93	94	80

[1] results of one sample

Section A7.2.3.2 Soil leaching study (1)

Annex Point IIIA XII 1.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	Ochsenbein, U. (1990): CGA 114597 (RO 13-5223), Leaching characteristics of Ro-13-5223 as its formulated end-use product Insegar WP in three soils, RCC AG, Itingen, Switzerland, unpublished report, Proj. No 233346. Study dates: May - June 1989. Issue date: 13 February, 1990. (Syngenta File No. CGA114597/0118)	
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; Biologische Bundesanstalt Deutschland (BBA): Richtlinien für die amtliche Prüfung von Pflanzenschutzmitteln Teil IV, 4-2: Versickerungsverhalten von Pflanzenschutzmitteln, Dezember 1986.	X
2.2	**GLP**	Yes (RCC Umweltchemie AG, Itingen, Switzerland)	
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 Formulation: 25% w/w WP	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2 of dossier	
3.1.3	Purity	-	
3.1.4	Further relevant properties	25 WP (Wettable Powder) is an agricultural formulation of fenoxycarb.	
3.1.5	Method of analysis	The concentration of unlabelled fenoxycarb in the column leachates was determined by HPLC analysis.	
3.2	**Reference substance**	CAS No.: 72490-01-8 Lot. 22028, Purity 99.3%	
3.2.1	Method of analysis for reference substance	HPLC methods	
3.3	**Soil types**	The leaching characteristics of fenoxycarb were studied in three German standard soils (BBA 2.1, BBA 2.2 and BBA 2.3), see Table A7_2_3_2-1	

Section A7.2.3.2 Soil leaching study (1)

Annex Point IIIA XII 1.3

3.4	**Testing procedure**		
3.4.1	Test system	Column leaching according to the guideline (see point 2.1). Leaching was performed in a 40 cm long glass column of 5 cm inner diameter (cross sectional area of 19.6 cm^2) containing at the outlet side a 5 cm porous glass support. Delivery of water onto the top of the soil column was achieved by a multichannel peristaltic pump (Type: IPN 12, Ismatec). In order to protect the test article from indirect light, the columns were wrapped up with aluminium foil. An aliquot of the leachate of each soil column was extracted with hexane and, after evaporation of the solvent, dissolved in acetonitrile and analysed by revered phase high performance liquid chromatography with UV-detection.	
3.4.2	Test solution and Test conditions	0.059 mg fenoxycarb was applied. The rate corresponds to 300 g a.s./ha.	
		4 RESULTS	
4.1		See point 5.2	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The compound was applied to the surface of the glass columns. The columns had been packed with dry soil and saturated with water before treatment. Triplicate columns were used per soil type. To simulate leaching the artificial rainwater was applied with a peristaltic pump. A total of 393 ml corresponding to 200 mm rain were applied over a period of 48 hours.	X
5.2	**Results and discussion**	A mean recovery of the untreated soil column leachates fortified at levels of 0.2 and 1.0 µg/190 ml was found to be 94.0 ± 2.5%. The fenoxycarb concentration in the leachates of the treated columns was below the detection limit of the analytical method, amounting to less than 0.68% of the starting material applied on top of the columns.	X
5.3	**Conclusion**	The results of the study demonstrate that the test compound has no leaching potential.	X
5.3.1	Reliability	1	X
5.3.2	Deficiencies	None	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/07/05
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_2_3_2-1: Characteristics of German standard soils used for leaching of fenoxycarb formulated as a 25%w/w WP

Origin of soil:		**BBA 2.1**	**BBA 2.2**	**BBA 2.3**
Classification (USDA):		**Sand low OC**	**Sand high OC**	**Sandy loam**
Particle size distribution:	% clay	5.3	4.9	10.9
	% silt	3.8	7.1	13.4
	% sand 0.02 - 0.2 mm	23.3	39.6	31.2
	% sand > 0.2 mm	67.6	48.4	44.5
Organic carbon content:	[%]	0.5	2.6	0.7
pH:		6.0	6.0	6.6
Cation exchange capacity:	[meq/100 g soil]	3.6	7.2	4.5

Section A7.2.3.2 Aged residues soil leaching study (2)

Annex Point IIIA XII 1.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	Galicia, H. (1990): CGA 114597 (RO 13-5223), Leaching characteristics of aged residues in BBA soil 2.1, RCC AG, Itingen, Switzerland, unpublished report, RCC Proj. No 233357, 9 February, 1990. (Syngenta File No. CGA114597/0083)	
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; Biologische Bundesanstalt Deutschland (BBA): Richtlinien für die amtliche Prüfung von Pflanzenschutzmitteln Teil IV, 4-2: Versickerungsverhalten von Pflanzenschutzmitteln, Dezember 1986.	X
2.2	**GLP**	Yes (RCC Umweltchemie AG, Itingen, Switzerland)	
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"-U-^{14}C-labelled fenoxycarb	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Specific radioactivity: 1.19 MBq/mg	
3.1.3	Purity	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	TLC methods with two systems	
3.2	**Reference substance**	Unlabeled fenoxycarb: Lot No. 22028, Purity 99.3%	
3.2.1	Method of analysis for reference substance	TLC methods	
3.3	**Soil types**	The leaching characteristics of aged ^{14}C-fenoxycarb were studied in German standard soil BBA 2.1, see Table A7_2_3_2-1.	
3.4	**Testing procedure**		

Section A7.2.3.2 Aged residues soil leaching study (2)

Annex Point IIIA XII 1.3

3.4.1	Test system	Aged residue soil leaching according to the guideline (see point 2.1). Leaching was performed in a 40 cm long glass column of 5 cm inner diameter containing at the outlet side a porous glass support. Delivery of water onto the top of the soil column was achieved by a multichannel peristaltic pump (Type: MP13 6310, Ismatec). All-glass metabolism flasks were equipped with gas-washing bottles to trap volatiles and CO_2. Soil samples were extracted on day 14 and day 30 with methanol/water (8+2, v/v), twice with H_2O and finally with acetone, followed by Soxhlet extraction with methanol for about 16 hours. The methanol/water and Soxhlet extracts as well as the H_2O-extracts were combined for TLC-analyses. See attached Table A7_2_3_2-2 for sample schedule of the test	
3.4.2	Test solution and Test conditions	For ageing, phenyl ring "B"-U-^{14}C labelled fenoxycarb was applied to soil at a concentration of 0.40 mg a.i./kg dry soil corresponding to an exaggerated field rate of 300 g a.i./ha assuming a top 5 cm even soil distribution and a bulk density of 1.5 g/cm^3.	
		4 RESULTS	
4.1		After 14 days of ageing, fenoxycarb (applied to the soil columns) accounted for 18.5% and total extractables and non-extractables for 30.4% and 57.6% of radioactivity originally applied to the soil. After 14 days of ageing 12.5% of radioactivity had evolved as $^{14}CO_2$, demonstrating the rapid mineralisation of fenoxycarb. The total recovery of applied radioactivity after 14 days was 105.5%. After simulation of rainfall, the total radioactivity appearing in the leachates accounted for 0.78% of the radioactivity originally applied to the soil or to 0.89% of the radioactivity applied to the leaching columns. Additional extractions of soil samples after 15 and 30 days of incubation time were performed to verify the DT_{50}-value obtained of less than 14 days. The calculated DT_{50}-value employing the results obtained for sample B (day 0) and sample A (day 14) 8.6 days.	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The incubation conditions were: aerobic, dark, 40% MWC, temperature 20 °C for 14, 15 and 30 days. After an ageing period of 14 days duplicate aliquots of the incubated soil were packed as 4 cm layers on top of the 28 cm columns filled with the same soils. The resulting application rate of aged residues corresponds to about 240 g a.i./ha aliquots. For the leaching, the precipitation of bidistilled water was 193 mm (380 ml) and was applied by the constant head method over a period of 2 days. Aged soil was analysed for extractables and non-extractables after incubation and leachates (collected daily) were analysed for total radioactivity. No attempt was made to identify the radioactivity in the leachates due to their low specific radioactivity.	X
5.2	**Results and discussion**	After 14 days of ageing, fenoxycarb (applied to the soil columns) accounted for 18.5% and total extractables and non-extractables for 30.4% and 57.6% of radioactivity originally applied to the soil. After 14 days of ageing 12.5% of radioactivity had evolved as $^{14}CO_2$,	X

Section A7.2.3.2 Aged residues soil leaching study (2)

Annex Point IIIA XII 1.3

		demonstrating the rapid mineralisation of fenoxycarb. The total recovery of applied radioactivity after 14 days was 105.5%. After simulation of rainfall, the total radioactivity appearing in the leachates accounted for 0.78% of the radioactivity originally applied to the soil or to 0.89% of the radioactivity applied to the leaching columns. Additional extractions of soil samples after 15 and 30 days of incubation time were performed to verify the DT_{50}-value obtained of less than 14 days. The calculated DT_{50}-value employing the results obtained for sample B (day 0) and sample A (day 14) 8.6 days.	
5.3	**Conclusion**	The results indicate a low mobility of aged fenoxycarb residues in the sandy BBA 2.1 standard soil, even at a simulated rainfall of 379.5 ml (corresponding to 193 mm) during two days.	X
5.3.1	Reliability	1	X
5.3.2	Deficiencies	None	

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date *2006/07/05*

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_2_3_2-1: Characteristics of BBA 2.1 standard soil

Origin of soil:		**BBA 2.1**
Classification (USDA):		**Sand low OC**
Particle size distribution:	% clay	5.3
	% silt	3.8
	% sand 0.02 - 0.2 mm	23.3
	% sand > 0.2 mm	67.6
Organic carbon content:	[%]	0.5
pH:		6.0
Cation exchange capacity:	[meq/100 g soil]	3.6
Max. water holding capacity (MWC)	[g/100 g soil]	21.1
Volume of wet (40% MWC) soil corresponding to 100 g dry soil	[ml]	77.5
Microbial biomass - at start of experiment - at end of experiment	[mg C/100 g soil]	 42.0 14.2

Table A7_2_3_2-2: Sample schedule of the leaching test (Incubation of the remaining five samples was discontinued on day 34)

Incubation time (days)	Sample	Experimental procedure
0	A	Extraction
0	B	Extraction
14	A	Extraction
14	B	Stored at -20°C for leaching experiment
15	Leach. A	Extraction
15	Leach B	Stored at -20°C
30	A	Extraction
30	B	Extraction
30	Res. A	Stored at -20°C

Section A7.2.3.2 Soil leaching study (3)

Annex Point IIIA XII 1.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	Shepler, K. (1995): Column leaching of ^{14}C-Fenoxycarb in five soil types, PTRL West, Inc, United States, unpublished report, Proj. No PTRL West 504W. Issue date: 12 September, 1995. (Syngenta File No. CGA114597/0568)	
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 (PTRL West, Inc. Richmond, California)	
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"-U-^{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	[redacted]	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	HPLC and TLC methods	
3.2	**Reference substance**	Unlabelled fenoxycarb: analytical standard No. S91-1536, purity 99.0% CGA-294847: Lot No. GB-LI-75, purity 99.6% CGA-294850: Lot No. GB-IL-8, purity 98.4% CGA-026021 or 26021: Lot No. NEH-VI-59, purity 99.0% CGA-195935: Lot No. GB-XLVIII-40-1, purity 99.8% CGA-294851: Lot No. GB-IL-24-1, purity 96.7% Dihydroxyphenyl: Ref. No. CAS-IV-48, purity > 99.9%	

Section A7.2.3.2 Soil leaching study (3)

Annex Point IIIA XII 1.3

3.2.1	Method of analysis for reference substance	HPLC and TLC methods	
3.3	**Soil types**	The soil leaching potential of fenoxycarb was studied in five representative agricultural soils; see Table A7_2_3_2-1	
3.4	**Testing procedure**		
3.4.1	Test system	Column leaching according to the guideline (see point 2.1).	
3.4.2	Test solution and Test conditions	The compound was formulated as a 25% w/w WP formulation and the target formulation of 57 µg of [^{14}C]-fenoxycarb corresponds to the proposed single maximum field rate of 0.28 kg a.s./ha.	
		4 RESULTS	
4.1		See point 5.2	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Radiolabelled fenoxycarb was applied to the top of 0.01 M calcium chloride saturated soil columns (5.1 cm inner diameter, 36 cm length) containing 30 cm soil. Duplicate columns were used for each of the five soils. The columns were eluted with 1030 ml 0.01 M calcium chloride solution corresponding to 508 mm of rainfall. Volatiles were collected from the top and bottom of each column throughout the leaching process by drawing ambient laboratory air through two polyurethane foam plugs and a series of silylated, glass gas dispersion tubes containing ethylene glycol and 10% KOH. Ethylene glycol and KOH trapping solutions were radioassayed when the leachate flow stopped. Leachate was collected in four or five fractions of each column and radioassayed. After leachate flow had ceased, each soil column was cut into five 6 cm sections and extracted with MeOH:0.1N NaOH (80:20, v/v). Extracts were pooled, analysed by LSC, and any soil section extract that contained ≥ 1% of applied dose were analysed with HPLC and TLC (2 systems). A second extraction with 0.5 N sodium hydroxide at 100 °C was conducted to reduce the soil bound residue of sections ≥ 10% of applied radiocarbon following the MeOH:0.1N NaOH extraction and the extracts were concentrated and analysed by two-dimensional TLC.	X
5.2	**Results and discussion**	Average total radiocarbon recovery for all columns ranged from 95.7 to 98.7% of applied radioactivity. The majority of radioactivity applied to the columns of four soil types (sand, sandy loam, loam and silt loam) remained in the top 12 cm layer (> 91%) and in the top 6 cm (> 92%) of the clay and consisted of fenoxycarb and non-extractable ^{14}C-residues. Mean [^{14}C]-fenoxycarb residue (by HPLC analysis) in the 0-6 cm and 6-12 cm sections of the columns accounted for 38.0 and 45.5 (sand), 42.6 and 32.2 (sandy loam), 73.9 and 6.1 (loam), 58.8 and 7.6% (silt loam) of	X

Section A7.2.3.2 Soil leaching study (3)

Annex Point IIIA XII 1.3

		the applied dose, respectively. The 0-6 cm soil sections of clay accounted for 39.8% of the applied dose as fenoxycarb. Only minor amounts (< 2%) of other extractable ^{14}C-components were present. Non-extractable (bound) radioactivity in the 0-6 cm layers ranged from 3.22% in the sand to 50.41% in the clay of the applied dose. Soil residue extraction with 0.5 N sodium hydroxide at 100 °C reduced bound residues. Fenoxycarb and several minor components were shown to be present in these extracts. The leachates of sand, sandy loam, loam, silt loam and clay columns contained an average of 0.39, 0.17, 0.17, 0.30 and 10% of applied radiocarbon. Minimal volatiles were detected during the leaching process (≤ 0.07% of the applied dose, average of replicates) for each soil. The majority of the radiocarbon detected in KOH solutions from the clay columns (0.41% of the applied dose, average of replicates) was confirmed to be $^{14}CO_2$. The mobility of fenoxycarb was very limited and slow for all five soil types. The average coefficient of distribution (K_d) for total radioactivity in each soil was determined to be 129.2 ml/g, 394.4 ml/g, 433.2 ml/g, 216.9 ml/g and 561.7 ml/g for the columns of sand, sandy loam, loam silt, silt loam and clay soil, respectively.	
5.3	**Conclusion**	Most of the applied fenoxycarb (> 91%) remained in the top 12 cm layer of the soil columns. Therefore fenoxycarb has no leaching potential.	X
5.3.1	Reliability	1	X
5.3.2	Deficiencies	None	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

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_2 _3_2-1: Classification and physico-chemical properties of soils used for column leaching studies

	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_2_3_2-2: Column leaching of ^{14}C- fenoxycarb after an artificial rainfall of 508 mm

Origin of soil:		**Leland Mississippi**		**Burtonsville Maryland**		**Lime Kiln Maryland**		**Middletown Maryland**		**Yakima Washington**	
Soil texture		**Clay**		**Sand**		**Sandy loam**		**Silt loam**		**Loam**	
Soil 0 - 6 cm	[%]*	95.4	92.4	39.2	45.0	57.2	41.8	82.9	83.5	84.5	90.7
Soil 6 - 12 cm	[%]*	0.7	1.8	56.8	46.8	38.0	49.7	12.4	14.0	12.3	6.0
Soil 12 - 18 cm	[%]*	0.1	0.7	2.4	3.4	0.8	3.0	0.3	0.3	0.1	0.1
Soil 18 - 24 cm	[%]*	0.1	0.3	0.3	0.5	0.1	0.1	0.1	0.1	0.1	0.1
Soil 24 - 30 cm	[%]*	<0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Soil Total	[%]*	96.3	95.3	98.8	95.7	96.1	96.1	96.0	98.1	97.1	97.0
Leachate	[%]*	0.1	0.1	0.4	0.4	0.2	0.2	0.3	0.3	0.2	0.2
Total recovery	[%]*	96.4	96.2	99.2	96.1	96.4	95.0	96.2	98.4	97.3	97.1

* Percent of radioactivity applied to the column.

Section A7.3.1 Phototransformation in air
Annex Point: IIIA 12.3 (estimation method)

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1 REFERENCE

1.1	**Reference**	Fàbregas, E. (2006): Fenoxycarb ([2-(4-phenoxy-phenoxy)-ethyl]-carbamic acid ethyl ester). Calculation of indirect photodegradation, date: 2006-01-05.
1.2	**Data protection**	Yes
1.2.1	Data owner	Janssen Pharmaceutica NV
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**	No; Calculation based on QSAR
2.2	**GLP**	Not applicable since the degradation behaviour of fenoxycarb in air was calculated.
2.3	**Deviations**	Not applicable since the degradation behaviour of fenoxycarb in air was calculated.

3 MATERIALS AND METHODS

The half-life of fenoxycarb in air due to indirect photodegradation, i.e. oxidation with photochemically produced hydroxyl radicals, was calculated using the software programme AOPWIN, v. 1.91, 2000 by US-EPA based upon QSAR methods developed by Dr. Roger Atkinson and co-workers.

AOPWIN requires only a chemical structure to make these predictions. Structures are entered into AOPWIN by SMILES (Simplified Molecular Input Line Entry System) notations.

4 RESULTS

With the improved software-version 1.91 the half-life of fenoxycarb in the troposphere was calculated to be 5.897 hours with a degradation rate of 65.3 x 10^{-12} cm^3*$molecule^{-1}$*s^{-1}. This corresponds to a chemical lifetime in air of 8.51 hours. These estimations were carried out with respect to the OH radical reaction, only, and using a 24-hours-day with 5 x 10^5 OH radicals/cm^3.

5 Conclusion

4.1	**Conclusion**	Due to the short chemical lifetime of fenoxycarb in air it is not to be expected that it can be carried in the gaseous phase over long distances or can accumulate in air. Hence, air will not be an environmental compartment of concern.

Section A7.3.1 Phototransformation in air (estimation method)

Annex Point: IIIA 12.3

4.1.1 Reliability 2

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/07/04
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	

Section A7.4.1.1 Acute toxicity to fish (1)

Annex Point IIA VII.7.1 Rainbow trout (*Oncorhynchus* mykiss), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)

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1 REFERENCE

1.1 Reference

[redacted] (1993a): Acute Flow-through Toxicity of Fenoxycarb to the Rainbow Trout (*Oncorhynchus mykiss*). [redacted] unpublished report No. 14-CG (Syngenta No. CGA114597/0416). Experimental period September 4th 1992 to September 8th 1992.

[redacted] (1993b): Acute Flow-through Toxicity of Fenoxycarb to the Bluegill Sunfish (*Lepomis macrochirus*). [redacted], unpublished report No. 13-CG (Syngenta No. CGA114517/0418). Experimental period August 20th 1992 to August 24th 1992.

[redacted] (1993c): Acute Flow-through Toxicity of Fenoxycarb to the Carp (*Cyprinus carpio*). [redacted] unpublished report No. 47-CG (Syngenta No. CGA114598/0421). Experimental period August 7th 1992 to August 11th 1992.

[redacted] (1993d): Acute Flow-through Toxicity of Fenoxycarb to the Channel Catfish (*Ictalurus punctatus*). [redacted] unpublished report No. 48-CG (Syngenta No. CGA114598/0419). Experimental period September 25th 1992 to September 29th 1992.

[redacted] (1993e): Acute Flow-through Toxicity of Fenoxycarb to the Sheepshead Minnow (*Cyprinodon variegatus*). [redacted], unpublished report No. 16-CG (Syngenta No. CGA11457/0417). Experimental period August 13th 1992 to August 17th 1992.

1.2 Data protection Yes

1.2.1 Data owner Syngenta

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;

[redacted] (1993a-b, e):

U.S. EPA (1985). Standard evaluation procedure. Acute toxicity test for freshwater invertebrates. Hazard Evaluation Division. Office of Pesticide Programs, Washington D.C: EPA 540/9-85-005.

U.S. EPA (1988). Pesticide Assessment Guidelines. Sub-division E. Hazard Evaluation Wildlife and aquatic organisms. Ecological Effect Branch. Hazard Evaluation Division. Office of Pesticide Programs, Washington D.C: Draft March 1988.

[redacted] (1993c,-d):

Section A7.4.1.1	**Acute toxicity to fish (1)**
Annex Point IIA VII.7.1	Rainbow trout (*Oncorhynchus* mykiss), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)

		OECD (1984). Fish acute toxicity test. Method 203 in OECD guideline for testing of chemicals. Adopted 4th April 1984.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	Fenoxycarb technical;
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2 of dossier
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	Water solubility: 7.9 mg/L at 25 °C (Ref.: Stulz, 1993)
3.1.6	Method of analysis	Identity of the a. i. has been confirmed by mass spectral analysis.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Solvent was used, for further details see Table A7_4_1_1-1
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	See table A7_4_1_1-2
3.4.2	Test organisms	In the respective tests: - juvenile Rainbow trout, *Oncorhynchus mykiss* - Bluegill Sunfish (*Lepomis macrochirus*) - Carp (*Cyprinus carpio*) - Channel Catfish (*Ictalurus punctatus*) - Sheepshead Minnow (*Cyprinodon variegatus*) For further details cf. Table A7_4_1_1-3
3.4.3	Test system	The juveniles of the respective species were exposed to five concentrations of the test substance, a dilution water control, and a solvent control, under flow-through conditions for a period of 96 hours. The test was performed at and above the apparent water solubility of fenoxycarb, as indicated by the observation of white particles in the diluter stock solution (concentration of the stock solution 4.0 mg/L) and all non-control test vessels. Twenty fish selected impartially were distributed equally between two

x

Section A7.4.1.1	Acute toxicity to fish (1)	
Annex Point IIA VII.7.1	Rainbow trout (*Oncorhynchus* mykiss), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)	

		replicates of each treatment (2 replicates of 10 fish/concentration) and 10 fish per water and per solvent control group. Fenoxycarb was supplied to the test vessels by an intermittent flow proportional diluter.	
		See table A7_4_1_1-4	
3.4.4	Test conditions	See table A7_4_1_1-5	
3.4.5	Duration of the test	96 hours	
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	Mortality was recorded after 24, 48, 72 and 96 hours.	
		Dissolved oxygen, pH values, conductivity (salinity for sheepshead minnow) and temperatures were measured and recorded daily in each test chamber that contained live animals.	
3.4.8	Monitoring of TS concentration	Yes, analytical measurements (HPLC) were performed at the beginning and at the end of the test. The mean measured concentrations are given in Table A7_4_1_1-6.	
3.4.9	Statistics	Results of the toxicity test were interpreted by standard statistical techniques (Stephan, 1983). LC_{50} values were calculated whereas the NOEC is the concentration that allowed at least 90% survival and did not cause sublethal effects.	
		4 RESULTS	
4.1	**Limit Test**	Not performed, various concentrations tested	
4.1.1	Concentration	-	
4.1.2	Number/ percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	Nominal concentrations of fenoxycarb were 0, 0.6, 1.0, 1.6, 2.4, and 4.0 mg/L.	
4.2.2	Actual concentrations of test substance	Measured concentrations of individual samples were within a range of 29-68 % of nominal values (reflecting the fact that the test concentrations were above the water solubility of fenoxycarb in the dilution water). Concentrations were stable throughout the tests. Results are based on mean measured concentrations of the test substance.	
4.2.3	Effect data (Mortality)	See Table A7_4_1_1-7	x
4.2.4	Concentration / response curve	Concentration / response curves are given in the reports.	

Section A7.4.1.1	**Acute toxicity to fish (1)**
Annex Point IIA VII.7.1	Rainbow trout (*Oncorhynchus* mykiss), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)

4.2.5	Other effects	Rainbow trout: Sublethal effects were observed in all fish from a mean measured concentration of 0.37 mg ai/L and above. Such sub-lethal symptoms included erratic swimming, a loss of equilibrium, lethargy, immobilisation and gasping on the bottom of test vessels. Bluegill Sunfish: Sublethal effects were observed at test concentrations of 0.64 mg ai/L and above. At 24, 48 and 72 hours affected fish were lethargic at 96 hours they were lethargic, but also exhibited a loss of equilibrium and swam erratically. The LC_0 was 0.42 mg ai/L. Carp: Sublethal effects were observed at test concentrations of 0.68 mg ai/L and above. Such effects included lethargy, bulging eyes, a loss of equilibrium and immobilisation. The LC_0 was 0.68 mg ai/L. Channel Catfish: Sublethal effects such as lethargy and a loss of equilibrium were observed at test concentrations of 0.77 and 1.0 mg ai/L. No sub-lethal effects were noted in the highest concentration tested, however, all fish in this treatment were dead within 24 hours of exposure. The LC_0 was 0.49 mg ai/L. Sheepshead Minnow: Sublethal effects including lethargy, a loss of equilibrium and erratic swimming were observed at test concentrations of 0.90 mg/L and above. The LC_0 was 0.90 mg ai/L.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	No mortality occurred in the control group
4.3.2	Nature of adverse effects	-
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	-
4.4.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Several 96 - hour flow-through studies were conducted in accordance with OECD Guideline 203 or U.S. EPA standard guideline which can be compared to OECD Guideline 203 in order to estimate the acute toxicity of fenoxycarb to several fish species: Rainbow trout (*Oncorhynchus mykiss*), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)

Section A7.4.1.1		**Acute toxicity to fish (1)**	
Annex Point IIA VII.7.1		Rainbow trout (*Oncorhynchus* mykiss), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)	
5.2	**Results and discussion**	Under flow-through conditions the 96-hour LC_{50} of fenoxycarb to the most sensitive species *Oncorhynchus mykiss* was 0.66 mg ai/L (95% confidence limits ranging from 0.60 to 0.72 mg/l) and the NOEC was 0.26 mg ai/L. Both results are related to measured concentrations.	
5.2.1	96h-LC_0	Between 0.37 and 0.90 mg a.i./L (results of the single tests are listed in Table A7_4_1_1-7)	
5.2.2	96h-LC_{50}	The toxicity of all tested species was in the range of 0.6-1.5 mg a.i./L, whereas the most sensitive species was *Oncorhynchus mykiss*	x
5.2.3	96h-LC_{100}	not determined (between 0.84 and >1.6 mg a.i./L), see results in Table A7_4_1_1-7	
5.3	**Conclusion**	The tests is considered as valid, the validity criteria are summarised in table A7_4_1_1-8	
5.3.1	Other Conclusions	-	
5.3.2	Reliability	1	
5.3.3	Deficiencies	No	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/06/12
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_4_1_1-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Acetone
Concentration of vehicle	0.1 ml/l acetone
Vehicle control performed	Yes
Other procedures	-

Table A7_4_1_1-2: Dilution water

Criteria	Details
Source	Carbon filtered, natural salt water collected at T[redacted]
Alkalinity	-
Hardness	Rainbow trout: 44 mg/L as $CaCO_3$ Bluegill Sunfish: 48 mg/L as $CaCO_3$ Carp: 24 mg/L as $CaCO_3$ Channel Catfish: 48 mg/L as $CaCO_3$
pH	Rainbow trout: 7.4 Bluegill Sunfish: 7.6 Carp: 7.2 Channel Catfish: 7.3 Sheepshead Minnow: 8.3
Oxygen content	Rainbow trout: 9.3 mg/L Bluegill Sunfish: 8.0 mg/L Carp: 8.3 mg/L Channel Catfish: 8.1 mg/L Sheepshead Minnow: 7.0 mg/L
Conductance	Rainbow trout: 170 to 200 µmhos/cm Bluegill Sunfish: 180 to 200 µmhos/cm Carp: 97 to 110 µmhos/cm Channel Catfish: 170 to 180 µmhos/cm Sheepshead Minnow: instead of that, the salinity is given: 15 to 16 ppt
Holding water different from dilution water	No

Table A7_4_1_1-3: Test organisms

Criteria	Details
Species/strain	Rainbow trout (*Oncorhynchus mykiss*, formerly *Salmo gairdneri*), Bluegill Sunfish (*Lepomis macrochirus*), Carp (*Cyprinus carpio*), Channel Catfish (*Ictalurus punctatus*), Sheepshead Minnow (*Cyprinodon variegatus*)
Source	All test animals were procured from commercial suppliers.
Wild caught	No
Age/size	Rainbow trout Mean body length: 31 mm, mean body weight: 0.24 g (both recorded at the end of the test in the control) Bluegill Sunfish Mean body length: 37 mm, mean body weight: 0.55 g (both recorded at the end of the test in the control) Carp Mean body length: 35 mm, mean body weight: 0.62 g (both recorded at the end of the test in the control) Channel Catfish Mean body length: 31 mm, mean body weight: 0.25 g (both recorded at the end of the test in the control) Sheepshead Minnow Mean body length: 34 mm, mean body weight: 0.71 g (both recorded at the end of the test in the control)
Kind of food	no data
Amount of food	no data
Feeding frequency	no data
Pretreatment	no data
Feeding of animals during test	no data

Table A7_4_1_1-4: Test system

Criteria	Details
Test type	Flow-through test, acute
Renewal of test solution	Renewed continuously
Volume of test vessels	Rainbow trout: 20 L containing 15 L test solution Bluegill Sunfish: 0.37 g/l Carp: 0.41 g/l Channel Catfish: 0.17 g/l Sheepshead Minnow: 0.47 g/l
Volume/animal	Loading rate in the test water: Rainbow trout: 0.16 g/l Bluegill Sunfish: 0.37 g/l Carp: 0.41 g/l Channel Catfish: 0.17 g/l Sheepshead Minnow: 0.47 g/l
Number of animals/vessel	10
Number of vessels/ concentration	2 vessels/concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_1-5: Test conditions

Criteria	Details
Test temperature	Rainbow trout: 11.5 to 12.9°C Bluegill Sunfish: 21.8-22.3°C Carp: 22.0-22.9°C Channel Catfish: 21.1-22.4°C Sheepshead Minnow: 22.0-22.3°C
Dissolved oxygen	Rainbow trout: 8.5 to 9.6 mg/L Bluegill Sunfish: 6.9 to 8.7 mg/L Carp: 4.3 to 8.6 mg/L Channel Catfish: 6.6 to 8.9 mg/L Sheepshead Minnow: 7.2 to 8.0 mg/L
pH	Rainbow trout: 7.1-7.4 Bluegill Sunfish: 7.3-7.6 Carp: 6.7-7.4 Channel Catfish: 7.1-7.4 Sheepshead Minnow: 7.8-8.3
Adjustment of pH	not data
Aeration of dilution water	not required (apart from the test with carp where aeration was initiated after 72 h)
Intensity of irradiation	cool-white fluorescent light (32 - 37 footcandles)
Photoperiod	16 hour light / 8 hours dark

Table A7_4_1_1-6a: Mortality of the different exposed species *Oncorhynchus mykiss*

Concentration [mg a.i./L]	Mean measured [mg a.i./L] (right column) Mortality [%] after 96 hr (left column)									
	Oncorhynchus mykiss		*Lepomis macrochirus*		*Cyprinus carpio*		*Ictalurus punctatus*		*Cyprinodon variegatus*	
Control	< 0.02	0	< 0.02	0	< 0.02	0	< 0.02	0	< 0.02	0
Solvent control	< 0.02	0	< 0.02	0	< 0.02	0	< 0.02	0	< 0.02	0
0.6	0.26	0	0.28	0	0.29	0	0.34	0	0.26	0
1.0	0.37	0	0.42	0	0.46	0	0.49	0	0.34	0
1.6	0.58	20	0.64	20	0.68	0	0.77	10	0.53	0
2.4	0.84	90	0.91	90	1.1	5	1.0	90	0.90	0
4.0	1.30	100	1.40	100	1.6	65	1.6	100	1.2	75

Table A7_4_1_1-7: Acute fish toxicity data of Fenoxycarb (based on measured concentrations)

Species	Exposure	NOEC [mg a.i./L]	LC_0 [mg a.i./L]	LC_{50} [mg a.i./L] (95 % conf. interval)	LC_{100} [mg a.i./L]
Oncorhynchus mykiss	96 hours	0.26	0.37	0.66 (0.60-0.72)	0.84-1.30
Lepomis macrochirus	96 hours	0.42	0.42	0.74 (0.67-0.80)	0.91-1.4
Cyprinus carpio	96 hours	0.46	0.68	1.5 (1.1-1.6)	>1.6
Ictalurus punctatus	96 hours	0.49	0.49	0.88 (0.77-1.0)	1.0-1.6
Cyprinodon variegatus	96 hours	0.53	0.90	1.1 (0.90-1.2)	>1.2

Table A7_4_1_1-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fulfilled
Mortality of control animals <10%	X	
Concentration of dissolved oxygen in all test vessels > 60% saturation	X	
Concentration of test substance ≥ 80% of initial concentration during test		X

Criteria for poorly soluble test substances	X	

Section A7.4.1.1 Acute toxicity to fish (2)

Annex Point IIA VII.7.1 CGA294847 (fenoxycarb metabolite) towards Rainbow trout (*Oncorhynchus mykiss*)

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		1 REFERENCE
1.1	**Reference**	[redacted] (2002): CGA294847 (fenoxycarb metabolite): Acute toxicity to rainbow trout (*Oncorhynchus mykiss*). [redacted]. Unpublished report number 2022502 (Syngenta No. CGA294848/0003). Experimental period: September 30th 2002 to October 4th 2002.
1.2	**Data protection**	Yes
1.2.1	Data owner	Syngenta
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 203, Fish Acute Toxicity Test (1992)
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	CGA 294847
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	-
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	Yes, HPLC
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Preparation with dilution water.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	See table A7_4_1_1-1

Section A7.4.1.1 Acute toxicity to fish (2)

Annex Point IIA VII.7.1 CGA294847 (fenoxycarb metabolite) towards Rainbow trout (*Oncorhynchus mykiss*)

3.4.2	Test organisms	Rainbow trout, *Oncorhynchus mykiss*
3.4.3	Test system	The effect of the test treatment CGA294847 at 7.5, 15, 30, 60 and 120 mg/L relative to a dilution water control on the rainbow trout (*Oncorhynchus mykiss)* was investigated. The test solutions were made up in the dilution water, which had been filtered, dechlorinated, had its hardness adjusted and UV sterilised prior to use. The test vessel was a borosilicate glass tank with a maximum capacity of 31L and a working volume of 15L. The test solutions in the tanks were gently aerated and maintained at 15 ± 1°C under fluorescent light (16 hour photoperiod). One test vessel was established per treatment and seven fish were randomly allocated to each vessel. The fish were neither fed for the duration of the test nor for the 24 hours immediately preceding the start of the test. See Table A7_4_1_1-2 and -3
3.4.4	Test conditions	See table A7_4_1_1-4
3.4.5	Duration of the test	96 hours
3.4.6	Test parameter	Mortality
3.4.7	Sampling	Observations of toxicity and mortality were made 3, 24, 48, 72 and 96 hours after the commencement of exposure. Dissolved oxygen, pH values and temperatures were measured daily in representative vessels.
3.4.8	Monitoring of TS concentration	Yes, analytical measurements were performed at day 24 and at the end of the test. The recovery rates are given in Chapter 4.2.2
3.4.9	Statistics	The LC_{50} values and their respective 95 % confidence intervals were calculated at the various time intervals by the [redacted] computer program "PCLC50" using Stephan´s method (1977).
		4 RESULTS
4.1	**Limit Test**	Not performed, various concentrations tested
4.1.1	Concentration	-
4.1.2	Number/ percentage of animals showing adverse effects	-
4.1.3	Nature of adverse effects	-
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Nominal concentrations were 7.5, 15, 30, 60 and 120 mg/L
4.2.2	Actual concentrations of test substance	The measured concentrations after 24 hours ranged from 101 to 108% of the nominal values and at test termination the measured values

Section A7.4.1.1	Acute toxicity to fish (2)
Annex Point IIA VII.7.1	CGA294847 (fenoxycarb metabolite) towards Rainbow trout (*Oncorhynchus mykiss*)

		ranged from 97 to 108% of the nominal values.
4.2.3	Effect data (Mortality)	See Table A7_4_1_1-5
4.2.4	Concentration / response curve	Given in the report.
4.2.5	Other effects	Although reliable levels of mortality were only generated by the 120mg/L CGA 294847 treatment, all treatments caused a range of sub-lethal effects and the 96-hour NOEC was 60 mg/L. For further details see Table A7_4_1_1-6.
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	No mortality occurred in the control group
4.3.2	Nature of adverse effects	-
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	-
4.4.2	Results	-
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A 96 - hour static (*Oncorhynchus mykiss*) study was conducted in accordance with the OECD guideline 203 in order to estimate the acute toxicity of the fenoxycarb metabolite CGA294847 to rainbow trout (*Oncorhynchus mykiss*).

5.2	**Results and discussion**	No fish died in the control. All results are based on nominal concentrations, as the recovery rate was > 80 % during the test. The 96-hour LC_{50} of fenoxycarb to rainbow trout was 100 mg ai/L. The measured concentrations after 24 hours ranged from 101 to 108% of the nominal values and at test termination the measured values ranged from 97 to 108% of the nominal values. Mortality was observed after 48 hours exposure in the 15mg CGA 294847 treatment. However, as no mortality was observed in the 30 and 60mg/L treatments and as only one fish died in the 15mg/L CGA294847 treatment the biological significance of this result must be questioned. After 48 hours or thereafter more than 50% mortality was observed in the 120mg/L CGA 294847 treatment. Although reliable levels of mortality were only generated by the 120mg/L CGA 294847 treatment, all treatments caused a range of sub-lethal effects and the 96-hour NOEC was 60 mg/L.
5.2.1	96h-LC_0	60 mg a.i./L
5.2.2	96h-LC_{50}	100 mg a.i./L
5.2.3	96h-LC_{100}	not determined (> 120 mg a.i./L)
5.3	**Conclusion**	The test is considered as valid, the validity criteria are summarised in table A7_4_1_1-8
5.3.1	Other Conclusions	-
5.3.2	Reliability	1
5.3.3	Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/06/13
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_4_1_1-1: Dilution water

Criteria	Details
Source	Dechlorinated tap water
Alkalinity	27.8 mg/L (as $CaCO_3$)
Hardness	47.0 mg/L $CaCO_3$
pH	7.92
Oxygen content	9.45 mg/L (94 % of the 100 % air saturation value)
Conductance	270 µS cm^{-1} at 25°C
Holding water different from dilution water	No

Table A7_4_1_1-2: Test organisms

Criteria	Details
Species/strain	Rainbow trout (*Oncorhynchus mykiss*, formerly *Salmo gairdneri*)
Source	[redacted]
Wild caught	No
Age/size	Weight: 1.01 g - 1.98 g (mean 1.42 g) Length: 42 - 51 mm (mean 46 mm)
Kind of food	Commercial fish food
Amount of food	Appropriate amounts
Feeding frequency	Not specified
Pretreatment	Prior to the test, fish were acclimatisated to the test temperature (15°C ± 1) for at least 7 days.
Feeding of animals during test	Fish were not fed during the study

Table A7_4_1_1-3: Test system

Criteria	Details
Test type	Static test, acute
Renewal of test solution	-
Volume of test vessels	Borosilicate glass tank with a maximum capacity of 31L and a working volume of 15L.
Volume/animal	At the end of the 96-hour exposure phase the loading of the fish in the dilution water control was determined to be 0.66g/L.
Number of animals/vessel	7
Number of vessels/ concentration	1 vessels/concentration

Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_1-4: Test conditions

Criteria	Details
Test temperature	15 ± 1°C
Dissolved oxygen	9.13 to 10.1 mg/L
pH	7.50 to 7.76
Adjustment of pH	-
Aeration of dilution water	Yes
Intensity of irradiation	-
Photoperiod	16 hour light / 8 hours dark

Table A7_4_1_1-5: Mortality of the exposed *Oncorhynchus mykiss*

Concentration [mg a.i./L]	Mortality [%]			
	24 hr	48 hr	72 hr	96 hr
Control	0	0	0	0
7.5	0	0	0	0
15	0	14	14	14
30	0	0	0	0
60	0	0	0	0
120	0	57	71	71

Table A7_4_1_1-6: Sublethal effects of the fenoxycarb metabolite CGA 294847

Nominal conc of CGA 294847 (mg/L)	Symptoms observed				
	3 hour	24 hour	48 hour	72 hour	96 hour
7.5	A	A	Cbc	Cc	A
15	Ca	Ba	Cac	Cc	Cc
30	Ca	Ca	Cac	Cac	Cac
60	Ca	Ca	Cacd	Cabc	Cac
120	Ca	Ca	Cacde	Cac	Cacef

A 10% or less of the test population dead or exhibiting symptoms of toxicity (not considered to be biologically significant)

B	Between 11% and 30% of test population dead or exhibiting symptoms of toxicity
C	More than 30% of test population dead or exhibiting symptoms of toxicity

a	Dark discoloured	d	Skittering
b	Surfacing	e	Loss of balance
c	Sounding	f	Weak

Table A7_4_1_1-7: Acute fish toxicity data of Fenoxycarb (based on nominal concentrations)

Species	Exposure	NOEC [mg a.i./L]	LC_{50} [mg a.i./L]
Oncorhynchus mykiss	96 hours	60	100

Table A7_4_1_1-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	**Not fulfilled**
Mortality of control animals <10%	**X**	
Concentration of dissolved oxygen in all test vessels > 60% saturation	**X**	
Concentration of test substance ≥ 80% of initial concentration during test	**X**	

Criteria for poorly soluble test substances	**Not applicable**	

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna*

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		1 REFERENCE
1.1	**Reference**	Ward, J.T. and Boeri, R.L. (1993f): Acute Flow-through Toxicity of Fenoxycarb to the Daphnid (*Daphnia magna*), T R Wilbury Laboratories, Marblehead, United States, unpublished report No. 15-CG (Syngenta No. CGA114597/0420). Experimental period: July 29th to July 31st 1992.
1.2	**Data protection**	Yes
1.2.1	Data owner	Syngenta
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; U.S. EPA (1985). Standard evaluation procedure. Acute toxicity test for freshwater invertebrates. Hazard Evaluation Division. Office of Pesticide Programs, Washington D.C: EPA 540/9-85-005. U.S. EPA (1988). Pesticide Assessment Guidelines. Sub-division E. Hazard Evaluation Wildlife and aquatic organisms. Ecological Effect Branch. Hazard Evaluation Division. Office of Pesticide Programs, Washington D.C: Draft March 1988
2.2	**GLP**	Yes
2.3	**Deviations**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	Fenoxycarb technical
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2 of dossier
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	Water solubility: 7.9 mg/L at 25 °C (Ref.: Stulz, 1993)
3.1.6	Method of analysis	The identity of the a. i. has been confirmed by mass spectral analysis.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Solvent used, type of solvent not specified, see table A7_4_1_2-1.
3.3	**Reference substance**	No
3.3.1	Method of analysis	-

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna*

	for reference substance		
3.4	**Testing procedure**		
3.4.1	Dilution water	See table A7_4_1_2-2	
3.4.2	Test organisms	See table A7_4_1_2-3	
3.4.3	Test system	Juvenile daphnids were exposed under flow-through conditions to a geometric series of five test concentrations, a solvent control and a negative (dilution water) control. Two replicate test chambers per treatment and controls groups were maintained with 10 daphnids in each test chamber for a total of 20 daphnids per concentration. The test was performed in 20 litre glass aquaria containing 15 L of test solution in which test organisms were exposed in glass cylinders to the test solution, suspended within each test vessel. Nominal concentrations of fenoxycarb were 0.38, 0.62, 1.0, 1.5 and 2.5 mg/L. The test was performed at and above the apparent water solubility of fenoxycarb, as apparent by the observation of white particles in the diluter stock solution (concentration of the stock solution 2.5 mg/L). Insoluble material was not observed in any test vessel during the test. See table A7_4_1_2-4	
3.4.4	Test conditions	See table A7_4_1_2-5	
3.4.5	Duration of the test	48 hours	
3.4.6	Test parameter	Mortality	x
3.4.7	Sampling	Mortality was observed after 24 and 48 hours Conductivity, pH, dissolved oxygen concentration and temperature were measured daily in each chamber that contained living animals.	
3.4.8	Monitoring of TS concentration	Yes, analytical measurements of test substance at 0 and 48 hours. see table A7_4_1_2-6	
3.4.9	Statistics	Results of the toxicity test were interpreted by standard statistical techniques (Stephan, 1983).	
		4 RESULTS	
4.1	**Limit Test**	Not performed	
4.1.1	Concentration	-	
4.1.2	Number/ percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Initial concentrations of	Nominal concentrations: 0.38, 0.62, 1.0, 1.5 and 2.5 mg/L	

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna*

	test substance		
4.2.2	Actual concentrations of test substance	Samples for test substance analyses, collected at the beginning of the test, ranged from 35 to 41.9% of nominal values and from 31.6 to 42.1% of nominals at the end of the exposure period. Reflecting the fact that the test concentrations were above the water solubility of fenoxycarb in the dilution water. Concentrations were stable throughout the test. Mean measured values were used in the calculation of LC_{50} values.	
4.2.3	Effect data (Immobilisation)	See table A7_4_1_2-6 and table A7_4_1_2-7.	
4.2.4	Concentration / response curve	Concentration / response curve is given in the report.	
4.2.5	Other effects	Of those daphnids surviving in the 0.39 and 0.60 mg ai/L fenoxycarb treatments, 50% and 100%, respectively were lethargic at 48 hours. All of the surviving daphnids in the highest concentration tested were immobilised after 48 hours of exposure.	
4.3	**Results of controls**	No mortality occurred in the controls after 24 h, one *Daphnia* was dead after 48 h in the solvent control.	x
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	-	
4.4.2	Results	-	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Juvenile Daphnia magna were exposed in a flow-through test system for 48 h to six nominal concentrations of 0, 0.38, 0.62, 1.0, 1.5, 2.5 mg a.i./L. Mortality of the daphnids was recorded after 24 and 48 hours.	x
5.2	**Results and discussion**	The EC_{50} (48 h) was determined to be 0.6 mg a.i./L.	
		Mortality in the control was < 10% after 48 h.	x
		The concentration of the test substance decreased at the beginning of the test, due to the low water solubility but afterwards the concentrations remained stable. Mean measured values were used in the calculation of EC_{50} values.	
5.2.1	NOEC	0.16 mg a.i./L after 48 h	
5.2.2	EC_{50}	0.6 mg a.i./L after after 48 h (95 % conf. interval: 0.51 – 0.73)	
5.2.3	EC_{100}	not determined	
5.3	**Conclusion**	The EC_{50} (48 hours, flow-through) was determined to be 0.6 mg a.i./L (95% confidence limits 0.51 – 0.73mg a.i./L). NOEC was 0.16 mg a.i./L.	
		The validity criteria are summarised in table A7_4_1_2-8. All validity criteria are fulfilled by the study.	
5.3.1	Reliability	1	

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna*

5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/06/15
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	