Table A7_4_1_2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	-
Vehicle	Acetone
Concentration of vehicle	0.1 ml/l acetone
Vehicle control performed	Yes
Other procedures	-

Table A7_4_1_2-2: Dilution water

Criteria	Details
Source	Carbon filtered, dechlorinated tap water collected at T.R. Wilbury, Marblehaed, Massachusetts
Alkalinity ($CaCO_3$)	-
Hardness ($CaCO_3$)	160 - 180 mg/L
pH	8.3
Ca / Mg ratio	-
Na / K ratio	-
Oxygen content	8.5 mg/L dissolved oxygen
Conductance	610 to 630µMhos/cm
Holding water different from dilution water	No

Table A7_4_1_2-3: Test organisms

Criteria	Details
Strain	*Daphnia magna*
Source	Obtained from single source, produced from in house culture at T.R. Wilbury
Age (at start of the study)	Juveniles
Breeding method	-
Kind of food	Freshwater algae and yeast/trout chow slurry
Amount of food	-
Feeding frequency	Daily before the test
Pre-treatment	-
Feeding of animals during test	During the test the water fleas were not fed.

Table A7_4_1_2-4: Test system

Criteria	Details
Renewal of test solution	The test was performed under flow-through conditions
Volume of test vessels	20 litre glass aquaria (glass cylinders) containing 15 L of test solution
Volume/animal	15 L/10 daphnids
Number of animals/vessel	10
Number of vessels/ concentration	2 replicates per concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_2-5: Test conditions

Criteria	Details
Test temperature	20.6 to 20.9°C
Dissolved oxygen	6.9-8.5 mg/L
pH	8.0 - 8.3
Adjustment of pH	-
Aeration of dilution water	Not required
Quality/Intensity of irradiation	Cool-white fluorescent light / 34 foot candles
Photoperiod	16 hour light / 8 hours dark

Table A7_4_1_2-6: Mortality of *Daphnia magna* after 24 h and 48 hours

Nominal test substance concentration (mg/L)	Mean measured	Number (percent) of immobilized daphnids	
		24 h	48 h
Control	0	0	0
Solvent control	0	0	5
0.38	0.16	0	0
0.62	0.26	5	5
1.0	0.39	15	20
1.5	0.60	10	50
2.5	0.84	5	75

Table A7_4_1_2-7: Toxicity data obtained in the acute *Daphnia* test

Species	Exposure	NOEC mg a.i./L	EC_{50} (95% confidence limits) mg a.i./L
Daphnia magna	24 hours	0.16	> 0.84 (-)
	48 hours	0.16	0.60 (0.51 – 0.73)

Table A7_4_1_2-8: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

	fulfilled	Not fulfilled
Immobilisation of control animals <10%	X	
Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	X	
Concentration of test substance ≥ 80% of initial concentration during test		X measured values used

Criteria for poorly soluble test substances	X	

Section A7.4.1.2 Acute toxicity to invertebrates (2)

Annex Point IIA VII.7.2 CGA 294847 (fenoxycarb metabolite) towards *Daphnia magna*

Official use only

		1 REFERENCE
1.1	**Reference**	Penwell, A. J. and Maynard, S. J (2002). CGA 294847 (fenoxycarb metabolite): Acute toxicity to Daphnia magna. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA. Unpublished report number 2022503 (Syngenta No. CGA294847/0004). Experimental period: October 1st 2002 to October 3rd 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 guidelines for testing chemicals (1993). Test guideline 202, Part 1-EC_{50} Acute immobilisation test. Environmental Protection Agency (1985) Hazard Evaluation Division Standard Evaluation Procedure 540/9-85-005. Acute toxicity test for freshwater invertebrates
2.2	**GLP**	Yes
2.3	**Deviations**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	CGA 294847 (fenoxycarb metabolite)
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	HPLC
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable, daphnid dilution water used
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section A7.4.1.2 Acute toxicity to invertebrates (2)

Annex Point IIA VII.7.2 CGA 294847 (fenoxycarb metabolite) towards *Daphnia magna*

3.4	**Testing procedure**		
3.4.1	Dilution water	See table A7_4_1_2-1	
3.4.2	Test organisms	less than 24 hours old , see table A7_4_1_2-2	
3.4.3	Test system	First instars of *Daphnia,* were exposed to the test treatment CGA 294847 and the effect of this test treatment relative to a dilution water control was noted. Four 250 mL borosilicate beakers covered with loose fitting glass lids and containing 200 mL of the test solution (made up in Elendt's M4 *Daphnia* medium) were established per treatment. The test was initiated when 5 *Daphnia* (in less than 2.0 mL of water) were added to each replicate treatment. The effect of the treatment on the *Daphnia* was made 24 and 48 hours after the commencement of the test. See table A7_4_1_2-3	
3.4.4	Test conditions	See table A7_4_1_2-4	
3.4.5	Duration of the test	48 hours	
3.4.6	Test parameter	Affection of Daphnia - no whole body movement within a 15 second observation period.	
3.4.7	Sampling	Mortality was observed after 24 and 48 hours pH and dissolved oxygen concentration of test samples were measured at the beginning and the end of the test. Temperature was determined daily.	x
3.4.8	Monitoring of TS concentration	Yes, analytical measurements of test substance at 0 and 48 hours.	
3.4.9	Statistics	The 24 and 48 EC_{50} values and their 95 % confidence limit were calculated using Stephan´s method (1977).	
		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 test substance	Nominal concentrations: 7.5, 15, 30, 60 and 120 mg/l	
4.2.2	Actual concentrations of test substance	The measured concentrations at the start of the test ranged from 99-100% of the nominal values and at the end of the test from 77-102% of the nominal values. Mean measured concentrations during the test are given in table	x

Section A7.4.1.2 Acute toxicity to invertebrates (2)

Annex Point IIA VII.7.2 CGA 294847 (fenoxycarb metabolite) towards *Daphnia magna*

		A7_4_1_2-5.	
		These results indicate that the test concentrations prepared for this test correspond to nominal concentrations and that the test substance was stable for the duration of the study.	
4.2.3	Effect data (Immobilisation)	See table A7_4_1_2-6 and table A7_4_1_2-7.	
		Mortality of daphnids showed a clear dose-response relationship. No daphnids died in the lowest concentration, while no Daphnia survived in the highest concentration.	x
4.2.4	Concentration / response curve	Concentration / response curve is given in the report.	
4.2.5	Other effects	No symptoms of toxicity other than immobilisation were observed	
4.3	**Results of controls**	No mortality occurred in the 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**	First instars of *Daphnia magna* (2 x 5 animals per concentration) were exposed in a static test system for 48 h to five nominal concentrations of 7.5, 15, 30, 60 and 120 mg a.i./L plus control. Mortality of the daphnids was recorded after 24 and 48 hours.	x
5.2	**Results and discussion**	Mortality increased with test substance concentration, no daphnids died in the lowest concentration, while no *Daphnia* survived in the highest concentration. The EC_{50} (48 h) was determined to be 61 mg a.i./L.	x
		The mean measured concentrations showed that the test concentrations prepared for this test correspond to nominal concentrations and that the test substance was stable for the duration of the study.	
5.2.1	NOEC	30 mg a.i./L after 48 h	
5.2.2	EC_{50}	61 mg a.i./L after after 48 h	
5.2.3	EC_{100}	not determined (EC100 between 61-120 mg/l)	
5.3	**Conclusion**	The EC_{50} (48 hours) was determined to be 61 mg a.i./L (95% confidence limits 71 – 110 mg a.i./L). NOEC was 30 mg a.i./L and LOEC 60 mg a.i./L, respectively.	
		The validity criteria are summarised in table A7_4_1_2-7. All validity criteria are fulfilled by the study.	
5.3.1	Reliability	1	
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	2006/06/19
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_2-1: Dilution water

Criteria	Details
Source	Standard Elendt's M4 Daphnia medium
Alkalinity ($CaCO_3$)	37.8 mg/L
Hardness ($CaCO_3$)	211.3 mg/L $CaCO_3$
pH	7.94 - 8.07
Ca / Mg ratio	approx. 8 : 1
Na / K ratio	approx 10 : 1
Oxygen content	8.6 - 9.0 mg/L
Conductance	614µScm^{-1}
Holding water different from dilution water	No

Table A7_4_1_2-2: Test organisms

Criteria	Details
Strain	*Daphnia magna*
Source	Laboratory reared
Age (at start of the study)	1st instar daphnids (< 24 – hours old)
Breeding method	-
Kind of food	Defined diet of algae *Chlorella vulgaris* and a commercial available microencapsulated diet
Amount of food	-
Feeding frequency	-
Pre-treatment	-
Feeding of animals during test	During the test the water fleas were not fed.

Table A7_4_1_2-3: Test system

Criteria	Details
Renewal of test solution	The test was performed under static conditions
Volume of test vessels	250 mL borosilicate beakers covered with loose fitting glass lids and containing 200 mL of the test solution
Volume/animal	5 Daphnia /200 mL water
Number of animals/vessel	5 Daphnia /vessel
Number of vessels/ concentration	2 replicates per concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_2-4: Test conditions

Criteria	Details
Test temperature	20.4 to 20.5°C
Dissolved oxygen	8.3-9.0 mg/L
pH	7.94 to 8.07
Adjustment of pH	No
Aeration of dilution water	No aeration during the test
Quality/Intensity of irradiation	-
Photoperiod	16:8 light-dark cycle (16-h daylight photoperiod)

Table A7_4_1_2-5: Acute toxicity of CGA 294847 (metabolite of fenoxycarb) to Daphnia magna

Nominal test substance concentration (mg/L)	Mean measured concentration	Total number immobilised (20 initial *Daphnia*) after 48-h	Percentage immobilisation after 48-h
Control	-	0	0
7.5	7.4	0	0
15	15	0	0
30	30	0	0
60	61	9	45
120	120	20	100

Table A7_4_1_2-6: Toxicity data obtained in the acute *Daphnia* test with 95% confidence values in parenthesis where appropriate

Species	Exposure	NOEC mg a.i./L	LOEC mg a.i./L	EC_{50} (95% confidence limits) mg a.i./L
Daphnia magna	24 hours	30	60	85 (71-110)
	48 hours	30	60	61 (54-71)

Table A7_4_1_2-7: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

	fulfilled	Not fulfilled
Immobilisation of control animals <10%	X	
Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	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 (3)

Annex Point IIA VII.7.2 CGA 294850 (fenoxycarb metabolite) towards *Daphnia magna*

Official use only

		1 REFERENCE
1.1	**Reference**	Bätscher, R. (2003): Acute Toxicity of CGA 294850 (Metabolite of CGA 114597) to *Daphnia magna* in a 48-hour Immobilization Test. RCC Ltd, Environmental Chemistry and Pharmanalytics, CH-4452 Itingen, Switzerland. Unpublished report No.2032539. (Syngenta No. CGA 294850/0001). Experimental period September 22nd 2003 to November 3rd 2003.
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 guideline 202, part 1, USA EPA OPPTS 850.1010
2.2	**GLP**	Yes
2.3	**Deviations**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	CGA 294850 (fenoxycarb metabolite)
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	-
3.1.6	Method of analysis	HPLC
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable, see table A7_4_1_2-1.
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_2-2

Section A7.4.1.2 Acute toxicity to invertebrates (3)

Annex Point IIA VII.7.2 CGA 294850 (fenoxycarb metabolite) towards *Daphnia magna*

3.4.2	Test organisms	See table A7_4_1_2-3
3.4.3	Test system	The mobility of *Daphnia magna* was tested. The effect of these treatments (initially dissolved in a solvent stock then added to reconstituted water) was compared to an untreated reconstituted water control and a solvent blank. The test vessel consisted of a 250 mL glass beaker (with a lid) containing 250 mL of the appropriate test solution. Five daphnids (6-24 hours old) were added to each of four replicate vessels for each treatment and control. The water was aerated until oxygen saturation prior to test initiation but for the 48-hours duration of the test the vessels were unaerated. The daphnids were not fed for the duration of the test. The daphnids were assessed visually for signs of immobility after 24 and 48 hours. 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	Immobilisation
3.4.7	Sampling	Immobilisation was observed after 24 and 48 hours pH and dissolved oxygen concentration of test samples and temperature were controlled at the beginning and at the end of the test.
3.4.8	Monitoring of TS concentration	Yes, analytical measurements of test substance at 0 and 48 hours;
3.4.9	Statistics	The 24 hours EC_{50} and the 95 % confidence interval were calculated by Moving Average Interpolation, whereas the 48 h EC_{50} value could not calculated this way due to steep concentration effect relationship. Instead, The 48 h EC_{50} value was determined as the geometric mean of the two consecutive test concentrations with 0 and 100 % immobility, confidence limits are test concentrations with 0 and 100 % immobility. The NOEC, EC_0 and EC_{100} were determined directly from the raw data.
		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 test substance	Nominal concentrations: 1.5, 3.0, 6.0, 12 and 24 mg/L
4.2.2	Actual concentrations of	The test substance was stable for the duration of the study. The measured concentrations at the start of the test ranged from 101-

Section A7.4.1.2 Acute toxicity to invertebrates (3)

Annex Point IIA VII.7.2 CGA 294850 (fenoxycarb metabolite) towards *Daphnia magna*

	test substance	107% of the nominal values and at the end of the test from 99-106% of the nominal values. At the highest concentration tested (24 mg/L) fine particles were visible at the start of the test and at the bottom of the test vessels after 24 and 48-hours indicating that this concentration was slightly above the maximum solubility of CGA 294850.
4.2.3	Effect data (Immobilisation)	See table A7_4_1_2-6 and table A7_4_1_2-7. Immobilisation of daphnids showed a clear dose-response relationship. No daphnids died in the lowest concentration, while no Daphnia survived in the highest concentration.
4.2.4	Concentration / response curve	-
4.2.5	Other effects	No symptoms of toxicity other than immobilisation were observed
4.3	**Results of controls**	No immobilisation occurred in the control after 24 h and 48 h.
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* (20 animals per concentration) were exposed in a static test system for 48 h to six nominal concentrations of 1.5, 3.0, 6.0, 12 and 24 mg a.i./L. Immobilisation of the daphnids was recorded after 24 and 48 hours.
5.2	**Results and discussion**	Immobilisation increased with test substance concentration, no daphnids died in the lowest concentration, while no Daphnia survived in the highest concentration. The EC_{50} (48 h) was determined to be 8.5 mg a.i./L. The mean measured concentrations showed that the test concentrations prepared for this test correspond to nominal concentrations and that the test substance was stable for the duration of the study.
5.2.1	NOEC	6 mg a.i./L after 48 h
5.2.2	EC_{50}	8.5 mg a.i./L after after 48 h
5.2.3	EC_{100}	not determined
5.3	**Conclusion**	The EC_{50} (48 hours, static) was determined to be 8.5 mg a.i./L (95% confidence limits 6 – 12 mg a.i./L). NOEC was 6 mg a.i./L and LOEC 12 mg a.i./L, respectively. 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
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	2006/06/19
Materials and Methods	[redacted].
Results and discussion	[redacted]
Conclusion	[redacted]d.
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_2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Solvent used: N,N-Dimethylformamide p.A
Concentration of vehicle	100 µl/L
Vehicle control performed	Yes
Other procedures	-

Table A7_4_1_2-2: Dilution water

Criteria	Details
Source	Reconstituted water
Alkalinity ($CaCO_3$)	0.08 mmol/L
Hardness ($CaCO_3$)	2.5 mmol/L (250 mg/L as $CaCO_3$)
pH	7.9
Ca / Mg ratio	4 : 1 (based on molarity)
Na / K ratio	10 : 1 (based on molarity)
Oxygen content	Test water was aerated until oxygen saturation was reached.
Conductance	-
Holding water different from dilution water	No

Table A7_4_1_2-3: Test organisms

Criteria	Details
Strain	*Daphnia magna*
Source	Laboratory reared
Age (at start of the study)	1st instar daphnids (6-24 – hours old)
Breeding method	-
Kind of food	During the test the water fleas were not fed.
Amount of food	During the test the water fleas were not fed.
Feeding frequency	-
Pre-treatment	-
Feeding of animals during test	During the test the water fleas were not fed.

Table A7_4_1_2-4: Test system

Criteria	Details
Renewal of test solution	The test was performed under static conditions
Volume of test vessels	250 mL glass beaker (with a lid) containing 250 mL of the appropriate test solution
Volume/animal	5 daphnids/ 250 mL
Number of animals/vessel	5/vessel
Number of vessels/ concentration	4 replicates per concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_2-5: Test conditions

Criteria	Details
Test temperature	20 to 21°C
Dissolved oxygen	Beginning: 8.2 to 8.7 mg/L End: 7.5 to 7.6 mg/L
pH	Beginning: 7.8-7.9 End: 7.9
Adjustment of pH	-
Aeration of dilution water	During the test period, test water was not aerated.
Quality/Intensity of irradiation	520-710 lux
Photoperiod	16-hour photoperiod

Table A7_4_1_2-7: Mortality of *Daphnia magna* after 24 h and 48 hours

Nominal test substance concentration (mg/L)	Daphnids exposed	Number (percent) of immobilized daphnids	
		24 h	48 h
Water control	20	0	0
Solvent control	20	0	0
1.5	20	0	0
3.0	20	0	0
6.0	20	0	0
12	20	18 (90)	20 (100)
24	20	20 (100)	20 (100)

Table A7_4_1_2-8: Toxicity data obtained in the acute *Daphnia* test

Species	Exposure	NOEC mg a.i./L	LOEC mg a.i./L	LC_{50} (95% confidence limits) mg a.i./L
Daphnia magna	24 hours	6	12	9.1 (8.0–10.4)
	48 hours	6	12	8.5 (6.0-12)

Table A7_4_1_2-9: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

	fulfilled	Not fulfilled
Immobilisation of control animals <10%	X	

Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	X	
Concentration of test substance ≥ 80% of initial concentration during test	X	

Criteria for poorly soluble test substances	X	

Section A7.4.1.2 Acute toxicity to invertebrates (4)

Annex Point IIA VII.7.2 *Daphnia magna*

Official use only

		1 REFERENCE
1.1	**Reference**	Ellgehausen, H. (1982): Acute toxicity of RO 13-5223 (CGA 114597 tech.) to Daphnia magna (48 Hours EC 50), RCC AG, Itingen, Switzerland, unpublished report No. 007435 (Syngenta No. CGA114597/0016). Experimental period: May 14th 1982 to May 26th 1982.
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**	No, The study was conducted before the introduction of an official test guideline for registration purposes.
2.2	**GLP**	No (Although the study was not conducted in compliance with modern GLP standards, it complies with sound scientific standards).
2.3	**Deviations**	None
		3 METHOD
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	-
3.1.6	Method of analysis	No data
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	The test concentrations were prepared from ethanol stock solutions by adding the desired volumes to the est media. The concentration of ethanol in all test samples including control was 0.1 %
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_3_4-1

Section A7.4.1.2 Acute toxicity to invertebrates (4)

Annex Point IIA VII.7.2 *Daphnia magna*

3.4.2	Test organisms	*Daphnia magna* See table A7_4_3_4-2 (further details are missing)	
3.4.3	Test system	The acute toxicity of fenoxycarb to *Daphnia magna* was determined with ten concentrations of the test substance and a blank control at a temperature of 20 ± 2 °C. Daphnids were exposed to the test concentrations in 50 mL beakers under static conditions. For each concentration and the control, two replicates were set up. Each replicate consisted of 10 daphnids in 20 mL test medium. The daphnids were observed for immobilisation after 24 h and 48 h of exposure. Nominal concentrations of fenoxycarb ranged between 0.025 and 8.0 mg ai/L. See table A7_4_3_4-3	
3.4.4	Test conditions	See table A7_4_3_4-4	
3.4.5	Duration of the test	48 hours	
3.4.6	Test parameter	Mortality	x
3.4.7	Sampling	The daphnids were observed for immobilisation after 24 h and 48 h of exposure. The oxygen concentration and pH value were measured at test initiation and termination.	
3.4.8	Monitoring of TS concentration	Yes, concentrations were measured at test initiation and termination	x
3.4.9	Statistics	Mean values used	
		4 RESULTS	
4.1	**Range finding test**	Not performed	
4.1.1	Concentrations	-	
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 ranged between 0.025 and 8.0 mg ai/L.	
4.2.2	Actual concentrations of test substance	Concentrations measured at the test initiation were 0.07, 0.37 and 7.24 mg/L for the 0.025, 0.5 and 8 mg/L nominal doses. At test termination measured concentrations were 0.06, 0.44 and 4.69 mg/L, respectively.	
4.2.3	Effect data (Immobilisation)	All results are summarised in Table A7_4_3_4-5. Other than immobilisation, no other symptoms of toxicity were found throughout the test period. The EC_0 (NOEC) values were 0.1 and 0.05 mg ai/L and the EC_{100} values were 4.0 and 2.0 mg ai/L after 24 and 48 hours of exposure respectively.	

Section A7.4.1.2 Acute toxicity to invertebrates (4)

Annex Point IIA VII.7.2 *Daphnia magna*

4.2.4	Concentration / response curve	Not given in the report.	
4.2.5	Other effects	No	
4.3	**Results of controls**	There was no mortality in the control	x
4.4	**Test with reference substance**		
4.4.1	Concentrations	Not performed	
4.4.2	Results	Not performed	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The effects of fenoxycarb technical on acute Daphnia toxicity were investigated using no standard procedure, since the study was conducted before the introduction of an official test guideline for registration purposes. In a static test system daphnids were exposed to six nominal concentrations of 0, 0.025, 0.050, 0.100, 0.125, 0.250, 0.500, 1.0, 2.0, 4.0 and 8.0 mg a.i./L for 48 h. Mortality of the daphnids was recorded after 24 and 48 hours.	x
5.2	**Results and discussion**	The 48-hour EC_{50} of fenoxycarb with *Daphnia magna* was 0.40 mg ai/L.	x
5.2.1	NOEC	0.05 mg ai/L	
5.2.2	EC_{50}	0.40 mg ai/L	
5.2.3	EC_{100}	2.00 mg ai/L	
5.3	**Conclusion**	The validity criteria can be considered as fulfilled (no mortality in the control) The validity criteria are summarised in table A7_4_3_2-6.	x
5.3.1	Reliability	2	
5.3.2	Deficiencies	Non-GLP and non guideline followed	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14.01.2008
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	**COMMENTS FROM ...** *(specify)*
Materials and Methods	*Give date of comments submitted*
Results and discussion	*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*
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_3_4-1: Dilution Water

Criteria	Details
Source	not specified
Salinity	not specified
Hardness	not specified
pH	7.5
Ca / Mg ratio	not specified
Na / K ratio	not specified
Oxygen content	8.9 mg/L
Conductance	not specified
TOC	not specified
Holding water different from dilution water	not specified

Table A7_4_3_4-2: Test Organisms

Criteria	Details
Strain / Clone	*Daphnia magna*
Source	Laboratory reared
Age	< 24 h
Breeding method	Not specified
Kind of food	Not specified
Amount of food	Not specified
Feeding frequency	Not specified
Pre-treatment	No
Feeding of animals during test	Not specified

Table A7_4_3_4-3: Test System

Criteria	Details
Test type	Static system
Renewal of test solution	No
Volume of test vessels	50 mL beakers
Volume/animal	20 mL test medium / 10 daphnids
Number of animals/vessel	10/vessel
Number of vessels/concentration	2 replicates/ concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_3_4-4: Test Conditions

Criteria	Details
Test temperature	20 ± 2 °C
Dissolved oxygen	7.7 – 8.9 mg/L
pH	7.5 – 7.8
Adjustment of pH	No
Aeration of dilution water	Not stated
Quality/Intensity of irradiation	-
Photoperiod	During exposure the animals were kept in the dark.

Table A7_4_3_4-5: Acute toxicity of fenoxycarb to *Daphnia magna* under static conditions

Concentration [mg ai/L]		[%]Immobilisation after		Exposure period [hours]	EC_{50}[a] [mg ai/L] (95 % conf. interval)
		24	48		
Nominal	**Measured End**				
Controls	0	0	0		
0.025	0.06	0	0		
0.050		0	0		
0.100		0	5		
0.125		5	5		
0.250		25	35		
0.500	0.44	25	65		
1.000		35	80	**48 h**	**0.40 (0.31 – 0.55)**
2.000		55	100		
4.000		100	100		
8.000	4.69	100	100	**NOEC: 0.05 mg ai/L**	

[a] calculated based on nominal concentrations

Table A7_4_3_4-6: Validity criteria for acute Daphnia test according to OECD Guideline 202

	Fulfilled	Not fulfilled
Immobilisation of control animals <10%	**X**	
Control animals not staying at the surface	**X**	
Concentration of dissolved oxygen in all test vessels >3 mg/l	**X**	
Concentration of test substance ≥ 80% of initial concentration during test		**X**
Criteria for poorly soluble test substances		**X**

Section A7.4.2 Bioconcentration in aquatic organisms (fish)

Annex Point IIA, VII.7.5

Official use only

		1 REFERENCE
1.1	**Reference**	Fàbregas, E. (2005): Calculation of the Bioconcentration Factor (BCF) of Fenoxycarb. Dr. Knoell Consult (unpublished) Report No. KC-BCF-02/06, date: 2006-09-29.
1.2	**Data protection**	Yes
1.2.1	Data owner	Janssen Pharmaceutica NV
1.2.2	Companies with letter of access	--
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Not applicable, calculation method
2.2	**GLP**	Not applicable
2.3	**Deviations**	Not applicable
		3 MATERIALS AND METHODS
3.1	**Test material**	Fenoxycarb
3.1.1	Lot/Batch number	Not applicable
3.1.2	Specification	Not applicable
3.1.3	Purity	Not applicable
3.1.4	Further relevant properties	Log Pow = 4.07 (Ref.: Rodler, 1992b)
3.1.5	Radiolabelling	--
3.1.6	Method of analysis	--
3.2	**Reference substance**	--
3.2.1	Method of analysis for reference substance	-
3.3	**Testing/estimation procedure**	
3.3.1	Test system/ performance	Not applicable
3.3.2	Estimation of bioconcentration	The bioconcentration factor in aquatic organisms (fish) was calculated using the equation 74 of the Technical Guidance Document (EU, 2003). The bioconcentration factor can be measured experimentally directly. A number of test guidelines are available for the direct measurement of bioconcentration, of which OECD 305 is the most widely applied. The assessment of the BCF is necessary for chemicals which are, based on base-set data, considered to have a logKow greater than 3. Another possibility is the estimation of BCF from logKow. A linear

model is recommended for logKow up to 6 and a non-linear model for logKow values from 6 to 10.

Linear equation logKow < 6

$$\log BCF_{fish} = 0.85 \times \log Pow - 0.70 \text{; n=55, } r^2\text{=0.90}$$

n	is the number of data
r^2	correlation coefficient
Kow:	octanol-water partition coefficient [-]
BCFfish:	bioconcentration factor for fish on wet weight basis [l*kg wet fish]

This relationship applies to compounds with a MW less than 700.

The linear model generated by Veith et al. (1979) is based on BCF data for fathead minnows (*Pimephales promelas*). LogKow is used as descriptor variable. This model has been validated externally in the past, using BCF data for 267 substances (Devillers et al., 1995). The root mean square error of the predictions was 0.58 for logKow < 6.

This model can be used to derive estimates for neutral, non-polar and non-ionised chemicals. These type of chemicals are usually biotransformed relatively slowly. They are not applicable to ionic substances, partly ionised chemicals and organometallics.

4 RESULTS

4.1	**Experimental data**	
4.1.1	Mortality/behaviour	--
4.1.2	Lipid content	--
4.1.3	Concentrations of test material during test	--
4.1.4	Bioconcentration factor (BCF)	Bioconcentration factor is not based on measurements
4.1.5	Uptake and depuration rate constants	--
4.1.6	Depuration time	--
4.1.7	Metabolites	--
4.1.8	Other Observations	--
4.2	**Estimation of bioconcentration**	The obtained BCF by this method is 574.78

Section A7.4.2 Bioconcentration in aquatic organisms (fish)

Annex Point IIA, VII.7.5

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The BCF of fenoxycarb in fish was estimated using the QSAR-approach as recommended in the Technical Guidance Document (EU, 2003) based on a measured log Kow value. If measured BCF values are not available, the BCF for fish can be predicted from the relationship between Kow and BCF. Various methods are available to calculate Kow. For substances with a log Kow of 2-6 the following linear relationship can be used as developed by Veith et al. (1979): log BCFfish = 0.85 x log Kow - 0.70
5.2	Results and discussion	Considering a log Kow-value of 4.07 which was obtained in a previously performed experimental study, the calculated BCF-value of fenoxycarb was about 575.
5.3	**Conclusion**	Based on a log Pow value of 4.07, obtained from an experimental study, a BCF of 547.78 is obtained. This value indicates a limited bioaccumulation potential of fenoxycarb in aquatic organisms. This result is consistent with the experimentally derived BCF value, which was obtained in a test by Volz (2001) and accounts for 569.
5.3.1	Reliability	2
5.3.2	Deficiencies	--

Section A7.4.2 Bioconcentration in aquatic organisms (fish)

Annex Point IIA, VII.7.5

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/01/16
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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Findings	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.4.3.1 Annex Point IIIA 12.1	Prolonged toxicity to an appropriate species of fish	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X].**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	–	
	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	
Evaluation of applicant's justification	[redacted].	
Conclusion	[redacted].	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.4.3.2 Effects on reproduction and growth rate of fish

Annex Point IIIA XIII 2.2

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (1990): Early Life Stage Toxicity of Fenoxycarb technical to Rainbow Trout (*Oncorhynchus mykiss*) in a Flow-through System. [redacted], unpublished report No 37431 (Syngenta No. CGA114597/0024). Experimental period: August 24th 1989 to November 28th 1989.
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; American Society for Testing and Material (1983). Proposed new standard practice for conducting fish early life stages toxicity tests. Draft no. 7, December 1983. ASTM Committee E-47.01. 90p. U.S. Environmental Protection Agency (1972). Proposed recommended Bioassay procedure for egg and fry stages of freshwater fish. Unpublished manuscript. Environmental Research Laboratory. Duluth, Minnesota January, 1972, 7p.
2.2	**GLP**	Yes
2.3	**Deviations**	None
		3 METHOD
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	-
3.1.6	Method of analysis	-
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	-
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section 7.4.3.2 Effects on reproduction and growth rate of fish
Annex Point IIIA XIII 2.2

3.4	**Testing procedure**		
3.4.1	Dilution water	See table A7_4_3_2-1	
3.4.2	Test organisms	Fish embryos of Rainbow trout (*Salmo gairdneri*) See table A7_4_3_2-2	
3.4.3	Handling of embryos and larvae (OECD 210/212)	-	
3.4.4	Test system	The effects of fenoxycarb on early life stages of Rainbow trout were investigated under flow-through conditions. Effects on hatchability, survival, growth and any abnormal sub-lethal changes of eggs and fry were observed during a period of 60-day post-hatch. Fish embryos were exposed to a geometric series of five concentrations of fenoxycarb ranging from nominal 0.0063 to 0.1 mg ai/L. Four replicate test chambers were maintained in each treatment and control group, with one egg incubation cup per test chamber. The test was initiated by distributing impartially selected newly fertilised rainbow trout eggs several at a time into successive incubator cups in each of the 4 replicate exposure aquarium per concentration. A total of 35 eggs were located in each incubator cup, i. e. 140 eggs per concentration for a total of 980 eggs in the study. In addition, 50 eggs in separate incubator cups were placed in the control chambers for determining viability. On day 12 post-hatch the fry were released from the incubation cups and monitored for mortality; abnormal behavioural or physical changes until day 60 post-hatch. The total duration of the study was 96 days, 36 days prior to hatch and 60-days post-hatch. Insoluble material was not observed and the substance appeared in solution in all test vessels and at all times and concentrations. See table A7_4_3_2-3	x
3.4.5	Test conditions	See table A7_4_3_2-4	
3.4.6	Duration of the test	The total duration of the study was 96 days, 36 days prior to hatch and 60-days post-hatch	
3.4.7	Test parameter(s)	Effects on hatchability, survival, growth and any abnormal sub-lethal changes of eggs and fry	
3.4.8	Examination / Sampling	On day 12 post-hatch the fry were released from the incubation cups and monitored for mortality; abnormal behavioural or physical changes until day 60 post-hatch. The total duration of the study was 96 days, 36 days prior to hatch and 60-days post-hatch.	
3.4.9	Monitoring of TS concentration	The concentrations of fenoxycarb were measured from samples taken on day 0, 1, 7, 14 and weekly thereafter until the end of the test	
3.4.10	Statistics	Statistical data were analyzed by a Systat® and a Toxstat® computer program package based upon a p = 0.05 significance level.	
		4 RESULTS	
4.1	**Range finding test**	Not performed	
4.1.1	Concentrations	-	

Section 7.4.3.2 Effects on reproduction and growth rate of fish
Annex Point IIIA XIII 2.2

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 0.0063, 0.013, 0.025, 0.050, 0.10 mg ai/L	
4.2.2	Actual concentrations of test substance	The mean measured concentrations of fenoxycarb based on samples taken on day 0, 1, 7, 14 and weekly thereafter until the end of the test were 0.0059, 0.012, 0.022, 0.048, and 0.092 mg test substance/L in the treatment groups. These values ranged from 88 to 96% of the nominal test concentrations. For further details see table A7_4_3_2-5.	x
4.2.3	Effect data	See table A7_4_3_2-5. Significant effects of fenoxycarb on the growth of juvenile Rainbow trout, measured as reduced fry length and weight, were observed only at a test concentration of 0.092 mg ai/L after 60 days of continuous exposure. No growth effect was measured 35 days after hatching in any treatment. Egg hatchability and fry survival were not affected at any exposure concentration tested.	
4.2.4	Concentration / response curve	Not given in report	
4.2.5	Other effects	None	
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	No adverse effects were visible.	
4.3.2	Nature of adverse effects	-	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	-	
4.4.2	Results	-	

Section 7.4.3.2 Effects on reproduction and growth rate of fish
Annex Point IIIA XIII 2.2

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was performed according to the American Society for Testing and Material (1983) and U.S. Environmental Protection Agency (1972). Proposed recommended Bioassay procedure for egg and fry stages of freshwater fish. Unpublished manuscript. Environmental Research Laboratory. Duluth, Minnesota January (1972) methods. The chronic toxicity of fenoxycarb was determined on fish embryos of Rainbow trout (*Salmo gairdneri*) using nominal concentrations of between 0.0063 to 0.1 mg ai/L. Chemical exposures were conducted for 96 days (36 days prior to hatch and 60-days post-hatch), during which measures of Effects on hatchability, survival, growth and any abnormal sub-lethal changes of eggs and fry were observed during a period of 60-day post-hatch.
5.2	**Results and discussion**	Growth effects (reduced fry length and weight) were observed only at a test concentration of 0.092 mg ai/L after 60 days of continuous exposure. Therefore, the NOEC was determined to be 0.048 mg/l and the LOEC was 0.092 mg/l based on mean measured concentrations. Egg hatchability and fry survival were not affected at any exposure concentration tested. The recovery of the initial nominal concentrations were ranged from 88 to 96 %.
5.2.1	NOEC	0.048 mg a.i./L based on measured concentrations
5.2.2	LOEC	0.092 mg a.i./L based on measured concentrations
5.3	**Conclusion**	Based on the findings stated above the overall NOEC of 96 days testing was determined as 0.048 mg test substance/l and the overall LOEC (60-day post-hatch) was 0.092 mg test substance/l. The validity criteria can be considered as fulfilled. The validity criteria are summarised in table A7_4_3_2-6.
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 2006/06/29

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted].

Reliability [redacted]

Acceptability [redacted]

Remarks [redacted]

COMMENTS FROM ... *(specify)*

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_3_2-1: Dilution water

Criteria	Details
Source	Uncontaminated deep-well water
Alkalinity ($CaCO_3$)	42 - 256 mg/L
Hardness ($CaCO_3$)	36-240 mg/L
pH	7.7 - 8.2
Oxygen content	9.0 - 10.5 mg/L during the test
Conductivity	80 - 400 µMhos/cm
TOC Content	< 1.0 - 2.6 mg/L
Holding water different from dilution water	No

Table A7_4_3_2-2: Test organisms

Criteria	Details
Species	Rainbow trout (*Salmo gairdneri*)
Source	[redacted]
Wild caught	No
Age/size	Fish embryos
Kind of food	Initially, fry were fed live, brine, shrimp nauplii, ground salmon starter was added to the diet at day 56.
Amount of food	-
Feeding frequency	3 times/day
Post-hatch larvae exposure	36 days
Time to first feeding	Day 53, 17 days post-hatch
Feeding of animals during test	Yes
Treatment for disease within 2 weeks proceeding test	No

Table A7_4_3_2-3: Test system

Criteria	Details
Test type	Flow-through
Renewal of test solution	Continuous renewal
Volume of test vessels	12 L replicate chamber at an average rate of approx. 78.5 L/replicate/day.
Volume/animal	-
Number of animals/vessel	One egg incubation cup per test chamber, 35 eggs per incubation cup, 50 eggs for the control chambers
Number of vessels/ concentration	4 replicates per control/solvent control/test concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_3_2-4: Test conditions

Criteria	Details
Test temperature	9.1 – 11.8 °C
Dissolved oxygen	9.0 - 10.5 mg/L
pH	7.7 – 8.2
Adjustment of pH	No
Aeration of dilution water	-
Intensity of irradiation	120 ± 17.8 footcandles at the water surface
Photoperiod	After hatch, the trout fry were on a 16 hours photoperiod.

Table A7_4_3_2-5 Effects of fenoxycarb on the early life stages of Rainbow trout of concentrations

Concentration [mg ai/L]		Percent hatch	Percent survival 35 d post hatch	Percent survival 60 d post hatch	Mean length 60 d post hatch (± SD)	Mean wet-weight 60-d post hatch (± SD)
Nominal	**Mean measured**	[%]	[%]	[%]	[mm]	[g]
Control	0	97	100	100	45.2 ± 2.62	1.38 ± 0.246
Sol. control	0	99	100	100	45.0 ± 3.11	1.40 ± 0.301
0.0063	0.0059	96	100	100	43.7 ± 3.53	1.31 ± 0.291
0.013	0.012	96	100	100	44.7 ± 3.47	1.35 ± 0.315
0.025	0.022	96	97	97	43.9 ± 3.08	1.27 ± 0.284
0.050	0.048	96	100	100	44.2 ± 2.76	1.27 ± 0.240
0.10	0.092	99	100	97	43.2 ± 2.58	1.18 ± 0.242

(± SD) - ± Standard deviation

Table A7_4_3_2-6: Validity criteria for fish tests according to OECD Guidelines 210/212

	fulfilled	**Not fulfilled**
Concentration of dissolved oxygen > 60% saturation throughout the test	**X**	
Difference of water temperature < 1.5% between test chambers or successive days at any time during test; temperature within range for specific test species	**X**	
Overall survival of fertilized eggs in controls (and solvent controls) ≥ value, specified for the specific test species	**X**	
Test substance concentrations maintained within ± 20% of mean measured values	**X**	
No effect on survival nor any other adverse effect found in solvent control	**X**	
Further criteria for poorly soluble test substances	**Not applicable**	

Section 7.4.3.3.1 **Annex Point IIIA XIII.2.3** **Section 7.4.3.3.2** **Annex Point IIIA XIII.2.3**	**Bio-accumulation in an appropriate species of fish/ Bio-accumulation in an appropriate invertebrate species**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ].**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/01/16	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.3.3.1 Bio-accumulation in an appropriate species of fish

Annex Point IIIA XIII.2.3 *Lepomis macrochirus*

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1 REFERENCE

1.1	**Reference**	[redacted] (2001): Accumulation and elimination of [Hydroquinone –(U)-^{14}C] CGA114597 by Bluegill Sunfish (*Lepomis macrochirus*) In a Dynamic Flow-Through System. [redacted] Unpublished report number: 2002502 (Syngenta No.CGA114597/0779). Experimental period: October 10th 2000 to April 9th 2001.
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; Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate: EPA 540/09-82-021, Section 165-4: "Laboratory studies of Pesticide accumulation in Fish". US Environmental Protection Agency, October 18, 1982; EPA 540/09-88-051, Addendum 8 on Data Reporting; by E. Brinson Conerly and Samuel M. Creeger, September 1988. OECD Guideline for Testing of Chemicals, Proposal for Updating Guideline 305: "Bioaccumulation: Flow-through Fish Test", Paris/France, June 1996.
2.2	**GLP**	Yes (certified Laboratory), with the exception of the development of the analytical method and the analysis of the fish food
2.3	**Deviations**	The lipid content of the fish (as mg/kg wet weight) at the end of the experiment differed from that at the start by more than ± 25%

3 MATERIALS AND METHODS

3.1	**Test material**	A mixture of: a) CGA 114597 (synonymous for fenoxycarb pure) b) Fenoxycarb labelled with ^{14}C-hydroquinone
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	a) as given in section 2 of dossier b) specific activity 2.05MBq/mg (55.4µCi/mg)
3.1.3	Purity	[redacted]

Section A7.4.3.3.1 Bio-accumulation in an appropriate species of fish

Annex Point IIIA XIII.2.3 *Lepomis macrochirus*

3.1.4	Further relevant properties	Water solubility: 7.9 mg/L at 25 °C (Ref.: Stulz, 1993) Fish toxicity: LC_{50} = 0.66 mg/L (Ref.: [redacted], 1993a; lowest toxicity value)
3.1.5	Radiolabelling	[Hydroquinone –(U)-^{14}C] CGA114597
3.1.6	Method of analysis	LSC
3.2	**Reference substance**	No
3.2.1	Method of analysis for reference substance	-
3.3	**Testing/estimation procedure**	
3.3.1	Test system/ performance	100 juvenile Bluegill Sunfish were maintained in each of three 153L glass aquaria containing 128L water and were fed on commercially prepared Discus fish food (feeding rate 2% of total biomass daily). A continuous flow chemical delivery system was used which delivered 1056L per day (per aquaria). Three aquaria were established, two of which contained the test treatments and the third containing a DMF (dimethylformamide) control (0.1mL DMF per litre of H_2O). The fish were continually exposed to 0.015mg/L (C_1) or 0.0015mg/L (C_2) ^{14}C-hydroquinone labelled CGA 114597 (fenoxycarb), which is equivalent to 0.52% and 0.052% of the 96-hour LC_{50}. In order to determine the bioconcentration factor, the time to reach steady state concentration, the amount of CGA 114597 and its metabolites, the lipid content in edible and non edible fish portions and the accumulation and depuration rates of CGA 114597 were recorded. The fish were exposed to the test treatments for 28-days in the dynamic flow-through system before the depuration of the radioactivity from fish in untreated water for 14-days. <u>Sampling and analysis</u> Water samples from each aquarium were taken for radiochemical analysis at days -4, -1, 0, 1, 2, 3, 7, 9, 13, 14, 17, 21, 24 and 28 days of the exposure phase and days 1, 2, 3, 7, 10, and 14 of the depuration phase. In order to determine the radioactivity in edible and non-edible portions of fish, 4 fish were removed from each of the treatments at days 0, 1, 3, 7, 14, 17, 21, 24 and 28 of the exposure phase and days 1, 3, 7, 10 and 14 of the depuration phase. At day 0 and 28 of the exposure phase and day 14 of the depuration phase, 4 fish from the control tank were taken for background radioactivity measurements. The fish were dissected into edible and non-edible portions, the corresponding portions were pooled, chemically solubilized and the radioactivity was determined via liquid scintillation counting (LSC). For the analysis of the amount of parent, metabolites and lipid content in fish, a total amount of 32 fish (2 portions of 16 fish each) were taken from each test tank at day 28 of exposure. For the analysis of the lipid content and determination of the storage stability, 16 additional fish specimens were taken from the control tank at day 0 of the study. For the determination of the lipid content at the end of the study, 8 additional fish were taken from the control tank at day 42.
3.3.2	Estimation of bioconcentration	In evaluating the data obtained from the bioconcentration study, a steady-state approach was used. This consists of a two compartment

model (water and fish-tissue) which is used to describe the movement of the test material in and out of the test fish. This approach is used to determine the steady-state bioconcentration factor (BCF).

$$\text{Bioconcentration factor} = \frac{C_{tissue}}{C_{Water}}$$

4 RESULTS

4.1 Experimental data

4.1.1	Mortality/behaviour	No mortality occurred during the test. The fish showed no sub-lethal symptoms during the accumulation and depuration phase
4.1.2	Lipid content	The lipid content was determined after solvent extraction of the edible and non-edible tissues at days 0, 28 and 42. The lipid amount of the whole fish was calculated from these results. The lipid content (% of weight) of edible parts was between 1.5% (day 0) - 3.7% (day 47) for all, control, low and high dose fish. The lipid content (% of weight) of non- edible parts was between 4% (day 0) - 7.2% (day 47) for all, control, low and high dose fish. The calculated lipid content (% of weight) of total fish at days 0, 28 and 42 was between 2.8% to 5.6% for control fish and 3.3 to 3.4 for both, low and high dose fish. Lipid content was found to be independent of exposure dose.
4.1.3	Concentrations of test material during test	From the third day of depuration no radioactivity could be measured in either of the test concentrations. CGA 114597 residues were rapidly concentrated in edible and non-edible portions of the fish as well as in the whole fish. The concentrations reached a constant plateau after approximately 17 days for both the higher (C1) and lower (C2) concentrations. At steady state, the measured concentrations of CGA 114597 equivalents in the non-edible and edible tissues and in the whole fish were 11.3, 1.71, 6.86 mg equivalents/kg tissue fresh weight for the higher concentration (C1) and 1.39, 0.169 and 0.825mg equivalent/kg tissue fresh weight for the lower (C2) concentration respectively. The measured radioactivity in water during the test is given in Table A7_4_3_3_1-01. The measured level of radioactivity in fish tissues during the test is given in Table A7_4_3_3_1-02. After termination of exposure, CGA 114597 residues were rapidly eliminated from the non-edible and edible tissues and the whole fish with DT_{90} values of 1.8, 1.8 and 2.0 days for the higher concentration (C_1) and 4.0, 1.3 and 3.7 days for the lower (C_2) concentration. Under constant exposure CGA 114597 will be bioconcentrated mainly in non-edible fish tissues and elimination of the bioconcentrated residues is ≥ 89% after 3 days and 95% after 10 days in CGA 114597 free water.
4.1.4	Bioconcentration factor (BCF)	The steady-state BCFs were 569 and 467 for 0.00145 µg/l and 0.0147 µg/l, respectively.

4.1.5	Uptake and depuration rate constants	The steady-state was achieved at day 17 of the exposure phase. The uptake rate was not determined. For the depuration phase an overall DT_{90} of 2.0 for the higher concentration and 3.7 for the lower concentration is given.
4.1.6	Depuration time	3 days
4.1.7	Metabolites	Metabolites of fenoxycarb, like parent, were found mostly in non-edible tissues (Table A7_4_3_3_1-3), and were rapidly depurated on cessation of exposure. Analysis of the metabolites showed that the metabolite pattern was qualitatively and almost quantitatively independent of the exposure concentration of CGA 114597 in the fish tank and that it was qualitatively comparable in the edible and non-edible fish parts.
4.1.8	Other Observations	The dissolved O_2 content ranged from 89-108% saturation, pH from 8.0 and 8.2 and recorded temperature from 22.0 to 22.3°C. The total hardness of the water ranged from 5.2 to 45.7mgC/L and the conductivity of the water ranged from 396 to 416µS/cm
4.2	**Estimation of bioconcentration**	Bioconcentration factor is based on measurements.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was performed according to several current guidelines, US-EPA Section 165-4 and OECD Guideline for Testing of Chemicals 305: "Bioaccumulation: Flow-through Fish Test". The test was initiated with 100 juvenile Bluegill Sunfish per glass aquaria containing 128 L test medium using a flow-through system. Concentrations chosen for the present study were 0.015 and 0.0015 µg a.i./L. The study shows no significant deviations from test guideline.
5.2	Results and discussion	CGA 114597 (fenoxycarb) residues were rapidly concentrated in fish tissues reaching a stable steady state concentration within about 17 days. Mean measured bioconcentration factors for CGA 114597 residues in non-edible, edible portions and whole fish were 864, 117 and 518 respectively. The calculated BCF's for the same tissues were 927, 113 and 543 respectively. The depuration time for 90% of the bioconcentrated radioactivity for the whole fish was less than 3 days for the higher test concentration (C1) and less than 7 days for the lower test concentration (C2). Thus CGA 114597 showed limited bioconcentration in Bluegill, *Lepomis macrochirus*, and bioconcentrated residues were rapidly eliminated in clean water. Metabolites of fenoxycarb, like parent, were found mostly in non-edible tissues (Table A7_4_3_3_1-3), and were rapidly depurated on cessation of exposure. A summary of the BCF factors is given in Table A7_4_3_3_1-4.
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. The maximal calculated steady-state bioconcentration factor (BCF) of 569 indicates a limited bioconcentration of the test substance. This is in

Section A7.4.3.3.1 Bio-accumulation in an appropriate species of fish

Annex Point IIIA XIII.2.3 *Lepomis macrochirus*

		accordance with the calculated BCF value. According to Mackay (1982) a chemical with a Log Pow of 4.07 has a predicted bioconcentration factor of 562.
5.3.1	Reliability	1
5.3.2	Deficiencies	The lipid content of the fish (as mg/kg wet weight) at the end of the experiment differed from that at the start by more than ± 25%

Section A7.4.3.3.1 Bio-accumulation in an appropriate species of fish

Annex Point IIIA XIII.2.3 *Lepomis macrochirus*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/01/10
Materials and Methods	[redacted]

Section A7.4.3.3.1 Bio-accumulation in an appropriate species of fish

Annex Point IIIA XIII.2.3 *Lepomis macrochirus*

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Section A7.4.3.3.1 Bio-accumulation in an appropriate species of fish

Annex Point IIIA XIII.2.3 *Lepomis macrochirus*

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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Findings	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_4_3_3_1-1: Level of Radioactivity in Water during Exposure and Depuration

Period	Nominal Concentration 0.015mg/L CGA 114597 (mg equiv/L)	Nominal Concentration 0.0015mg/L CGA 114597 (mg equiv/L)
-4	0.0150	0.00150
-1	0.0163	0.00153
0	0.0142	0.00139
1	0.0148	0.00144
2	0.0150	0.00150
3	0.0144	0.00136
7	0.0160	0.00159
9	0.0143	0.00143
13	0.0130	0.00136
14	0.0138	0.00134
17	0.0138	0.00145
21	0.0149	0.00150
24	0.0149	0.00149
28	0.0150	0.00137
29 (1)	0.00015	0.00000
30 (2)	0.00003	0.00000
31 (3)	0.00000	0.00000
35 (7)	0.00000	0.00000
38 (10)	0.00000	0.00000
42 (14)	0.00000	0.00000

Table A7_4_3_3_1-2: Level of radioactivity in fish tissues

Time (days)	Nominal concentration 0.015mg/L CGA 114597			Nominal concentration 0.0015mg/L CGA 114597		
	Edibles (mg/Kg)	Non Edibles (mg/Kg)	Total (mg/Kg)	Edibles (mg/Kg)	Non Edibles (mg/Kg)	Total (mg/Kg)
0	0.49	1.05	0.766	0.054	0.105	0.079
1	1.31	9.14	5.23	0.132	0.783	0.491
3	1.33	9.61	5.76	0.130	1.06	0.600
7	1.90	11.3	6.55	0.145	1.50	0.848
14	1.73	16.7	10.0	0.152	1.89	0.998
17	1.51	11.0	6.54	0.133	1.29	0.741
21	1.70	11.6	7.34	0.166	1.45	0.860
24	1.58	10.9	6.52	0.179	1.54	0.915
28	2.05	11.8	7.04	0.196	1.27	0.782
29	0.36	3.02	1.80	0.021	0.37	0.200
31	0.11	0.85	0.50	0.014	0.15	0.087
35	0.09	0.64	0.38	0.010	0.08	0.046
38	0.07	0.55	0.3	0.009	0.07	0.042
42	0.060	0.43	0.25	0.007	0.06	0.033
Average steady state (days 17-28)	1.71	11.3	6.86	0.169	1.39	0.825

Table A7_4_3_3_1-3: Level of metabolites in edible and non-edible tissues

Metabolite	Edible		Non-Edible	
	%	ppb	%	ppb
B3 (2U)	4.0	80	26.8	3324
B5	0.8	16	2.7	340
B6 (F-9)	0.6	13	1.5	191
B7 (CGA 294848)	0.2	3	0.8	94
B8	0.6	11	1.3	159
B9 (U-14)	8.2	163	21.2	2634
B11 (CGA 294850)	4.7	94	10.5	1304
B12 (CGA 114597) (fenoxycarb)	68.6	1359	17.9	2227

Table A7_4_3_3_1-4: Bioaccumulation factors: Steady state from day 17 to day 28

Average concentration in water	**0.00145mg/L**			**0.0147mg/L**		
Location	Edibles	Non Edibles	Total	Edibles	Non Edibles	Total
Measured (C_{tissue}/C_{water})	117	959	569	116	769	467

Section 7.4.3.3.2 Annex Point IIIA XIII.2.3	Bio-accumulation in an appropriate invertebrate species	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ].**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	–	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/01/16	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species (1)

Official use only

1 REFERENCE

1.1	**Reference**	Forbis, A.D. (1987): Chronic Toxicity of ^{14}C-Fenoxycarb to *Daphnia magna* under flow-through test conditions. ABC Analytical Bio-Chemistry Lab. Inc., Columbia, United States, unpublished report No. 35568 (Syngenta No. CGA114597/0019). Experimental period: April 13th 1987 to May 4th 1987.
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. Federal Register (1978). Guidelines for deriving water quality criteria for the protection of aquatic life. Federal Register 43 (12506 & 29028). American Society for Testing and Materials (1979). Standard practice for conducting toxicity tests on the early life stages of fishes. ASTM Committee, E-47.01. Draft No 3, March 1981, 4 p. and ASTM Committee, E-35.21. Draft No 2, September 1979 American Society for Testing and Materials (1981). Proposed standard practice for conducting *Daphnia magna* chronic toxicity tests in a flow-through system. ASTM Committee, E-47.01. Draft No 3, March 1981, 4 p. Committee on Methods for Toxicity Tests with Aquatic Organisms (C.E. Stephen, Chairman). (1975). Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians, Environmental Protection Agency, Ecological Research Series EPA-660/3-75-009, April 1975, 61p U.S. Congress (1976) Toxic Substances Control Act. Public Law 94-469. Federal Register, 11th October 1976, 2003-2051. U.S. Environmental Protection Agency (1978). Hazardous waste: Proposed guidelines and regulations and proposal on identification and listing. Federal Register, 18th October, 1978, 58992-29028. OECD Guideline No.: 202, Paris 1984
2.2	**GLP**	Yes
2.3	**Deviations**	None

3 METHOD

3.1	**Test material**	Fenoxycarb technical
3.1.1	Lot/Batch number	[redacted]

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species (1)

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	-
3.1.6	Method of analysis	LSC
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Solvent used not specified
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_3_4-1
3.4.2	Test organisms	*Daphnia magna* See table A7_4_3_4-2
3.4.3	Handling of offspring	See table A7_4_3_4-2
3.4.4	Test system	Daphnids were exposed in a 21-day life cycle study to a geometric series of five concentrations of ^{14}C-fenoxycarb under flow-through test conditions using a proportional diluter system. Seven sets of four replicate one-litre test chambers, designated as control, solvent control and five test concentrations were employed in the study. The test was initiated with 10 first-instar daphnids placed in each of the test chambers. Nominal test concentrations for ^{14}C-fenoxycarb were: 0.0010, 0.0017, 0.0035, 0.006 and 0.014 µg ai/L. The mean measured concentration levels, as determined by liquid scintillation counting, ranged from 113 to 160% of nominal values. See table A7_4_3_4-3
3.4.5	Test conditions	See table A7_4_3_4-4
3.4.6	Duration of the test	21 days
3.4.7	Test parameter	Biological observations on adult survival, immobilisation and changes in behaviour or appearance were recorded daily. With the onset of brood production, young survival and immobilisation were recorded three times per week.
3.4.8	Examination / Sampling	See above (3.4.7)
3.4.9	Monitoring of TS concentration	Yes
3.4.10	Statistics	4 replicates were available per concentration. The results were based on

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species (1)

		the mean measured concentrations of ^{14}C-fenoxycarb derived from all sample days.	
		4 RESULTS	
4.1	**Range finding test**	Not performed	
4.1.1	Concentrations	-	
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: 0.0010, 0.0017, 0.0035, 0.006 and 0.014 µg ai/L	
4.2.2	Actual concentrations of test substance	Mean measured concentrations for ^{14}C-fenoxycarb were 0.0016, 0.0023, 0.0045, 0.0068, 0.017 µg ai/L. The results were based on the mean measured concentrations of ^{14}C-fenoxycarb derived from all sample days.	
4.2.3	Effect data	All results for alls biological endpoints are summarised in Table A7_4_3_4-5. Survival of *Daphnia magna* exposed to ^{14}C-fenoxycarb for 21 days was not significantly affected up to a concentration of 0.017 µg ai/L. The growth length of daphnids was significantly reduced at treatment levels of 0.0023 µg ai/L and higher. A reduced reproduction rate, as measured by the number of young per female was observed at concentrations of 0.0023 µg ai/L and higher. Adults with ephippial eggs were found in the 0.0068 and the 0.017 µg ai/L treatment levels. The 21-day LOEC was determined to be 0.0023 µg ai/L	
4.2.4	Concentration / response curve	-	
4.2.5	Other effects	No	
4.3	**Results of controls**	There was no mortality in the control and the solvent control higher than 20 %.	x
4.4	**Test with reference substance**		
4.4.1	Concentrations	Not performed	
4.4.2	Results	Not performed	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The effects of fenoxycarb technical on reproduction capacity of Daphnia magna were investigated according to several current standard methods. Biological observations on adult survival, immobilisation and changes	

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species (1)

		in behaviour or appearance and with the onset of brood production, young survival and immobilisation were investigated in a flow-through test which prolonged to 21 days. Test organisms were exposed to aqueous test medium containing the test substance at various concentrations.
5.2	Results and discussion	The NOEC for *Daphnia magna* following long-term exposure to fenoxycarb was determined to be 0.0016 µg fenoxycarb/L and the LOEC was determined to be 0.0023 µg fenoxycarb/L, based on measured results.
5.2.1	NOEC (21 d)	0.0016 µg/L
5.2.2	LOEC (21 d)	0.0023 µg/L
5.2.3	EC_{50} (EC_x)	Not determined
5.3	**Conclusion**	The 21-day NOEC (based on reproduction) of fenoxycarb with Daphnia magna was determined to be 0.0016 µg ai/L The validity criteria can be considered as fulfilled. The validity criteria are summarised in table A7_4_3_2-6.
5.3.1	Reliability	1
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	21/02/2008
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
Date	**COMMENTS FROM ...** *(specify)*
Materials and Methods	*Give date of comments submitted*
Results and discussion	*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*
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_3_4-1: Dilution Water

Criteria	Details
Source	not specified
Salinity	-
Hardness	225 – 275 mg/l $CaCO_3$
pH	7.8 - 8.3
Ca / Mg ratio	not reported
Na / K ratio	not reported
Oxygen content	6.8 - 8.2 mg/l
Conductance	540 – 630 µmhos/cm
TOC	1.6 mg/l
Holding water different from dilution water	No

Table A7_4_3_4-2: Test Organisms

Criteria	Details
Strain / Clone	*Daphnia magna*
Source	In-house culture which has been maintained by ABC since 1977.
Age	first instar, less than 24 hours old
Breeding method	-
Kind of food	Suspension of algae, supplemented with Tetramin®, cereal leaves and yeast suspansio.
Amount of food	20 - 30 ml per test chamber
Feeding frequency	At least 3 times per day
Pre-treatment	No
Feeding of animals during test	Yes, see above

Table A7_4_3_4-3: Test System

Criteria	Details
Test type	Flow-through system
Renewal of test solution	Continuously renewed
Volume of test vessels	one-litre test chambers
Volume/animal	10 mL
Number of animals/vessel	10 /vessel
Number of vessels/concentration	4 replicates/ concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_3_4-4: Test Conditions

Criteria	Details
Test temperature	20 °C
Dissolved oxygen	6.8 – 8.2 mg/L
pH	8.2 – 8.4
Adjustment of pH	No
Aeration of dilution water	Not stated
Quality/Intensity of irradiation	50 - 70 footcandles
Photoperiod	16 hours day light period with 30 min dusk/dawn

Table A7_4_3_4-5: Chronic toxicity of fenoxycarb to *Daphnia magna*

Concentration [µg ai/L]		Percent Survival of daphnids	Mean Young/ female/ day	Mean Adult Length
Nominal	Mean Measured	21 d [%]	[number]	21 d [mm]
Control	-	98	6.1	4.0
Sol. control	-	98	6.2	4.0
0.0010	0.0016	100	6.2	3.9
0.0017	0.0023	100	4.5	3.8
0.0035	0.0045	100	2.6	3.7
0.0060	0.0068	100	1.8	3.5
0.0140	0.0170	95[a]	0.90	3.4

[a]One adult out of twenty was killed in transfer on day 15 and was included in total compound related mortality

Table A7_4_3_4-6: Validity criteria for invertebrate reproduction test according to OECD Guideline 211

	Fulfilled	Not fulfilled
Mortality of parent animals < 20% at test termination	X	
The dissolved oxygen concentration must have been ≥ 60 % of the air saturation value	X	

Criteria for poorly soluble test substances	X	

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species (2)

Official use only

1 REFERENCE

1.1	**Reference**	Ward, T.J., Magazu, J.P. and Boeri, R.L. (1995): Chronic toxicity of fenoxycarb to the daphnid, *Daphnia magna* exposed to environmentally realistic concentrations. T.R. Wilbury Laboratories, INC., 40 Doake Lane, Marblehead, Massachusetts, 01945, USA. Unpublished report No. 193-CG (Syngenta No. CGA114597/0514). Experimental period: July 21st 1994 to August 11th 1994.
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, Based where possible on U.S. EPA (1985). Hazard Evaluation Division. Standard evaluation procedure - *Daphnia magna*. Life-cycle (21-day renewal) Chronic toxicity test. Hazard Evaluation Division. Office of Pesticide Programs, Washington, D.C.
2.2	**GLP**	Yes
2.3	**Deviations**	None

3 METHOD

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	-
3.1.6	Method of analysis	HPLC-UV
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Solvent used was acetone 0.1 ml/L
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section 7.4.3.4 Annex Point IIIA XIII 2.4 Effects on reproduction and growth rate with an invertebrate species (2)

3.4	**Testing procedure**	
3.4.1	Dilution water	See table A7_4_3_4-1
3.4.2	Test organisms	*Daphnia magna*, see table A7_4_3_4-2
3.4.3	Handling of offspring	See table A7_4_3_4-2
3.4.4	Test system	*Daphnia magna* less than 24 hours old, 4-6 days old, 8 days old and reproductive adults 11 days old from in-house cultures (original cultures obtained from Aquatic Research Organisms, Hampton, New Hampshire, USA). The study was designed to examine the effects of fenoxycarb on *Daphnia magna* growth and reproduction under realistic conditions. In addition Daphnids of four age groups were tested. The test was conducted with five concentrations of fenoxycarb, with initial nominal concentrations of 0.2, 0.8, 3.2, 13 and 50 µg ai/L. A solvent control (0.1 mL/L acetone, equivalent to the highest amount of solvent in the highest concentration) and a dilution water control were also included. Throughout the test period the concentrations of fenoxycarb were manipulated (pulse dose) in each exposure vessel in a manner designed to mimic the reduction that occurs following field application of fenoxycarb to natural waters, where the half-life is approximately 10 hours. The test item was supplied to the test vessels under flow-through conditions. By an intermittent flow proportional diluter (constructed by the testing facility). The design of the diluter ensured that the test media only contacted glass stainless steel or Teflon® surfaces (no silicone adhesive or nitex was present). The diluter was calibrated before and after the test. The diluter resulted in an average of 3.3 volume exchanges per 24 hours in each test vessel. The proportional diluter was modified in order that the 5 concentrations of fenoxycarb in the test media were gradually reduced to approximately 50% of the initial concentration during the first 10 hours and further reduced by approximately 50% during each successive 10-hour period throughout the 21-day test period. During each of the 3-4 diluter cycles per hour additional solvent was injected into the initial stock solution vessel by the diluter such that during the next diluter cycle a slightly more dilute stock solution was used to formulate test media. Two replicate vessels were used per treatment group, each of which initially contained 10 daphnids in each of four 300 mL glass beakers (each containing 250 mL media) with stainless steel screened overflows into a 2 L glass culture dish that contained approximately 1L of media. Each of the beakers in a replicate received 10 daphnids (20 daphnids of each age per concentration) and the daphnids in each beaker were a different age (< 24 hours old, 4-6 days old, 8 days old or reproductive adults 11 days). The treatments were arranged randomly in a water bath (20 ± 1°C) during the test and maintained under a 16 h light and 8 h dark photoperiod. The daphnids were fed a yeast/trout chow suspension twice per day and the freshwater alga *Selenastrum capricornutum* at least once per day. See table A7_4_3_4-3
3.4.5	Test conditions	See table A7_4_3_4-4
3.4.6	Duration of the test	21 days

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3.4.7	Test parameter	The number of surviving first generation daphnids on day 21, the number of young per female, dry weight of surviving first and second generation daphnids, time to first brood of second generation daphnids and the occurrence of any sublethal effects such as immobilization, loss of equilibrium, erratic swimming, discolouration or behaviour changes were determined daily during the test.
3.4.8	Examination / Sampling	Following the onset of brood production, the number of offspring produced was recorded each day prior to their removal. At the end of the test the dry weights of the surviving first generation adults were determined. In addition, the time to the appearance of the first offspring by each batch of second-generation daphnids was determined. This was determined for three batches of 10 second-generation daphnids collected from each exposure concentration (i.e. 5 test item concentrations, control and solvent control for each of the four ages of daphnids tested). After 10 to 12 days each such batch of daphnids were dried and their weights determined.
3.4.9	Monitoring of TS concentration	Analytical determination of fenoxycarb concentrations was performed on samples collected from non-control test vessels after approximately 0, 4, 8, 12, 24, 30, 48, 72, 96, 120 and 144 hours and after 7, 14 and 21 days. Samples were collected from the control and solvent control vessels on days 0, 7, 14 and 21 days.
3.4.10	Statistics	Results of the toxicity test were interpreted by standard statistical techniques using TOXSTAT 3.3. Dichotomus data were transformed (arc sine square root) prior to analysis. Control and solvent control data were compared (t-test, $\alpha = 0.054$) and in all cases, these data sets pooled were pooled because no significant differences were detected. A chi-square test was used to determine if data were normally distributed, and Bartlett's test was used to determine if variances were homogenous. If the assumption of homogeneity of variance was met and variances were homogenous, a parametric one-way analysis of variance (ANOVA) follwed by Bonferroni's test was used to compare treatment and control means. If the assumption of homogeneity of variance was not met or variances were heteroscedastic, control and treatment data were compared using a Kruskal-Wallis test.
		4 RESULTS
4.1	**Range finding test**	Not performed
4.1.1	Concentrations	-
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: 0.2, 0.8, 3.2, 13 and 50 µg ai/L
4.2.2	Actual	Measured concentrations were in agreement with calculated nominal

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Effects on reproduction and growth rate with an invertebrate species (2)

	concentrations of test substance	values throughout the test. The measured concentrations of fenoxycarb fell to below the analytical detection limit of 0.001 µg/L within 5-7 days at all test levels.	
4.2.3	Effect data	All results for alls biological endpoints are summarised in Table A7_4_3_4-5.	
		Acceptable survival and reproduction for all four age groups of daphnids tested were recorded in the control and solvent control treatments. After 21 days 100% survival was recorded in the control and solvent control groups with those daphnids < 24 hours old at test start. Survival of the older daphnids in the control and solvent control groups was 80-95% over the same test period. Brood development by those daphnids < 24 hours old at test start was first observed on day 10 in the control and solvent control groups. Production of young by those daphnids 4 days old at the test start was first observed on days 4 or 5 in these same control groups. Those daphnids that were 8 or 11 days old at the test start first produced young on day 1. An average of 40-50 young were produced during the 21-day exposure period by daphnids of each age group in the control and solvent control groups. At the end of the test the control and solvent control daphnids had an average dry weight of 0.40-0.51 mg, regardless of age.	X
		The 21-day survival of daphnids of any age group was not significantly reduced by any of the concentrations of fenoxycarb tested and no sublethal effects were noted during the test. Nor were there significant reductions in the dry weight of surviving first or second generation at any concentration of fenoxycarb tested. A significant difference was detected in the mean weight of one batch of first generation daphnids. However, as there were no differences detected between the controls and the 4 higher fenoxycarb concentrations this result was discounted. A significant reduction in the number of young produced per daphnid was only observed in those daphnids < 24 hours old at test start and exposed to the highest concentration of fenoxycarb. No other reductions in brood production were noted in any other age of daphnid or with any other concentration of fenoxycarb. The time to first brood by the second-generation daphnids appeared to have been slightly extended among the offspring of daphnids that were 8 or 11 days old at the start of the test. These apparent increases in the time to first brood were not statistically significant. No other effects were observed.	
4.2.4	Concentration / response curve	Not given in the report, instead the effect concentrations are represented in a bar graph.	
4.2.5	Other effects	No	
4.3	**Results of controls**	There was no mortality in the control and the solvent control higher than 20 %.	
4.4	**Test with reference substance**		
4.4.1	Concentrations	Not performed	
4.4.2	Results	Not performed	

5 APPLICANT'S SUMMARY AND CONCLUSION

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species (2)

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5.1	**Materials and methods**	The effects of fenoxycarb technical on reproduction capacity of *Daphnia magna* was investigated according to the Standard evaluation procedure - Daphnia magna. Life-cycle (21-day renewal) by the Hazard Evaluation Division of the U.S. EPA (1985). The number of surviving first generation daphnids and the occurrence of any sublethal effects such as immobilization, loss of equilibrium, erratic swimming, discolouration or behaviour changes were investigated in a flow-through test which prolonged to 21 days. Test organisms were exposed to aqueous test medium containing the test substance at various concentrations.
5.2	Results and discussion	The NOEC for *Daphnia magna* following long-term exposure to fenoxycarb was determined to be 13 µg fenoxycarb/L and the LOEC was determined to be 50 µg fenoxycarb/L, based on results of the study in which daphnids were exposed to environmentally realistic concentrations.
5.2.1	NOEC (21 d)	13 µg/L
5.2.2	LOEC (21 d)	50 µg/L
5.2.3	EC_{50} (EC_x)	Not determined
5.3	**Conclusion**	Based on the findings stated above the overall NOEC after 21 days was determined as 13 µg/L and the overall LOEC (21 days) was 50 µg/L. The validity criteria can be considered as fulfilled. The validity criteria are summarised in table A7_4_3_2-6.
5.3.1	Reliability	1
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	21/02/2008
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	**COMMENTS FROM ...** *(specify)*
Materials and Methods	*Give date of comments submitted*
Results and discussion	*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*
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_3_4-1: Dilution Water

Criteria	Details
Source	Carbon-filtered, dechlorinated tap water collected at Marblehead, Massachusetts. It was adjusted to a hardness of 160-180 mg/L as $CaCO_3$ and stored in a polyethylene tank where it was aerated (water used for the toxicity test was also passed through a particle filter).
Hardness	160 – 168 mg/l as $CaCO_3$
Alkalinity	104 – 115 mg/l as $CaCO_3$
pH	8.2
Ca / Mg ratio	not specified
Na / K ratio	not specified
Oxygen content	6.8 - 8.5 mg/l
Conductance	540 – 630 µmhos/cm
TOC	≥ 1 mg/L
Holding water different from dilution water	No

Table A7_4_3_4-2: Test Organisms

Criteria	Details
Strain / Clone	*Daphnia magna*
Source	Original cultures obtained from Aquatic Research Organisms, Hampton, New Hampshire, USA
Age	Daphnids of four age groups were tested (less than 24 hours old, 4-6 days old, 8 days old and reproductive adults 11 days old)
Breeding method	In-house culture was established 15 to 26 days before removal of the offspring. Adult daphnids were transferred to fresh media every 1-4 days and they were transferred less than 24 hours prior to the removal of the offspring used for the test.
Kind of food	*Selenastrum capricornutum* and a mixture of yeast and trout chow
Amount of food	Not specified
Feeding frequency	Daily before the start of the test
Pre-treatment	No
Feeding of animals during test	Yes, yeast/trout chow suspension twice each day and the freshwater alga at least once per day

Table A7_4_3_4-3: Test System

Criteria	Details
Test type	Flow-through system
Renewal of test solution	Continuously renewed
Volume of test vessels	300 mL glass beakers
Volume/animal	250 mL
Number of animals/vessel	10 /vessel
Number of vessels/concentration	2 replicates/ concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_3_4-4: Test Conditions

Criteria	Details
Test temperature	29.2 – 20.9 °C
Dissolved oxygen	6.8 – 8.5 mg/L
pH	8.1 – 8.7
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	30 footcandles provided by a cool-white fluorescent light
Photoperiod	16 hour light and 8 hour dark photoperiod

Table A7_4_3_4-5: Summary of survival, reproduction, sublethal effects, length and weight data from the chronic toxicity test with *Daphnia magna*

Biological end point	Age of 1st generation at test start	Initial nominal concentration of fenoxycarb (µg/L)						
		control	s.control	0.20	0.80	3.2	13	50
% survival of 1st generation at day 21	< 24 hours	100	100	100	85	95	75	85
	4-6 days	85	90	85	90	100	75	85
	8 days	85	80	80	80	95	70	90
	11 days	95	90	75	90	90	85	90
First day of Offspring by 1st generation	< 24 hours	10.0	10.0	11.0	9.5	10.0	9.5	10.0
	4-6 days	5.0	4.5	5.0	4.5	5.5	7.0	5.5
	8 days	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	11 days	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Sublethal Effects of 1st generation	< 24 hours	None	None	None	None	None	None	None
	4-6 days	None	None	None	None	None	None	None
	8 days	None	None	None	None	None	None	None
	11 days	None	None	None	None	None	None	None
Mean young/ 1st generation daphnid	< 24 hours	50.0	39.5	41.7	40.8	34.7	34.2	21.8*
	4-6 days	50.2	39.5	53.0	34.6	38.4	40.4	36.1
	8 days	47.1	45.0	51.0	49.8	37.2	47.1	41.1
	11 days	45.0	45.5	41.5	44.2	35.6	44.3	42.0
Mean dry weight of 1st generation [mg]	< 24 hours	0.416	0.402	0.396	0.470	0.415	0.469	0.461
	4-6 days	0.422	0.424	0.434	0.449	0.449	0.514	0.467
	8 days	0.505	0.445	0.389*	0.513	0.463	0.527	0.474
	11 days	0.455	0.418	0.384	0.487	0.481	0.491	0.423
Mean dry weight of 2nd generation [mg]	< 24 hours	0.150	0.152	0.130	0.151	0.137	0.140	0.143
	4-6 days	0.175	0.162	0.163	0.164	0.168	0.183	0.165
	8 days	0.182	0.198	0.177	0.189	0.188	0.160	0.157
	11 days	0.196	0.177	0.178	0.142	0.169	0.154	0.152
First day of Offspring by 2nd generation	< 24 hours	8.0	7.7	8.0	8.0	7.7	8.3	8.3
	4-6 days	8.0	8.0	8.0	8.0	8.0	8.0	8.0
	8 days	8.0	8.0	8.0	8.0	8.0	8.7	>10.0
	11 days	8.0	8.0	8.0	8.0	8.0	9.0	9.7

s. control – solvent control * - statistically different than the control ($\alpha = 0.05$)

Table A7_4_3_4-6: Validity criteria for invertebrate reproduction test according to OECD Guideline 211

	Fulfilled	Not fulfilled
Mortality of parent animals < 20% at test termination	X	
Mean number of live offspring produced per parent animal surviving at test termination ≥ 60	X	

Criteria for poorly soluble test substances	X	-

Section A7.4.3.5.1 Effects on sediment dwelling organisms

Annex Point IIIA, XIII.3.4 *Chironomus riparius*

Official use only

		1 REFERENCE
1.1	**Reference**	Pfeifle, V. (2002a): Toxicity Test of CGA 114597 tech. On Sediment-Dwelling *Chironomus riparius* (syn. *Chironomus thummi*) under Static Conditions. Solvias AG, GLP Test Facility Solvias, CH-4002 Basel, Switzerland. Unpublished report number: 2012538 (Syngenta No CGA114597/0804). Experimental period: 23rd October 2001 to 27th February 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 guideline 219 (2001) U.S. EPA OPPTS Number 850.1790
2.2	**GLP**	Yes
2.3	**Deviations**	Water at test start was briefly below 20 ± 2°C
		3 MATERIALS AND METHODS
3.1	**Test material**	CGA 114597 (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	-
3.1.6	Method of analysis	HPLC
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	DMF was used to make up the test treatment spikes
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section A7.4.3.5.1 Effects on sediment dwelling organisms

Annex Point IIIA, XIII.3.4 *Chironomus riparius*

3.4	**Testing procedure**		
3.4.1	Dilution water, Test sediment	M4-medium, (see also table A7_4_1_2-1). The test sediment used was artificial sediment. Details on test sediment see table A7_4_1_2-1a.	
3.4.2	Test organisms	*Chironomus riparius*, see table A7_4_1_2-2	
3.4.3	Test system	The test chamber was composed of a 1L glass beaker measuring 9cm in diameter. 130g moist weight of sediment (1-2cm deep) was placed in the bottom of the beaker and covered with 540g of reconstituted water (M4-medium) to a depth of approximately 8cm. The beakers were covered with Parafilm through which small holes had been punched. The test beakers were established 7 days before the addition of the test treatments and were gently aerated via a glass Pasteur pipette situated 2 to 3 cm above the sediment. 20 first instar larvae (2-3 days old) of *Chironomus riparius* were added to each of four replicate beakers per treatment. Aeration was stopped for 24 hours. Application of the test item treatments was carried out one day after the addition of the larvae and aeration was restarted. The water columns were spiked with 0.188, 0.375, 0.75, 1.5 and 3.0µg CGA 114597/L. A blank control and a vehicle control (containing the DMF used to make up the test treatment spikes) were also established. see table A7_4_1_2-3	
3.4.4	Test conditions	see table A7_4_1_2-4	
3.4.5	Duration of the test	25 days	
3.4.6	Test parameter	Sex and number of midges, survival (criteria for death, was immobility and or lack of reaction to a mechanical stimulus), and visual assessment of behaviour	
3.4.7	Sampling	During the period of emergence (day 11 till day 22, day 25) a daily check of emerged midges was carried out. The sex and number of midges was recorded before the adults were removed. Visual assessments of any behavioural differences compared to the control were made on test days 6, 7, 11, 12, 14, 15, 16, 17, 18, 20 and 21. For an estimation of larval survival and growth at day 11 additional vessels were set up at the start.	
3.4.8	Monitoring of TS concentration	Water samples were removed from 2 beakers for each treatment on days 0, 2, 7, 14 and at the end of the exposure and analysed for concentration of CGA 114597. At the beginning of exposure, after 7 days and at the end of the exposure phase the concentration of CGA 114597 in the sediment was measured in the control and the highest and lowest test concentrations.	X
3.4.9	Statistics	Regression analysis and Dunnett-test	
		4 RESULTS	
4.1	**Limit Test**	Not performed	
4.1.1	Concentration	-	
4.1.2	Number/ percentage of	-	

Section A7.4.3.5.1 Effects on sediment dwelling organisms

Annex Point IIIA, XIII.3.4 *Chironomus riparius*

	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: 0.188, 0.375, 0.75, 1.5 and 3.0µg CGA 114597/L plus a control	
4.2.2	Actual concentrations of test substance	Measured concentrations of fenoxycarb in the water column were close to nominal concentrations at test start, in the range 99-118%. After 2 days the concentration of CGA 114597 had dropped below the limit of detection (< 0.2µg/L) except at the highest test concentration 3.0 µg CGA 114597/L. After 7 days the measured concentration in all the test treatments was below the limit of detection. Similarly the measured concentration of CGA11459 in the sediment and interstitial water was below the detection limit for all rates and sampling times.	X
4.2.3	Effect data	see table A7_4_1_2-5 and A7_4_1_2-6.	X
4.2.4	Concentration / response curve	Given in the report	
4.2.5	Other effects	There was no indication that there is a concentration dependent decrease of average weight of larvae at the tested treatment level. No changes in behaviour were observed in any of the test treatments throughout the study.	
4.3	**Results of controls**	Mean development rate per day: 0.074	
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**	The toxicity of fenoxycarb to the sediment dwelling life stage of *Chironomus riparius* was therefore investigated in a 25-day static sediment-water study according to OECD guideline 209. 20 first instar Chironomid larvae per test chamber were exposed to 5 test concentrations of 0.188, 0.375, 0.75, 1.5 and 3.0µg CGA 114597/L in overlying water plus a control with 4 replicates/test concentration.	X
5.2	**Results and discussion**	**Emergence of midges and symptoms of toxicity:** There were no indications on different sensitivities of sexes at treatments of 0.188, 0.375 and 0.75µg/L (the number of emerged midges at 1.5 and 3.0µg/L were to low and therefore excluded from the statistical analysis). For the calculation of ECx-values for emergence, data was corrected for mortality before regression analysis was carried out.	
		The EC_{50} based on emergence was determined to be 1.07µg/L	X

Section A7.4.3.5.1 Effects on sediment dwelling organisms

Annex Point IIIA, XIII.3.4 *Chironomus riparius*

		Emergence ratio: The highest concentration of CGA 114597 tech. without significant effect on emergence ratio of midges was determined to be 0.75µg/L (NOEC-emergence ratio) the LOEC (emergence ratio) was determined to be a test concentration of 1.5µg/L CGA 114597 tech.
5.3	**Conclusion**	The average recovery of the initially measured test item concentration was below the limit of detection (< 0.2 µg/l). Therefore the results were calculated on the basis of nominal concentrations. The overall calculated NOEC of CGA 114597 tech. (spiked water phase) with *Chiromomus riparius* was determined to be **0.75 µg/l.** For the parameter development rate, the following results were given: **NOEC-development rate: 1.5µg/L** **LOEC-development rate 3.0µg/L** **EC_{10} (development rate): 0.66µg/L** **EC_{20} (development rate): 1.07µg/L** **EC_{50} (development rate): 2.69µg/L** The test showed no significant deviations from the guideline.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.4.3.5.1 Effects on sediment dwelling organisms

Annex Point IIIA, XIII.3.4 *Chironomus riparius*

	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	[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_2-1: Dilution water

Criteria	Details
Source	Reconstituted bi-distilled water, M4-medium
Alkalinity	Not specified
Hardness	249 mg $CaCO_3$/L
pH	7.8 - 8.4
Ca / Mg ratio	Not specified
Na / K ratio	Not specified
Oxygen content	60.2 - 94 %
Conductance	Not specified
Holding water different from dilution water	No

Table A7_4_1_2-1a: Test sediment

Sediment characterisation	Details
Particle size distribution (USDA-Norm)	Peat 5.5 % Industrial Sand: 74.5 % Kaolinite clay: 20 % Sediment layer: approx. 2 cm thick
Organic carbon (%)	2.2 %
Water content (%)	540 g water /130 g sediment
pH	7.4 (1.3 % calcium carbonate used for adjustment)
TOC (Total organic carbon)	-

Table A7_4_1_2-2: Test organisms

Criteria	Details
Strain	*Chironomus riparius*, first larval stage
Source	Syngenta Crop Protection AG
Age (at start of the study)	1st instars, 2-3 days old
Breeding method	-
Kind of food	Commercially available fish food (Tetramin®)
Amount of food	1 mg food/day/larvae
Feeding frequency	At least every third day
Pretreatment	one day prior to the treatment they were placed in the test sediment and aeration was stopped
Feeding of animals during test	Yes, see above

Table A7_4_1_2-3: Test system

Criteria	Details
Static test	130 g moist weight of sediment (1-2 cm deep) was placed in the bottom of the beaker and covered with 540 g of reconstituted water (M4-medium) to a depth of approximately 8cm. The beakers were covered with Parafilm through which small holes had been punched
Volume of test vessels	1L glass beaker measuring 9cm in diameter
Volume water/animal	540 g test water + 130 g sediment / 20 animals
Number of animals/vessel	20
Number of vessels/ concentration	4 replicates per test concentration
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_2-4: Test conditions

Criteria	Details
Test temperature	17.8-21.2 °C
Dissolved oxygen	60.2-94 %
pH	7.8 - 8.4 (pH of overlying water)
Adjustment of pH	No
Aeration of dilution water	Yes, gently aerated via a glass Pasteur pipette situated 2 to 3 cm above the sediment during acclimation and exposure (except 24 h after addition of larvae).
Quality/Intensity of irradiation	760 Lux
Photoperiod	16:8 light-dark-cycle

Table A7_4_1_2-5: Summary of development rates

Concentration (µg/L)	Mean development rate per day	Development rate/day compared to control [%]	Inhibition compared to control [%]
Control	0.0704	100	0.00
Vehicle	0.0696	98.94	1.06
0.188	0.0683	97.07	2.93
0.375	0.0669	95.04	4.96
0.75	0.0684	97.20	2.80
1.5	0.0485	68.97	31.03
3.0	0.0295*	41.99	58.01

* Statistically different from the control (Dunnett-test)

Table A7_4_1_2-6: NOEC, LOEC and EC_x values for *Chironomus riparius* exposed to fenoxycarb based on the initially measured concentration in overlying water (92.5 % of the nominal concentration).

	Endpoints			
	NOEC [µg a.i./L]	LOEC [µg a.i./L]	EC_{10} [µg a.i./L]	EC_{50} [µg a.i./L]
Emergence ratio (ER)	0.75	1.5	n.d.	1.07
Development rate (DR)	1.5	3.0	0.66	2.69

n.d. = not determined

Table A7_4_3_4-7: Validity criteria for sediment-water chironomid toxicity test using spiked water according to OECD Guideline 219

	Fulfilled	Not fulfilled
Mean emergence in the control ≥ 70%	X	
Emergence of adults in the control between day 12 and 23 after start of exposure	X	
Dissolved oxygen concentration in at least one replicate per concentration and control ≥ 60 % of the air saturation value	X	
pH of the overlying water at the end of the test between 6 - 9	X	
Water temperature difference between vessels not more than ± 1°C	X	

Section 7.4.3.5.2 Annex Point IIIA 13.2	Aquatic plant toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X].**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	–	
	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	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.3 Effects on aquatic organisms, further studies

Annex Point IIIA XIII.2 Microcosm study

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1 REFERENCE

1.1	**Reference**	[redacted] (1995): Assessment of the Potential Biological Effects of Fenoxycarb Exposures on Aquatic Ecosystems as Measured in an Outdoor Microcosm Tank System (microcosms). [redacted] Unpublished report Number. CMP3 (Syngenta No. CGA11457/0555). Experimental period: May 1993 to September 1993.
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**	Not cited
2.2	**GLP**	Yes (certified laboratory), with the exception of screening tests for organochloride pesticides and PCB's in sediment and water samples, sediment characterisations and zooplankton identifications.
2.3	**Deviations**	None

3 MATERIALS AND METHODS

3.1	**Test material**	Fenoxycarb
3.1.1	Lot/Batch number	Not specified
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	-
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	**Treatment Rates and Application Details:** There were a total of eight treatments with three replicate tanks per treatment. Fenoxycarb was applied to the microcosms as a dissolved phase in the form of an acetone/water solution (simulating drift) and as an absorbed phase (125.5 g of sediment per tank) in the form of slurry (simulating run-off). To ensure even distribution throughout the water column all applications were made evenly to the water surface and the water was stirred immediately following addition of the adsorbed phase (applied after the dissolved phase). One replicate was a control (D0), which received an application of acetone/water solutions and soil slurries. The remaining seven replicates (D1 – D7) were dosed at 0.014, 0.041, 0.123, 0.37, 1.11, 3.33, 10.0 µg/L per application. The three lower doses received single applications; the higher doses (D4 to D7) received a second application after four weeks. The first application to the tanks

		was made on 17 May 1993. The dosing was at concentrations that approximate and bracket expected environmental fenoxycarb exposures. Eighty percent of the total fenoxycarb applied represented exposure by spray drift and/or dissolved phase run-off and the remaining twenty percent represented the soil load and adsorbed fenoxycarb from a run-off event. Exposure concentrations for the study were estimated by using US environmental fate and transport models. See Table A7_4_3-1 and Table A7_4_3-2
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Test organisms	Water from the supply pond acted as the source matrix of algae, zooplankton and other invertebrate organisms. Macroinvertebrates also possibly entered the ponds via aerial colonisation and egg deposition from adult insects native to the study site. Submergent vascular plants were transplanted to the tanks from on-site ponds at least five months before the first treatment. Caged crayfish were introduced to the tanks and effects on their growth were monitored. Forty juvenile bluegill *Lepomis macrochirus* (mean weight 0.34 g/fish, approximately 2-5 cm total length) were stocked in each tank approximately three weeks before the first application of fenoxycarb at a stocking density of approximately 1.4 g/m^3.
3.4.2	Test system	**Description of Field Microcosm Installation:** The outdoor microcosm was located at [redacted]. Individual microcosm pond tanks [fabricated fiberglass, 3.0 m internal diameter, height 1.7 m; lined with clay overlain with 0.15 m of top soil (to provide a habitat for benthic organisms), overlain by approximately 1.4 m of water], each of 10 m^3 volume were installed in the ground, surrounded by soil in order to minimise rapid temperature fluctuations and they were individually connected to a communal supply pond. **Preparation of Field Microcosms for Study:** Twenty four microcosms were set-up six months in advance of the application date to allow a period of acclimatisation. After all microcosms were filled, water recirculation (pumping water from the nearby supply pond) was initiated between all tanks in order to maximise the inter-tank water homogeneity. Water from the supply pond acted as the source matrix of algae, zooplankton and other invertebrate organisms. Macroinvertebrates also possibly entered the ponds via aerial colonisation and egg deposition from adult insects native to the study site. Refuges for invertebrates, which helped, minimise predation by fish, consisted of a 12.7 mm mesh nylon cylinder (1.2 m x 0.4 m) filled with actifil surface area enhancers were placed upright in the centre of each tank prior to stocking of the fish. Before they were introduced to the tanks, these refuges were colonised by macroinvertebrates in an on-site pond for approximately four weeks. Submergent vascular plants were transplanted to the tanks from on-site ponds at least five months

		before the first treatment. Caged crayfish were introduced to the tanks and effects on their growth were monitored. Forty juvenile bluegill *Lepomis macrochirus* (mean weight 0.34 g/fish, approximately 2-5 cm total length) were stocked in each tank approximately three weeks before the first application of fenoxycarb at a stocking density of approximately 1.4 g/m^3. See Table A7_4_3-3
3.4.3	Test conditions	See Table A7_4_3-3
3.4.4	Duration of the test	114 days
3.4.5	Test parameter	Biological data evaluation comprised of developing criteria and end-point definitions. The relevant end-points to be established for the **phytoplankton, zooplankton and macroinvertebrate** communities were defined as: total abundance; abundance of major taxonomic groups; abundance of individual taxa; taxa richness - based on lowest taxonomic level identified. Data also were collected for the analysis of **crayfish growth, fish growth, macrophyte biomass, plankton biomass** (Chlorophyll a).
3.4.6	Sampling	Samples for the biological and analytical measurements were taken from –7 days to 114 days. To aid sampling each tank was divided into quadrants, and representative water samples from each quadrant sector were taken for residue chemistry and pysico-chemical and biological samples. Water Quality Measurements – Dissolved O_2, pH, conductivity, temperature and NO_3 were measured during the study. Biological Monitoring – The phytoplankton standing crop was estimated by direct enumeration and analysis of chlorophyll *a*. using spectrophotometry. Samples were collected using an integrated column sampler, sampling a column of water from the surface of to approximately 10 cm above the sediment (approximately 2.5 L/ column sample). One such sample was collected in each quadrant of the tank before mixing the four samples to form a composite sample for that tank, upon which the analysis was performed. Determination of total numbers and identification of individual taxa of phytoplankton was performed under the microscope. The extent of macrophyte coverage and growth was observed. The total biomass (g dry weight) per unit area of a randomly selected 1 m^2 area of the tank was determined. Samples (15 L/tank) for determination of the zooplankton community were collected using the integrated column sampler before being filtered through a 35 µm mesh. Collected zooplankton species were preserved in a 1 to 2% Lugol's solution prior to taxonomic identification and counting under the microscope. Macroinvertebrates may be divided into two communities, those typically living on or around aquatic plants or other submerged substrates and those living in or on the bottom sediment. In order to study both communities, two sampling techniques were employed. Artificial substrate samplers were allowed to colonise for a minimum of four weeks on the tank bottom before collection. Following careful retrieval the samples were concentrated using a sieve with ≤ 0.18 mm mesh before being preserved with Kahle's solution for subsequent identification and counting of macroinvertebrates.

		Monitoring of macroinvertebrates inhabiting the sediments in the tank was aided by the use of Ekman grab samples. Collected sediment was rinsed in a sieve less or equal to 0.18 mm mesh and retained sediment was placed in a sample bottle and preserved with formaldehyde. To help distinguish macroinvertebrates from the sediment samples they were stained with Rose Bengal, before separation under the microscope and preservation in 75% ethanol. Emerging adult insects were collected with a floating pyramid-shaped emergence trap, with a collection bottle filled with Kahle's solution fixed at the apex. Emerging insects fly upwards and are trapped in the collecting jar. One such trap was placed in a randomly selected quadrant in each tank. The collecting jars were replaced weekly with jars containing fresh Kahle's solution, whilst the traps remained continuously in the tanks. Routine identification of invertebrates collected in this study was to the family or subfamily level. Growth of caged immature crayfish (*Procambarus*) was evaluated in each tank. Three cages were placed in each treatment tank and four cages were placed in each control tank, each cage containing one crayfish. Prior to their introduction the width of the carapace and the weight of each crayfish were determined. During the study the carapace width was determined and they were studied periodically to observe whether any obvious molts had occurred. Towards the end of the study they were removed from the tanks to obtain a final carapace width and weight measurements. During the study the tanks were monitored for bluegill mortality or abnormal behaviour. At the end of the study the fish were removed and the average fish growth was determined. Any dead fish were inspected for any abnormalities, weighed, measured and frozen.
3.4.7	Monitoring of TS concentration	In order to measure the dissipation rate of fenoxycarb in the tanks at different concentrations, water and hydrosoil samples were collected at selected time points during the study. Water samples were taken for residue analysis just prior to and after each application. On study weeks 11 and 13 (the last week of sampling), samples from treated tanks were only collected from those with the highest two dose levels of fenoxycarb because analysis demonstrated that fenoxycarb had already reached non-detectable levels in the lower levels tested.
3.4.8	Statistics	Statistical evaluation was employed to analyse the dynamics of the biological communities in the treated and control systems
		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**	

Section A7.4.3 Effects on aquatic organisms, further studies

Annex Point IIIA XIII.2 Microcosm study

4.2.1	Initial concentrations of test substance	Nominal concentrations: 0.014, 0.041, 0.123, 0.37, 1.11, 3.33, 10.0 µg/L
4.2.2	Actual concentrations of test substance	Fenoxycarb reached non-detectable levels in the course of the test. Results obtained during the analysis of water and sediment samples taken throughout the study are presented in detail in Section 7.1.2.2.2. The fate of fenoxycarb applied to this system is discussed in the same section and thus will not be further deliberated herein.
4.2.3	Effect data (Immobilisation)	**Phytoplankton** There were no apparent treatment-related effects on phytoplankton populations or the concentration of phytoplankton chlorophyll *a* (a reflection of biomass). **Zooplankton** Reduced populations of the cladocerans *Diaphanosoma brachyurum* and *Bosmina longirostris* indicated possible adverse effects of fenoxycarb. Development of the populations of *D. brachyurum* was comparable in all doses except dose 7, in which a delay in population growth was apparent (comparable populations with other treatments were observed on week 11). Populations of *B. longirostris* appeared to have been reduced in weeks 3 through to 7 in the four highest doses tested. Zooplankton community similarity analysis also indicated possible effects at the highest dose of fenoxycarb tested. On weeks 7 to 13 dose 7 clustered separately from all other treatment groups. **Macroinvertebrates** There appeared to be very few negative effects of applications of fenoxycarb on the community of macroinvertebrates. However, declines in the populations of Hydroptilidae and Leptoceridae (Trichoptera) in artificial substrates may be related to treatment, particularly at the highest two dose levels tested (D6 & D7). Although it should be noted that the difference in D6 was not statistically significant. **Crayfish** No treatment related trends on crayfish mortality and no significant differences in their moulting or growth were observed. However, in the highest treatment level an apparent lower number of molts, and a small decrease in the growth as determined by carapace width and total weight in the same treatment group may indicate an effect. **Fish** No indications of effects of fenoxycarb on survival or growth of fish were noted.
4.2.4	Concentration / response curve	-
4.2.5	Other effects	Application of fenoxycarb appeared to have no effect on the physico-chemical parameters that were recorded, such as temperature, dissolved oxygen, turbidity, pH, total alkalinity and total water hardness. However, it should be noted that the actual concentration of fenoxycarb in those replicates which received 2 applications (D4-D7) may be higher than the nominal concentrations. See Table A7_4_3-2.

Section A7.4.3 Effects on aquatic organisms, further studies

Annex Point IIIA XIII.2 Microcosm study

4.3	**Results of controls**	The growth of population observed for the several communities was compared to the growth observed in the tanks where fenoxycarb had been added. Therefore, the results of the growth test in the control were considered to derive the NOEL or NOEAEC of the study.	
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**	The purpose of this study was to assess the potential biological effects of fenoxycarb administered as technical grade material (purity 97.8%) on the structure and function of aquatic ecosystems as measured in field microcosms and to follow its chemical fate. Two application scenarios of entry in water and soil-slurry were included to simulate exposure of aquatic ecosystems via spray drift and run-off. Details of the chemical fate of fenoxycarb in this system can be found under Section A7.1.2.2.2.	
5.2	**Results and discussion**	No indications of effects of fenoxycarb on survival or growth of fish were noted. Of all invertebrate species present 90% demonstrated no effects of fenoxycarb following exposure to 1.11 µg ai/L or lower. Additionally, all observed effects were short-lived and occurred on only one or two collection dates. No community level effects were apparent to indicate indirect repercussions from the observed effects on invertebrates. The biologically significant invertebrate NOEL for this study was determined to be 1.11 µg fenoxycarb/L.	X
5.2.1	NOEC or EAC	NOEL was determined to be 1.11 µg fenoxycarb/L. No Observed Ecologically Adverse Effect Concentration (NOEAEC) of 3.33 µg fenoxycarb/L.	X
5.3	**Conclusion**	In this study the biologically significant NOEL was determined to be 1.11 µg fenoxycarb/L. However, as the effects which are observed are "pronounced short-term effects" as outlined in point 5.4.3.3 of the aquatic Ecotoxicology guidance document (Sanco/3268/2001/ rev. 4 October 2002) it is more appropriate to use a No Observed Ecologically Adverse Effect Concentration (NOEAEC) of 3.33 µg fenoxycarb/L.	X
5.3.1	Reliability	1	
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	2006/07/04
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_3-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Solvent, acetone Fenoxycarb was applied as a dissolved phase in the form of an acetone/water solution (simulating drift) and as an absorbed phase (125.5 g of sediment per tank) in the form of slurry (simulating run-off).
Concentration of vehicle	Not specified
Vehicle control performed	Yes (acetone/water control)
Other procedures	Spray drift and run-off

Table A7_4_3-2: Details concerning the theoretical direct overspray rates corresponding to the test concentrations in the microcosm

Treatment group	Application Details Number of applications	Nominal concentration per application in the tanks [µg ai/L]
D0 Control	NA	-
D1	1	0.014
D2	1	0.041
D3	1	0.123
D4	2	0.370
D5	2	1.11
D6	2	3.33
D7	2	10.00

NA = Not applicable

Table A7_4_3-3: Test system

Criteria	Details
Artificial sediment test substrate	Clay for an artificial pond from the university of north Texas Water Research Field Station, Denton County, Texas USA
Water source	Communal supply pond
Size, volume and material of test container	Pond tanks were made of fabricated fiberglass, 3.0 m internal diameter, height 1.7 m; lined with clay overlain with 0.15 m of top soil (to provide a habitat for benthic organisms), overlain by approximately 1.4 m of water; each of 10 m^3 volume were installed in the ground, surrounded by soil in order to minimise rapid temperature fluctuations and they were individually connected to a communal supply pond.
Ration water/sediment	In the pond tanks of 3.0 m internal diameter there was clay overlain with 0.15 m of top soil.
Nominal levels of test concentrations	Control (applications of acetone/water solution and soil slurry), 0.014, 0.041, 0.123, 0.37, 1.11, 3.33, 10.0 µg/L The three lower doses received single applications; the higher doses (D4 to D7) received a second application after four weeks. 80 % of the total fenoxycarb applied represented exposure by spray drift and/or dissolved phase run-off and the remaining 20 % represented the soil load and adsorbed fenoxycarb from a run-off event.
Number of replicates/concentration	3
Species tested	Algae Zooplankton Macroinvertebrates Crayfish 40 juvenile/tank bluegill *Lepomis macrochirus* (mean weight 0.34 g/fish, approximately 2-5 cm total length) at a stocking density of approximately 1.4 g/m^3.
Light source	Outdoor exposure, natural light cycle
Test performed in closed vessels due to significant volatility of test substrate	No

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

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1 REFERENCE

1.1	**Reference**	Völkel, W. (2001): The Effects of FENOXYCARB TECH. on Soil Respiration and Nitrification. RCC AG, Itingen, Switzerland unpublished report No. 833130 (Syngenta file No. CGA114597/0794). Experimental period August 29th 2001 to October 10th 2001.
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 Guidelines 216 and 217 (2000) EPPO, Chapter 7, Soil microflora, volume 24, No.1 (1994)
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	-
3.1.6	Method of analysis	**Microbial respiration**: the amount of CO_2 evolved after the addition of glucose to soil was measured semi continuously over a 24-h period. Glucose was added at one of seven concentrations to the soil and a fixed mass of a glucose/talc mixture was added to each of the soils. After the addition of the glucose/talc mixes the soil aliquots were packed into glass columns and connected via a trapping system to an IR gas analyser. The concentration of CO_2/L air was used to calculate the volume of CO_2 evolved/h/kg dry soil. **Microbial Biomass determination**: For the microbial biomass determination those three glucose concentrations which provided the three highest initial and constant CO_2 production rates and were then used to calculate the microbial biomass. **Glucose induced short-term respiration**: For the short-term respiration component of the study the glucose concentration that exerted a maximum respiration response was added to the soil samples. Three aliquots of 40g wet soil were amended with 1.15g glucose/kg dry

		soil and the short-term respiration rate over a 22-h period was measured. The respiration rates between treated and control soils were compared over the first 12 hours of the study. **Nitrification of Lucerne meal:** Three replicates of wet soil were treated to extract nitrite and nitrate and the concentration of nitrate and nitrite was then determined using standard analytical techniques.
3.2	**Reference substance**	Yes, dinoseb acetate
3.2.1	Method of analysis for reference substance	Not analysed, only CO_2
3.3	**Testing procedure**	
3.3.1	Soil sample / inoculum / test organism	see table A7_5_1_1-1
3.3.2	Test system	The effect of the test substance at 0.60 and 3.0 mg/kg dry soil (equivalent to 2 and 10 times the maximum expected field dose) on microbial soil respiration and nitrification was compared to an untreated control and a toxic standard treatment (dinoseb acetate at 25 mg/kg dry soil).The sandy loam soil was collected from a field trial plot and sieved through a 2mm sieve. The technical fenoxycarb was dissolved in acetone and the fenoxycarb acetone solution was added to quartz sand and the acetone was then evaporated under a stream of nitrogen. The quartz sand amended with fenoxycarb was then used to dose the soil with the appropriate amount of fenoxycarb. The toxic standard replicates were also dissolved in acetone which was added to quartz sand and then used to dose the test soils. Those soils which were to be used to determine the effect on microbial nitrification were additionally amended with 0.7g Lucerne meal. The soil moisture was adjusted 40% of the maximum soil water holding capacity. After treatment the test soils were incubated in the dark at 20 ± 2°C for 28 days. Respiration, nitrification and ammonification was determined 0-3 hours after treatment and after 7 14 and 28 days. see table A7_5_1_1-2
3.3.3	Application of TS	see table A7_5_1_1-3 The technical fenoxycarb was dissolved in acetone and the fenoxycarb acetone solution was added to quartz sand and the acetone was then evaporated under a stream of nitrogen. The quartz sand amended with fenoxycarb was then used to dose the soil with the appropriate amount of fenoxycarb.
3.3.4	Test conditions	see table A7_5_1_1-4
3.3.5	Test parameter	**Microbial respiration**: In order to measure microbial respiration the amount of CO_2 evolved after the addition of glucose to soil was measured semi continuously over a 24-h period. Glucose was added at one of seven concentrations to the soil and a fixed mass of a glucose/talc mixture was added to each of the soils. After the addition of the glucose/talc mixes the soil aliquots were packed into glass columns and connected via a trapping system to an IR gas analyser. The concentration of CO_2/L air was used to calculate the volume of CO_2 evolved/h/kg dry soil.

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

		Microbial Biomass determination: For the microbial biomass determination those three glucose concentrations which provided the three highest initial and constant CO_2 production rates and were then used to calculate the microbial biomass. **Glucose induced short-term respiration**: For the short-term respiration component of the study the glucose concentration that exerted a maximum respiration response was added to the soil samples. Three aliquots of 40g wet soil were amended with 1.15g glucose/kg dry soil and the short-term respiration rate over a 22-h period was measured. The respiration rates between treated and control soils were compared over the first 12 hours of the study. **Nitrification of Lucerne meal:** Three replicates of wet soil were treated to extract nitrite and nitrate and the concentration of nitrate and nitrite was then determined using standard analytical techniques.
3.3.6	Analytical parameter	a) CO_2 measurement b) Nitrate and nitrite measurement
3.3.7	Duration of the test	28 days
3.3.8	Sampling	Respiration, nitrification and ammonification was determined 0-3 hours after treatment and after 7 14 and 28 days.
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Untreated control
3.3.11	Statistics	Mean value from several samplings
		4 RESULTS
4.1	**Range finding test**	not performed for the a.i.
4.1.1	Concentration	n.a.
4.1.2	Effect data	n.a.
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	0.60 and 3.0 mg/kg dry soil (equivalent to 2 and 10 times the maximum expected field dose)
4.2.2	Actual concentrations of test substance	No measurements were done. However, fenoxycarb is expected to degrade at least by 50 % of the initial concentration after 1.1 to 4.5 days day forming CO_2 and non-extractable residues. The DT90 was estimated to be 3.8 – 14.8 days [**Ref.: Adam and Nicollier, 2001**]. As a result, the actual concentration is expected to decline throughout the study
4.2.3	Growth curves	Not applicable
4.2.4	Cell concentration data	Not applicable
4.2.5	Concentration/ response curve	-

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

4.2.6	Effect data	No adverse effects regarding all the endpoints tested See table A7_5_1_1-5 for detailed results
4.2.7	Other observed effects	
4.3	**Results of controls**	See also table including data for all controls applied: Table A7_5_1_1-5
4.4	**Test with reference substance**	Yes, with dinoseb acetate
4.4.1	Concentrations	25 mg/kg dry soil
4.4.2	Results	The reference substance showed a clear influence on the microflora, thereby showing the sensitivity of the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effect of the test substance at 0.60 and 3.0 mg/kg dry soil (equivalent to 2 and 10 times the maximum expected field dose) on microbial soil respiration and nitrification was compared to an untreated control and a toxic standard treatment (dinoseb acetate at 25 mg/kg dry soil). Those soils which were to be used to determine the effect on microbial nitrification were additionally amended with 0.7g Lucerne meal. Tests were performed according to: OECD Guidelines 216 and 217 (2000) EPPO, Chapter 7, Soil microflora, volume 24, No.1 (1994)
5.2	**Results and discussion**	The test item had no detrimental effects on microbial short-term respiration at up to 10 times the maximum concentration expected under field conditions. The effect of fenoxycarb technical on the nitrification processes in soil was low and transient. At concentrations up to 10 times the maximum expected field rates negligible effects were observed after 28 days incubation and the were clearly within the 25% effects deemed to be acceptable as outlined in the guidance documents. Therefore it may be concluded that under field conditions fenoxycarb at up to 10 times the maximum concentration will have no adverse effect on organic matter turnover and hence fertility.
5.2.1	NOEC	$\geq$ 3.0 mg/kg dw
5.2.2	EC_{10}	Not determined
5.2.3	EC_{50}	Not determined
5.3	Conclusion	Fenoxycarb at up to 10 times the maximum predicted soil concentration is predicted to have minimal effects on organic turnover and soil fertility.
5.3.1	Reliability	Reliability indicator 2
5.3.2	Deficiencies	This test was not performed in a way allowing the derivation of EC50- or NOEC values. Therefore, the test can be regarded as a "limit-test" since the tested concentrations are below a level with significant effects.

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2010-02-18

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_5_1_1-1: Properties of the soil sample

Criteria	Details
Nature	One soil sample (sandy loam soil: Speyer 2.3)
Source	LUFA, Speyer, Germany, batch F232901
Geographical reference on the sampling site	Not specified
Data on the history of the site	The soil has not been subjected to any pesticide or organic fertilizer treatment for at least four years.
Use pattern	Not specified
Depth of sampling [cm]	Not specified
Sand / Silt / Clay content [% dry weight]	Classification DIN < 0.002 (silt) 9 0.002 - 0.063 (clay) 36.6 > 0.063 (sand) 54.6
pH	pH ($CaCl_2$) 6-5 ± 0.1 pH (water) 7.5
Organic carbon content [% dry weight]	1.32 ± 0.1
Nitrogen content [% dry weight]	0.09
Cation exchange capacity [mval/100 g dry wt soil]	10 ± 0
Initial microbial biomass [mg C/kg dry wt soil]	142 (1.1 % of organic content)
Reference of methods	OECD Guidelines 216 and 217 (2000) EPPO, Chapter 7, Soil microflora, volume 24, No.1 (1994)
Collection / storage of samples	The sandy loam soil was collected from a field trial plot and sieved through a 2mm sieve
Preparation of inoculum for exposure	n.a.
Pretreatment	n.a.

Table A7_5_1_1-2: Test system for soil respiration / nitrification tests

Criteria	Details
Culturing apparatus	After mixing, soil was incubated in glass columns and connected via a trapping system to an IR gas analyser
Number of vessels / concentration	3
Aeration device	Not specified
Measuring equipment	IR gas analyser. The concentration of CO_2/L air was used to calculate the volume of CO_2 evolved/h/kg dry soil.
Test performed in closed vessels	No

Table A7_5_1_1-3: Application of test substance and sampling

Criteria	Details
Application procedure	Addition of premixtures in a carrier and mixing the carrier with native soil
Carrier	The technical fenoxycarb was dissolved in acetone and the fenoxycarb acetone solution was added to quartz sand and the acetone was then evaporated under a stream of nitrogen
Concentration of liquid carrier [% v/v]	Not specified
Liquid carrier control	no
sampling procedure	Respiration, nitrification and ammonification was determined 0-3 hours after treatment and after 7 14 and 28 days.

Table A7_5_1_1-4: Test conditions

Criteria	Details
Organic (inorganic) substrate	Addition of: a) glucose, quantity not specified b) 0.7g Lucerne meal (for determination of nitrification)
Incubation temperature	20 ± 2 °C
Soil moisture	adjusted to 40% of the maximum soil water holding capacity
Method of soil incubation	Bulk
Aeration	-

Table A7_5_1_1-5: Effect of fenoxycarb technical on the glucose induced short-term respiration, nitrite formation and nitrate formation relative to an untreated and a dinoseb acetate control

Treatment	Incubation time (days)	Respiration rates (mL CO_2/h/kg dry soil)		NO_2^-N (mg NO_2^-N/kg dry soil)		$NO3^-N$ (mg NO_3^-N/kg dry soil)	
		Mean ± SD	% deviation from control	Mean ± SD	% deviation from control	Mean ± SD	% deviation from control
Control	0	7.76 ± 0.41	-	0.1 ± <0.1	-	14.8 ± 0.1	-
	7	5.84 ± 0.31	-	<0.1 ± <0.1	-	5.1 ± 0.1	-
	14	6.98 ± 0.78	-	<0.1 ± <0.1	-	9.0 ± 0.1	-
	28	5.49 ± 0.05	-	<0.1 ± <0.1	-	23.7 ± 0.3	-
0.6 mg/kg fenoxycarb	0	7.35 ± 0.04	-5.3	0.1 ± <0.1	<0.1	13.9 ± 0.1*	-6.1
	7	6.09 ± <0.01	4.2	<0.1 ± <0.1	n.a.	4.0 ± 0.1*	-21.6
	14	6.15 ± 0.04	-11.9	<0.1 ± <0.1	n.a.	8.1 ± 0.1*	-10.0
	28	5.41 ± 0.06	-1.6	<0.1 ± <0.1	n.a.	20.9 ± 0.5*	-11.8
3.0 mg/kg fenoxycarb	0	7.46 ± 0.15	-3.9	0.1 ± <0.1	<0.1	13.7 ± 0.1*	-7.4
	7	6.58 ± 0.91	12.7	<0.1 ± <0.1	n.a.	5.4 ± <0.1	5.9
	14	6.03 ± 0.08*	-13.6	<0.1 ± <0.1	n.a.	9.5 ± 0.1	5.6
	28	5.38 ± 0.17	-2.1	<0.1 ± <0.1	n.a.	21.8 ± 0.1*	-8.0
25 mg/kg Dinoseb acetate	0	4.99 ± 0.35*	-35.8	0.1 ± <0.1	<0.1	13.6 ± 0.1*	-8.1
	7	5.57 ± 0.76	-4.6	0.4 ± <0.1	n.a.	9.6 ± 0.4*	88.2
	14	3.41 ± 0.11*	-51.1	0.7 ± <0.1	n.a.	20.0 ± 0.5*	122.2
	28	2.08 ± 0.08*	-62.2	0.3 ± <0.1	n.a.	40.0 ± 1.3*	68.8

* Statistically significantly different from the control ($p \leq 0.05$)
n.a. not applicable

Section A7.5.1.2 Earthworm, acute toxicity test (1)

Annex Point IIIA XIII 3.2

Eisenia foetida

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hakin, B. and Johnson, A. B. (1990): The acute toxicity (LC_{50}) of Ro 13-5223/000 to the earthworm (*Eisenia foetida*). Huntingdon Research Centre Ltd., Cambridgeshire, England, unpublished report No. HLR 183/90934 (Syngenta No. CGA114597/0011).Experimental period: May 15th to May 29th 1990.	
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-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test	
2.2	**GLP**	Yes	
2.3	**Deviations**	None	
		3 METHOD	
3.1	**Test material**	Ro 13-5223/000 (synonymous with Fenoxycarb tech.)	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2 of the dossier	
3.1.3	Purity	[redacted]	
3.1.4	Composition of Product	-	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	-	
3.2	**Reference substance**	Cloroacetamide	
3.2.1	Method of analysis for reference substance	Data from a positive control study are included in the report (as addendum) for comparative purposes.	X
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	The solvent used for dissolving the test item was acetone	
3.3.2	Application of the test substance	Solvent used: acetone	
3.3.3	Test organisms	*Eisenia foetida*, see Table A7_5_1_2-2	

Section A7.5.1.2 Earthworm, acute toxicity test (1)

Annex Point IIIA XIII 3.2

Eisenia foetida

3.3.4	Test system	Earthworms were dosed by uniformly mixing the test substance into an artificial soil substrate that was then dispensed into each test vessel. The test item was evaluated at 5 concentrations ranging from 62.5 to 1000 mg ai/kg dry weight soil and an acetone control (solvent for dissolving/diluting the test item) was also included. The artificial soil substrate used contained, by weight 69.7% quartz sand, 20% kaolin clay, 10% sphagnum peat and 0.3% Calcium carbonate. The pH of the soil at test start was 5.9 and the moisture content of the soil was 35% of the dry weight at test start and 23 – 24% of the dry weight at the end. Experimental design: 40 earthworms with 4 replicates per treatment (each replicate with 10 earthworms). Details of a test conducted under similar conditions with a known toxic compound (chloraceteamide) were included. See Table A7_5_1_2-3	X
3.3.5	Test conditions	See Table A7_5_1_2-4	X
3.3.6	Test duration	14 days	
3.3.7	Test parameter	Mortality and weight alteration of the survivors	
3.3.8	Examination	Assessments on mortality and abnormal behaviour were made at 7 and 14 days after treatment. The worms were weighed at the beginning and end of the test.	
3.3.9	Monitoring of test substance concentration	No	
3.3.10	Statistics	The 14 day LC_{50} and its confidential limits were calculated by probit analysis (Finney, 1978).	
		4 RESULTS	
4.1	**Filter paper 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	**Soil test**		
4.2.1	Initial concentrations of test substance	Control with reference substance, solvent control, 62.5, 125, 250, 500 and 1000 mg a.i./kg dry weight soil	
4.2.2	Effect data (Mortality)	see Table A7_5_1_2-5	
4.2.3	Concentration / effect curve	-	
4.2.4	Other effects	see Table A7_5_1_2-6	
4.3	**Results of controls**		

Section A7.5.1.2 Earthworm, acute toxicity test (1)

Annex Point IIIA XIII 3.2

Eisenia foetida

4.3.1	Mortality	0 % mortality was observed in the solvent control (acetone). See also Table A7_5_1_2-6
4.3.2	Number/ percentage of earthworms showing adverse effects	-
4.3.3	Nature of adverse effects	-
4.4	**Test with reference substance**	Yes: chloracetamide
4.4.1	Concentrations	Not specified
4.4.2	Results	LC_{50} (14 days) = 24.6 mg chloracetamide/kg dry weight substrate. The LC_{50} of the reference substance is within the usual range. The test conditions are therefore equivalent to the standard.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Acute earthworm toxicity of fenoxycarb was investigated according to OECD Guideline 207. The test animals were exposed to following concentrations of fenoxycarb : 62.5, 125, 250, 500 and 1000 mg/kg dry weight soil After 14 days, the number of surviving animals and their weight alteration was determined and abnormal behaviour was observed.
5.2	**Results and discussion**	The 14-day LC_{50} in the toxic standard test with chloracetamide was determined to be 24.6 mg ai/kg dry weight soil (with 95% confidence limits of 20.2 – 30.5 mg ai/kg dry weight soil). Other than in the highest fenoxycarb dose group tested, worms were not observed on the soil surface and all surviving worms observed at days 7 and 14 appeared normal. Earthworms in all treatments including the control gained weight during the 14-day test period. However there appeared to be a treatment-related increase in bodyweight observed in the worms exposed to fenoxycarb. Current guidance is that such increases should not be defined as an adverse effect.
5.2.1	LC_0	NOEC = 500 mg a.i./kg dry weight soil
5.2.2	LC_{50}	LC_{50} = 850 mg a.i./ kg dry weight soil
5.3	**Conclusion**	Validity criteria according to the OECD Guideline 207 are fulfilled, test results can be considered reliable (see Table A7_5_1_2-7).
5.3.1	Other Conclusions	-
5.3.2	Reliability	1
5.3.3	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	2007/01/29
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ... *(specify)*
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_5_1_2-1: Preparation of TS solution

Criteria	Details
Type and source of dilution water	Not applicable
Alkalinity / Salinity	Not applicable
Hardness	Not applicable
pH	Not applicable
Oxygen content	Not applicable
Conductance	Not applicable
Holding water different from dilution water	Not applicable
In case of the use of an organic solvent	
Dispersion	-
Vehicle	Yes Acetone
Concentration of vehicle	Vehicle was allowed to evaporate off prior to incorporation with the main bulk.
Vehicle control performed	Yes, a solvent control run in parallel
Other procedures	-

Table A7_5_1_2-2: Test organisms

Criteria	Details
Species/strain	*Eisenia foetida*
Source	Local supplier in Houghton, St. Ives, Cambridgeshire
Culturing techniques	Not specified
Age/weight	Weight range of earthworms per replicate at test start 330 to 377 mg.
Pre-treatment	Not specified

Table A7_5_1_2-3: Test system

Criteria	Details
Artificial soil test substrate	Yes. The test substrate consists of 69.7 % quartz, 20 % kaolin clay, 10 % sphagnum peat, 0.3 % calcium carbonate
Test mixture	The dose concentration was thoroughly mixed with a small pre-mix of weighed soil and the vehicle was allowed to evaporate off prior to incorporation with the main bulk. Water was gradually mixed with the treated soil to give a moisture content equivalent to 35 % of the dry weight.
Size, volume and material of test container	Not reported
Amount of artificial soil (kg)/ container	Not reported
Nominal levels of test concentrations	Solvent control, 62.5, 125, 250, 500 and 1000 mg a.i./kg dry weight soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Continuous light
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	22.4 to 24.8°C
Moisture content	35 % of the dry weight at test start and 23-24 of the dry weight at the end
pH	5.9 at test start
Adjustment of pH	Yes; around 0.3 % calcium carbonate was added to the test substrate
Light intensity / photoperiod	continuous light
Relevant degradation products	Degradation products were not investigated in this study

Table A7_5_1_2-5: Acute toxicity of fenoxycarb to *Eisenia foetida*

Test item	Concentration [mg ai/kg soil]	Mortality [%]		Average live eight [mg]		% weight increase
		7 d	14 d	0 d	14 d	0 – 14 d
Acetone control		0.0	0.0	353	379	7.4
Fenoxycarb	62.5	0.0	0.0	353	387	9.6
	125	0.0	0.0	354	418	18.1
	250	0.0	0.0	353	417	18.1
	500	0.0	2.5	353	429	21.5
	1000	5.0	72.5	353	476	34.8

Table A7_5_1_2-6: Effect data after 14 days (nominal concentrations)

	[mg a.i./kg d.wt.soil]	95 % c.l.
LC_{50}	850	761 - 944
$NOEC_{Mortality}$	250[a]	-
$LOEC_{Mortality}$	500	-

[a] Although mortality is clearly within acceptable mortality levels for the control of less than 10%. Therefore, a NOEC of 500 mg a.i./kg d.wt.soil is suggested

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD Guideline 207

	fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Earthworm, acute toxicity test (2)

Eisenia foetida

CGA 294850 (metabolite of fenoxycarb)

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schmidt, T. (2003): Acute toxicity of CGA 294850 (Metabolite of CGA 114597) to the Earthworm, Eisenia foetida in a 14-day test in Artificial soil.RCC Ltd. Environmental Chemistry and Pharmanalytics, CH-4452 Itingen, Switzerland. Unpublished Report number 2032529. (Syngenta No. CGA 294850/0002). Experimental period November 24th 2003 to December 9th 2003.	
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 Guidelines for testing of chemicals, Section 2, No.207, "Earthworm, Acute Toxicity Tests", adopted April 4th 1984. EU Commission Directive 87/302/EEC, L 133, "Toxicity for Earthworms, Artificial Soil Test", pp. 95-98, 1988.	
2.2	**GLP**	Yes	
2.3	**Deviations**	None	
		3 METHOD	
3.1	**Test material**	CGA 294850 (metabolite of fenoxycarb)	
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	None	
3.2	**Reference substance**	No	X
3.2.1	Method of analysis for reference substance	-	
3.3	**Testing procedure**		
3.3.1	Preparation of the	The test treatment was dissolved in acetone	