Section A7.5.1.2
Annex Point IIIA XIII 3.2

Earthworm, acute toxicity test (2)

Eisenia foetida

CGA 294850 (metabolite of fenoxycarb)

	test substance	
3.3.2	Application of the test substance	The test treatment was dissolved in acetone and added to sand, the acetone was allowed to evaporate off before 10g of the sand mixture was incorporated into the definitive test soil
3.3.3	Test organisms	*Eisenia foetida*, see Table A7_5_1_2-2
3.3.4	Test system	The purpose of the study was to assess the acute toxicity of CGA 294850 (metabolite of fenoxycarb to adult earthworms (*Eisenia foetida*, approximately 6 months old with a clitellum). The worms were exposed to the test treatment at 95, 171, 309, 556 and 1000mg/kg dry weight of soil. The treatments were compared to an untreated control (incorporated sand had been exposed to an appropriate volume of acetone). The test treatment was dissolved in acetone and added to sand, the acetone was allowed to evaporate off before 10g of the sand mixture was incorporated into 556g of artificial soil, 2.6g of calcium carbonate and 185mL of purified water (gives a moisture content of 35%). The treated soil mixture was added to cylindrical glass beakers with a glass lid which reduced moisture loss whilst still permitting gas exchange. Four replicate test units each with 10 worms placed on the soil surface were established per treatment. The worms were acclimatised to the test conditions for 24 hours before test initiation and were not fed for the duration of the study. The worms were kept in a controlled environment chamber (19-20°C) under constant illumination (510-560lux). See Table A7_5_1_2-3
3.3.5	Test conditions	See Table A7_5_1_2-4
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality and weight alteration of the survivors
3.3.8	Examination	The weight of each earthworm was recorded at the beginning and end of the test together with the pH and moisture content of the soil. The condition of the worms was assessed after 7 and 14 days (test end).
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	Probit analysis (LC_{50}), Williams-Test (body weighty)
		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	-

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Earthworm, acute toxicity test (2)

Eisenia foetida

CGA 294850 (metabolite of fenoxycarb)

4.2	**Soil test**		
4.2.1	Initial concentrations of test substance	Solvent control, 95, 171, 309, 556 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_2-5 (body weight alteration)	
4.3	**Results of controls**		
4.3.1	Mortality	0 % mortality was observed in the solvent control See also Table A7_5_1_2-5	
4.3.2	Number/ percentage of earthworms showing adverse effects	-	
4.3.3	Nature of adverse effects	-	
4.4	**Test with reference substance**	No	X
4.4.1	Concentrations	-	
4.4.2	Results	-	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Acute earthworm toxicity of the main degradation product in soil of fenoxycarb (CGA 294850) was investigated according to OECD Guideline 207. The test animals were exposed to following concentrations of CGA 294850: 95, 171, 309, 556 and 1000 mg/kg dry weight soil After 0, 7 and 14 days, the number of surviving animals and their weight alteration was determined
5.2	**Results and discussion**	Mortality and signs of toxicity were only observed in the 1000mg/kg treatment group and therefore the NOEC was 556 mg CGA 294850/kg dry soil and the LOEC was 1000 mg CGA 294850/kg dry soil. The 14-day LC_{50} was calculated to be 843 mg CGA 294850/kg dry soil. The mean bodyweight of worms in all test treatments and the control decreased due to starvation. However, in the 1000 mg/kg dry weight test treatment the weight decrease was statistically different from the control (based on the Williams-test).
5.2.1	LC_0	556 mg a.i./kg dry weight soil
5.2.2	LC_{50}	843 mg a.i./ kg dry weight soil

Section A7.5.1.2
Annex Point IIIA XIII 3.2

Earthworm, acute toxicity test (2)

Eisenia foetida

CGA 294850 (metabolite of fenoxycarb)

5.3	Conclusion	Validity criteria according to the OECD Guideline 207 are fulfilled, test results can be considered reliable: The mortality rate in the control was 0 % which is below 10 % i.e. regarded as the limit for natural mortality. The properties of the substrate are in agreement with the nominal values.
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	Purified water
Alkalinity / Salinity	-
Hardness	-
pH	-
Oxygen content	-
Conductance	-
Holding water different from dilution water	-
In case of the use of an organic solvent	
Dispersion	No
Vehicle	Yes Acetone
Concentration of vehicle	-
Vehicle control performed	Yes, a solvent control run in parallel
Other procedures	Test item was dissolved and diluted in acetone and applied to a portion of sand. Solvent was completely evaporated at room temperature under a hood for two hours. Defined volumes of the sand/test substance mixture were then incorporated into the artificial soil.

Table A7_5_1_2-2: Test organisms

Criteria	Details
Species/strain	*Eisenia foetida*
Source	Breeding stock maintained by RCC.
Culturing techniques	Not specified
Age/weight	Only adult worms (6 months with a clitellum)
Pre-treatment	The worms were acclimatised to the test conditions for 24 hours before test initiation

Table A7_5_1_2-3: Test system

Criteria	Details
Artificial soil test substrate	556g of artificial soil (10% peat, 20% Kaolinite clay, 70% sand and 0.5% Calcium carbonate), 2.6g of calcium carbonate and 185mL of purified water
Test mixture	556g of artificial soil were thoroughly mixed with 10 g sand/test item mixture by intense mixing in a laboratory mixture.
Size, volume and material of test container	Cylindrical glass beakers with a glass lid, 10 cm diameter, 14 cm height, size is sufficient to contain 556 g dry weight soil.
Amount of artificial soil (kg)/ container	556 g dry weight
Nominal levels of test concentrations	Solvent control, 95, 171, 309, 556 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 (510 - 560 Lux)
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	19 - 20 °C
Moisture content	35 % at the test start 33 - 35 % at test termination
pH	6 at the test start 5.5 – 5.7 at test termination
Adjustment of pH	Yes; Around 0.5 % calcium carbonate was added to the test substrate to adjust the pH value to 6.0
Light intensity / photoperiod	510 – 560 Lux, continuous light
Relevant degradation products	Degradation products were not investigated in this study.

Table A7_5_1_2-5 Acute toxicity of CGA 294850 (metabolite of fenoxycarb) to the *Eisenia foetida*

CGA 294840 (mg/Kg dry soil)	% Mortality		Mean body weight (mg) ± SD		
	Day 7	Day 14	Test start (0day)	Test end (14day)	% Decrease
0	0	0	400 ± 13	368 ± 5	8
95	0	0	394 ± 31	350 ± 36	11
171	0	0	383 ± 10	335 ± 6	12
309	0	0	360 ± 12	330 ± 11	8
556	0	0	397 ± 12	352 ± 12	11
1000	10	85	381 ± 18	238 ± 73	37*

* Statistically different from the control based on the Williams-test (one sided, $\alpha = 0.05$)

Table A7_5_1_2-6 Effect data of CGA 294850 (metabolite of fenoxycarb) after 14 days

	Nominal [mg a.i./kg d.wt.soil]	95 % c.l.
LC_{50}	843	not calculable
NOEC	556	-
LOEC	1000	-

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 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

			Official use only
		1 REFERENCE	
1.1	**Reference**	Wälder, L. (2000): Herbicide profiling test to evaluate the phytotoxicity of CGA 114597 25 WG (A-8995 B) to terrestrial non-target higher plants. Novartis Crop Protection AG, Research Biology Weed Control, CH-4332 Stein, Switzerland. Unpublished report No. SMQ 00006, Report no 41 (Syngenta No. CGA 114597/0748). Experimental period March 30th 2000 to April 20th 2000.	
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	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 METHOD	
3.1	**Test material**	CGA 114597 WG 25 (A-8995 B)	X
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Formulation containing 25 % w/w fenoxycarb	
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**	In both test systems the test treatments were applied using a laboratory sprayer at 6 rates (18.75, 37.5, 75, 150, 300 and 600g A-8995 B/ha). All treatments were applied in a volume equivalent to 500L/ha.	
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_5_1_3-2	
3.4.2	Test plants	See Table A7_5_1_3-3	

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

3.4.3	Test system	The effect of the test substance CGA 114597 WG 25 (A-8995 B) on a representative range of economically important plant species was investigated in a laboratory study. Two warm season plant species were tested: Maize and Soybean. Four cool season plant species were also tested: Wild oat, Onion, Sugar beet, and Oilseed rape. The study had two distinct components firstly, to investigate the effect of the test substance on seedling emergence and secondly to study any effect the test substance treatments had on vegetative vigour. In both test systems the test treatments were applied using a laboratory sprayer at 6 rates (18.75, 37.5, 75, 150, 300 and 600g A-8995 B/ha) and compared to untreated controls. All treatments were applied in a volume equivalent to 500L/ha. Two replicates per treatment were established. **Seedling emergence**: The seeds were planted in a mineral soil (26% clay, 34% silt and 40% sand with a pH of 7.5 and containing 2.6% organic matter) in 10cm deep plastic trays. Within 24-hours of watering the seeds in, the test substance treatments were applied by spray application directly to the soil surface, visual assessments of phytotoxicity were made 21 days after application. **Vegetative vigour**: The plants were grown (in the mineral soil as described above) to the 2-4 leaf stage before being treated via foliar application. Treatments were applied 14 days after emergence for the warm season plants and seventeen days after emergence for the cool season plants. Visual assessments of phytotoxicity were made 14 days after the application of the test treatments. See Table A7_5_1_3-4
3.4.4	Test conditions	See Table A7_5_1_3-5
3.4.5	Test duration	Exposure time: 21 days after application
3.4.6	Test parameter	Seedling emergence and vegetative vigour. Phytotoxicity was assessed according to a visual rating scale ranging from 1 (complete destruction or no emergence of the plants) and 9 (normal growth), compared to an untreated control.
3.4.7	Sampling	Visual phytotoxicity ratings: at day 14 in the test for vegetative vigour and at day 21 in the test for seedling emergence
3.4.8	Method of analysis of the plant material	Not applicable
3.4.9	Quality control	No
3.4.10	Statistics	Data are given as the average of two replicates
		4 RESULTS
4.1	**Results test substance**	
4.1.1	Applied initial concentration	The dosages of the test substance were (nominal): 18.75, 37.5, 75, 150, 300 and 600g A-8995 B/ha
4.1.2	Phytotoxicity rating	See Table A7_5_1_3-6a and Table A7_5_1_3-6b **Seedling emergence**: The only treatment that had an effect on seedling

		emergence was the 600g A-8995 B treatment applied to *A. cepa*, were a slight reduction in emergence was observed. **Vegetative vigour**: No effect of test substance treatment on vegetative vigour was observed on *B. napus, A. fatua or B. vulgaris*. However when the test substance was applied to G. max and A. cepa at rates greater than or equal to 150g A-8995 B/ha a very slight reduction in vegetative vigour was noted. A reduction in vigour was also noted in *Z. mays* when A-8995 B was at rates of 75g/ha and above, although the reduction in vigour was minimal.	
4.1.3	Plant height	Not specified in the report	
4.1.4	Plant dry weights	Not specified in the report	
4.1.5	Root dry weights	Not specified in the report	
4.1.6	Root length	Not specified in the report	
4.1.7	Number of dead plants	No dead plants were observed during the test.	
4.1.8	Effect data	See Table A7_5_1_3-6a (effect data based on results of emergence) and Table A7_5_1_3-6b (effect data based on results of vegetative vigour).	
4.1.9	Concentration / response curve	-	
4.1.10	Other effects	None	
4.2	**Results of controls**		
4.2.1	Number/ percentage of plants showing adverse effects	See Tables A7_5_1_3-6a and A7_5_1_3-6b	
4.2.2	Nature of adverse effects	Not relevant	
4.3	**Test with reference substance**	Not performed	
4.3.1	Concentrations	-	
4.3.2	Results	-	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Test was performed for 21 days in a growth chamber under controlled test conditions with two warm season plant species: Maize and Soybean and four cool season plant species were also tested: Wild oat, Onion, Sugar beet, and Oilseed rape. The test procedure was very similar to other current test guidelines (e.g. OECD test guidelines 208 and 227).	
5.2	**Results and discussion**	**Seedling emergence**: The only treatment that had an effect on seedling emergence was the 600g A-8995 B treatment applied to *A. cepa*, were a slight reduction in emergence was observed.	X

Section 7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

		Vegetative vigour: No effect of test substance treatment on vegetative vigour was observed on *B. napus, A. fatua* or *B. vulgaris*. However when the test substance was applied to *G. max* and *A. cepa* at rates greater than or equal to 150g A-8995 B/ha a very slight reduction in vegetative vigour was noted. A reduction in vigour was also noted in *Z. mays* when A-8995 B was at rates of 75g/ha and above, although the reduction in vigour was minimal.	X
5.2.1	EC_{20}	Not determined	
5.2.2	EC_{50}	For those species effected the effects were very slight and were clearly less than 50% effect at 600g A-8995 B/ha for all species, this equals 0.8 mg product / kg dw soil, i.e. 0.2 mg a.s. / kg dw soil.	X
5.2.3	EC_{80}	Not determined	
5.3	Conclusion	CGA 114597 25 WG (A-8995 B) has no effect on seedling emergence for five of the six species tested and no effect on vegetative vigour for three of the six species tested. However, for those species effected the effects were very slight and were clearly less than 50% effect at 600g A-8995 B/ha for all species (0.2 mg a.s. / kg dw soil).	X
5.3.1	Reliability	2	X
5.3.2	Deficiencies	The study does not meet all the requirements of GLP. However, standardised treatment protocols were in place at the time the data were collected and the data presented are scientifically valid.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/06/2006
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_5_1_3-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Not applicable
Vehicle	Not applicable
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	Not applicable

Table A7_5_1_3-2: Dilution water

Criteria	Details
Source	Not reported
Alkalinity / Salinity	Not reported
Hardness	Not reported
pH	Not reported
Oxygen content	Not reported
Conductance	Not reported
Holding water different from dilution water	Not applicable

Table A7_5_1_3-3: Test plants

	Season	Family	Species	Common name
Monocotyledonae	warm	Gramineae/ Panicoideae	***Zea mays* L.**	Maize
	cool	Gramineae/ Pooideae	***Avena fatua* L.**	Wild oat
	cool	Liliaceae/ Allioideae	***Allium cepa***	Onion
Dicotyledonae	warm	Leguminoseae	***Glycine max* (L.) Merr.**	Soybean
	cool	Chenopodiaceae	***Beta vulgaris* L.**	Sugar beet
	cool	Cruciferae	***Brassica napus***	Oilseed Rape

Table A7_5_1_3-4: Test system

Criteria	Details
Test type	Test was performed in a growth chamber under controlled test conditions.
Container type	10 cm deep plastic trays
Seed germination potential	Not specified
Identification of the plant species	Each test unit was uniquely identified with at least study number, treatment and replicate number
Number of replicates	2 pots per treatment group were tested
Numbers of plants per replicate per dose	Zea mays L. 3 seeds were sown Avena fatua L. 6 " Allium cepa 20 " Glycine max L. 3 " Beta vulgaris L. 5 " Brassica napus 20 "
Date of planting	Not specified
Plant density	Not specified
Date of test substance application	Not specified
High of plants at application	Not specified
Date of phytotoxicity rating or harvest	Visual phytotoxicity ratings: at day 14 in the test for vegetative vigour and at day 21 in the test for seedling emergence
Dates of analysis	Not specified

Table A7_5_1_3-5: Test conditions

Criteria	Details
Test type	Terrestrial plants, Seedling emergence and vegetative vigour, no guideline followed, but procedure was similar to guideline
Method of application	In the **seedling emergence test** within 24-hours of watering the seeds in, the test substance treatments were applied by spray application directly to the soil surface In the **vegetative vigour test** the plants were grown to the 2-4 leaf stage before being treated via foliar application.
Application levels	Nominal dosages: 18.75, 37.5, 75, 150, 300 and 600g A-8995 B/ha
Dose rates	Dose rates: See above; Application scheme: 1. control, 2. test substance (increasing concentrations)
Substrate characteristics	Mineral soil (26% clay, 34% silt and 40% sand with a pH of 7.5 and containing 2.6% organic matter)
Watering of the plants	Plants were watered from the top of the trays as needed.
Temperature	The warm season plants were maintained at 18-20°C during the night and maintained at 25-27°C during the day. The cool season plants were maintained at a temperature which ranged from 15-17°C during the night and 20-22°C during the day.
Thermoperiod	14 h-photoperiod
Light regime	Light regime: 14 hours light : 10 hours dark; Minimum light intensity: 10,000 Lux
Relative humidity	Relative humidity ranged from 40-60%
Wind volatility	Not specified
Observation periods and duration of test	Test period: 21 days The emergence was assessed 14 days after seedling and the vigour of plants was rated after 21 days
Pest control	Not applicable
Any other treatments and procedures	No

Table A7_5_1_3-6a: The effect of CGA 114597 25 WG (A-8995 B) on the emergence of six plant species following direct application to the soil surface.

Application rate (g/ha A-8995 B)	*Brassica napus*	*Avena fatua*	*Beta vulgaris*	*Zea mays*	*Glycine max*	*Allium cepa*
18.75	9	9	9	9	9	9
37.5	9	9	9	9	9	9
75	9	9	9	9	9	9
150	9	9	9	9	9	9
300	9	9	9	9	9	9
600	9	9	9	9	9	6.5

Rating Scale from 1-9: 1 = no emergence or complete destruction of above ground parts and 9 = no visual damage. Data are given as the average of two replicates.

Table A7_5_1_3-6b: The effect of CGA 114597 25 WG (A-8995 B) on the vegetative vigour of six plant species following foliar application at the 2-4 leaf stage.

Application rate (g/ha A-8995 B)	*Brassica napus*	*Avena fatua*	*Beta vulgaris*	*Zea mays*	*Glycine max*	*Allium cepa*
18.75	9	9	9	9	9	9
37.5	9	9	9	9	9	9
75	9	9	9	8.5	9	9
150	9	9	9	8.5	8	8.5
300	9	9	9	8.5	8	8
600	9	9	9	8.5	8	7

Rating Scale from 1-9: 1 = no emergence or complete destruction of above ground parts and 9 = no visual damage. Data are given as the average of two replicates.

Section 7.5.1.3
Annex Point IIIA XIII 3.4

Terrestrial plant toxicity (2)
Triticum aestivum, Brassica napus, Lactuca sativa

			Official use only
		1 REFERENCE	
1.1	**Reference**	Porch, J. R., Martin, K. H. and Krueger, H. O. (2007): Fenoxycarb – A Glasshouse Toxicity Study to Determine the Effects on the Seedling Emergence and Growth of Three Species of Plants. Wildlife International, Ltd., Easton, Maryland, USA 21601. Unpublished report Project number: 528-243 (Syngenta study number: T001614-07). Date: 2007-10-27.	
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, the test was performed according to the OECD Guideline for the Testing of Chemicals, Guideline 208, "Terrestrial Non-Target Plant Tests".	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 METHOD	
3.1	**Test material**	Fenoxycarb	
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	The method used for the analysis of the soil samples was based upon the methodology developed by the sponsor and modified by Wildlife International, Ltd.. The samples were extracted with 0.1 % phosphoric acid and acetone. Concentrations of fenoxycarb in the sample extracts were determined by HPLC/VWD (variable wavelength detector).	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Containers of the test substance were heated in a water-bath (approximately 65° C) in order to liquefy the test substance to facilitate weighting. A primary stock solution was prepared by diluting 39.60 g of the liquefied test substance with 200 mL of acetone and mixing by stirring and sonication. Proportional dilutions of the stock solution were made using 0.41, 1.23, 3.7, 11.1 and 33.3 mL of the primary stock, each diluted to 100 mL with acetone. The 100 mL were then added to beakers containing 200 g of sand and stirred. A one kilogram pre-mix was then prepared by adding the stock/sand mixture to a second beaker	

Section 7.5.1.3 **Terrestrial plant toxicity (2)**
Annex Point IIIA XIII 3.4 *Triticum aestivum, Brassica napus, Lactuca sativa*

		containing 800 g artificial soil and stirring to soil.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	Not applicable
3.4.2	Test plants	*Triticum aestivum, Brassica napus* and *Lactuca sativa*. These species were chosen because they serve as surrogates for non-target vegetation, are economically important and are readily cultivated test organisms that are widely used in research. See Table A7_5_1_3-3 for details
3.4.3	Test system	The effect of the test substance fenoxycarb on the seedling emergence and growth of three species of terrestrial non-target higher plants. The experimental design consisted of six treatment groups, a solvent control, and a negative control for all test species. Each group had four replicate pots with ten seeds planted in each pot. A single application of fenoxycarb was made to the treatment groups by soil incorporation, while the negative and solvent control soils had no test substance added. The following nominal concentrations were tested: 0 (control), 3, 9, 27, 80, 240 and 720 mg a.i./kg soil dry weight. Seeds were impartially assigned to pre-labelled growth pots on the day of test initiation. The replicate pots were placed in a randomized block design on a glasshouse table after planting occurred. The soil used for the test represented a sandy loam soil and was composed of kaolinite clay, industrial quartz, sand and peat. The composition was as follows: 75 % sand, 11 % silt and 14 % clay, with an organic matter content of 1.3 %. The soil pH was measured to be 7.2. See Table A7_5_1_3-4
3.4.4	Test conditions	See Table A7_5_1_3-5
3.4.5	Test duration	Exposure time: 21 days after application
3.4.6	Test parameter	Seedling emergence and growth. Phytotoxicity was assessed according to a seedling condition rate system ranging from 0 (no noticeable affect) and 100 (death of entire plant), compared to an untreated control. See Table A7_5_1_3-10.
3.4.7	Sampling	Observations of emergence were made on days 7, 14 and 21, while observations of height and condition were made only on day 21. Dry weights were determined from seedling shoots collected at test termination on day 21.
3.4.8	Method of analysis of the plant material	Not applicable
3.4.9	Quality control	No
3.4.10	Statistics	Statistical analyses were used to evaluate affects of test substance application on seedling emergence, survival, biomass and seedling

		height. A t-test was used to compare mean values from the two control groups in order to determine if any observed differences in control group means were statistically significant. Mean seedling emergence, survival, biomass and height of the control and treatment groups were compared in the test with a Dunnett´s t-test, using the Dunnett option of the GLM (general linear model) procedure of SAS (see above). Additionally test data were evaluated to determine the LOEC and NOEC for plant emergence, survival, biomass and height. When possible, calculations of EC estimates were made using the non-linear regression analysis of Bruce and Versteeg (see above). SAS Institute, Inc. 1999. SAS Proprietary Software Version 8, Cary, NC, SAS Institute, Inc. Bruce, R. D. and Versteeg, D. J. (1992): A Statistical Procedure for Modelling Continuous Toxicity Data. Environmental Toxicology and Chemistry. 11: 1485-1494,	
		4 RESULTS	
4.1	**Results test substance**		
4.1.1	Applied initial concentration	The dosages of the test substance were (nominal): 0 (control), 3, 9, 27, 80, 240 and 720 mg a.i./kg soil dry weight.	
4.1.2	Phytotoxicity rating	See Table A7_5_1_3-6a, A7_5_1_3_6b and A7_5_1_3_6c for detailed results.	
4.1.3	Plant height	See Tables A7_5_1_3_6a, A7_5_1_3_6b and A7_5_1_3_6c.	
4.1.4	Plant dry weights	Not specified in the report	
4.1.5	Root dry weights	Not specified in the report	
4.1.6	Root length	Not specified in the report	
4.1.7	Number of dead plants	No dead plants were observed during the test.	
4.1.8	Effect data	Refer to Tables A7_5_1_3_6a, A7_5_1_3_6b and A7_5_1_3_6c for detailed results. Soil samples were collected on June 8, 2007 from the 3.00 and 720 ppm a.i. test concentrations and were analysed to evaluate the homogeneity of the test substance in the soil. Means and standard deviations for the two test concentrations were 2.42 ± 0.459 ppm a.i. and 720 ± 164 ppm a.i., respectively. These results represented 81 and 100 % of nominal concentrations. Additional soil samples were collected on September 6, 2007 from the 3.00 and 720 ppm a.i. test concentrations and were analysed to evaluate the homogeneity of the test substance in the soil. Means and standard deviations for the two test concentrations were 3.17 ppm a.i. and 723 ppm a.i., respectively. These results represented 106 and 100 % of nominal concentrations.	X
4.1.9	Concentration / response curve	-	

Section 7.5.1.3
Annex Point IIIA XIII 3.4

Terrestrial plant toxicity (2)

Triticum aestivum, Brassica napus, Lactuca sativa

4.1.10	Other effects	None
4.2	**Results of controls**	
4.2.1	Number/ percentage of plants showing adverse effects	See Tables A7_5_1_3-6a and A7_5_1_3-6b The control samples showed no indication of the presence of the test substance or of the presence of a co-eluting substance at the characteristic retention time of the test substance.
4.2.2	Nature of adverse effects	Not relevant
4.3	**Test with reference substance**	Not performed
4.3.1	Concentrations	-
4.3.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Test according to OECD Guideline 208 (Proposal for Updating Guideline 208, Draft Document, July 2000): Seedling Emergence and Seedling Growth Test. Test was performed for 21 days in a growth chamber under controlled test conditions with three plant species: *Triticum aestivum, Brassica napa and Lactuca sativa.*
5.2	**Results and discussion**	Soil incorporation of fenoxycarb at nominal concentrations of 3, 6, 27, 80, 240 and 720 mg a.i./kg dry soil resulted in effects on the seedling height and biomass of *Brassica napus* and *Lactuca sativa.* Effects on *Triticum aestivum* were noted 21 days after planting. See Tables A7_5_1_3-7, A7_5_1_3-8 and A7_5_1_3-9 for detailed NOEC and EC_{50} values.
5.2.1	EC_{20}	Not determined
5.2.2	EC_{50}	See Tables A7_5_1_3-7, A7_5_1_3-8 and A7_5_1_3-9
5.2.3	EC_{80}	Not determined
5.3	Conclusion	The test was considered valid for *T. aestivum*, *B. napus* and *L. sativa* based on the following criteria: - Seedling emergence in the control group was greater than 70 % for all species, - There were no phytotoxic effects observed in the control groups, - Survival of emerged control seedlings was greater than 90 % for all species, - The environmental conditions and growing medium for each species was the same for all test groups.
5.3.1	Reliability	1
5.3.2	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/01/2008
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_3-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Not applicable
Vehicle	Not applicable
Concentration of vehicle	-
Vehicle control performed	-
Other procedures	-

Table A7_5_1_3-2: Dilution water

Criteria	Details
Source	Not applicable, no dilution with water
Alkalinity / Salinity	-
Hardness	-
pH	-
Oxygen content	-
Conductance	-
Holding water different from dilution water	-

Table A7_5_1_3-3: Test plants

	Family	Species	Common name	Source (seed/plant)
Dicotyledonae	Brassicaceae	***Brassica napus***	Oilseed Rape	Source not mentioned in report. Seeds used in study were not treated with fungicides, insecticides or repellents prior to test initiation.
	Asteaceae	***Lactuca sativa***	Lettuce	
Monocotyledonae	Poaceae	***Triticum aestivum***	Wheat	

Table A7_5_1_3-4: Test system

Criteria	Details
Test type	Test was performed in a glasshouse under controlled test conditions. Parameters measured were fresh weight, germination, mortality, phytotoxicity and growth stage
Container type	Commercial plastic flower pots Size of pots: 16 cm diameter and 12 cm deep, 1940 cm^3)
Seed germination potential	Not reported
Identification of the plant species	Each test unit was uniquely identified with at least project number, species name, treatment group and replicate.
Number of replicates	4 pots per treatment group were tested
Numbers of plants per replicate per dose	Each pot contained 10 seeds; in total 40 seeds per treatment group were tested.
Date of planting	Experimental starting date: 2007-06-08
Plant density	Each pot contained 10 seeds
Date of test substance application	Experimental starting date: 2005-04-22
High of plants at application	The test seeds were sowed in soil incorporated with the test item
Date of phytotoxicity rating or harvest	- Visual phytotoxicity ratings (e.g. chlorosis, necrosis, abnormal growth): Days 7, 14 and 21 - Weight and condition: at the end of the test (Day 21) - Dry weights from seedling shoots: Day 21 - Emergence: Days 7, 14 and 21 Experimental completion date (2 species): 2007-10-23
Dates of analysis	2007-06-08 (analytical verification)

Table A7_5_1_3-5: Test conditions

Criteria	Details
Test type	Terrestrial plants, seedling emergence and seedling growth test according to OECD guideline 208
Method of application	The test substance was heated in a water-bath (approx. 65 °C) in order to liquefy and facilitate weighting. A primary stock solution was prepared in acetone. Proportional dilutions of the stock solution were made. Dilutions in acetone were added to beakers containing 200 g of sand and stirred. A one kilogram pre-mix was then prepared by adding the stock/sand mixture to a second beaker containing 800 g artificial soil and stirring to soil. Treatment of the control: The same amount of untreated quartz sand was mixed into the soil
Application levels	The dosages of the test substance were: 3, 9, 27, 80, 240 and 720 mg/kg soil dw
Dose rates	Dose rates: See above; Application scheme: 1. control, 2. test substance (increasing concentrations)
Substrate characteristics	The soil was analysed by Agvise Laboratories, Inc., in Northwood, North Dakota, Soil Type (USDA): Sandy loam pH = 7.2
Watering of the plants	Seedlings were subirrigated to minimize the potential for the leaching of the test substance through the soil. Subirrigation trays were filled to a predetermined depth to help standardize the amount of water delivered to each tray.
Temperature	The test plants were grown at 26.15 °C (range 19.08 – 42.74 °C)
Thermoperiod	See above
Light regime	
Relative humidity	65.64 % (range 31.35-92.80 %);
Wind volatility	Not mentioned in report
Observation periods and duration of test	- Visual phytotoxicity ratings (e.g. chlorosis, necrosis, abnormal growth): Days 7, 14 and 21 - Weight and condition: at the end of the test (Day 21) - Dry weights from seedling shoots: Day 21 - Emergence: Days 7, 14 and 21 Test duration: 21 days
Pest control	Not applicable
Any other treatments and procedures	

Table A7_5_1_3-6a: Effects of Fenoxycarb on *Triticum aestivum* (Wheat) Seedling Emergence, Survival, Biomass and Height in a 21-Day Seedling Emergence Test

Treatment Group [mg a.i./kg]	Emergence (per 10 Planted Seeds) Mean ± SD (% Reduction)			Survival (per 10 Planted Seeds) Mean ± SD (% Reduction)	Biomass (g) Mean ± SD (% Reduction)	Height (cm) Mean ± SD (% Reduction)
	7 DAA	14 DAA	21 DAA	21 DAA	21 DAA	21 DAA
Pooled control	8.75 ± 0.71	8.88 ± 0.83	8.88 ± 0.83	8.75 ± 0.71	2.56 ± 0.367	35.8 ± 2.58
3	9.00 ± 1.15 (-3 %)	9.00 ± 1.15 (-1 %)	9.00 ± 1.15 (-1 %)	9.00 ± 1.15 (-3 %)	2.57 ± 0.648 (0 %)	36.2 ± 4.93 (-1 %)
9	9.25 ± 0.96 (-6 %)	9.50 ± 1.00 (-7 %)	9.50 ± 1.00 (-7 %)	9.50 ± 1.00 (-9 %)	3.14 ± 0.513 (-22 %)	39.6 ± 5.31 (-11 %)
27	8.75 ± 1.50 (0 %)	8.75 ± 1.50 (1 %)	8.75 ± 1.50 (1 %)	8.75 ± 0.71 (3 %)	2.43 ± 0.109 (5 %)	34.1 ± 4.61 (5 %)
80	8.50 ± 1.73 (3 %)	8.50 ± 1.73 (4 %)	8.50 ± 1.73 (4 %)	8.50 ± 1.73 (3 %)	2.28 ± 0.561 (11 %)	32.5 ± 7.50 (9 %)
240	9.00 ± 1.41 (-3 %)	9.00 ± 1.41 (-1 %)	9.00 ± 1.41 (-1 %)	8.75 ± 1.89 (0%)	1.99 ± 0.667 (22 %)	33.2 ± 8.46 (7 %)
720	9.75 ± 0.50 (-11 %)	9.75 ± 0.50 (-10 %)	9.75 ± 0.50 (-10 %)	9.75 ± 0.50 (-11 %)	2.01 ± 0.222 (22 %)	35.5 ± 0.88 (1 %)

Mean ± SD = Mean plus minus one standard deviation
DAA – Days after application

Table A7_5_1_3-6b: Effects of Fenoxycarb on *Brassica napus* (Oilseed Rape) Seedling Emergence, Survival, Biomass and Height in a 21-Day Seedling Emergence Test

Treatment Group [mg a.i./kg]	Emergence (per 10 Planted Seeds) Mean ± SD (% Reduction)			Survival (per 10 Planted Seeds) Mean ± SD (% Reduction)	Biomass (g) Mean ± SD (% Reduction)	Height (cm) Mean ± SD (% Reduction)
	7 DAA	14 DAA	21 DAA	21 DAA	21 DAA	21 DAA
Pooled control	8.00 ± 1.20	8.13 ± 1.25	8.13 ± 1.25	8.13 ± 1.25	7.00 ± 1.275	19.7 ± 2.73
3	6.75 ± 0.50 (16 %)	6.75 ± 0.50 (17 %)	7.50 ± 0.58 (8 %)	7.50 ± 0.58 (8 %)	6.07± 1.227 (13 %)	15.7 ± 2.38 (20 %)
9	7.50 ± 1.73 (6 %)	7.50 ± 1.73 (8 %)	7.50 ± 1.73 (8 %)	7.50 ± 1.73 (8 %)	5.96 ± 1.549 (15 %)	17.8 ± 4.90 (10 %)
27	8.50 ± 0.58 (-6 %)	8.50 ± 0.58 (-5 %)	8.50 ± 0.58 (-5 %)	8.50 ± 0.58 (-5 %)	6.87 ± 1.063 (2 %)	20.8 ± 2.16 (-5 %)
80	8.25 ± 0.96 (-3 %)	8.25 ± 0.96 (-2 %)	8.25 ± 0.96 (-2 %)	8.25 ± 0.96 (-2 %)	3.69 ± 0.485* (47 %)	15.5 ± 1.24* (21 %)
240	8.25 ± 0.50 (-3 %)	8.25 ± 0.50 (-2 %)	8.25 ± 0.50 (-2 %)	8.00 ± 0.00 (2%)	2.05 ± 0.296* (71 %)	10.2 ± 1.24* (48 %)
720	7.75 ± 2.22 (3 %)	7.75 ± 2.22 (5 %)	7.75 ± 2.22 (5 %)	7.75 ± 2.22 (5 %)	1.58 ± 0.716* (77 %)	8.0 ± 3.07* (59 %)

Mean ± SD = Mean plus minus one standard deviation
DAA – Days after application
*: Treatment group mean is significantly different from the pooled control mean ($p<0.05$)

Table A7_5_1_3-6c: Effects of Fenoxycarb on *Lactuca sativa* (Lettuce) Seedling Emergence, Survival, Biomass and Height in a 21-Day Seedling Emergence Test

Treatment Group [mg a.i./kg)]	Emergence (per 10 Planted Seeds) Mean±SD (% Reduction)			Survival (per 10 Planted Seeds) Mean±SD (% Reduction)	Biomass (g) Mean±SD (% Reduction)	Height (cm) Mean±SD (% Reduction)
	7 DAA	14 DAA	21 DAA	21 DAA	21 DAA	21 DAA
Pooled control	9.38 ± 0.74	9.50 ± 0.53	9.50 ± 0.53	9.50 ± 0.53	2.76 ± 0.676	11.3 ± 1.28
3	9.25 ± 0.50 (1 %)	9.25 ± 0.50 (3 %)	9.25 ± 0.50 (3 %)	9.25 ± 0.50 (3 %)	2.70 ± 0.910 (2 %)	11.7 ± 1.16 (-3 %)
9	9.00 ± 0.82 (4 %)	9.75 ± 0.50 (-3 %)	9.75 ± 0.50 (-3 %)	8.75 ± 1.89 (8 %)	2.43 ± 1.047 (12 %)	10.4 ± 2.97 (8 %)
27	9.75 ± 0.50 (-4 %)	9.75 ± 0.50 (-3 %)	9.75 ± 0.50 (-3 %)	9.75 ± 0.50 (-3 %)	2.37 ± 0.283 (14 %)	10.6 ± 0.62 (7 %)
80	9.50 ± 1.00 (-1 %)	9.50 ± 1.00 (0 %)	9.50 ± 1.00 (0 %)	9.25 ± 0.96 (3 %)	1.38 ± 0.445* (50 %)	7.7 ± 0.74* (32 %)
240	9.25 ± 0.96 (1 %)	9.25 ± 0.96 (3 %)	9.25 ± 0.96 (3 %)	9.25 ± 0.96 (3 %)	0.64 ± 0.145* (77 %)	4.0 ± 1.10* (65 %)
720	8.75 ± 0.96 (7 %)	8.75 ± 0.96 (8 %)	8.75 ± 0.96 (8 %)	8.75 ± 0.96 (8 %)	0.41 ± 0.093* (85 %)	3.3 ± 0.52* (71 %)

Mean±SD = Mean plus minus one standard deviation
DAA – Days after application
*: Treatment group mean is significantly different from the pooled control mean ($p<0.05$)

Table A7_5_1_3-7: The Effect Concentrations of Fenoxycarb on 21-Day Emergence and Survival

Species	21-Day Emergence [mg a.i./kg]			21-Day Survival [mg a.i./kg]		
	NOEC	LOEC	EC_{50}	NOEC	LOEC	EC_{50}
Monocot.						
Triticum aestivum (wheat)	720	>720	>720	720	>720	>720
Dicot.						
Brassica napus (oilseed rape)	720	>720	>720	720	>720	>720
Lactuca sativa (lettuce)	720	>720	>720	720	>720	>720

Table A7_5_1_3-8: The Effect Concentrations of Fenoxycarb on 21-Day Height and Biomass

Species	Height [mg a.i./kg]			Biomass [mg a.i./kg]		
	NOEC	LOEC	EC_{50}	NOEC	LOEC	EC_{50}
Monocot.						
Triticum aestivum (wheat)	720	>720	>720	720	>720	>720
Dicot.						
Brassica napus (oilseed rape)	27	80	435	27	80	131
Lactuca sativa (lettuce)	27	80	174	27	80	88.2

Table A7_5_1_3-9: The Relative Sensitivity and Most Sensitive Endpoint of Three Species in Response to Pre-Emergence Soil-Incorporated Fenoxycarb

Species Latin name (common name)	Family	EC_{50}		NOEC	
		Relative Sensitivity [mg a.i./kg]	Most Sensitive Endpoint	NOEC [mg a.i./kg]	Most Sensitive Endpoint
Triticum aestivum (wheat)	Poaceae	>720	-[1]	720	-[2]
Brassica napus (oilseed rape)	Brassicaceae	131	Biomass	27	Biomass, Height
Lactuca sativa (lettuce)	Asteraceae	88.2	Biomass	27	Biomass, Height

-[1] Not applicable since there was no adverse effect greater than 50 %
-[2] Not applicable since there was no LOEC

A7_5_1_3-10: Seedling Condition Rating System

Rating	Category	Description
0	No effect	No noticeable effect
10	Slight Effect	Effect barely noticeable
20		Some effect, not apparently detrimental
30		Effect more pronounced, not obviously detrimental
40	Moderate Effect	Effect moderate, plants aplettucer able to recover
50		More lasting effect, recovery doubtful
60		Lasting effect, recovery doubtful
70	Severe Effect	Heavy injury, loss of individual leaves
80		Plants nearly destroyed, a few surviving leaves
90		Occasional surviving leaves
100	Complete Effect	Death of entire plant

Section A7.5.2.1 Annex Point IIIA 13.3	Reproduction study with earthworms or other soil non-target macro-organisms	
	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 FI	
Date	12/02/2008	
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 A7.5.2.2 Annex Point IIIA 13.3	Long-term tests with terrestrial plants	
	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 FI	
Date	12/02/2008	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.5.3.1.1 Acute oral toxicity on birds (1)

Annex Point IIIA XIII 1.1 Bobwhite quail

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1982a): The acute oral toxicity (LD_{50}) of Ro 13-5223/000 to the Bobwhite quail, [redacted] unpublished report No. HLR 104WL/82371 (Syngenta study number CGA 114597/0026). Experimental period: March to April 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**	Yes, EPA Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organisms, Series 71-Avian and Mammalian Testing, § 71-1, Avian single dose oral LD_{50} test. Published in the Federal register Vol. 43, No. 132 on 10 July 1978, Part II, Pages 29726 to 29727.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Fenoxycarb technical (Ro 13-5223/000)	
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 in the diet	n.a (see administration, section 3.2)	X
3.2	**Administration of the test substance**	Fenoxycarb, dispersed in corn oil was administered to individual Bobwhite quail (Colinus virginianus) by oral intubation using a catheter and a disposable syringe. See table A7_5_3_1_1-1	
3.3	**Reference substance**	No	
3.3.1	Method of	-	

Section A7.5.3.1.1 Acute oral toxicity on birds (1)

Annex Point IIIA XIII 1.1 Bobwhite quail

	analysis for reference substance	
3.4	**Testing procedure**	
3.4.1	Test organisms	See table A7_5_3_1_1-2
3.4.2	Test system	Fenoxycarb, dispersed in corn oil was administered to individual Bobwhite quail (*Colinus virginianus)* by oral intubation using a catheter and a disposable syringe. Sixty adult birds (30 males and 30 females) with a bodyweight range of 153-233 g at study initiation were distributed into 6 groups of ten birds each (five males / five females), with five treatment groups and one control group. In addition, 3 males and 3 females were maintained under the same conditions as the test group. These birds were retained for use as possible replacements of any birds that died during the pre-treatment observation period. Of these 3 males and 1 female were used in the study. The birds were housed (groups of 5 males and 5 females separately) in cages made from polythene coated steel wire measuring approximately 31.5 x 38.5 x 24 cm. Each cage contained an automatic nipple drinker together with a stainless steel food hopper containing standard HRC diet in pellet form. Food was provided *ad libitum*, with the exception of an overnight starvation period prior to dosing. Water was available at all times. Treatment levels: 2867, 3584, 4480, 5600 and 7000 mg/kg. All the treatment levels reported refer to the compound as supplied (i.e. no adjustment has been made for purity). The birds were examined for mortality, clinical signs, body weight gain and food consumption for a period of 14 days after dosing. See table A7_5_3_1_1-3
3.4.3	Diet	Each cage contained an automatic nipple drinker together with a stainless steel food hopper containing standard HRC diet in pellet form. Food was provided ad libitum, with the exception of an overnight starvation period prior to dosing. Water was available at all times.
3.4.4	Test conditions	See table A7_5_3_1_1-4
3.4.5	Duration of the test	Post-dosing observation: 14 days
3.4.6	Test parameter	The birds were examined daily for mortality, clinical signs, body weight gain and food consumption for a period of 14 days after dosing.
3.4.7	Examination/ Observation	Mortality and birds health were observed daily, bodyweight was determined on days -14, -7, 0 (day of treatment), 3, 7 and 14. Food consumption was determined for the following periods: days -7 to 0. days 1 to 7 and days 8 to 14. All birds were examined at death or termination of the study for gross pathological changes.
3.4.8	Statistics	Since there was no test mortality an LC_{50} could not be calculated
		4 RESULTS
4.1	**Limit Test / Range finding test**	No

Section A7.5.3.1.1 Acute oral toxicity on birds (1)

Annex Point IIIA XIII 1.1 Bobwhite quail

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	Applied concentrations	2867, 3584, 4480, 5600, 7000 mg/kg bodyweight	
4.2.2	Effect data (Mortality)	There were no mortalities	
4.2.3	Body weight	Group mean bodyweight changes during the pre-treatment period were within normal limits. All groups dosed with fenoxycarb showed small mean bodyweight decreases in comparison to the control over days 0 to 3. This decrease was greatest at the highest test item level tested. Bodyweight changes from days 3 to 14 were within normal limits.	
4.2.4	Feed consumption	Food consumption was generally within normal limits, with evidence of a small reduction in feeding over days 1 to 7 in the group dosed at 7000 mg/kg bodyweight.	
4.2.5	Concentration / response curve	-	
4.2.6	Other effects	Clinical signs: Birds dosed with 2867, 3584, 4480, 5600, 7000 mg/kg bodyweight were quiet approximately 2 to 3 hours after dosing. Birds dosed with 3584 and 4480 mg/kg bodyweight had recovered by the end of Day 2. Birds dosed with 5600 and 7000 mg/kg bodyweight had recovered by the end of days 3 and 4, respectively. Gross necropsy: No abnormalities were observed in any of the birds examined at the end of the study. The one bird that was sacrificed 7 days after dosing in the 3584 mg/kg bodyweight group showed no sign of abnormalities during post-mortem.	X
4.3	**Results of controls**	There were mortalities in the control group. All birds were normal in appearance and behaviour throughout the test period.	X
4.3.1	Number/ percentage of animals showing adverse effects	-	
4.3.2	Nature of adverse effects	-	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	-	

Section A7.5.3.1.1 Acute oral toxicity on birds (1)

Annex Point IIIA XIII 1.1 Bobwhite quail

4.4.2	Results	-
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	A sample of fenoxycarb was tested for acute oral toxicity to adult Bobwhite quails. The test complies with US-EPA Pesticide Assessment Guidelines, FIFRA Subdivision E, § 71-1 "Avian single dose oral LD_{50} test". Groups of ten mallards, five males and five females were assigned randomly to each of the five treatment groups (2867, 3584, 4480, 5600, 7000 mg a.i./kg b.w.) and the control group. Following test initiation until termination all birds were observed for mortality, clinical signs, body weight gain and food consumption
5.2	**Results and discussion**	No Bobwhite died in almost all the treatments and the control throughout the study. One bird died at dosage 3584 mg/kg bodyweight, but this can be neglected, as at higher doses no mortality occurred, and this is within the range of the acceptable mortality in the controls. There were no overt signs of toxicity at any dosage. All birds recovered from the anomalies presented at the beginning of the study
5.2.1	LD_{50}	> 7000 mg a.i./kg bw
5.2.2	NOEC	= 2867 mg a.i./kg bw (based on abnomal behaviour, although they recovered afterwards)
5.3	**Conclusion**	The mortality rate in the control was below 10%. Therefore the validity criterion for avian acute oral toxicity test according to US-EPA method is fulfilled.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/07/04
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_3_1_1-1: Method of administration of the test substance

Carrier/Vehicle	Details
Water	No
Organic carrier	Yes; corn oil
concentration of the carrier [% v/v]	Not mentioned
Other vehicle	No
Function of the carrier / vehicle	Solvent for test substance

Table A7_5_3_1_1-2: Test animals

Criteria	Details
Species/Strain	Bobwhite quail (*Colinus virginianus*)
Source	Not specified
Age (in weeks), sex and initial body weight (bw)	Age: adult animals Sex: males and females; Body weights ranged from 153-233 grams at study initiation
Breeding population	No data
Amount of food	Food was provided ad libitum, with the exception of an overnight starvation period prior to dosing. Water was available at all times.
Age at time of first dosing	Age: adult animals
Health condition / medication	All birds appeared to be in good health at initiation of the study.

Table A7_5_3_1_1-3: Test system

Criteria	Details
Test location	Indoor, cages
Holding pens	Cages made from polythene coated steel wire measuring approximately 31.5 x 38.5 x 24 cm; cages were not changed during the study
Number of animals	60 (30 males and 30 females)
Number of animals per pen [cm²/bird]	5 birds of a single sex
Number of animals per dose	One control groups, each with 5 males + 5 females, Five dose groups, each with 5 males + 5 females
Pre-treatment / acclimatisation	Overnight starvation period prior to dosing
Diet during test	Each cage contained an automatic nipple drinker together with a stainless steel food hopper containing standard HRC diet in pellet form. Food was provided ad libitum, with the exception of an overnight starvation period prior to dosing. Water was available at all times.
Dosage levels (of test substance)	2867, 3584, 4480, 5600 and 7000 mg/kg
Replicate/dosage level	Five dose groups were investigated, each dose group with 5 males and 5 females;
Feed dosing method	oral intubation using a catheter and a disposable syringe
Dosing volume per application	n.a.
Frequency, duration and method of animal monitoring after dosing	After treatment, birds were observed daily (post-dosing observation for 14 days). Mortality and adverse effects on behaviour were recorded.
Time and intervals of body weight determination	Daily

Table A7_5_3_1_1-4: Test conditions (housing)

Criteria	Details
Test temperature	15–23°C
Shielding of the animals	No data
Ventilation	No data
Relative huminity	45-64%,
Photoperiod and lighting	17:7 hours light:dark

Table A7_5_3_1_1-5: Acute oral toxicity of fenoxycarb to the bobwhite quail

Dose [mg/kg bw]	Toxicological results [a]	LD_{50} [mg/kg bw]	NOEL [mg/kg bw]
Control	0 / 0 / 10	> 7000	2867 [b]
2867	0 / 0 / 10		
3584	1 / 2d / 10		
4480	0 / 2d/ 10		
5600	0 / 3d / 10		
7000	0 / 4d / 10		

[a] number of birds which died following dosing/ time after dosing when birds were considered to have recovered / total number of birds exposed

[b] based on no clinical signs of toxicity following dosing

Section A7.5.3.1.1 Acute oral toxicity on birds (2)

Annex Point IIIA XIII 1.1 Mallard Duck

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1982b): The acute oral toxicity (LD_{50}) of Ro 13-5223/000 to the Mallard Duck, [redacted], unpublished report No. HLR 103WL/82372 (Syngenta study number CGA114598/0025). Experimental period: March to April 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**	Yes, EPA Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organisms, Series 71-Avian and Mammalian Testing, § 71-1, Avian single dose oral LD_{50} test. Published in the Federal register Vol. 43, No. 132 on 10 July 1978, Part II, Pages 29726 to 29727.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Fenoxycarb technical (Ro 13-5223/000)	
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 in the diet	n.a (see administration, section 3.2)	X
3.2	**Administration of the test substance**	Fenoxycarb, dispersed in corn oil was administered to individual Mallard duck (Anas platyrhynchos) by oral intubation using a catheter and a disposable syringe. See table A7_5_3_1_1-1	
3.3	**Reference substance**	No	
3.3.1	Method of	-	

Section A7.5.3.1.1 Acute oral toxicity on birds (2)

Annex Point IIIA XIII 1.1 Mallard Duck

	analysis for reference substance	
3.4	**Testing procedure**	
3.4.1	Test organisms	See table A7_5_3_1_1-2
3.4.2	Test system	Fenoxycarb, dispersed in corn oil was administered to individual Mallard duck (*Anas platyrhynchos)* by oral intubation using a catheter and a disposable syringe. Sixty adult birds (30 males and 30 females) with a bodyweight range of 785-1230 g at study initiation, were distributed into 6 groups of ten birds each (five males/five females), with five treatment groups and one control group. In addition, 3 males and 3 females were maintained under the same conditions as the test group. These birds were retained for use as possible replacements of any birds that died during the pre-treatment observation period. Of these only 1 male duck was required as a replacement. The birds were housed in pens, each measuring approximately 1.2 x 1.5 m. The pens were constructed from galvanised steel with solid sides and a wire mesh floor. Each pen contained an automatic nipple drinker together with a food hopper containing standard HRC diet in pellet form. Food was provided *ad libitum*, with the exception of an overnight starvation period prior to dosing. Water was available at all times. Treatment levels: 1229, 1536, 1920, 2400 and 3000 mg/kg bodyweight. All the treatment levels reported refer to the compound as supplied (i.e. no adjustment has been made for purity). The birds were examined for mortality, clinical signs, bodyweight gain and food consumption for a period of 14 days after dosing. See table A7_5_3_1_1-3
3.4.3	Diet	Each pen contained an automatic nipple drinker together with a food hopper containing standard HRC diet in pellet form. Food was provided ad libitum, with the exception of an overnight starvation period prior to dosing. Water was available at all times.
3.4.4	Test conditions	See table A7_5_3_1_1-4
3.4.5	Duration of the test	Post-dosing observation: 14 days
3.4.6	Test parameter	The birds were examined daily for mortality, clinical signs, body weight gain and food consumption for a period of 14 days after dosing.
3.4.7	Examination/ Observation	Mortality and birds health were observed daily, bodyweight was determined on days -14, -7, 0 (day of treatment), 3, 7 and 14. Food consumption was determined for the following periods: days -7 to 0. days 1 to 7 and days 8 to 14. All birds were examined at death or termination of the study for gross pathological changes.
3.4.8	Statistics	Since there was no test mortality an LC_{50} could not be calculated
		4 RESULTS
4.1	**Limit Test / Range finding test**	No

Section A7.5.3.1.1 Acute oral toxicity on birds (2)

Annex Point IIIA XIII 1.1 Mallard Duck

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	Applied concentrations	1229, 1536, 1920, 2400 and 3000 mg/kg bodyweight	
4.2.2	Effect data (Mortality)	There were no mortalities	
4.2.3	Body weight	Group mean bodyweight changes were within normal limits and no treatment-related effects were apparent.	
4.2.4	Feed consumption	No anomalies observed	
4.2.5	Concentration / response curve	-	
4.2.6	Other effects	Gross necropsy: At the end of the study 3 birds (1 male and 2 females), 4 birds (2 males and 2 females), 5 birds (1 male and 4 females), 3 birds (1 male and 2 females), 4 birds (1 male and 3 females) and 4 birds (1 male and 3 females) in the control, 1229, 1536, 1920, 2400 and 3000 mg test item/kg bodyweight treatments, respectively were found to have pale livers during the post-mortem. The observations made were not considered to be related to treatment with fenoxycarb.	
4.3	**Results of controls**	There were mortalities in the control group. All birds were normal in appearance and behaviour throughout the test period.	X
4.3.1	Number/ percentage of animals showing adverse effects	-	
4.3.2	Nature of adverse effects	-	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	-	
4.4.2	Results	-	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A sample of fenoxycarb was tested for acute oral toxicity to adult Mallard ducks. The test complies with US-EPA Pesticide Assessment Guidelines, FIFRA Subdivision E, § 71-1 "Avian single dose oral LD_{50} test". Groups of ten mallards, five males and five females were assigned	

Section A7.5.3.1.1 Acute oral toxicity on birds (2)

Annex Point IIIA XIII 1.1 Mallard Duck

		randomly to each of the five treatment groups (1229, 1536, 1920, 2400 and 3000 mg a.i./kg b.w.) and the control group. Following test initiation until termination all birds were observed for mortality, clinical signs, body weight gain and food consumption
5.2	**Results and discussion**	No Mallard duck died in all treatments and the control throughout the study. At the end of the study some birds were found to have pale livers during the post-mortem, at all treatment levels. The observations made were not considered to be related to treatment with fenoxycarb.
5.2.1	LD_{50}	> 3000 mg a.i./kg bw
5.2.2	NOEC	= 3000 mg a.i./kg bw
5.3	**Conclusion**	The mortality rate in the control was below 10%. Therefore the validity criterion for avian acute oral toxicity test according to US-EPA method is fulfilled.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.5.3.1.1 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/07/04
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_3_1_1-1: Method of administration of the test substance

Carrier/Vehicle	Details
Water	No
Organic carrier	Yes; corn oil
concentration of the carrier [% v/v]	Not mentioned
Other vehicle	No
Function of the carrier / vehicle	Solvent for test substance

Table A7_5_3_1_1-2: Test animals

Criteria	Details
Species/Strain	Mallard duck (*Anas platyrhynchos*)
Source	Not specified
Age (in weeks), sex and initial body weight (bw)	Age: adult animals Sex: males and females; Body weights ranged from 785-1230 grams at study initiation
Breeding population	No data
Amount of food	Food was provided ad libitum, with the exception of an overnight starvation period prior to dosing. Water was available at all times.
Age at time of first dosing	Age: adult animals
Health condition / medication	All birds appeared to be in good health at initiation of the study.

Table A7_5_3_1_1-3: Test system

Criteria	Details
Test location	Indoor, pens
Holding pens	Pens measured approximately 1.2 x 1.5 m. The pens were constructed from galvanised steel with solid sides and a wire mesh floor.
Number of animals	60 (30 males and 30 females)
Number of animals per pen [cm²/bird]	5 birds of a single sex
Number of animals per dose	One control groups, each with 5 males + 5 females, Five dose groups, each with 5 males + 5 females
Pre-treatment / acclimatisation	Overnight starvation period prior to dosing
Diet during test	Each pen contained an automatic nipple drinker together with a food hopper containing standard HRC diet in pellet form. Food was provided ad libitum, with the exception of an overnight starvation period prior to dosing. Water was available at all times.
Dosage levels (of test substance)	1229, 1536, 1920, 2400 and 3000 mg/kg
Replicate/dosage level	Five dose groups were investigated, each dose group with 5 males and 5 females;
Feed dosing method	oral intubation using a catheter and a disposable syringe
Dosing volume per application	n.a.
Frequency, duration and method of animal monitoring after dosing	After treatment, birds were observed daily (post-dosing observation for 14 days). Mortality and adverse effects on behaviour were recorded.
Time and intervals of body weight determination	Daily

Table A7_5_3_1_1-4: Test conditions (housing)

Criteria	Details
Test temperature	14–21°C
Shielding of the animals	No data
Ventilation	No data
Relative huminity	60-84%
Photoperiod and lighting	17:7 hours light:dark

Table A7_5_3_1_1-5: Acute oral toxicity of fenoxycarb to the mallard duck

Dose [mg/kg bw]	Toxicological results [a]	LD_{50} [mg/kg bw]	NOEL [mg/kg bw]
Control	0 / 10	**> 3000**	**3000** [b]
1229	0 / 10		
1536	0 / 10		
1920	0 / 10		
2400	0 / 10		
3000	0 / 10		

[a] number of birds which died following dosing / time after dosing when birds were considered to have recovered / total number of birds exposed

[b] based on no clinical signs of toxicity following dosing

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2 Bobwhite quail

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1993): Fenoxycarb - A dietary LC_{50} study with the Northern bobwhite. [redacted] unpublished project No. 108-354 (Syngenta study number CGA114597/0424). Experimental period: October 1st to October 9th 1992.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Syngenta	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, EPA Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organisms, Series 71-Avian and Mammalian Testing, § 71-2, Avian dietary LC_{50} test, dated October 1982 OECD Guidelines for Testing of Chemicals number 205, "Avian Dietary Toxicity Test" adopted 4th April 1984. ASTM Standard E857-87. (1987) "Standard practice for conducting subacute dietary toxicity tests with avian species". American Society for Testing and Materials.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Technical grade fenoxycarb, and 97.8%	
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 in the diet	Analysis was performed but the analytical method is not mentioned in the report.	X
3.2	**Administration of the test substance**	Fenoxycarb was dispersed in acetone/corn oil (comprising 2% of diet) and incorporated into the standard feed by homogenising with a Hobart mixer. See table A7_5_3_1_2-2	

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2 Bobwhite quail

3.3	**Reference substance**	No	
3.3.1	Method of analysis for reference substance	-	
3.4	**Testing procedure**		
3.4.1	Test organisms	See table A7_5_3_1_2-1	
3.4.2	Test system	Bobwhite quail (*Colinus virginianus*) were reared from eggs incubated at [redacted] until required for testing. The birds were 10 days old at the initiation of the study. Healthy bobwhite quail (19-20 g at test start) were assigned to the various treatment groups by indiscriminate draw without regard to sex, which could not be determined due to the chicks age. Ten birds were utilised per group, with five treatment groups and four control groups. The appropriate diet and water was provided *ad libitum*. Fenoxycarb was dispersed in acetone/corn oil (comprising 2% of diet) and incorporated into the standard feed by homogenising with a Hobart mixer. Nominal dietary concentrations used in this study were 562, 1000, 1780, 3160 and 5620 mg ai/kg feed. The birds were exposed to the appropriate dietary concentrations for five days and then maintained on basal (fenoxycarb-free) diet for an additional three-day observation period. The control birds received the basal diet containing an amount of carrier equivalent to the greatest amount used in the treated diets. The birds were housed in pens (10 chicks/pen), each measuring approximately 72 x 90 cm, with a ceiling height of approximately 23 cm. Mortality and symptoms of toxicity were recorded at least twice daily following dosing throughout the study. Bird body weights were registered upon initiation of the study and also on Days 5 and 8. Feed consumption was recorded during the five-day exposure period and three-day observation period. Feed consumption although accurately measured is presented as an estimate due to unavoidable wastage by the birds. See table A7_5_3_1_2-2	
3.4.3	Diet	See table A7_5_3_1_2-2	
3.4.4	Test conditions	See table A7_5_3_1_2-3	
3.4.5	Duration of the test	9 days: 5 treatment days and 3 days post-exposure observation period	X
3.4.6	Test parameter	Mortality, toxic signs, body weight changes, feed consumption	
3.4.7	Examination/ Observation	Mortality and symptoms of toxicity were recorded at least twice daily following dosing throughout the study. Bird body weights were registered upon initiation of the study and also on Days 5 and 8. Feed consumption was recorded during the five-day exposure period and three-day observation period. Feed consumption although accurately measured is presented as an estimate due to unavoidable wastage by the birds.	
3.4.8	Statistics	Since there was no mortality at the highest concentration tested, an LC_{50} could not be determined	
		4 RESULTS	
4.1	**Limit Test / Range**	No	

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2 Bobwhite quail

	finding test	
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	Applied concentrations	Nominal dietary concentrations: 0, 562, 1000, 1780, 3160 and 5620 mg ai/kg feed Samples collected from the 562 and 5620 mg/kg diets and analysed to determine homogeneity of the test item in the diets gave mean measured values that were equivalent to 104% and 103% of nominal, respectively. Diet samples from the same treatments taken after five days from the feeders used in the study gave mean measured values that were equivalent to 106% and 117% of nominal, respectively. Measured concentrations of the test item in the diet for verification samples submitted for analysis were 101%, 101%, 104%, 102% and 106% of nominal values for the 562, 1000, 1780, 3160 and 5620 mg/kg feed, respectively.
4.2.2	Effect data (Mortality)	A single mortality occurred in one of the control groups on day 8. Prior to death the bird was noted as depressed, in addition to being ruffled in appearance, this bird also demonstrated lower limb weakness and stumbled when walking. All other birds in the control group demonstrated no adverse or abnormal effects, either in appearance or in behavioural character during the test period. No mortalities or overt signs of treatment-related toxicity were observed at any of the fenoxycarb concentrations tested. See Table A7_5_3_1_2-4.
4.2.3	Body weight	When compared to the controls there may have been a slight reduction in body weight gain between days 0 and 5 among birds in the 3160 and 5620 mg/kg treatment groups.
4.2.4	Feed consumption	Feeding consumption appeared to be unaffected in all of the concentrations tested.
4.2.5	Concentration / response curve	-
4.2.6	Other effects	Except for one bird in one of the controls, all birds at all concentrations were normal in appearance and behaviour throughout the study
4.3	**Results of controls**	At day 8 (3 day pot-exposure) one of the 40 birds died, which is within the accepted range of mortality for this type of test
4.3.1	Number/ percentage of animals showing adverse effects	-
4.3.2	Nature of adverse	-

Section A7.5.3.1.2 Short-term toxicity on birds

Annex Point IIIA XIII 1.2 Bobwhite quail

	effects	
4.4	**Test with reference substance**	Not performed
4.4.1	Concentrations	-
4.4.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	In a five-day dietary toxicity study according to US-EPA FIFRA Guideline 71-2, OECD guidelines 205 and ASTM Standard E857-87, 10 days old juvenile bobwhite quails (*Colinus virginianus*) were fed nominal dietary levels of 562, 1000, 1780, 3160 and 5620 mg fenoxycarb/kg diet. The control groups received an amount of carrier in their diet equivalent to the greatest amount used in the treated diets. During the treatment mortality and symptoms of toxicity were recorded at least twice daily. After treatment, the condition of the quails was monitored on untreated feed for three days.
5.2	**Results and discussion**	There were no mortalities or overt signs of toxicity at any of the concentrations tested. All birds were normal in appearance and behaviour throughout the test period. There was only slight reduction of body weight at the two highest test concentrations when compared with the controls.
5.2.1	LC_{50}	LC_{50} > 5620 mg a.i./kg diet
5.2.2	NOEC	NOEC = 1780 mg a.i./kg diet
5.3	**Conclusion**	Validity criteria for short-term avian toxicity test according to OECD Guideline 205 which are given in Table A7_5_3_1_2-5, can be considered as fulfilled.
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	
	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_3_1_2-1: Test animals

Criteria	Details
Species/Strain	Bobwhite quail (*Colinus virginianus*)
Source	reared from eggs incubated at [redacted] until required for testing
Age, sex and initial body weight (bw)	Age: 10 days at study initiation Sex: unknown (could not be determined due to the chicks age) Body weight of birds at test start: 19-20 g at study initiation
Breeding population	No data.
Amount of food	Water and feed were provided *ad libitum*.
Age at time of first dosing	Age: 10 days
Health condition / medication	All birds appeared to be in good health at initiation of the study.

Table A7_5_3_1_2-2: Test system

Criteria	Details
Test location	Indoor, pens
Holding pens	The birds were housed in pens, each measuring approximately 72 x 90 cm, with a ceiling height of approximately 23 cm.
Number of animals	90 (10 per group, with five treatment groups and four controls)
Number of animals per pen [cm²/bird]	10 birds of unknown sex
Number of animals per dose	Four control groups and five test concentrations (nominal dietary concentrations: 562, 1000, 1780, 3160 and 5620 mg a.i./kg diet). Each treatment or control group contained ten Bobwhite quails.
Pre-treatment / acclimatisation	Birds exhibiting abnormal behaviour or physical injury were not used for the test.
Diet during test	The appropriate diet and water was provided *ad libitum*. Fenoxycarb was dispersed in acetone/corn oil (comprising 2% of diet) and incorporated into the standard feed by homogenising with a Hobart mixer.. The birds were exposed to the appropriate dietary concentrations for five days and then maintained on basal (fenoxycarb-free) diet for an additional three-day observation period. The control birds received the basal diet containing an amount of carrier equivalent to the greatest amount used in the treated diets.
Dosage levels (of test substance)	Birds were exposed for five days to nominal dietary concentrations of 0, 562, 1000, 1780, 3160 and 5620 mg a.i./kg diet.
Replicate/dosage level	Five dose groups were investigated, no replicates
Feed dosing method	Orally by feed
Dosing volume per application	Food was available *ad libitum*
Frequency, duration and method of animal monitoring after dosing	Mortality and symptoms of toxicity were recorded at least twice daily following dosing throughout the study. Bird body weights were registered upon initiation of the study and also on Days 5 and 8. Feed consumption was recorded during the five-day exposure period and three-day observation period.
Time and intervals of body weight determination	Bird body weights were registered upon initiation of the study and also on Days 5 and 8.

Table A7_5_3_1_2-3: Test conditions (housing)

Criteria	Details
Test temperature	average temperature in the brood compartment of the pens was 37 ± 2°C
Shielding of the animals	No data
Ventilation	No data
Relative humidity	47 ± 14%.
Photoperiod and lighting	16-hour photoperiod was maintained throughout the study with an estimated light intensity of 439 lux.

Table A7_5_3_1_2-4: Short-term dietary toxicity of fenoxycarb to the Bobwhite quail

Nominal Concn. Level (mg/kg feed)	Toxicological Results - Mortalities on Day x			LLC (mg/kg feed)	LC_0 (mg/kg feed)	LC_{50} (mg/kg feed)	NOEC (mg/kg feed)
	Day 1	Day 4	Day 8				
0	0 / 40	0 / 40	1 / 40	**> 5620**	**> 5620**	**> 5620**	**1780**
562	0 / 10	0 / 10	0 / 10				
1000	0 / 10	0 / 10	0 / 10				
1780	0 / 10	0 / 10	0 / 10				
3160	0 / 10	0 / 10	0 / 10				
5620	0 / 10	0 / 10	0 / 10				

LLC Lowest Lethal Concentration

Table A7_5_3_1_2-5: Validity criteria for short-term avian toxicity test according to OECD Guideline 205

	fulfilled	Not fulfilled
Mortality of control animals < 10 %	X	
Test substance concentration > 80 % of nominal concentration throughout the dosing period	X	
Lowest treatment level causing no compound-related mortality or other observable toxic effects	X	

Section A7.5.3.1.3 Annex Point IIIA 13.1.3	Effects on birds: Effects on reproduction	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure** [X]	**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 FI	
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 A7.5.4.1

Annex Point IIIA XIII.3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators (1)

Apis mellifera (honeybee)

Official use only

1 REFERENCE

1.1	**Reference**	Wilde, P. (1982): Acute oral toxicity test on RO 13-5223/000 in Honey bees, RCC Ltd. P.O. Box, CH-4452; Itingen; Switzerland. Unpublished report No. 007446 (Syngenta No. CGA114597/0031). Reported June 3rd 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**	Yes; Pesticides safety precautions scheme, United Kingdom, Working Document D3. Laboratory testing for toxicity to honey bees, "Oral toxicity test", revised 1979, Ministry of Agriculture, Fisheries and Food, London.
2.2	**GLP**	No
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	RO 13-5223/000 (synonymous with fenoxycarb technical)
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	No analysis conducted
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	The technical material was dissolved in acetone, before the test concentration series was prepared by diluting in 20% sucrose solution. The treatments were as follows: Four concentrations of fenoxycarb (ranging from 750 – 1750 mg ai/L), one control dose (20% sucrose-water solution: acetone, 9:1). See table A7_5_4_1-1
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Section A7.5.4.1

Annex Point IIIA XIII.3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators (1)

Apis mellifera (honeybee)

3.4	**Testing procedure**		
3.4.1	Test organisms	Honeybees (Hymenoptera: Apidae); Source: local beekeeper.	
3.4.2	Test system	Bees were dosed by group feeding, using a 20% sucrose solution. The technical material was dissolved in acetone, before the test concentration series was prepared by diluting in 20% sucrose solution. The treatments were as follows: Four concentrations of fenoxycarb (ranging from 750 – 1750 mg ai/L), one control dose (20% sucrose-water solution: acetone, 9:1). Experimental design: 1 replicate/treatment. 10 bees/replicate. Biological observations on mortality and behaviour were made at 4 and 24 hours after dosing. See Table A7_5_4_1-1	
3.4.3	Test conditions	Test temperature 28°C	
3.4.4	Duration of the test	24 hours	
3.4.5	Test parameter	Mortality and behaviour	
3.4.6	Sampling	Biological observations on mortality and behaviour were made at 4 and 24 hours after dosing. Test conditions not monitored.	
3.4.7	Monitoring of TS concentration	No	
3.4.8	Statistics	Logit Model was used to calculate the LC_{50} with its confidential limits.	
		4 RESULTS	
4.1	**Limit Test**	Not performed, various concentrations tested	
4.1.1	Concentration	-	
4.1.2	Number/ percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	Nominal concentrations were 15, 25, 30, 35 µg/bee	X
4.2.2	Actual concentrations of test substance	Not measured	
4.2.3	Effect data (Mortality)	Mortality occurred at every dose tested See Table A7_5_4_1-2	
4.2.4	Concentration / response curve	-	
4.2.5	Other effects	Bees in groups dosed with fenoxycarb at 25 µg ai/bee and above were recorded as tumbling, excited and demonstrating ventral positioning.	X

Section A7.5.4.1
Annex Point IIIA XIII.3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators (1)

Apis mellifera (honeybee)

		Such abnormal behaviours being recorded within 1 hour of the test start. Assuming 20 µL of each concentration was consumed/bee the 24-h acute oral LD_{50} value was determined to be 20.44 µg a.i./bee. For further details see Table A7_5_4_1-2	
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	At the end of the test 20 % mortality had occurred	
4.3.2	Nature of adverse effects	-	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	-	
4.4.2	Results	-	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A 24 - hour oral toxicity test with *Apis mellifera* was conducted in accordance with a UK guideline of 1979 in order to estimate the acute toxicity of fenoxycarb to the honeybee.	
5.2	**Results and discussion**	The 24-hour oral LD_{50} of fenoxycarb to adult honeybees was determined to be 20.44 µg ai/bee.	X
5.2.1	96h-LC_0	not determined (0 % mortality recorded at 15 µg//bee)	X
5.2.2	96h-LC_{50}	20.44 µg a.i./bee	X
5.2.3	96h-LC_{100}	not determined (100 % died at 30 µg//bee)	X
5.3	**Conclusion**	The test can be regarded to give a hint on the toxicity of fenoxycarb to honeybees, although the duration of the test was less than the recommended in current guidelines and details on the test conditions are missing. Furthermore, the validity criteria are not fulfilled, as > 10 % bees died in the control.	
5.3.1	Other Conclusions	-	
5.3.2	Reliability	3	
5.3.3	Deficiencies	Non-GLP, only 24 hours tested (according to current guidelines the test period should be at least 48 hours), test conditions data missing, > 10 % mortality in the control.	

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_5_4_1-1: Test system

Criteria	Details
Test type	acute oral
Test substance application	Bees were dosed by group feeding, using a 20% sucrose solution.
Number of animals/vessel	10 bees/replicate
Number of vessels/ concentration	1 replicate/treatment

Table A7_5_4_1-2: Acute oral toxicity of fenoxycarb to adult honey bees

Dose level[a] [µg ai/bee]		Mortality following oral exposure [%]		Exposure period [hours]	LD_{50}[a] [µg ai/bee]
		4 h	24 h		
Control	sucrose	10	20		
Fenoxycarb	15	0	20	4	23.48 (95% confidence limits of 20.36 – 27.1)
	25	50	60		
	30	100	100		
	35	100	100	24	20.44 (95% confidence limits of 15.44 – 25.4)

[a] Assumes 20µL of dose consumed by each bee, as all doses were consumed within 4 hours.

Section A7.5.4.1

Annex Point IIIA XIII.3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators (2)

Apis mellifera (honeybee)

Official use only

1 REFERENCE

1.1	**Reference**	Winter, P.A., Hoxter, K.A. & Smith, G.J. (1992): Fenoxycarb technical - An acute contact toxicity study with the honey bee, Wildlife International Ltd. 8598 Commerce Drive, Easton, Maryland. MD 21601, USA. Unpublished report No. 294-102A (Syngenta No. CGA114597/0411). Experimental period: October 9th 1990 to October 11th 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; Environmental Protection Agency. 1982. (October). Pesticide Assessment Guidelines, FIFRA Subdivision L., Hazard Evaluation: Non-target Insects, Subsection 141-1. Office of Pesticide Programs Washington, D.C.
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	-
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	No analysis conducted
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	The test substance was dissolved in acetone. Bees received five test doses of fenoxycarb ranging from 13 to 100 µg ai/bee. In addition an untreated control and a solvent control (acetone) were included in the test. See table A7_5_4_1-1
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

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Annex Point IIIA XIII.3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators (2)

Apis mellifera (honeybee)

3.4	**Testing procedure**	
3.4.1	Test organisms	Honeybees (Hymenoptera: Apidae); Source: hives maintained by Wildlife International Ltd., Easton, Maryland, USA Age: 1-6 days old.
3.4.2	Test system	Bees were dosed by topical application (volume of applied dose 2 µl/bee). Nominal concentrations were used. The test substance was dissolved in acetone. Bees received five test doses of fenoxycarb ranging from 13 to 100 µg ai/bee. In addition an untreated control and a solvent control (acetone) were included in the test. Test duration: 48 h. For each control or test item treatment two replicate groups of 25 bees were tested. Biological observations on mortality and behaviour were made immediately following dosing and at 24 and 48 hours after application. See Table A7_5_4_1-1
3.4.3	Test conditions	Photoperiod was 8 hours of light per day. Ambient temperatures in the test rooms ranged from 22 to 23°C. Mean relative humidity was 91%.
3.4.4	Duration of the test	48 hours
3.4.5	Test parameter	Mortality and behaviour
3.4.6	Sampling	Biological observations on mortality and behaviour were made immediately following dosing and at 24 and 48 hours after application. Test conditions not monitored.
3.4.7	Monitoring of TS concentration	No
3.4.8	Statistics	LD_{50} value was calculated by probit analysis.
		4 RESULTS
4.1	**Limit Test**	Not performed, various concentrations tested
4.1.1	Concentration	-
4.1.2	Number/ percentage of animals showing adverse effects	-
4.1.3	Nature of adverse effects	-
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Nominal concentrations were 13, 22, 36, 60, 100 µg/bee
4.2.2	Actual concentrations of test substance	Not measured
4.2.3	Effect data (Mortality)	Mortality in the 13 and 22 µg ai/bee doses were 8% and 6%, respectively after 48 hours. One immobile bee was observed soon after dosing in the higher of these two doses, but neither this nor the mortality

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Annex Point IIIA XIII.3.1

Acute toxicity to honeybees and other beneficial arthropods, for example predators (2)

Apis mellifera (honeybee)

		were considered to be treatment related. The 48-hour mortality in the 36, 60 and 100 µg ai/bee doses were 14%, 22% and 28%, respectively. The mortality that occurred in the group was dose response-related and was considered to be treatment related. See Table A7_5_4_1-2	
4.2.4	Concentration / response curve	Not given	
4.2.5	Other effects	Immobile bees were observed soon after treatment in the 36 and 100 µg ai/bee treatments and at least in the latter of these two treatments this was possibly treatment related. For further details see Table A7_5_4_1-2	
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	At the end of the test 2 % mortality had occurred	X
4.3.2	Nature of adverse effects	-	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	-	
4.4.2	Results	-	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A 48 - hour topic toxicity test with *Apis mellifera* was conducted in accordance with a US-EPA guideline for pesticides (Subsection 141-1) in order to estimate the acute toxicity of fenoxycarb to the honeybee.	
5.2	**Results and discussion**	The 48-hour contact LD_{50} for fenoxycarb with adult honeybees is >100 µg ai/bee. The mortality that occurred in the groups was treatment related.	
5.2.1	96h-LC_0	not determined	
5.2.2	96h-LC_{50}	> 100 µg a.i./bee	
5.2.3	96h-LC_{100}	>> 100 µg a.i./bee	
5.3	**Conclusion**	The test is considered valid, since <10 % mortality was seen in the control	X
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	2006/07/04
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_5_4_1-1: Test system

Criteria	Details
Test type	Acute contact
Test substance application	Droplets of the test solution in acetone were applied to the honeybees Volume of the applied bees: 2µL/bee
Number of animals/vessel	25 bees/replicate
Number of vessels/ concentration	2 replicate/treatment

Table A7_5_4_1-2: Acute contact toxicity of fenoxycarb to adult honey bees

Dose level [µg/bee]		Mortality following contact exposure [%]		Exposure period [hours]	LD_{50} (95 % conf. interval) [µg ai/bee]
	nominal	24 h	48 h		
control	untreated	2	2		
control	acetone	40	42		
fenoxycarb technical	13	6	8	48	> 100
	22	6	6		
	36	14	14		
	60	16	22		
	100	24	28		

Section A7.5.5 Bioconcentration, terrestrial / further studies

Annex Point IIIA 13.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	Fàbregas, E. (2007): Calculation of the Bioconcentration Factor in earthworms ($BCF_{earthworm}$) of fenoxycarb. Dr. Knoell Consult, Leverkusen, Germany, Report No. KC-BCF-02/07, date: 2007-03-12 (unpublished).	
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 K_{ow} = 4.07; K_{ow} = 11600 (Ref.: Rodler, 1992)	X
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 earthworm was calculated using the equation 82d of the Technical Guidance Document (EU, 2003). The bioconcentration factor can be measured experimentally directly. However, a specific test guideline for such a test is not available at the time being. The assessment of the $BCF_{earthworm}$ is necessary for chemicals which are, based on the use pattern, considered to enter the soil compartment.	

Another possibility is the estimation of $BCF_{earthworm}$ from $logK_{ow}$. When measured data on bioconcentration in earthworms is not available the BCF will have to be estimated. For organic chemicals, the main route of uptake into earthworms will be via the interstitial water.

Bioconcentration can be described as a hydrophobic partitioning between the pore water and the phases inside the organism and can be modelled according to the following equation as described by Jager (1998):

$BCF_{earthworm} = (0.84 + 0.012K_{ow})/RHO_{earthworm}$

where for $RHO_{earthworm}$ by default a value of 1 ($kg_{wwt}.L^{-1}$) can be assumed.

Jager (1998) has demonstrated that this approach performed very well in describing uptake in experiment with earthworms kept in water. For soil exposure, the scatter is larger and the experimental BCFs are generally somewhat lower than the predictions by the model. The reasons for this discrepancy are unclear but may include experimental difficulties (a lack of equilibrium or purging method) or an underestimated sorption*.

*According to certain studies some soil ingesting organisms may accumulate chemical substances not only from the soil pore water but also directly (possibly by extraction in the digestive tract) from the fraction of the substance adsorbed onto soil particles. This may become important for strongly adsorbing chemicals, e.g. those with a $logK_{ow} > 3$. For these compounds the total uptake may be underestimated. In other studies however it has been shown that soil digesters virtually only bioaccumulate the substance via the pore water, i.e. bioconcentrate chemical substances from the soil pore water. At present the latter process can be modelled by use of the equilibrium partitioning theory (cf. also Section 3.5 of TGD).

The model was supported by data with neutral organic chemicals in soil within the range log K_{ow} 3-8 and in water-only experiments from 1-6. An application range of 1-8 is advised and it is reasonable to assume that extrapolation to lower K_{ow} values is possible. The model could also be used for chlorophenols when the fraction in the neutral form was at least 5% and when both sorption and BCF are derived from the K_{ow} of the neutral species. The underlying data are however too limited to propose this approach in general for ionised chemicals.

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 ($BCF_{earthworm}$)	Bioconcentration factor in earthworm is not based on measurements
4.1.5	Uptake and depuration rate constants	--

Section A7.5.5 Bioconcentration, terrestrial / further studies

Annex Point IIIA 13.3

4.1.6	Depuration time	--	
4.1.7	Metabolites	--	
4.1.8	Other Observations	--	
4.2	**Estimation of bioconcentration**	The obtained $BCF_{earthworm}$ by this method is 140.04	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The $BCF_{earthworm}$ of fenoxycarb was estimated using the QSAR-approach as recommended in the Technical Guidance Document (EU, 2003) based on a measured log K_{ow} value. If measured $BCF_{earthworm}$ values are not available, the BCF for earthworms can be predicted from the relationship between K_{ow} and $BCF_{earthworm}$. For organic chemicals, the main route of uptake into earthworms will be via the interstitial water. Bioconcentration can be described as a hydrophobic partitioning between the pore water and the phases inside the organism and can be modelled according to the following equation as described by Jager (1998): $BCF_{earthworm} = (0.84 + 0.012K_{ow})/RHO_{earthworm}$	
5.2	Results and discussion	Considering a log K_{ow}-value of 4.07 or K_{ow} of 11600 which was obtained in a previously performed experimental study, the calculated $BCF_{earthworm}$-value of fenoxycarb was about 140.04.	X
5.3	**Conclusion**	Based on a log K_{ow} value of 4.07, obtained from an experimental study, a $BCF_{earthworm}$ of 140.04 is obtained. This value indicates a moderate bioaccumulation potential of fenoxycarb in earthworms.	X
5.3.1	Reliability	2	
5.3.2	Deficiencies	--	

[redacted]

	[redacted]
	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	acceptable
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 A7.5.6 Annex Point IIIA 13.3	Effects on other terrestrial non-target organisms	
	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 FI	
Date	12/02/2008	
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 A7.5.7.1.1 Annex Point IIIA 13.3	Effects on mammals: Acute oral 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 FI	
Date	2006/07/05	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Subsection (Annex point)		Official use only
8.1 (IIA, VIII 8.1)	**Recommended methods and precautions concerning handling, use, storage, transport or fire**	
8.1.0 Methods and precautions concerning placing on the market	Please refer to information given below.	
8.1.1 Methods and precautions concerning handling and use of the active substance	General information: Avoid contact with skin, eyes and clothing. Avoid inhalation by dust. Do not eat, drink or smoke while working. In addition to the measures usually taken in chemical works like dustproof filling and measuring equipment (including dust extraction), further personal protection measures may have to be implemented to avoid possible contact with the product.	X
	Personal protection equipment for exposure control: Suitable personal protective equipment, including goggles or face-shield, impervious gloves and body protection (closed heavy duty cotton or synthetic fabric working clothes (e.g. overalls); heavy duty shoes or boots) must be worn when handling this material. Respiratory protection is normally not required under normal treatment and at room temperature. In case of heavy exposure a dusk mask must be worn. (Reference: Anonymous, 2002)	X
8.1.2 Methods and precautions concerning storage of the active substance	Keep out of the reach of children, in well closed containers away from food and feed. Protect from light and humidity. Storage temperature: Max. storage temperature: 35 °C Min. storage temperature: -5 °C (Reference: Anonymous, 2002)	
8.1.3 Methods and precautions concerning transport of the active substance	Transport information: environmentally hazardous substance, solid, n.o.s. (fenoxycarb). UN No.: 3077 (Reference: Anonymous, 2002)	
8.1.4 Methods and precautions concerning fire of the active substance	Extinguishing media: Dry chemical powder, foam, carbon dioxide or waterspray (no direct jet of water). Protective equipment: gloves, protective clothing and respiratory protection. Measures have to be taken to prevent the contaminated extinguishing agent from seeping into the ground or from spreading uncontrollably. (Reference: Anonymous, 2002)	X
8.2 (IIA, VIII 8.2)	**In case of fire, nature of reaction products, combustion gases, etc.** Fenoxycarb contains the elements carbon, hydrogen, nitrogen and oxygen. In the event of fire the formation of carbon monoxide, carbon dioxide, nitrogen oxides must be anticipated.	

Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.3 (IIA, VIII 8.3) **Emergency measures in case of an accident**

8.3.1 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available

Personal precautions:

Avoid contact with skin, eyes and clothing. Avoid inhalation by dust. Please consider the recommended personal protective equipment concerning handling and use of the active substance (Subsection 8.1.1).

First aid measures:

EYE CONTACT: Immediately flush eyes with plenty of water for at least 10 minutes and call a physician.

INGESTION: Repeatedly administer a large quantity of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

SKIN CONTACT: Remove contaminated clothing and wash exposed skin with plenty of soap and water.

INHALATION: If symptoms are experienced, move to fresh air and get medical attention.

NOTE TO PHYSICIAN: No specific antidote is known. Symptomatic treatment.

(Reference: Anonymous, 2002)

8.3.2 Emergency measures to protect the environment

Collect product in containers for safe disposal. Dampen solid material carefully to prevent its being blown away. Collect material in specially marked, tightly closing containers. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative. Do not contaminate waters and sewers.

(Reference: Anonymous, 2002)

8.4 (IIA, VIII 8.4) **Possibility of destruction or decontamination following release in or on the following: (a) air, (b) water, including drinking water, (c) soil**

8.4.1 Possibility of destruction or decontamination following release in the air

The active substance fenoxycarb is a solid with a very low vapour pressure. Therefore a decontamination of the environmental compartment air by fenoxycarb is negligible after its release into the environment due to an accidental misuse.

8.4.2 Possibility of destruction or decontamination following release in water, including drinking water

Contaminated water must be contained. It may be decontaminated by filtration using charcoal and then concentrated. The water should be incinerated. The charcoal can be disposed of in a suitable waste incineration plant in accordance with official regulations.

Section A8	MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT	
8.4.3 **Possibility of destruction or decontamination following release in or on soil**	Dampen solid material carefully to prevent its being blown away. Collect product in containers for safe disposal. Collect material in specially marked, tightly closing containers. Clean dirty areas with carbonated or soapy water. Put washing water in containers too, to avoid any contamination of surface and ground water, water supplies and drains. Hose down the area for a prolonged period. Heavily contaminated soil layers have to be dug out down to clean soil. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative and dispose of in an incinerator approved for chemicals. Do not contaminate waters and sewers. (Reference: Anonymous, 2002)	
8.5 **(IIA, VIII 8.5)**	**Procedures for waste management of the active substance for industry or professional users**	
8.5.1 **Possibility of re-use or recycling** **(IIA, VIII 8.5.1)** **8.5.2** **Possibility of neutralisation of effects** **(IIA, VIII 8.5.2)** **8.5.3** **Conditions for controlled discharge including leachate qualities on disposal** **(IIA, VIII 8.5.3)** **8.5.4** **Conditions for controlled incineration** **(IIA, VIII 8.5.4)**	Product disposal: Pay attention to protective clothing and measures. Dampen solid material carefully to prevent its being blown away. Collect product in containers for safe disposal. Collect material in specially marked, tightly closing containers. Clean dirty areas with carbonated or soapy water. Put washing water in containers too, to avoid any contamination of surface and ground water, water supplies and drains. Hose down the area for a prolonged period. Heavily contaminated soil layers have to be dug out down to clean soil. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative and dispose of in an incinerator approved for chemicals. Container disposal: Dispose of empty containers in an incinerator approved for chemicals. Damaged containers: place originals in specially marked larger ones. Check possibilities of recycling large empty containers, drums and barrels. (Reference: Anonymous, 2002)	X
8.6 **(IIA, VIII 8.6)**	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms** No undesirable or unintended side-effects on beneficial or other non-target organisms were observed for the active substance fenoxycarb.	
8.7 **(IIIA, VIII 1)**	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances** Biocides and their derivatives are classed in List II of the Annex to Directive 80/68/EEC.	

Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10.08.2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

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

Section A8 **Subsection A8.6** **Annex Point IIA, VIII 8.6**	**Measures necessary to protect man, animals and the environment** OBSERVATIONS ON UNDESIRABLE OR UNINTENDED SIDE-EFFECTS, E.G. ON BENEFICIAL AND OTHER NON-TARGET ORGANISMS	
	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	2008-02-11	
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 A9 Classification and Labelling

Annex Point IIA, IX Active substance fenoxycarb

Official use only

Current classification / labelling according to Directive 1967/548/EEC:

Hazard symbol:	N
Indication of danger:	Dangerous for the environment
Risk phrases:	R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Safety phrases:	S60: This material and its container must be disposed of as hazardous waste.
	S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

Justification: No classification results from the physico-chemical and toxicological properties of the active substance. Ecotoxicological studies with fish, invertebrates and algae indicate that fenoxycarb is dangerous for the environment and should be classified as very toxic to aquatic organisms. The active substance must be labelled with R-phrase R50/53.

Proposed classification / labelling according to Directive 1967/548/EEC: For classification / labelling of fenoxycarb please refer to the above given current classification and labelling.

Section A9 Classification and Labelling

Annex Point IIA, IX Active substance fenoxycarb

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008-02-11
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Adam, D., Nicollier, G.	A7.2.1/01	Fenoxycarb	2001	Rate of Degradation of [Phenoxy-U-14C]-labelled CGA 114597 in one Soil under Various Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland, Report No 01GN02 Syngenta File N° CGA114597/0793 GLP Unpublished	Y	Syngenta
Anonymous	A8.1/01 A8.3/01 A8.4/01 A8.5/01	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen
Anonymous	A8.3/01 A8.1/01 A8.4/01 A8.5/01	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen
Anonymous	A8.4/01 A8.1/01 A8.3/01 A8.5/01	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen
Anonymous	A8.5/01 A8.1/01 A8.3/01 A8.4/01	Fenoxycarb	2002	Safety Data Sheet Farox technical (fenoxycarb). Janssen Pharmaceutica N.V., Beere, Belgium Report No N/A GLP N/A Unpublished	N	Janssen
Anonymous	A6.12/01		12.04.2006	Medical surveillance data on manufacturing plant personnel		

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Anonymous	A6.12/02		12.04.2006	Health monitoring of personnel		
Anonymous	A6.12/03:		12.04.2006	Health records, both from industry		
Anonymous	A6.12/04		12.04.2006	Signs of poisoning		
Anonymous	A6.12/05		12.04.2006	Diagnosis of poisoning		
Anonymous	A6.12/06		12.04.2006	Sensitisation/allergenicity observations		
Anonymous	A6.12/07		12.04.2006	Specific treatment in case of an accident or poisoning		
[redacted]	A6.4.1/01	Fenoxycarb	1993	3-Month Oral Toxicity Study In Rats (Administration In Food). CGA 114597 tech. [redacted], Report No. 92211	N	Syngenta
[redacted]	A6.7/02	Fenoxycarb	1995	18-Month Oncogenicity Study In Mice. CGA 114597 tech. [redacted], Report No. 922117	N	Syngenta
[redacted]	A6.8.2/01	Fenoxycarb	1986	Ro 13-5223/000: 2 Generation Oral (Dietary Administration) Reproduction Study In The Rat. [redacted] Report No. 4623-161/124	N	Syngenta
Bätscher, R.	A7.4.1.2/03	CGA 294850 (fenoxycarb metabolite)	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 GLP Unpublished	Y	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
[redacted]	A6.10/01	Fenoxycarb	1996a	CGA 114597 tech.(Fenoxycarb) - Effects On Biochemical Liver Parameters Following Dietary Administration To Male And Female Mice. [redacted], Report No. CB 95/36	N	Syngenta
[redacted]	A6.10/02	Fenoxycarb	1996b	CGA 114597 tech. (Fenoxycarb) - Effects On Biochemical Lung Parameters Following Dietary Administration To Male And Female Mice. [redacted], Report No. CB 95/46	N	Syngenta
[redacted]	A6.10/04	Fenoxycarb	1997	CGA 114597 (Fenoxycarb) - In Vitro Metabolism By Liver And Lung Of Mouse, Rat, Marmoset And Man. [redacted], Report No. CB 95/45	N	Syngenta
[redacted]	A6.10/05	Fenoxycarb	1998	CGA 114597 tech. (Fenoxycarb) - In Vitro Formation Of Urethane From Fenoxycarb By Liver Microsomes Of Mouse And Man. [redacted], Report No. CB 97/16	Y	Syngenta
[redacted]	A6.3.3/01	Fenoxycarb	1987	Subacute (28-Day) Repeated Dose Inhalation Toxicity Study In Rats. [redacted], Report No. RCC-085500	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Britt, T.	A7.1.1.1.1/01	Fenoxycarb	1994	Hydrolysis of 14C-Fenoxycarb at pH 5, 7 and 9 Novartis Crop Protection AG, Basel, Switzerland Mckenzie Laboratories, Inc., Phoenix, United States, Report No RC-0001 Syngenta File N° CGA114597/0468 GLP Unpublished	N	Syngenta
Burkhard, N.	A3.2/02	No test material (Calculation)	1998	Henry`s law constant. Novartis Crop Protection AG, Basel, Switzerland Brian Christensen Companies, Inc., Minnetonka, United States Report No. N/A GLP Unpublished	N	Syngenta
[redacted]	A7.5.3.1.2	Fenoxycarb	1993	Fenoxycarb - A dietary LC50 study with the Northern bobwhite. [redacted] unpublished project No. 108-354 (Syngenta study number CGA114597/0424). Experimental period: October 1st to October 9th 1992 GLP Unpublished	N	Syngenta
[redacted]	A6.1.5/01	Fenoxycarb	1998	Skin Sensitization in the Guinea Pig (Maximization Test). CGA 114597 tech. [redacted] Report No. 972170	N	Syngenta
[redacted]	A6.2/03	[hydroquinone-U-14C]-Fenoxycarb	1993	Metabolism of 14C-Fenoxycarb in rats (preliminary and definitive phases). [redacted] Report No. HWI 6117-209	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Clark, A.	A7.1.1.1.2/01	Fenoxycarb	1994	Photodegradation of [14C]-Fenoxycarb (Phenyl-14C-CGA-114597) in pH 7 buffered solution under artificial sunlight Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-94071 Syngenta File N° CGA114597/0513 GLP Unpublished	N	Syngenta
Clark, A., Phelps, L. and Cruz, S.	A7.1.1.1.2/01	Fenoxycarb	1995	Photodegradation of [14C]-Fenoxycarb (Phenyl-14C-CGA-114597) in pH 7 buffered solution under artificial sunlight Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-94072 Syngenta File N° CGA114597/0529 GLP Unpublished	N	Syngenta
Das, R.	A3.1.2/01 A3.10/01	Fenoxycarb (pure substance)	1997	Report on boiling point / boiling range. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 55883 GLP Unpublished	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Das, R.	A3.3/01	Fenoxycarb (pure and technical substance)	1999	General physico-chemical properties of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 78916 GLP Unpublished	N	Syngenta
Das, R.	A3.10/01 A3.1.2/01	Fenoxycarb (pure substance)	1997	Report on boiling point / boiling range. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 55883 GLP Unpublished	N	Syngenta
Dorn, R.	A7.2.2.2/02	Fenoxycarb	2003	Calculation of degradation rates for field trials in Europe Syngenta Crop Protection AG, Basel, Switzerland, Report No Ass03RD01 Syngenta File N° CGA114597/0866 non-GLP Unpublished	Y	Syngenta
[redacted]	A6.8.1/02	Fenoxycarb	1983	Embryotoxicity Study In Rats With Oral Administration Of Ro 13 5223/000. Segment II – Teratological Study With Post-Natal Evaluations. [redacted], Report No. B-104875	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Ellgehausen, H	A7.4.1.2/04	Fenoxycarb	1982	Acute toxicity of RO 13-5223 (CGA 114597 tech.) to Daphnia magna (48 Hours EC 50). RCC AG, Itingen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No 007435 Not GLP Unpublished	N	Syngenta
Ellgehausen, H	A7.4.1.3/01	Fenoxycarb	1984	Acute toxicity of Ro 13-5223/000 to Scenedesmus subspicatus (OECD: Algae growth inhibition test). RCC Research and Consulting Company AG CH-4452, Itingen, Switzerland, unpublished report No. 025266 (Syngenta No. CGA114597/0012). Experimental period: November 7th to December 9th 1983 GLP Unpublished	N	Syngenta
Emburey, S.N.	A4.2/02	Fenoxycarb	2004	Validation of a residue analytical method for the determination of residues in soil. Syngenta Crop Protection, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4912B GLP Unpublished	Y	Syngenta
Fàbregas, E.	A7.3.1/01	No test material (Calculation)	2006	Calculation of the Indirect Photodegradation Dr. Knoell Consult, Leverkusen, Germany, 05.01.2006 not GLP Unpublished	Y	Janssen NV

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Fàbregas, E.	A7.4.2	Fenoxycarb	2005	Calculation of the Bioconcentration Factor (BCF) of Fenoxycarb. Dr. Knoell Consult (unpublished) Report No. KC-BCF-02/06, date: 2006-09-29.	Y	Janssen
Fàbregas, E.	A7.5.5	Fenoxycarb	2007	Calculation of the Bioconcentration Factor in earthworms (BCFearthworm) of fenoxycarb. Dr. Knoell Consult, Leverkusen, Germany, Report No. KC-BCF-02/07, date: 2007-03-12 (unpublished).	Y	Janssen
Forbis, A.D.	A7.4.3.4/01	Fenoxycarb	1987b	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 GLP Unpublished	N	Syngenta
Füldner, H.	A3.1.3/01	Fenoxycarb (pure substance)	1992	Report on densitiy of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.VPC GLP Unpublished	N	Syngenta
Galicia, H.	A7.2.3.2/02	Fenoxycarb	1990	CGA 114597 (RO 13-5223), Leaching characteristics of aged residues in BBA soil 2.1 Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 233357 Syngenta File N° CGA114597/0083 GLP Unpublished	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Geffroy, A.	A3.1.1/02 A3.1.2/02	Fenoxycarb	2007	Melting point and boiling point of Fenoxycarb Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland Study Number L07-000500 GLP Unpublished	Y	Syngenta
[redacted]	A6.1.4/01	Fenoxycarb	1992a	Primary Dermal Irritation Study of Fenoxycarb Technical in Rabbits. [redacted], Report No. HWI 20800880	N	Syngenta
[redacted]	A6.1.4/02	Fenoxycarb	1992b	Primary Eye Irritation Study of Fenoxycarb Technical in Rabbits. [redacted], Report No. HWI 20800882	N	Syngenta
Gocke E	A6.6.1/01	Fenoxycarb	1988	Mutagenicity evaluation of fenoxycarb (Ro 13 5223/000) in the Ames assay. F. Hoffmann-La Roche & Co. Ltd., Basel, Switzerland, Report No. B-153'219	N	Syngenta
[redacted]	A6.5/02 A6.7/01	Fenoxycarb	1992	Ro 13 5223/000:104-Week Oral (Dietary Administration) Carcinogenicity And Toxicity Study In The Rat With A 52-Week [redacted] Report No. 5191-161/123R	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Grade, R.	A7.4.1.4/01	Fenoxycarb	2001	Test for Activated Sludge Respiration Inhibition of CGA 1145797 tech.. Syngenta Crop Protection AG, Ecotoxicology, CH-4002 Basel, Switzerland. Unpublished report number: 2002645 (Syngenta No. CGA 114597/0778). Experimental period October 25th 2000 to October 25th 2000 GLP Unpublished	Y	Syngenta
Graf, E., Barkhoff, M., Hamberg, R., Büttner, H. and Pallaske, M.	A5.3/02	Fenoxycarb	2002	The use of insect hormones as non-neurotoxic insecticides in wood preservatives. The International Research Group on Wood Preservation. Sponsored by the "Deutsche Bundestiftung Umwelt", Projekt Nr. DBSU 08176 Report No. IRG/WP 02-30277 Not GLP Published	N	Published
Greulich, K., Alder, L.	A4.2/03		2006	Fast multi residue screening of 300 pesticides in drinking water. Federal Institute for Risk Assessment, Berlin, Germany Report No. BFR-IX-2005 GLP published: http://www.bfr.bund.de/cd/5832	No	Public
Grube and Rudplph	A5.3/01	Fenoxycarb	1998	Abschlußbericht zur Wirksamkeit von FAROX (Fenoxycarb) gegen Hylotrupes bajulus. BAM, FG IV.1, Berlin, Germany ReportNo N/A Not GLP Unpublished	Y	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Haag, M., Leusink-Muis, T., Le Bouquin, R., Nijkamp, F. P., Lugnier, A., Frossard, N., Folkerts, G., Pons, F.	A6.10.2	toluene diisocyana	2002	Increased expression and decreased activity of cytochrome P450 1A1 in a murine model of toluene diisocyanate-induced asthma. Arch Toxicol (2002) 76:621-627	No	Public
Hänni, R.	A7.2.2.2/02	Fenoxycarb	1990	CGA 114597 (Ro-5223), Dissipation of fenoxycarb in soil after application of Insegar (ACR 2907B) under outdoor conditions Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No 6158-88034-88039 Syngenta File N° CGA114597/0110 non-GLP Unpublished	N	Syngenta
Hakin, B. and Johnson, A. B.	A7.5.1.2/01	Fenoxycarb	1990	The acute toxicity (LC50) 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 GLP Unpublished	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Hargreaves, S.L.	A4.2/03	Fenoxycarb	2003a	Residue Analytical method for the Determination of Fenoxycarb Residues in Air (RAM 409/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4834 GLP Unpublished	Y	Syngenta
Hargreaves, S.L.	A4.2/04	Fenoxycarb	2003b	Fenoxycarb: Validation of an Analytical Method for the Determination of Residues in Air (RAM 409/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4834 GLP Unpublished	Y	Syngenta
Hargreaves, S.L.	A4.2/05	Fenoxycarb	2003c	Residue Analytical Method for the determination of Residues of Fenoxycarb in Water (RAM 408/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. RJ3391B GLP Unpublished	Y	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Hargreaves, S.L.	A4.2/06	Fenoxycarb	2003d	Fenoxycarb: Validation of a Residue Analytical Method for the Determination of Residues of Fenoxycarb in Surface Water (RAM 408/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. RJ3391B GLP Unpublished	Y	Syngenta
[redacted]	A6.1.3/01	Fenoxycarb	1992	CGA 114597: Acute Inhalation Toxicity in the Rat. CGA 114597 tech. [redacted] Report No. 911362	N	Syngenta
[redacted]	A6.2/01	[hydroquinone-U-14C]-Fenoxycarb	2003a	The Percutaneous Penetration of [Hydroquinone-U-14C] CGA 114597 Formulated as INSEGAR® 25 WG (A-8995 B) Through Rat and Human Split-Thickness Skin Membranes (in vitro). [redacted] Report No. 029AM03	Y	Syngenta
[redacted]	A6.2/02	[hydroquinone-U-14C]-Fenoxycarb	2003b	Dermal Absorption of [hydroquinone-U-14C] CGA 114597 formulated as INSEGAR□ 25 WG (A 8995 B) in the rat (in vivo). [redacted] Report 029AM03	Y	Syngenta
[redacted]	A6.8.1/01	Fenoxycarb	1984	Embryotoxicity Study In Rabbits With Oral Administration Of Ro 13 5223/000. Segment II – Teratological Study. [redacted], Report No. B-104700	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
[redacted]	A6.2/04	phenyl-14C-(B)-Fenoxycarb	1995	Characterisation and identification of metabolites in rats administered phenyl-14C-(B)-Fenoxycarb. [redacted] Unpublished Report No. ABR-94068	N	Syngenta
Jäkel, K.	A3.6/01	Fenoxycarb (pure substance)	1992	Report on dissociation constant in water. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.DCW GLP Unpublished	N	Syngenta
[redacted]	A6.9/01	Fenoxycarb	1982	Effect Of Ro 13 5223/000 (IGR) On Plasma Cholinesterase In Rats.	N	Syngenta
[redacted]	A6.5/01	Fenoxycarb	1988	Chronic Toxicity Study Following Oral Administration of Ro 13 5223/000, An Insect Growth Regulator, To Dogs For A Period Of One Year. [redacted], Report No. B-153778	N	Syngenta
[redacted]	A7.4.3/01 A7.1.2.2.2/01	Fenoxycarb	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 GLP Unpublished	N	Syngenta

Author(s)	Section No / Reference No	Test Material	Year	Title. Source (where different from company), Company, Report No., GLP (where relevant) / (Un)Published	Data Protection Claimed, (Yes/No)	Owner
Kettner, R.	A3.7/01	Fenoxycarb (technical substance)	2000	Solubility in organic solvents of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 78917 GLP Unpublished	N	Syngenta
[redacted]	A6.1.2/01	Fenoxycarb	1981	Acute Percutaneous Toxicity to Rats of Ro 13□5223/000. [redacted], Report No. 80648D/HLR85/AC	N	Syngenta
Lebertz, H.	A7.1.1.2.1/01	Fenoxycarb	1990	CGA 114597, Ready Biodegradability (modified Sturm test) of RO-13-5223 Novartis Crop Protection AG, Basel, Switzerland Battelle Institut, Frankfurt Germany, Germany, Report No BE-EA-25-89-01-STT-03 Syngenta File N° CGA114597/0093 GLP Unpublished	N	Syngenta
McDonald, J.	A7.2.2.2/01	Fenoxycarb	1995	Terrestrial Field Dissipation of 14C-Fenoxycarb 25WP on Bareground Soil in California Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95022 Syngenta File N° CGA114597/0534 GLP Unpublished	N	Syngenta

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Martin-Keusch, Ch.	A3.13/02	Fenoxycarb	2007	Fenoxycarb techn. Surface tension Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland Study Number 117423 GLP Unpublished	Y	Syngenta
Maynard, S. J. and Swarbrick, R.H.	A7.4.1.3/02	CGA 294847 (fenoxycarb metabolite)	2002	CGA 294847 (fenoxycarb metabolite): Toxicity to the Green Alga, Selenastrum capricornutum. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon TQ5 8BA. Unpublished report number 2022504 (Syngenta No. CGA294847/0005). Experimental period: September 30th 2002 to October 4th 2002 GLP Unpublished	Y	Syngenta
[redacted]	A7.4.1.1/02	CGA294847 (fenoxycarb metabolite)	2002	CGA294847 (fenoxycarb metabolite): Acute toxicity to rainbow trout (Oncorhynchus mykiss). [redacted] Unpublished report number 2022502 (Syngenta No. CGA294848/0003). Experimental period: September 30th 2002 to October 4th 2002 GLP Unpublished	Y	Syngenta
Meyer, K.	A3.17/01	Fenoxycarb	1991	Statement of corrosion characteristics of CGA 114 597. Ciba-Geigy AG, Packaging development Syngenta Crop Protection AG, Basel, Switzerland Report No. N/A Not GLP Unpublished	N	Syngenta

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Nicollier, G.	A7.1.2.2.2/02	Fenoxycarb	2000	Degradation and metabolism of Phenyl-U-14C labelled CGA 114597 under aerobic laboratory conditions in aquatic systems Novartis Crop Protection AG, Basel, Switzerland, Report No 99GN05 Syngenta File N° CGA114597/0763 GLP Unpublished	N	Syngenta
Ochsenbein, U.	A7.2.3.2/01	Fenoxycarb	1990	CGA 114597 (RO 13-5223), Leaching characteristics of Ro-13-5223 (A its formulated end-use product insegar WP) in trhee soils Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 233346 Syngenta File N° CGA114597/0118 GLP Unpublished	N	Syngenta
Oggenfuss, P.	A3.4/01	Fenoxycarb (pure substance)	1999a	Spectra of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 77493 GLP Unpublished	N	Syngenta
Ogorek B	A6.6.2/01	Fenoxycarb	1998	Cytogenetic test on Chinese hamster cells in vitro. CGA 114597 tech. Genetic Toxicology, Novartis Crop Protection AG, Basel, Switzerland, Report No. 972169	Y	Syngenta

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[redacted]	A6.6.4/01	Fenoxycarb	1996	Micronucleus test, mouse, in vivo study. CGA 114597 tech. - (Fenoxycarb). [redacted] Report No. 962052	N	Syngenta
Penwell, A. J. and Maynard, S. J	A7.4.1.2/02	CGA 294847 (fenoxycarb metabolite)	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 GLP Unpublished	Y	Syngenta
Pfeifle V.	A7.4.3.5.1	Fenoxycarb	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 GLP Unpublished	Y	Syngenta

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Pryde, A.	A7.1.3/02	Fenoxycarb	1982	CGA 114597 (RO 13-5223), Freundlich adsorption and desorption constants of 14C RO 13-5223/024 in four soils Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No 041-2674 Syngenta File N° CGA114597/0080 non-GLP Unpublished	N	Syngenta
[redacted]	A7.5.3.1.1/01	Fenoxycarb	1982a	The acute oral toxicity (LD50) of Ro 13-5223/000 to the Bobwhite quail, [redacted], unpublished report No. HLR 104WL/82371 (Syngenta study number CGA 114597/0026). Experimental period: March to April 1982 GLP Unpublished	N	Syngenta
[redacted]	A7.5.3.1.1/02	Fenoxycarb	1982b	The acute oral toxicity (LD50) of Ro 13-5223/000 to the Mallard Duck, [redacted], unpublished report No. HLR 103WL/82372 (Syngenta study number CGA114598/0025). Experimental period: March to April 1982 GLP Unpublished	N	Syngenta

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Robinson, N.J.	A4.2/01	Fenoxycarb	2004	Residue analytical method for the determination of residues of fenoxycarb in soil (RAM 406/01). Syngenta Crop Protection, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Syngenta Crop Protection AG, Basel, Switzerland Report No. - GLP Unpublished	Y	Syngenta
Rodler, M.	A3.1.1/01 A3.3/02	Fenoxycarb (pure substance)	1992a	Report on general physico-chemical properties (aspect, odour, melting point, pH). Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
Rodler, M.	A3.3/02 A3.1.1/01	Fenoxycarb (pure substance)	1992a	Report on general physico-chemical properties (aspect, odour, melting point, pH). Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta

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Rodler, M.	A3.9/01	Fenoxycarb (pure substance)	1992b	Report on octanol/water partition coefficient. Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
Rodler, M.	A4.1/01	Fenoxycarb	1992c	Analytical Method for CGA 114597. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AW-164/1 Not GLP Unpublished	N	Syngenta
Rodler, M.	A4.1/02	Fenoxycarb	1991	Method Validation for technical active substances. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AW-164/1 Not GLP Unpublished	N	Syngenta
Rordorf, B.	A3.2/01	Fenoxycarb (pure substance)	1992	Report on vapor pressure curve. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.VPC GLP Unpublished	N	Syngenta
Ryser, M.	A3.13/01	Fenoxycarb (technical substance)	1992	Report on surface tension of aqueous solutions. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.SUR GLP Unpublished	N	Syngenta

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Sack, S.	A7.1.1.1.2/02	Fenoxycarb	1991	Photodegradation studies in aquous solution Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No RES-MET-J58 Syngenta File N° CGA114597/0109 GLP unpublished	N	Syngenta
[redacted]	A6.10/06	Fenoxycarb	1998	CGA 114597 tech. (Fenoxycarb) - Investigation Of The Formation Of Urethane-Derived DNA Adducts In Male Mice. [redacted], Report No. CB 96/48	Y	Syngenta
Sapone, A., Pozzetti, L., Canistro, D., Broccoli, M., Bronzetti, G., Potenza, G., Affatato, A., Biagi, G. L., Cantelli-Forti, G., Paolini, M.	A6.10.2	diflubenzuron, acephate	2003	CYP superfamily perturbation by diflubenzuron or acephate in different tissues of CD1mice. Food Chem Toxicol (2003) 43:173-183	No	Public

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Schmidt, T.	A7.5.1.2/02	CGA 294850 (fenoxycarb metabolite)	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 GLP Unpublished	Y	Syngenta
Schürch, H.	A3.11/01	Fenoxycarb (technical substance)	1992a	Report on flammability of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.FLS GLP Unpublished	N	Syngenta
Schürch, H.	A3.11/02	Fenoxycarb (technical substance)	1992b	Report on autoflammability of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.AFS GLP Unpublished	N	Syngenta
Schürch, H.	A3.15/01	Fenoxycarb (technical substance)	1992c	Report on explosive properties. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.EXP GLP Unpublished	N	Syngenta

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Schürch, H.	A3.16/01	Fenoxycarb (technical substance)	1992d	Report on oxidizing properties. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.OXP GLP Unpublished	N	Syngenta
Schwager, L.	A7.2.2.2/02	Fenoxycarb	1990	CGA 114597 (RO-13-5223), Dissipation in soil after application of Insegar (ACR 2907B) under outdoor conditions Novartis Crop Protection AG, Basel, Switzerland Dr. R. Maag Ltd., Dielsdorf, Switzerland, Report No RES-ANA-89030-38 Syngenta File N° CGA114597/0094 non-GLP Unpublished	N	Syngenta
Shepler, K.	A7.2.3.2/03	Fenoxycarb	1995	Column leaching of [14C] Fenoxycarb in five soil types Novartis Crop Protection AG, Basel, Switzerland PTRL West, Inc., Hercules, United States, Report No 504W Syngenta File N° CGA114597/0568 GLP Unpublished	N	Syngenta
Smulders C, Bueters TJ, Van Kleef RG, and Vijverberg HP	A6.10	carbamate pesticides	2003	Selective effects of carbamate pesticides on rat neuronal nicotinic acetylcholine receptors and rat brain acetylcholinesterase. Toxicology and Applied Pharmacology 193 (2), 139-146.	N	Public

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Spare, W. C.	A7.2.1/02 A7.2.2.4/01	Fenoxycarb	1995a	Aerobic and Aerobic/Anaerobic Metabolism of "A" Label 14C-Fenoxycarb in a Sandy Loam Soil: In-Life/Balance Phase Syngenta Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12212 Syngenta File N° CGA114597/0873 GLP Unpublished	N	Syngenta
Spare, W. C.	A7.2.1/03 A7.2.2.4/02	Fenoxycarb	1995b	Aerobic and anaerobic metabolism of 14C-Fenoxycarb in sandy loam soil: in-life/balance phase Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12209 Syngenta File N° CGA114597/0525 GLP Unpublished	N	Syngenta
Spare, W. C.	A7.1.3/01	Fenoxycarb	1995c	Adsorption/Desorption of 14C-Fenoxycarb by the Batch Equilibrium Method on Representative Agricultural Soils Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12213 Syngenta File N° CGA114597/0526 GLP Unpublished	N	Syngenta

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Spare, W. C.	A7.1.3/03	CGA 294847 (fenoxycarb metabolite)	1995d	Adsorption/Desorption of 14C-CGA-294847 by the Batch Equilibrium Method on Representative Agricultural Soils Novartis Crop Protection AG, Basel, Switzerland Agrisearch Inc., Frederick, United States, Report No 12214 Syngenta File N° CGA294847/0001 GLP Unpublished	N	Syngenta
Spare, W. C.	A7.1.3/03	CGA 294847 (fenoxycarb metabolite)	1995e	Analytical phase report: adsorption/desorption of 14C-CGA-294847 by the batch equilibrium method on representative agricultural soils Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95044 Syngenta File N° CGA294847/0002 GLP Unpublished	N	Syngenta
Strobel R	A6.6.3/01	Fenoxycarb	1982	Mutagenicity evaluation of the insect growth regulator Ro 13 5223/000 in Chinese hamster cells in vitro in the absence and presence of a mouse liver homogenate metabolic activation system. F. Hoffmann-La Roche & Co. Ltd., Basel, Switzerland, Report No. B-96728	N	Syngenta

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Stulz, J.	A3.5/01	Fenoxycarb (pure substance)	1993	Report on water solubility. Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 16650 GLP Unpublished	N	Syngenta
[redacted]	A6.3.1/01	Fenoxycarb	1986	28-Day Cumulative Toxicity (Gavage) Study with CGA 114597 in the Rat. [redacted], Report No. 056283 / 85090	N	Syngenta
Thede, B.	A7.2.1/02 A7.2.2.4/01	Fenoxycarb	1995a	Aerobic and aerobic/anaerobic metabolism of "A" label 14C-Fenoxycarb in a sandy loam soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95019 Syngenta File N° CGA114597/0570 GLP Unpublished	N	Syngenta
Thede, B.	A7.2.1/03 A7.2.2.4/02	Fenoxycarb	1995b	Aerobic and anaerobic metabolism of 14C-Fenoxycarb in sandy loam soil Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, United States, Report No ABR-95018 Syngenta File N° CGA114597/0566 GLP Unpublished	N	Syngenta

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[redacted]	7.4.3.2/01	Fenoxycarb	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 GLP Unpublished	N	Syngenta
[redacted]	A6.1.1/01	Fenoxycarb	1982	Acute Oral LD50 In Rats On Ro 13 5223/000. [redacted], Report No. 007402 GLP Unpublished	N	Syngenta
[redacted]	A6.3.2/01	Fenoxycarb	1985	21 Day Dermal Toxicity Study In The Rat. [redacted], Report No. 4552-161/157 (CGA 114597/0043)	N	Syngenta
Völkel, W.	A7.5.1.1/01	Fenoxycarb	2001	The Effects of FENOXYCARB TECH. on Soil Respiration and Nutrification. RCC AG, Itingen, Switzerland unpublished report No. 833130 (Syngenta file No. CGA114597/0794). Experimental period August 29th 2001 to October 10th 2001 GLP Unpublished	Y	Syngenta

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[redacted]	A7.4.2/01 A7.4.3.3.1	Fenoxycarb	2001	Accumulation and elimination of [Hydroquinone –(U)-14C] 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 GLP Unpublished	Y	Syngenta
Wälder L.	A7.5.1.3/01	Fenoxycarb	2000	Herbicide profiling test to evaluate the phytotoxicity of CGA 114597 25 WG (A-8995 B) to terrestrial non-target higher plants. Novartis Crop Protection AG, Research Biology Weed Control, CH-4332 Stein, Switzerland. Unpublished report No. SMQ 00006, Report no 41 (Syngenta No. CGA 114597/0748). Experimental period March 30th 2000 to April 20th 2000 non-GLP Unpublished	N	Syngenta
Ward, J.T. and Boeri, R.L.	A7.4.1.2/01	Fenoxycarb	1993f	Acute Flow-through Toxicity of Fenoxycarb to the Daphnid (Daphnia magna), T R Wilbury Laboratories, Marblehead, United States, unpublished report No. 15-CG (Syngenta No. CGA114597/0420). Experimental period: July 29th to July 31st 1992 GLP Unpublished	N	Syngenta

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[redacted]	A7.4.1.1/01a	Fenoxycarb	1993a	Acute Flow-through Toxicity of Fenoxycarb to the Rainbow Trout (Oncorhynchus mykiss). Experimental period September 4th 1992 to September 8th 1992. [redacted] Report No. 14-CG (Syngenta No. CGA114597/0416) GLP Unpublished	N	Syngenta
[redacted]	A7.4.1.1/01b	Fenoxycarb	1993b	Acute Flow-through Toxicity of Fenoxycarb to the Bluegill Sunfish (Lepomis macrochirus). Experimental period August 20th 1992 to August 24th 1992. [redacted] Report No. 13-CG (Syngenta No. CGA114517/0418) GLP Unpublished	N	Syngenta
[redacted]	A7.4.1.1/01c	Fenoxycarb	1993c	Acute Flow-through Toxicity of Fenoxycarb to the Carp (Cyprinus carpio). [redacted], unpublished report No. 47-CG (Syngenta No. CGA114598/0421). Experimental period August 7th 1992 to August 11th 1992 GLP Unpublished	N	Syngenta

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[redacted]	A7.4.1.1/01d	Fenoxycarb	1993 d	Acute Flow-through Toxicity of Fenoxycarb to the Channel Catfish (Ictalurus punctatus). [redacted] unpublished report No. 48-CG (Syngenta No. CGA114598/0419). Experimental period September 25th 1992 to September 29th 1992 GLP Unpublished	N	Syngenta
[redacted]	A7.4.1.1/01e	Fenoxycarb	1993e	Acute Flow-through Toxicity of Fenoxycarb to the Sheepshead Minnow (Cyprinodon variegatus). [redacted] unpublished report No. 16-CG (Syngenta No. CGA11457/0417). Experimental period August 13th 1992 to August 17th 1992 GLP Unpublished	N	Syngenta
Ward, T.J., Magazu, J.P. and Boeri, R.L.	A7.4.3.4/02	Fenoxycarb	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 GLP Unpublished	N	Syngenta

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[redacted]	A6.10/03	Fenoxycarb	1996	CGA 114597 tech. - Assessment Of Replicative DNA Synthesis In The Lung And Liver Of Male Mice Treated For 7, 14 And 42 Days. Investigation Of The Reversibility In A 42-Day Treatment/28-Day Recovery Experiment. [redacted], Report No. CB 95/03	N	Syngenta
Wilde, P.	A7.5.4.1/01	Fenoxycarb	1982	Acute oral toxicity test on RO 13-5223/000 in Honey bees, RCC Ltd. P.O. Box, CH-4452; Itingen; Switzerland. Unpublished report No. 007446 (Syngenta No. CGA114597/0031). Reported June 3rd 1982 non-GLP Unpublished	N	Syngenta
Winter, P.A., Hoxter, K.A. & Smith, G.J	A7.5.4.1/02	Fenoxycarb	1992	Fenoxycarb technical - An acute contact toxicity study with the honey bee, Wildlife International Ltd. 8598 Commerce Drive, Easton, Maryland. MD 21601, USA. Unpublished report No. 294-102A (Syngenta No. CGA114597/0411). Experimental period: October 9th 1990 to October 11th 1990 GLP Unpublished	N	Syngenta

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A3.1.1/01 A3.3/02	Rodler, M.	Fenoxycarb (pure substance)	1992a	Report on general physico-chemical properties (aspect, odour, melting point, pH). Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
A3.1.1/02 A3.1.2/02	Geffroy, A.	Fenoxycarb	2007	Melting point and boiling point of Fenoxycarb Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland Study Number L07-000500 GLP Unpublished	Y	Syngenta
A3.1.2/01 A3.10/01	Das, R.	Fenoxycarb (pure substance)	1997	Report on boiling point / boiling range. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 55883 GLP Unpublished	N	Syngenta
A3.1.3/01	Füldner, H.	Fenoxycarb (pure substance)	1992	Report on densitiy of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.VPC GLP Unpublished	N	Syngenta

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A3.2/01	Rordorf, B.	Fenoxycarb (pure substance)	1992	Report on vapor pressure curve. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.VPC GLP Unpublished	N	Syngenta
A3.2/02	Burkhard, N.	No test material (Calculation)	1998	Henry`s law constant. Novartis Crop Protection AG, Basel, Switzerland Brian Christensen Companies, Inc., Minnetonka, United States Report No. N/A GLP Unpublished	N	Syngenta
A3.3/01	Das, R.	Fenoxycarb (pure and technical substance)	1999	General physico-chemical properties of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 78916 GLP Unpublished	N	Syngenta
A3.3/02 A3.1.1/01	Rodler, M.	Fenoxycarb (pure substance)	1992a	Report on general physico-chemical properties (aspect, odour, melting point, pH). Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta

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A3.4/01	Oggenfuss, P.	Fenoxycarb (pure substance)	1999a	Spectra of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 77493 GLP Unpublished	N	Syngenta
A3.5/01	Stulz, J.	Fenoxycarb (pure substance)	1993	Report on water solubility. Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 16650 GLP Unpublished	N	Syngenta
A3.6/01	Jäkel, K.	Fenoxycarb (pure substance)	1992	Report on dissociation constant in water. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.DCW GLP Unpublished	N	Syngenta
A3.7/01	Kettner, R.	Fenoxycarb (technical substance)	2000	Solubility in organic solvents of CGA 114597. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 78917 GLP Unpublished	N	Syngenta

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A3.9/01	Rodler, M.	Fenoxycarb (pure substance)	1992b	Report on octanol/water partition coefficient. Ciba-Geigy Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. EA-162180 GLP Unpublished	N	Syngenta
A3.10/01 A3.1.2/01	Das, R.	Fenoxycarb (pure substance)	1997	Report on boiling point / boiling range. Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. 55883 GLP Unpublished	N	Syngenta
A3.11/01	Schürch, H.	Fenoxycarb (technical substance)	1992a	Report on flammability of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.FLS GLP Unpublished	N	Syngenta
A3.11/02	Schürch, H.	Fenoxycarb (technical substance)	1992b	Report on autoflammability of solids. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.AFS GLP Unpublished	N	Syngenta
A3.13/01	Ryser, M.	Fenoxycarb (technical substance)	1992	Report on surface tension of aqueous solutions. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.SUR GLP Unpublished	N	Syngenta

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A3.13/02	Martin-Keusch, Ch.	Fenoxycarb	2007	Fenoxycarb techn. Surface tension Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland Study Number 117423 GLP Unpublished	Y	Syngenta
A3.15/01	Schürch, H.	Fenoxycarb (technical substance)	1992c	Report on explosive properties. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.EXP GLP Unpublished	N	Syngenta
A3.16/01	Schürch, H.	Fenoxycarb (technical substance)	1992d	Report on oxidizing properties. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AG 91/12T.OXP GLP Unpublished	N	Syngenta
A3.17/01	Meyer, K.	Fenoxycarb	1991	Statement of corrosion characteristics of CGA 114 597. Ciba-Geigy AG, Packaging development Syngenta Crop Protection AG, Basel, Switzerland Report No. N/A Not GLP Unpublished	N	Syngenta
A4.1/01	Rodler, M.	Fenoxycarb	1992c	Analytical Method for CGA 114597. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AW-164/1 Not GLP Unpublished	N	Syngenta

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A4.1/02	Rodler, M.	Fenoxycarb	1991	Method Validation for technical active substances. Ciba-Geigy Ltd., Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland Report No. AW-164/1 Not GLP Unpublished	N	Syngenta
A4.2/01	Robinson, N.J.	Fenoxycarb	2004	Residue analytical method for the determination of residues of fenoxycarb in soil (RAM 406/01). Syngenta Crop Protection, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Syngenta Crop Protection AG, Basel, Switzerland Report No. - GLP Unpublished	Y	Syngenta
A4.2/02	Emburey, S.N.	Fenoxycarb	2004	Validation of a residue analytical method for the determination of residues in soil. Syngenta Crop Protection, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4912B GLP Unpublished	Y	Syngenta

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A4.2/03	Hargreaves, S.L.	Fenoxycarb	2003a	Residue Analytical method for the Determination of Fenoxycarb Residues in Air (RAM 409/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4834 GLP Unpublished	Y	Syngenta
A4.2/04	Hargreaves, S.L.	Fenoxycarb	2003b	Fenoxycarb: Validation of an Analytical Method for the Determination of Residues in Air (RAM 409/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. TMJ4834 GLP Unpublished	Y	Syngenta
A4.2/05	Hargreaves, S.L.	Fenoxycarb	2003c	Residue Analytical Method for the determination of Residues of Fenoxycarb in Water (RAM 408/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. RJ3391B GLP Unpublished	Y	Syngenta

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A4.2/06	Hargreaves, S.L.	Fenoxycarb	2003d	Fenoxycarb: Validation of a Residue Analytical Method for the Determination of Residues of Fenoxycarb in Surface Water (RAM 408/01). Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Report No. RJ3391B GLP Unpublished	Y	Syngenta
A4.2/03	Greulich, K., Alder, L.		2006	Fast multi residue screening of 300 pesticides in drinking water. Federal Institute for Risk Assessment, Berlin, Germany Report No. BFR-IX-2005 GLP published: http://www.bfr.bund.de/cd/5832	No	Public
A5.3/01	Grube and Rudolph	Fenoxycarb	1998	Abschlußbericht zur Wirksamkeit von FAROX (Fenoxycarb) gegen Hylotrupes bajulus. BAM, FG IV.1, Berlin, Germany ReportNo N/A Not GLP Unpublished	Y	Syngenta