analysis. At each sampling time, one trap containing *Daphnia*, was also removed for analysis. Fish and *Daphnia* were also sampled for analysis throughout the depuration period.

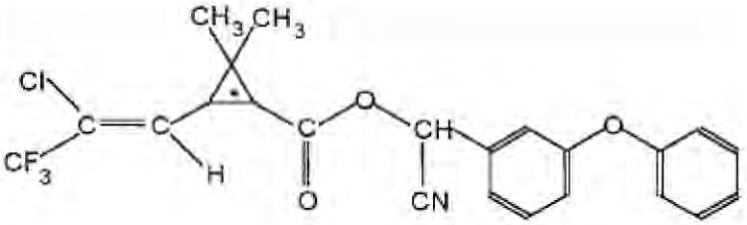
Findings:
During the aerobic incubation period approximately 40% of the applied radioactivity was lost from the soil (presumably by mineralisation to CO_2). After flooding, no significant change in the level of residues on the soil was detected, with the level of radioactivity remaining in the soil being approximately 50% of that nominally applied. On day 0, >99% of the radioactivity was extracted from the soil, with the parent only being present. After aerobic incubation other compounds were identified, similar to those found in the aerobic soil studies (refer to Document L-II: Point 7 for further information), and the amount of unextracted radioactivity increased to approximately 20%. The ratio of the diastereoisomers changed to a 1:1 racemic mixture after 2 weeks aerobic incubation and remained this way throughout exposure of the organisms.

The amount of ^{14}C-residues in the water in the treated tank increased gradually throughout the exposure phase, to a maximum of 8% of the applied radioactivity when the fish exposure was terminated. No parent Cyhalothrin was detected in the water, the only product constituting more than 1% of the applied radioactivity was the ester hydrolysis product, cis-3-(ZE-2-chloro-3,3,3-trifluoropropenyl)-2,2-dimethylcyclopropanecarboxylic acid (Compound Ia), which represented up to 5.3% of the applied radioactivity.

During the exposure period the maximum bioconcentration factors (BCFs - total radioactivity in the organism/total radioactivity in the water) in whole fish and *Daphnia* were 19 (after 14 days exposure) and 194 (after 3 days exposure), respectively. Fish muscle and viscera maximum BCFs were 7 and 66, respectively. The concentration of residues in the fish and *Daphnia* decreased rapidly during the depuration period, with half of the accumulated residues being eliminated in 7 days and 1 day, respectively.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.3.3.2 /01	Bioaccumulation in an appropriate invertebrate species

Section A7.4.3.3.2 Annex Point IIA XIII.2.3	**Bioaccumulation in invertebrates**	
	1. REFERENCE	**Official use only**
1.1 Reference	Muller, K., Hamer, M. J., Goggin, U., Lane, M.C.G. (1995): Bioavailability and bioconcentration by *Chironomus riparius* in water-only sediment/water systems, Zeneca Agrochemicals, Report No.: RJ1933B, 26 October 2004 (unpublished).	
1.2 Data protection	Yes.	
1.2.1 Data owner	Syngenta Crop Protection	
1.2.2 Companies with letter of access	None.	
1.2.3 Criteria for data protection	[redacted]	
	GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No, in-house test method uses, fully described in the report.	
2.2 GLP	Yes	
2.3 Deviations	No	
	MATERIALS AND METHODS	
3.1 Test material	^{14}C-cyclo labelled *lambda*-cyhalothrin	X1
3.1.1 Lot/Batch number	[redacted]	
3.1. Specification	Specific activity of 1.378 G Bq mmol^{-1}	
3.1.3 Purity	Radiochemical purity, determined by thin layer chromatography (TLC) was [redacted]	
3.1.4 Further relevant properties	Not applicable	
3.1.5 Radiolabelling	 * position of radiolabel	

Section A7.4.3.3.2 **Annex Point IIA XIII.2.3**	**Bioaccumulation in invertebrates**	
3.1.6 Method of analysis	TLC was used to determine the purity of the ^{14}C-*lambda*-cyhalothrin and in the application solutions and to characterise the radioactivity in water and sediment extracts. TLC plates (Sorbsil C-30) were used; radioactive areas on the plates were read using either a Rita 68000 or 3200 Automatic TLC Analyser. Autoradiographic images of the developed chromatograms were made using a Fuji BAS Phosphorimager.	
3.2 Reference substance	No	
3.2.1 Method of analysis for reference substance	Not applicable	
3.3 Testing/estimation procedure		
3.3.1 Sediment sources	See Table A7.4.3.3.2-01	
3.3.2 Physicochemical properties of the sediments	See Table A7.4.3.3.2-02	
3.3.3 *C. riparius* details	See Table A7.4.3.3.2-03	
3.3.4 Biocentration water-only test systems	See Table A7.4.3.3.2-04	
3.3.5 Biocentration sediment/water systems	See Table A7.4.3.3.2-05	
3.3.6 Test system/ performance	Details of the test systems are presented in the tables detailed above. Analysis of test systems was as follows: **Water only tests** - aqueous phase – analysis was performed by extraction of the parent ^{14}C-*lambda*-cyhalothrin into hexane before quantification by liquid scintillation counting (LSC). Analysis also determined the amount of ^{14}C-*lambda*-cyhalothrin adsorbed on to pipette and test unit walls. - *C. riparius* analysis – live organisms were removed on each sampling occasion, rinsed in clean water, blotted dry on tissue paper, combined, wet weighed into a combustion cone. **Sediment/water tests** - aqueous phase – 100 mL aliquots were centrifuged at 4000 rpm (2122 G) for 15 minutes. After drying the sediment pellet was removed, the tube was extracted with hexane to remove adsorbed residues. Counting by LSC was performed and the two extracts combined to give a total ^{14}C-*lambda*-cyhalothrin in the aqueous phase. Representative extracts were analysed by TLC to	

Section A7.4.3.3.2 **Annex Point IIA XIII.2.3**	**Bioaccumulation in invertebrates**	
	characterise the extracted radioactivity. - sediment analysis – after removal of the *C. riparius* the tubes containing the sediment pellets dried suing compressed air. The dry pellet (plus the pellet from the aqueous phase extract) was extracted with solvent, shaken and centrifuged. Counting by LSC was performed. Residual sediment was air dried and remaining radioactivity was determined by combustion. Representative extracts were analysed by TLC to characterise the extracted radioactivity. - *C. riparius* analysis – After removal of the overlying water the C. riparius were gently removed from the sediment and rinsed in water to remove any soil particles. They were then blotted dry on tissue paper, combined, wet weighed into a combustion cone. Combustion – After drying the sediment were combusted using an Oxidiser along with the prepared *C. riparius* samples. The $^{14}CO_2$ evolved from the oxidation of samples was trapped and radioassayed by LSC. The efficiency of the combustion process was 93% and this was used as a correction factor for the combusted samples.	

Section A7.4.3.3.2 Annex Point IIA XIII.2.3	**Bioaccumulation in invertebrates**	
3.3.7 Estimation of bioconcentration	**Sediment Adsorption Coefficients and Bioconcentration Factors** Various coefficients are used to describe the adsorption of chemicals to sediment and the uptake of chemical by the organisms. They are calculated as follows from the measured concentrations of the chemical in the sediment, aqueous and organism phases: $Kd = \frac{Cs}{Cw}$ $K_{oc} = \frac{Kd \times 100}{\%OC}$ $\text{Aqueous BCF} = \frac{Co}{Cw}$ $\text{Sediment BCF} = \frac{Co}{Cs}$ Where:- Kd is the sediment adsorption partition coeffidient K_{oc} is the the Kd as a function of the percentage organic carbon (%OC) in a sediment BCF is the bioconcentration factor, the concentration in the organism relstive to the concentration in another phase of the system and Cs = soil equilibrium concentration in µg chemical kg^{-1} dry soil Cw = aqueous equilibrium concentration in µg chemical l^{-1} soil solution $\%OC = \frac{\%\text{ organic matter}}{1.724}$ Co = *Chironomus riparius* concentration in µg chemical kg^{-1} wet weight larvae	
	RESULTS	
4.1 Experimental data		
4.1.1 Mortality/ behaviour	Mortality data for the water-only system are presented in Table A7.4.3.3.2-06.	
4.1.2 Lipid content	Not applicable	
4.1.3 Concentrations of test material during test	Measured ^{14}C-*lambda*-cyhalothrin concentrations are presented in Table A7.4.3.3.2-06 for the water only studies and Table A7.4.3.3.2-07 for the water/sediment studies.	
4.1.4 Bioconcentration factor (BCF)	Bioconcentration factors are presented in Table A7.4.3.3.2-06 for the water only studies and Table A7.4.3.3.2-07 for the water/sediment studies.	
4.1.5 Uptake and depuration rate constants	Not applicable	

Section A7.4.3.3.2 **Annex Point IIA XIII.2.3**	**Bioaccumulation in invertebrates**	
4.1.6 Depuration time	Not applicable	
4.1.7 Metabolites	Not applicable	
4.1.8 Other Observations	Not applicable	
4.2 Estimation of bioconcentration	Bioconcentration factors were calculated using the equations shown in Section 3.3.7.	

Section A7.4.3.3.2 **Annex Point IIA XIII.2.3**	**Bioaccumulation in invertebrates**	
	APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	Two studies were performed, one to determine the bioconcentration of ^{14}C-*lambda*-cyhalothrin by *Chironomus riparius* in a water only system and the other to determine bioconcentration in 10 sediment/water systems. There was particular guideline used for this non-standard study, the methods used are fully described in the report.	
5.2 Results and discussion	**Water only test** There was little difference between the results from the treated systems at the different analysis times. Bioconcentration factors ranged between 1500 and 2000. These data demonstrate that ^{14}C-*lambda*-cyhalothrin concentrations had effectively equilibrated in *C. riparius* within 24 hours. **Sediment/water test** Aqueous phase concentrations in the different test systems varied between 0.031 to 0.141 µg/L. These differences from the nominal concentrations of 0.225 µg/L can be explained by the apparent differences between the K_{oc} values measured in this study and those in the previous study (not reported here). In addition substantial losses by adsorption onto the walls of the test vessels were clearly demonstrated. The lower than nominal concentrations had no impact on the results as all adsorption coefficients and BCFs were calculated using measured concentrations. Of the total radioactivity recovered from the sediment, water and organisms phases >99% was adsorbed to the sediment in all systems. TLC analysis of the representative sediment extract phases demonstrated that there had been little or no degradation of ^{14}C-*lambda*-cyhalothrin. Equilibrium partitioning theory predicts that the amount of chemical adsorbed to the sediment organic matter would be biologically unavailable. Consequently the amount of chemical bioavailable is equivalent to the concentration in the water phase as determined from the distribution of the chemical between the phases based on the K_{oc}. Calculated aqueous BCFs showed little variation between the test systems, ranging from 1300 – 3400, with a mean of 2300 and a coefficient of variation (CV) of 25%. This mean is very similar to the 48 hour mean BCF in water alone of 2000. Thus the aqueous phase concentration was a very good predictor of bioavailability, validating the predictions made by equilibrium partitioning theory. BCFs calculated using sediment concentrations were all <1, and much more variable than aqueous BCFs, ranging from 0.11-0.84 (based on extracted radioactivity), with a mean of 0.39 and a CV	

Section A7.4.3.3.2 **Annex Point IIA XIII.2.3**	**Bioaccumulation in invertebrates**	
	of 61% Aqueous BCFs for Chironomus riparius exposed to *lambda*-cyhalothrin in a water-only test system and in ten different sediment/water systems were very similar. These data support the hypothesis that in sediment water systems, the *lambda*-cyhalothrin which is bioavailable to organisms is best predicted by the concentration in the water phase.	
5.3 Conclusion	Aqueous BCFs for Chironomus riparius exposed to *lambda*-cyhalothrin in a water-only test system and in ten different sediment/water systems were very similar. These data support the hypothesis that in sediment water systems, the *lambda*-cyhalothrin which is bioavailable to organisms is best predicted by the concentration in the water phase.	
5.3.1Reliability	1	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		

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98/8 Doc IIIA section No.	7.4.3.4/01	Effects on reproduction and growth rate with an appropriate invertebrate species
91/414 Annex Point addressed	II 8.2.5/01	Chronic toxicity to aquatic invertebrates

		Official use only
Reference point (location) in dossier	**7.4.3.4/01**	
Title:	PP321 : *Daphnia magna* life-cycle study using a flow-through system	
Project/Report number:	RJ0764B	
Author(s):	Farrelly, E. and Hamer, M. J.	
Date of report:	1989	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, ICI Agrochemicals, Bracknell, UK	
Test substance:	^{14}C-phenyl labelled *lambda*-Cyhalothrin (PP321) radiochemical purity: [redacted] by TLC	
Study dates	May – June 1989	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

	Official use only
Materials and methods: *Daphnia magna* were exposed to a range of concentrations of *lambda*-Cyhalothrin for 21 days. At the start of the study seven replicates (A-G) had a single first instar *Daphnia magna* introduced and the remaining three (H-J) had five *Daphnia* added. The range of concentrations tested was nominally, 1.0, 2.6, 6.4, 16 and 40 ng/L plus solvent and untreated controls. Throughout the 21-day exposure period, *Daphnia* survival, growth and reproduction were monitored. On each assessment day any mortalities of the *Daphnia* originally introduced were recorded. Any young produced in chambers A-G were removed, counted and discarded. Young produced in chambers H-J were removed and discarded. On day 21 the length of surviving adult *Daphnia* in chambers A-G was measured. Measured weekly at each test concentration, dissolved oxygen was in the range 8.2-9.1 mg/L and pH 8.1-8.2. Temperature, monitored continuously, was in the range 19.5-23°C. **Findings**: The biological data are summarised in the tables below. The 21 day LC_{50} was 3.6 ng/L. There was no significant effect on growth of surviving *Daphnia* and there was no significant effect on reproduction at the two lowest concentrations. The 21-day NOEC was therefore 1.98 ng/L.	X1

Mortality endpoints for adult *D. magna* following 21-day exposure to *lambda*-Cyhalothrin

Exposure time (days)	LC_{50} (ng/L)	95% Confidence Limits
3	13	10 - 17
5	8.7	not calculable
7	8.3	not calculable
10	8.3	not calculable
12	7.9	not calculable
14	6.9	5.3 - 8.9
17	5.2	4.0 - 6.8
19	4.1	3.0 - 5.7
21	3.6	not calculable

Effects on reproduction and growth of *D. magna* following 21-day exposure to *lambda*-Cyhalothrin

Mean measured Concentration (ng/L)	Total Young per Chamber	Young per Female Reproductive Day	Mean Length, Day 21 (mm)
Control	78.9	6.1	3.51
Solvent Control	67.7	5.5	3.48
0.83	84.6	6.6	3.34
1.98	61.4	4.7	3.51
3.50	27.1^{+*}	2.5^{+*}	3.50
9.37	5.6^{+*}	0.8^{+*}	3.28
19.1	0^{+*}	0^{+*}	all dead

$^{+}$ significantly different from the control (p = 0.05)
* significantly different from the solvent control (p = 0.05)

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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98/8 Doc IIIA section No.	**7.4.3.5**	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk *(headline)***

98/8 Doc IIIA section No.	**7.4.3.5.1/01**	**Effects on sediment dwelling organism**
91/414 Annex Point addressed	**II 8.2.7/01**	**Effects on sediment dwelling organisms**

		Official use only
Reference point (location) in dossier	**7.4.3.5.1/01**	X1
Title:	*Lambda*-Cyhalothrin: BBA toxicity test with sediment-dwelling *Chironomus riparius*.	
Project/Report number:	RJ2234B	
Author(s):	Hamer, M.J. and Rapley, J.H.	
Date of report:	1997	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Agrochemicals, Bracknell, UK	
Test substance:	^{14}C-cyclopropane labelled *lambda*-Cyhalothrin, radiochemical purity [redacted]	
Study dates	June - October 1996	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

	Official use only
Materials and methods: ^{14}C-cyclopropane labelled *lambda*-Cyhalothrin (specific activity of 2.2 GBq/mmol and nominal purity [redacted]). *Chironomus riparius* larvae (first instar) were exposed to ^{14}C-cyclopropane labelled *lambda*-Cyhalothrin in laboratory water-sediment systems, following the test method recommendations of the SETAC-Europe Guidance Document on Sediment Toxicity Tests and Bioassays for Freshwater and Marine Environments, and the ASTM (1993) Standard Guide for Conducting Sediment Toxicity Tests with Freshwater Invertebrates. For this method the test chemical is incorporated into the sediment before introduction of the test organisms into the system. The test systems were prepared by applying ^{14}C-labelled *lambda*-Cyhalothrin to a sediment-water slurry (30 g dry weight sediment : 250 ml water), which was then mixed by rolling for 2 hours. Four replicate water-sediment systems (A to D) were prepared at six nominal sediment concentrations of *lambda*-Cyhalothrin : 62, 125, 250, 500, 100 and 2000 µg/kg sediment (dry weight). Two additional sets of 4 replicate water-sediment systems were prepared, one set to serve as untreated controls and the other to be treated with carrier solvent only (solvent controls). After leaving the test systems to settle for 2 days, twenty 2-day old *C.*	X2

riparius were introduced to the systems (day 0). The systems were gently aerated and maintained at 20°C for 28 days. **Findings:** Actual concentrations of ^{14}C-*lambda*-Cyhalothrin in the overlying waters and in the sediments were determined by extraction and radiochemical analysis of one of the replicate systems on days 0 (rep D) and 28 (rep C). The vast majority of the *lambda*-Cyhalothrin applied to the water-sediment systems was recovered from the sediment and less than 0.5% of the amount nominally applied was recovered from the overlying water. Measured concentrations in the sediment taken on day 0 ranged between 54 and 1794 ug/kg, 83 to 90% of the nominal initial concentration. By day 28, concentrations of *lambda*-Cyhalothrin in the test systems had dropped slightly to between 76 and 90% of nominal. Test results are based on measured concentrations of *lambda*-Cyhalothrin on Day 0. Numbers of emerged adult midges were recorded daily over the 28-day test period in the replicate systems A, B and C. The emergence of *C. riparius* as an average percentage of the larvae introduced and the time for the emergence of the last adult are shown below for the various measured treatment concentrations at day 0.	X3 X4 X5

Effects on larvae of *C. riparius* following 28-day exposure to *lambda*-Cyhalothrin

Measured *lambda*-Cyhalothrin concentration (µg/kg dry sediment)	Total Number Emerged (% of introduced larvae)	Time to Emergence of Last Adult (Days)
Untreated Control	97	26
Solvent Control	95	22
54	88	23
105	95	23
213	67	23
414	27	23
845	0	-
1794	0	-

Based on the concentrations of *lambda*-Cyhalothrin measured in the sediment at day 0, the 28 day EC_{50} for total emergence to first instar *C. riparius* was 250 µg/kg, with a 95% confidence interval of 190 to 330 µg/kg, and the NOEC (no observed effect concentration) based on total emergence was 105 µg/kg. There was also a significant effect of the test chemical at higher concentrations on time to emergence in the test systems compared to the combined controls. The NOEC based on mean time to emergence was 213 µg/kg.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]

	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	**7.4.3.5.1/02**	**Effects on sediment dwelling organism**
91/414 Annex Point addressed	**II 8.2.7/02**	**Effects on sediment dwelling organisms**

		Official use only
Reference point (location) in dossier	**7.4.3.5.1/02**	X1
Title:	*Lambda*-Cyhalothrin : Sediment toxicity test with *Chironomus riparius*	
Project/Report number:	RJ2227B	
Author(s):	Hamer, M.J. and Gentle, W.E.	
Date of report:	1997	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Agrochemicals, Bracknell, UK	
Test substance:	^{14}C-cyclopropane labelled *lambda*-Cyhalothrin, radiochemical purity [redacted]	
Study dates	June – September 1996	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

	Official use only
Materials and methods: ^{14}C-cyclopropane labelled *lambda*-Cyhalothrin (specific activity of 2.2 GBq/mmol and purity [redacted]). Effects of *lambda*-Cyhalothrin on the sediment dwelling invertebrate, *Chironomus riparius* were assessed in laboratory water-sediment systems, in accordance with the BBA (1995) test guideline "Effects of Plant Protection Products on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system". For this method, the test organisms are first introduced into the water-sediment system and the test chemical is subsequently applied to the overlying water. *C. riparius* larvae (first instar, 2 days old) were exposed to ^{14}C-labelled *lambda*-Cyhalothrin in freshwater in a static water-sediment system for 25 days at 20°C. The test system contained 2 cm sediment (total dry weight 266 g) with 18 cm overlying water. Twenty-five first instar larvae were introduced into each test vessel 24 hours prior to treatment. Aliquots of *lambda*-Cyhalothrin solutions in acetone (250 µL) were applied to the overlying water in each test system to give three replicate systems (A to C) at six nominal concentrations: 0.16, 0.31, 0.62, 1.25, 2.5 and 5.0 µg *lambda*-Cyhalothrin per litre. Two additional sets of 3 replicate water-sediment systems were prepared, one set to serve as untreated controls and the other to be treated with carrier solvent only (solvent controls).	X2

Findings: Aliquots of the overlying water were taken for determination of ^{14}C-*lambda*-Cyhalothrin concentrations on days 0, 7 and 28. The concentration of ^{14}C-*lambda*-Cyhalothrin in the sediments was determined on day 28 after removal of the overlying water. On day 0, the concentration of ^{14}C-*lambda*-Cyhalothrin in the overlying water 1 hour after application were 75 to 93% of nominal. After day 0, the vast majority of the ^{14}C-*lambda*-Cyhalothrin applied to the water-sediment systems was recovered from the sediment. By days 7 and 28 less than 5% and 2%, respectively, of the amount nominally applied was recovered from the overlying water. Measured concentrations in the sediment on day 28 represented 40 to 54% of the ^{14}C-*lambda*-Cyhalothrin applied to the overlying water on day 0. Numbers of emerged adult midges were recorded daily over the 28-day test period in the replicate systems A, B and C. The emergence of *C. riparius* as an average percentage of the larvae introduced and the time for the emergence of the last adult are shown below for the various nominal treatment concentrations at day 0.	X3 X4

Effects on larvae of *C. riparius* following 28-day exposure to *lambda*-Cyhalothrin

Nominal Initial *lambda*-Cyhalothrin concentration in water (µg/L)	Total Number Emerged (% of introduced larvae)	Time to Emergence of Last Adult (Days)
Untreated Control	95	16
Solvent Control	96	14
0.16	96	15
0.31	95	24
0.62	96	17
1.25	59	20
2.5	77	23
5.0	9	21

Based on the nominal initial concentrations of *lambda*-Cyhalothrin in the water on day 0, the 28 day EC_{50} for total emergence to first instar *C. riparius* was 2.4 µg/L, with a 95% confidence interval of 1.4 to 5.2 µg/L, and the NOEC (no observed effect concentration) based on total emergence was 0.62 µg/L. Comparing the treatments to the solvent controls showed them all to have a significant difference in time to emergence. However, this difference amounted to only one day in mean emergence time at the lowest concentration. This is the same time interval as that between the observations, and therefore is not considered to be ecologically relevant.	X5

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	[redacted]

[redacted]

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

98/8 Doc IIIA section No.	7.4.3.5.2 Aquatic plant toxicity

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [×] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE Not relevant [redacted] [redacted]	

98/8 Doc IIIA section No.	**7.5**	**Effects on terrestrial organisms *(headline)***

98/8 Doc IIIA section No.	**7.5.1**	**Terrestrial toxicity, initial tests *(headline)***

98/8 Doc IIIA section No.	**7.5.1.1/01**	**Inhibition of microbiological activity**
91/414 Annex Point addressed	**II 8.5/01**	**Effects on soil non-target micro-organisms**

		Official use only
Reference point (location) in dossier	**7.5.1.1/01**	
Title:	PP321: Studies on microorganisms and their activities in soil	
Project/Report number:	RJ0853B	
Author(s):	Aze, C.J., Tarry, A.R. and Lewis, F.J.	
Date of report:	1990	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, ICI Agrochemicals, Bracknell, UK	
Test substance:	*lambda*-Cyhalothrin, 5% EC formulation (JF9509)	X1
Study dates	December 1989 to March 1990	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

Materials and methods: *Lambda*-Cyhalothrin, as an emulsifiable concentrate formulation, was applied at a rate of 1.67 mg/kg soil, equivalent to a field rate of 1.25 kg ai/ha. There were three replicates for the treated soil and the control. The effect of the compound on nitrogen transformation and carbon mineralisation was studied. Two soil types were used in this study; a sandy loam soil (organic carbon content 1.2%) and a loam soil (organic carbon content 2.4%). **Nitrogen Transformation:** The effect of the compound on the mineralisation of added organic nitrogen was investigated using ground lucerne. Three 1 kg samples of each soil were treated with *lambda*-Cyhalothrin or water (controls) and amended with 5 g of ground lucerne. At 0, 7, 14, and 28 days after treatment, two 10 g sub-samples were removed from each replicate and analysed for nitrate, nitrite and ammonium ions. The levels of these ions in the *lambda*-Cyhalothrin treated soils was then compared to the control soils at each sample time. In both the loam and sandy loam soil small, but statistically significant differences were observed between the level of ammonium ions in treated and control samples. At no time did	Official use only X2

these differences exceed 21% and, considering the very low levels of ammonium present at 28 days after treatment, are of little ecological importance. There were no significant differences in the levels of nitrate ions between treated and control soils except for a single transient decrease in the sandy loam soil which had disappeared by 28 days after treatment. **Carbon Mineralisation** : The effect of *lambda*-Cyhalothrin on carbon mineralisation was investigated using the short term respiration method of Anderson and Domsch (1978). As above triplicate 1.2 kg samples of each soil were treated with *lambda*-Cyhalothrin or water (controls). At 0, 14, and 28 days after treatment, two 75 g subsamples were taken from each replicate and amended with a predetermined optimum level of glucose. The mineralisation of this added glucose was then monitored for a minimum of 12 hours using a respirometer system connected to an infra-red gas analyser. The level of active biomass in treated and control soils was calculated from the level of CO_2 produced, according to the procedure described in Anderson and Domsch (1978). On comparison of the level of microbial biomass carbon calculated from the mineralisation of glucose there were no statistical differences between the *lambda*-Cyhalothrin treated loam soil and the relevant control. In the sandy loam soil there was a transient statistically significant decline in microbial biomass carbon in the treated soil at the Day 0 sampling interval. This difference was small (15%), had disappeared by Day 14, and was not apparent at any subsequent sample time.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	**7.5.1.2/01**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1/01**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/01**	
Title:	*Lambda*-Cyhalothrin: Toxicity to the earthworm *Eisenia foetida*	
Project/Report number:	TMJ3062B	
Author(s):	Yearsdon, H.A., Coulson, J.M. and Edwards, P.J.	
Date of report:	1993	
Published:	Not published	
Testing facility:	Jealott's Hill Research Station, ICI Agrochemicals, Bracknell, UK	
Test substance:	*lambda*-Cyhalothrin technical, purity [redacted]	X1
Study dates	May to June 1986	
GLP:	Yes.	X2
Deficiencies:	None	
Reliability indicator	1	

	Official use only
Materials and methods: Earthworms (clitellate adults) were exposed for 14 days to technical *lambda*-Cyhalothrin at concentrations of 0, 32, 100 and 1,000 mg/kg dry soil (equivalent to approximate field application rates of 0, 24, 75 and 750 kg *lambda*-Cyhalothrin/ha, respectively) in artificial soil. The artificial soil comprised the following ingredients (in dry weight proportions): 70% fine silica sand, 20% kaolinite clay, 10% peat (organic matter = 93.6%). Calcium carbonate was added to the soil at 5 g/kg to adjust the pH. Test conditions were maintained at 19°C, soil moisture content 31-34% and light intensity 750 lux. There were 4 replicates, each containing 10 *E. foetida* per treatment. Chloroacetamide was tested, as a toxic standard, on the same batch of *E. foetida* at 0, 32, 56 and 100 mg/kg dry soil. **Findings:** The LC_{50} of *lambda*-Cyhalothrin was greater than 1,000 mg a.s./kg soil (the highest concentration tested). At 100 mg/kg soil there were no deaths, behavioural effects, effects on external condition or significant bodyweight changes. The No Observed Effect Concentration (NOEC) for effects on earthworms was 100 mg/kg.	

Effects on *E. foetida* following 14-day exposure to *lambda*-Cyhalothrin in artificial soil

Nominal Concentration (mg a.s./kg dry soil)	Mean % mortality		Mean group weight (g)[a]		
	day 7	day 14	day 7	day 14	% change
Solvent Control	0	0	6.0	4.1	-31.7
32	2.5	2.5	5.9	4.2	-28.8
100	0	0	5.9	3.6	-39.0
1,000	5.0	7.5	5.9	3.0	-49.2**

[a] Per replicate group of 10 worms, adjusted as necessary to compensate for mortalities.
** Significantly different (p = 0.01) from the solvent control.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.1.3	Acute toxicity to plants
91/414 Annex Point addressed	II 8.6/01	Effects on terrestrial plants

		Official use only
Reference point (location) in dossier	**7.5.1.3/01**	
Title:	PP321 : Effects on the plants in the weed science and plant growth regulator screens of the Biological Group	
Project/Report number:	RJ0565B	
Author(s):	Rea, D., Mannion, S.K., Martin, E.A. and Hill, I.R.	
Date of report:	1989	
Published:	Not published	
Testing facility:	Jealott's Hill Research Station, ICI Agrochemicals, Bracknell, UK	
Test substance:	*lambda*-Cyhalothrin EC formulation, 120 g/L, 14.2% w/w	X1
Study dates	March – May 1986	
GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1	

	Official use only
Study 1 **Materials and methods:** *Lambda*-Cyhalothrin as an EC formulation *Lambda*-Cyhalothrin was applied at rates of 30 and 90 g a.s./ha to replicates of seeds/nuts (pre-emergence test) and seedlings (post-emergence test) of 10 plant species. Subsequent growth and assessments for germination, phytotoxicity and symptomology were carried out under glasshouse conditions. Comparisons were made with two toxic reference compounds and unsprayed controls. The reference chemicals Fernimine (a broad-leaf herbicide containing 2,4-D as active ingredient) and Fusilade (a graminicide containing fluazifop-P-butyl as active ingredient) were similarly applied at 300 and 250 g a.s./ha, respectively. The test species are listed in the following table.	

Non-target plant species used to determine the pre- and post-emergence effects of *lambda*-Cyhalothrin on seedling emergence and vegetative vigour

Test species	Family
Beta vulgaris (Sugarbeet)[1]	Chenopodiaceae
Brassica napus (Oilseed rape)[1]	Cruciferae
Xanthium spinosum (Spiny cocklebur)[2]	Compositae
Glycine max (Soybean)[1]	Leguminosae
Cassia obtusifolia[3]	Leguminosae
Galium aparine (Cleavers/Goose grass)[3]	Rubiaceae
Zea mays (Maize)[2]	Gramineae
Triticum aestivum (Wheat)[2]	Gramineae
Avena fatua (Common wild oat)[2]	Gramineae
Cyperus rotundus (Purple nutsedge)[4]	Cyperaceae

[1]10 seeds and 5 plants per replicate for pre- and post-emergence tests respectively.
[2]10 seeds and 6 plants per replicate for pre- and post-emergence tests respectively.
[3]15 seeds and 6 plants per replicate for pre- and post-emergence tests respectively.
[4]10 nuts and 6 plants per replicate for pre- and post-emergence tests respectively.

After spraying, all plants were maintained under glasshouse conditions with 70% relative humidity, 14 hour photoperiod and temperature regimes appropriate as possible for the test species. All watering was to the soil surface, avoiding treated foliage.

For the pre-emergence test, assessments were made of percent germination at full emergence and percent damage (compared against the controls), with symptomology, at 14, 21 and 28 days after spraying. For the post-emergence test, assessments were made of percent damage (compared against the controls), with symptomology, at 7, 14, 21 and 28 days after spraying.

Findings:
Pre-emergence. In the pre-emergence test, 30 g *lambda*-Cyhalothrin/ha, had little or no effect on germination or subsequent growth of the test species. *Z. mays* and *X. spinosum* showed some very slight reduction in growth in one replicate at 28 days after spraying, with a 7% reduction in germination of *Z. mays*. Moderate growth inhibition was recorded in one replicate of *C. rotundus* at 14 days, with some recovery evident at 28 days. At 90 g a.s./ha, the most affected species was *X. spinosum,* with a 12% (overall) reduction in germination and considerable growth inhibition recorded in one replicate at all assessments. *G. max* and *C. rotundus* showed some moderate growth effects, but the remaining species showed virtually no effects at 90 g a.s./ha. The reference compounds both resulted in some germination and growth effects.

Post-emergence. In the post-emergence test, six species were virtually unaffected by 30 g *lambda*-Cyhalothrin/ha with all six showing no effects at 28 days. *B. napus* showed growth inhibition at 7 days in all replicates, but there was complete recovery by 28 days. *T. aestivum, A. fatua* and *G. aparine* showed some growth effects, though these were considered unlikely to be apparent in the field. At 90 g a.s./ha, *Z. mays, B. napus, G. aparine, A. fatua, T. aestivum* and *X. spinosum* showed some growth effects, though *X. spinosum* showed recovery by 28 days. The reference compounds both resulted in expected growth effects.

Study 2
Materials and methods:

Lambda-Cyhalothrin as an EC formulation In a further study, *lambda*-Cyhalothrin was applied at rates of 30 and 90 g a.s/ha to 11 plant species. Subsequent assessments for changes in morphology were carried out under glasshouse conditions. Comparisons were made with five toxic reference compounds and water-sprayed controls. The reference chemicals paclobutrazol, maleic hydrazide, 2,4-D, ethephon and gibberellic acid (GA_3) were sprayed at concentrations to give a variety of plant growth effects. Each treatment was applied to three replicates of 3-6 plants (depending on species). The test species are given in the following table.	

Non-target species used to determine the effects of *lambda*-Cyhalothrin on non-target plant morphology

Test species	Family
Beta vulgaris (Sugarbeet)[1]	Chenopodiaceae
Glycine max (Soybean)[1]	Leguminosae
Malus sylvestris (Apple)[1]	Rosaceae
Lycopersicon esculentum (Tomato)[1]	Solanaceae
Zea mays (Maize)[2]	Gramineae
Triticum aestivum (Wheat)[1]	Gramineae
Hordeum vulgare (Barley)[2]	Gramineae
Oryza sativa (rice)[2]	Gramineae
Agrostis tenuis (Common bent-grass)[3]	Gramineae
Cynosurus cristatus (Crested dog's-tail)[3]	Gramineae
Dactylis glomerata (Cock's-foot)[3]	Gramineae

[1] 6 plants per replicate.
[2] 3 plants per replicate.
[3] 3 species sown together in bands per replicate tray.

After spraying, all plants were maintained under glasshouse conditions under a 16 hour photoperiod and temperature regimes appropriate to the test species. All watering was to the soil surface avoiding treated foliage. Assessments were carried out for up to 41 days after spraying (depending on the species) for changes in morphology when compared with control plants and the reference treatments. Phytotoxicity and the type and level of effect were recorded. **Findings:** *Lambda*-Cyhalothrin, at 30 g a.s./ha, had little or no effect on any of the plant species tested, other than a considerable reduction in leaf area in one replicate only of *C. cristatus*. At 90 g a.s./ha, *L. esculentum* showed moderate stunting with reductions in both plant size and leaf area, *C. cristatus* exhibited considerable reduction in leaf area and *O. sativa* showed some evidence of enhanced growth.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	**7.5.2**	**Terrestrial long-term tests *(headline)***

98/8 Doc IIIA section No.	**7.5.2.1/01**	**Reproduction study with other soil non-target macro-organisms**
91/414 Annex Point addressed	**II 8.4.2/01**	**Sublethal effects on earthworms**

		Official use only
Reference point (location) in dossier	**7.5.2.1/01**	
Title:	PP321: - Effects on earthworms *Lumbricidae* of repeated annual field applications	
Project/Report number:	RJ0511B	
Author(s):	Coulson, J.M., Collins, I.G. and Edwards, P.J.	
Date of report:	1986	
Published:	Not published	
Testing facility:	Jealott's Hill Research Station, ICI Agrochemicals, Bracknell, UK	
Test substance:	*Lambda*-Cyhalothrin EC formulation, 2.4% w/v	X1
Study dates	May 1983 – March 1986	
GLP:	No	
Deficiencies:	None	
Reliability indicator	2	

	Official use only
Materials and methods: *Lambda*-Cyhalothrin 2.5% w/v EC formulation, (a.s. content 2.4% w/v, measured). The trials were carried out on 3 blocks of six replicate plots (6m x 6 m) with permanent grassland on sandy loam soil located in '18 Acres' field, Jealott's Hill Farm, Berkshire, UK. Three replicate plots, one in each block, were treated at either 25 or 250 g ai/ha. Two plots were used as untreated controls, and 2 plots were treated with the toxic reference benomyl at 2 or 3 kg/ha. The plots were sprayed once a year for three years, on 20 May 1983, 17 April 1984 and 26 April 1985. Samples were taken prior to any treatments, and then 1, 5 and 11 months post treatment in the first year, 6 and 12 months after the second treatment and 7 and 11 months after the third treatment. Earthworms were sampled using the formaldehyde expellent method. Formaldehyde solution (4.5 or 9 litres 0.2% formaldehyde) of were applied to the soil surface in twelve 60 × 60cm square sampling areas within each treatment plot in order to expel the earthworms. The worms expelled over a period of 20 minutes were collected, counted, weighed and in most instances identified prior to storage. The numbers of adult and immature earthworms of the most abundant species, the total number of earthworms, and the total earthworm weights were recorded. Data were transformed, then analysed using analysis of	X2

variance to compare treatment means. **Findings:** Significant differences were detected between the benomyl treatments and the control, indicating that the experimental method could reliably detect effects on earthworm populations. Transitional significant differences in total earthworms numbers were identified between the control and 250 g *lambda*-Cyhalothrin/ha treatments for immature *Allolobophora rosea* one month after the first treatment, and for adult *Allolobophora caliginosa* 12 months after the second treatment. A significant difference in total worm weight was detected after the second 25 g *lambda*-Cyhalothrin/ha treatment. However, no consistent adverse differences were observed between the *lambda*-Cyhalothrin treatments and control, and full recovery occurred within a year in those instances where a difference was detected. Earthworm populations were therefore not adversely affected by *lambda*-Cyhalothrin applications at either 25 or 250 kg ai/ha. *Lambda*-Cyhalothrin will not adversely affect earthworm populations when applied repeatedly at annual intervals at rates up to 250 g a.s./ha.	X3 X4

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A7.5.2.1 Annex Point IIIA XIII 3.2	Reproduction study with other soil non-target macro-organisms (*Folsomia candida*)

Reference	Study submitted in March 2010	Official use only
Reference	Friedrich, S. (2009) Lambda-cyhalothrin SC (A12690B) - Effects on the reproduction of the collembolans *Folsomia candida*, Report Number 09 10 48 038 S. BioChem agrar GmbH, Kupferstraße 6, 04827 Gerichshain, Germany	
Data protection	Yes	
1. Data owner	Syngenta Crop Protection AG	
2. Companies with letter of access	-	
3. Criteria for data protection	[redacted]	
	Guidelines and Quality Assurance	
Guideline study	Yes ISO 11267 (1999): Soil quality – inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants. International Standard, First edition 1999-04-01.	
GLP	Yes	
Deviations	None	
	MATERIALS AND METHODS	
Test Material:	A12690B.	X1
Description:	off-white opaque liquid	
Lot/Batch No.:	[redacted]	
Purity:		nominal: analysed
	lambda-cyhalothrin (PP321): 100 g/L: 96.8 g/L	
Density:	1.059 g/cm³	
Stability:	Stable under normal use and storage conditions	
Control:	Prepared with deionised water	
Toxic standard:	Betosip (Phenmedipham 157 g/L) at 50, 100, 200 and 400 mg product/kg (separate test run)	
Test concentrations:	20.5, 51.2, 128, 320, 800, 2000 mg A12690B/kg soil d.w.	X2

Test organisms	*Folsomia candida*	
Source:	Originally purchased from "Biologische Bundesanstalt (BBA)", Berlin-Dahlem. Reared under ambient laboratory conditions in the test facility	
Food:	2 mg granulated dry yeast at the start of the test and after 14 days	
Age at test start:	juvenile collembolans, 10-12 days old	
Test design		
Test substrate:	Artificial soil comprising 10 % sphagnum peat, 20 % kaolin clay (kaolinite content > 30 %), 69.5 % industrial quartz sand (> 50 % of the particles between 0.05 mm and 0.2 mm) and 0.5 % calcium carbonate. 30 g wet weight soil, corresponding to about 22.3 g dry weight of artificial soil, was added to each test vessel	
Replication:	5 (+ 2 replicates not loaded with collembolans for measurement purposes)	
No. of collembolans/vessel:	10	
Environmental test conditions		
Temperature:	18.8 – 21.2 °C	
pH:	5.6 – 6.0	
Water content of soil:	53.1 – 54.2 % of WHC	
Photoperiod:	16 hours light : 8 hours dark photoperiod (approximately 590 lux)	
Duration of test:	28 days	

Study Design and Methods

Experimental dates: 08 May to 05 June 2009.

The test concentrations were prepared by dispersing an exactly weighed amount of the test item in deionised water to make a stock solution. This stock solution was diluted with deionised water for each test concentration and was thoroughly mixed with the artificial soil using a mixing machine, achieving a final nominal water content of 40-60 % of WHC. The control was treated with deionised water only. 30g (wet weight) of test substrate was added to each vessel, avoiding compression. Ten juvenile collembolans were transferred after the application to the substrate surface of each test vessel using an exhauster. Five replicates (+ two replicates not loaded with collembolans for measurement purposes) were used per test concentration and control. The test organisms were fed twice during the experiment (at the start of the test and after 14 days) with approximately 2 mg of granulated dry yeast per test vessel. Four weeks after introducing the test organisms, the surviving parental collembolans and offspring (juveniles) were counted, by means of a digital image processing system.

The glass lids covering the test vessels were briefly opened twice a week for aeration. The water content was checked weekly by reweighing the two additional test vessels. Water loss was compensated in all vessels if exceeding 2 % of the initial water content.

The statistical analysis was performed with the software ToxRat Professional 2.10 (Ratte 2009). Fisher`s Exact Binomial Test with Bonferroni Correction and Dunnett-test were used to compare the control with the independent test item groups. LC_{50} and EC_{50} were calculated by Probit analysis using weighted regression and linear max. likelihood regression, respectively. Mortality of adult collembolans was corrected using the formula by Abbott (1925).

Results and Discussion

Mortality and fecundity are summarised in the table below.

Table 7.5.2.1-1 Effects of residues of A12690B on mortality and reproduction of *Collembola candida*

Endpoint	Treatment group (mg A12690B/kg soil d.w.)						
	Control	20.5	51.2	128	320	800	2000
% Mortality of parental collembolans after 4 weeks	6	6	6	18	28*	48*	90*
% corrected mortality (Abbott)	-	0	0	13	23	45	89
Mean number of juveniles after 4 weeks	634.8	606.2	584.8	353.2*	285.6*	155.0*	31.6*
SD	104.0	140.6	103.1	52.1	79.4	50.4	9.6
CV %	16.4	23.2	17.6	14.7	27.8	32.5	30.2
% reduction of reproduction compared to control	-	5	8	44	55	76	95
NOEC (mortality)	**128 mg A12690B/kg soil d.w.**						
NOEC (reproduction)	**51.2 mg A12690B/kg soil d.w.**						
LC_{50}	**507 mg A12690B/kg soil d.w.** (95 % confidence limits 171 to 1500 mg A12690B/kg soil d.w.)						
EC_{50}	**236 mg A12690B/kg soil d.w.** (95 % confidence limits 148 to 377mg A12690B/kg soil d.w)						

* statistically significant differences compared to the control (Fisher-exact test for mortality; Dunnett-t-test for reproduction; $p \leq 0.05$), SD: standard deviation CV: coefficient of variation
Abbott`s formula for corrected mortality (Abbott, 1925): M (%) = ((A-B)/A) * 100 %
A = mean number of surviving parental collembolans in the control group
B = mean number of surviving parental collembolans in the treated groups
Percent reduction: $(1-R_t/R_c) * 100$ %, R_t = the reproduction observed in the treated groups, R_c = the reproduction observed in the control group

All validity criteria for the control group were met:
Parental mortality: ≤ 20 % (observed: 6 %)
Minimum number of instars/vessel: ≥ 100 (observed: average of 634.8/vessel)
Coefficient of variation of juvenile number: ≤ 30 % (observed: 16.4 %)

To verify the sensitivity of the test system the reference item Betosip is routinely tested at concentrations of 50, 100, 200 and 400 mg product/kg soil dry weight. In the most recent study (BioChem project No. TC-R 08 10 48 001, dated 16 December 2008) the determined EC_{50} (reproduction) was 181.0 mg Betosip/kg soil d.w. The EC_{50} value for the reduction of reproduction

was within the range of 100-200 mg product/kg soil dry weight specified in ISO 11267 (1999), the EC_{50} therefore showed that the test system was sensitive.

	Applicant's Summary and conclusion
Materials and methods	The toxicity of A12690B to the reproduction and the parental mortality of collembolan species *Folsomia candida* were determined.
Results and discussion	The NOEC for the parental collembolans was determined to be 128 mg A12690B/kg soil dry weight. The LC_{50} was calculated to be 507 mg A12690B/kg soil d.w. The NOEC for reproduction was determined to be 51.2 mg A12690B/kg soil d.w. The EC_{50} was calculated to be 236 mg A12690B/kg soil d.w.
Conclusion	Validity criteria according to the test method are fulfilled, test results can be considered reliable.
Reliability	1
Deficiencies	None
	Evaluation by Competent Authorities
	Evaluation by Rapporteur Member State
Date	April 2010
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.2.2	Long-term test with terrestrial plants
91/414 Annex Point addressed		

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant	
Evaluation of applicant's justification	[redacted].	
Conclusion	[redacted]	
Remarks		

98/8 Doc IIIA section No.	7.5.3	Effects on birds *(headline)*

98/8 Doc IIIA section No.	7.5.3.1.1/01	Acute oral toxicity
91/414 Annex Point addressed	II 8.1.1/01	Effects on birds - Acute oral toxicity

		Official use only
Reference point (location) in dossier	**7.5.3.1.1/01**	
Title:	The acute oral toxicity (LD_{50}) of PP321 to the mallard duck	
Project/Report number:	[redacted]/C/1240	
Author(s):	[redacted]	
Date of report:	1984	
Published:	Not published	
Testing facility:	[redacted]	
Test substance:	*Lambda*-Cyhalothrin (PP321)[redacted]	X1
Study dates	20 September - 18 October 1983	
GLP:	Yes	X2
Deficiencies:	None.	
Reliability indicator	1	

	Official use only
Materials and methods: Six groups of 10 young adult mallard ducks, comprising 5 male and 5 females, were dosed by oral intubation of *lambda*-Cyhalothrin in corn oil. Dose levels were 0 (corn oil control), 739, 1040, 1620, 2580 and 3950 mg a.s./kg bodyweight. Birds were preconditioned for 14 days prior to dosing. Post-treatment observations lasted 14 days, during which mortality and bird health was monitored daily and bodyweight and food consumption measured weekly. All birds were examined at termination for gross pathological changes. **Findings:** The acute oral LD_{50}, Lowest Lethal Dose (LLD), and NOEL to the mallard duck were all >3950 mg/kg, the maximum dose tested. There were no dose related gross macroscopic abnormalities at termination of the study.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.3.1.2/0 1	Short term toxicity
91/414 Annex Point addressed	II 8.1.2/01	Effects on birds - Short-term dietary toxicity

○○		Official use only
Reference point (location) in dossier	**7.5.3.1.2/01**	
Title:	The subacute dietary toxicity of PP321 to the mallard duck	X1
Project/Report number:	[redacted]/C/1358	
Author(s):	[redacted]	
Date of report:	1985	
Published:	Not published	
Testing facility:	[redacted]	
Test substance:	*Lambda*-Cyhalothrin (PP321), purity [redacted]	X2
Study dates	24 September - 05 October 1984	X3
GLP:	Yes	X4
Deficiencies:	None.	
Reliability indicator	1	

	Official use only
Materials and methods: Groups of 10 juvenile mallard ducks (*Anas platyrhynchos*) were exposed to diets containing 0 (control), 508, 1030, 2030, 3020, 4020 or 5040 mg ai/kg *lambda*-Cyhalothrin for 5 days. Test diets were then replaced with untreated diet, and the birds observed for a further 4 days. Mortality and clinical observations were monitored daily. Bodyweights were measured on days -3, 0, 5, 8 and 9. Food consumption was measured on days -3 to -1, 1 to 5 (treated diet) and 6 - 9 (untreated diet). All birds were examined macroscopically *post-mortem*. **Findings:** The subacute dietary LC_{50} was 3978 mg/kg diet. During the treatment period, mean group bodyweight increases at dietary concentrations of 508 and 1030 mg/kg were lower than the controls, while at 2030 to 5040 mg/kg there was a decline in mean bodyweight. All groups showed a mean bodyweight increase over days 5 to 9. There was a dose-related reduction in mean food consumption over the 5-day treatment period. The food consumption in the post-treatment periods was within normal limits for all groups. No gross macroscopic post-mortem abnormalities were detected	X1 X5 X6 X7

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Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
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Remarks	

98/8 Doc IIIA section No.	7.5.3.1.2/0 1	Short term toxicity
91/414 Annex Point addressed	II 8.1.2/01	Effects on birds - Short-term dietary toxicity

		Official use only
Reference point (location) in dossier	**7.5.3.1.2/02**	
Title:	The subacute dietary toxicity of PP321 to the mallard duck	
Project/Report number:	[redacted]/C/1358	
Author(s):	[redacted]	
Date of report:	1985	
Published:	Not published	
Testing facility:	[redacted]	
Test substance:	*Lambda*-Cyhalothrin (PP321), purity [redacted]	X1
Study dates	24 September - 05 October 1984	
GLP:	Yes	X2
Deficiencies:	None.	
Reliability indicator	1	

	Official use only
Materials and methods: Groups of 10 juvenile mallard ducks (*Anas platyrhynchos*) were exposed to diets containing 0 (control), 508, 1030, 2030, 3020, 4020 or 5040 mg ai/kg *lambda*-Cyhalothrin for 5 days. Test diets were then replaced with untreated diet, and the birds observed for a further 4 days. Mortality and clinical observations were monitored daily. Bodyweights were measured on days -3, 0, 5, 8 and 9. Food consumption was measured on days -3 to -1, 1 to 5 (treated diet) and 6 - 9 (untreated diet). All birds were examined macroscopically *post-mortem*. **Findings:** The subacute dietary LC_{50} was 3978 mg/kg diet. During the treatment period, mean group bodyweight increases at dietary concentrations of 508 and 1030 mg/kg were lower than the controls, while at 2030 to 5040 mg/kg there was a decline in mean bodyweight. All groups showed a mean bodyweight increase over days 5 to 9. There was a dose-related reduction in mean food consumption over the 5-day treatment period. The food consumption in the post-treatment periods was within normal limits for all groups. No gross macroscopic post-mortem abnormalities were detected	

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Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.3.1.3/01	Effects on reproduction
91/414 Annex Point addressed	II 8.1.3/01	Effects on birds - Short-term dietary toxicity

		Official use only
Reference point (location) in dossier	**7.5.3.1.3/01**	
Title:	PP321: A one-generation reproduction study with the mallard (*Anas platyrhynchos)*	
Project/Report number:	123-143	
Author(s):	[redacted]	
Date of report:	1989	
Published:	Not published	
Testing facility:	[redacted]	
Test substance:	*Lambda*-Cyhalothrin (PP321), purity [redacted]	X1
Study dates	05 October 1988 - 30 March 1989	
GLP:	Yes	X2
Deficiencies:	None.	
Reliability indicator	1.	

	Official use only
Materials and methods: Eighty male and 80 female young adult mallard ducks were given treated diet for 20 weeks. Nominal concentrations were 0 (control), 0.5, 5.0, 15 and 30 mg ai/kg in diet. Birds were preconditioned for 3 weeks before a 20-week exposure period to treated diets. During the first 8 weeks of exposure, birds received an 8 hour light:16 hour dark photoperiod. The photoperiod was then increased to a 17 hour light:7 hour dark to bring the birds into egg-laying condition in about 2 weeks. Egg laying and collection started after 10 weeks on treated diet and lasted 10 weeks. The following parameters were measured for each pen: adult mortality, clinical symptoms of toxicity, food consumption, bodyweight and post-mortem examination at completion of the study; numbers of eggs laid, cracked and set; numbers of viable and live 3-week old embryos; numbers of hatchlings, numbers and bodyweight of 14-day old survivors and 14 day old survivors; and eggshell thickness. **Findings:** In adults, dietary concentrations at 0.5, 5.0, 15, and 30 mg/kg did not cause any treatment related mortality, clinical symptoms of toxicity, effects on food consumption and bodyweight or gross abnormalities found at *post-mortem*. The adult chronic (long term) NOEL to mallard duck was 30 mg/kg in diet for 20 weeks. For reproductive effects, dietary concentrations of 0.5, 5.0, 15, and 30 mg/kg did not cause any treatment related effects on any reproductive parameter (see below). There were no statistically significant effects. The reproductive NOEL of *lambda*-Cyhalothrin to mallard duck was 30 mg/kg in diet for 20 weeks.	X3

Effects on reproductive performance of mallard duck following 20-week dietary exposure to *lambda*-Cyhalothrin

Reproductive parameter	Dietary concentration (mg *lambda*-Cyhalothrin/kg)				
	Control	0.5	5.0	15	30
Eggs laid	567	564	645	632	563
Eggs cracked	17	5	6	6	7
Eggs set	486	501	581	567	499
Viable embryos	454	474	524	499	463
Live 3-week embryos	450	463	495	477	451
Hatchlings	350	274	295	337	324
14-day old survivors	337	268	282	311	315
Eggs laid/female	35	35	40	40	35
Eggs laid/female/day	0.55	0.54	0.62	0.61	0.54
14-day old survivors/female	21	17	18	19	20
Egg-shell thickness (mm)	0.39	0.40	0.39	0.38	0.39

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98/8 Doc IIIA section No.	7.5.4.1/01	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.1.1	Bees: Acute toxicity

		Official use only
Reference point (location) in dossier	**7.5.4.1/01**	
Title:	PP321: Acute contact and oral toxicity to honey bees (*Apis mellifera*)	
Project/Report number:	RJ0390B	
Author(s):	Gough, H.J., Collins, I.G., Everett, C.J. and Wilkinson, W.	
Date of report:	1984	
Published:	Not published	
Testing facility:	Jealott's Hill Research Station, ICI Plant Protection Division, Bracknell, UK	
Test substance:	*Lambda*-Cyhalothrin technical (PP321), purity [redacted]	X1
Study dates	13 August - 24 August 1984	
GLP:	Yes	X2
Deficiencies:	None.	
Reliability indicator	1.	

	Official use only
Materials and methods: Two contact and two oral tests were done with technical *lambda*-Cyhalothrin. A range of dose rates and a control were used for each test, with three replicate cages of 10 bees per dose rate. **Contact tests**: A 1 µl drop of a given concentration of *lambda*-Cyhalothrin, dissolved in acetone and mixed with an aqueous solution of Agral 90 wetting agent, was applied to the thorax of each bee. Control bees were treated with the appropriate solvent plus wetting agent only. Dose levels were 0 (control), 0.005, 0.01, 0.02, 0.05, 0.1 and 0.2 µg/bee. After dosing, the bees were returned to the cage, allowed to recover and kept in the controlled environment room, with a constant supply of aqueous 50% sucrose solution. **Oral tests**: each group of 10 bees was fed 0.2 ml of a given concentration of *lambda*-Cyhalothrin, dissolved in acetone and mixed with 50% aqueous sucrose feeding solution, the dose being measured into the feeding tube before the bees were put into the cage. This is equivalent to 20 µl per bee. Control bees were fed with 50% sucrose solution containing the appropriate solvent at the highest concentration used with the test material. Dose levels were 0 (control), 0.05, 0.1, 0.20, 0.5, 1.0, 2.0 and 5.0 µg/bee. When all the test material had been taken, the feeding tubes were replaced by similar tubes containing 2 ml of unamended 50% sucrose solution, and these were replenished when necessary. In both contact and oral tests, numbers of dead bees were counted at 1, 2, 4, 24 and 48 hours	X3

after treatment. Technical dimethoate was used as a toxic standard. **Findings:** The 24- and 48-hour LD_{50} values for technical *lambda*-Cyhalothrin are shown below. The results for dimethoate, the toxic standard, show that the bees were reacting normally to toxic compounds under the test conditions.	X4

Acute toxicity endpoints for *A. mellifera* following contact exposure to technical *lambda*-Cyhalothrin

Test	Contact LD_{50} and 95% confidence limits (µg *lambda*-Cyhalothrin/bee)			
	24 hours		48 hours	
1	0.036	(0.025 - 0.052)	0.027	(0.022 - 0.033)
2	0.073	(0.055 - 0.099)	0.054	(0.043 - 0.070)
mean	0.051		0.038	

Acute toxicity endpoints for *A. mellifera* following oral exposure to technical *lambda*-Cyhalothrin

Test	Oral LD_{50} and 95% confidence limits (µg *lambda*-Cyhalothrin/bee)			
	24 hours		48 hours	
1	0.896	(0.772 - 1.042)	0.812	(0.701 - 0.928)
2	1.040	(0.834 - 1.307)	1.018	(0.842 - 1.223)
mean	0.965		0.909	

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