

98/8 Doc IIIA section No.	7.4.1.1/12	Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1/12	Acute toxicity to fish

		Official use only
Reference point (location) in dossier	7.4.1.1/12	
Title:	PP890: Determination of acute toxicity to rainbow trout (<i>Salmo gairdneri</i>).	
Project/Report number:	BL/B/2457	
Author(s):	██████████	
Date of report:	1984	
Published:	Not published.	
Testing facility:	██ ██████████	
Test substance:	lambda-Cyhalothrin metabolite (PP890), purity ██████████	
Study dates	1984	
GLP:	No	X1
Deficiencies:	None.	
Reliability indicator	2	

		Official use only
Materials and methods: <i>Lambda</i> -Cyhalothrin metabolite Compound Ia (termed PP890 in the report),		X2
The acute toxicity to fish of the <i>lambda</i> -Cyhalothrin metabolite Compound Ia, the cyclopropane acid, was assessed with rainbow trout (<i>Onchorynchus mykiss</i> - formerly <i>Salmo gairdneri</i>), exposed to a series of concentrations of Compound Ia in a semi-static system. Ten juvenile fish were exposed at each test concentration. Nominal test concentrations were 3.2, 5.6, 7.5, 10 and 18 mg/L, plus solvent and untreated controls. The test solutions were refreshed daily at each 24 hour period. The fish were assessed for mortality and symptoms of toxicity at 24, 48, 72 and 96 hours. Measured throughout the test, dissolved oxygen was in the range 10.0-11.2 mg/L, pH in the range 7.4-8.0, water hardness was 60.6-68.3 mg CaCO ₃ /L and temperature 11.4-13.0°C.		X3
Findings: The mean measured concentrations of Compound Ia in the test vessels, based on analyses of fresh and expired media at each 24 hour renewal, ranged from 60 to 92% of the nominal values. The measured values determined in fresh media varied from 33 to 88% of nominal. These lower concentrations were due to incomplete dissolution of the test compound. Analyses of expired media showed Compound Ia had dissolved, bringing the test concentrations to between 88 and 97% of nominal. Measured concentrations of Compound Ia in the test solutions are shown in the table below. At the highest concentration of Compound Ia tested (mean measured concentration 15.8 mg/L) the fish exhibited rapid respiration and at		X4

the mean measured concentration of 7.3 mg/L, one fish died. There were no other symptoms of toxicity in this test and the NOEC was considered to be 5.3 mg/L, based on mean measured concentrations.

Measured concentrations of Compound Ia in a semi-static acute toxicity test with rainbow trout

Nominal Concn mg/L	Mean measured concentrations (mg/L)			
	Fresh media (% of nominal)		Expired (24 h media (% of nominal)	
Fresh-water control	<0.2	(-)	<0.2	(-)
Solvent control	<0.2	(-)	<0.2	(-)
3.2	2.8	(87.5)	3.1	(96.9)
5.6	4.0	(71.4)	5.3	(94.6)
7.5	4.8	(64.0)	7.3	(97.3)
10	5.8	(58.0)	9.3	(93.0)
18	5.9	(32.8)	15.8	(87.8)

Effects on rainbow trout exposed to Compound Ia for 96 hours under semi-static conditions

Nominal concn mg/L	Mean measured expired concn mg/L	Cumulative Percentage Mortality			
		24 hours	48 hours	72 hours	96 hours
Fresh-water control	<0.2	0	0	0	0
Solvent control	<0.2	0	0	0	0
3.2	3.1	0	0	0	0
5.6	5.3	0	0	0	0
7.5	7.3	0	0	10	10
10	9.3	0	0	0	0
18	15.8	0	0	0	0

The LC₅₀ values were calculated based on the mean measured concentrations in expired media. LC₅₀ values are presented below.

The 96h LC₅₀ of lambda-Cyhalothrin metabolite Compound Ia to rainbow trout (*Oncorhynchus mykiss*) exceeded 15.8 mg/L (mean measured), the highest concentration tested. The no observed effect concentration (NOEC) based on mortality and symptoms of toxicity was 5.3 mg/L.

X5

Compound Ia rainbow trout LC₅₀ values

Time (hours)	LC ₅₀ (mg/L)
24	> 15.8
48	> 15.8

72	> 15.8
96	> 15.8

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]

98/8 Doc IIIA section No.	7.4.1.1/13	Acute toxicity to fish
91/414 Annex	II	Acute toxicity to fish
Point addressed	8.2.1/13	

		Official use only
Reference point (location) in dossier	7.4.1.1/13	
Title:	PP890: Determination of acute toxicity to bluegill sunfish (<i>Lepomis macrochirus</i>).	
Project/Report number:	BL/B/3029	
Author(s):	████████████████████	
Date of report:	1984	
Published:	Not published.	
Testing facility:	████████████████████ ████████████████████	
Test substance:	lambda-Cyhalothrin metabolite (PP890), purity ██████████	
Study dates	1984	
GLP:	No	X1
Deficiencies:	None.	
Reliability indicator	2	

		Official use only
Materials and methods: <i>Lambda</i> -Cyhalothrin metabolite Compound Ia (termed PP890 in the report),		X2
The acute toxicity to fish of the <i>lambda</i> -Cyhalothrin metabolite Compound Ia, the cyclopropane acid, was assessed with a second fish species, bluegill sunfish (<i>Lepomis macrochirus</i>), exposed to a series of concentrations of Compound Ia in a static system. Ten fish were exposed at each test concentration for 96 hours. Two separate sequential tests (Test I and Test II) were carried out. For each test, nominal test concentrations were 3.2, 5.6, 10, 18 and 32 mg/L, plus solvent and freshwater controls. The fish were assessed for mortality and symptoms of toxicity at 24, 48, 72 and 96 hours. Measured throughout both tests, dissolved oxygen was in the range 3.0-9.0 mg/L, pH in the range 6.6-8.2 and temperature 19.7-23.0°C. Water hardness, as CaCO ₃ , at the start of tests I and II was in the range 54.0-56.0 mg/L.		X3
Findings: The concentration of Compound Ia in the test solutions was determined at 0, 45 h and 96 hours during the exposure period. Results of these analyses indicated that the Compound Ia tended to come out of solution on addition to the test vessels, particularly at the higher concentrations, and then slowly re-dissolved during the test period. The mean measured concentrations of Compound Ia in the test vessels ranged from 44 to 100% and from 53 to 100% of the nominal values in tests I and II, respectively. The observations of mortality during tests I and II are shown in the tables below.		

Measured concentrations and mortality of bluegill sunfish exposed to Compound Ia for 96 hours under static conditions (Test I)

Nominal Concn mg/L	Measured Concn mg/L				Cumulative Percentage Mortality			
	0 h	45 h	96 h	Mean	24 h	48 h	72 h	96 h
Fresh-water control	<0.32	<0.32	<0.32	-	0	0	0	0
Solvent control	<0.32	<0.32	<0.32	-	0	0	0	0
3.2	3.0	3.4	3.3	3.2	0	0	0	0
5.6	2.8	5.6	5.6	4.7	0	0	0	0
10	2.8	9.7	9.9	7.5	0	0	0	0
18	2.4	13.0	16.0	10	0	0	10	10
32	2.2	17.0	22.0	14	0	10	10	10

Measured concentrations and mortality of bluegill sunfish exposed to Compound Ia for 96 hours under static conditions (Test II)

Nominal Concn mg/L	Measured Concn mg/L				Cumulative Percentage Mortality			
	0 h	45 h	96 h	Mean	24 h	48 h	72 h	96 h
Fresh-water control	<0.32	<0.32	<0.32	-	0	0	0	0
Solvent control	<0.32	<0.32	<0.32	-	0	0	0	0
3.2	2.5	3.0	4.1	3.2	0	0	0	0
5.6	3.0	5.5	6.2	4.9	0	0	0	0
10	3.9	10.0	10.0	8.0	0	0	0	0
18	3.4	13.0	18.0	11	0	10	10	10
32	5.8	17.0	27.0	17	0	0	0	0

The LC₅₀ values were calculated based on the mean measured concentrations over the 96 hour exposure period for each test. The LC₅₀ values are shown in the table below.

The 96 hour LC₅₀ for Compound Ia to bluegill sunfish was considered to be >14 mg/L. There were no mortalities or other symptoms of toxicity in any test solutions with a measured mean concentration of 7.5 mg/L or lower during the 96 hour exposure period and the NOEC was considered to be 7.5 mg/L.

Compound Ia bluegill sunfish LC₅₀ values

Time (hours)	LC ₅₀ (mg/L)	
	Test I	Test II
24	> 14	> 17
48	> 14	> 17
72	> 14	> 17
96	> 14	> 17

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

98/8 Doc IIIA section No.	7.4.1.2/01	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4/01	Acute toxicity to invertebrates

		Official use only
Reference point (location) in dossier	7.4.1.2/01	
Title:	PP321: Toxicity to first instar <i>Daphnia magna</i> .	
Project/Report number:	RJ0359B	
Author(s):	Farrelly, E., Hamer, M.J. and Hill, I.R.	
Date of report:	1984	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	lambda-Cyhalothrin (PP321), purity █████	
Study dates	Not stated	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

		Official use only
Materials and methods: <i>Daphnia magna</i> , less than 24 hours old at the start of the test, were exposed to a series of concentrations of lambda-Cyhalothrin in hard, reconstituted water (160-180 mg/L as CaCO ₃) in a static test system. Two separate sequential tests (Test I and Test II) were carried out.		X1
Findings: Test concentrations were nominally, 0.0625 (Test II only), 0.125, 0.25, 0.5, 1, 2, 4, 8, 16, and 32 ug/L, plus solvent control. The toxicity of lambda-Cyhalothrin to the <i>Daphnia</i> was assessed after 3, 9, 24 and 48 hours. <i>Daphnia</i> were recorded as affected if they were immobilised or showing only minor movements of appendages. Measured at 0 and 48 hours, dissolved oxygen was in the range 7.6-9.1 mg/L and pH 7.7-8.6. Temperature was 20 ± 1°C throughout the tests. The EC ₅₀ values and 48 hour NOECs, based on mean measured concentrations at 0 and 48 hours are shown in the table below.		X2

Toxicity of lambda-Cyhalothrin to First Instar *Daphnia magna* Based on Mean Measured Concentrations

Test	EC ₅₀ values in ug/L (95% confidence limits)				48 h NOEC (ug/L)
	3	9	24	48	
I	>19.3	14.3(10.4-22.6)	3.8(2.9-5.1)	0.57(0.45-0.73)	<0.10
II	>15.1	>15.1	6.7(4.6-11.1)	0.23(0.18-0.29)	0.04

	Official use only
The mean EC ₅₀ values for 24 and 48 hours were 5.04 and 0.36 ug/L, respectively. The 48 hour NOEC was 0.04 ug/L.	

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]

98/8 Doc IIIA section No.	7.4.1.2/02	Acute toxicity to invertebrates
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/02	

		Official use only
Reference point (location) in dossier	7.4.1.2/02	
Title:	Lambda-Cyhalothrin: Acute toxicity to <i>Daphnia magna</i> in water only and water-sediment systems	
Project/Report number:	BL4912/B	
Author(s):	Stewart, K.M., Kent, S.J., Johnson, P.A. and Morris, D.S.	
Date of report:	1995	
Published:	Not published.	
Testing facility:	Brixham Environmental Laboratory, Zeneca Limited, Brixham, UK	
Test substance:	lambda-Cyhalothrin technical, purity █████	
Study dates	08 - 11 June 1993	
GLP:	Yes	
Deficiencies:	None	
Reliability indicator	1	

<p>Materials and methods: Lambda-Cyhalothrin technical, Purity: █████ w/w lambda-Cyhalothrin.</p> <p>Water-sediment systems were prepared using three different sediments: SED 1 "Iron Hatch" (3.0% organic matter), SED 2 "Mill Stream" (21.0% organic matter), SED 3 "18 Acres" (5.9% organic matter). Parallel sets of six water-sediment systems were prepared for each of three difference sediments (one set stirred and the other set unstirred), plus a solvent control water-sediment system. Each system contained 8 g sediment (dry wt) and 200 mL water (including sediment moisture). In each set, one replicate system was prepared at each of six concentrations of lambda-Cyhalothrin. The sediment in the "stirred" replicates was disturbed by stirring at 24 and 48 hours into the test. Additionally water-only test systems were set up with one replicate at each of seven test concentrations, plus an untreated control.</p> <p><i>Daphnia</i> (4 ± 1 days old) were exposed to nominal concentrations of 0.4, 1.28, 4, 12.8, 40 and 128 ug/L of lambda-Cyhalothrin in each of the three water-sediment systems (assumes all the lambda-Cyhalothrin was present in the water phase for comparative purposes). Concurrently, <i>Daphnia</i> were exposed in water only systems at nominal concentrations of 0.0032, 0.01, 0.032, 0.1, 0.32, 1 and 3.2 ug/L of lambda-Cyhalothrin. Only one replicate system was employed at each concentration for each system type. In addition <i>Daphnia</i> were maintained in the relevant dilution water (untreated control) and solvent control (0.5 ml acetone/L) systems. Each test system contained 10 <i>Daphnia</i> in a water volume of 200 ml, the animals were exposed at 20 ± 1oC over a 72 hour period. The <i>Daphnia</i> were not fed during the course of the test. At the start of the study the concentrations of lambda-Cyhalothrin technical in the stock solutions were determined by chemical analyses.</p>	Official use only X1 X2 X3
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<p>Findings: The concentrations of lambda-Cyhalothrin technical in stock solutions used in the water sediment and water only systems ranged from 84 to 98% of the nominal values. In the water sediment systems the 24 and 48 hour assessments were impeded by suspended sediment and led to inconsistencies with observations made at 72 hours. Therefore, results from the 24 and 48 hour observations were not used to calculate EC₅₀ values.</p> <p>Symptoms of toxicity observed in the study were slower swimming movements, swimming nearer to the substrate or vessel bottom, paler colour, particulates adhering to appendages and decrease in size compared to the respective dilution water control or solvent control. The effects were very slight in the lower concentrations with a gradual increase in severity with increasing concentration.</p> <p>The median effect concentration (EC₅₀) was defined as the concentration resulting in 50% immobilisation of the <i>Daphnia</i> at the time specified. The relative differences between the 72 hour EC₅₀ value determined in the water only (EC_{50w}) and the 72 hour EC₅₀ value determined in the water-sediment systems (EC_{50s}) was calculated as EC_{50s} divided by EC_{50w}.</p> <p>There was no significant difference (P = 0.05, paired t-test) between the EC₅₀ values determined in the stirred (S) and unstirred (NS) water-sediment systems for each sediment type. The 72 hour EC₅₀ values determined in the water-sediment systems ranged from 73 to 280 times greater than the water only EC₅₀ value. The relative differences were highest for the SED 2 water-sediment systems with the highest organic matter content (21% w/w). The relative increase in the 72 hour EC₅₀ values in the presence of sediment was considered to be due to adsorption of the lambda-Cyhalothrin onto the sediment and a subsequent reduction in bioavailability.</p>	<p>X4</p> <p>X5</p> <p>X6</p> <p>X7</p>
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EC₅₀ and NOEC values determined for *Daphnia magna* exposed to lambda-cyhalothrin in water-sediment and water only systems

Test system			EC ₅₀ (Confidence interval) ug/L ⁽¹⁾			72 hour NOEC (ug/L)	EC _{50s} /EC _{50w} (0.26 ug/L)
			24 hours	48 hours	72 hours		
Water-sediment	SED 1 3.0% OM	S	*	*	21 (12-40)	1.3	81 : 1
		NS	*	*	31 (20-52)	13	120 : 1
	SED 2 21% OM	S	*	*	72 (40-130)	40	280 : 1
		NS	*	*	63 (40-130)	13	240 : 1
	SED 3 5.9% OM	S	*	*	20 (8.3-41)	4	77 : 1
		NS	*	*	19 (11-35)	4	73 : 1
Water only			>3.2	0.96 (0.62 - 1.7)	0.26 (0.14-0.53)	0.032	-

⁽¹⁾ EC₅₀ values based on nominal concentrations as ug lambda-cyhalothrin technical per litre of total water
 EC_{50s} 72 hour EC₅₀ determined in water sediment system
 EC_{50w} 72 hour EC₅₀ determined in water only system (0.26 ug/L)
 * Insufficient data, complete response assessments not possible due to suspended sediment
 S Stirred
 NS Not stirred

	Official use only
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<p>Conclusion: The 48 and 72 h EC₅₀ values for lambda-Cyhalothrin to <i>Daphnia</i> in water only test systems were 0.96 ug/L and 0.26 ug/L respectively, based on nominal concentrations. The 72 h EC₅₀ values in three different water-sediment systems were 73 to 280 times greater than the 72 h EC₅₀ value in the water only system. This amounts to an apparent reduction of approximately 2 orders of magnitude in the effects of lambda-Cyhalothrin to <i>Daphnia magna</i> in water-sediment compared to water-only systems. This is considered to be due to reduced bioavailability of lambda-Cyhalothrin in the presence of sediment.</p>	
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Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant
Materials and Methods	[Redacted]
Results and discussion	[Redacted]

	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	7.4.1.2/03	Acute toxicity to invertebrates
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/03	

		Official use only
Reference point (location) in dossier	7.4.1.2/03	
Title:	PP-563 (Cyhalothrin „acid“): Acute toxicity to <i>Daphnia</i>	X1
Project/Report number:	MITES Report No. 58-367	
Author(s):	Yamauchi, F. and Suzuki, Y.	
Date of report:	1984	
Published:	Not published.	
Testing facility:	Mitsubishi Kasei Institute of Toxicological and Environmental Sciences, Japan	
Test substance:	Cyhalothrin cyclopropane carboxylic acid, purity ██████████	
Study dates	1 October 1983 – 31 March 1984	
GLP:	Yes	
Deficiencies:	None	
Reliability indicator	1.	

		Official use only
Materials and methods:	<p>The acute toxicity of the lambda-Cyhalothrin metabolite Compound Ia, the cyclopropane acid to aquatic invertebrates was assessed using <i>Daphnia magna</i>. Organisms, less than 24 hours old at the start of the test, were exposed to a series of concentrations of Compound Ia in dechlorinated tap water in a static test system. Two separate sequential tests (Test I and Test II) were carried out. Test concentrations were nominally 30, 50, 80, 130 and 200 mg/L, plus a control (dilution water only). Triplicate test systems were prepared at each concentration for each test and ten organisms were exposed in each test vessel. The toxicity of Compound Ia to the <i>Daphnia</i> was assessed after 3, 6, 24 and 48 hours. <i>Daphnia</i> were recorded as affected if they were immobilised or showing only minor movements of appendages.</p>	X2
		X3
Findings:	<p>Measurements at 0 and 48 hours in the test systems, showed that dissolved oxygen was in the range 6.2-8.4 mg/L, pH was 7.3-7.6 in both tests I and II and water hardness, was 48.8 mg CaCO₃/L. Temperature was 20 ± 1°C throughout the tests. Measured concentrations of Compound Ia in the test solutions were close to nominal in both tests at 0 hours (between 93 and 106%) and 48 hours (between 90 and 121%). EC₅₀ values are, therefore, based on nominal concentrations of Compound Ia. There was good agreement between the results of tests I and II and the results were combined to calculate the overall EC₅₀ values and 95% confidence intervals. These values are shown in the table below. The overall EC₅₀ values for Compound Ia at 24 and 48 hours were 182 and 105 mg/L, respectively.</p>	X4
		X5
		X4

Endpoints for *D. magna* exposed to Compound Ia for 48 hours under static conditions

Test	EC ₅₀ Values in mg/L (95% confidence limits)			
	3 hour	6 hour	24 hour	48 hour
I	>200	>200	165 (138-198)	98 (84-114)
II	>200	>200	200 (138-290)	117 (99-138)
Combined I & II	>200	>200	182 (164-202)	105 (95-116)

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	7.4.1.2/04	Acute toxicity to invertebrates
section No.		
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/04	

		Official use only
Reference point (location) in dossier	7.4.1.2/04	
Title:	(Cyhalothrin): Toxicity to <i>Daphnia</i> and fish (carp) in the presence and absence of soil	
Project/Report number:	MITES/563/3	
Author(s):	Yamauchi, F, and Shigeoka, T.	
Date of report:	1984	
Published:	Not published.	
Testing facility:	Mitsubishi-kasei Institute of Toxicological and Environmental Sciences, Japan	
Test substance:	Cyhalothrin technical, purity ██████	
Study dates	01 October 1983 – 16 April 1984	
GLP:	Yes	X1
Deficiencies:	None	X2
Reliability indicator	1	
		Official use only
Materials and methods:	Cyhalothrin technical material, Purity: ██████ w/w Cyhalothrin.	X3
	<i>Daphnia pulex</i> and carp (<i>Cyprinus carpio</i>) were exposed to Cyhalothrin in static water systems, with or without soil. Toxicity in the following four test systems was determined with various Cyhalothrin application methods:	
	<ol style="list-style-type: none"> 1. Water only, application to the water; 2. Water with undisturbed soil layer, application to the water phase; 3. Water with stirring to suspend the soil layer, application to the water phase with suspended material; 4. Water with undisturbed soil layer, application to the soil before adding the water. 	
	The test doses used provided the following nominal water concentrations in the <i>D. pulex</i> tests, assuming all the Cyhalothrin applied was dissolved in the water phase in each system (details for the <i>C. carpio</i> tests are presented separately under point IIIA 7.4.1.1/11):	X4

Nominal Cyhalothrin concentrations applied in systems containing *D. pulex*, with and without soil

Nominal Concentrations in the Water ⁽¹⁾ (µg a.s./L)			
System 1 water only application to water	System 2 water + undisturbed soil application to water	System 3 water + suspended soil application to water	System 4 water + undisturbed soil application to soil
Solvent control	Solvent control	Solvent control	Solvent control
0.02	0.08	0.31	5
0.08	0.31	1.28	20
0.31	1.28	5	80
1.28	5	20	320
5	20	80	1280
20	30	320	5120

(1) Assuming all the Cyhalothrin applied was distributed evenly through the water phase.

<p><i>Daphnia pulex</i> 5-6 days old were selected for the study. For the <i>Daphnia</i> tests, the systems were comprised of 250 mL dechlorinated water, with or without 20 g dry weight of paddy field soil (5 mm sieved). Two replicate systems were prepared for each Cyhalothrin test concentration, plus a solvent control.</p>	X5
<p>Ten <i>Daphnia</i> were introduced into the respective test systems at 0 hours. The exposure duration in all test systems was 72 hours. The <i>Daphnia</i> were assessed after 24, 48 and 72 hours (no visible movement or only minor movements of appendages to the naked eye). <i>Daphnia</i> in system 3 with the suspended soil could not be observed clearly during the test and for observation at 72 hours, these animals were removed to a separate vessel with clean water. The test systems were maintained at 25±1°C with a 16-hour photoperiod.</p>	
<p>Findings: In all the test systems that included soil, toxicity to <i>Daphnia</i> was reduced compared with the results from the water only system. The reduction in toxicity following application to the surface water was greater when the soil was suspended (System 3) than when it was undisturbed (System 2). This was probably due to the enhanced rate of adsorption of Cyhalothrin when the concentration of soil particles in the water column was increased. The greatest reduction in toxicity compared to the water only system was in System 4 in which the Cyhalothrin dose was applied into the soil before adding the water component. This indicates that Cyhalothrin was extensively adsorbed to the soil. The <i>Daphnia</i> EC₅₀ values and 95% confidence intervals, based on nominal initial water concentrations and obtained in the various test systems with and without soil after 24, 48 and 72 hours are shown below.</p>	X7
<p>The acute toxicity of Cyhalothrin to <i>Daphnia pulex</i> over 72 hours based on nominal initial concentrations in the water phase was reduced when soil was included in the test system. The 72 h EC₅₀ values were increased by approximately 3 times with an undisturbed soil layer, 6-40 times where the soil was suspended in the water and 71-175 times when the Cyhalothrin was applied to the soil before adding the overlying water. These data indicate that, under environmentally realistic conditions in which soil or sediment is present, exposure will be substantially reduced, thereby reducing the apparent toxicity of the compound.</p>	

Endpoints for *D. pulex* exposed to Cyhalothrin for 72 hours under static conditions, in the presence and absence of sediment

Test system	<i>Daphnia pulex</i> EC ₅₀ ug/L (95% confidence interval)		
	24 hour	48 hour	72 hour

	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

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section No.		
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/05	

		Official use only
Reference point (location) in dossier	7.4.1.2/05	
Title:	Lambda-Cyhalothrin. Acute toxicity of short-term exposures to <i>Gammarus pulex</i>	
Project/Report number:	RJ2542B	
Author(s):	Goggin, U.M. and Hamer, M.J.	
Date of report:	1998	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	¹⁴ C-cyclopropane labelled lambda-Cyhalothrin, purity [REDACTED]	X1
Study dates	January to February 1998	
GLP:	Yes	
Deficiencies:	None.	X2
Reliability indicator	1.	

		Official use only
Materials and methods:	¹⁴ C-cyclopropane labelled lambda-Cyhalothrin (specific activity 2.2 GBq/mmol and purity [REDACTED]).	
	The effects on <i>Gammarus pulex</i> of lambda-Cyhalothrin were examined at various exposure concentrations and with varying exposure durations. Sexually mature adult <i>G. pulex</i> (mean length 8.6 mm) were exposed to ¹⁴ C-labelled lambda-Cyhalothrin in hard-blended water at nominal test concentrations of 1.6, 3.1, 6.2, 12.5, 25, 50, 100 and 200 ng/L in a static system maintained at 14°C. Five replicate test systems were prepared at each concentration, providing one replicate at each concentration at each of the following exposure times: 1, 3, 6, 12 and 96 hours. Two additional sets of 5 replicate systems were prepared, one set to serve as untreated controls and the other to be treated with carrier solvent only (solvent controls). The test systems were treated with aliquots (50 µL) of the ¹⁴ C-lambda-Cyhalothrin application solutions in acetone and the water stirred to mix the dose. Aliquots of the water in the test systems were taken immediately to determine the concentration of ¹⁴ C-lambda-Cyhalothrin and then ten <i>G. pulex</i> were introduced to each system at 0 hours. At the end of each of the five exposure periods, one set of test organisms at each test concentration were transferred to clean, hard-blended water for the remainder of 96-hour test. The organisms exposed to ¹⁴ C-lambda-Cyhalothrin for 96 h were transferred to freshly prepared test solutions every 24 hours. Concentrations of ¹⁴ C-lambda-Cyhalothrin in each of the test solutions were determined again at the end of each exposure duration.	X3 X4
		X5

<p>Findings: Measured concentrations of ¹⁴C-lambda-Cyhalothrin in the water in the test systems were 70 to 139% of nominal directly after application of the test doses, and at 1, 3, 6, and 12 hours after application were 98-104%, 89-106%, 53-90% and 42-49% of nominal, respectively. Concentrations of ¹⁴C-lambda-Cyhalothrin in the test systems measured at 24-hour intervals ranged between 11 to 70% of nominal.</p> <p><i>G. pulex</i> were assessed after 96 hours for affects (inability to swim in response to a gentle stimulus) and numbers of dead (no visible movement to the naked eye). The total numbers of <i>G. pulex</i> affected (immobilised) and dead at 96 hours after various exposure durations to the various test concentrations are tabulated below.</p>	<p>X6</p> <p>X7</p> <p>X8</p>
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Effects on *G. pulex* exposed to lambda-Cyhalothrin for 1 to 96 hours under static conditions

Nominal Concentration (ng/L)	Affected ⁽¹⁾					Dead ⁽¹⁾				
	Duration of Exposure					Duration of Exposure				
	1 h	3 h	6 h	12 h	96 h	1 h	3 h	6 h	12 h	96 h
Untreated control	2	2	1	0	2	2	2	1	0	2
Solvent control	1	2	0	0	1	1	2	0	0	1
1.6	0	0	0	0	1	1	2	0	0	1
3.1	0	2	0	1	0	0	2	0	1	0
6.2	2	0	1	0	3	2	0	1	0	3
12.5	1	2	2	2	5	1	2	1	2	2
25	0	2	3	2	10	0	2	2	2	2
50	2	2	5	3	9	2	2	3	2	3
100	4	2	8	9	10	2	1	3	2	5
200	5	7	8	9	10	2	4	6	6	9
400	6	10	10	10	10	5	5	7	9	8
800	10	10	10	10	10	9	8	10	7	10

⁽¹⁾ Out of 10 introduced.

<p>Toxicity increased with increasing duration of exposure. At 96 hours, the numbers of organisms affected were greater than those dead, therefore, as a worst-case, EC₅₀ values rather than LC₅₀ values were calculated. The EC₅₀ values determined for each exposure duration tested, based on nominal initial test concentrations are tabulated below.</p> <p>Short-term exposures of <i>G. pulex</i> to lambda-Cyhalothrin had significantly less effect than long-term exposures. Toxic effects concentrations with 1 and 3 hour exposure periods were more than an order of magnitude less toxic than those determined following exposure for 96 hours.</p>	
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	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

98/8 Doc IIIA	7.4.1.2/06	Acute toxicity to invertebrates
section No.		
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/06	

		Official use only
Reference point (location) in dossier	7.4.1.2/06	
Title:	Lambda-Cyhalothrin. Acute toxicity to different life-stages of <i>Gammarus pulex</i>	
Project/Report number:	RJ2483B	
Author(s):	Hamer, M.J. and Goggin, U.M.	
Date of report:	1998	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	¹⁴ C-cyclopropane labelled lambda-Cyhalothrin, purity [REDACTED]	X1
Study dates	June to November 1997	
GLP:	Yes	
Deficiencies:	None.	X2
Reliability indicator	1.	

		Official use only
<p>Materials and methods: ¹⁴C-cyclopropane labelled lambda-Cyhalothrin (specific activity 2.2 GBq/mmol and radiochemical purity [REDACTED]).</p> <p>The relative sensitivities to lambda-Cyhalothrin of the adult, juvenile and neonate life-stages of the amphipod Crustacean, <i>Gammarus pulex</i> have been investigated.</p> <p>Three age groups of <i>G. pulex</i> were tested: sexually mature adults (length approximately 8 mm), juveniles (length 4 mm) and neonates (≤ 7 days old). Each test group was exposed to labelled lambda-Cyhalothrin in hard-blended water at nominal test concentrations of 0.78, 1.56, 3.13, 6.25, 12.5, 25, 50, 100 and 200 ng/L in a static system maintained at 15°C. Two additional sets of 3 replicate systems were prepared, one set to serve as untreated controls and the other to be treated with carrier solvent only (solvent controls).</p> <p>Findings: Concentrations of lambda-Cyhalothrin were determined in aliquots of the water taken from the test systems immediately after dosing, and after 48 and 96 hours. Measured concentrations of ¹⁴C-lambda-Cyhalothrin in the test systems were 72 to 112% of nominal directly after application of the test doses, 24 to 48% after 48 hours and 18 to 40% after 96 hours. <i>G. pulex</i> were assessed after 96 hours for effects (inability to swim in response to a gentle stimulus) and numbers of dead (no visible movement to the naked eye). The results are</p>		
		X3
		X4
		X5

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[Redacted]	[Redacted]	[Redacted]
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Results and discussion

[Redacted text block]

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Conclusion

[Redacted text block]

Reliability
Acceptability

[Redacted text block]

Remarks

98/8 Doc IIIA	7.4.1.2/07	Acute toxicity to invertebrates
section No.		
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/07	

		Official use only
Reference point (location) in dossier	7.4.1.2/07	
Title:	Lambda-Cyhalothrin: Acute toxicity to <i>Gammarus pulex</i> in a sediment-water system.	
Project/Report number:	RJ2484B	
Author(s):	Hamer, M.J. and Goggin, U.M.	
Date of report:	1998	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	¹⁴ C-cyclopropane labelled lambda-Cyhalothrin, purity ██████	X1
Study dates	September and November 1997	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

		Official use only
<p>Materials and methods: The sediment adsorption coefficient (K_{oc}) for lambda-Cyhalothrin is extremely high. Therefore, on entering a water body via spray drift the compound will adsorb rapidly and extensively to the sediment and other organic matter containing substrates such as aquatic macrophytes and phytoplankton in the water column. To incorporate the influence of the rapid dissipation of lambda-Cyhalothrin from the water column, which would occur under more realistic conditions, the effects of the chemical on <i>Gammarus pulex</i> were assessed in a water-sediment system.</p> <p>Juvenile organisms (mean length 3.4 mm) were selected for the study. The test system was static, containing a bottom layer of sediment (equivalent to 20 g dry weight) and 430 ml hard blended water. Aliquots of lambda-Cyhalothrin in acetone (50 µL) were applied to the overlying water in each test system to give one replicate at six nominal concentrations of lambda-Cyhalothrin: 18, 24, 32, 42, 56, 75, 100, 133, 178 and 237 ng/L. A control and a solvent control were prepared in the same way as the treated systems. The test systems were maintained at 15°C for 24 hours to allow the sediment to settle before introducing twenty juvenile <i>G. pulex</i> into each test vessel at 0 hours.</p>		
Findings:		X2
		X3

Results and discussion

Conclusion

Reliability
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Remarks

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98/8 Doc IIIA	7.4.1.2/08	Acute toxicity to invertebrates
section No.		
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/08	

		Official use only
Reference point (location) in dossier	7.4.1.2/08	
Title:	<i>Lambda</i> -Cyhalothrin: Acute toxicity to aquatic arthropods	
Project/Report number:	RJ2437B	
Author(s):	Hamer, M.J., Ashwell, J.A. and Gentle, W.E.	
Date of report:	1998	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	¹⁴ C-cyclopropane labelled <i>lambda</i> -Cyhalothrin, purity ██████	
Study dates	02 September - 03 October 1997	
GLP:	Yes	
Deficiencies:	None	
Reliability indicator	1.	

	Official use only
<p>Materials and methods: ¹⁴C-cyclopropane labelled <i>lambda</i>-Cyhalothrin, with a specific activity of 2.2 GBq/mmol, Purity ██████</p> <p>The aquatic invertebrates employed in this study are listed in the table below. A series of application solutions was prepared to give the following nominal concentrations when added to the test systems: 0.5, 1, 2, 3.9, 7.8, 16, 31, 62, 125, 250, 500, 1000, 2000, 4000, and 8000 ng/L of ¹⁴C-<i>lambda</i>-Cyhalothrin. Test concentrations were determined from preliminary range finding tests or previous data and selected from the range above. With the exception of the tests with damselfly nymphs a single replicate for each concentration was prepared by adding 100 µl of the application solution to 200 ml of test water in 400 ml tall-form glass beakers. A control solvent (spiked with 100 µl acetone) was prepared as for the treated systems. Ten organisms were added to each test vessel. The tests were conducted at 20±2°C, with a 16:8 light:dark cycle. The effects of the test chemical to the organisms were assessed after 48 hours. The organisms were not fed for the period of the test.</p> <p>Damselfly nymphs were tested individually as preliminary studies had shown them to be cannibalistic. Test concentrations were prepared by adding 250 µl of application solution to 500 ml test water in volumetric flasks and dispensing 40 ml into each of 10 × 50 ml glass beakers. A control and solvent control were set up in the same way. From the remaining volume of each test concentration 10 ml was sampled for analysis by (LSC).</p>	

<p>After 48 hours the organisms were assessed as affected and dead. Assessment criteria for an effect varied between organisms. <i>Chaoborus</i> were assessed as affected if they were unable to maintain body shape or their equilibrium below the water surface. The remaining organisms were deemed affected if they were unable to move/swim/crawl freely compared to the controls. All organisms were assessed as dead if there was no detectable movement to the naked eye, except in the case of copepods where because of their size a magnifier was used. Any missing organisms (presumably cannibalised) were recorded as dead and affected. EC₅₀s based on nominal concentrations were determined by analysis of the data using the method of iteratively re-weighted linear regression of the logit transformation of percent effect against log₁₀ (concentration). Where necessary the data were corrected for control effects using Abbott's correction.</p> <p>At 0 and 48 hours the test solutions were sampled for radiochemical analysis by liquid scintillation counting (LSC).</p> <p>Findings: Water samples taken at time 0 gave measured concentrations of between 75 and 131% of nominal values. After 48 hours this had declined to between 35 and 82% of nominal ¹⁴C-concentrations measured in representative application solutions after each test were in the range of 94 to 156% of nominal. TLC of water extracts from representative test solutions showed ≥90% of the extracted radioactivity was ¹⁴C-lambda-Cyhalothrin.</p> <p>The data generated demonstrated a good concentration response at 48 hours, whereas this was not always true for mortality. Statistical analysis was therefore based on organisms affected rather than dead as this undoubtedly represents the worst case. The 48-hour EC₅₀ values based on nominal concentrations are presented below and ranged from 2.3 ng/L for <i>Hyaella azteca</i> to 3300 ng/L for Ostracoda.</p>	<p>X1 X2 X3 X4</p>
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Endpoints for sub-lethal effects on aquatic arthropods exposed to lambda-Cyhalothrin for 48 hours under static conditions

Organism	48 hour EC ₅₀ (ng/L)	95% Confidence Interval
<i>Hyaella azteca</i>	2.3	1.0 – 7.8 ^a
<i>Chaoborus</i> sp.	2.8	1.8 – 4.1
<i>Gammarus pulex</i>	14	9.1 – 19
<i>Asellus aquaticus</i>	26	18 – 36
<i>Corixa</i> sp.	30	21 – 42
<i>Cloeon dipterum</i>	38	23 – 93
<i>Hydracarina</i>	47	33 – 62
<i>Ischmura elegans</i>	130	92 – 190
<i>Cyclops</i> sp.	300	200 – 460
Ostracoda	3300	2100 - 6600

^a 95% confidence intervals not calculable using logit

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant
Materials and Methods	Accept the applicant's version.
Results and discussion	<div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div>

98/8 Doc IIIA section No.	7.4.1.2/09	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4/09	Acute toxicity to invertebrates

		Official use only
Reference point (location) in dossier	7.4.1.2/09	
Title:	<i>Lambda-Cyhalothrin</i> : Investigation into the effects on and recovery of <i>Gammarus pulex</i> (L.) using a stage-structured population model	
Project/Report number:	TMJ4491B	
Author(s):	Kedwards, T.J.	
Date of report:	2000	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	Not applicable	
Study dates	Not applicable	
GLP:	Not applicable	
Deficiencies:	Not applicable	
Reliability indicator	Not applicable	

		Official use only
Materials and methods:		
A stage-structured population model was used to determine population recovery times of the freshwater amphipod <i>Gammarus pulex</i> after exposure to concentrations of the pyrethroid insecticide <i>lambda-Cyhalothrin</i> . The model was based on the processes of immigration and emigration, embryonic development time, and birth-, growth- and death-processes. The influence of ambient water temperature on these processes was also included to derive realistic seasonal population dynamics. The model is fully described in Kedwards (1998). Mortality of different life-stages of <i>G. pulex</i> at varying <i>lambda-Cyhalothrin</i> concentrations was also incorporated alongside the natural population dynamics to investigate potential effects and recovery.		X1
Immigration by organism 'drift' is an important population process for <i>G. pulex</i> . Reported drift values from previous field surveys have shown that <i>G. pulex</i> drift rates vary, with the daily proportion of animals in the drift ranging from 6 to 82% of the population. The model was used to simulate the effects on and recovery of <i>G. pulex</i> populations resulting from worst-case Ganzelmeier 95th percentile initial predicted environmental concentrations of <i>lambda-Cyhalothrin</i> in surface water (PEC _{sw}) for typical European spring and summer applications relevant to uses in plant protection products. The various migration conditions pertinent to European streams were also incorporated.		X2
Findings:		
In the absence of natural immigration processes (e.g. as would be the case in most mesocosm		

<p>studies), the model predicted that recovery rates (i.e. return to control conditions) would be slow, principally because there was no source of organisms to re-establish the population. If daily immigration rates were increased to only 1.5% (more than an order of magnitude lower than those reported in the scientific literature), the resulting recovery of the population was rapid. For example, at an initial PEC_{sw} of 38 ng/L, equivalent to the spray drift deposition anticipated from a typical application rate of 26 g a.s./ha at a distance of 20 m into a water body of 30 cm depth, the predicted maximum recovery time was 62 days based on a 0.4% daily immigration rate. Increasing the daily immigration rate to 1.5%, three times less than the lowest 'drift' rate quoted in the scientific literature, with the same exposure scenario resulted in a recovery time of 21 days.</p> <p>Under the immigration conditions that are typical for water bodies reported in the scientific literature, the model demonstrated that recovery of <i>G. pulex</i> populations from exposures to lambda-Cyhalothrin (resulting from the worst-case uses and mitigation measures proposed by Syngenta) would be rapid.</p>	X3
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Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant
Materials and Methods	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>
Results and discussion	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	

98/8 Doc IIIA	7.4.1.2/10	Acute toxicity to invertebrates
section No.		
91/414 Annex	II	Acute toxicity to invertebrates
Point addressed	8.2.4/10	

		Official use only
Reference point (location) in dossier	7.4.1.2/10	
Title:	3-Phenoxybenzoic acid: Toxicity to first instar <i>Daphnia magna</i> (II)	
Project/Report number:	RJ0318B	
Author(s):	Everett, C.J., Hamer, M.J. and Hill, I.R.	
Date of report:	1983	
Published:	Not published.	
Testing facility:	Jealott's Hill Research Station, Zeneca Limited, Bracknell, UK	
Test substance:	3-Phenoxybenzoic acid supplied as m-phenoxybenzoic acid [REDACTED] pure	
Study dates	Not stated	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

		Official use only
Materials and methods: <i>Daphnia magna</i> , less than 24 hours old at the start of the test, were exposed to a series of concentrations of 3-Phenoxybenzoic acid in hard, reconstituted water in a static test system. Two separate sequential tests (Test I and Test II) were carried out.		X1
Findings: Test concentrations were nominally, 25, 50, 100, 200 and 400 mg/L, plus control. The toxicity of 3-Phenoxybenzoic acid to the <i>Daphnia</i> was assessed after 3, 9, 24 and 48 hours. <i>Daphnia</i> were recorded as affected if they were immobilised or showing only minor movements of appendages. Measured at 0 and 48 hours, dissolved oxygen was in the range 9.0 - 9.3 mg/L and pH 7.0 - 8.2. Temperature was 20 ± 1°C throughout the tests. The EC ₅₀ values and 48 hour NOECs, based on mean measured concentrations between 0 and 48 hours are shown in the table below.		X2

Toxicity of 3-Phenoxybenzoic to First Instar *Daphnia magna* Based on Mean Measured Concentrations

Test	EC ₅₀ values in mg/L (95% confidence limits)				48 h NOEC (mg/L)
	3	9	24	48	
I	178	135	155	85	52.2

	(151-205)	(104-220)	(133-181)	(52-104)	
II	168	142	139	85	50.7
	(104-216)	(104-216)	(104-216)	(51-104)	

	Official use only
The mean EC ₅₀ value for 48 hours was 85 mg/L.	

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]

98/8 Doc IIIA section No.	7.4.1.3/01	Growth inhibition test on algae
91/414 Annex	II	Effects on algal growth
Point addressed	8.2.6/01	

		Official use only
Reference point (location) in dossier	7.4.1.3/01	
Title:	PP321: Toxicity to the green alga <i>Selenastrum capricornutum</i>	
Project/Report number:	BL/B/2584	
Author(s):	Thompson, R.S. and Williams, T.D.	
Date of report:	1985	
Published:	Not published.	
Testing facility:	Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, UK	
Test substance:	Lambda-Cyhalothrin (PP321), Purity [REDACTED]	
Study dates	09 - 13 April 1984	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	
		Official use only
Materials and methods:	Lambda-Cyhalothrin (PP321), Purity [REDACTED] w/w.	X1
<p>The green alga, <i>Selenastrum capricornutum</i> (strain ATCC 22662) was cultured in a series of concentrations of lambda-Cyhalothrin. Test concentrations were nominally, 0.056, 0.1, 0.18, 0.32, 0.56, 1.0 mg/L, plus solvent controls and untreated control. Measured at each test concentration, pH ranged from 7.2-7.4 at the start of the test and 7.7-9.0 at the end. Measured daily, temperature ranged from 23.5-23.9°C. After 24, 48, 72 and 96 hours samples were removed from each test vessel and cell density determined.</p>		
Findings:	The mean values at each concentration for integrated biomass (area under the growth curve) and growth rate are shown in the tables below.	

Effects on the growth of *S. capricornutum* exposed to lambda-Cyhalothrin for 96 hours under static conditions

Nominal concentration (mg/L)	Mean area under growth curve (days 0 to 4)	% of solvent control	Mean growth rate (days 0 to 3)	% of solvent control
Control	398	95	1.62	98
Solvent Control [†]	417	(100)	1.65	(100)
0.056	345**	83	1.57**	95
0.10	424	102	1.66	101
0.18	372	89	1.62	98
0.32	366	88	1.62	98
0.56	399	96	1.65	100
1.0	411	98	1.65	100

[†] Solvent control data pooled for analysis.

** Significantly different (p < 0.01) from the solvent control.

The only concentration significantly different from the control was the lowest and as the effect was clearly not dose-related it was not considered to be biologically significant. The 96 hour E _b C ₅₀ and 72 hour E _r C ₅₀ values for area under the growth curve and growth rate, respectively, were therefore both >1.0 mg/L, based on nominal concentrations, and the NOEC was 1.0 mg/L for both growth indices.	X2
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Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant
Materials and Methods	[Redacted]
Results and discussion	[Redacted]
Conclusion	[Redacted]

98/8 Doc IIIA	7.4.1.4/01	Inhibition of microbiological activity
section No.		
91/414 Annex	II	Effects on biological methods for sewage treatment
Point addressed	8.7/01	

		Official use only
Reference point (location) in dossier	7.4.1.4/01	
Title:	ZA0321 (<i>lambda</i> -Cyhalothrin technical); Effect on the respiration rate of activated sludge.	
Project/Report number:	BL7331/B	
Author(s):	Wallace, S.J.	
Date of report:	2002	
Published:	Not published.	
Testing facility:	Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, UK	
Test substance:	<i>Lambda</i> -Cyhalothrin technical, Purity [REDACTED]	
Study dates	06 - 14 June 2002	
GLP:	Yes	
Deficiencies:	None.	
Reliability indicator	1.	

		Official use only
Materials and methods: <i>Lambda</i> -Cyhalothrin (ZA0321) technical, Batch Sample [REDACTED]. Purity [REDACTED] w/w.		X1
The effect of <i>lambda</i> -Cyhalothrin on bacterial activity of sewage sludge was investigated by exposing activated sludge to <i>lambda</i> -Cyhalothrin at nominal concentrations of 1, 3.2, 10, 32 and 100 mg as/L. The test incorporated a dose response to a reference standard (3,5-dichlorophenol) at five nominal concentrations (1, 3.2, 10, 32 and 100 mg as/L) and 2 replicates of an untreated control. The activated sludge was obtained from Buckland Sewage Treatment Works, Newton Abbot, Devon, UK, 1 day prior to the study. Each test system contained an excess of synthetic sewage and sufficient activated sludge, giving a final solids concentration of 1600 mg/L in a total volume of 500 mL. After continuous aeration for 3 hours at 20 ± 2°C, the respiration rate of each culture was determined by measuring oxygen uptake with a polarographic oxygen electrode. The inhibitory effect of the test substance was expressed as a percentage of the mean respiration rates of two controls.		X2
Findings: The effects of <i>lambda</i> -Cyhalothrin technical and the toxic reference substance, 3,5-dichlorophenol, on activated sewage sludge are presented in the table below. <i>Lambda</i> -Cyhalothrin at concentrations up to 100 mg/L resulted in <10% inhibition of activated sewage sludge respiration. Percentage inhibition <10% is within expected experimental variability and is not considered to be an effect of the test substance. 3,5-dichlorophenol caused		X3

substantial inhibition of the respiration rate, indicating that the activated sludge was responding normally and contained viable sludge organisms.	
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Effects on the respiration of activated sludge exposed to *lambda*-Cyhalothrin for 3 hours

Treatment	Nominal concentration (mg/L)	Respiration rate (mg O ₂ /L/h)	Inhibition (%) ¹
Control 1	-	29.3	-
Control 2	-	31.7	-
<i>Lambda</i> -Cyhalothrin	1.0	31.0	<10
	3.2	32.6	<10
	10	31.0	<10
	32	32.6	<10
	100	30.4	<10
3,5-dichlorophenol	1.0	28.5	<10
	3.2	27.4	10
	10	13.7	55
	32	6.0	80
	100	2.7	91

¹ relative to the mean control rate of 30.5 mg O₂/l/h.

Based on nominal concentrations of <i>lambda</i> -Cyhalothrin, the EC ₅₀ (3 hour) with respect to respiration of activated sludge was estimated to be > 100 mg a.s./L and the no observed effect concentration (NOEC) was 100 mg a.s./L.	
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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	