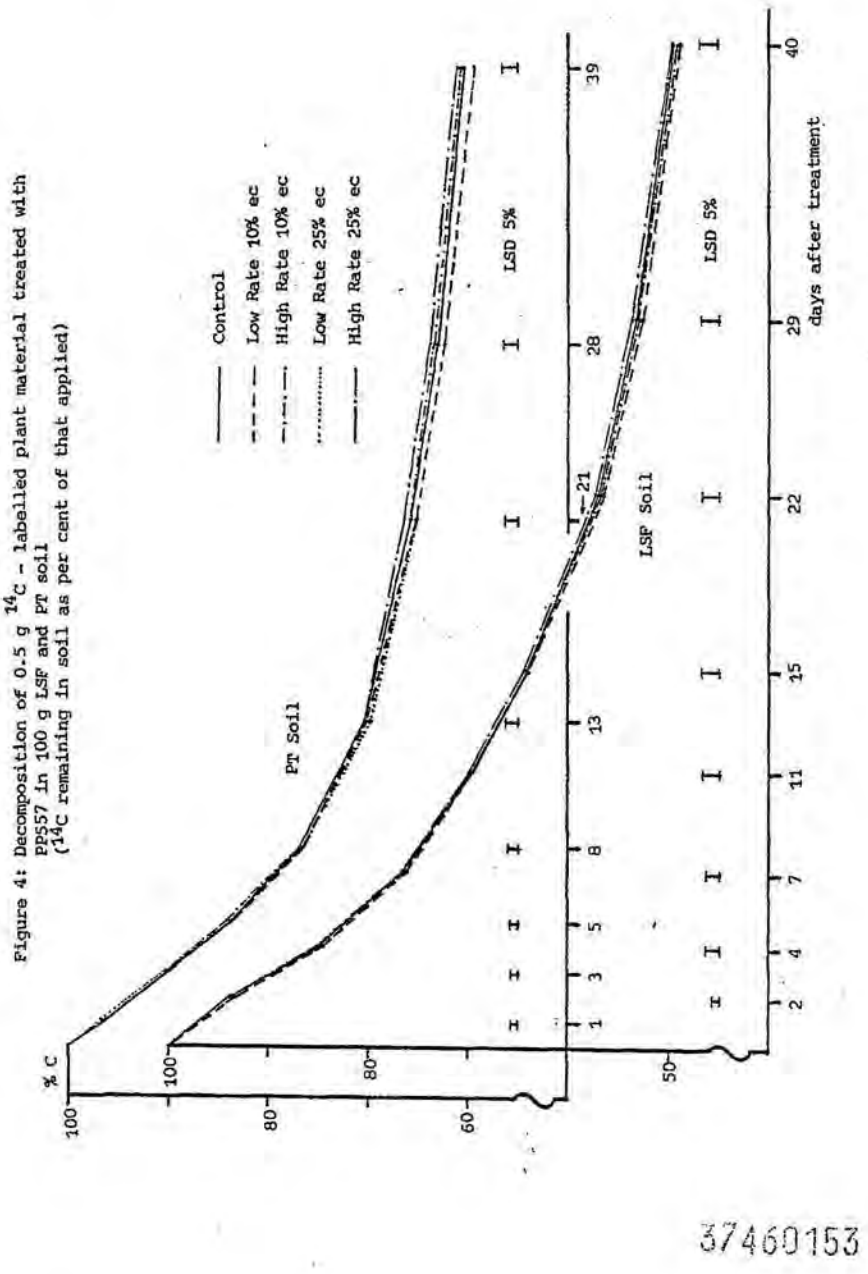


Figure 4: Decomposition of 0.5 g ^{14}C - labelled plant material treated with PP557 in 100 g LSF and PT soil (^{14}C remaining in soil as per cent of that applied)

37460153

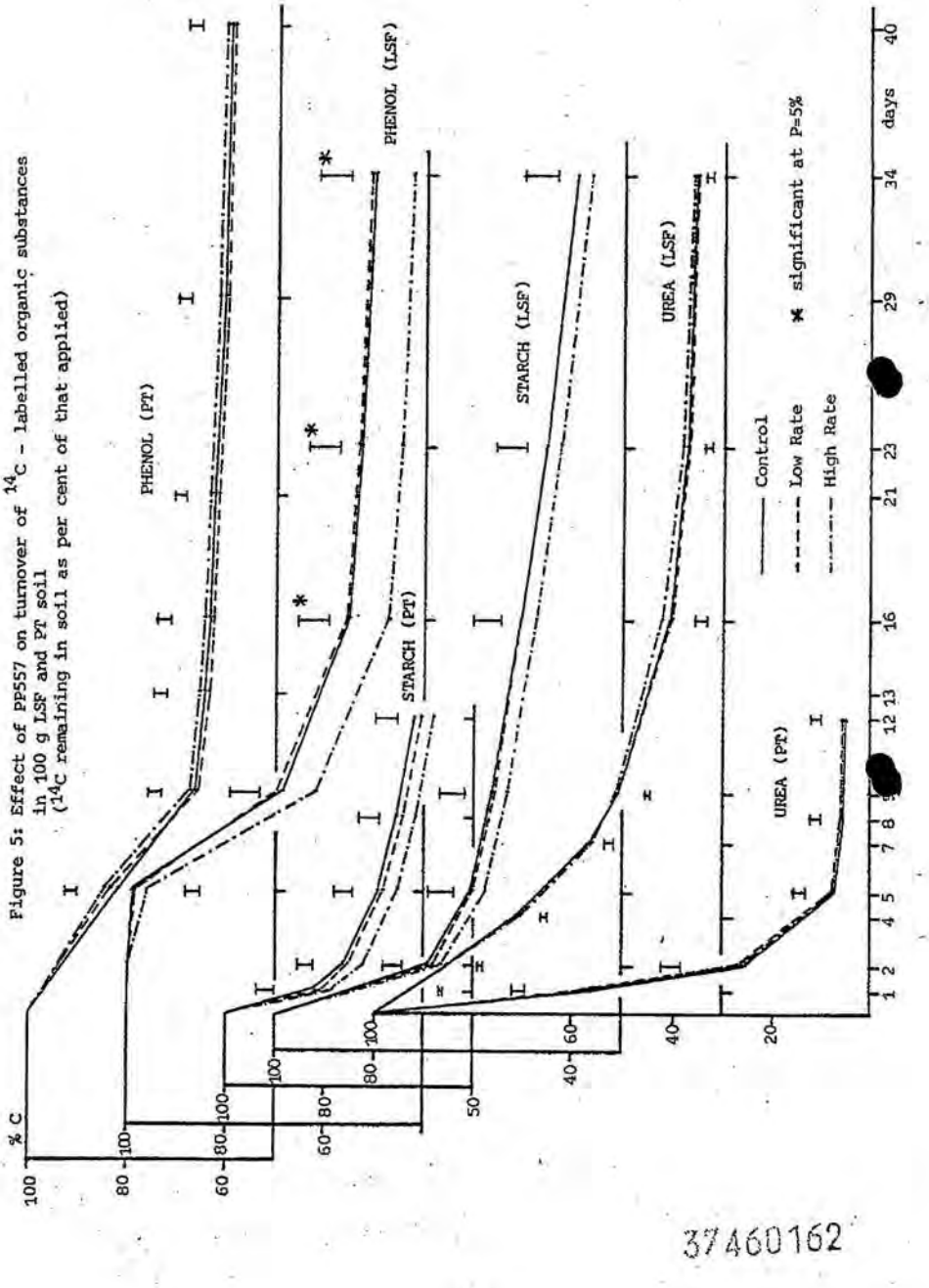


Figure 5: Effect of PP557 on turnover of ^{14}C - labelled organic substances in 100 g LSF and PT soil (^{14}C remaining in soil as per cent of that applied)

37460162

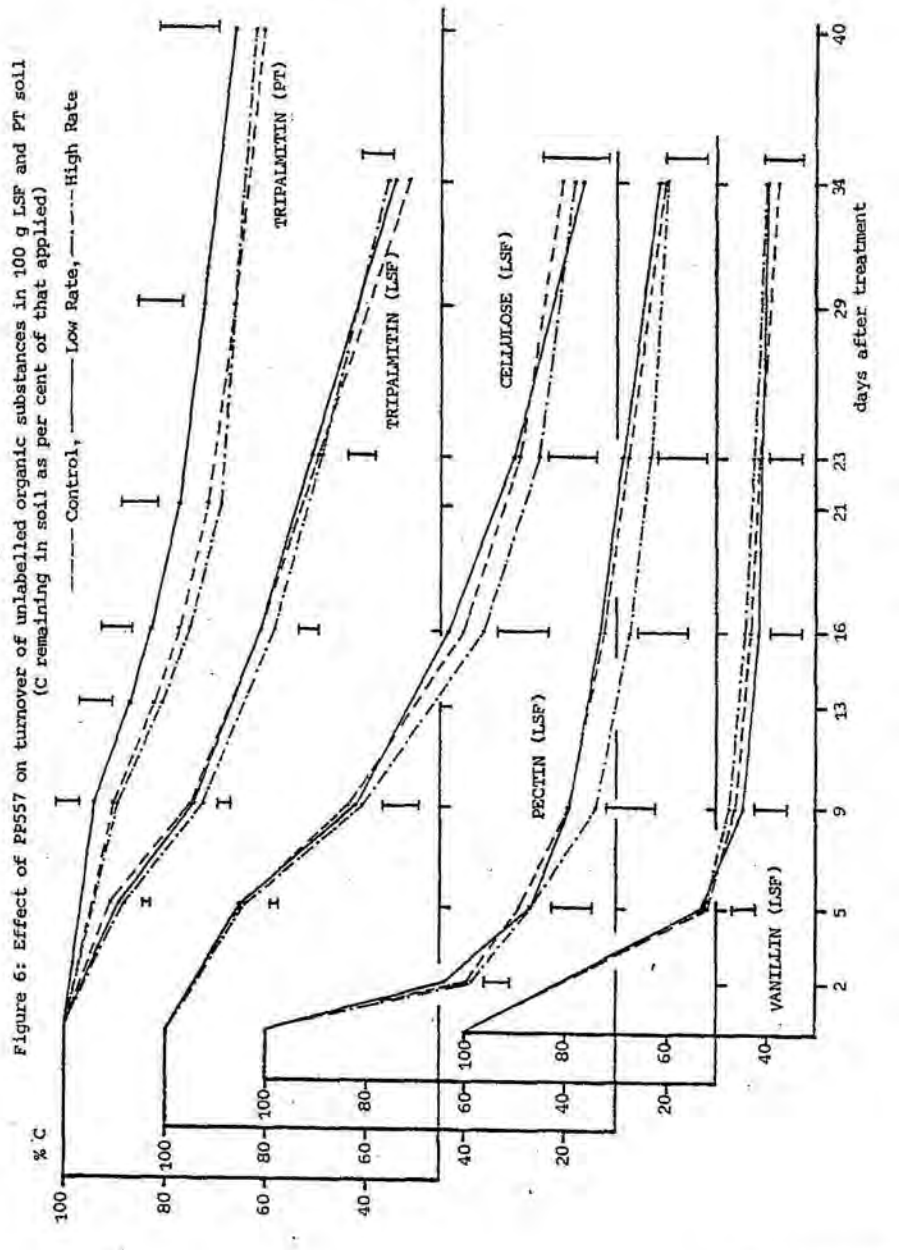


Figure 6: Effect of PP557 on turnover of unlabelled organic substances in 100 g LSF and PT soil (C remaining in soil as per cent of that applied)
---- Control, ——— Low Rate, -.-.- High Rate

37460163

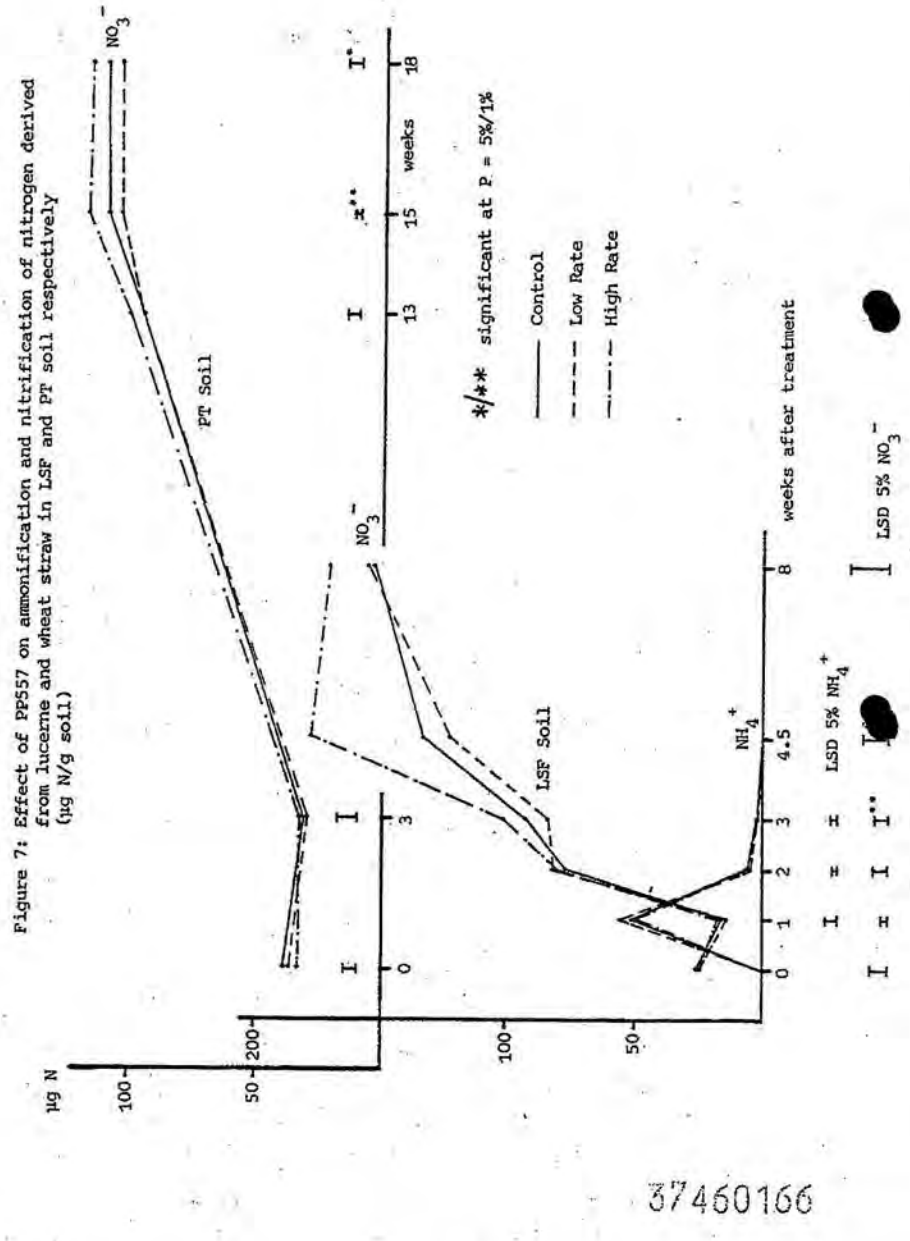


Figure 7: Effect of PP557 on ammonification and nitrification of nitrogen derived from lucerne and wheat straw in LSF and PT soil respectively (µg N/g soil)

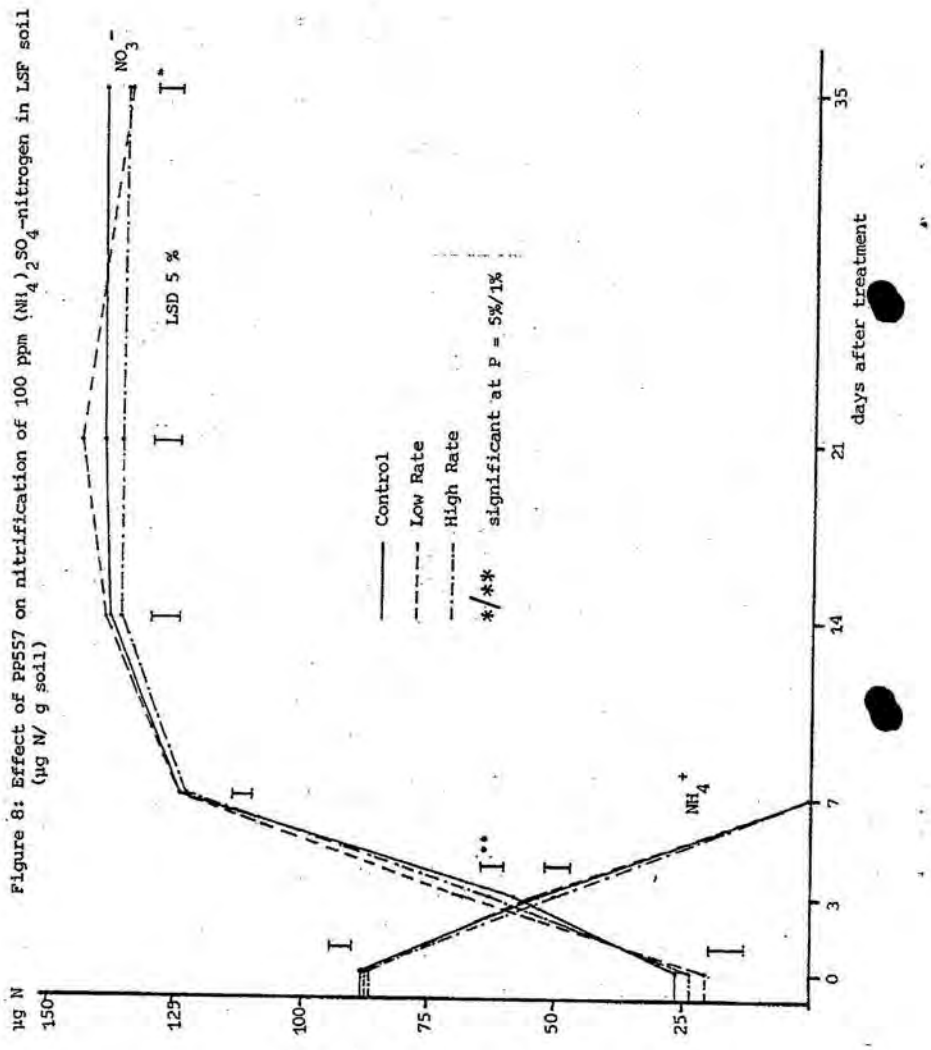


Figure 8: Effect of PP557 on nitrification of 100 ppm $(NH_4)_2SO_4$-nitrogen in LSF soil (µg N/ g soil)

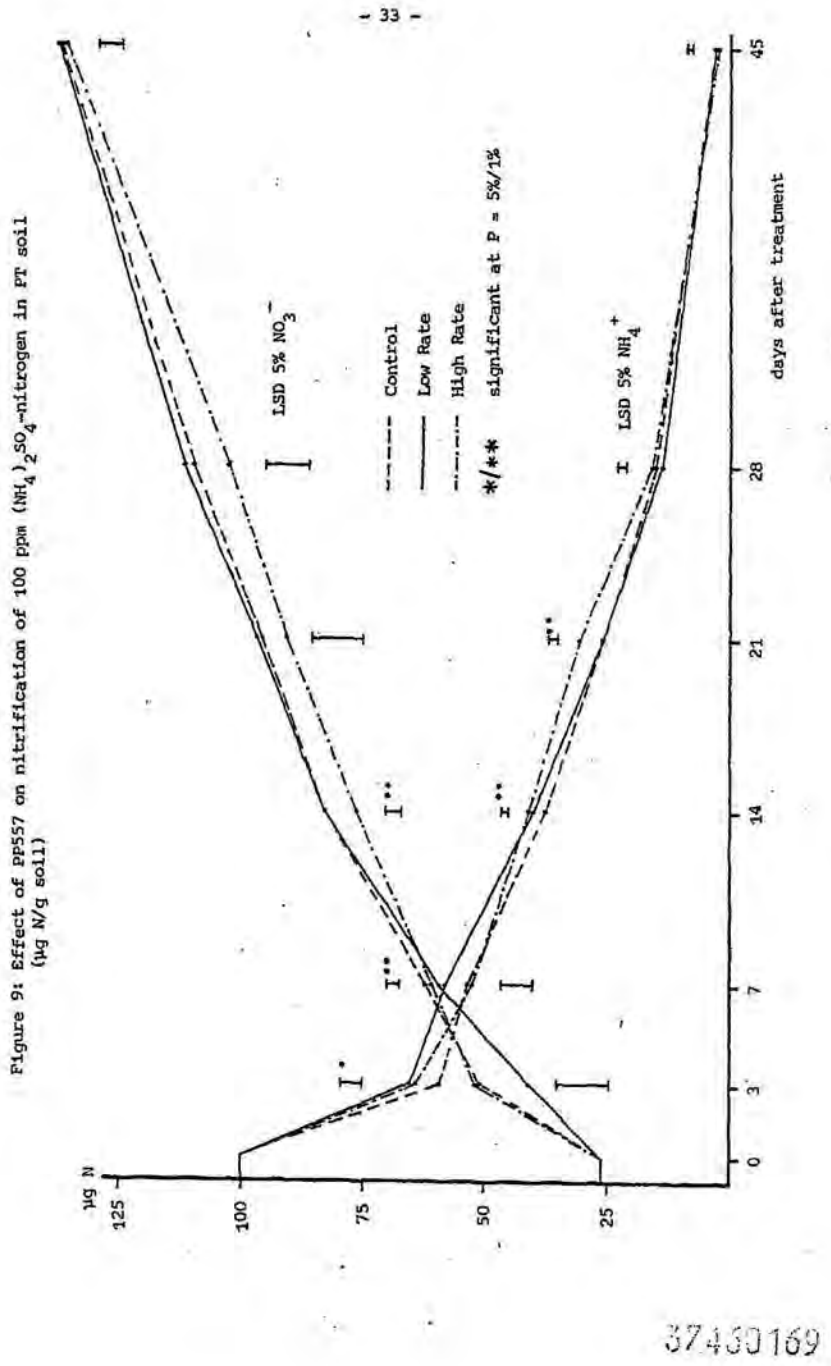


Figure 9: Effect of PP557 on nitrification of 100 ppm $(NH_4)_2SO_4$-nitrogen in PT soil (µg N/g soil)

37430169

ANNEX I

In the carbon and nitrogen studies, no effects were observed in any of the soils at the highest application rates. Therefore, the PNEC should be derived from the highest NOEC.
As the soils tested were very different in organic matter content, the highest NOEC can only be determined once the NOECstandards for each soil have been calculated.

The NOECstandard have herein been determined for both soil types assessed using the following equation:

$$NOEC\ or\ L(E)C_{50(standard)} = NOEC\ or\ L(E)C_{50(exp)} \cdot \frac{Fom_{soil(standard)}}{Fom_{soil(exp)}} \quad (71)$$

NOEC or L(E)C50(standard)	output	[mg.kg^{-1}dwt soil]
Fomsoil(standard)	0.034	[mg.kg^{-1}]
Fomsoil(exp)	0.055 (Peer Three site)	[mg.kg^{-1}]
	0.015 (Lower sand field site)	[mg.kg^{-1}]
NOEC(exp)	16 (Peer Three site)	[mg.kg^{-1}dwt soil]
	14 (Lower sand field site)	[mg.kg^{-1}dwt soil]

The followind NOECstandard were obtained

Soils	study	NOECstandard
Peer Three site	C	9.89 mg.kg-1dwt soil
Lower sand field site	C	31.73 mg.kg-1dwt soil
Peer Three site	N	9.89 mg.kg-1dwt soil
Lower sand field site	N	31.73 mg.kg-1dwt soil

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Kumar, A.; 1997; Permethrin Technical Acute toxicity in Earthworm. Jai Research Foundation Report 1054/JRF/ECO/97; GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Bayer CropScience AG	
1.2.2	**Companies with letter of access**	Sumitomo Chemical (UK) PLC	
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes – OECD207	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2	
3.1.1	**Lot/Batch number**	002/96	
3.1.2	**Specification**	As given in section 2	
3.1.3	**Purity**	94%	
3.1.4	**Composition of Product**	Not applicable	
3.1.5	**Further relevant properties**	None	
3.1.6	**Method of analysis**	No analysis performed	
3.2	**Reference substance**	No	
3.3	**Testing procedure**		
3.3.1	**Preparation of the test substance**	see table A7.5.1.2(1)-1	
3.3.2	**Application of the test substance**	Appropriate amounts of permethrin were dissolved in 10 ml acetone and thoroughly mixed with 3000 g of artificial soil for each concentration group.	
3.3.3	**Test organisms**	see table A7.5.1.2-2	
3.3.4	**Test system**	(see table A7.5.1.2-3	
3.3.5	**Test conditions**	(see table A7.5.1.2-4	
3.3.6	**Test duration**	14 days	

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

Key Study

3.3.7	**Test parameter**	Mortality
3.3.8	**Examination**	Examined on days 7 and 14
3.3.9	**Monitoring of test substance concentration**	No
3.3.10	**Statistics**	LC50 and EC50 were determined by probit analysis and logit analysis, respectively using the SAS software package. NOEC values were determined using the derivation of the Williams test.
		4 RESULTS
4.1	**Filter paper test**	Not performed
4.2	**Soil test**	
4.2.1	**Initial concentrations of test substance**	0, 100, 200, 400, 800, 1600 mg kg^{-1}
4.2.2	**Effect data (Mortality)**	see table A7.5.1.2-5 see table A7.5.1.2-6
4.2.3	**Concentration / effect curve**	see Figure 1
4.2.4	**Other effects**	None
4.3	**Results of controls**	
4.3.1	**Mortality**	see table A7.5.1.2-5
4.3.2	**Number/ percentage of earthworms showing adverse effects**	None observed
4.3.3	**Nature of adverse effects**	None observed
4.4	**Test with reference substance**	Not performed
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The artificial soil was prepared following OECD guideline No. 207 (OECD 1984). Appropriate amounts of permethrin were dissolved in 10 ml acetone and thoroughly mixed with 3000 g of artificial soil for each concentration group. The test substance was mixed with the soil to give a percentage water content of 33%. The same volume of distilled water was added to each of the controls. The concentration of permethrin was 0, 100, 200, 400, 800, 1600 mg/kg. All worms were adult, at least 8 weeks old and fully clitellate, and

Section A7.5.1.2 Earthworm, acute toxicity test
Annex Point IIIA XIII 3.2

Key Study

		were not fed during the exposure period 3 litre glass beakers, with lids to prevent water loss were used, and there were 4 replicates/concentration with 10 test animals/vessel. The test duration was 14 days, during which time animals were exposed to constant light. The number of worms alive in each container were counted after 7 and 14 days.
5.2	**Results and discussion**	On day 14, percent mortalities were 0, 2.5, 32.5, 47.5, 75.0 and 97.5 on concentration groups of 0, 100, 200, 400, 800, 1600 mg/kg respectively. Statistical analysis (Probit) determined the 14 day LC50 to be 371 mg kg^{-1} with 95% confidence intervals of 304 to 452 mg/kg.
5.2.1	**LC_0**	100 mg kg^{-1}
5.2.2	**LC_{50}**	371 mg kg^{-1} Converted to artificial soil **126 mg/kg dwt** Conversion is calculated in annex I
5.2.3	**LC_{100}**	1600 mg kg^{-1}
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. The dose-response relationship indicates that at 1600 mg kg^{-1}, effectively all (97.5%) of the earthworms are killed. At 100 mg kg^{-1} only one worm (out of 40) died. The pass criteria (permissible random mortality) for control mortality is <10%, therefore 2.5% can be considered a random mortality, and 100 mg kg^{-1} is therefore considered a No Effect Concentration.
5.3.1	**Other Conclusions**	
5.3.2	**Reliability**	1
5.3.3	**Deficiencies**	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*28/04/05*
Materials and Methods	*Applicant's version is acceptable*
Results and discussion	*Adopt applicant's version*
Conclusion	*Adopt applicant's version*
Reliability	*1*
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.2-1: Preparation of TS solution

Dispersion	No
Vehicle	Yes - Appropriate amounts of permethrin were dissolved in 10 ml acetone and thoroughly mixed with 3000 g of artificial soil for each concentration group. Solvent was evaporated completely before introduction of the earthworms.
Concentration of vehicle	Not calculable
Vehicle control performed	No
Other procedures	None

Table A7.5.1.1-2: Test organisms

Criteria	**Details**
Species/strain	Eisenia foetida
Source of the initial stock	Nisarg Sampada, Plot No. 25, Happy colony, Kothrod, Pune-411 029
Culturing techniques	Not reported
Age/weight	All worms were at least 8 weeks old and fully clitellated weighing between 300 – 600 mg.
Pre-treatment	None

Table A7.5.1.2-3: Test system

Criteria	**Details**
Artificial soil test substrate	The artificial soil was prepared following OECD guideline No. 207 (OECD 1984). Sand: 14kg (70%) Kaolin clay: 4kg (20%) Sphagnum peat (organic matter): 2kg (10%) pH: 6.4 Moisture content (day 0) 26.2% (day 14) 22.7%
Test mixture	The test substance was mixed with the dry soil to give the required percentage water content (33%) and metal concentrations. The same volume of distilled water was added to each of the controls
Size, volume and material of test container	3 litre glass beakers, with lids to prevent water loss.
Amount of artificial soil (kg)/ container	750g soil
Nominal levels of test concentrations	0, 100, 200, 400, 800, 1600 mg kg^{-1}
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Continuous lighting (mean intensity 484.6 ± 6.02 lux)
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7.5.1.2-4: Test conditions

Criteria	Details
Test temperature	19.6 ± 0.2°C
Moisture content	Day 0: 26.2% Day 14: 22.7%
pH	6.4
Adjustment of pH	No
Light intensity / photoperiod	Continuous lighting (mean intensity 484.6 ± 6.02 lux)
Relevant degradation products	None measured

Table A7.5.1.2-5: Mortality data

Test Substance Concentration (nominal)[1] [mg/kg artificial soil]	**Mortality**			
	Number		**Percentage**	
	7 d	**14 d**	**7 d**	**14 d**
Control	0	0	0.0	0.0
100	0	1	0.0	2.5
200	5	13	12.5	32.5
400	11	19	27.5	47.5
800	16	30	40.0	75.0
1600	20	39	50.0	97.5
Temperature [°C]	19.6 ± 0.2°C	19.6 ± 0.2°C		
pH	6.4	6.4		
Moisture content	-	22.7%		

[1] TS concentrations were nominal

Table A7.5.1.2-6: Effect data

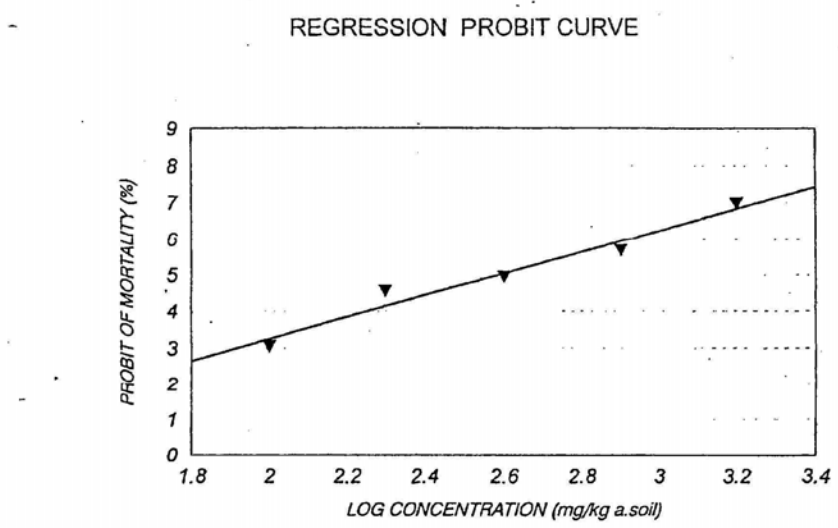
	14 d [mg/kg soil][1]	**95 % c.l.**
LC_0	100	-
LC_{50}	371	304 – 452
LC_{100}	1600	-

[1] effect data are based on nominal (n) concentrations

Table A7.5.1.2-7: Validity criteria for acute earthworm test according to OECD 207

	fulfilled	**Not fulfilled**
Mortality of control animals < 10%	**X**	

Figure 1: Log concentration – Probit mortality



Annex I

The NOEC should be normalized to a standard soil, which is defined as a soil with an organic carbon matter of 3.4%.

The NOECstandard have herein been determined using the following equation:

$$NOEC\ or\ L(E)C_{50(standard)} = NOEC\ or\ L(E)C_{50(exp)} \cdot \frac{Fom_{soil(standard)}}{Fom_{soil(exp)}} \quad (71)$$

NOEC	output	[mg.kg^{-1}dwt soil]
Fomsoil(standard)	0.034	[mg.kg^{-1}]
Fomsoil(exp)	0.10	[mg.kg^{-1}]
NOEC$_{reproduction}$	371	[mg.kg^{-1}dwt soil]

The normalized NOEC is 126 mg.kg^{-1} (dry weight)

Section A7.5.1.3 Annex Point IIIA XIII 1.1	Acute toxicity to plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	Permethrin has been used in the crop protection field since 1977. During that time it has been cleared for use on several crops, including cotton plants, corn, soybean, coffee, tobacco, oil seed rape, wheat, barley, alfalfa, vegetables, and fruits. Product safety data sheets (IUCLID 4.6.2) for crop protection products give application rates from 0.1 to 0.4 lb ai/A, equivalent to 0.112 and 0.448 kg/ha (11.2 to 44.8 mg/m^3). Work undertaken at the Ohio State University Department of Entomology (IUCLID 4.6.2) to investigate the efficacy of permethrin against lawn pests observed no phytotoxicity in lawn turf up to an application rate of 1.12 kg/ha (112 mg/m^3). Therefore a justification for non-submission is suggested on the following grounds; Permethrin has been used for several decades on a wide variety of crops, from grain to both monocots and dicots, and has been used on home and garden plants including woody-stemmed plants such as roses. The requirement to undertake testing on non-target plants is to ensure the protection of terrestrial plants during the application of permethrin. From the available historical data on usage, it can clearly be seen that permethrin when used at application rates up to 112 mg/m^3 has no phytotoxic effects.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date Evaluation of applicant's justification Conclusion Remarks	30/05/05 Applicant's justification is adequate Applicant's justification is acceptable	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section A7.5.1.3 Annex Point IIIA XIII 1.1	Acute toxicity to plants
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.5.2.1 **Annex Point IIIA XIII 1.1**	**Terrestrial tests: long-term tests;** **Reproduction study with other soil non-target macro-organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	According to Figure 3.2: Testing strategy for terrestrial ecotoxicity studies (Technical Guidance on Data Requirements), further terrestrial testing is only required if the acute toxicity data indicates risk of long-term harm or exposure. The risk assessment, and a review of the terrestrial toxicity data indicate the use of permethrin as a wood preservative poses little or no risk of long term harm or exposure. A justification for non-submission of data is proposed on the grounds of limited exposure and no indication of long-term harm to terrestrial organisms.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	29/04/05	
Evaluation of applicant's justification	Applicant's justification is valid	
Conclusion	Adopt applicant's justification	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.2.1 **Annex Point IIIA XIII 1.1**	**Terrestrial tests: long-term tests;** **Reproduction study with other soil non-target macro-organisms**
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.5.2.1(2)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Th. Moser, T, Scheffczyk, A., (2005); Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1)., ECT Oekotoxikologie GmbH, Germany. Report No. P15HR BES N° M-259607-01-1; 27 October 2005; unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Bayer CropScience AG	
1.2.2			
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.* 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).	
2.2	**GLP**	Yes	
2.3	**Deviations**	None.	
		3 METHOD	
3.1	**Test material**	*Cis* and *trans* -3-(2,2-dichlorovinyl)2,2-dimethylcylopropane carboxylic acid (Beta-Cyfluthrin Permethric-acid) (1:1 mixture of the *cis*- and *trans*- isomer)	
3.1.1	**Lot/Batch number**	a. (*cis*-isomer) 920622ELB03 b. (*trans*-isomer) 920622ELB04	
3.1.2	**Specification**	Not relevant, metabolite testing	
3.1.3	**Purity**	99.8% w/w	
3.1.4	**Composition of Product**	1:1 mixture of the *cis*- and *trans*- isomer	
3.1.5	**Further relevant properties**	Stability under correct storage conditions: June 02, 2010	
3.1.6	**Method of analysis**	The test item was identified by MS and NMR,	
3.2	**Toxic standard**	Yes, Dimethoate	
3.2.1	**Method of analysis for reference**	N/A	

Section 7.5.2.1(2)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

	substance	
3.3	**Test methods**	
3.3.1	**Test organisms**	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table A7.5.1.2(2)-1
3.3.2	**Test system**	See table A7.5.1.2(2)-2
3.3.3	**Test conditions**	See table A7.5.1.2(2)-3
3.3.4	**Test duration**	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
3.3.5	**Test parameter**	Mortality and reproduction
3.3.6	**Examination**	14 days after test initiation mortality was assessed; Reproduction was examined on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
3.3.7	**Monitoring of test substance concentration**	No
3.3.8	**Statistics**	Mortality: A One-Way Analysis of Variance (ANOVA), followed by a Dunnett's t-test (1-sided, $p \leq 0.05$) was used to determine whether or not there were significant differences. The LC50 value was calculated by Probit analysis using Linear Max. Likelihood Regression. Reproduction: The Welch t-test for inhomogeneous variances (1-sided, $p \leq 0.05$) was used to determine significant differences The statistical software package ToxRat Professional 2.09 was used for these calculations.
		4 RESULTS
4.1	**Soil test**	
4.1.1	**Initial concentrations of test substance**	10, 32, 100, 316 and 1000 mg/kg dry soil
4.1.2	**Effects data** Mortality/ Reproduction	Mortality: After 14 days of exposure, mortality ranged from 6.3-13.8% in the samples treated with up to 100 mg/kg soil (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed respectively (corrected mortality 24.7 and 93.3%). Reproduction: Statistical analysis (Welch t-test; 1-sided, $p \leq 0.05$) showed no significant difference concerning the cumulative number of juveniles per female over a total period of 7 days between the control and the concentrations of 100 and 316 mg test item/kg soil (dw).

Section 7.5.2.1(2)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

See table A7.5.1.2(2)-4 and table A7.5.1.2(2)-5

4.2	**Results of controls**	
4.2.1	**Mortality**	In the control groups 7% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	Reproduction	The mean reproductive performance of the controls was 24.1 (no of juvenile/emale/7 days). Both control parameters are within acceptable guideline limits.
4.2.2	**Number/ percentage of predator mites showing adverse effects**	Not stated except reproduction and mortality see 4.2.2
4.2.3	**Nature of adverse effects**	no other endpoints than mortality and reproduction success reported
4.3	**Test with toxic standard**	Performed
4.3.1	**Concentrations**	5.0 mg/kg dry soil
4.3.2	**Results**	The toxic reference, dimethoate, caused 96.4% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) was performed with permethric-acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett et al. 1994). Validity criteria were fulfilled and no major deviations were noted. Permethric-acid was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content of 1.21 ± 0.27) at five nominal rates of 10, 32, 100, 316 and 1000 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation. Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of the two highest concentrations of the test item which caused less than 50% corrected mortality (i.e. 100 and 316 mg test item/kg soil (dw)). After 7 days

Section 7.5.2.1(2)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

		in an untreated mating units, 20 females of each of the test item treatments and the water treatment were transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days. Mortality and reproduction success in the treatment groups was statistically compared to the water control group.
5.2	**Results and discussion**	After 14 days of exposure, seven percent of adult mites died in the control. Mortality in the concentrations of 10, 32 and 100 mg test item/kg soil (dw) ranged from 6.3 – 13.8% mortality (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed, respectively (corrected mortality 24.7 and 93.3%). The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) showed a significant difference in the mortality after 14 days between the control and these concentrations. The LC50 value calculated by Probit analysis using Linear Max. Likelihood Regression was determined as 400.9 mg test item/kg soil (dw) (95% confidence limits could not be calculated due to mathematical reasons). Based upon the statistically significant different at 316 mg/kg soil (dw), the $NOEC_{Mortality}$ was determined to be 100 mg test item/kg soil (dw) and the $LOEC_{Mortality}$ was determined to be 316 mg test item/kg soil (dw). Reproduction in both the 100 and 316 mg/kg dry soil treatments were 23.7 and 26.4 juveniles per female over the 7-day reproduction period, with the control having produced 24.1 juveniles per female. The statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed no significant difference, thus the $NOEC_{Reproduction}$ was determined as >316 mg/kg soil.
5.2.1	**NOEC**	>316 mg/kg dry soil (reproduction) Converted to artificial soil **>526 mg/kg dwt** 100 mg/kg dry soil (mortality) Converted to artificial soil **167 mg/kg dwt** Conversion is calculated in annex I
5.3	**Conclusion**	Permethric-acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of <100 mg/kg dry soil (NOEC) and theLC_{50} was 400.9 mg/kg dry soil. There were no adverse effects on reproduction at concentrations of >316 mg/kg dry soil.
5.3.1	**Other Conclusions**	Validity criteria were fulfilled
5.3.2	**Reliability**	1

Section 7.5.2.1(2) BPD Data set IIIA/ Annex Point XIII.3	**Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites**

Key Study

5.3.3 Deficiencies None

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*15/1/09*
Materials and Methods	*Applicant's version is acceptable.*
Results and discussion	*Adopt applicant's version with the following additions:* *The Notifiers did not convert the LC50 value to artificial soil values. RMS calculations are as follows:* 14 day LC_{50} (Mortality) = 400.9 mg.kg-1soil converted to artificial soil = 668 mg/kg dwt
Conclusion	*Adopt applicant's version*
Reliability	*1*
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.2(2)-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae)
Source of the initial stock	MITOX, laboratory-reared
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table A7.5.1.2(2)-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0,01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 36.6
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameter. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 10, 32, 100, 316 and 1000 mg/kg dry soil
Number of replicates/concentration	4 (5 for water control)
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table A7.5.1.2(2)-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table A7.5.1.2(2)-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	7%		24.1
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
10	5.9%	P>0.05	Not assessed
32	-0.8%	P>0.05	Not assessed
100	7.3	P>0.05	1.9%
316	24.7	P<0.05*	-9.3%
1000	93.3	P<0.05*	Not assessed

* Statistically significantly different from deionised water control.

Table A7.5.1.2(2)-5: Effect data

	[mg/kg soil dry weight]
NOEC	>316 mg/kg dry soil (reproduction) 100 mg/kg dry soil (mortality)

Table A7.5.1.2(2)-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)	**Yes**	

Annex I

The NOEC should be normalized to a standard soil, which is defined as a soil with an organic carbon content of 2%.

The NOECstandard have herein been determined using the following equation:

$$NOEC\ or\ L(E)C_{50(standard)} = NOEC\ or\ L(E)C_{50(exp)} \cdot \frac{Fom_{soil(standard)}}{Fom_{soil(exp)}} \qquad (71)$$

NOEC	output	[mg.kg^{-1}dwt soil]
Fomsoil(standard)	0.02	[mg.kg^{-1}]
Fomsoil(exp)	0.012	[mg.kg^{-1}]
$NOEC_{reproduction}$	100	[mg.kg^{-1}dwt soil]
$NOEC_{mortality}$	>316	[mg.kg^{-1}dwt soil]

The normalized NOEC is

DCVA : $NOEC_{repro\text{-}standard}$ = 167 mg.kg^{-1} (dry weight)

DCVA : $NOEC_{mortality\text{-}standard}$ > 526 mg.kg^{-1} (dry weight)

Section 7.5.2.1(3)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

Official use only

1 REFERENCE

1.1	**Reference**	Moser, T, Scheffczyk, A., (2005) ; Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1). ECT Oekotoxikologie GmbH, Germany. Bayer AG, Report No. P14HR BES Ref M-258697-01-1; 12 October 2005 Unpublished
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Bayer CropScience AG
1.2.2	**Companies with letter of access**	
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett et al. 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).
2.2	**GLP**	Yes
2.3	**Deviations**	None.

3 METHOD

3.1	**Test material**	4-Fluoro-3-phenoxybenzoic acid
3.1.1	**Lot/Batch number**	M23458, AE F105561 001C94 0001
3.1.2	**Specification**	Not relevant, metabolite testing
3.1.3	**Purity**	94% w/w
3.1.4	**Composition of Product**	Not relevant, metabolite testing
3.1.5	**Further relevant properties**	Stability under correct storage conditions: April 19,2007
3.1.6	**Method of analysis**	Identity of the test material confirmed by MS and NMR
3.2	**Toxic standard**	Yes, Dimethoate

Section 7.5.2.1(3)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

3.2.1	**Method of analysis for reference substance**	N/A
3.3	**Test methods**	
3.3.1	**Test organisms**	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table A7.5.2.1(3)-1
3.3.2	**Test system**	See table A7.5.2.1(3)-2
3.3.3	**Test conditions**	See table A7.5.2.1(3)-3
3.3.4	**Test duration**	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
3.3.5	**Test parameter**	Mortality and reproduction
3.3.6	**Examination**	14 days after test initiation mortality was assessed. Reproduction was tested on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
3.3.7	**Monitoring of test substance concentration**	No
3.3.8	**Statistics**	Mortality : The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) Reproduction: Welch t-test; 1-sided, $p \leq 0.05$
		4 RESULTS
4.1	**Soil test**	
4.1.1	**Initial concentrations of test substance**	9.4, 30.1, 94, 297 and 940 mg /kg dry soil
4.1.2	**Effects data** Mortality/ Reproduction	Mortality: There was no concentration dependent mortality after 14 days. Mortality ranged from 5.00 - 16.25% in the treated samples corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.66%. The ANOVA and Dunnett's t-test showed not significant difference in the mortality compared to the control. The LC50 was hence > 940 mg test item/kg soil. Reproduction : Statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed a significant difference concerning the cumulative number of juveniles per female after 7 days between the control and the concentration of 940.0 mg test item/kg soil (dw).At 297.0 mg/kg soil effects were not statistically significant, the NOEC was determined to be 297.0 mg test item/kg soil. See table A7.5.2.1(3)-4 and table A7.5.2.1(3)-5

Section 7.5.2.1(3)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

4.2	**Results of controls**	
4.2.1	**Mortality**	In the control groups 3% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	**Reproduction**	The mean reproductive performance of the controls was 21.95% (fertile eggs/female/7 days). Both control parameters are within acceptable guideline limits.
4.2.3	**Number/ percentage of predator mites showing adverse effects**	Not stated except reproduction and mortality see 4.2.2
4.2.4	**Nature of adverse effects**	see 4.2.1 and 4.2.2., based upon initial number of test organisms and the number of mites retrieved.
4.3	**Test with toxic standard**	Performed
4.3.1	**Concentrations**	5.0 mg/kg dry soil
4.3.2	**Results**	The toxic reference, dimethoate, caused 96.56% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed on 4-Fluoro-3-phenoxybenzoic acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett *et al.* 1994). The test compound was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content 1.27 ± 0.27) at five nominal rates of 9.4, 30.1, 94, 297 and 940 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation. Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of two highest concentrations of the test item which caused less than 50% corrected mortality. After 7 days in an untreated mating unit, 20 females of each of the test item treatments and the water treatment were

Section 7.5.2.1(3)
BPD Data set IIIA/ Annex Point XIII.3

Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites

Key Study

		transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days. Mortality and egg production in the treatment groups was evaluated for statistical significance in comparison to the water control group.
5.2	**Results and discussion**	After 14 days of exposure, three percent of adult mites died in the control. Mortality in the treatment ranged from 5.00 - 16.25% m (corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.66%). Since the mortality observed with the test item was not higher than 16.25%, the LC50 value could not be calculated and was estimated as being > 940.0 mg test item/kg soil (dw). The ANOVA and the Dunnett's t-test (1-sided, $p < 0.05$) showed no significant difference in the mortality after 14 days between the control and all concentrations of the test item tested. Therefore, the $NOEC_{Mortality}$ was determined as > 940 mg test item/kg soil (dw). The $LOEC_{Mortality}$ could not be determined and was assumed to be > 940.0 mg test item/kg soil (dw). A statistical significant difference (Welch t-test; 1-sided, $p < 0.05$) concerning the cumulative number of juveniles per female after 7 days between the control females and the females of the concentration of 940.0 mg/kg soil (dw) was evident. Analysis of the reproduction success in the next lower concentration of 297.0 mg/kg soil revealed no statistical difference to the untreated control Thus the $NOEC_{Reproduction}$ was determined as 297 mg/kg soil.
5.2.1	**NOEC**	297 mg/kg soil. (reproduction) Converted to artificial soil **495 mg/kg dwt** > 940 mg/kg dry soil (mortality) Converted to artificial soil **1567 mg/kg dwt** Conversion is calculated in annex I
5.3	**Conclusion**	-Fluoro-3-phenoxybenzoic acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of > 940 mg/kg dry soil. A statistical significant difference in reproductive potential (cumulative number of juveniles per female after 7 days) was observed between the control females and the females of the concentration of 940 mg/kg soil (dw). The NOEC reproduction was determined with 297.0 mg test item/kg soil.
5.3.1	**Other Conclusions**	Validity criteria were fulfilled

Section 7.5.2.1(3) BPD Data set IIIA/ Annex Point XIII.3	**Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites**

Key Study

5.3.2	**Reliability**	1
5.3.3	**Deficiencies**	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*15/1/09*
Materials and Methods	*Applicant's version is acceptable*
Results and discussion	*Adopt applicant's version*
Conclusion	*Adopt applicant's version*
Reliability	*1*
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.2.1(3)-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* Canestrini (Acari: Laelapidae)
Source of the initial stock	MITOX, laboratory-reared
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table A7.5.2.1(3)-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0.01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 32.7
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameters. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 9.4, 30.1, 94, 297 and 940 mg/kg dry soil, toxic standard
Number of replicates/concentration	4 (5 for water control), 3 for toxic standard
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table A7.5.2.1(3)-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table A7.5.2.1(3)-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	3%		21.95
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
9.4	8.5%	P>0.05	Not assessed
30.1	3.4%	P>0.05	Not assessed
94	2.1%	P>0.05	Not assessed
297	13.7%	P>0.05	8.4%
940	9.8%	P>0.05	29.4%*

* Statistically significantly different from deionised water control.

Table A7.5.2.1(3)-5: Effect data

LC_{50}	297 mg/kg soil. (reproduction)[1] > 940 mg/kg dry soil (mortality)[1]

[1] effect data are based on nominal (n) concentrations

Table A7.5.2.1(3)-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)	**Yes**	

Annex I

The NOEC should be normalized to a standard soil, which is defined as a soil with an organic carbon content of 2%.

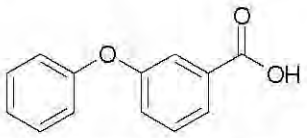
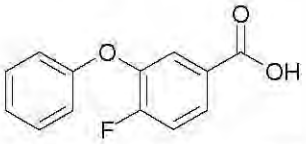
The NOECstandard have herein been determined using the following equation:

$$NOEC\ or\ L(E)C_{50(standard)} = NOEC\ or\ L(E)C_{50(exp)} \cdot \frac{Fom_{soil(standard)}}{Fom_{soil(exp)}} \quad (71)$$

NOEC	output	[mg.kg^{-1}dwt soil]
Fomsoil(standard)	0.02	[mg.kg^{-1}]
Fomsoil(exp)	0.012	[mg.kg^{-1}]
$NOEC_{reproduction}$	297	[mg.kg^{-1}dwt soil]
$NOEC_{mortality}$	> 940	[mg.kg^{-1}dwt soil]

The normalized NOEC is

FBP-acid : $NOEC_{repro\text{-}standard}$ = 495 mg.kg^{-1} (dry weight)
FBP-acid : $NOEC_{mortality\text{-}standard}$ > 1567 mg.kg^{-1} (dry weight)

Section A7.5.2.1 (4) Annex Point IIIA XIII 1.1	**Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	The study on the effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) performed with the betacyfluthrin metabolite 4-fluoro-3-phenoxybenzoic acid is considered relevant for the permethrin metabolite, 3-phenoxybenzoic acid. The only difference in structure between these two compounds results in the substitution of a hydrogen atom by a fluorine atom attached in the para position of the carboxylic acid group.  3-phenoxybenzoic acid (PBA)  4-fluoro-3-phenoxybenzoic acid (FPBA) There is no study with 3-phenoxybenzoic acid for soil organisms available. However, it could be assumed that the effect of a fluorine-substituent does not influence toxicity dramatically. For estimating the extent of a possible effect studies with suitable model substances e.g. halogen-substituted benzoic acids could be used. According to Y.H Zhao[1], the toxicity of benzoic acids may be predicted with reasonable accuracy mainly by non-polar narcosis. The 1-octanol/water partition coeffiecient (Log Pow) and parameters to describe ionization (pKa and Log D) were used for the calculations. These parameters are shown in table 1 The log Pow and the log D of the 4-flurobenzoic acid is closer to the benzoic acid than any other halogen-substituted benzoic acid. The data on toxicity of these various para substituted benzoic acids to *Daphnia magna* and *Vibrio. fischeri* have been measured. The results are used to evaluate the effect of the para fluorine relative to hydrogen and the other halogens. The data is presented in Table 2. The toxicity of the para halobenzoic acids to *D. magna* and *V. fischeri* decreases in the order of bromo > chloro > fluoro. The ratios of the benzoic acid compared to the para halobenzoic acid were calculated and are shown in parenthesis. 4-chlorobenzoic acid is only slightly (1.5) more toxic than benzoic acid whilst 4-	

Section A7.5.2.1 (4) Annex Point IIIA XIII 1.1	**Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites**
	fluorobenzoic acid is slightly less toxic than benzoic acid on both organisms (0.6 and 0.7). The effects of 4-chloro and 4-fluoro benzoic are not significantly different (factor <2) to the effect of benzoic acid itself. Therefore, it can be concluded that the fluorine substitution in the para position of the carboxylic acid group has no significant effect on two different organisms such as a crustacean, *D. magna* and a marine bacteria, *V. fischeri.* On this ground, BES believe that the study on the effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) performed with the betacyfluthrin metabolite 4-fluoro-3-phenoxybenzoic acid can be considered relevant for the permethrin metabolite, 3-phenoxybenzoic acid. As no data were generated with the 3-phenoxybenzoic acid itself on soil organisms, it is proposed to add an additional assessment factor of 3 to determine the PNECsoil taking into account the possible minimal effect of the para fluoro-substituent.compared to 3-phenoxybenzoic acid . This approach can be regarded as very conservative. A QSAR estimation with the program ECOSAR vs. 0.99h revealed a 1-day LC50 of 3400 mg/kg dry wt soil for earthworms, indicating that 3-phenoxybenzoic acid is not toxic to soil organisms[2]. **Reference:** 1) QSAR study of the toxicity of benzoic acids to *Vibrio fischeri, Daphnia magna* and carp; Y.H. Zhao, G.D. Ji, M.T.D. Cronin,U, J.C. Dearden; The Science of the Total Environment 216 (1998) .205-215 2) Pross 2008; Calculation of the Ecotoxicity Hazard Profile for m-Phenoxybenzoic acid (CAS 3739-38-6) by ECOSAR
Undertaking of intended data submission [ ]	
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE

Section A7.5.2.1 (4) Annex Point IIIA XIII 1.1	**Terrestrial tests: long-term tests; Reproduction study with other soil non-target macro-organisms-metabolites**
Date	15/1/09
Evaluation of applicant's justification	The applicants justification is well-argued and considered acceptable
Conclusion	*Accept applicants justification* - the study on the effects on survival and reproduction of *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) performed with the betacyfluthrin metabolite 4-fluoro-3-phenoxybenzoic acid can be considered relevant for the permethrin metabolite, 3-phenoxybenzoic acid, provided an additional assessment factor of 3 is used when determining the PNECsoil (to take into account the possible minimal effect of the para fluoro-substituent.compared to 3-phenoxybenzoic acid).
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 1 : Properties of benzoic acids

	benzoic acid	4-chloro benzoic acid	4-bromo benzoic acid	4-fluorobenzoic acid
pKa	4.21	3.98	4.00	3.87
Log Pow	1.87	2.70	2.85	2.13
Log D	-1.72	-1.12	-0.95	-1.80

Table 2: effects of benzoic acids to *D. magna* and bacteria

Structure	*D. magna* (IC_{50}) 24h mg/L		*V. fischeri* (EC_{50}) 24h mg/L
	pH 6.0	pH 7.8	pH 5.7
benzoic acid	222 (1)	703 (1)	9.93 (1)
4-fluorobenzoic acid	344 (0.7)	992 (0.7)	15.4 (0.6)
4-chlorobenzoic acid	150 (1.5)	609 (1.2)	6.38 (1,6)
4-bromobenzoic acid	78.2 (2.8)	567 (1.2)	2.97 (3.3)

Section A7.5.2.2 **Annex Point IIIA XIII 1.1**	**Terrestrial tests: long-term tests; Long term test with terrestrial plants**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	According to Figure 3.2: Testing strategy for terrestrial ecotoxicity studies (Technical Guidance on Data Requirements), further terrestrial testing is only required if the acute toxicity data indicates risk of long-term harm or exposure. The risk assessment, and a review of the terrestrial toxicity data indicate the use of permethrin as a wood preservative poses little or no risk of long term harm or exposure. A justification for non-submission of data is proposed on the grounds of limited exposure and no indication of long-term harm to terrestrial organisms.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	29/04/05	
Evaluation of applicant's justification	Applicant's justification is adequate	
Conclusion	Accept applicant's justification	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section A7.5.2.2 Annex Point IIIA XIII 1.1	Terrestrial tests: long-term tests; Long term test with terrestrial plants
Remarks	

Section A7.5.3 Annex Point IIIA.XII.2.1	Effects on Birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
Detailed justification:	Headline only – no data requirement	
Undertaking of intended data submission [ ]		

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*15/1/09*
Evaluation of applicant's justification	*Accept justification*
Conclusion	*Accept justification*
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.5.3.1.1 Effects on birds : Acute oral toxicity
Annex Point IIIA XIII 1.1

Key Study

Official use only

	1 REFERENCE	
1.1	**Reference**	[redacted] 1975a; Acute oral LD50 in Mallard Duck with FMC33297. [redacted]; Not GLP; Unpublished
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC
1.2.2	**Companies with letter of access**	Bayer Environmental Science
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
	2 GUIDELINES AND QUALITY ASSURANCE	
2.3	**Guideline study**	No – no guidelines available
2.4	**GLP**	No - GLP was not compulsory at the time the study was performed
2.5	**Deviations**	No – no guidelines followed
	3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2
3.1.1	**Lot/Batch number**	Mr R176, C6699-65
3.1.2	**Specification**	As given in section 2
3.1.3	**Purity**	95.7
3.1.4	**Composition of Product**	Not applicable
3.1.5	**Further relevant properties**	None
3.1.6	**Method of analysis in the diet**	No analysis
3.2	**Administration of the test substance**	see table A7_5_3_1_1-1
3.3	**Reference substance**	Yes - Dieldrin
3.3.1	**Method of analysis for reference substance**	No analysis
3.4	**Testing procedure**	
3.4.1	**Test organisms**	see table A7_5_3_1_1-2

Section 7.5.3.1.1 Effects on birds : Acute oral toxicity
Annex Point IIIA XIII 1.1

3.4.2	**Test system**	see table A7_5_3_1_1-3
3.4.3	**Diet**	Food (Truslow Farms game bird starter ration) and water available ad libitum following dosing
3.4.4	**Test conditions**	see table A7_5_3_1_1-4
3.4.5	**Duration of the test**	8 days
3.4.6	**Test parameter**	Mortality, growth (body weight)
3.4.7	**Examination / Observation**	Symptom of toxicity and mortality were recorded daily
3.4.8	**Statistics**	Litchfield, J.T, Wilcoxon, F; Journal Pharmacol. Exptl. Therap. **96**, 99; 1949

4 RESULTS

4.1	**Limit Test / Range finding test**	Not performed
4.1.1	**Results test substance**	
4.1.2	**Applied concentrations**	Applied concentrations of the test substance per dose level (mg/kg bw)
4.1.3	**Effect data (Mortality)**	see table A7_5_3_1_1-5 LD_{50} value >4640 mg/kg bw
4.1.4	**Body weight**	see table A7_5_3_1_1-6
4.1.5	**Feed consumption**	see table A7_5_3_1_1-6
4.1.6	**Concentration / response curve**	Not applicable
4.1.7	**Other effects**	There was an incidental death observed at 1000 mg/kg bw, and a lack of co-ordination at the 4640 mg/kg bw.
4.2	**Results of controls**	
4.2.1	**Number/ percentage of animals showing adverse effects**	None
4.2.2	**Nature of adverse effects**	None
4.3	**Test with reference substance**	Performed
4.3.1	**Concentrations**	21, 32, 46, 68, 100 mg/kg bw

Section 7.5.3.1.1 Effects on birds : Acute oral toxicity
Annex Point IIIA XIII 1.1

4.3.2	**Results**	LD50 65 mg/k bw

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Permethrin was dosed in corn oil by gavage to 14 day old chicks. The chicks were held in observation pens and observed for 8 days post-dosing. Body weight, feeding and behavioural abnormalities were recorded.
5.2	**Results and discussion**	No mortalities were observed at all tested concentrations up to 4640 mg/kg bw. There was an incidental death observed at 1000 mg/kg bw, and a lack of co-ordination at the 4640 mg/kg bw. No effects were observed in the control pens.
5.2.1	**LD50**	>4640 mg/kg bw
5.3	**Conclusion**	Validity criteria can be considered as fulfilled as no control mortalities were observed. As with many reports from the early days of ecotoxicity testing, there is little detail to assess the housing environment of the test animals, but this does not detract from the overall reliability of the result.
5.3.1	**Reliability**	2
5.3.2	**Deficiencies**	Yes - As with many reports from the early days of ecotoxicity testing, there is little detail to assess the housing environment of the test animals, but this does not detract from the overall reliability of the result.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	29/04/05
Materials and Methods	Information about the housing of the birds during the study is lacking. However, considering the date of the study this is not unusual. Therefore the Materials and Methods section is considered to be adequate
Results and discussion	Adopt applicant's version
Conclusion	Adopt applicant's version
Reliability	2
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... ***(specify)***
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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

Carrier / Vehicle	Details
Water	No
Organic carrier	Yes - corn oil
Concentration of the carrier [% v/v]	100% corn oil
Other vehicle	None
Function of the carrier / vehicle	Solvent for test substance

Table A7_5_3_1_1-2: Test animals

Criteria	Details
Species/strain	Mallard Duck (*Anas platyrhynchas*)
Source	[redacted]
Age (in weeks), sex and initial body weight (bw)	2 weeks; 175 to 251 g
Breeding population	[redacted]
Amount of food	Controls 3350 – 3925 g Permethrin 3000 – 3550 g Dieldrin 125 – 3625 g
Age at time of first dosing	14 days
Health condition / medication	Blood tested US Pullorum-Typhoid clean

Table A7_5_3_1_1-3: Test system

Criteria	Details
Test location	indoor in holding pens
Holding pens	No data
Number of animals	150
Number of animals per pen [cm²/bird]	10
Number of animals per dose	10
Pre-treatment / acclimation	None
Diet during test	Food (Truslow Farms game bird starter ration) and water available ad libitum following dosing
Dosage levels (of test substance)	Single dose Dieldrin controls; 21, 32, 46, 68, 100 mg/kg bw Permethrin; 215, 464, 1000, 2150, 4640 mg/kg bw
Replicate/dosage level	Not applicable
Feed dosing method	gavage
Dosing volume per application	Not reported
Frequency, duration and method of animal monitoring after dosing	Symptoms recorded daily
Time and intervals of body weight determination	Prior to dosing (day 0) and end of observation period (day 8)

Table A7_5_3_1_1-4: Test conditions (housing)

Criteria	Details
Test temperature	Not reported
Shielding of the animals	Not reported
Ventilation	Not reported
Relative humidity	Not reported
Photoperiod and lighting	Not reported

Table A7_5_3_1_1-5: Mortality data after test termination

Test substance dosage level [mg/kg bw]	Mortality after test termination (8 days)[1]									
	Total number per dose level					Percentage per dose level				
	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5
0	0	0	0	0	0	0	0	0	0	0
215	0	-	-	-	-	0	-	-	-	-
464	0	-	-	-	-	0	-	-	-	-
1000	0	-	-	-	-	0	-	-	-	-
2150	0	-	-	-	-	0	-	-	-	-
4640	0	-	-	-	-	0	-	-	-	-
Temperature [°C]	NR	NR	NR	NR	NR					
Relative humidity	NR	NR	NR	NR	NR					

1 10 animals per test pen
NR Not reported

Table A7_5_3_1_1-6: Average body weights and food consumption

Permethrin Concentration mg/kg bw	Average bw (g) Day 0	Average bw (g) Day 8	% increase	Food consumption (/10 animals)
215	251	422	168%	3275
464	249	437	176%	3500
1000	245	430	176%	3550
2150	210	418	199%	3000
4640	219	395	180%	3175
Negative controls				
0	192	387	202%	3500
0	215	390	181%	3350
0	207	405	196%	3675
0	190	387	204%	3550
0	197	410	208%	3925

Table A7_5_3_1_1-7: Validity criteria for avian acute oral toxicity test according to EPA OPPTS 850.2100

	Fulfilled	Not fulfilled
Mortality of control animals <10%	X	

Section 7.5.3.1.2 Annex Point IIIA XIII 1.2 — Effects on birds : Short-term toxicity

Key Study

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted], 1975b; Eight-day dietary LC50 in Bobwhite Quail with FMC33297. [redacted]; Not GLP; Unpublished
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC
1.2.2	**Companies with letter of access**	Bayer Environmental Science
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	No – no guidelines available
2.2	**GLP**	No - GLP was not compulsory at the time the study was performed
2.3	**Deviations**	No – no guidelines followed
		3 MATERIALS AND METHODS
3.1	**Test material**	As given in section 2
3.1.1	**Lot/Batch number**	Mr R176, C6699-65
3.1.2	**Specification**	As given in section 2
3.1.3	**Purity**	95.7
3.1.4	**Composition of Product**	Not applicable
3.1.5	**Further relevant properties**	None
3.1.6	**Method of analysis in the diet**	No analysis
3.2	**Administration of the test substance**	see table A7_5_3_1_2-1
3.3	**Reference substance**	*Yes*
3.3.1	**Method of analysis for reference substance**	No analysis
3.4	**Testing procedure**	

Section 7.5.3.1.2 Annex Point IIIA XIII 1.2 — Effects on birds : Short-term toxicity

3.4.1	**Test organisms**	see table A7_5_3_1_2-2
3.4.2	**Test system**	see table A7_5_3_1_2-3
3.4.3	**Diet**	Experimental material was dissolved in corn oil such that the addition of two parts by weight to 98 parts game bird starter ration resulted in the series of dosages required.
3.4.4	**Test conditions**	see table A7_5_3_1_2-4
3.4.5	**Duration of the test**	
3.4.6	**Test parameter**	Mortality, growth (body weight)
3.4.7	**Examination / Observation**	Symptom of toxicity and mortality were recorded daily
3.4.8	**Statistics**	Litchfield, J.T, Wilcoxon, F; Journal Pharmacol. Exptl. Therap. **96**, 99; 1949
		4 RESULTS
4.1	**Limit Test / Range finding test**	Not performed
4.2	**Results test substance**	
4.2.1	**Applied concentrations**	Dietary concentrations (ppm) 464, 1000, 2150, 4640, 10000 ppm
4.2.2	**Effect data (Mortality)**	see table A7_5_3_1_2-5 LC_{50} value >10,000 ppm
4.2.3	**Body weight**	see table A7_5_3_1_2-6
4.2.4	**Food consumption**	see table A7_5_3_1_2-6
4.2.5	**Concentration / response curve**	Not applicable
4.2.6	**Other effects**	Wing droop was observed on day 3. Otherwise no abnormalities were observed.
4.3	**Results of controls**	
4.3.1	**Number/ percentage of animals showing adverse effects**	None
4.3.2	**Nature of adverse effects**	None
4.4	**Test with**	Performed

Section 7.5.3.1.2 Annex Point IIIA XIII 1.2 — Effects on birds : Short-term toxicity

	reference substance	
4.4.1	**Concentrations**	10.0, 14.7, 21.5, 31.6, 46.4 ppm
4.4.2	**Results**	LC_{50} value for mortality: 31 ppm (95% CI 24 to 39 ppm)
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	Permethrin was dissolved in corn oil such that the addition of two parts by weight to 98 parts game bird starter ration resulted in the series of dosages required to dose 14 day old chicks. The chicks were held in observation pens and observed for 8 days for the duration of the exposure period. Body weight, feeding and behavioural abnormalities were recorded.
5.2	**Results and discussion**	No mortalities were observed at all tested concentrations up to 10000 ppm. Wing droop was observed on day 3. No effects were observed in the control pens. The average weight increase was lower with permethrin treated birds. There is no concentration related response to this observation, and the average food consumption was lower in the treated animals. This implies the lower weight gain may be attributed to palatability of food treated with up to 10 g per kg food.
5.2.1	**LC_0**	10,000 ppm
5.2.2	**LC_{50}**	>10,000 ppm
5.2.3	**LC_{100}**	>10,000 ppm
5.3	**Conclusion**	Validity criteria can be considered as fulfilled as no control mortalities were observed. As with many reports from the early days of ecotoxicity testing, there is little detail to assess the housing environment of the test animals, but this does not detract from the overall reliability of the result.
5.3.1	**Reliability**	2
5.3.2	**Deficiencies**	Yes - As with many reports from the early days of ecotoxicity testing, there is little detail to assess the housing environment of the test animals, but this does not detract from the overall reliability of the result.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	29/04/05
Materials and Methods	Little information is given about the housing of the birds but this does not detract from the overall reliability of the study.
Results and discussion	Adopt applicant's version
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	Clearly permethrin influenced food intake and consequent weight gain in the birds however this was not in a dose response manner. The study is considered to have attained the goal of determining the LC50 and is therefore acceptable.
Remarks	
	COMMENTS FROM ... ***(specify)***
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_3_1_2-1: Method of administration of the test substance

Carrier / Vehicle	Details
Water	No
Organic carrier	Yes - corn oil
Concentration of the carrier [% v/v]	100% corn oil
Other vehicle	None
Function of the carrier / vehicle	Not applicable

Table A7_5_3_1_2-2: Test animals

Criteria	Details
Species/strain	Bobwhite Quail (*Colinus virginianus*)
Source	[redacted]
Age (in weeks), sex and initial body weight (bw)	2 weeks; 27 to 30 g
Age range within the test	14 days
Breeding population	[redacted]
Age at time of first dosing	14 days
Health condition / medication	Blood tested US Pullorum-Typhoid clean

Table A7_5_3_1_2-3: Test system

Criteria	Details
Test location	indoor in holding pens
Holding pens	No data
Number of animals	150
Number of animals per pen [cm²/bird]	10
Number of animals per dose	10
Pre-treatment / acclimation	None
Diet during test	Food (Truslow Farms game bird starter ration) and water available ad libitum following dosing
Dosage levels (of test substance)	Single dose Dieldrin controls; 10.0, 14.7, 21.5, 31.6, 46.4 ppm Permethrin; 464, 1000, 2150, 4640, 10000 ppm
Replicate/dosage level	Dietary exposure
Dosing method	Dietary
Dosing volume per application	Not reported
Frequency, duration and method of animal monitoring after dosing	Symptoms recorded daily
Time and intervals of body weight determination	Prior to dosing (day 0) and end of dosing observation period (day 8)

Table A7_5_3_1_2-4: Test conditions (housing)

Criteria	Details
Test temperature	Not reported
Shielding of the animals	Not reported
Ventilation	Not reported
Relative humidity	Not reported
Photoperiod and lighting	Not reported

Table A7_5_3_1_2-5: Mortality data after test termination

Test substance dosage level [mg/kg bw]	Mortality after test termination (.... days)									
	Total number per dose level					Percentage per dose level				
	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5
0	0	0	0	0	0	0	0	0	0	0
464	0	-	-	-	-	0	-	-	-	-
1000	0	-	-	-	-	0	-	-	-	-
2150	0	-	-	-	-	0	-	-	-	-
4640	0	-	-	-	-	0	-	-	-	-
10000	0	-	-	-	-	0	-	-	-	-
Temperature [°C]	NR	NR	NR	NR	NR					
Relative humidity	NR	NR	NR	NR	NR					

1 10 animals per test pen
NR Not reported

Table A7_5_3_1_2-6: Average body weights and food consumption

Permethrin Concentration	Average bw (g) Day 0	Average bw (g) Day 8	% increase	Food consumption
464	30	42	140%	525
1000	30	43	143%	425
2150	27	41	152%	425
4640	30	45	150%	600
10000	30	38	127%	400
			Average	475
Negative controls				
0	30	47	157%	450
0	30	47	157%	525
0	30	45	150%	630
0	30	45	150%	550
0	30	48	160%	495
			Average	530

Table A7_5_3_1_2-6: Validity criteria for short-term toxicity test according to OECD 205

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

Section 7.5.3.1.3 Effects on birds : Effects on reproduction

Annex Point IIIA XIII 1.3

Key Study

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted]; 1992; Permethrin: A one-generation study with the Northern Bobwhite *(Colinus virginianus)*; [redacted]; GLP; Unpublished
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC
1.2.2	**Companies with letter of access**	Bayer Environmental Science
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes - FIFRA GUIDELINE 71-4
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	As given in section 2
3.1.1	**Lot/Batch number**	B9152-247; 4/15/91 PLM
3.1.2	**Specification**	As given in section 2
3.1.3	**Purity**	95.2%
3.1.4	**Composition of Product**	Not applicable
3.1.5	**Further relevant properties**	None
3.1.6	**Method of analysis**	Gas Chromatography - ECD
3.2	**Administration of the test substance**	see table A7_5_3_1_3-1
3.3	**Testing procedure**	
3.3.1	**Test organisms**	see table A7_5_3_1_3-2
3.3.2	**Test system**	see table A7_5_3_1_3-3
3.3.3	**Diet**	Basal diet for the adult birds and their offspring was formulated to Wildlife International Ltd. specifications by Agway Inc. The diet contained 27% protein minimum, 2.5% fat minimum and 5% fiber maximum. Five percent (w/w) limestone was added to the diet to

Section 7.5.3.1.3 **Effects on birds : Effects on reproduction**
Annex Point IIIA XIII 1.3

		provide a calcium source. Water was supplied by the town of Easton public water supply. Feed and water are analyzed periodically. Neither the adults nor offspring received any form of medication in the diet during the study. The adults were fed a gamebird ration formulated f o r breeding birds. During the study the birds received the appropriate test or control diet from test initiation to terminal sacrifice. Water and feed were provided ad libitum during acclimation and during the test. All offspring received a gamebird ration formulated for young growing birds (identical to adult diet, but without the addition o f limestone). The test substance was not mixed into the diet of the offspring. All offspring received a water soluble vitamin and electrolyte mix (Durvet, Incorporated, Blue Springs, Missouri 64015) in their water from the day o f hatch until the birds were 14 days o f age. Feed and water were provided t o the offspring ad libitum. **Diet Preparation:** Test diets were prepared by mixing permethrin into a premix which was used for weekly preparation o f the final diet. Control diet and three test concentrations (25, 125 and 500 ppm) were prepared weekly beginning on June 18, 1991 and normally presented to the birds on Tuesday of each week. When necessary during the study additional feed was prepared. Dietary concentrations were not adjusted for purity of the test substance. **Diet Analysis**: On Day 0 of Week 1, immediately following diet preparation, six samples were collected from each concentration t o determine homogeneity of the diet. A single sample o f each test concentration was collected immediately following mixing on Day 0 of Weeks 1, 2, 3, 4, 8, 12, 16 and 20 and from feed remaining in the feeders presented t o the birds on Day 7 of Week 1.
3.3.4	**Test conditions**	see table A7_5_3_1_2-4
3.3.5	**Duration of the test**	20 weeks
3.3.6	**Test parameter**	Effects on adult health, weight gain and feed consumption were evaluated. In addition, the effects of adult exposure to permethrin on the number of eggs laid, normal development o f eggs, viability of the embryos, percent hatchability, offspring survival and eggshell thickness were evaluated.
3.3.7	**Examination / Observation**	1. Adult Body Weight - Individual body weight was measured at initiation, Weeks 2, 4, 6, 8 and at termination of the study. Statistical comparisons were made between the control group and each treatment group at each weighing interval by sex. 2. Adult Feed Consumption - Feed consumption expressed as grams of feed per bird per day was examined by pen weekly during the study. Statistical comparisons were made between the control and each treatment group.

3. Eggs Laid of Maximum Laid - The number of eggs laid per hen divided by the largest number of eggs laid by any one hen. This transformation was used to convert the number of eggs laid to a percentile value less than or equal to 100.
4. Eggs Cracked of Eggs laid - The number of eggs determined by candling to be cracked divided by the number of eggs laid, per pen.
5. Viable Embryos of Eggs Set - The number of viable embryos at the Day 11 candling was divided by the number o f eggs set, per pen.
6. Live 3-Week Embryos of Viable Embryos - The number of live embryos at the Day 21 candling was divided by the number of viable embryos, per pen.
7. Hatchlings of 3-Week Embryos - The number of hatchlings removed from the hatcher was divided by the number o f live 3-week embryos, per pen.
8. 14-Dav Old Survivors of Hatchlings - The number of 14-day old survivors was divided by the number o f hatchlings per week, by pen.
9. Hatchlings of Eggs Set - The number of hatchlings was divided by the number of eggs set per week, by pen.
10. 14-Day Old Survivors of Eggs Set - The number of 14-day old survivors was divided by the number of eggs set per week, by pen.
11. Hatchlings o f Maximum Set - The number of hatchlings per hen divided by the largest number of eggs set from any one hen. This transformation was used to convert the number o f hatchlings to a percentile value equal to or less than 100.
12. 14-Day Old Survivors o f Maximum Set - The number o f 14-day old survivors per pen divided by the largest number of eggs set.
13. Egg Shell Thickness - The average egg shell thickness of indiscriminately selected eggs per pen, was measured.
14. Offsprings Body Weight - The group body weights of hatchlings and 14-day old survivors was measured by parental pen group.

3.3.8 Statistics

Upon completion o f the study, Dunnett's method (4,5) was used to determine statistically significant differences between the control group and each o f the treatment groups. Sample units were the individual pens within each experimental group. Percentage data were examined using Dunnett's method following arcsine transformation. The pens in which mortality occurred were not used in statistical comparisons of the reproductive data. Each of the

Section 7.5.3.1.3 **Effects on birds : Effects on reproduction**
Annex Point IIIA XIII 1.3

		parameters mentioned in 3.3.7 was analyzed statistically:
		4 RESULTS
4.1	**Limit Test / Range finding test**	Not performed
4.2	**Results test substance**	
4.2.1	**Applied concentrations**	Dosed at 0, 25, 125, 500 ppm
4.2.2	**Effect data (Mortality and reproductivity)**	see table A7_5_3_1_3-5 NOEC values (including 95 % c.l.) 500 ppm
4.2.3	**Body weight**	see table A7_5_3_1_3-8 NOEC values (including 95 % c.l.) 500 ppm
4.2.4	**Food consumption**	see table A7_5_3_1_3-9 NOEC values (including 95 % c.l.) 500 ppm
4.2.5	**Results of residue analysis**	Recoveries from the homogeneity samples averaged 81 ± 4% for the 25 ppm samples, 91 ± 4% for the 125 ppm samples and 95 ± 7% for the 500 ppm samples. Mean recovery from the stability samples was 91 ± 5%. Verification samples had mean measured concentrations of 23 ± 4 ppm, 110 ± 9 ppm and 470 ± 24 ppm, respectively, representing 92%, 88% and 94%, respectively, of the nominal concentrations. Values were not corrected f o r a mean recovery of 91 ± 13% from quality control samples analyzed concurrently.
4.2.6	**Other effects**	There were no treatment related mortalities at any o f the concentrations tested. Three incidental mortalities occurred in the 25 ppm treatment group. No mortalities occurred in the control group or in the 125 and 500 ppm treatment groups. No overt signs of toxicity were observed at any of the concentrations tested during the course of the study. One hen in the 125 ppm test concentration was noted carrying her head curled t o the side for one day during Week 7. Other observations normally associated with penwear and/or interactions among penmates, such as foot and head lesions or feather loss, were noted at various concentrations during the course of the study. Except for the mortality and incidental clinical signs noted previously, a11 birds appeared normal throughout the study.
4.3	**Results of controls**	
4.3.1	**Number/ percentage of animals showing**	None

Section 7.5.3.1.3 **Effects on birds : Effects on reproduction**
Annex Point IIIA XIII 1.3

	adverse effects	
4.3.2	**Nature of adverse effects**	None
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	A one-generation bobwhite reproduction study was conducted with permethrin. The test was initiated on June 17, 1991 and completed on February 5, 1992. This study was conducted in compliance with the Environmental Protection Agency Registration Guidelines Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms. Subsection 71-4. The test substance, permethrin, was administered ad libitum in the diet of young adult bobwhite (20 weeks old at test initiation) approaching their first breeding season. Test diets containing permethrin at nominal concentrations of 0, 25, 125 or 500 ppm were fed to the adults for 20 weeks. The bobwhite were observed daily for mortality, abnormal behaviour, and signs of toxicity. All adult birds found dead during the study were necropsied. In addition, necropsies were performed on all adults surviving until study termination. For the first 7 weeks of the test the birds were held under a photoperiod of 8 hours of light per day. The photoperiod was increased to 17 hours of light per day during Week 8 to induce egg laying. The adults continued on a photoperiod of 17 hours of light per day until sacrifice. Eggs were collected daily from the onset of egg production and set weekly for incubation. The first eggs were set during Week 13. Weekly throughout the laying period, eggs were collected from every other pen for eggshell thickness measurements. In addition, effects upon egg production and quality, and hatchling health and survivability also were examined.
5.2	**Results and discussion**	Bobwhite were exposed to permethrin at dietary concentrations of 0, 25, 125 and 500 ppm for 20 weeks. There were no treatment related mortalities or overt signs of toxicity in any treatment group. There were no apparent treatment related effects upon body weight, feed consumption or any reproductive parameter at any of the concentrations tested. The no observed effect level in this study for northern bobwhite exposed to permethrin in the diet was 500 ppm, the highest concentration tested.
5.2.1	**NOEC**	500 ppm
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. Permethrin was shown to be non-toxic to bobwhite quail and have no impasct on reproductive functionality up to dosing concentrations of 500 ppm in a dietary exposure test.

Section 7.5.3.1.3 Effects on birds : Effects on reproduction

Annex Point IIIA XIII 1.3

5.3.1	Reliability	1
5.3.2	Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	29/04/05
Materials and Methods	Despite some minor deviations the applicant's version is acceptable
Results and discussion	Adopt applicant's version
Conclusion	Adopt applicant's version
Reliability	1
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... ***(specify)***
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.3.1.3-1: Method of administration of the test substance

Carrier / Vehicle	Details
Water	No
Organic carrier	Yes
Concentration of the carrier [% v/v]	Premix: See Table A7_5_3_1_3-7 for detail on the ration 0 ppm: 250 ml acetone + 180 ml (162 g) corn oil + 7938.0 g ration 25 ppm: 5.0625 g permethrin + 250 ml acetone + 180 ml corn oil + 7932.9 g ration 125 ppm: 25.3125 g permethrin + 250 ml acetone + 180 ml corn oil + 7912.7 g ration 500 ppm: 101.2500 g permethrin + 250 rnl acetone + 180 ml corn oil + 7836.8 g ration
Other vehicle	None
Function of the carrier / vehicle	Acetone and corn oil were to facilitate mixing, uptake and digestion

Table A7.5.3.1.3-2: Test animals (if more than one species is used, for each species one table)

Criteria	Details
Species/strain	Bobwhite Quail (*Colinus virginianus*)
Source	[redacted]
Age (in weeks), sex and initial body weight (bw)	20 weeks at initiation
Age range within the test	20 weeks at initiation
Breeding population	Approaching their first breeding season
Amount of food	*Ad libitum*
Age at time of first dosing	20 weeks at initiation
Health condition / medication	All animals in good health at test initiation
Pre-treatment	6 weeks pre-acclimation

Table A7.5.3.1.3-3: Test system

Criteria	Details
Test location	indoor in holding pens
Holding pens	30 x 51 cm constructed of galvanised wire grid and galvanized sheeting
Number of animals (male/female)	64 male, 64 female distributed into 4 groups
Number of animals per pen [cm²/bird]	2 [765 cm^2 per bird]
Number of animals per dose	32
Pre-treatment / acclimation	The test birds were acclimated to the facilities for 6 weeks prior to initiation of the test. During acclimation and upon initiation o f the test, the birds were maintained under a photoperiod o f eight hours of light per day. During Week 8 the photoperiod was increased t o seventeen hours of light per day to induce egg laying. The photoperiod was maintained at 17 hours o f light per day until adult sacrifice. The first eggs were set for incubation during Week 13.
Diet during test	See Table A7_5_3_1_3-1 for preparation of the premix. 0 ppm: 2000 g Premix + 45.50 kg ration + 2500 g limestone 25 ppm: 2000 g Premix + 45.50 kg ration + 2500 g limestone 125 ppm: 2000 g Premix + 45.50 kg ration + 2500 g 1imestone 500 ppm: 2000 g Premix + 45.50 kg ration + 2500 g 1imestone
Dosage levels (of test substance)	Dietary levels of the test substance: 0, 25, 125, 500 ppm
Replicate/dosage level	Not applicable
Dosing method	Dietary
Dosing volume per application	Dietary exposure fed ad libitum
Frequency, duration and method of animal monitoring after dosing	Details of parameters are given in 3.3.7. Animals were monitored daily.
Time and intervals of body weight determination	Weeks 0, 2, 4, 6, 8 and termination
Test period after egg-laying	See Collection period for eggs
Turning of eggs	See Incubation, storing and hatching
Collection period for eggs	Acclimation - 6 weeks. Pre-photostimulation - 7 weeks. Pre-egg laying (with photostimulation) - 4 weeks. Egg laying - 10 weeks. Post-adult sacrifice (final incubation, hatching, and 14-day offspring rearing period) - 6 weeks.

Incubation, storing and hatching	Eggs were collected daily and stored in a cold room maintained at a mean temperature o f 13.5 ± 1.0°C (SD) with an average relative humidity of approximately 64 ± 7% (SD). All eggs to be incubated were fumigated to reduce the possibility of pathogen contamination prior to incubation. The eggs were fumigated by placing them in an airtight cabinet equipped with a circulating fan for approximately two hours. Formaldehyde gas was generated by placing 38 grams of potassium permanganate in a porcelain bowl in the base of the cabinet to which was added 37 ml of 37% (w/w) commercial grade formalin. Eggs were set for incubation on a weekly basis. The eggs were placed in the incubator where the temperature was maintained at an average 37.5 ± 0.0°C (SD) with an average wet bulb temperature of approximately 29.4 ± 0.0°C (SD) (an average relative humidity of approximately 56%). The incubator was equipped with a pulsator fan and blades that produced a mild breathing air movement that was designed to eliminate intracabinet temperature and humidity variation during incubation. In order to prevent adhesion of the embryo to the shell membrane, the incubator was also equipped with an automatic egg rotation device, designed to rotate the eggs from 50° off vertical in one direction to 50° off vertical in the opposite direction (total arc of rotation is I00°) each hour through Day 21 of incubation. The eggs were transferred to the hatcher on Day 21. Eggs were not rotated in the hatcher. The average temperature in the hatcher was 37.2 ± 0.1°C (SD) and the average wet bulb temperature was raised to 33.3 ± 0.1°C (SD) (an average relative humidity of approximately 76%).

Table A7.5.3.1.3-4: Test conditions (housing)

Criteria	Details
Test temperature	Average temperature 22.5 ± 2.8°C
Shielding of the animals	Yes – housed in such a way as to avoid excessive disturbances
Ventilation	15 room volumes per hour
Relative humidity	62 ± 13%
Photoperiod and lighting	First 7 weeks – 8 hours per day 8 weeks to termination – 17 hours per day 501 lux
Storing, incubation and hatching conditions for eggs	See Table A7_5_3_1_3-3

Environmental conditions for young birds	Not applicable

REPRODUCTIVE DATA - BOBWHITE

PERMETHRIN - PROJECT NUMBER 104-166

		PERMETHRIN		
	0 PPM	25 PPM	125 PPM	500 PPM
Eggs Laid	710	594	706	755
Eggs Cracked	24	25	15	14
Eggs Set	616	499	618	667
Viable Embryos	554	454	563	614
Live 3-Week Embryos	544	447	558	608
Hatchlings	515	412	528	580
14-Day Old Survivors	464	382	478	507
Eggs Laid/Hen	44	46	44	47
Eggs Laid/Hen/Day @	0.66	0.68	0.66	0.70
14-Day Old Survivors/Hen	29	29	30	32

@ - Based on 67 days.

Table A7.5.3.1.3-5: Values of reproduction ability

Eggs Laid	710	594	706	755
Eggs Laid/Max. Laid (%)	67	69	67	71
Eggs Cracked/Eggs Laid (%)	6	4	2	2
Viable Embryos/Set (%)	83	91	91	93
Live 3-Week Embryos/Viable (%)	98	98	99	99
Hatchlings/3-Week (%)	95	92	95	95
14-Day Old Survivors/Hatch (%)	90	93	92	88
Hatchlings/Set (%)	77	82	86	88
14-Day Old Survivors/Set (%)	70	76	79	77
Hatchlings/Max. Set (%)	52	51	53	58
14-Day Old Survivors/Max. Set (%)	47	47	48	51

The above differences from the control are not statistically significant.

Table A7.5.3.1.3-6: Validity criteria for bird reproduction test according to OECD 206

	Fulfilled	Not fulfilled
Mortality of control animals <10%	X	
Average number of 14-day-old survivors per hen in controls ≥ 14, 12 and 24 for mallard duck, bobwhite quail and Japanese quail	X	
Average eggshell thickness for the control group ≥ 0.34, 0.19 and 0.19 mm for mallard duck, bobwhite quail and Japanese quail	X	
Concentration of the test substance in the diet ≥ 80 % of the nominal concentration throughout the test period	X	

Table A7.5.3.1.3-7: Wildlife International Ltd. Game bird ration

INGREDIENTS	PERCENT (%)
Fine Corn Meal	37.45
Ground Oats	5.00
Alfalfa Meal Dehydrated, 17% Protein	3.00
CDP (Phosphate Source)	0.70
Dried Whey	2.50
Fish Meal, 60% protein	6.00
Meat Poultry Blend, 58% Protein	4.00
Wheat Midds	5.00
Soy Bean Meal, 48% Protein	34.80
Salt Iodized	0.10
Ground Limestone	0.60
GL Ferm (Fermatco)[3]	0.25
Methionine Premix	0.20
Vitamin and Mineral Premix (see below)	0.40
Total	100.00

VITAMIN AND MINERAL PREMIX	AMOUNT ADDED PER TON
Vitamin D_3	2,000,000 I.C.U.
Vitamin A	7,000,000 I.U.
Riboflavin	6 grams
Niacin	40 grams
Pantothenic Acid	10 grams
Vitamin B_{12}	8 mgs
Folic Acid	600 mgs
Biotin	64 mgs
Pyridoxine	1.2 grams
Thiamine	1.2 grams
Vitamin E	20,000 I.U.
Vitamin K (Menadione Dimethylpyrimidinol Bisulfite)	5.8 grams
Manganese	102 grams
Zinc	47 grams
Copper	6.8 grams
Iodine	1.5 grams
Iron	51 grams
Selenium	182 mgs

Table A7.5.3.1.3-8: Body weight data

BODY WEIGHT DATA (g) - HATCHLINGS

BOBWHITE

PERMETHRIN - PROJECT NUMBER 104-166

		PERMETHRIN		
	0 PPM	25 PPM	125 PPM	500 PPM
No. of Chicks Weighed	513	412	528	573
Mean Body Weight (g)	5.7 ±0.6	5.7 ±0.6	5.7 ±0.7	5.7 ±0.6

BODY WEIGHT DATA (g) - 14-DAY SURVIVORS

BOBWHITE

PERMETHRIN - PROJECT NUMBER 104-166

		PERMETHRIN		
	0 PPM	25 PPM	125 PPM	500 PPM
No. of Chicks Weighed	464	382	473	507
Mean Body Weight (g)	22 ± 4	22 ± 4	22 ± 4	22 ± 3

Table A7.5.3.1.3-9: Food consumption

APPENDIX VI
PAGE 1
FEED CONSUMPTION DATA BY WEEK - BOBWHITE - GRAMS/BIRD/DAY
PERMETHRIN - PROJECT NUMBER 104-166
0 PPM

PEN NO.	WEEK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
501	16	16	16	15	15	16	15	16	17	22	20	27	28	27	28	27	32	29	28	34	41
502	14	17	17	13	14	16	16	25	15	15	16	20	20	22	26	22	28	29	26	28	39
503	12	13	13	12	14	13	14	14	15	17	15	22	21	20	22	23	25	24	24	22	28
504	15	21	16	17	20	15	18	20	18	20	19	26	25	24	29	32	30	34	31	30	35
505	18	26	20	19	22	22	17	22	20	28	27	34	34	35	36	36	36	46	44	49	46
506	17	20	22	17	20	18	25	21	24	27	26	29	26	28	30	29	31	31	28	28	41
507	17	24	20	15	24	22	26	23	28	34	30	35	38	34	39	40	38	43	43	35	63
508	14	20	20	17	18	16	19	16	17	21	20	28	27	32	35	30	30	32	30	31	36
509	14	14	14	14	15	23	15	15	17	19	18	17	17	17	19	20	23	21	21	23	27
510	16	24	20	21	27	17	21	24	19	25	30	30	39	37	36	43	43	36	36	28	46
511	19	23	20	18	25	12	25	20	22	29	29	31	29	39	28	31	33	36	33	31	40
512	16	23	20	14	16	20	21	23	21	24	21	25	34	33	28	28	33	31	31	44	49
513	13	14	13	13	13	13	13	14	16	15	19	22	25	28	27	26	27	28	26	25	37
514	14	15	14	13	13	11	14	14	16	20	22	20	22	24	22	28	30	31	32	36	37
515	16	16	16	15	18	16	16	14	15	18	21	22	24	27	26	29	35	36	35	34	34
516	13	14	14	13	13	13	14	15	16	19	21	19	21	22	18	22	23	22	22	21	31
Mean	15	19	17	15	18	16	18	18	18	22	22	25	27	28	28	29	31	32	31	31	39
sd	2	4	3	3	5	4	4	4	4	5	5	6	6	6	6	6	5	7	7	7	9

(Continued)

Table A7.5.3.1.3-9: Food consumption (cont'd)

APPENDIX VI
PAGE 2
FEED CONSUMPTION DATA BY WEEK - BOBWHITE - GRAMS/BIRD/DAY
PERMETHRIN - PROJECT NUMBER 104-166
25 PPM

PEN NO.	WEEK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
517	14	22	14	16	19	14	18	20	16	21	21	23	32	26	-	-	-	-	-	-	-
518	16	23	15	15	21	14	21	15	15	20	21	26	29	27	30	33	29	31	30	31	38
519	14	23	14	15	19	13	17	21	14	21	19	21	24	25	26	26	29	29	28	27	30
520	12	14	12	12	13	12	12	-	-	-	-	-	-	-	-	-	-	-	-	-	-
521	14	18	15	16	21	15	19	23	18	20	19	23	26	28	29	26	28	27	26	30	32
522	14	21	14	15	18	13	17	17	14	17	17	19	23	22	25	24	29	31	26	28	32
523	15	19	18	18	21	15	20	20	17	19	21	20	25	25	27	26	28	30	26	30	32
524	16	22	15	17	23	16	18	14	14	16	21	20	24	26	29	25	30	30	27	29	35
525	13	17	13	14	20	16	22	17	15	18	21	25	22	20	28	25	27	27	25	30	32
526	14	19	13	14	20	14	17	20	20	25	21	25	28	25	26	29	29	30	29	26	34
527	14	14	14	14	13	14	14	12	14	24	17	17	20	19	20	22	22	23	22	24	18
528	17	25	17	21	24	20	23	25	24	-	-	-	-	-	-	-	-	-	-	-	-
529	14	13	10	14	17	14	14	15	18	18	21	20	26	19	20	20	21	20	23	28	25
530	14	22	13	16	19	15	17	17	18	22	24	23	25	24	27	30	36	27	31	32	31
531	15	22	13	18	24	18	23	20	18	22	21	19	30	30	32	29	31	27	30	31	40
532	13	15	13	13	13	12	13	14	14	14	17	17	20	18	23	26	23	25	24	23	24
			**																		
Mean	14	19	14	16	19	15	18	18	16	20	20	21	25	24	26	26	28	28	27	28	31
sd	1	4	2	2	4	2	3	4	3	3	2	3	4	4	4	3	4	3	3	3	6

- = Data not available due to mortality.
**Difference from the control statistically significant at $p < 0.01$.

(Continued)

Table A7.5.3.1.3-9: Food consumption (cont'd)

APPENDIX VI
PAGE 3
FEED CONSUMPTION DATA BY WEEK - BOBWHITE - GRAMS/BIRD/DAY
PERMETHRIN - PROJECT NUMBER 104-166
125 PPM

PEN NO.	WEEK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
533	13	14	14	13	18	16	14	16	15	19	20	21	19	20	25	27	28	33	28	26	29
534	16	23	16	19	26	21	19	21	18	23	24	28	21	26	32	31	35	38	35	30	32
535	16	22	18	16	24	20	18	25	21	23	24	27	26	29	36	32	38	39	38	41	44
536	15	21	14	17	22	17	20	21	19	17	22	27	29	24	24	26	29	25	26	29	26
537	14	23	16	16	23	18	23	20	15	17	20	23	26	22	28	30	30	31	30	33	39
538	14	19	15	15	17	14	15	16	13	15	18	19	22	25	27	29	26	27	29	33	42
539	16	23	23	17	22	22	22	21	24	20	24	27	33	28	34	29	35	32	30	32	42
540	18	26	19	19	21	20	24	21	18	24	21	27	33	33	37	33	33	33	31	35	44
541	17	23	18	15	22	22	18	27	20	19	24	25	25	25	24	26	29	28	32	36	49
542	12	12	12	13	14	13	23	14	13	18	19	20	21	18	21	20	24	29	29	29	36
543	16	27	20	21	24	23	10	25	24	21	27	30	27	28	33	31	35	37	42	44	49
544	12	13	12	13	14	12	22	14	12	15	19	24	28	29	27	27	27	32	32	29	43
545	14	18	15	14	21	17	18	19	16	19	17	18	25	21	21	20	26	26	28	28	36
546	15	24	20	17	25	24	22	23	20	23	22	28	26	26	32	32	32	35	35	33	41
547	12	12	12	12	12	12	12	15	17	18	17	22	22	22	28	26	26	30	29	34	41
548	13	16	15	13	17	15	15	16	16	16	18	17	20	20	21	23	22	26	26	24	28
Mean	14	20	16	16	20	18	18	19	18	19	21	24	25	25	28	28	30	31	31	32	39
sd	2	5	3	3	4	4	4	4	4	3	3	4	4	4	5	4	5	4	4	5	7

Differences from the control are not statistically significant.

Table A7.5.3.1.3-9: Food consumption (cont'd)

APPENDIX VI
PAGE 4
FEED CONSUMPTION DATA BY WEEK - BOBWHITE - GRAMS/BIRD/DAY
PERMETHRIN - PROJECT NUMBER 104-166
500 PPM

PEN NO.	WEEK 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
549	13	14	13	13	15	14	16	15	10	13	16	16	18	19	21	20	24	24	27	24	24
550	14	20	14	17	19	17	16	18	13	20	19	23	23	27	28	24	29	30	29	26	31
551	15	23	17	18	18	15	17	19	16	17	20	26	27	27	32	31	32	30	29	37	40
552	17	22	21	21	26	20	17	22	22	22	24	31	31	29	32	33	34	37	34	30	42
553	15	17	14	14	17	21	14	18	18	16	19	23	22	24	25	33	33	30	30	23	31
554	17	23	19	19	28	24	19	23	16	22	22	29	31	28	37	37	35	35	46	40	45
555	16	27	17	17	22	25	19	19	19	24	27	30	33	29	34	31	32	33	32	43	50
556	17	25	18	17	23	22	21	20	23	24	28	33	34	30	29	31	41	51	56	50	63
557	16	23	17	20	22	22	20	24	20	22	28	29	31	31	31	34	34	38	42	38	60
558	15	24	22	23	27	22	21	24	18	24	29	30	32	33	34	34	39	38	44	41	57
559	16	21	22	21	24	23	21	23	26	21	32	31	33	30	35	38	39	52	50	45	60
560	15	19	15	23	26	16	16	19	17	20	21	26	29	26	32	32	34	31	39	31	47
561	15	17	14	13	16	15	14	15	15	17	19	23	19	18	19	23	26	27	31	27	26
562	18	23	17	19	26	19	21	21	17	23	31	30	37	33	34	36	38	42	51	38	40
563	14	18	15	15	15	13	16	17	14	18	19	19	23	24	29	29	27	26	31	30	31
564	16	20	16	15	18	15	17	15	14	17	20	19	22	22	31	25	30	30	30	30	45
Mean	15	21	17	18	21	19	18	20	17	20	23	26	28	27	30	31	33	35	37	34	43
sd	1	3	3	3	5	4	3	3	4	3	5	5	6	4	5	5	5	8	9	8	12

** | * | *

* Difference from the control statistically significant at $p < 0.05$.
**Difference from the control statistically significant at $p < 0.01$.

(Continued)

Section 7.5.4.1 Annex Point IIIA XIII 3.1 — Effects on Honybees : Acute toxicity to honeybees and other beneficial arthoprods, forexample predators

Key Study

Official use only

		1 REFERENCE
1.1	**Reference**	Gough, H.J, Jackson, D, Lewis, G.B; 1993; Permethrin: Acute Contact and Oral toxicity to Honey Bees (*Apis mellifera*) of technical material; Jealott's Hill Research Station; Report No. RJ1344B; 18 Jan 1993; GLP; Unpublished
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC
1.2.2	**Companies with letter of access**	Bayer Environmental Science
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes – UK Pesticides Safety Precautions Scheme Working Document D3: Laboratory testing for toxicity to honey bees.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 METHOD
3.1	**Test material**	
3.1.1	**Lot/Batch number**	Batch P58
3.1.2	**Specification**	As given in section 2
3.1.3	**Purity**	93.1% w/w
3.1.4	**Composition of Product**	Not applicable
3.1.5	**Further relevant properties**	Not applicable
3.1.6	**Method of analysis in the diet**	No analysis performed
3.2	**Administration of the test substance**	see table A7.5.4.1-1
3.3	**Reference substance**	Dimethoate
3.3.1	**Method of analysis for reference substance**	No analysis performed
3.4	**Testing procedure**	

Section 7.5.4.1 Annex Point IIIA XIII 3.1 — Effects on Honybees : Acute toxicity to honeybees and other beneficial arthoprods, forexample predators

3.4.1	**Test organisms**	see table A7.5.4.1-2
3.4.2	**Test system**	Contact toxicity: Bees were anaesthatised and 1 µl-of permethrin in acetone was applied to the thorax of each bee. The bees were returned to their cages and allowed to recover with a continuous supply of aqueous 50% sucrose solution as food. Oral toxicity: Each group of 10 bees was offered 0.2 ml of a given concentration, the dose being measured into the feeding tube from a Gilson P1000 variable volume pipette. This was equivalent to 0.02 ml per bee. After dosing, a continuous supply of untreated 50% sucrose solution was supplied.
3.4.3	**Diet**	The bees were fed a continuous supply of aqueous 50% sucrose solution
3.4.4	**Test conditions**	see table A7.5.4.1-3
3.4.5	**Duration of the test**	48 hours
3.4.6	**Test parameter**	Mortality, sublethal (behavioural) effects (Classified as A, B or C, depending on severity, see table A7.5.4.1-5)
3.4.7	**Examination / Observation**	1, 2, 4, 24, 48 hours
3.4.8	**Statistics**	Estimates of LD50 were made by the iteratively re-weighted linear regression of the logit transformation of percentage mortality, adjusted *via* Abbotts correction.
		4 RESULTS
4.1	**Limit Test / Range finding test**	Not performed
4.2	**Results test substance**	
4.2.1	**Applied concentrations**	Contact toxicity: 0.2, 0.1, 0.05, 0.02, 0.01, 0.005 µg ai bee^{-1} plus control Oral toxicity: 0.025, 0.01, 0.005, 0.0025, 0.001, 0.0005 µg ai bee^{-1} plus control
4.2.2	**Effect data (Mortality)**	see table A7.5.4.1-4 24 h LD_{50} value (contact toxicity) 0.0262 µg ai bee^{-1} (0.0207 – 0.0333) 48 h LD_{50} value (contact toxicity) 0.0235 µg ai bee^{-1} (0.0189 – 0.0294) 24 h LD_{50} value (oral toxicity) 0.169 µg ai bee^{-1} (0.0721 – 0.763) 48 h LD_{50} value (oral toxicity) 0.163 µg ai bee^{-1} (0.0717 – 0.636)
4.2.3	**Other effects**	see table A7.5.4.1-5
4.3	**Results of**	

Section 7.5.4.1
Annex Point IIIA XIII 3.1

Effects on Honybees : Acute toxicity to honeybees and other beneficial arthoprods, forexample predators

	controls	
4.3.1	**Number/ percentage of animals showing adverse effects**	see table A7.5.4.1-4 to 5
4.3.2	**Nature of adverse effects**	see table A7.5.4.1-4 to 5
4.4	**Test with reference substance**	LD50 values (contact: 0.111, oral: 0.143 µg ai bee^{-1}) indicated the bees were reacting normally to pesticide doses under the conditions of the test
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test was undertaken according to guidelines provided by the UK Pesticides Safety Precautions Scheme Working Document D3: Laboratory testing for toxicity to honey bees. The contact and oral toxicity to honey bees was determined as described; Contact toxicity: Bees were anaesthatised and 1 µl-of permethrin in acetone was applied to the thorax of each bee. The bees were returned to their cages and allowed to recover with a continuous supply of aqueous 50% sucrose solution as food. Oral toxicity: Each group of 10 bees was offered 0.2 ml of a given concentration, the dose being measured into the feeding tube from a Gilson P1000 variable volume pipette. This was equivalent to 0.02 ml per bee. After dosing, a continuous supply of untreated 50% sucrose solution was supplied. Observations for mortality and sublethal effects were made over a 48 hour period.
5.2	**Results and discussion**	The 24 hour contact and oral LD50 values for permethrin were 0.026 and 0.17 µg ai bee^{-1}, respectively. The 24 hour No Observed Effect Levels were 0.01 and 0.02 µg ai bee^{-1} respectively. The 48 hour results were similar to the 24 hour results, indicating there were no delayed effects. Results obtained for Dimethoate tested concurrently as a toxic standard indicate that the bees were reacting normally under the test conditions.
5.2.1	**LD_{50}**	24 h LD_{50} value (contact toxicity) 0.0262 µg ai bee^{-1} (0.0207 – 0.0333) 48 h LD_{50} value (contact toxicity) 0.0235 µg ai bee^{-1} (0.0189 – 0.0294) 24 h LD_{50} value (oral toxicity) 0.169 µg ai bee^{-1} (0.0721 – 0.763) 48 h LD_{50} value (oral toxicity) 0.163 µg ai bee^{-1} (0.0717 – 0.636)

Section 7.5.4.1 Annex Point IIIA XIII 3.1 — Effects on Honybees : Acute toxicity to honeybees and other beneficial arthoprods, forexample predators

5.3	**Conclusion**	Validity criteria can be considered as fulfilled.
5.3.1	**Reliability**	1
5.3.2	**Deficiencies**	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*16/1/09*
Materials and Methods	*Applicant's version is acceptable*
Results and discussion	*Adopt applicant's version*
Conclusion	*Adopt applicant's version*
Reliability	*1*
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.4.1-1: Method of administration of the test substance

Carrier / Vehicle	Details
Water	No
Organic carrier	Yes Contact toxicity: Acetone Oral toxicity: 50% sucrose solution in water, from a stock solution prepared in acetone
Concentration of the carrier [% v/v]	Contact toxicity: Acetone Oral toxicity: no greater than 1% acetone present in dose solution
Other vehicle	None
Function of the carrier / vehicle	Acetone: Solvent for test substance Sucrose: Facilitation of uptake and digestion

Table A7.5.4.1-2: Test animals

Criteria	Details
Species/strain	*Apis mellifera*
Source	Collected from a hive by gentle sweeping. Bees were taken from the honey supers to avoid including the queen, and any drones collected were rejected.
Age (in weeks), sex and initial body weight (bw)	Not measurable
Breeding population	Not applicable
Amount of food	Not fed, other than dosing solutions
Age at time of first dosing	Not measurable
Health condition / medication	Not measurable

Table A7.5.4.1-3: Test conditions (housing)

Criteria	Details
Test temperature	23°C
Housing	Bees were housed in cylindrical, stainless steel mesh cages 165 mm long and 45 mm diameter. One end was sealed with a steel plate, the other by a cork (contact toxicity) or cork/feeding tube apparatus (oral toxicity).
Ventilation	Not reported
Relative humidity	61-64%
Photoperiod and lighting	Kept in the dark

Table A7.5.4.1-4: Contact and Oral toxicity results – mortality

Table 5 : Contact Toxicity of Technical Permethrin

Test started : 9 September 1992

Assessment		1h	2h	4h	24h	48h
Dose (µg ai bee^{-1})	Rep	Numbers Dead Out of 10				
0.2	a	0	0	1	10	10
	b	0	0	1	10	10
	c	0	0	2	10	10
0.1	a	0	0	1	9	10
	b	0	0	0	8	9
	c	0	0	0	9	9
0.05	a	0	0	0	8	10
	b	0	0	1	7	7
	c	0	0	2	10	10
0.02	a	0	0	0	4	4
	b	0	0	0	4	4
	c	0	0	0	3	3
0.01	a	0	0	0	0	0
	b	0	0	0	0	0
	c	0	0	0	4	4
0.005	a	0	0	1	1	1
	b	0	0	0	0	0
	c	0	0	0	0	0
Control	a	0	0	0	0	0
	b	0	0	0	0	0
	c	0	0	0	0	0

Table 6 : Oral Toxicity of Technical Permethrin

Test started : 9 September 1992

Assessment		1h	2h	4h	24h	48h
Dose Consumed (µg ai bee^{-1})	Rep	Numbers Dead Out of 10				
0.5	a	0	0	1	9	9
	b	0	0	1	10	10
	c	0	0	0	9	9
0.2	a	0	0	0	5	6
	b	0	0	0	5	5
	c	0	0	2	7	7
0.1	a	0	0	0	2	2
	b	0	0	0	5	5
	c	0	0	0	2	2
0.05	a	0	0	1	8	8
	b	0	0	0	1	1
	c	0	0	0	0	0
0.02	a	0	0	0	0	0
	b	0	0	0	0	0
	c	0	0	0	0	0
0.01	a	0	0	0	0	1
	b	0	0	0	0	0
	c	0	0	0	0	0
Control	a	0	0	0	4	4
	b	0	0	0	0	0
	c	0	0	0	0	0

Table 9 : Sublethal Effects Recorded - Permethrin Contact Test

Test started : 9 September 1992

Assessment			1h			2h			4h			24h			48h		
Category of Effect		Number of Survivors Affected	A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
Dose (µg ai bee^{-1})	Rep																
0.2	a		0	10	0	0	0	10	0	0	9	0	0	0	0	0	0
	b		0	10	0	0	0	10	0	0	9	0	0	0	0	0	0
	c		0	10	0	0	0	10	0	0	8	0	0	0	0	0	0
0.1	a		0	10	0	0	0	10	0	0	9	0	0	1	0	0	0
	b		0	10	0	0	0	10	0	0	10	0	0	1	0	0	0
	c		0	10	0	0	0	10	0	0	10	0	0	0	0	0	0
0.05	a		0	10	0	0	3	7	0	0	2	0	1	0	0	0	0
	b		0	10	0	0	1	9	0	2	4	0	0	0	0	0	0
	c		0	10	0	0	2	8	0	4	5	0	0	0	0	0	0
0.02	a		0	4	0	0	4	0	0	1	1	0	0	0	0	0	0
	b		0	5	0	0	8	0	0	2	3	0	0	0	0	0	0
	c		0	6	0	0	6	0	0	3	1	0	0	0	0	0	0
0.01	a		0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
	b		0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
	c		0	1	0	0	1	0	0	0	0	0	0	0	0	0	0
0.005	a		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	b		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	c		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	a		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	b		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	c		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Category A - Bees are hyperactive, compared with controls, and show the first signs of paralysis

Category B - Partial paralysis and poor co-ordination of movement. Bees find it difficult to right themselves if they fall on their backs

Category C - Almost complete paralysis. Bees cannot walk and show only feeble movement of legs and antennae.

Table 10 : Sublethal Effects Recorded - Permethrin Oral Test

Test started : 9 September 1992

Assessment		1h			2h			4h			24h			48h		
Category of Effect		A	B	C	A	B	C	A	B	C	A	B	C	A	B	C
Dose Consumed (µg ai bee^{-1})	Rep	Number of Survivors Affected														
0.5	a	0	0	0	0	4	0	0	4	3	0	0	0	0	0	0
	b	0	1	0	0	4	0	0	4	5	0	0	0	0	0	0
	c	0	0	0	0	3	0	0	9	1	0	0	0	0	0	0
0.2	a	0	0	0	0	1	0	0	2	2	0	0	0	0	0	0
	b	0	0	0	0	3	0	0	1	3	0	0	0	0	0	0
	c	0	0	0	0	3	0	0	1	3	0	0	0	0	0	0
0.1	a	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	b	0	0	0	0	1	0	0	2	2	0	0	0	0	0	0
	c	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
0.05	a	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
	b	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	c	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0.02	a	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	b	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	c	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
0.01	a	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	b	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
	c	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Control	a	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
	b	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	c	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Sections 7.5.5 **BPD Data Set IIA/ Annex Point VII.7.5**	**Bioconcentration, terrestrial**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [✓]**	
Detailed justification:	According to the Technical Guidance Document on Risk Assessment Part II (page 132), for organic chemicals, the main route of uptake into earthworms will be *via* interstitial water. Bioconcentration can be described as a hydrophobic partitioning between the pore water and the phases inside the organism, and can be modelled according to the following equation as described by Jager (1998): $BCF_{earthworm} = [(0.84 + 0.012 \times Kow)/RHO_{earthworm}$ where for $RHO_{earthworm}$ a value of 1 (kg $_{wwt}$/L) can be assumed by default. Therefore, since the Kow of permethrin is 1258925 (Log Pow = 6.1), $BCF_{earthworm} = [(0.84 + 0.012 \times 12589925)/1] = 15108$ According to the Technical Guidance Document on Risk Assessment Part II (page 131), when birds and mammals consume worms, this includes the gut of the earthworms which can contain substantial amounts of soil. The exposure of predators (birds and small mammals) may be affected by the amount of active substance in this consumed soil. The $PEC_{oral\ predator}$ is calculated as: $PEC_{oral\ predator} = C_{earthworm}$ where $C_{earthworm}$ is the total concentration of the active substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the active substance to the soil present in the earthworms gut. The total concentration in an entire worm can be calculated as the weighted average of the worm's tissues (through BCF and porewater) and guts contents (through soil concentration). Based on the following equation, the concentration of permethrin in an entire worm is: $C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] / [1$	

	+ (F_{gut} x $CONV_{soil}$)] = 1.70 mg/kg wet earthworm = $PEC_{oral\ predator}$	
	With as an example: - $C_{porewater}$ = $1.24x10^{-4}$ $mg.L^{-1}$ (calculation provided below) - C_{soil} = 0.168 mg/kg wet weight soil corresponding to Fence DIP/SPRAY-TREATED WOOD scenario considering biodegradation (Tier 2) as an example - F_{gut} = 0.1 (TGD on Risk Assessment page 132) - $CONV_{soil}$ = RHO_{soil} / (F_{solid} x RHO_{solid}) = 1700 / (0.6 / 2500) = 1.13.	