5.2	**Results and discussion**	In the control group 4% of the adult *Hypoaspis* died which is within the recommended range of ≤ 25% mortality. Fisher's Exact Test revealed no significant different mortality rates for all treatment groups. Concerning the number of juveniles statistical analysis (Dunnett's Test, two-sided, $\alpha = 0.05$) revealed no significant differences between the control and all treatment groups. Therefore the No-Observed-Effect-Concentration (NOEC) for mortality and reproduction is considered to be ≥ 1.78 mg deltamethrin/kg dry weight soil, the highest concentration tested. The Lowest-Observed-Effect-Concentration (LOEC) for mortality and reproduction is > 1.78 mg deltamethrin/ kg dry weight soil.	X
5.3	**Conclusion**	The NOEC was determined to be ≥1.78 mg deltamethrin/kg dry weight soil. The LOEC was determined to be ≥1.78 mg deltamethrin/kg dry weight soil.	
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.2.1/04-1 Test Organisms

Criteria	Details
Species / strain	*Hypoaspis aculeifer* (Acari: Laelapidae)
Source of the initial stock	The culture of the soil mite *Hypoaspis aculeifer* used in this test has been bred at [redacted] since April 2002. The strain was originally obtained from [redacted]
Culturing techniques	This strain is held in the laboratory of the Institute of Ecotoxicology under following conditions: 20 +/- 2°C, 70 – 90% relative humidity, in permanent darkness. The mites were bred on a mixture of plaster of Paris, activated charcoal and demineralised water (11:1:10 w/w) in Bella Plast vessels (9.5 cm ∅). These vessels were filled up to a height of approximately 1 cm with this mixture and are closed with lids. The hypoaspis were fed with Tyrophagus putrescentiae (cheese mite), which were bred on brewer's yeast. The feeding was done directly at test start, 2, 5, 7, 9, 12 and 14 days after test start.
Age	Adult fertilised, female Hypoaspis (30 days after starting of egg laying) from a synchronised cohort were exposed to the test item.
Synchronisation	In order to obtain adult, female Hypoaspis of a uniform age, 150 adult, female Hypoaspis were transferred to fresh breeding vessels 30 days before start of the test. After two days of egg laying these females were removed. The Hypoaspis hatched from the eggs were fed with with Tyrophagus putrescentiae (cheese mite). Adult, fertilised females were used as test organisms in the study 30 days after starting of egg laying.

Table A7.5.2.1/04-2 Test System

<table>
<tr><th>Criteria</th><th>Details</th></tr>
<tr><td>Artificial soil</td><td>The artificial soil was prepared according to the guideline with the following constituents: 75% fine quartz sand (sort F 36) (particle size 0.2 – 0.05 mm = 89.5%); 5% sphagnum peat (air dried and finely ground), 20% kaolin clay (content of kaolinite 56%) and approx. 0.2% calcium carbonate (for the adjustment to pH 6.0 +/- 0.5).
The artificial soil was prepared by mixing the dry components intensively in a laboratory mixer. Three days before test start the dry artificial soil was pre-moistened with deionised water with approximately half of the required amount of water. During the application of the test item water content was adjusted to a final water content of approximately 50% of the maximum water holding capacity.</td></tr>
<tr><td>Test mixture</td><td>All test item solutions were prepared freshly on the day of the application. Prior to the start of the test a stock solution (= solution 1) was prepared with 152.7 mg test item filled up to a volume of 250 ml with deionised water (1.78 mg deltamethrin/kg dry weight soil). The test item solutions were prepared as follows:
<table>
<tr><th>Solutions</th><th>Final volume 250 ml (filled up with deionised water)</th><th>Corresponding nominal test item concentration mg a.s./kg soil (dw)</th></tr>
<tr><td>1</td><td>152.7 mg Deltamethrin EC 25</td><td>1.78</td></tr>
<tr><td>2</td><td>140 ml of solution 1</td><td>1.00</td></tr>
<tr><td>3</td><td>140 ml of solution 2</td><td>0.56</td></tr>
<tr><td>4</td><td>143 ml of solution 3</td><td>0.32</td></tr>
<tr><td>5</td><td>141 ml of solution 4</td><td>0.18</td></tr>
</table></td></tr>
<tr><td>Size, volume and material of test container</td><td>Reusable glass vessels (volume 140 ml; diameter 5 cm at the bottom, height 7 cm) covered with glass lids</td></tr>
<tr><td>Amount of artificial soil (kg)/container</td><td>20 g (dry weight) - height soil layer approximately 1.5 cm</td></tr>
<tr><td>Nominal levels of test concentrations</td><td>0.18, 0.32, 0.56, 1.00, 1.78 mg deltamethrin/kg soil (dw)</td></tr>
<tr><td>Number of replicates/concentration</td><td>5 (+1 without Hypoaspis for measurement of pH and soil moisture at the end of the test)</td></tr>
<tr><td>Number of Hypoaspis/container</td><td>10</td></tr>
<tr><td>Light source</td><td>Artificial light</td></tr>
<tr><td>Test performed in closed vessels due to significant volatility of test substrate</td><td>No</td></tr>
</table>

Table A7.5.2.1/04-3 Test Conditions

Criteria	Details
Test temperature	20 +/- 2 °C
Water content	Start: 20.1 - 20.7% (48.8 - 50.7% of WHCmax) End: 19.6 – 20.5% (47.3 - 50.1% of WHCmax)
pH	Start: pH 5.86 - 5.96 End: pH 5.70 - 5.75
Adjustment of pH	No
Light intensity / photoperiod	Light intensity: between 560 and 630 lux. Light regime: 16 h light : 8 h dark
Relevant degradation products	Not measured

Table A7.5.2.1/04-4 Effects on Mortality and Reproduction of *Hypoaspis aculeifer*

Test item Test object Exposure	**Deltamethrin EC25 G** *Hypoaspis aculeifer* Artificial Soil			
mg deltamethrin/kg dry weight soil	% mortality (Adults)	% corr. mortality (Abbott)	Mean number of juveniles per test vessel ± standard dev.	Reproduction (% of control)
Control	4	0	290.2 ± 23.5	100
0.18	2	-2.08	279.8 ± 40.6	96.42
0.32	6	2.08	268.2 ± 55.0	92.42
0.56	8	4.17	250.8 ± 52.4	86.42
1.00	2	-2.08	294.0 ± 33.7	101.31
1.78	14	10.42	260.2 ± 28.9	89.66
10 mg dimethoate/kg	100	100	0.4 ± 0.9	0.14
		Adult mortality		Reproduction
NOEC (mg a. s./kg soil (dw))		≥ 1.78		≥ 1.78
LOEC (mg a. s./kg soil (dw))		> 1.78		> 1.78

* Statistically significant (Dunnett's Test two-sided, $\alpha = 0.05$)

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	**3.3.9:** To not monitor the test substance concentration during and by the end of the test is considered to be a limitation, but RMS recognises that this is difficult. For this reason it is also not required in the referred test guidelines, or in the more recently adopted OECD TG 226 (2008).
Results	**4.1:** It is correct that there were no significant differences between the control and the treatment groups. Even so, the mortality in the group with test substance concentration 1.78 mg/kg was 14%, but the standard deviation was large. The Coefficience of Variance (CoV), however, was calculated to 24% which is below the validity criteria of max 30% in OECD 226, and the test is therefore considered acceptable.
Conclusion	**5.3**: The RMS agrees that the NOEC was 1.78 mg/kg soil (dw) and that the LOEC was >1.78 mg/kg soil (dw).
Reliability	1
Acceptability	The study is considered to be acceptable. The test seems to have been well performed according to available test guideline.
Remarks	

7.5.2.2 Long-term test with terrestrial plants

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Deltamethrin is an insecticide used/registered for years for crop protection and is not phytotoxic. Further data should not be necessary.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.5.3 Effects on birds

7.5.3.1.1 Acute oral toxicity

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1986) Deltamethrin – An Acute Oral Toxicity Study with the Bobwhite – Final Report [redacted] Document A41913 **7.5.3.1.1/01** 17 February 1986 Unpublished See Monograph 91/414 from 1998 – Point B.8.1.1	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	n.a.	
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; US EPA 71-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	5L0205	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	99.3%	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	Not analysed	
3.2	**Administration of the test substance**	See Table A7.5.3.1.1-1.	
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Test organisms	See Table A7.5.3.1.1-2.	

3.4.2	Test system	See Table A7.5.3.1.1-3.	
3.4.3	Diet	See Table A7.5.3.1.1-3, (under Point 3.4.2).	
3.4.4	Test conditions	See Table A7.5.3.1.1-4.	
3.4.5	Duration of the test	14 days	
3.4.6	Test parameter	Mortality, toxic effects and symptoms, body weights, feed consumption.	
3.4.7	Examination / Observation	Daily for toxic symptoms; bodyweights measured on Days 0, 3, 7 and 14. Average feed consumption determined on Days 0 – 3, 4 – 7 and 8 – 14.	
3.4.8	Statistics	The mortality pattern in this study was not conducive to calculating the LD_{50} value. Therefore, an estimation of the LD_{50} value was made by a visual inspection of the mortality data.	
		4. RESULTS	
4.1	**Limit test / Range finding test**	None	
4.1.1	Concentration	Not applicable	
4.1.2	Number / percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Applied concentrations	292, 486, 810, 1350 and 2250 mg/kg bw	
4.2.2	Effect data (mortality)	There were no deaths in animals administered either the test material or in the controls.	
4.2.3	Body weight	There were no effects on bodyweight.	
4.2.4	Feed consumption	There were no effects on feed consumption.	
4.2.5	Concentration / response curve	Not applicable as there was no mortality.	
4.2.6	Other effects	No other treatment-related effects were noted.	
4.3	**Results of controls**		
4.3.1	Number / percentage of animals showing adverse effects	There were no deaths or effects noted.	
4.3.2	Nature of adverse effects	There were no adverse effects noted.	
4.4	**Test with reference substance**		

4.4.1	Concentrations	None	
4.4.2	Results	Not applicable	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In an acute oral LD_{50} study bobwhite quails (*Colinus virginianus*), in groups of ten birds, were given a single dose of 0, 292, 486, 810, 1350 and 2250 mg deltamethrin/kg body weight. The purity of the test substance was 99.3%. The test substance in corn oil was administered by oral intubation and a 14-day post-dosing observation period followed. The birds were 22 weeks old.	
5.2	**Results and discussion**	No mortalities or overt signs of toxicity were noted and there was no apparent effect on body weight or feed consumption at any dose level. The acute oral LD_{50} was determined to be > 2250 mg as/kg bw and the NOEC 2250 mg as/kg bw.	
5.2.1	LD_{50}	> 2250 mg/kg bw	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.3.1.1-1 Method of Administration of the Test Substance

Criteria	Details
Water	No
Organic carrier	Corn oil
Concentration of the carrier [% v/v]	Not reported
Other vehicle	No
Function of the carrier / vehicle	Gavage of a dry powder

Table A7.5.3.1.1-2 Test Animals

Criteria	Details
Species/strain	*Colinus virginianus*
Source	Fritts Quail Farm, USA
Age (in weeks), sex and initial body weight (bw)	22 weeks, weights 166 – 204 g
Breeding population	Pen reared
Amount of food	Not reported
Age at time of first dosing	22 weeks
Health condition / medication	Healthy, no medication reported.

Table A7.5.3.1.1-3 Test System

Criteria	Details
Test location	Indoor holding pens of galvanised wire and steel.
Holding pens	Floor space of 78 x 51 cm. Height of 20 – 25 cm.
Number of animals	60
Number of animals per pen [cm^2/bird]	5 with sexes housed separately.
Number of animals per dose	5 males/5 females.
Pre-treatment / acclimation	25 day acclimation
Diet during test	Game bird ration (fasted 15 h prior to dosing)
Dosage levels (of test substance)	292, 486, 810, 1350 and 2250 mg/kg bw
Replicate / dosage level	No
Feed dosing method	Gavage
Dosing volume per application	Not reported
Frequency, duration and method of animal monitoring after dosing	Daily for toxic symptoms; bodyweights measured on Days 0, 3, 7 and 14. Average food consumption determined on Days 0 – 3, 4 – 7 and 8 – 14.
Time and intervals of body weight determination	Days 0, 3, 7 and 14.

Table A7.5.3.1.1-4 Test Conditions (housing)

Criteria	Details
Test temperature	67 ± 3°F
Shielding of the animals	Not reported
Ventilation	Not reported
Relative humidity	66%
Photoperiod and lighting	8 h light, 12 footcandles of illumination

Table A7.5.3.1.1-5 Validity Criteria for Avian Acute Oral Toxicity According to EPA OPPTS 850.2100

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted
Results	Applicant's version is adopted
Conclusion	Applicant's version is adopted
Reliability	1
Acceptability	The study is acceptable. The acute oral LD_{50} of deltamethrin to bobwhite quails was >2250 mg/kg body weight.
Remarks	No further remarks

A7.5.3.1.1/02

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1977) Acute Oral LD_{50} – Mallard Duck: Technical DECIS Final Report [redacted] Document A20231 **7.5.3.1.1/02** 6 June 1977 Unpublished See Monograph 91/414 from 1998 – Point B.8.1.1	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	n.a.	
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**	Conducted before an appropriate guideline.	
2.2	**GLP**	No, the study was conducted prior to the introduction of GLP as a standard requirement. However, the study was conducted in line with good scientific practice.	
2.3	**Deviations**	No	X
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	6E0861	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	98%	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	Not analysed	
3.2	**Administration of the test substance**	See Table A7.5.3.1.1-6.	
3.3	**Reference substance**	Dieldrin	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Test organisms	See Table A7.5.3.1.1-7.	
3.4.2	Test system	See Table A7.5.3.1.1-8.	

3.4.3	Diet	See Table A7.5.3.1.1-8 (under Point 3.4.2).	
3.4.4	Test conditions	See Table A7.5.3.1.1-9.	
3.4.5	Duration of the test	8 days	
3.4.6	Test parameter	Mortality, toxic effects and symptoms, body weights, food consumption.	
3.4.7	Examination / Observation	Daily for toxic symptoms and lethality, body weights at initiation and termination, food consumption daily.	
3.4.8	Statistics	Litchfield and Wilcoxon.	
		4. RESULTS	
4.1	**Limit test / Range finding test**	None	
4.1.1	Concentration	Not applicable	
4.1.2	Number / percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Applied concentrations	215, 464, 1000, 2150 and 4640 mg/kg bw	
4.2.2	Effect data (mortality)	There were no deaths in animals administered either the test material or in the controls.	
4.2.3	Body weight	There were no effects on bodyweight.	
4.2.4	Feed consumption	There were no effects on food consumption.	
4.2.5	Concentration / response curve	Not applicable as there was no mortality.	
4.2.6	Other effects	There were no deaths at any dose level. Immediately after dosing, birds at the 4640 mg/kg dose level exhibited signs of depression and reduced reaction to external stimuli (sound and movement), followed by hyper excitability, with constant circling and preening activity. There was a loss of coordination and equilibrium, with the birds assuming an upright grebe-like posture, having deeply flexed necks and upturned tails. Lower limb weakness was also evident. Though the severity decreased, the grebe-like posture and loss of coordination were evident at this dose level through Day 6 of the test. While intensity and duration of effect decreased, the grebe-like posture and loss of coordination were noticeable at all levels, persisting through Day 4 at the 215 mg/kg dose level.	
4.3	**Results of controls**		
4.3.1	Number / percentage of animals showing adverse effects	There were no deaths or effects noted.	

4.3.2	Nature of adverse effects	There were no adverse effects noted.	
4.4	**Test with reference substance**		
4.4.1	Concentrations	14.7, 21.5, 31.6, 46.6 and 68.2 mg/kg bw	
4.4.2	Results	Deaths occurred at the four highest levels tested. The LD_{50} was 35.8 mg/kg bw.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In an acute oral LD_{50} study mallard ducks *(Anas platyrhynchos),* in groups of 10 birds, were dosed with 0, 215, 464, 1000, 2150 and 4640 mg deltamethrin/kg body weight. The purity of the test substance was 98%. Corn oil was used as a vehicle. The birds were 14 days old at the beginning of the study. The observation period was 8 days. The test material was administered once by oral intubation.	
5.2	**Results and discussion**	No mortalities were noted at any dose level. The acute oral LD_{50} was > 4640 mg/kg bw. Birds at 4640 mg/kg dose level exhibited signs of depression and reduced reaction to external stimuli (sound and movement). At all dose levels a loss of coordination was noticed. The birds were younger (14 days instead of 16 weeks) and the observation period was shorter (8 days instead of 14 days) compared to EPA guideline 71.1. This had no influence on the test results because the birds were free of symptoms by day 4.	
5.2.1	LD_{50}	> 4640 mg/kg, the highest dose tested.	
5.3	**Conclusion**		
5.3.1	Reliability	2	
5.3.2	Deficiencies	No	

Table A7.5.3.1.1-6 Method of Administration of the Test Substance

Criteria	Details
Water	No
Organic carrier	Corn oil
Concentration of the carrier [% v/v]	Not reported
Other vehicle	No
Function of the carrier / vehicle	Gavage of a dry powder

Table A7.5.3.1.1-7 Test Animals

Criteria	Details
Species/strain	*Anas platyrhynchos*
Source	Laboratory production flock
Age (in weeks), sex and initial body weight (bw)	14 days
Breeding population	Production flock
Amount of food	*Ad libitum*
Age at time of first dosing	2 weeks
Health condition / medication	Healthy, no medication reported.

Table A7.5.3.1.1-8 Test System

Criteria	Details
Test location	Not reported
Holding pens	Not reported
Number of animals	70
Number of animals per pen [cm^2/bird]	Not reported
Number of animals per dose	10
Pre-treatment / acclimation	Raised from chicks until 14 days old in battery brooders.
Diet during test	Commercial game bird starter ration.
Dosage levels (of test substance)	215, 464, 1000, 215 and 4640 mg/kg bw
Replicate / dosage level	None
Feed dosing method	Gavage
Dosing volume per application	Not reported
Frequency, duration and method of animal monitoring after dosing	Daily for toxic symptoms and lethality, body weights at initiation and termination, food consumption daily.
Time and intervals of body weight determination	At initiation and termination.

Table A7.5.3.1.1-9 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 A7.5.3.1.1-10 Validity Criteria for Avian Acute Oral Toxicity According to EPA OPPTS 850.2100

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comment: **2.3** It is correctly stated that the study did not follow any guideline. However, when comparing to EPA guideline 71-1, there were some deviations, which are mentioned under Applicant's summary and conclusion, 5.2.
Conclusion	Applicant's version is adopted.
Reliability	2
Acceptability	The study is considered acceptable. The acute oral LD_{50} of deltamethrin to mallard duck was >4640 mg/kg body weight.
Remarks	No further remarks

7.5.3.1.2 Short-term toxicity

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1986a) Deltamethrin: A Dietary LC_{50} Study with Bobwhite. Final report [redacted] Document A41915 **7.5.3.1.2/01** 2 May 1986 Unpublished See Monograph 91/414 from 1998 – Point B.8.1.1	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	n.a.	
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; US EPA 71-2 – OECD 205	
2.2	**GLP**	Yes	
2.3	**Deviations**	No testing of the maintenance of the test concentration in the diet during the study exposure period	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	Not reported	
3.1.2	Specification	As given in Section 2	
3.1.3	Purity	99.3%	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	Not analysed	
3.2	**Administration of the test substance**	Dietary	X
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
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	See Table A7.5.3.1.2-3.	
3.4.4	Test conditions	See Table A7.5.3.1.2-4.	
3.4.5	Duration of the test	8 days (5 Days administration, 3 days observation.)	
3.4.6	Test parameter	Mortality, signs of toxicity, abnormal behaviour, body weight, feed consumption,	
3.4.7	Examination / Observation	Twice daily for mortality; body weights on Days 0, 5 and 8; average estimated feed consumption on Days 0 – 5 and 6 – 8.	
3.4.8	Statistics	Probit, moving average angle or binomial probability.	
		4. RESULTS	
4.1	**Limit test / Range finding test**		
4.1.1	Concentration	Not applicable	
4.1.2	Number / percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Applied concentrations	562, 1000, 1780, 3160 and 5620 ppm.	X
4.2.2	Effect data (mortality)	No mortality or signs of toxicity	
4.2.3	Body weight	No effects on bodyweight	
4.2.4	Feed consumption	When compared with the controls, there was no effect on feed consumption at the 562, 1000 and 1780 ppm concentrations. A possible dose-responsive reduction in feed consumption was noted at the 3160 and 5620 ppm concentrations during the exposure period.	
4.2.5	Concentration / response curve	Not applicable	
4.2.6	Other effects	None	
4.3	**Results of controls**		
4.3.1	Number / percentage of animals showing adverse effects	One control animal died on Day 5 without demonstrating any overt symptoms.	
4.3.2	Nature of adverse effects	Not applicable	
4.4	**Test with reference substance**		
4.4.1	Concentrations	None	

4.4.2	Results	Not applicable	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In a 5-day dietary toxicity test, bobwhite quails *(Colinus virginianus)* were exposed to concentrations of 0, 562, 1000, 1780, 3160 and 5620 mg deltamethrin/kg diet (ppm). The purity was 99.3%. The birds were 11 days of age at the initiation of the study. There were ten birds per test concentration and five control groups of ten birds each. Corn oil was used as a carrier. The post-exposure observation was three days.	
5.2	**Results and discussion**	No mortalities or overt signs of toxicity were observed at any test concentration throughout the test period. There was no apparent effect on body weight gain but there was a possible dose-responsive reduction in feed consumption at the 3160 and 5620 ppm concentrations during the exposure period. The LC_{50} was determined to be > 5620 ppm and the NOEC 5620 ppm.	
5.2.1	NOEC	5620 ppm	
5.2.2	LC_{50}	> 5620 ppm	X
5.2.3	LC_{100}	> 5620 ppm	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.3.1.2-1 Method of Administration of the Test Substance

Criteria	Details
Water	No
Organic carrier	Corn oil
Concentration of the carrier [% v/v]	2%
Other vehicle	No
Function of the carrier / vehicle	Dietary admixture

Table A7.5.3.1.2-2 Test Animals

Criteria	Details
Species/strain	*Colinus virginianus*
Source	Fritts Quail Farm, USA
Age (in weeks), sex and initial body weight (bw)	11 days
Age range within the test	11 – 16 days
Breeding population	Not reported
Age at time of first dosing	11 days
Health condition / medication	Healthy; vitamin supplement only was administered before study initiation.

Table A7.5.3.1.2-3 Test System

Criteria	Details
Test location	Indoor in galvanised wire and steel holding pens.
Holding pens	Floor space 72 x 90 cm; height ~ 23 cm
Number of animals	60
Number of animals per pen [cm^2/bird]	10
Number of animals per dose	10
Pre-treatment / acclimation	4 Days acclimation
Diet during test	Game bird ration
Dosage levels (of test substance)	562, 1000, 1780, 3160 and 5620 ppm
Replicate / dosage level	None
Dosing method	Dietary
Dosing volume per application	2% corn oil
Frequency, duration and method of animal monitoring after dosing	Twice daily for mortality; body weights on Days 0, 5 and 8; average estimated feed consumption on Days 0 – 5 and 6 – 8.
Time and intervals of body weight determination	Days 0, 5 and 8

Table A7.5.3.1.2-4 Test Conditions (housing)

Criteria	Details
Test temperature	~ 24°C
Shielding of the animals	Not reported
Ventilation	Not reported
Relative humidity	51%
Photoperiod and lighting	17 h light, 12 footcandles

Table A7.5.3.1.2-5 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	Not reported	
Lowest treatment level causing no compound-related mortality or other observable toxic effects	X	

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comment: **3.2** For more information about administration of the test substance, see Table A7.5.3.1.2-1.
Results	Applicant's version is adopted with the following comment: **4.2.1** The applied concentrations were in mg/kg diet (or ppm as given).
Conclusion	Applicant's version is adopted with the following comment: **5.2.2** The LC_{50} of >5620 ppm is equivalent to >5620 mg/kg food.
Reliability	1
Acceptability	The study is regarded as acceptable. The short-term oral LC_{50} of deltamethrin to bobwhite quails was >5620 mg/kg diet.
Remarks	No further remarks

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1986b) Deltamethrin: A Dietary LC_{50} Study with the Mallard. Final report [redacted] Document A41870 **7.5.3.1.2/02** 22 July 1986 Unpublished See Monograph 91/414 from 1998 – Point B.8.1.1	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	n.a.	
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; US EPA 71-2, OECD 205	
2.2	**GLP**	Yes	
2.3	**Deviations**	No testing of the maintenance of the test concentration in the diet during the 5-day exposure period	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	6B0221	
3.1.2	Specification	As given in Section 2	
3.1.3	Purity	99.3%	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	Not analysed	
3.2	**Administration of the test substance**	Dietary	X
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Test organisms	See Table A7.5.3.1.2-7.	
3.4.2	Test system	See Table A7.5.3.1.2-8.	
3.4.3	Diet	See Table A7.5.3.1.2-8.	

3.4.4	Test conditions	See Table A7.5.3.1.2-9.	
3.4.5	Duration of the test	8 days (5 days administration, 3 days observation).	
3.4.6	Test parameter	Mortality, signs of toxicity, abnormal behaviour, body weight, feed consumption,	
3.4.7	Examination / Observation	Twice daily for mortality; body weights on Days 0, 5 and 8; average estimated feed consumption on Days 0 – 5 and 6 – 8.	
3.4.8	Statistics	Probit, moving average angle or binomial probability.	
		4. RESULTS	
4.1	**Limit test / Range finding test**		
4.1.1	Concentration	None	
4.1.2	Number / percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Applied concentrations	562, 1000, 1780, 3160 and 5620 ppm.	X
4.2.2	Effect data (mortality)	There were no mortalities at the 562 ppm, 1000 ppm and 3160 ppm concentrations. There was 10% mortality at the 1780 ppm concentration and 40% mortality at the 5620 ppm concentration. See Table A7.5.3.1.2-10.	X
4.2.3	Body weight	Slight reduction at 562 and 1000 ppm. Reduction at 1780 ppm and higher.	
4.2.4	Feed consumption	There was a reduction in feed consumption at concentrations of 1780 ppm and higher during the exposure period when compared with the control group.	
4.2.5	Concentration / response curve	-	
4.2.6	Other effects	Overt signs of toxicity noted at 3160 and 5620 ppm.	
4.3	**Results of controls**		
4.3.1	Number / percentage of animals showing adverse effects	There was no mortality or adverse effects in the study.	
4.3.2	Nature of adverse effects	Not applicable	
4.4	**Test with reference substance**		
4.4.1	Concentrations	None	

4.4.2	Results	Not applicable	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In an 5-day dietary toxicity test, mallard ducks *(Anas platyrhynchos)* were exposed to concentrations of 0, 562, 1000, 1780, 3160 and 5620 mg deltamethrin/kg diet (ppm). The purity was 99.3%. The birds were 10 days of age at the initiation of the study. There were ten birds per test concentration and five control groups of ten birds each. Corn oil was used as a carrier. The post-exposure observation was three days.	
5.2	**Results and discussion**	One bird died at 1780 ppm and four birds died at 5620 ppm. The 5-day LC_{50} was calculated to be 8039 ppm (4759-3.3 x 10^7, 95% CL). The NOEC was 1000 ppm. Overt signs of toxicity were also noted at the 3160 ppm concentration. There was a reduction in body weight gain and feed consumption at concentrations ≥ 1780 ppm during the exposure period.	
5.2.1	NOEC	1000 ppm	
5.2.2	LC_{50}	8039 ppm	X
5.2.3	LC_{100}	> 8039 ppm	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.3.1.2-6 Method of Administration of the Test Substance

Criteria	Details
Water	No
Organic carrier	Corn oil
Concentration of the carrier [% v/v]	2%
Other vehicle	No
Function of the carrier / vehicle	Dietary admixture

Table A7.5.3.1.2-7 Test Animals

Criteria	Details
Species/strain	*Anas platyrhynchos*
Source	Whistling Wings, USA
Age (in weeks), sex and initial body weight (bw)	10 days
Age range within the test	10 – 15 days
Breeding population	Not reported
Age at time of first dosing	10 days
Health condition / medication	Healthy; no medication

Table A7.5.3.1.2-8 Test System

Criteria	Details
Test location	Indoor in galvanised wire and steel holding pens
Holding pens	Floor space 72 x 90 cm; height 24 cm.
Number of animals	60
Number of animals per pen [cm^2/bird]	10
Number of animals per dose	10
Pre-treatment / acclimation	8 days
Diet during test	Game bird ration
Dosage levels (of test substance)	562, 1000, 1780, 3160 and 5620 ppm
Replicate / dosage level	None
Dosing method	Dietary
Dosing volume per application	2% corn oil
Frequency, duration and method of animal monitoring after dosing	Twice daily for mortality; body weights on Days 0, 5 and 8; average estimated feed consumption on Days 0 – 5 and 6 – 8.
Time and intervals of body weight determination	Days 0, 5 and 8

Table A7.5.3.1.2-9 Test Conditions (housing)

Criteria	Details
Test temperature	~ 28°C
Shielding of the animals	Not reported
Ventilation	Not reported
Relative humidity	72%
Photoperiod and lighting	17 h light, 12 footcandles

Table A7.5.3.1.2-10 Mortality Data After Test Termination

Test-Substance dosage level [mg/kg bw]	Mortality after test termination (8 days: 5 days administration and 3 days observation)	
	Total number per dose level	Percentage per dose level
0	0/10	0
562	0/10	0
1000	0/10	0
1780	1/10	10
3160	0/10	0
5620	4/10	40
Temperature [°C]	~ 28	-
Relative humidity	72%	-

Table A7.5.3.1.2-11 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	Not measured	
Lowest treatment level causing no compound-related mortality or other observable toxic effects	X	

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comment: **3.2** For more information about administration of the test substance, see Table A7.5.3.1.2-6.
Results	Applicant's version is adopted with the following comments: **4.2.1** The applied concentrations were in mg/kg diet (or ppm as given). **4.2.2** In Table A7.5.3.1.2-10, the test substance dosage level should be in mg/kg diet, and not bw as is stated.
Conclusion	Applicant's version is adopted with the following comment: **5.2.2** The LC_{50} of >8039 ppm is equivalent to >8039 mg/kg diet. It appears a bit strange that the LC_{50} is this high when the LC_{40} was 5620 ppm, but RMS has not recalculated the LC_{50}.
Reliability	1
Acceptability	The study is regarded as acceptable. The short-term oral LC_{50} of deltamethrin to mallard ducks was >8039 mg/kg diet.
Remarks	No further remarks

7.5.3.1.3 Effects on reproduction

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1991a) Deltamethrin: A One-Generation Reproduction Study with the Northern Bobwhite (*Colinus virginianus*) [redacted] Document A97605 **7.5.3.1.3/01** 13 September 1991 Unpublished See Monograph 91/414 from 1998 – Point B.8.1.2	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	n.a.	
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; US EPA 71-4, OECD 206	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	8N0701B2	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	99.4%	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	Dietary samples were analysed from Day 0 and Weeks 2, 3, 4, 8, 12, 16, 20 and 22, and were found to be in line with nominal concentrations.	
3.2	**Administration of the test substance**		X
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	See Table A7.5.3.1.3-3.	
3.3.4	Test conditions	See Table A7.5.3.1.3-4.	
3.3.5	Duration of the test	22 weeks	

3.3.6	Test parameter	Reproductive performance, mortality, bodyweight, feed consumption, overt signs of toxicity.	
3.3.7	Examination / Observation	Daily for mortality, signs of toxicity; bodyweights taken at initiation, weeks 2, 4, 6 and 8 and at termination; feed consumption measured for a seven day period every week.	
3.3.8	Statistics	Dunnett's multiple comparison procedure.	
		4. RESULTS	
4.1	**Limit test / Range finding test**	A range-finding study was conducted but results were not reported.	
4.1.1	Concentration	-	
4.1.2	Number / percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Applied concentrations	50, 150 and 450 ppm.	X
4.2.2	Effect data (mortality and reproductivity)	There were no treatment-related effects (mortality or reproduction).	
4.2.3	Body weight	No treatment-related effects on bodyweight.	
4.2.4	Feed consumption	No treatment-related effects on feed consumption.	
4.2.5	Results of residue analysis	Results confirmed nominal dietary concentrations.	
4.2.6	Other effects	No treatment-related effects.	
4.3	**Results of controls**		
4.3.1	Number / percentage of animals showing adverse effects	No effects.	
4.3.2	Nature of adverse effects	Not applicable	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In a one-generation reproduction study northern bobwhites *(Colinus virginianus)* were exposed to deltamethrin at nominal concentrations of 0, 50, 150 and 450 mg/kg diet (ppm). The birds were 18 weeks old at the test initiation and they were exposed for 22 weeks. There were 16 pens per test concentration and control with one hen and one cock each. Corn oil and acetone was used as a vehicle. The following reproductive parameters were recorded; eggs laid, cracked and set; viable embryos, live three-week embryos; hatchlings, 14-day old survivors, body weight of 14-day old survivors and egg shell thickness. In addition, effects on the adult birds were recorded.	
5.2	**Results and discussion**	There were no apparent adverse effects on either the reproductive parameters or on the adult birds at any of the concentrations tested, but there was a significant increase in egg production at 50 and 150 ppm. The NOEC was > 450 ppm or approximately 55 mg/kg/day.	
5.2.1	NOEC	> 450 ppm (~ 55 mg/kg/day)	X
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.3.1.3-1 Method of Administration of the Test Substance

Criteria	Details
Water	No
Organic carrier	Corn oil
Concentration of the carrier [% v/v]	Not reported
Other vehicle	Acetone
Function of the carrier / vehicle	Acetone as solvent; corn oil for dietary admixture.

Table A7.5.3.1.3-2 Test Animals

Criteria	Details
Species/strain	*Colinus virginianus*
Source	Fritts Quail Farm, USA
Age (in weeks), sex and initial body weight (bw)	18 weeks; 64 male/64 female.
Age range within the test	All the same age
Breeding population	Not reported
Amount of food	Not reported
Age at time of first dosing	18 weeks
Health condition / medication	Healthy; no reported medication
Pre-treatment	4 weeks acclimation under test conditions

Table A7.5.3.1.3-3 Test System

Criteria	Details
Test location	Indoors in galvanised steel and wire holding pens.
Holding pens	Floor space: 30 x 51 cm; height: 21 – 26 cm
Number of animals (male/female)	64 / 64
Number of animals per pen [cm^2/bird]	2
Number of animals per dose	32
Pre-treatment / acclimation	4 week acclimation under test conditions
Diet during test	2.5% fat, 27% protein, 5% fibre, 5% limestone
Dosage levels (of test substance)	50, 150 and 450 ppm
Replicate / dosage level	16 pens of 1 male/1 female per dose
Dosing method	Dietary
Dosing volume per application	Not reported
Frequency, duration and method of animal monitoring after dosing	Daily for mortality, signs of toxicity; bodyweights taken at initiation, weeks 2, 4, 6 and 8 and at termination; feed consumption measured for a seven day period every week.
Time and intervals of body weight determination	Bodyweights taken at initiation, weeks 2, 4, 6 and 8 and at termination
Incubation, storing and hatching	Eggs were collected daily and stored in a cold room maintained at a mean temperature of 13.0°C ± 1.6°C (SD) with an average relative humidity of approximately 76%. 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 37.4 ± 0.1°C (SD) with an average wet bulb temperature of approximately 29.0 ± 1.0°C (SD) (an average relative humidity of approximately 54%). 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 of vertical in one direction to 50° off of vertical in the opposite direction (total arc of rotation is 100°) 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 33.0 ± 0.6°C (SD) (an average relative humidity of approximately 76%).

Criteria	Details
Test period after egg-laying	14 days after hatching
Turning of eggs	Automatic egg rotation device
Collection of period for eggs	Collected daily

Table A7.5.3.1.3-4 Test Conditions (housing)

Criteria	Details
Test temperature	20.2 ± 3.2°C
Shielding of the animals	Not reported
Ventilation	Vent up to 15 room air changes/h
Relative humidity	51 ± 21%
Photoperiod and lighting	8 h light for first 7 weeks; 17 h light thereafter. 130 lux.
Storing, incubation and hatching conditions for eggs	See table on test system.
Environmental conditions for young birds	Hatchlings maintained in batteries of 72 x 90 x 23 cm at 38°C with a 16 h light photoperiod.

Table A7.5.3.1.3-5 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, 21 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	

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comment: **3.2** The test substance was administered by mixing it into a premix of food, together with acetone and corn oil. The premix was then mixed with the entire diet. See also Table A7.5.3.1.3-1.
Results	Applicant's version is adopted with the following comment: **4.2.1** The applied concentrations are equivalent to mg deltamethrin/kg food.
Conclusion	Applicant's version is adopted with the following comment: **5.2.1** The NOEC was >450 ppm (mg/kg food) or 55 mg/kg bw/day.
Reliability	1
Acceptability	The study is acceptable. The NOEC of deltamethrin for northern bobwhites was >450 mg/kg food.
Remarks	No further remarks

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1991b) Deltamethrin: A One-Generation Reproduction Study with the Mallard (*Anas platyrhynchos*) [redacted] Document A97604 **7.5.3.1.3/02** 13 September 1991 Unpublished See Monograph 91/414 from 1998 – Point B.8.1.2	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	n.a.	
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; US EPA 71-4, OECD 206	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	8N0701B2	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	99.4%	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	Dietary samples were analysed from Day 0 and Weeks 2, 3, 4, 8, 12, 16, 20 and 22, and were found to be in line with nominal concentrations.	
3.2	**Administration of the test substance**		X
3.3	**Testing procedure**		
3.3.1	Test organisms	See Table A7.5.3.1.3-7.	
3.3.2	Test system	See Table A7.5.3.1.3-8.	
3.3.3	Diet	See Table A7.5.3.1.3-8.	
3.3.4	Test conditions	See Table A7.5.3.1.3-9.	
3.3.5	Duration of the test	21 weeks	

3.3.6	Test parameter	Reproductive performance, mortality, bodyweight, feed consumption, overt signs of toxicity.	
3.3.7	Examination / Observation	Daily for mortality, signs of toxicity; bodyweights taken at initiation, weeks 2, 4, 6 and 8 and at termination; feed consumption measured for a seven day period every week.	
3.3.8	Statistics	Dunnett's multiple comparison procedure.	
		4. RESULTS	
4.1	**Limit test / Range finding test**	A range-finding study was conducted but results were not reported.	
4.1.1	Concentration	-	
4.1.2	Number / percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Applied concentrations	50, 150 and 450 ppm.	X
4.2.2	Effect data (mortality and reproductivity)	There were no treatment-related effects (mortality or reproduction).	
4.2.3	Body weight	No treatment-related effects on bodyweight.	
4.2.4	Feed consumption	No treatment-related effects on feed consumption.	
4.2.5	Results of residue analysis	Results confirmed nominal dietary concentrations.	
4.2.6	Other effects	No treatment-related effects.	
4.3	**Results of controls**		
4.3.1	Number / percentage of animals showing adverse effects	No effects.	
4.3.2	Nature of adverse effects	Not applicable	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In a one-generation reproduction study, mallard ducks *(Anas platyrhynchos)* were exposed to deltamethrin at nominal concentrations of 0, 50, 150 and 450 mg/kg diet (ppm). The birds were 23 weeks old at the test initiation and they were exposed for 21 weeks. There were 16 pens per test concentration and control with one hen and one cock each. Corn oil and acetone was used as a vehicle. The following reproductive parameters were recorded; eggs laid, cracked and set, viable embryos, live three-week embryos, hatchlings, body weight of hatchlings, 14-day old survivors, body weight of 14-day old survivors and egg shell thickness. In addition, effects on the adult birds were recorded.	
5.2	**Results and discussion**	There were no apparent adverse effects on either the reproductive parameters or on the adult birds at any of the concentrations tested. The NOEC was > 450 ppm or approximately 70 mg/kg/day. The measured concentrations were > 88 % of nominals.	
5.2.1	NOEC	> 450 ppm (~ 70 mg/kg/day)	X
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.3.1.3-6 Method of Administration of the Test Substance

Criteria	Details
Water	No
Organic carrier	Corn oil
Concentration of the carrier [% v/v]	Not reported
Other vehicle	Acetone
Function of the carrier / vehicle	Acetone as solvent; corn oil for dietary admixture.

Table A7.5.3.1.3-7 Test Animals

Criteria	Details
Species/strain	*Anas platyrhynchos*
Source	Whistling Wings, USA
Age (in weeks), sex and initial body weight (bw)	23 weeks; 64 male/64 female.
Age range within the test	Animals were all the same age
Breeding population	Not reported
Amount of food	Not reported
Age at time of first dosing	23 weeks
Health condition / medication	Healthy; no reported medication
Pre-treatment	6 weeks acclimation under test conditions

Table A7.5.3.1.3-8 Test System

Criteria	Details
Test location	Indoor in a galvanized wire grid holding pens
Holding pens	Floor space 75 x 90 cm; height 45 cm.
Number of animals	16 males, 16 females
Number of animals per pen [cm^2/bird]	Two
Number of animals per dose	32
Pre-treatment / acclimation	6 week acclimation under test conditions
Diet during test	2.5% fat, 27% protein, 5% fibre, 5% limestone
Dosage levels (of test substance)	50, 150 and 450 ppm
Replicate / dosage level	-
Dosing method	Dietary
Dosing volume per application	Not reported
Frequency, duration and method of animal monitoring after dosing	Daily for mortality, signs of toxicity; bodyweights taken at initiation, weeks 2, 4, 6 and 8 and at termination; feed consumption measured for a seven day period every week.
Time and intervals of body weight determination	Bodyweights taken at initiation, weeks 2, 4, 6 and 8 and at termination
Incubation, storing and hatching	Eggs were collected daily and stored in a cold room maintained at a mean temperature of 12.8 ± 1.6°C (SD) with an average relative humidity of approximately 70%. All eggs to be incubated were washed to reduce the possibility of pathogen contamination before storing them in the cold room. Eggs were washed in a commercial egg washer with a chlorine based detergent. Water in the washer was warmed to approximately 46°C. The eggs were placed in the wash water and soaked for approximately 15 seconds. The washer's circulation motor was then turned on for approximately three minutes. The eggs were removed from the washer, allowed to cool to approximately room temperature and rinsed with fresh water. The eggs were then ready for storage in the cold room.
	Eggs were set for incubation on a weekly basis. The eggs were placed in the incubator where the temperature was maintained at an average 37.4 ± 0.1°C (SD) with an average wet bulb temperature of approximately 29.0 ± 1.0°C (SD) (relative humidity of approximately 54%). 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 of vertical in one direction to 50° off of vertical in the opposite direction (total arc of rotation is 100°) each hour through Day 24 of incubation. The eggs were transferred to the hatcher on Day 24. Eggs were not rotated in the hatcher. The average temperature in the hatcher was 37.1 ± 0.4°C (SD) and the average wet bulb temperature was raised to 32.2 ± 1.3°C (SD) (relative humidity of approximately 70%).

Criteria	Details
Test period after egg-laying	14 days after hatching
Turning of eggs	Automatic egg rotation device
Collection of period for eggs	Weekly

Table A7.5.3.1.3-9 Test Conditions (housing)

Criteria	Details
Test temperature	19.8 ± 2.7°C
Shielding of the animals	Not reported
Ventilation	Vent up to 15 room air changes/h
Relative humidity	51 ± 21%
Photoperiod and lighting	8 h light for 8 weeks; increased to 17 h light
Storing, incubation and hatching conditions for eggs	See Table A7.5.3.1.3.8.
Environmental conditions for young birds	Hatchlings were placed in batteries of brooding pens. Each pen measured approximately 72 x 90 x 24 cm high. The external walls and ceilings of each pen were constructed of galvanized wire mesh and galvanized sheeting. Floors were of galvanized wire mesh. Thermostats in the brooding compartment of each pen were set to maintain a temperature of approximately 38°C from the time of hatching until the birds were 5 to 7 days of age. At that time, thermostats were reset to maintain a temperature of approximately 26°C. Hatchlings were then maintained at an average ambient room temperature of 20.3 ± 2.1°C (SD) with an average relative humidity of 34 ± 12%. The photoperiod for the hatchlings was maintained by a time clock at 17 hours of light per day.

Table A7.5.3.1.3-10 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, 21 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	

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comment: **3.2** The test substance was administered by mixing it into a premix of food, together with acetone and corn oil. The premix was then mixed with the entire diet. See also Table A7.5.3.1.3-6.
Results	Applicant's version is adopted with the following comment: **4.2.1** The applied concentrations are equivalent to mg deltamethrin/kg food.
Conclusion	Applicant's version is adopted with the following comment: **5.2.1** The NOEC was >450 ppm (mg/kg food) or ~70 mg/kg bw/day.
Reliability	1
Acceptability	The study is acceptable. The NOEC of deltamethrin for mallard duck was >450 mg/kg food.
Remarks	No further remarks

7.5.4 Effects on honeybees

7.5.4.1 Acute toxicity to honeybees and other beneficial arthropods

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	Based on the use pattern of deltamethrin biocidal product used outdoor for ant control (DP 0.05), there will be no application to plants and flower beds. Furthermore, the treated areas (entrances of ant nests) are not visited by honey bees. Therefore, no exposure to honey bees is anticipated. Exposure (if any) to honey bees and other beneficial arthropods would in any case be extremely localised to the immediate vicinity of the treated areas. Consequently, on population level, no significant risk to honey bees and other beneficial arthropods is anticipated. Thus, studies on bees and other beneficial arthropods should not be required.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.5.5 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:	The use of K-Othrine DP 0.05 results in a spot-wise application of deltamethrin to soil within a limited timeframe. Although it is considered very unlikely that such a focused exposure would lead to bioconcentration in earthworms, and subsequently cause a risk to earthworm-eating birds and small mammals, the intrinsic bio-concentration potential of deltamethrin has been estimated below, based on its physical-chemical properties as indicated in the Technical Guidance Document on Data Requirements for Active Substances and Biocidal Products. 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 deltamethrin is 40200 (Yoder, 1991b – A47915), $BCF_{earthworm} = [(0.84 + 0.012 \times 40200)/1] = 483.24$. 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 deltamethrin in an entire worm is: $C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] / [1 + (F_{gut} \times CONV_{soil})] = PEC_{oral\ predator}$	

	with: - $C_{porewater} = [C_{soil} \times RHO_{soil}] / [K_{soil-water} \times 1000]$ - $C_{soil} = 4.24 \times 10^{-3}$ mg/kg wet weight soil (see Recalculation ERA for K-OTHRINE DP 0.05) - $F_{gut} = 0.1$ (TGD on Risk Assessment page 132) - $CONV_{soil} = RHO_{soil} / (F_{solid} \times RHO_{solid}) = 1700 / (0.6 / 2500) = 1.13$. - $K_{soil-water} = (0.2 \times K_{air-water}) + 0.2 + [0.6 \times (K_{psoil}/1000) \times 2500]$ where: - $K_{air-water} = 0.031 / (8.314 \times 285) = 1.31 \times 10^{-5}$ - $K_{psoil} = Koc \times Foc = 408250 \times 0.02 = 8165$ This gives: $K_{soil-water} = 12247.7$ $C_{porewater} = 5.9 \times 10^{-7}$ mg/L and $C_{earthworm} = 6.9 \times 10^{-4}$ mg/kg Considering the reproduction studies conducted in birds (bobwhite quail and mallard duck) with deltamethrin ([redacted] 1991a & b – A97605 & A97604), the lowest NOEC exceeds 450 ppm. Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a $PNEC_{bird}$ of 15 mg/kg food is obtained. Considering the reproduction study conducted in rats with deltamethrin (2 generation study; [redacted] 1992 – A70863), the NOAEL was set at 80 ppm for parents and pups. Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a $PNEC_{small\ mammal}$ of 2.67 mg/kg food is obtained. Therefore, by comparing the $PEC_{oral\ predator}$ with the respective PNEC, PEC/PNEC ratios of 4.6×10^{-5} and 2.6×10^{-4} are obtained for birds and small mammals respectively, indicating no unacceptable risk for earthworm-eating birds and small mammals.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.5.5.1 Bioconcentration, further studies

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	As demonstrated under Point 7.5.5 and explained in the Environmental Risk Assessment, deltamethrin does not present a risk of secondary poisoning in the environment. Therefore, further studies should not be required.	
Undertaking of intended data submission [ ]		

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.5.6 Effects on other terrestrial non-target organisms

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The risk assessment for the terrestrial compartment, based on the results from the acute toxicity test on earthworm and the realistic environmental exposure indicates no concern for the terrestrial compartment. Therefore, long-term and field studies should not be required.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS does not fully agree with the applicant's justification. RMS considers that earthworm is probably not the most sensitive organism to an insecticide like deltamethrin, and a test with for example springtails, would probably have resulted in a lower effect concentration. The fact that the calculated $PNEC_{soil}$ for the metabolite Br_2CA is lower than for deltamethrin, despite a much lower toxicity to other invertebrates, further supports this notion. A common approach among member states how to deal with effects on other terrestrial non-target organisms has to be agreed upon.
Conclusion	Applicant's justification is acceptable for now. Further studies may be requested.
Remarks	No further remarks

7.5.7 Effects on mammals

7.5.7.1 Direct and/or indirect exposure to mammals – further tests

7.5.7.1.1 Acute oral toxicity

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Given that there is a wide range of laboratory studies conducted on a number of different species no further information is required here.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.5.7.1.2 Short-term toxicity

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Given that there is a wide range of laboratory studies conducted on a number of different species no further information is required here.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.5.7.1.3 Effects on reproduction

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Given that there is a wide range of laboratory studies conducted on a number of different species no further information is required here.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Evaluation of applicant's justification	The RMS agrees with the applicant's justification.
Conclusion	Applicant's justification is acceptable.
Remarks	No further remarks

7.6 Summary of ecotoxicological effects and fate and behaviour in the environment

The applicant had submitted a summary for ecotoxicological effects and fate and behaviour in the environment, but since this has been updated after the evaluation and submission of further studies, this part has been deleted and RMS refers to Doc II-A for a summary.

A.8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

The applicant had submitted this information, but since it can be found in Doc IIC, section 15, it has been deleted from this document.

A.9 CLASSIFICATION AND LABELLING

The applicant had submitted this information, but since it can be found elsewhere in the CAR, it has been deleted from this document

A.10 SUMMARY AND EVALUATION OF SECTIONS 2 TO 9

The applicant had submitted a summary for these sections, but since these have been updated after the evaluation and submission of further studies, this part has been deleted and RMS refers to Doc II-A for a summary.

Reference List by Annex Point

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
A7.1.1.1.1/01	Smith A.M.	1990a	Determination of aqueous hydrolysis rate constant and half-life of deltamethrin Bionomics Laboratories Bayer CropScience AG Report No.: A45079 02 July 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.1.1.1/02	Maurer T.; Schaefer D.	2002	Additional information on hydrolysis of deltamethrin at pH8 and contribution of hydrolysis to the overall dissipation of deltamethrin from surface/natural water bodies Aventis CropScience GmbH, Germany Bayer CropScience AG Report No.: C018813 21 January 2002 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.1.1.2/01	Bowman B.; Carpenter M.	1987	Determination of photodegradation of 14C-Deltamethrin in aqueous solution Anal. Bio-Chem. Lab., USA Bayer CropScience AG Report No.: A41919 25 June 1987 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.1.1.2/02	Maurer T.	2000	Determination of the quantum yield of direct photolysis in aqueous solution - Deltamethrin Aventis CropScience GmbH, Germany Bayer CropScience AG Report No.: C008524 26 May 2000 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.1.1.2/03	Wang W.W.; Reynolds J.L.	1991a	Aqueous photolysis of 14C-deltamethrin Bayer CropScience AG Report No.: A47960 18 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.1.2.1/01	Wuethrich V.	1994	Ready biodegradability: "Manometric respirometry test" for deltamethrin Research & Consulting Company Ltd, Switzerland Bayer CropScience AG Report No.: A71006 01 July 1994 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
A7.1.2.2.2/01	Muttzall P.I.	1993	Water / sediment biodegradation of (benzyl-14C) Deltamethrin TNO, Netherlands Bayer CropScience AG Report No.: A50953 24 May 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.2.2.2/02	Schaefer D.; Schwedhelm S.	2005	First-tier predicted environmental concentrations of deltamethrin and its metabolite Br2CA in surface water and sediment Bayer CropScience AG Report No.: C048212 15 April 2005 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.1.2.2.2/03	Heimbach, F.; Arnold, M.; Brumhard, B.	2005	Biological effects and fate of Deltamethrin EW 015 in outdoor mesocosm ponds [redacted] Report No.: MO-05-004459 / M-246137-01-1 24 February 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.1/01	Kaufman D.D.; Kaiser A.J.; Barnett E.A.; Daniels P.W.; Russell B.A.	1978	Preliminary soil metabolism investigations with decamethrin United States Department of Agriculture Bayer CropScience AG Report No.: A12524 01 January 1978 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.1/02	Kaufman D.D.; Kayser A.J.; Barnett E.A.; Russell B.	1979a	Degradation of 14C-phenoxy- and 14C-cyano-decamethrin in soil United States Department of Agriculture Bayer CropScience AG Report No.: A71064 01 January 1979 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.1/03	Kaufman D.D.; Kayser A.J.; Russell B.; Barnett E.A.	1979b	The effect of soil temperature on the degradation of 14C-cyano-decamethrin in soil. United States Department of Agriculture Bayer CropScience AG Report No.: A71051 01 January 1979 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.1/04	Wang W.W.	1991a	Aerobic soil metabolism of 14C-deltamethrin. Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A47917 21 June 1991 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
A7.2.1/05	Feyerabend M.; John B.M.	1997	Deltamethrin ^{14}C-labelled Calculation of the half-life times of Deltamethrin and becisthemic acid in soil using TOPFIT 2.0 AgrEvo Report No.: A74227 October 1997 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.1/06	Schaefer D.; Mikolasch B.	2004	Kinetic evaluation of soil laboratory studies with deltamethrin and its metabolites D-COOH, Br2CA and mPBacid to determine input parameters for model calculations Bayer CropScience AG Report No.: C044585 08 October 2004 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.2.4 /01	Wang W.W.; Reynolds J.L.	1991b	Soil photolysis of 14C-deltamethrin. Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A47919 29 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.3.1/01	Smith A. M.	1990b	Determination of the adsorption and desorption coefficients of deltamethrin Bionomics Laboratories Bayer CropScience AG Report No.: A47159 29 June 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.3.1/02	Christensen, K.P.	1993	Deltamethrin - Determination of the Sorption and Desorption Properties Springborn Laboratories Inc, USA Report No: A73876 13 October 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.2.3.1/03	Wang W.W.	1991b	Adsorption and desorption of 14C-Br2CA in five soils Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A72145 16 December 1991 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
A7.2.3.1/03	Reynolds J.L.	1992	Adsorption and desorption of 14C-m-phenoxybenzoic acid in four soils Xenobiotics Laboratories Inc Bayer CropScience AG Report No.: A71037 18 November 1992 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.3.1/01	Meichsner C.	1999	Calculation of the indirect photolysis reaction using the incremental method of Atkinson and the Program AOPWIN, Version 1.80 - Deltamethrin Bayer CropScience AG Report No.: C002214 19 January 1999 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.3.2/01	Ruedel H.; Waymann B.	1993	Testing for volatility of 14C-deltamethrin (formulated as the product Decis fluessig EC): Volatilisation from plant surfaces volatilisation from soil Bayer CropScience AG Report No.: A53910 23 April 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.1/01	[redacted]	1986	Acute toxicity of deltamethrin to rainbow trout (*Salmo gairdneri*) [redacted] Report No.: A70935 06 January 1986 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.1/02	[redacted]	1990a	(IS-002A) - Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions [redacted] Report No.: A47096 21 June 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.1/03	Grau, R.; Maus, C.	2006	Aquatic toxicity of Br2CA, a metabolite of deltamethrin Bayer CropScience AG Report No.: M-264711-01-1 16 January 2006 Non GLP. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
A7.4.1.2/01	Putt A.E.	1999	Acute toxicity to Daphnids (*Daphnia magna*) under flow-through conditions - Deltamethrin (14C-labelled) [redacted] Report No.: C003959 13 May 1999 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.2/02	Putt A.E.	2000a	Acute toxicity to gammarids (*Gammarus fasciatus*) under flow-through conditions Decis EC 25 g/L [redacted] Report No.: C006608 07 January 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.2/03	Putt A.E.	2000b	Acute toxicity to gammarids (*Gammarus fasciatus*) in a sediment-water system Decis EC 25 g/L [redacted] Report No.: C009363 14 August 2000 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.2/04	Gries T.; van der Kolk J.	2001	Acute toxicity test with fresh water isopods (*Asellus aquaticus*) under semi-static conditions (14C)-Deltamethrin formulated as emusifiable concentrate (25 g/L deltamethrin) [redacted] Report No.: C015003 30 July 2001 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.2/05	Grau, R.; Maus, C.	2006	Aquatic toxicity of Br2CA, a metabolite of deltamethrin Bayer CropScience AG Report No.: M-264711-01-1 16 January 2006 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.3/01	Giddings Jeffrey M.; Bayne Mary C.R.; Mitchell Karen L.; Shepherd Susan P.	1990	LX165-08 (deltamethrin technical) - Toxicity to the freshwater green alga, *Selenastrum capricornutum* [redacted] Report No.: A47090 02 May 1990 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
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A7.4.1.3/03	Grau, R.; Maus, C.	2006	Aquatic toxicity of Br2CA, a metabolite of deltamethrin Bayer CropScience AG Report No.: M-264711-01-1 16 January 2006 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.4/01	Hertl J.	2001	Toxicity of AE F032640 deltamethrin, substance technical to activated sludge in a respiration test [redacted] Report No.: C012186 26 March 2001 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.1.4/02	Weyers A.	2007	Deltamethrin Techn. (AE F032640) – Toxicity to Bacteria [redacted] Document M-292974-01-1 25 September 2007 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.2/01	[redacted]	1990	(Deltamethrin) - Bioconcentration and elimination of 14C-residues by bluegill (*Lepomis macrochirus*) [redacted] Report No.: A47117 05 July 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.2/02	[redacted]	1992	Supplemental information to the study: (deltamethrin): Bioconcentration and elimination of 14C-residues by Bluegill (*Lepomis macrochirus*) [redacted] Report No.: A70929 03 September 1992 GLP. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
A7.4.3.1/01	[redacted]	1990b	(LX 165-08, deltamethrin technical) - Acute (28-Day) toxicity to rainbow trout (*Oncorhynchus mykiss*) under flow-through conditions [redacted] Report No.: A47111 11 April 1990 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.3.2/01	[redacted]	1991	Deltamethrin: Toxicity test with Fathead minnow (*Pimephales promelas*) embryos and larvae [redacted] Report No.: A70931 18 July 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.3.2/02	[redacted]	1993	Deltamethrin: The chronic toxicity to the fathead minnow (*Pimephales promelas*) during a full life-cycle exposure [redacted] Report No.: A70972 20 May 1993 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.3.4/01	McNamara Pauline C.	1991	(Deltamethrin) - The Chronic Toxicity To Daphnia magna Under Flow-Through Conditions [redacted] Report No.: A44479 22 May 1991 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.3.5.1/01	Heusel R.; Gildemeister H.; Gosch H.	1998	Chronic toxicity to the sediment dwelling chironomid larvae *Chironomus riparius* Deltamethrin 14C-labelled [redacted] Report No.: A74315 06 April 1998 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.3.5.1/02	Grau, R.	2006	Toxicity of deltamethrin to sediment dwelling organisms Bayer CropScience AG Report No.: M-264713-01-1 18 January 2006 GLP n/a. Unpublished	Y	Bayer Crop-Science AG

Section No. / Reference No.	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
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A7.4.3.5.3/02	Heimbach, F.; Arnold, M.	2005	Bioassay on the effects of Deltamethrin EW 015 on *Gammarus pulex* in mesocosm water [redacted] Report No.: MO-05-004496 / M-246173-01-1 24 February 2005 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.4.3.5.3/03	Verboom, J.; Baveco, J. M. H.; Brink, P. J.	2005	A simulation model for spatial population dynamics of *Asellus aquaticus* after a spray drift event of deltamethrin in aquatic ecosystems Alterra, Netherlands Bayer CropScience AG Report No.: MO-05-004734 24 February 2005 Non GLP. Unpublished	Y	Bayer Crop-Science AG
A7.5.1.1/01	Frings H.; Bock K.D.	1994a	Deltamethrin; technical substance (Hoe 032640 00 ZD99 0001): Investigating the effect on the microbial activity in soil (short-term effects on aerobic soil respiration in accordance with BBA, VI, 1-1, 2nd edition) [redacted] Report No.: A52240 18 February 1994 GLP. Unpublished	Y	Bayer Crop-Science AG
A7.5.1.1/02	Frings H.; Bock K.D.	1994b	Deltamethrin; technical substance (Hoe 032640 00 ZD99 0001) - Investigating the effect on the nitrogen cycle in soil (in accordance with BBA, VI, 1-1 2nd edition) [redacted] Report No.: A52241 21 February 1994 GLP. Unpublished	Y	Bayer Crop-Science AG
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