Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE (*)	
Date	March 2009
Materials and methods	The Applicant's version is considered to be acceptable with the following amendment: Section 3.4.6 Test parameter: Mortality, clinical signs, bodyweight, food consumption and *post mortem* examinations.
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
COMMENTS FROM ...	
Date	
Materials and methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.5.3.1.2- 1: Test organisms.

Criteria	Details
Species/strain	*Colinus virginianus* (Northern Bobwhite quail)
Source	Monkfield Nutrition, Church Farm Barn, Wendy, Royston, Herts., UK
Age	14 days at the onset of the study
Sex	Unknown Sex is indeterminable at this age
Group mean body weight (day 0)	16.6–17.9 g
Age range within the test	All individuals from the same hatch
Breeding population	Not reported
Amount of food	*Ad libitum*
Age at time of first dosing	10 days
Health condition/medication	Birds were not medicated; health condition were deemed appropriate for the test

Table A7.5.3.1.2- 2: Test system.

Criteria	Details
Test location	The Department of Large Animal and Avian Studies, Huntingdon Life Sciences, Huntingdon, England
Holding pens	Printboard boxes fitted with wire mesh lids, measuring 80 × 60 × 50 cm (l × w × h)
Number of animals	80
Number of animals per pen [cm²/bird]	10 individuals per pen, separated by treatment group; 480 cm^2/individual
Number of animals per dose	10
Pre-treatment/ acclimation	Acclimation period: 4 d Environmental conditions as in the test Feed: basal diet as in the test, without test substance (see below) Feed and water available *ad libitum*
Diet during test	Composition of the diet is given in Table A7.5.3.1.2- 3; the diet was known to contain no antibiotic or other non-nutritional feed additive; supplier is Parker Brothers Ltd, Lark Mills, Mildenhall, Suffolk, UK
Dosage levels of test substance	0, 156, 313, 625, 1250, 2500 or 5000 ppm Alphacypermethrin; test or control diets were offered *ad libitum* during the 5-day treatment period
Replicate/dosage level	Two negative controls
Dosing method	Dietary, for 5 days
Dosing volume per application	Not applicable
Frequency, duration and method of animal monitoring after dosing	Observation for mortality and clinical signs daily
Time and intervals of body weight determination	At days –4, 0, 5 and 8
Group mean food consumption	Over days –4 to 1, 1 to 5 and 6 to 8
Macroscopic examination at termination	All birds from the highest dose group and all birds from the control group (group 1); tissues examined included digestive tract, liver, kidneys, heart, spleen, muscle and subcutaneous fat

Table A7.5.3.1.2- 3: Composition of the commercial diet from source specified in Table A7.5.3.1.2- 2.

Ingredient	Fraction [% w/w]
Provimi 66	15.00
Soya 48%	13.75
Wheat	30.00
Barley	10.00
Maize	25.00
Wheatfeed	5.00
Limestone	0.50
Dicalcium phosphate	0.25
Vitamin/mineral supplement	0.50

Table A7.5.3.1.2- 4: Test conditions.

Criteria	Details
Test temperature	27–28 °C; an infra-red heat source was suspended over each pen
Shielding of the animals	Not stated
Ventilation	Ventilation fans were adjusted as required
Relative humidity	35%
Photoperiod and lighting	14:10 h (L:D) controlled artificial lighting

Table A7.5.3.1.2- 5: Treatment-related mortality data after test termination.

Group	Dietary test substance concentration [ppm]	Day of study							
		Treatment					Post-treatment		
		1	2	3	4	5	6	7	8
1	0								
2	0								
3	156								
4	313				1	2+			
5	625								
6	1250								
7	2500								
8	5000								

+) Birds sacrificed for reasons of humaneness

Table A7.5.3.1.2- 6: Group mean body weights and body weight increases (g)[+].

Group	Dietary test substance concentration [ppm]	Day of study						
		–4	0	5	8	–4 to 0	0 to 5	5 to 8
		Body weight				Body weight increase		
1	0	11.7	17.3	22.9	27.7	5.6	5.6	4.8
2	0	11.7	17.2	23.4	27.8	5.5	6.2	4.4
3	156	11.7	17.7	23.6	28.3	6.0	5.9	4.7
4	313	11.7	16.6	21.9[9]	29.1[7]	4.9	5.0	5.0
5	625	11.8	17.6	23.9	28.1	5.8	6.3	4.2
6	1250	11.7	17.9	23.7	29.4	6.2	5.8	5.7
7	2500	11.7	17.3	22.5	27.6	5.6	5.2	5.1
8	5000	11.7	17.5	21.9	26.6	5.8	4.4	4.7

+) Increases based on means of birds surviving between the two time-points

7, 9) Where less than ten birds weighed, number indicated by superscript

Table A7.5.3.1.2- 7: Group mean food consumption [g/bird/day].

Group	Dietary test substance concentration [ppm]	Day of study							
		–4 to –1	1	2	3	4	5	1 to 5	6 to 8
1	0	3.3	7.6	5.2	3.9	5.9	5.4	6.2	7.2
2	0	3.5	6.3	4.3	4.1	3.5	3.5	4.3	5.5
3	156	3.5	5.3	3.9	4.1	3.9	3.8	4.2	5.6
4	313	3.1	6.0	3.6	4.4	4.3	4.4	4.6	6.8
5	625	3.8	9.0	4.5	4.7	3.9	4.5	5.3	5.9
6	1250	3.5	8.2	4.3	4.4	3.7	4.3	5.0	5.4
7	2500	3.1	6.8	3.4	4.2	3.8	4.3	4.5	5.2
8	5000	3.7	5.7	3.5	3.8	3.9	3.8	4.1	5.4

Table A7.5.3.1.2- 8: 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 A7.5.3.1.3 Effects on reproduction of birds

Annex Point IIIA 13.1.3

Official use only

1 REFERENCE

1.1	**Reference**	**A7.5.3.1.3/01:** [redacted] (2001) Alphacypermethrin (BAS 310 I) assessment to determine the effects of reproduction in the Northern Bobwhite (*Colinus virginianus*). [redacted], Report no. ETX-00-183, September 19, 2001 (unpublished), BASF RDI No.: AL-534-002.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2	Companies with letter of access	No
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 OECD 206 (1984), US EPA OPPTS 850.2300
2.2	**GLP**	Yes (certified laboratory)
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	Alphacypermethrin, as given in Section A2.
3.1.1	Lot/Batch number	AC12395-18
3.1.2	Specification	As given in Section A2.
3.1.3	Purity	96.1% w/w
3.1.4	Further relevant properties	The physical-chemical properties of the test substance, as given in Section A3, are not considered to have affected the test performance.
3.1.5	Method of analysis	HPLC/UV (230 nm) A detailed analytical report including description of the method is appended to the original study report. The mean concentrations of Alphacypermethrin in test diet formulations prepared for feeding during the study were within ± 5% of nominal concentrations, confirming the accuracy of formulation. The homogeneity of Alphacypermethrin in avian diet formulations was confirmed at nominal concentrations of 14.4 ppm and 4997 ppm. The stability was confirmed during ambient temperature storage for 15 days.

Section A7.5.3.1.3 Effects on reproduction of birds

Annex Point IIIA 13.1.3

3.2	**Administration of the test substance**	Dietary administration No vehicle was necessary for incorporation of the test substance in the diet; a pre-mix of suitable strength was prepared by mixing Alphacypermethrin with untreated basal diet. The required concentration was prepared by dilution of the prepared pre-mix.	
3.3	**Testing procedure**		
3.3.1	Test organisms	Northern bobwhite (*Colinus virginianus*) as described in Table A7.5.3.1.3- 1.	
3.3.2	Test system	Refer to Table A7.5.3.1.3-2.	
3.3.3	Diet	The basal diet is specified in Table A7.5.3.1.3- 4.	
3.3.4	Test conditions	Refer to Table A7.5.3.1.3-3.	X
3.3.5	Duration of the test	22 weeks	
3.3.6	Test parameter	Mortality and reproductive success	
3.3.7	Examination/ observation	Observation of mortalities, behaviour and clinical signs was performed daily. Individual adult body weights were recorded on weeks –2, 0 (immediately prior to the introduction of test diets), 2, 4, 6, 8 and at termination (week 22). Individual chick weights were determined within 24 hours of hatching and at the end of the observation period. Food consumption was recorded weekly throughout the pre-treatment and treatment period of the adult phase. Reproductive success was assessed by examining number of eggs laid (daily from week 11 to 22), eggs damaged, egg shell thickness, embryonic viability and chick survival and growth. Gross pathological examinations were performed on all adult birds. For birds surviving until study termination additional tissue examination included gastrointestinal tract, liver, kidneys, heart, spleen and reproductive organs.	
3.3.8	Statistics	Bartlett's test, ANOVA, Dunnett's test	
		4 RESULTS	
4.1	**Limit Test/ Range finding test**	Performed	
4.1.1	Concentration / dose	0, 50, 500, 2500 ppm	
4.1.2	Number/ percentage of animals showing adverse effects	No mortality occurred and no clinical signs of toxicity were observed. No serious adverse treatment-related effects were observed during the four-week period.	

Section A7.5.3.1.3 Effects on reproduction of birds

Annex Point IIIA 13.1.3

4.1.3	Nature of adverse effects	At 2500 ppm, food consumption was reduced during week 1 and subsequently increased thereafter. Body weights remained slightly low in male birds. It is likely that these effects were caused by initially compromised palatability of the diet at 2500 ppm.
4.2	**Results test substance**	
4.2.1	Applied concentrations	0, 50, 150 and 450 ppm in the diet were equivalent to a test compound intake of 0, 5.0, 15.2 and 46.7 mg/kg bw/day in males, and 4.6, 14.7 and 41.6 mg/kg bw/day in females. (Calculated according to the following equation: Test item intake = dietary level * daily feed consumption / body weight)
4.2.2	Effect data (Mortality and reproductivity)	No adverse effects on survival and health of adults were observed during the study. The only treatment-related effect observed on reproductive parameters was significantly reduced chick survival on day 14 (see Table A7.5.3.1.3-5).
4.2.3	Body weight	At 450 ppm, significantly reduced body weights in comparison to the control were recorded for males upon study termination.

Mean bodyweight [g]

Week	Sex	Control	50 ppm	150 ppm	450 ppm
0	Male	190.2	188.6	195.0	196.7
22	Male	209.1	208.1	206.7	202.4*
0	Female	190.8	193.3	187.3	191.1
22	Female	225.3	230.6	214.0	227.4

* significantly lower than control ($p < 0.05$)

4.2.4	Feed consumption	Feed consumption was similar in all treated groups although statistical analysis indicated that at 150 and 450 ppm consumption was higher than control. This was considered to be of no adverse biological significance. Mean feed consumption amounted to 19 g/bird/day in the control group and 21 g/bird/day in all treated groups.		
4.2.5	Results of residue analysis			

Concentration [ppm]

Week	Nominal	Analysed, mean	Rel. mean error [%]
1	0	ND	–
	50	47.6	–4.8
	150	145	–3.3
	450	447	–0.7
12	0	ND	–
	50	47.8	–4.4
	150	148	–1.3
	450	448	–0.4
22	0	ND	–
	50	48.7	–2.6
	150	153	+2.0
	450	460	+2.2

4.2.6	Other effects	No treatment-related mortalities occurred during the study, and no treatment-related clinical signs of toxicity were observed. Upon necropsy, no treatment-related macroscopic abnormalities were noted.

Section A7.5.3.1.3 Effects on reproduction of birds

Annex Point IIIA 13.1.3

4.3	**Results of controls**	
4.3.1	Number/percentage of animals showing adverse effects	No control animals showed adverse effects.
4.3.2	Nature of adverse effects	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The reproductive toxicity of Alphacypermethrin to Northern bobwhite quail was determined according to the guidelines OECD 206 and US-EPA OPPTS 850.2300.
5.2	**Results and discussion**	Dietary administration of Alphacypermethrin to the Northern bobwhite quail at concentrations of up to 150 ppm had no adverse effect on health or reproductive performance of adult birds or on the health and growth of their chicks. At 450 ppm, group mean male adult bodyweights were significantly lower than the controls at study termination and chick survival was significantly reduced compared with the controls.
5.2.1	NOEC	150 ppm Corresponding to 15.2 and 14.7 mg/kg bw/day in males and females, respectively.
5.3	**Conclusion**	The validity criteria are considered to be fulfilled (Table A7.5.3.1.3-6). Other circumstances that may have negatively affected the integrity and quality of the results are not reported. Thus, the study is considered to be valid without restrictions.
5.3.1	Reliability	1
5.3.2	Deficiencies	Yes

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	March 2009
Materials and Methods	The Applicant's version is considered to be acceptable with the following amendment: Section 3.3.4 Table A7.5.3.1.3-3: ventilation fans were adjusted as required.
Results and discussion	The Applicant's version is acceptable
Conclusion	The Applicant's version is acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.5.3.1.3- 1: Test animals.

Criteria	Details
Species/strain	Northern bobwhite (*Colinus virginianus*)
Source	Monkfield Nutrition, Church Farm Barn, Wendy, Royston, Hertfordshire, UK
Age	Approximately 12 month old at the start of the pre-treatment period
Age range within the test	Not specified
Sex	Male and female
Group mean body weight (day 0)	188.6–196.7 g (males) 187.3–193.3 g (females)
Breeding population	Not reported
Amount of food	*Ad libitum*
Health condition / medication	Birds were not medicated; no health problems were reported
Pre-treatment	No abnormal observations during pre-treatment were reported

Table A7.5.3.1.3-2: Test system.

Criteria	Details
Test location	Indoor in holding pens
Holding pens	Each cage was constructed of polythene coated steel wire and measured approx. 0.31 x 0.39 x 0.29 m
Number of animals (male/female)	80 per sex
Number of animals per pen [cm^2/bird]	2 [605 cm^2/bird]
Number of animals per dose	40
Pre-treatment / acclimation	Acclimation period: 2 weeks Environmental conditions as in the test Feed: basal diet as in the test, without test substance (see below) Feed and water available *ad libitum*
Diet during test	Composition of the diet is given in Table A7.5.3.1.3- 4; the diet was known to contain no antibiotic or other non-nutritional feed additive; supplier is Special Diets Services, Witham, Essex, UK
Dosage levels (of test substance)	0, 50, 150, 450 ppm, daily, *ad libitum*
Replicate/dosage level	20 replicates/dosage level with one male and one female per replicate
Dosing method	Dietary, for 22 weeks (10 weeks prior to the start of egg production and 12 weeks during egg production)
Dosing volume per application	Not applicable
Frequency, duration and method of animal monitoring after dosing	Adult birds and chicks were observed daily for mortalities and clinical signs of toxicity
Time and intervals of body weight determination	Weeks -2, 0 , 2, 4, 6, 8 and 22 for adults; within 24 hours of hatching and at the end of the observation period for chicks
Incubation, storing and hatching	Eggs were stored on plastic egg trays in a refrigerator at 16 °C prior to incubation. After 21 days of incubation, eggs were transferred to wire mesh trays in a still air Bristol hatcher
Test period after egg-laying	12 weeks
Turning of eggs	Yes Once every hour through 90° throughout the incubation period
Collection period for eggs	Daily for 12 weeks

Table A7.5.3.1.3-3: Test conditions (housing).

Criteria	Details
Test temperature	Mean daily maximum / minimum: 22 °C / 20 °C
Shielding of the animals	No
Ventilation	Not stated
Relative humidity	Mean daily value: 44%
Photoperiod and lighting	7-hour light during acclimatisation and during the first five weeks of the treatment period; thereafter 16 hours light; light intensity ranged from 40–80 lux
Storing, incubation and hatching conditions for eggs	Eggs were stored at 16 °C for up to 7 days before incubation at 37.7 °C and 55% relative humidity for 21 days; thereafter the incubated eggs were transferred to a still air Bristol hatcher run at 37.5 °C
Environmental conditions for young birds	Chicks were housed in wooden box floor pens; bedding consisted of wood shavings; 14-hour photoperiod, mean relative humidity of 38–40%, room temperature 23–29 °C

Table A7.5.3.1.3- 4: Composition of the commercial diet from source specified in Table A7.5.3.1.3-2.

Ingredient	Fraction [%]
Barley, wheat, wheat feed	56.50
Extracted soya bean meal, poultry meat meal, fish meal, un-extracted dried yeast	33.0
Soya oil	4.50
Vitamin/mineral mix	6.00

Table A7.5.3.1.3-5: Values of reproduction ability in Northern bobwhite quail.

Parameter	Control	50 ppm	150 ppm	450 ppm
Egg production (number of eggs laid per hen)	53.4	55.2	51.3	60.5
Percentage of cracked eggs (of eggs laid)	5.5	3.3	4.1	3.0
Viability (per cent viable embryos of eggs set)	91	92	94	93
Hatchability (per cent hatching of eggs set)	94	85	90	94
Percentage of hatchings that survive to 14 days (of normal hatchlings)	98	97	98	89*
Number of 14-day old survivors per hen	39.5	37.3	38.1	41.7
Eggshell thickness (mm)	0.22	0.21	0.21	0.21

* significantly lower than control ($p < 0.05$)

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 ≥ 12	X	
Average eggshell thickness for the control group ≥ 0.19	X	
Concentration of the test substance in the diet ≥ 80 % of the nominal concentration throughout the test period	X	

Section A7.5.4.1 Acute toxicity to honeybees

Annex Point IIIA 13.3.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Based on the intended use as a domestic insecticide (indoor use only, with application technique excluding generation of aerosols), the concern for adverse effects to honeybees is considered to be minimal. Any relevant exposure of honeybees living outdoors is considered to be negligible in view of the intended use pattern. Thus, the submission of studies on the toxicity to honeybees is not considered to be required.	
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	March 2009
Evaluation of applicant's justification	BE CA accept the Applicant's justifications
Conclusion	Acceptable
Remarks	Possible risk if there is application of sewage sludge to soil as manure
COMMENTS FROM ...	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.5.5.1 **Bioconcentration in terrestrial organisms**
Annex Point IIA7.5

Official use only

1 REFERENCE

1.1	**Reference**	**A7.5.5.1/01:** Sendor T (2005) Estimation of the terrestrial bioconcentration factor (BCF) of Alphacypermethrin. EBRC Consulting GmbH, Hannover, Germany, Report no. BAS-20051214-01, December 14, 2005 (unpublished), BASF DocID: 2005/1034075.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF AG
1.2.2	Companies with letter of access	No
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**	Not applicable
2.2	**GLP**	Not applicable
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Test material**	As given in Section A2.
3.1.1	Lot/Batch number	Not applicable
3.1.2	Specification	Not applicable
3.1.3	Purity	Not applicable
3.1.4	Further relevant properties	Not applicable
3.1.5	Method of analysis	Not applicable
3.2	**Reference substance**	None
3.2.1	Method of analysis for reference substance	Not applicable
3.3	**Testing/estimation procedure**	
3.3.1	Test system/ performance	Not applicable

Section A7.5.5.1 Bioconcentration in terrestrial organisms

Annex Point IIA7.5

3.3.2	Estimation of bioconcentration	On the basis of log P_{ow}, as specified in the TGD on risk assessment. Experimentally determined log P_{ow} values are reported by reference A3.9/01. log P_{ow} = 5.5

4 RESULTS

4.1	**Experimental data**	
4.1.1	Mortality/ behaviour	Not applicable
4.1.2	Lipid content	Not applicable
4.1.3	Concentrations of test material during test	Not applicable
4.1.4	Bioconcentration factor (BCF	Not applicable
4.1.5	Uptake and depuration rate constants	Not applicable
4.1.6	Depuration time	Not applicable
4.1.7	Metabolites	Not applicable
4.1.8	Other Observations	Not applicable
4.2	**Estimation of bioconcentration**	BCF = 3796 Due to absence of dissociating groups in the molecule, the BCF is considered to be independent of pH.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Estimation of the terrestrial bioconcentration factor ($BCF_{earthworm}$) based on the partition coefficient P_{ow}, as specified by the TGD on risk assessment.

Section A7.5.5.1 Bioconcentration in terrestrial organisms

Annex Point IIA7.5

5.2	**Results and discussion**	Based on experimentally determined partition coefficients (log P_{ow} = 5.5), the bioconcentration factor was estimated at $BCF_{earthworm} = 3796$ There is a large discrepancy between the theoretical estimate for the BCF in fish (9440) and that determined in an experimental bioaccumulation study (910), see sections A7.4.2 and and A7.4.3.3.1 of this dossier. Since the model for estimating the terrestrial BCF from the physical-chemical properties assumes uptake from the water phase only (pore water), the underlying mechanism is comparable between aquatic and terrestrial bioconcentration. In view of this, it may be assumed that the terrestrial BCF for Alphacypermethrin is an overestimate by approximately an order of magnitude.
5.3	**Conclusion**	Since the estimation was performed using an officially recommended model, based on measured values determined under GLP by fully valid experimental procedures, this calculation is considered to be valid, apart from the restriction discussed under 5.2 above.
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	March 2009
Materials and Methods	The Applicant's version is acceptable
Results and discussion	The Applicant's version is acceptable
Conclusion	The Applicant's version is acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.5.6 Effects on other terrestrial non-target organisms

Annex Point IIIA 13.3

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Based on the intended use as a domestic insecticide, the concern for acute and long-term effects to the terrestrial compartment other than already addressed in the previous sections of the dossier is considered to be minimal. Any relevant exposure of terrestrial further organisms that may not be covered by the model species in standard tests is considered to be negligible. It is also noted that this study type is neither a common core data requirement, nor a product-type specific additional data requirement according to the TNsG. Thus, the conduct of further studies on terrestrial organisms is not considered to be required.	
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	March 2009	
Evaluation of applicant's justification	Applicant's justifications are acceptable	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.5.7.1.1 Acute oral toxicity to mammalian wildlife

Annex Point IIIA 13.3.4

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Based on the intended use as a domestic insecticide, the concern for acute and long-term effects to mammalian wildlife is considered to be minimal: Any relevant exposure of wild mammals is considered to be negligible in view of the intended use. Mammalian toxicology is covered in sufficient detail in Section A6. It is also noted that this study type is neither a common core data requirement, nor a product-type specific additional data requirement according to the TNsG. Thus, the conduct of further mammalian toxicity studies is not considered to be required.	
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	March 2009	
Evaluation of applicant's justification	Applicant's justifications are acceptable	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.5.7.1.2 Short term toxicity to mammalian wildlife

Annex Point IIIA 13.3.4

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Based on the intended use as a domestic insecticide, the concern for acute and long-term effects to mammalian wildlife is considered to be minimal: Any relevant exposure of wild mammals is considered to be negligible in view of the intended use. Mammalian toxicology is covered in sufficient detail in Section A6. It is also noted that this study type is neither a common core data requirement, nor a product-type specific additional data requirement according to the TNsG. Thus, the conduct of further mammalian toxicity studies is not considered to be required.	
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	March 2009	
Evaluation of applicant's justification	Applicant's justifications are acceptable	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.5.7.1.3 Effects on reproduction of mammalian wildlife

Annex Point IIIA 13.3.4

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Based on the intended use as a domestic insecticide, the concern for acute and long-term effects to mammalian wildlife is considered to be minimal: Any relevant exposure of wild mammals is considered to be negligible in view of the intended use. Mammalian toxicology is covered in sufficient detail in Section A6, with particular focus on reproductive toxicity in sections A6.8.1 and A6.8.2. It is also noted that this study type is neither a common core data requirement, nor a product-type specific additional data requirement according to the TNsG. Thus, the conduct of further mammalian toxicity studies is not considered to be required.	
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	March 2009	
Evaluation of applicant's justification	Applicant's justifications are acceptable	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A8 (Annex Point)

Measures to be adopted to protect man, animals and the environment

Official use only

8.1	**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA, 8.8.1)**	**Reference:** **A8.1/01:** Anonymous (2006): Safety data sheet according to 91/155/EEC – Alphacypermethrin technical, BASF AG, April 19, 2006, BASF Doc-ID: 2006/1010032.
8.1.1	Handling	Avoid the formation and deposition of dust. Dust deposits that cannot be avoided must be taken up regularly. Ensure thorough ventilation of stores and work areas. Protection against fire and explosion: Avoid dust formation. Dust can form an explosive mixture with air. Prevent electrostatic charge – sources of ignition should be kept well clear – fire extinguishers should be kept handy. Personal protective equipment: *Respiratory protection:* Breathing protection if dusts are formed. Breathing protection if breathable aerosols/dusts are formed. Wear respiratory protection if ventilation is inadequate. Particle filter Type P2 or FFP2, (medium efficiency for solid and liquid particles e.g. EN143,149). *Hand protection:* Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), polyvinylchloride (0.7 mm) and other. *Eye protection:* Safety glasses with side-shields (frame goggles) (EN 166) *Body protection:* Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to DIN-EN 465). *General safety and hygiene measures:* Handle in accordance with good industrial hygiene and safety practice. Avoid contact with the skin, eyes and clothing. Wearing of closed work clothing is recommended. Remove contaminated clothing immediately and dispose of safely. Store work clothing separately. Keep away from food, drink and animal feeding stuffs. No eating, drinking, smoking or tobacco use at the place of work. Hands and/or face should be washed before breaks and at the end of the shift.

Section A8 (Annex Point)

Measures to be adopted to protect man, animals and the environment

Official use only

8.1.2 Storage

Segregate from foods and animal feeds. Segregate from strong bases.

Further information on storage conditions: Keep away from heat. Protect from direct sunlight. Protect against moisture.

Storage stability: Storage duration 48 months

Protect from temperatures above 40 °C

Changes in the properties of the product may occur if substance/product is stored above indicated temperature for extended periods of time.

8.1.3 Transport

<u>Land transport</u>

ADR:	Class	6.1
	Packaging group	III
	UN-number	3349
	Designation of goods	PYRETHROID PESTICIDE, SOLID, TOXIC (Contains: ALPHA-CYPERMETHRIN 93%)
RID:	Class	6.1
	Packaging group	III
	UN-number	3349
	Designation of goods	PYRETHROID PESTICIDE, SOLID, TOXIC (Contains: ALPHA-CYPERMETHRIN 93%)

<u>Inland waterway transport</u>

ADNR:	Class	6.1
	Packaging group	III
	UN-number	3349
	Designation of goods	PYRETHROID PESTICIDE, SOLID, TOXIC (Contains: ALPHA-CYPERMETHRIN 93%)

<u>Sea transport</u>

IMDG/GGVSee:	Class	6.1
	Packaging group	III
	UN-number	3349
	Marine pollutant	YES
	Exact technical name	PYRETHROID PESTICIDE, SOLID, TOXIC (Contains: ALPHA-CYPERMETHRIN 93%)

<u>Air transport</u>

ICAO/IATA:	Class	6.1
	Packaging group	III
	UN-number	3349
	Exact technical name	PYRETHROID PESTICIDE, SOLID, TOXIC (Contains: ALPHA-CYPERMETHRIN 93%)

Section A8 (Annex Point) — Measures to be adopted to protect man, animals and the environment

Official use only

8.1.4	Fire	Extinguishing media:	Water spray, water fog, dry extinguishing media, carbon dioxide or foam.
		Protective clothing:	Wear self-contained breathing apparatus and chemical-protective clothing.
		Further information:	Keep containers cool by spraying with water if exposed to fire. In case of fire and/or explosion do not breathe fumes. Collect contaminated extinguishing water separately, do not allow reaching sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.
8.2	**In case of fire, nature of reaction products, combustion gases, etc. (IIA, 8.8.2)**	Specific hazards: Hydrogen chloride, carbon monoxide, nitrogen oxides, organochloric compounds (see MSDS).	
8.3	**Emergency measures in case of an accident (IIA, 8.8.3)**		
8.3.1	Protection of emergency workers and bystanders	Keep unnecessary people away. Emergency workers should wear self-contained, positive pressure breathing apparatus and full fire protective clothing, if a fire. Otherwise, protective eyewear is required if respiratory protection does not provide eye protection. Protective clothing: Wear apron, protecting boots, chemical-protection suit (according to DIN-EN 465), as appropriate.	
8.3.2	Accidental release measures	<u>Personal precautions:</u> Use personal protective clothing. Avoid contact with the skin, eyes and clothing. Leave the danger area immediately. Avoid dust formation. <u>Environmental precautions:</u> Do not discharge into the subsoil/soil. Do not discharge into drains/surface waters/groundwater. <u>Methods for cleaning up or taking up:</u> For small amounts: Sweep/shovel up. For large amounts: Sweep/shovel up. Cleaning operations should be carried out only while wearing breathing apparatus. Collect waste in suitable containers, which can be labelled and sealed. Clean contaminated floors and objects thoroughly with water and detergents, observing environmental regulations. Incinerate or take to a special waste disposal site in accordance with local authority regulations.	

Section A8 (Annex Point)

Measures to be adopted to protect man, animals and the environment

Official use only

8.3.3	First aid measures	General advice: Avoid contact with the skin, eyes and clothing. Take off immediately all contaminated clothing. First aid personnel should pay attention to their own safety. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). If difficulties occur: Obtain medical attention. Show container, label and/or safety data sheet to physician. If inhaled: Keep patient calm, remove to fresh air, and seek medical attention. On skin contact: After contact with skin, wash immediately with plenty of water and soap. If irritation develops, seek medical attention. On contact with eyes: Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open; consult an eye specialist. On ingestion: Rinse mouth immediately and then drink plenty of water, seek medical attention. Do not induce vomiting unless told to by a poison control centre or doctor. Never induce vomiting or give anything by mouth if the victim is unconscious or having convulsions. Note to physician: Treatment: Treat according to symptoms (decontamination, vital functions); no known specific antidote.
8.4	**Possibility of destruction or decontamination following release to: (IIA, 8.8.4)**	
	a) Air	Not relevant due to limited volatility.

Section A8 (Annex Point)

Measures to be adopted to protect man, animals and the environment

Official use only

b) Water

Reference:

A8.4/01:

Schenk W (2001) Possible procedures for the decontamination of water from ALPHA-CYPERMETHRIN. BASF AG, Ludwigshafen/Rhein, Germany, Report no. 900049, February 2001 (unpublished) BASF DocID: 2001/1003822.

Principle of determination:

The adsorbancy of organic substances onto activated carbon can be evaluated by means of the adsorption isotherm according to Freundlich.

Summary of findings:

Alphacypermethrin (BAS 310 I) is to be classified as efficiently adsorbed onto activated carbon under neutral pH conditions.

Conclusions:

Incineration of the contaminated solid product. In case of contamination of water, the aqueous phase is to be collected and the non-dissolved amount of product has to be separated by filtration or centrifugation or by extraction with a suitable solvent. The separated solid or the organic phase should be incinerated, too.

The remaining aqueous phase is to be collected and treated with 1 g/l of activated carbon for 2 hours by intensive stirring. After the treatment, the separated activated carbon must be incinerated, too. The treated wastewater (pH 6.5–9) should be discharged into a public sewer leading to a publicly owned wastewater treatment works (POTW).

Small amounts of contaminated water can be as well sucked off by means of combustible adsorbents like sawdust, which must be incinerated in a proper manner. The contaminated area has to be purified with detergent-containing water, which is then discharged to the public sewer.

c) Soil

Dike spill area to prevent spill from spreading. Absorb the spilled material with inert absorbent such as granular clay or sawdust. Shovel or sweep up carefully and place in suitable container for disposal. If spilled to hard surface, rinse the spill area and any tools or implements several times with soapy water. Contain and absorb this rinsate with inert absorbents and place into same disposal container as the spilled material.

Small spills to the soil may be shovelled directly into a covered container for disposal. In the event of a large spill, call BASF at +49 / 18 02 27 31 12 (emergency information) for guidance on available clean-up options.

Section A8 (Annex Point) — Measures to be adopted to protect man, animals and the environment

Official use only

8.5	**Procedures for waste management of the active substance for industry and professional users (IIA, 8.8.5)**	To avoid disposal, all attempts should be made to use this product completely, in accordance with its intended use. If this is not possible, handle with care and dispose of in a safe manner. Empty containers or liners may retain some product residues. DO NOT REUSE. Render the container unusable by crushing or puncturing. Dispose of the container and any rinsate in a safe manner. Follow all applicable community, national or regional regulations regarding waste management methods. It is the ultimate responsibility of the waste generator to determine at the time of disposal whether this product and/or "empty" container residue meets any hazardous waste criteria.
8.5.1	Possibility of re-use or recycling (IIA, 8.8.5.1)	Re-use or recycling is not recommended.
8.5.2	Possibility of neutralisation of effects (IIA, 8.8.5.2)	Not appropriate; the substance is neither acidic nor alkaline and does therefore not require neutralisation.
8.5.3	Conditions for controlled discharge including leachate qualities on disposal (IIA, 8.8.5.3)	Must be dumped or incinerated in accordance with local regulations.
8.5.4	Conditions for controlled incineration (IIA, 8.8.5.4)	Recommended incineration conditions are approx. 1100 °C and a residence time of approx. 2 seconds.
8.6	**Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms (IIA, 8.8.6)**	When applied according to use instructions, the products containing Alphacypermethrin are considered to be safe. No cases of observations on undesirable or unintended side-effects of Alphacypermethrin are known to the applicant.
8.7	**Identification of any substances falling within the scope of List I or II of the Annex to Directive 80/68/EEC (IIIA, 8.1)**	Alphacypermethrin when used as a biocide by definition falls within the scope of List I of Directive 80/68/EEC. Pure Alphacypermethrin contains two organohalogen compounds as summarised in Appendix 1 to Document III-A (confidential information) as impurities which fall within the scope of List I of the Annex to Directive 80/68/EEC.

Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)	
Date	April, 2009	
Materials and Methods	In 8.1.1. : it is not chioroprene rubber but chloroprene rubber	
Results and discussion	Applicant's version adopted	
Conclusion	Applicant's version adopted	
Reliability	1	
Acceptability	acceptable	
Remarks	none	
	COMMENTS FROM APPLICANT	
Date	4 May 2009	
Materials and Methods	Thank you for spotting this typo. This has been corrected in the current version of this document.	
Results and discussion		
Conclusion		
Reliability		
Acceptability		
Remarks		

Section A9 **Classification and labelling**
Annex Point IIA9

Official use only

1 CLASSIFICATION PROPOSAL

1.1 Classification proposal

Symbol(s) and indication of danger:

"T" Toxic
"Xi" Irritant
"N" Dangerous for the environment

Risk Phrases:

R20 Harmful by inhalation
R25 Toxic if swallowed
R37/38 Irritating to respiratory system and the skin
R48/22 Harmful: Danger of serious damage to health by prolonged exposure if swallowed
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Safety Phrases:

S2 Keep out of reach of children.
S13 Keep away from food, drink and animal feeding stuffs
S20/21 When using do not eat, drink or smoke
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

1.2 Justification of the proposals

Symbol(s) and indication of danger:

T Derives from the acute oral LD_{50} in rats of technical Alphacypermethrin in corn oil 57 mg/kg bw, which is between 25 and 200 mg/kg bw.
Xi ECB ruling (25–27 April 2001; ECBI/64/01). Irritating to respiratory system.
N Required as the aquatic toxicity is < 1 mg/l (48 h EC_{50} *Daphnia magna* = 0.3 µg/l)

Risk Phrases:

R20 Derives from the acute inhalation LC_{50} in rats of technical Alphacypermethrin (administered with Aerosil) of 1.21 mg/l/4 h
R25 Derives from the acute oral LD_{50} in rats of technical Alphacypermethrin in corn oil (LD_{50} = 57 mg/kg bw)
R37 ECB ruling (25-27 April 2001; ECBI/64/01)
R38 Derives from results of skin irritation testing in rabbits according to classification criteria of Commission Directive 2001/59/EC (OJ L 225)
R48/22 ECB ruling (25-27 April 2001; ECBI/64/01)
R50 Derives from observed toxicity to *Daphnia magna* in standard laboratory studies where EC_{50} value for *Daphnia magna* was $\leq$ 1 mg/l (48 h EC_{50} *Daphnia magna* = 0.3 µg/l)
R53 Derives from observed toxicity to *Daphnia magna*, log $P_{ow} \geq 3$ and from the results of studies on ready biodegradation

Section A9 **Classification and labelling**
Annex Point IIA9

2 LABELLING PROPOSAL

2.1	**Labelling proposal**	Hazard Symbol(s):	T, Xi, N
		Indication of Danger:	Toxic, Irritant, Dangerous for the environment
		Risk Phrases:	R20, R25, R37, R38, R48/22, R50/53
		Safety Phrases:	S2, S13, S20/21, S45

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	
Materials and Methods	
Results and discussion	OK
Conclusion	
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	