		The slower rate of deltamethrin degradation at 10°C is not surprising, since soil microbial activities are generally reduced at lower temperatures. The reduced rate of degradation at the higher temperature (40°C) is similar to what was observed with permethrin degradation. Investigations with ^{14}C-carbonyl *cis*, *trans*-permethrin revealed that degradation of this chemical occurred most rapidly at 25°C and slowest at 10°C. The degradation of permethrin at 40°C was slower than at 25°C, but more rapid than at 10°C. Excellent ^{14}C-recoveries and balances were obtained from all treatments. The average recoveries from ^{14}C-cyano-deltamethrin treated soil was 94.9%, and 96.5% from ^{14}C-vinyl-deltamethrin treated soil. Extractable ^{14}C-activity decreased steadily with time at all temperatures with both ^{14}C-labels, and correlated with increased $^{14}CO_2$ evolution. Only slight differences were observed in residual (nonextractable) ^{14}C-activity at the different soil temperatures. As in previous investigations, residual ^{14}C-activity from the cyano group was primarily distributed in the fulvic and humic fractions, whereas the vinyl label occurred primarily in the fulvic acid fraction. Such differences in the distribution of residual ^{14}C-activity indicate that the unextractable ^{14}C-activity (bound residue) is not parent material, but rather, some product derived therefrom.	
4.2	**Degradation product(s)**	TLC analysis of the processed soil extracts from ^{14}C-deltamethrin treated soil indicate that deltamethrin is rapidly degraded in soil to several products. Only 2 – 3 products appeared in quantities greater than 1% of the parent material in any of the soil samples examined, and only one of these appeared consistently. This product possessed both the cyano and vinyl label, and was tentatively identified as D-COOH. Br_2CA was also identified as one or the main degradation products occurring in ^{14}C-vinyl-deltamethrin treated soil. Another product which was also tentatively identified and occurred at concentrations of less than 1% was D-$CONH_2$. This product is an intermediate in the formation of D-COOH. The appearance and dissipation of D-COOH and Br_2CA was also affected by soil temperature. D-COOH was formed to a maximum amount of 6.4% in the lower temperature (10°) soils before its dissipation was noted. Very little D-COOH occurred in soils at 40°C. In contrast, Br_2CA was formed in soils at 10° and 25°C, but dissipated rapidly. At 40°C, however, it was formed up to 5.3% before it began to dissipate. In summary, the results of this investigation indicate that while a somewhat longer half-life of deltamethrin may occur at certain temperature extremes, the principle pathway of degradation is the same as that observed at more normal temperatures.	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Aerobic degradation of ^{14}C-vinyl and ^{14}C-cyano labelled deltamethrin in soil was studied at different temperatures: 10, 25 or 40°C. Purity was not given, but the specific activity was 2.0 mCi/mg and 51.5 mCi/mmol, respectively. Dubbs fine sandy loam was used (see Table A7.2.1-8 for characteristics). Test material dissolved in ethanol, was applied at 0.1 mg/kg for the cyano label, and 0.2 mg/kg for the vinyl label, corresponding to approximately 220 and 450 g/ha, respectively. The higher rate for vinyl labelled material was used for its lower specific activity. The soil samples were incubated in the dark, at 75% of field capacity, for up to 64 days. The flasks were connected to traps for $^{14}CO_2$ (KOH). Control samples were included. Soil was sampled in duplicate and extracted with chloroform:methanol (1:3) and subsequently with methanol. Analysis was carried out with LSC and TLC. Unextractable residues were determined by LSC after combustion. Solids were subject to humin fractionation.	
5.2	**Results and discussion**	Average recoveries were 95 (83 – 100) and 96 (74 – 106)%, for cyano and vinyl labelled deltamethrin, respectively. The degradation was most rapid at 25°C and slowest at 10°C, as is shown in Table A7.2.1-9. At 25°C, the extent and rate of degradation was essentially the same for both forms of ^{14}C labelling. Considerably more degradation of the cyano labelled material occurred at 10 and 40°C than for vinyl labelled deltamethrin, showing that the cyano group is more labile. The results further suggest that degradation of the cyano group is less sensitive to the effects of temperature than the vinyl group. The principal pathway of degradation was the same at the two temperature extremes as that observed at 25°C. Only two transformation products were identified in quantities > 1% of applied ^{14}C. D-COOH (carboxylic acid analogue) was found at a maximum of 6.4% of applied ^{14}C, day 32 at 10°C. Br_2CA was found at a maximum level of 5.3% day 16, at 40°C, in vinyl labelled samples. The amide analogue to deltamethrin (D-$CONH_2$), an intermediate in the formation of D-COOH, was found as < 1%. Unextractable residues in soil treated with vinyl labelled deltamethrin were mainly found in the fulvic acid fraction, whereas the cyano labelled material was prevalent in fulvic acid and humin fractions. These differences indicate that the unextractable activity is not parent material. Assuming first-order kinetics, the following half-lives were calculated by the RMS : (r^2 = 0.96 – 0.99): 35 – 55 days at 10°C; 20 – 25 days at 25°C and; 31 days at 40°C. DT_{90} values, predicted from the rate constants, were: 117 – 183 days at 10°C; 66 – 82 days at 25°C and; 102 – 103 days at 40°C. The DT50 of deltamethrin and its metabolites D-COOH, Br_2CA and mPBacid was re-calculated applying first order kinetics to the data (Schaefer, D. and Mikolasch, B. 2004).	X X

		When the degradation rate differed between the two positions of labelling, it was slowest for the vinyl labelled material. The report did not discuss the effect of increased treatment rate, but since the vinyl labelled material was applied at doubled rate, a combined effect of high dose and unfavourable temperature should not be excluded.	
5.3	**Conclusion**		
5.3.1	Reliability	2	
5.3.2	Deficiencies	No	

Table A7.2.1-8 Classification and Physico-Chemical Properties of Soils Used

	Soil 1
Classification	Fine sandy loam (Dubbs)
Sand [%]	48.8
Silt [%]	44.0
Clay [%]	7.2
Organic carbon [%]	1.0
Carbonate as $CaCO_3$ (g/kg)	-
pH (1:1 H_2O)	5.9
Cation exchange capacity (MEQ/100 g)	8.5

Table A7.2.1-9 Distribution of Deltamethrin, $^{14}CO_2$ and Unextractable Residues of Cyano and Vinyl Labelled Material, at 10, 25 and 40°C (as % of applied ^{14}C)

	Temp.	Days					
		0	4	8	16	32	64
Cyano-label Deltamethrin	10°C	95	86	82	74	59	26
	25°C	95	74	60	33	25	9.2
	40°C	95	74	64	57	43	20
$^{14}CO_2$	10°C	0	2.4	3.9	8.5	18	32
	25°C	0	8.6	19	35	49	62
	40°C	0	10	16	25	39	54
Unextractable	10°C	0.9	4.4	6.0	8.5	12	21
	25°C	0.9	8.4	14	21	18	20
	40°C	0.9	9.3	10	10	12	14
Vinyl-label Deltamethrin	10°C	96	92	84	82	73	41
	25°C	96	74	64	51	39	14
	40°C	96	82	75	65	50	22
$^{14}CO_2$	10°C	0	0.9	1.2	2.4	5.9	13
	25°C	0	6.3	14	27	44	60
	40°C	0	1.8	3.3	7.8	17	31
Unextractable	10°C	1.1	5.7	2.6	5.8	9.2	14
	25°C	1.1	11	13	16	19	21
	40°C	1.1	8.4	13	14	18	25

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comment: **2.1** RMS can not find any reference to guideline US EPA 162-1 in the study report, but it is possible that the principle of this guideline was followed.
Conclusion	Applicant's version is adopted with the following comments: **5.2** This summary is taken from the Monograph 91/414 from 1998 and it is the RMS calculations in this evaluation that is referred to. The re-calculated DT_{50}s by Schaefer and Mikolasch are presented in A7.2.1/06.
Reliability	2 The study seems to have been well performed, but reporting was a bit scarce.
Acceptability	The study is regarded as acceptable. The estimated DT_{50} in soil was 35-55 days at 10 °C, 20-25 days at 25 °C, and 31 days at 40 °C. The unextractable residues were 14-25% after 64 days.
Remarks	No further remarks

A7.2.1/04

			Official use only
		1. REFERENCE	
1.1	**Reference**	Wang, W.W. (1991a) Aerobic Soil Metabolism of ^{14}C-Deltamethrin XenoBiotic Laboratories Inc, USA Document A47917 **7.2.1/04** 21 June 1991 Unpublished See Monograph 91/414 from 1998 – Point B.7.1.1	
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 162-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	7B0235B (unlabelled deltamethrin) X8595A (^{14}C-benzyl) X7506A (^{14}C-gem dimethyl)	
3.1.2	Specification	As given in Section 2 for unlabelled deltamethrin	
3.1.3	Purity	Unlabelled deltamethrin: 99.3% ^{14}C-benzyl: 96.65% with a specific activity of 59 mCi/mMole ^{14}C-gem: 98.16% with a specific activity of 60 mCi/mMole	
3.1.4	Further relevant properties	-	
3.1.5	Method of analysis	TLC and HPLC (LSC for unextractable residues)	
3.2	**Degradation products**		
3.2.1	Method of analysis for degradation products	TLC and HPLC (LSC for unextractable residues)	
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Soil types**	See Table A7.2.1-10	

3.5	**Testing procedure**		
3.5.1	Test systems	Biometer flasks with side tubes were prepared, each containing approximately 50 g of the sandy loam soil (dry weight basis; dwb). Duplicate samples were treated at a nominal concentration of 0.2 ppm (approximately 10 times the maximum label rate). The chemical was applied to the soil surface, dropwise, using a syringe, and the solvent was allowed to evaporate before mixing the chemical into the soil with a probe. After ^{14}C-deltamethrin was applied, the field moisture capacity of the soil was adjusted to 75% using deionised water. 10 ml of 0.1 N potassium hydroxide (KOH) solution was added to the side-arm of each flask. The flasks were incubated at 25 ± 1°C in the dark, in a constant temperature incubator. Two control and six exaggerated application rate (2 ppm) biometer flasks for each labelled test material were prepared in the same manner as described above. Sampling of the 0.2 ppm dosed flasks was performed at days 0, 1, 3, 5, 7, 14, 30, 59, 90, 120 and 181. At each sampling, duplicate sample flasks were harvested for analysis. The 2 ppm samples were harvested on day 120 and day 180 post-treatment. Carbon dioxide evolved from the incubation system was trapped in 10 ml of 0.1 N KOH, and duplicate aliquots were counted in a liquid scintillation counter. The KOH in each flask was sampled for assay at each of the early intervals, then every other week. The traps were recharged with fresh KOH solution. Blank KOH samples were taken before initiation of the study and at each sampling interval as controls. Radioactivity trapped in the KOH solution was further confirmed to be $^{14}CO_2$ via barium hydroxide [$Ba(OH)_2$] precipitation. Duplicate samples were precipitated with equal volume of $Ba(OH)_2$ (~1 ml), vortexed, and refrigerated for one hour. At the end of refrigeration, the same volume of $Ba(OH)_2$ was added to each sample and centrifuged for 10 minutes to separate the precipitate (barium carbonate, $Ba^{14}CO_3$) from the supernatant. Both the precipitate and the supernatant were assayed for liquid scintillation counting (LSC). Samples were then extracted, fractioned and then subjected to analysis.	
		4. RESULTS	
4.1	**Parent compound**	The percent distributions of the parent compound remaining and metabolite formation were based on the total recovered radioactivity. Data indicate that the parent compound readily degraded in soil under aerobic conditions. In both labels, the percentage of parent compound declined to about 50% within two weeks of incubation. For half-life calculations, only data from the first seven intervals (0 to 59 days) were used.	

4.2	**Degradation product(s)**	The major metabolite detected was Br_2CA [(1R-cis)-3-(2, 2-dibromoethenyl) -2,2-dimethylcyclopropanecarboxylic acid; metabolite #1). In the gem-labelled samples, Br_2CA was detected on day 1, peaked on day 14 (23.28%), and disappeared by the end of the incubation period. Some very minor polar metabolites were also detected in both labelled samples, but none that exceeded 3.96% (unknown #1, day-59) of the applied radioactivity. In the benzyl-labelled samples, aside from parent deltamethrin, only two other minor unknown metabolites (unknowns #2 and #3) were detected in all of the samples analysed. This indicated that the mPBacid (3-phenoxy-benzoic acid) moiety was not stable under the aerobic incubation conditions and probably more susceptible to further microbial degradation once it was formed. There was no other radioactive HPLC peak of significant amount detected that would match with the standard mixture analysed.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Aerobic degradation of ^{14}C-benzyl and ^{14}C-gem-dimethyl labelled deltamethrin in soil was studied, in accordance with US EPA Guideline 162-1. Radiochemical purity was 96.6 and 98.2% for ^{14}C-benzyl and ^{14}C-gem-dimethyl labelled substance, respectively. Unlabelled deltamethrin (purity 99.3%) was used in high treatment rate samples and as analysis standard. Stability of the test substance and reference standards (purity 97 – 102%) at refrigerated conditions for at least the length of the study was confirmed. A sandy loam soil was collected and sieved (∅ 2 mm). Analyses of the soil showed: 66% sand; 16% silt; 18% clay; 0.5% organic matter; 13.8 meq/100 g; pH 8.1; bulk density 1.51 g/cm^3; 23.4% field capacity. Test substance was dissolved in acetonitrile and applied at a rate of 0.2 mg/kg soil. Assuming incorporation to a depth of 5 cm, this corresponds to 150 g/ha. Controls and high treatment samples (2 mg/kg) were also prepared, however, no results from these were reported. The flasks were incubated at 25 ± 1°C in the dark, with moisture adjusted to 75% of field capacity. $^{14}CO_2$ traps (KOH) were connected to each flask. Duplicate flasks were sampled at intervals, for up to 181 days. Samples were blended with methylene chloride:acetonitrile (1:3) and the extracts were analysed with HPLC and TLC. Unextractable residues were determined by LSC after combustion, and the day-181 samples also subject to humus fractionation. $^{14}CO_2$ was measured by LSC and further confirmed by precipitation with barium hydroxide. Only values > 0.01 mg/kg were considered to be significant. First order kinetic was assumed and half-life calculated through the first seven sampling points (0 – 59 days).	

5.2	**Results and discussion**	The average recovery in benzyl and gem-dimethyl labelled samples was 89 and 106%, respectively. Distribution of radioactivity is presented in Table A7.2.1-11. The metabolite mPBacid (3-phenoxy-benzoic acid) was undetectable at all sampling points. Some minor polar metabolites were detected, but none of them exceeded 4.0% of applied dose, at any sampling point. The major metabolite detected was Br_2CA [(1R-cis)-3-(2, 2-dibromoethenyl) -2,2-dimethylcyclopropanecarboxylic acid; metabolite #1). In the gem-labelled samples, Br_2CA was detected on day 1, peaked on day 14 (23.28%), and disappeared by the end of the incubation period. Difference in mineralisation rate indicates that the benzyl moiety was more susceptible to microbial degradation than the cyclopropane moiety. Result of humus fractionation is presented in Table A7.2.1-12, showing predominantly distribution to the humin fraction. Using the results from the benzyl and gem-dimethyl labelled samples, half-life was calculated to 22 days ($r^2 = 0.99$) and 26 days ($r^2 = 0.96$), respectively. Average half-life was 24 days. From the rate constants obtained using sampling points 0 – 59 days, predicted DT_{90} was 72 – 85 days (calculated by Rapporteur Member State, RMS). As a conclusion, degradation of deltamethrin was relatively fast to moderate. Extensive mineralisation was shown, but also incorporation into bound residues. The percentage unextractable residues differed between the different positions of labelling, indicating that metabolites constitute part of the bound residues. Using data from 14 – 90 days samples, a DT_{50} of 21 days (r^2 = 0.95, 4 sampling points, 1 soil, estimated from study on deltamethrin) for Br_2CA was indicated. The DT50 of deltamethrin and its metabolite Br_2CA was re-calculated applying first order kinetics to the data (Schaefer, D. and Mikolasch, B. 2004).	X X X
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.2.1-10 Classification and Physico-Chemical Properties of Soil Used

	Soil 1
Classification	Sandy loam
Location	Casa Grand (Arizona, USA)
Sand [%]	66%
Silt [%]	16%
Clay [%]	18%
Organic carbon [%]	0.5%
pH (1:1 H_2O)	8.1
Cation exchange capacity	13.8 meq/100 g

Table A7.2.1-11 Distribution of ^{14}C, following incubation in sandy loam for 181 days, as % of applied ^{14}C (average of duplicate samples)

	Days									
	0	1	3	7	14	30	59	90	120	182
Benzyl-label deltamethrin	94	92	81	67	50	32	14	8.6	5.7	3.7
Unknowns 2 – 3	nd	nd	1.3	3.2	1.2	1.4	0.5	nd	nd	nd
$^{14}CO_2$	0.0	0.8	5.6	7.9	22	30	45	52	56	61
Unextractable	6.4	11	12	15	21	18	22	18	18	15
Total	100	104	100	93	95	81	82	79	80	80
Gem-label deltamethrin	92	95	85	80	51	34	20	12	9.6	7.8
Br_2CA^{1}	nd	2.6	7.4	11	23	22	8.6	2.0	nd	nd
Unknowns 1 – 3	nd	nd	1.5	2.9	1.9	3.9	5.5	3.0	0.4	nd
$^{14}CO_2$	0.0	0.2	0.6	1.1	4.5	8.4	25	36	42	50
Unextractable	8.4	15	17	18	29	35	44	48	48	44
Total	100	113	112	113	110	103	103	101	101	102

nd = not detected
[1] Decamethrinic acid, or (1R-cis)-3-(2, 2-dibromoethenyl) -2,2-dimethylcyclopropanecarboxylic acid

Table A7.2.1-12 Distribution of radioactivity in humus fractions on day 181 as % of applied ^{14}C (average of duplicate samples)

	Humin	Humic acid	Fulvic acid	Total
Benzyl-label	9.3	1.7	4.4	15
Gem-dimethyl-label	24	4.3	15	43

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted.
Conclusion	Applicant's version is adopted with the following comments: **5.2** The average half-life of 24 days is for 25 °C. This summary is taken from the Monograph 91/414 from 1998 and it is the RMS calculations in this evaluation that is referred to. The re-calculated DT_{50}s by Schaefer and Mikolasch are presented in A7.2.1/06.
Reliability	1 The study seems to have been well performed and reported.
Acceptability	The study is regarded as acceptable. The estimated DT_{50} in soil was 24 days at 25 °C. The unextractable residues were 15 and 44 %, respectively, for benzyl- and gem-labelled deltamethrin after 182 days.
Remarks	No further remarks

A7.2.1/05

			Official use only
		1. REFERENCE	
1.1	**Reference**	Feyerabend M. and 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 Document A74227 7.2.1/05 October 1997 Unpublished See Addendum to the Monograph 91/414 from 2002 – Point B.7.1	
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**	Not applicable	
2.2	**GLP**	Not applicable	
2.3	**Deviations**	Not applicable	
		3. MATERIALS AND METHODS	
3.1	**Test material**		
3.1.1	Lot/Batch number	Not applicable	
3.1.2	Specification	Not applicable	
3.1.2.1	Description	Not applicable	
3.1.2.2	Purity	Not applicable-	
3.1.2.3	Stability	Not applicable	
3.2	**Test conditions**	See 4.2.1	
		4. RESULTS	
4.1	**Materials and methods**	The aim of this study is to address the rate of degradation of the metabolite Br_2CA. DT_{50s} for deltamethrin and the metabolite Br_2CA were calculated using the method of compartmental analysis of pharmacokinetics program TOPFIT2.0. The calculation was done with a set of coupled first order differential equations for a three-compartment model (deltamethrin in soil/ Br_2CA in soil/elimination compartment). The degradation of Br_2CA was assumed to start before the degradation of deltamethrin had finished. Measured concentrations of deltamethrin and Br_2CA were taken from Kaufman *et al.* (1978) and Wang (1991a) for three different soils with varying moisture and dose. Both studies were performed at 25°C.	

4.2	**Results and discussion**	Calculated DT_{50s} for Br_2CA were as follows: Dubbs fine sandy loam, 0.2 kg/ha: 1.1 days (r^2 0.92) Dubbs fine sandy loam, 2 kg/ha: 0.80 day (r^2 0.60) Hagerstown silty clay loam, 0.2 kg/ha: 0.67 day (r^2 0.97) Hagerstown silty clay loam, 2 kg/ha: 0.68 day (r^2 0.95) Saturated Hagerstown silty clay loam, 0.2 kg/ha: 1.6 days (r^2 0.98) Saturated Hagerstown silty clay loam, 2 kg/ha: 1.9 days (r^2 0.99) Casa Grand sandy loam, 0.15 kg/ha (Wang 1991a): 9.1 days (r^2 0.97) Mean value: 2.3 days The results show that Br_2CA is degraded at faster rate than it is formed, which is also reflected in the fairly low amounts detected; max 11% in the study by Kaufman *et al.* (1978), and 23% in the study by Wang (1991a). The authors conclude that compartmental analysis is more realistic than log-linear regression, since the former takes the simultaneous formation and degradation into account. For deltamethrin, calculated DT_{50s} were 9-23 days, average 14.7 days (n = 7).	
4.3	**Conclusion**		
4.3.1	Reliability	1	
4.3.2	Deficiencies	No	

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted
Conclusion	Applicant's version is adopted
Reliability	1
Acceptability	The study is acceptable. The study gives information about the intrinsic degradation rate of Br_2CA in soil. A mean DT_{50} of 2.3 days is calculated and as a worst case, 9 days can be used.
Remarks	No further remarks

A7.2.1/06

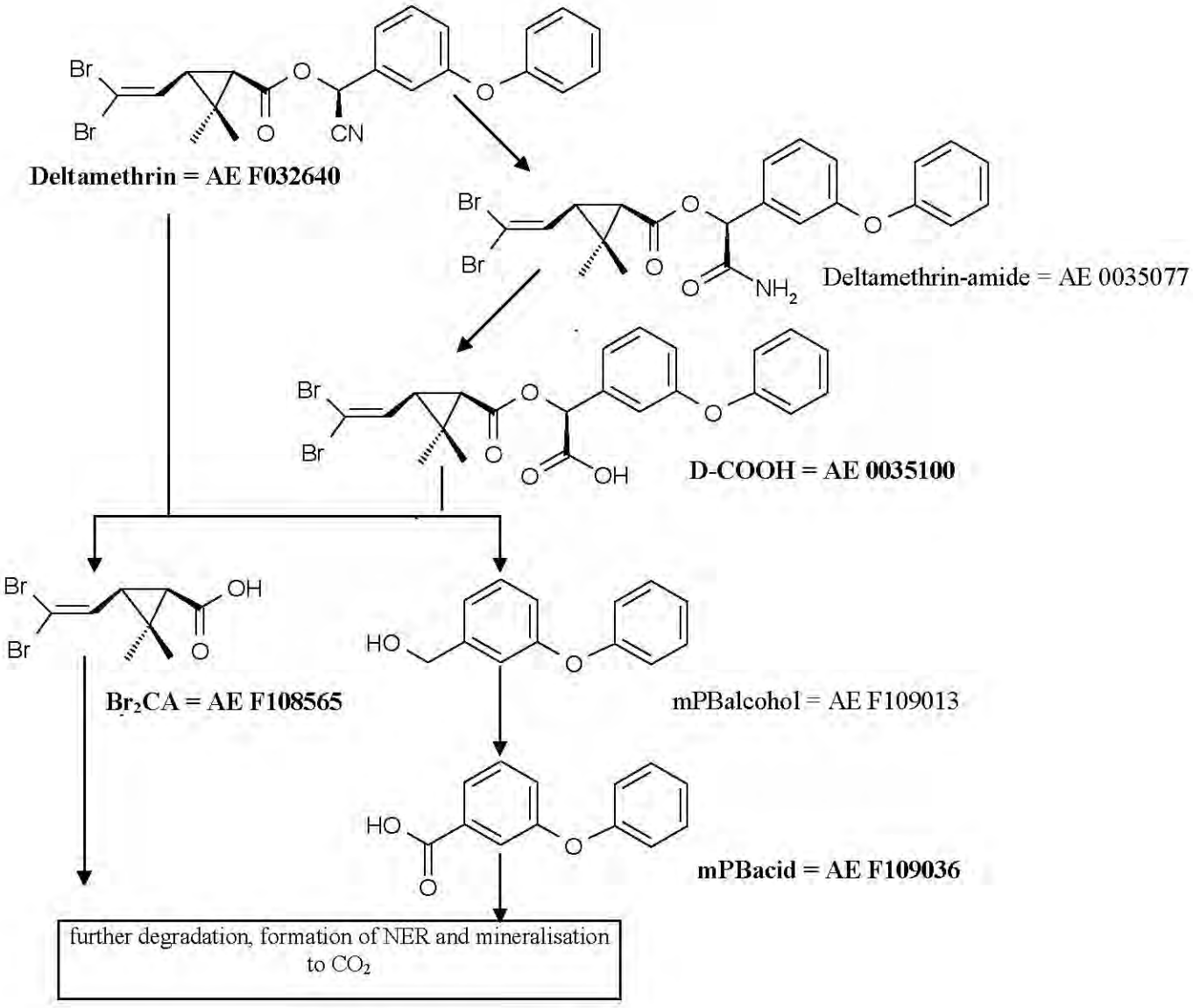
			Official use only
		1. REFERENCE	
1.1	**Reference**	Schäfer, D. and Mikolasch, B. (2004) Kinetic Evaluation of Soil Laboratory Studies with Deltamethrin and its Metabolites D-COOH, Br_2CA and mPBacid to Determine Input Parameters for Model Calculations Bayer CropScience AG, Germany Document C044585 **7.2.1/06** 8 October 2004 Unpublished	
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**	Not applicable	
2.2	**GLP**	Not applicable	
2.3	**Deviations**	Not applicable	
		3. MATERIALS AND METHODS	
3.1	**Test material**		
3.1.1	Lot/Batch number	Not applicable	
3.1.2	Specification	Not applicable	
3.1.2.1	Description	Not applicable	
3.1.2.2	Purity	Not applicable	
3.1.2.3	Stability	Not applicable	
3.2	**Test conditions**	Experimental data from four laboratory soil degradation studies (Kaufman *et al*, 1978, 1979 a, b; Wang, 1991) were used to quantify the degradation kinetics of deltamethrin and its metabolites D-COOH (AE 0035100). Br_2CA (AE F108565) and mPBacid (AE F109036) in soil. The kinetic evaluation was conducted with the ACSL Optimize software package (ACSL, 1996). The objective was to determine first-order soil DT_{50} values as input parameters for simulation models.	

		4. RESULTS	
4.1	**Materials and methods**	The degradation of deltamethrin in soil is a microbial process and the main degradation pathway is ester cleavage, followed by oxidation that leads to the formation of the main metabolites Br_2CA and mPBacid, which are relatively fast mineralised to CO_2. A second degradation route of deltamethrin is the oxidation of the nitrile group, which forms deltamethrin-amide and deltamethrin-carboxylic acid (D-COOH). The latter is subject to ester cleavage and oxidation, again forming the metabolites Br_2CA and mPBacid. The proposed metabolic pathway of deltamethrin in soil is shown in Figure A.7.1.2-1.	X
		Only the metabolite Br_2CA was found at more than 10% of the applied radioactivity in any soil degradation study, while D-COOH and mPBacid were found at maximum levels between 5% and 10%. The metabolites deltamethrin-amide (D-$CONH_2$) and mPBalcohol never exceeded 0.5% of the applied radioactivity and were not included in the kinetic evaluation.	
		Experimental data from four laboratory soil degradation studies (Kaufman *et al*, 1978, 1979 a, b; Wang, 1991) were used to quantify the degradation kinetics of deltamethrin and its metabolites D-COOH (AE 0035100). Br_2CA (AE F108565) and mPBacid (AE F 109036) in soil. The kinetic evaluation was conducted with the ACSL Optimize software package (ACSL, 1996). The objective was to determine first-order soil DT_{50} values as input parameters for simulation models.	
4.2	**Results and discussion**	In all cases the chemical reactions could be well described by first-order kinetics and all kinetic parameters passed a significance test. The first-order DT_{50} values were normalised to a reference temperature of 25°C and a reference soil moisture (field capacity), using the standard procedures described in FOCUS (2000).	
		The normalised DT_{50} values for deltamethrin ranged from 11.0 to 26.5 days in four soils (Table A7.2.1-13). The three metabolites were found to degrade more rapidly, with DT_{50} values of 4.5 days (D-COOH), 0.7 to 11.6 days (Br_2CA) and 0.6 to 0.9 days (mPBacid). The kinetic evaluation also indicated that on average 31% of the initial degradation of deltamethrin occurs via oxidation of the nitrile group (forming D-COOH), while 69% occurs via ester cleavage (forming Br_2CA and mPBacid).	X
		It can be concluded that deltamethrin is relatively rapidly degraded in soil, with first-order DT_{50} values 11 to 27 days, and forms short-lived metabolites.	
4.3	**Conclusion**		
4.3.1	Reliability	1	
4.3.2	Deficiencies	No	

Table A7.2.1-13 **First-order DT_{50} Values of Deltamethrin and its Metabolites D-COOH (AE 0035100), Br_2CA (AE F108565) and mPBacid (AE F109036) in Soil Under Laboratory Conditions, Normalised to 25°C and Field Capacity (they are the geometric means from multiple values for each soil).**

Soil	Deltamethrin (days)	D-COOH (days)	Br_2CA (days)	mPBacid (days)
Casa Grand	16.7	-	11.6	-
Dubbs	17.6	4.5	0.9	0.9
Hagerstown	11.0	-	0.7	0.6
Memphis	26.5	-	-	-

Figure 7.2.1-1. **Proposed Metabolic Pathway of Deltamethrin in Soil.**
The compounds in bold were addressed in the kinetic evaluation; none of the other metabolites exceeded 0.5% in any laboratory soil degradation study.



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 with the following comment: **4.1** The correct number of the figure with the metabolic pathway of deltamethrin in soil is 7.2.1-1 and not 7.1.2-1. **4.2** For deltamethrin and Br_2CA the applicant submitted during peer review more detalied tables (A.7.2.1-14 and A.7.2.1-15) over the results from report 7.2.1/06 for each individual soil and experiment. These tables also present further normalisation of each individual result to 12°; these normalisations were not done in 7.2.1/06. The RMS has added a table A.7.2.1-16 showing the detailed results from A.7.2.1/06 for mPBacid and and D-COOH.
Conclusion	Applicant's version is adopted
Reliability	1
Acceptability	The study is acceptable. The calculations are considered to be valid and the first-order DT_{50} of deltamethrin in soil is 11-27 days, at 25 °C. The recalculated DT_{50}s for deltamethrin and metabolites presented in this report are considered as more appropriate values to use than the DT_{50}s presented in the study summaries of each individual study.
Remarks	No further remarks

Table A.7.2.1-14 Summary of laboratory soil degradation data for deltamethrin showing DT50 values at study conditions and normalised at 25°C and FC, and normalised at 12°C and FC, and normalised at 12°C only

Soil	Reference	Study conditions (radio-label, treatment rate, temperature)	DT_{50} at study conditions (days)*	DT_{50} at 25°C and FC (days)*#	DT_{50} at 12°C and FC (days)#	DT_{50} at 12°C (days)
Casa Grand	Wang 1991a (A47917)	benzyl-label, high	19.0	17.9	49.9	53.8
		gem-label, high	16.4	15.5	43.2	46.4
Geometric mean, soil Casa Grand:			*17.7*	*16.7*	*46.4*	*50.0*
Dubbs	Kaufman et al 1978 (A12524)	vinyl-label, high	12.9	12.3	34.3	36.5
		vinyl-label, exagg'd. **	***(9.9)***	*(9.5)*	*(26.5)*	*(28.0)*
		benzyl-label, high	11.0	10.5	29.3	31.1
		benzyl-label, exagg'd	16.1	15.4	42.9	45.6
	Kaufman et al 1979a (A71051)	vinyl-label, 10°C, high	56.8	16.8	46.8	48.4
		vinyl-label, 25°C, high	30.3	28.9	80.5	85.7
		vinyl-label, 10°C, high	59.1	17.5	48.8	50.4
		vinyl-label, 25°C, high	21.9	20.9	58.2	62.0
		cyano-label, 10°C, high	39.1	11.6	32.3	33.3
		cyano-label, 25°C, high	14.6	13.9	38.7	41.3
	Kaufman et al 1979b (A71064)	phenoxy-label, normal	23.5	22.5	62.7	66.5
		phenoxy-label, high	25.7	24.6	68.6	72.7
		cyano-label, normal	19.5	18.6	51.8	55.2
		cyano-label, high	27.6	26.4	73.6	78.1
geometric mean, soil Dubbs:			*24.1*	*17.6*	*49.0*	*51.8*
Hagerstown	Kaufman et al 1978 (A12524)	vinyl-label, high	9.9	8.6	24.0	28.0
		vinyl-label, exagg'd	16.0	13.9	38.7	45.3
		benzyl-label, high	9.9	8.6	24.0	28.0
		benzyl-label, exagg'd	16.6	14.4	40.1	47.0
geometric mean, soil Hagerstown:			*12.7*	*11.0*	*30.7*	*35.9*
Memphis	Kaufman et al 1979b (A71064)	phenoxy-label, normal	24.5	24.5	68.3	69.3
		phenoxy-label, high	27.0	27.0	75.3	76.4
		cyano-label, normal	32.2	32.2	89.7	91.1
		cyano-label, high	23.0	23.0	64.1	65.1
geometric mean, soil Memphis:			*26.5*	*26.5*	*73.7*	*74.9*
overall geometric mean:			***21.3***	***17.3***	***48.2***	***51.7***

**: this result was considered an outlier and was not included in the averaging
*: data presented in report C044585 (Schäfer & Mikolasch, IIIA7.2.1/06)
#: data presented in Environmental Risk Assessment submitted in April 2006 (Mason P., March 2006)

Table A.7.2.1-15 Summary of laboratory soil degradation data for Br2CA showing DT50 values at study conditions calculated and normalised at 25°C and FC, and normalised at 12°C and FC, and normalised at 12°C only

Soil	Reference	Study conditions (radio-label, treatment rate, temperature)	DT_{50} at study conditions (days)*	DT_{50} at 25°C and FC (days)*#	DT_{50} at 12°C and FC (days)#	DT_{50} at 12°C (days)
Casa Grand	Wang 1991a (A47917)	gem-label, high	12.3	11.6	32.3	34.8
Dubbs	Kaufman et al 1978 (A12524)	vinyl-label, high	1.4	1.3	3.6	4.0
		*vinyl-label, exagg'd.***	*(28.2)*	*(26.9)*	*(75.0)*	*(79.8)*
	Kaufman et al 1979a (A71051)	vinyl-label, 10°C	2.4	0.7	2.0	2.0
		vinyl-label, 25°C	0.9	0.9	2.5	2.5
geometric mean, soil Dubbs:			*1.4*	*0.9*	*2.6*	*2.7*
Hagerstown	Kaufman et al 1978 (A12524)	vinyl-label, high	0.7	0.6	1.7	2.0
		vinyl-label, exagg'd	1.0	0.9	2.5	2.8
geometric mean, soil Hagerstown:			*0.8*	*0.7*	*2.1*	*2.4*
overall geometric Mean (of soil-specific geometric means):			***1.7***	***2.0***	***5.6***	***4.0***

**: this result was considered an outlier and was not included in the averaging
*: data presented in report C044585 (Schäfer & Mikolasch, IIIA7.2.1/06)
#: data presented in Environmental Risk Assessment submitted in April 2006 (Mason P., March 2006)

Table A.7.2.1-16 DT_{50}s for mPBacid and D-COOH: Kinetic re-evaluation and (where necessary) normalisation to 25° and to field capacity. Results from Schäfer and Mikolasch, 2004, (7.2.1/06) but here shown in more detail than in the applicant's study summary.

Soil	Reference	Study conditions (^{14}C-label, treatment rate, temperature)	First-order DT50 at study conditions (days)*		First-order DT50 at 25° and field capacity (days)*	
			mPBacid	D-COOH	mPBacid	D-COOH
Casa Grand	Wang, 1991a (7.2.1/04)	benzyl, high, 25°			-	-
		gem, high, 25°			-	-
Geometric mean, soil Casa Grand:					-	-
Dubbs	Kaufman et al, 1978 (7.2.1/01)	vinyl, high, 25°			-	-
		vinyl, exagg'd, 25°**			-	-
		benzyl, high, 25°	1.0		1.0	-
		benzyl, exagg'd, 25°	0.9		0.9	-
	Kaufman et al, 1979a (7.2.1/02)	vinyl, high, 10°			-	-
		vinyl, high, 25°			-	-
		vinyl, high, 10°		12.5	-	3.7
		vinyl, high, 25°		3.9	-	3.7
		cyano, high, 10°		15.7	-	4.6
		cyano, high, 25°		6.9	-	6.6
	Kaufman et al, 1979b (7.2.1/03)	phenoxy, norm, 25°			-	-
		phenoxy, high, 25°			-	-
		cyano, normal, 25°			-	-
		cyano, high, 25°			-	-
Geometric mean, soil Dubbs:			*0.9*	*8.5*	*0.9*	*4.5*
Hagers-town	Kaufman et al, 1978 (7.2.1/01)	vinyl, high, 25°			-	-
		vinyl, exagg'd, 25°			-	-
		benzyl, high, 25°	0.6		0.5	-
		benzyl, exagg'd, 25°	0.9		0.8	-
Geometric mean, soil Hagerstown:			*0,7*		*0.6*	-
Mem-phis	Kaufman et al, 1979b (7.2.1/03)	phenoxy, norm, 25°			-	-
		phenoxy, high, 25°			-	-
		cyano, normal, 25°			-	-
		cyano, high, 25°			-	-
Geometric mean, soil Memphis:					-	-
Overall geometric mean:			***0,8 (2 soils)***	***8.5 (1 soil)***	***0.7 (2 soils)***	***4.5 (1 soil)***

** The result from this experiment was considered an outlier and not included in the averaging.
* Data presented in report C044585 (Schäfer & Mikolasch, IIIA7.2.1/06

7.2.2 Aerobic degradation in soil, further studies

7.2.2.1 Rate and route of degradation

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Laboratory aerobic soil degradation studies in at least three soil types are summarised under Point 7.2.1. The rate and route of degradation of deltamethrin is addressed under this point as well.	
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

7.2.2.2 Field soil dissipation and accumulation

	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 experimental data from the laboratory aerobic soil degradation studies, the degradation kinetics of deltamethrin and its metabolites in soil have been quantified. It has been concluded that deltamethrin is relatively rapidly degraded in soil, with first-order DT_{50} values of 11 to 27 days, and forms short-lived metabolites. Therefore, field soil dissipation and accumulation 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

7.2.2.3 Extent and nature of bound residues

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The extent and nature of bound residues are presented under Point 7.2.1 where laboratory aerobic soil degradation studies are summarized.	
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

7.2.2.4 Other soil degradation studies

			Official use only
		1. REFERENCE	
1.1	**Reference**	Wang, W. and Reynolds, J.L. (1991b) Soil Photolysis of ^{14}C-Deltamethrin XenoBiotic Laboratories Inc., USA Document A47919 7.2.2.4/01 29 July 1991 Unpublished See Monograph 91/414/EEC from 1998 – Point B7.1.2	
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**	US EPA 161-3	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin	
3.1.1	Lot/Batch number	X7506A	
3.1.2	Specification	As in Section 2 but radiolabelled.	
3.1.3	Purity	98.2%	
3.1.4	Radiolabelling	^{14}C- gem-dimethyl labelled deltamethrin	
3.1.5	UV/VIS absorption spectra and absorbance value	Not reported	
3.1.6	Further relevant properties	-	
3.2	**Reference substances**	Deltamethrin, alpha-R-deltamethrin, trans-deltamethrin, deltamethrin-amide, mPBacid, cis-Br_2CA, trans-Br_2CA.	
3.3	**Test solution**	Gem-labelled deltamethrin treatment solution was prepared by dissolving deltamethrin in a 1 dram vial containing acetonitrile (ACN).	
3.4	**Testing procedure**		

3.4.1	Test system	The sandy loam used had the following characteristics: 62% sand; 19% silt; 19% clay; 0.6% organic matter and pH 7.5. Two grams of soil, which were screened through a 2 mm sieve, were mixed with deionized water to form a slurry of proper consistency, in a glass dish. This was then allowed to air dry, to form a soil layer of ~1.3 mm in thickness. These soil-layered dishes were then placed in the photolysis chamber. Two different application rates were used; 1 and 10 mg/kg soil (dry weight), in preliminary study only 1 mg/kg. Dark controls were prepared. Volatile compounds were collected in a series of traps.	
3.4.2	Properties of light source	A xenon arc lamp provided artificial light (wavelengths > 290 nm), with light and dark cycles (12h/12h), for a period of 30 days (14 d in preliminary study).	
3.4.3	Determination of irradiance	The spectral distribution of the artificial light was measured prior to and at the end of the test. Solar spectral distribution during June and August was measured in New Jersey (at about 40°N). The distributions were stated to correspond well. The average intensity of the lamp was ~ 159 W/m^2 (measured in the 330-800 nm region).	
3.4.4	Temperature	25 ± 1°C	
3.4.5	pH	Soil pH 7.5	
3.4.6	Duration of the test	30 days	
3.4.7	Number of replicates	2	
3.4.8	Sampling	Sampling of the 1 mg/kg treated layers was scheduled at 0, 3, 7, 14, 21 and 30 days post-treatment. The 10 mg/kg treated layers were only sampled on day 30.	
3.4.9	Analytical methods	LSC, HPLC and TLC.	
3.5	**Transformation products**	See 4.5	
		4. RESULTS	
4.1	**Screening test**	Not applicable	
4.2	**Actinometer data**	-	
4.3	**Controls**	Dark controls held under the same conditions as the irradiated samples.	
4.4	**Photolysis data**		
4.4.1	Concentration values	Soil treated with deltamethrin at 1 and 10 mg/kg soil.	
4.4.2	Mass balance	Average recovery of irradiated samples in preliminary study (1 mg/kg) was 84% (66-101%), in definite study (1 mg/kg) 96% (87-102%) and (10 mg/kg) 92%.	
4.4.3	Kinetic order	Half-life was calculated, assuming first order kinetics.	
4.4.4	Half-life ($t_{½E}$)	9 days	

4.5	**Specification of the transformation products**	In one of the 14-day samples in the definitive test (1 mg/kg), alpha-R-deltamethrin was found, as 4.7% of the applied dose. Trans-deltamethrin was not detected. Approximately 7% of the Br_2CA found in day 30-samples was characterised as trans-Br_2CA, the remaining part (29-30%) as cis-Br_2CA.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Photochemical reactions of ^{14}C-gem-dimethyl labelled deltamethrin (radiopurity 98.2%) on thin soil layers was studied, in accordance with US EPA Guideline 161-3. In a preliminary study, ^{14}C-benzyl labelled deltamethrin (radiopurity 96.6%) was used. The sandy loam used had the following characteristics: 62% sand; 19% silt; 19% clay; 0.6% organic matter and pH 7.5. The substance, dissolved in acetonitrile, was applied to dry soil layers (~ 1.3 mm). Two different application rates were used; 1 and 10 mg/kg soil (dry weight), in preliminary study only 1 mg/kg. Dark controls were prepared. During the test, temperature was approx. 25 ± 1°C, and moisture 75% of field capacity. Volatile compound were collected in a series of traps. A xenon arc lamp provided artificial light (wavelengths > 290 nm), with light and dark cycles (12h/12h), for a period of 30 days (14 d in preliminary study). The spectral distribution of the artificial light was measured prior to and at the end of the test. Solar spectral distribution during June and August was measured in New Jersey (at about 40°N). The distributions were stated to correspond well. The average intensity of the lamp was ~ 159 W/m² (measured in the 330-800 nm region). Duplicate samples were taken out on days 0, 3, 7, 14, 21 and 30, for analysis with LSC, HPLC and TLC. Dark controls were sampled on days 14 and 30. The 10 mg/kg treated layers were only sampled on day 30. Soil was extracted twice with acetonitrile:methylene chloride (1:3). Radioactivity remaining in solids were analysed after combustion. Depending on the level of residues in solids, these were further extracted with acidic methanol. Only values > 0.01 mg/kg were considered to be significant. Half-life was calculated, assuming first order kinetics.	
5.2	**Results and discussion**	Average recovery of irradiated samples in preliminary study (1 mg/kg) was 84% (66-101%), in definite study (1 mg/kg) 96% (87-102%) and (10 mg/kg) 92%. Distribution of radioactivity at selected sampling dates is presented in Tables A7.2.2.4-1 and A7.2.2.4-2. Distribution of activity in samples treated with 10 mg/kg is omitted since it resembled the 1 mg/kg-samples. In one of the 14-day samples in the definitive test (1 mg/kg), alpha-R-deltamethrin was found, as 4.7% of the applied dose. Trans-deltamethrin was not detected. Approximately 7% of the Br_2CA found in day 30-samples was characterised as trans-Br_2CA, the remaining part (29-30%) as cis-Br_2CA. Half-life, calculated from the result of the definitive study, was 9 days (r^2 = 0.996).	X

		Theoretically, the carbonyl, cyano, phenyl, and phenoxy moieties are all capable to transfer electrons from their ground state, to a higher energy state, producing either singlet of triplet excited states. The energy may be intramolecularly transferred to photolabile portions of deltamethrin. The authors suggested that main reactions responsible for the results of this study was photoinduced excitation of the oxygen-benzylic carbon bond resulting either in recombinations (R/S epimerisation) or ester cleavage forming alpha-R-deltamethrin and cis-Br_2CA, respectively. During the 91/414/EEC review, the RMS (Sweden) made the following comment: Since the soil matrix may contain sensitising substances, the results may in part reflect indirect photochemical reactions of deltamethrin. Such reactions may be of environmental relevance but the environmentally realistic rate of reaction is difficult to estimate. Since extensive transformation was observed also in the dark control, it is, however, concluded that other routes of transformation than photochemical reactions accounted for most of the loss of parent compound in this study. DT_{50} in the dark control was ≤ 14 days.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.2.2.4-1 Distribution of Activity in Preliminary Study, as % of Applied ^{14}C. Irradiation of ^{14}C-Benzyl Labelled Deltamethrin, on Thin Soil Layers (1 mg/kg). Mean of Duplicate Samples

	Deltamethrin	mPBacid[1]	Unknown[2]	Gas traps	Unextracted	Total
Day 0	90	2.9	Not detected	Not analysed	7.0	101
Day 14	32	11	4.5	6.1	27	82
Dark control: Day 14	41	Not detected	1.3	8.6	24	75

1 3-phenoxy-benzoic acid
2 Sum of 3 unidentified metabolites

Table A7.2.2.4-2 Distribution of Activity in Definitive Study, as % of Applied ^{14}C. Irradiation of ^{14}C-Gem Labelled Deltamethrin, on Thin Soil Layers (1 mg/kg). Mean of Duplicate Samples

	Deltamethrin	Br_2CA[1]	Unknown[2]	Gas traps[3]	Unextracted	Total
Day 0	95	Not detected	Not detected	Not analysed	6.0	101
Day 14	34	28	9.3	1.7	25	97
Day 21	17	40	4.6	1.3	26	89
Day 30	10	36	4.3	2.5	35	88
Dark control:						
Day 14	49	31	3.2	0.7	20	104
Day 30	13	54	1.5	0.6	25	94

[1] Decamethrinic acid
[2] Sum of 3 unidentified metabolites
[3] In KOH trap ($^{14}CO_2$ and acidic volatiles)

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted
Conclusion	Applicant's version is adopted with the following comment: **5.2** From the results in table A7.2.2.4-2 it can be concluded that slightly other transformation products are formed in the irradiated samples, for example a higher percentage of unknown metabolites and unextracted residues, compared to the dark control.
Reliability	1
Acceptability	The study is acceptable. The DT_{50} of deltamethrin in irradiated soil was calculated to be 9 days. However, since the degradation of deltamethrin in dark controls (13 % left after 30 d) was almost as high as in irradiated samples (10% left after 30 d) it can be concluded that other routes of transformation accounted for most of the loss of parent compound and that photochemical reactions probably contributed to a minor part of the transformation.
Remarks	No further remarks

7.2.3 Adsorption and mobility in soil, further studies

7.2.3.1 Adsorption and desorption

		1. REFERENCE	Official use only
1.1	**Reference**	Smith, A.M. (1990b) Determination of the Adsorption and Desorption Coefficients of Deltamethrin Springborn Laboratories Inc, USA Document A47159 **7.2.3.1/01** 29 June 1990 Unpublished See Monograph 91/414 from 1998 – Point B.7.2.1	
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 163-1; OECD 106 (in part)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3. MATERIALS AND METHODS	
3.1	**Test material**	Labelled Deltamethrin	
3.1.1	Lot/Batch number	X6819A	
3.1.2	Specification	-	
3.1.2.1	Description	^{14}C-benzyl labelled with a specific activity of 59 mCi/mMole	
3.1.2.2	Purity	100%	
3.1.2.3	Stability	Not specified	
3.2	**Test conditions**		
3.2.1	Type of study	Batch equilibrium	
3.2.2	Number of soils	Four	
3.2.3	Description of soils	See Table A7.2.3.1-1.	X
3.2.4	Concentrations	14.2, 6.6, 2.8 and 1.4 µg/l	X
3.2.5	Vehicle	Acetonitrile	
3.2.6	Test system	Vessels were pre-treated with a coating solution of deltamethrin to prevent absorption onto glassware.	

		The test system for this study consisted of 200 ml capped centrifuge tubes containing soil, 0.01 M $CaCl_2$ aqueous solution, and deltamethrin. All test systems were shaken for the necessary equilibrium period. Tests were conducted in an environmental chamber with temperature maintained at 20.0 ± 2.0°C. Centrifuge tubes were covered with aluminium foil and kept inside a dark box while being agitated in order to prevent photolysis.	
		The equilibrium phase test was performed at a solution:soil ratio of 1000:1 (this ratio was selected based on criteria published by ASTM) for Arizona sandy loam (AZI), Arizona sandy loam (AZII), Arizona clay (AZIII) and Mississipi silty clay loam (MS) and for an equilibration period of 2, 4, 8, 24 and 48 hours. A solution with a nominal concentration of 14.4 µg/l was prepared by addition of an acetonitrile stock of ^{14}C-deltamethrin to 0.01 M $CaCl_2$. Centrifuge tubes had 220 ml capacity, and contained approximately 0.2 grams soil and 200 ml solution. Centrifuge tubes containing only 200 ml of a 14.4 µg/l nominal concentration of deltamethrin served as soilless controls. All tubes were shaken for the specified time period at approximately 125 rpm, whereupon 5.00 ml aqueous samples were removed from each tube for radioassay after centrifugation as in the screening test.	X X
		The adsorption phase of the advanced test was performed at a solution:soil ratio of 1000:1 for all four soil types for an equilibration period of 24 hours, as determined from the equilibrium test. Nominal solution concentrations of 14.2, 6.60, 2.80 and 1.40 µg deltamethrin/l were prepared by addition of an acetonitrile stock of deltamethrin to 0.01 M $CaCl_2$.	
		Triplicate 0.2 gram soil aliquots of AZI, AZII, AZIII and MS were placed into 200 ml centrifuge tubes for each solution concentration. A 200 ml aliquot of the aqueous solution followed by fortification of the appropriate concentration were added to individual centrifuge tubes. In addition, three soilless controls for each test concentration and one blank sample for each soil type was prepared. The entire sample set was shaken for the necessary equilibration period (24 hours) at 125 rpm, whereupon 5.00 ml aqueous samples were removed for radioassay after centrifugation.	
3.2.7	Desorption time	16 hours	
3.2.8	Replicates	Three	
3.3	**Reference substance**		
3.3.1	Analytical method	Combustion followed by scintillation counting	
3.3.2	Other	-	
3.4	**Further remarks**	The Freundlich isotherm equation was used for data evaluation	
		4. RESULTS	
4.1	**Equilibrium time**	24 hours	
4.2	**Material balance**	AZI: 73.6 – 103.9%; AZII: 84.4 – 111.6%; AZIII: 82.4 – 97.6%; MS: 90.8 – 116.1%	

4.3	**K_{oc}**	K_{oc} values were as follows: 16,300,000 (AZI); 12,800,000 (AZII); 11,400,000 (AZIII); 460,000 (MS)	X
4.4	**K_{ads}**	K_{ads} values were as follows: 9,600 (AZI); 30,000 (AZII); 26,700 (AZIII); 3,790 (MS).	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Adsorption/desorption of ^{14}C-benzyl labelled deltamethrin (radiopurity 100%) to four soils was studied in accordance with US EPA Guideline 163-1, and in some parts following recommendations of ASTM and OECD Guideline No 106. The test substance was applied to 0.01 M $CaCl_2$ solutions, at nominal concentrations of 14.3 – 14.4 µg/l (screening test and advanced test). For adsorption isotherm test (definitive test) nominal concentrations of 1.4, 2.8, 6.6 and 14.2 µg/l were used. Acetonitrile was used as co-solvent (< 0.2%). Soil characteristics are presented in Table A7.2.3.1-1. Tubes containing 0.2 g soil and 200 ml solution (soil:solution ratio 1:1000) were prepared in triplicate for each soil. To avoid adsorption to glass tubes these were pre-coated with unlabelled deltamethrin. The test was performed in the dark, at 20 ± 2°C. Soil-less and deltamethrin-free controls were included. In the screening test, solutions of each soil were shaken for 16 hours, followed by two desorption steps (16 hours each). In the advanced test, equilibrium periods were 2, 4, 8, 24 and 48 hours. For the adsorption isotherm test the equilibrium period was 24 hours. Soil and aqueous phases were separated and ^{14}C-content in aliquots of supernatant and soil (ie after combustion) were analysed with LSC. The linear adsorption constant, K_d, was determined, and also calculated as a function of the organic carbon content of the soils, K_{oc}. The Freundlich isotherm equation was used to evaluate the data.	
5.2	**Results and discussion**	The radioactive material balance ranged from 67 to 106%. Balance was corrected for soil-less control recovery, due to adsorption of the test substance to the glass equipment. Adsorption constants, K_d, from the advanced test ranged from 3,790 (silty clay loam) to 30,000 (sandy loam). Corresponding K_{oc} values ranged from 460,000 to 12,800,000. Coefficients of determination were ≥ 0.90, and the slopes of the lines, 1/n, varied from 0.74 to 1.2. It was concluded that adsorption and desorption of deltamethrin did not vary significantly between the soils, and that the substance does not have a leaching potential. The constants derived from the advanced test generally supported the estimations from the screening test, in which K_{oc} were 708,000 – 3,140,000. Approximately 66 – 87% of the applied deltamethrin was adsorbed and 18 – 43% desorbed in the screening test. Water solubility was stated to be approximately 25 µg/l, as determined in preliminary testing, but according to study on solubility (Jordan and Mühlberger, 2000a), water solubility is lower than 0.0050 mg/l (at 20°C). However, the recovery was acceptable, despite the use of relatively high concentrations. OECD Guideline No 106 recommend a soil:solution ratio of 1:5, while ASTM recommends a lower ratio for substances that are strongly bound in order to achieve a proper analysis of test substance. The results indicate a very strong adsorption to soil.	

5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.2.3.1-1 Characteristics of Soils Used in Study on Adsorption/Desorption of Deltamethrin (prior to testing the soils were sieved [∅ 2 mm])

		Sand %	Silt %	Clay %	OM %	pH	CEC meq/100g
Arizona I	Sandyloam	80	9	11	0.1	8.5	10.0
Arizona II	Sandy loam	66	17	17	0.4	8.1	15.3
Arizona III	Clay	32	25	43	0.4	7.6	23.9
Mississippi	Silty clay loam	14	47	39	1.4	6.5	17.1

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EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **2.3** The study probably followed US EPA 163-1, but there were deviations from OECD 106. **3.2.3** The organic content of the soils was lower than recommended for the respective soil type according to OECD 106. Additionally, the guideline states that soils with less than 0.3% organic carbon (OC) content may disturb the correlation between organic content and adsorption. Thus, the use of soils with a minimum organic carbon content of 0.3% is recommended. In this study only the Mississippi soil had an OC content above 0.3%. The Arizona soils had organic carbon content 0.06-0.24%. Also the pH values in the Arizona soils were higher than recommended in OECD 106. **3.2.4** All the water concentrations are above the water solubility of deltamethrin, but this is possible considering that acetonitrile was used as a cosolvent. However, these high concentrations are not very environmentally realistic. **3.2.6** According to OECD 106, the recommended solution:soil ratio is 1:1-25:1. For substances with very high adsorption, a ratio of 100:1 can be used, but 1000:1 is never mentioned. This might affect the results, but perhaps it is not possible to perform the test with deltamethrin with a lower ratio, due to its low water solubility. OECD 106 also recommends using more soil; 1-2g, compared to 0.2g used in the study.
Results	Applicant's version is adopted with the following comment: **4.3** The Koc-values for the Arizona soils are very high and seem unrealistic. In the screening test, the corresponding values were between 766 000 and 3 140 000 L/kg , which also indicate a high variability. The low organic carbon content in the soils probably caused these unreliable results.
Conclusion	In the adsorption test with the soils Arizona I-III, the organic carbon contents were too low and therefore the results are not reliable. The only reliable Koc-value that can be derived from this study is 460 000 L/kg for the Mississippi soil.
Reliability	2 for the Mississippi soil 4 for the Arizona soils
Acceptability	The study is partly acceptable. The test conducted with Mississippi soil, yielding a Koc of 460 000 L/kg and Freundlich exponent 1/n 1.01 (r^2 0.986), is accepted and can be used. The other soil tests and values are not acceptable.
Remarks	Since only one reliable Koc-value could be derived from this study, further data on adsorption was requested and was submitted by applicant (7.2.3.1/02).

Section 7 Annex Point IIIA XII.1.2	Ecotoxicological Profile Including Environmental Fate and Behaviour A7.2.3.1 Adsorption and desorption in accordance with the new test guideline EC C18

			Official use only
		1. REFERENCE	
1.1	**Reference**	Christensen, K.P. (1993) Deltamethrin - Determination of the Sorption and Desorption Properties Springborn Laboratories Inc, USA Document A73876 **7.2.3.1/02** 13 October 1993 Unpublished	
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 163-1; OECD 106	X
2.2	**GLP**	Yes	
2.3	**Deviations**	Yes. Due to the very low water solubility of deltamethrin a higher solution:soil ratio was chosen to ensure that enough compound remains in the water phase, which is important for a reliable analysis.	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Labelled Deltamethrin	
3.1.1	Lot/Batch number	X8595A	
3.1.2	Specification	-	
3.1.2.1	Description	^{14}C-benzyl labelled with a specific activity of 58.9 mCi/mMole	
3.1.2.2	Purity	> 95%	
3.1.2.3	Stability	Not specified	
3.2	**Test conditions**		
3.2.1	Type of study	Batch equilibrium	
3.2.2	Number of soils	Three	
3.2.3	Description of soils	See Table A7.2.3.1-2.	X
3.2.4	Concentrations	0.10, 0.25, 0.50 and 1.0 µg/L	
3.2.5	Vehicle	Acetone	X
3.2.6	Test system	Vessels were pre-treated with a coating solution of non-radiolabelled deltamethrin to prevent absorption onto glassware.	

		The test system for this study consisted of 200 ml capped centrifuge tubes containing soil, 0.01 M $CaCl_2$ aqueous solution, and deltamethrin. All test systems were shaken for the necessary equilibrium period. Tests were conducted in an environmental chamber with temperature maintained at 20.0 ± 2.0°C. Centrifuge tubes were maintained in the dark while being agitated in order to prevent photolysis.	
		The equilibrium phase test was performed at a solution:soil ratio of 1000:1 for Arkansas silt loam, Georgia silt loam and Texas sandy loam and for an equilibration period of 2, 4, 16, 24 and 48 hours. A solution of ^{14}C-deltamethrin in acetone with a nominal concentration of 1.00 µg/ml was prepared. Centrifuge tubes contained approximately 0.2 g soil (dry weight) and 200 ml aliquot of the 0.01M $CaCl_2$ solution. One centrifuge tube was prepared with 0.2 g of soil (dry weight) and 200 ml of 0.01M $CaCl_2$ solution to serve as a control blank and one centrifuge tube was prepared containing 200 ml of 0.01M $CaCl_2$ solution to serve as a soil-less control. The vessels (except the one for the control blank) were spiked with 200 µl of the 1.00 µg/ml stock solution of ^{14}C-deltamethrin to achieve a nominal concentration of 1.00 µg/L. Test systems were gently shaken (at approximately 125 rpm) in the dark, and one system from each soil type was sampled after 2, 4, 16, 24 & 48 hours. The tubes were centrifuged at 1000 rpm for 60 minutes to separate the soil and aqueous phases. A hexane extraction was performed on the supernatant for each test system and the organic fraction transferred to scintillation vial for radioassay.	X
		The adsorption phase of the advanced test was performed at a solution:soil ratio of 1000:1 for all three soil types for an equilibration period of 16 hours, as determined from the equilibrium test. Three 0.2 g (dry weight) aliquots of each soil were placed into separate test systems for each solution concentration. Exactly 200 ml of 0.01M $CaCl_2$ solution was added to test systems containing Arkansas, Georgia and Texas soils (three for each soil). In addition, one soil-less control for each test concentration and four blank samples for each soil type were prepared. For each soil type, three experiment vessels and the soil-less control vessels were spiked with the 1.00 µg/ml stock solution of ^{14}C-deltamethrin to achieve a nominal concentration of 0.10, 0.25, 0.50 and 1.0 µg/L. The entire sample set was shaken for 16 hours at approximately 125 rpm, followed by phase separation and sampling for radioassay.	X
3.2.7	Desorption time	16 hours	X
3.2.8	Replicates	Three	
3.3	**Reference substance**	None	
3.3.1	Analytical method	Combustion followed by scintillation counting for soil and scintillation counting for supernatant.	
3.3.2	Other	-	
3.4	**Further remarks**	The Freundlich isotherm equation was used for data evaluation	

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		4. RESULTS	
4.1	**Equilibrium time**	16 hours	
4.2	**Material balance**	Arkansas: 112 - 163%; Georgia: 90.1 - 113%; Texas: 95.3 - 126%. The material balance was corrected against the mean amount of deltamethrin found to bind on the glass equipment for each deltamethrin concentration tested in soil free control samples. The material balance for soil free control samples was 61 – 65% and 35 – 39% of the test substance was found to bind to the glass equipment.	
4.3	**K_{oc}**	K_{oc} values were as follows: 392 000 Arkansas; 577 000 Georgia; 204 000 Texas	
4.4	**K_{ads}**	K_{ads} values were as follows: 3000 Arkansas; 4750 Georgia; 960 Texas.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Adsorption/desorption of ^{14}C-benzyl labelled deltamethrin (radiopurity > 95%) to three soils was studied in accordance with US EPA Guideline 163-1. For adsorption isotherm test, the test substance (1.00 µg/ml of ^{14}C-deltamethrin) was applied to 0.01 M $CaCl_2$ solutions to achieve nominal concentrations of 0.10, 0.25, 0.50 and 1.0 µg/L. Acetone was used as co-solvent. Soil characteristics are presented in Table A7.2.3.1-2. Tubes containing 0.2 g soil and 200 ml solution (soil:solution ratio 1:1000) were prepared in triplicate for each soil. Due to the extremely low solubility of deltamethrin in water, the solution:soil ratio of 1000:1 was chosen to ensure that enough deltamethrin remains in the water phase to allow accurate analysis. To avoid adsorption to glass tubes these were pre-coated with unlabelled deltamethrin. The test was performed in the dark, at 20 ± 2°C. However, control samples containing only 200 mL of 0.01 M $CaCl_2$ solution spiked with 1.00 µg/ml stock solution of ^{14}C-deltamethrin were analysed for each nominal concentration to account for deltamethrin binding to the glass equipment during the test. In addition, deltamethrin-free controls were included. In the screening test, solutions of each soil were shaken for 16 hours, followed by two desorption steps (16 hours each). In the soil kinetic test, equilibrium periods were 2, 4, 16, 24 and 48 hours. For the adsorption isotherm test the equilibrium period was 16 hours. Soil and aqueous phases were separated and ^{14}C-content in aliquots of supernatant and soil (ie after combustion) were analysed with LSC. The linear adsorption constant, K_d, was determined, and also calculated as a function of the organic carbon content of the soils, K_{oc}. The Freundlich isotherm equation was used to evaluate the data.	

5.2	**Results and discussion**	The radioactive material balance for the soil free control tubes ranged from 60.8 to 64.9%. 35 – 39% of the test substance was found to bind to the glass equipment based on the recovery of the oils free control samples. Adsorption constants, K_d, from the advanced test ranged from 960 Texas (sandy loam) to 4750 Georgia (silt loam). Corresponding K_{oc} values ranged from 204000 to 577000.	X
		Coefficients of determination were ≥ 0.90, and the slopes of the lines, 1/n, varied from 0.848 to 1.13. It was concluded that deltamethrin is considered to be immobile in Arkansas, Georgia and Texas soils.	X
		The constants derived from the advanced test generally supported the estimations from the screening test, in which K_{oc} were 255000 – 516000. Approximately 65.3 – 70.2% of the applied deltamethrin was adsorbed and 44.9 – 52.6% desorbed in the screening test.	X
5.3	**Conclusion**	Deltamethrin showed a very high adsorption to soil. Therefore, deltamethrin is considered to be immobile in Arkansas, Georgia and Texas soils.	
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.2.3.1-2 Characteristics of Soils Used in Study on Adsorption/Desorption of Deltamethrin (prior to testing the soils were sieved [∅ 2 mm])

		Sand %	Silt %	Clay %	OM %	OC %	pH	CEC meq/100g
Arkansas	Silt loam	23	61	16	1.3	0.75	6.3	9.7
Georgia	Silt loam	13	70	17	1.4	0.81	8.2	26.4
Texas	Sandy loam	64	29	6.7	0.8	0.46	5.1	4.2

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EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **2.1** The study was not performed according to the new test guideline, but this is not considered to have affected the results substantially. **3.2.3** The organic carbon content in Arkansas and Georgia soils are lower than in the guidance for soil selection in OECD 106, 0.75 and 0.81%, compared to the recommended 1.5-3%. This is, however, not expected to have affected the results substantially. **3.2.5** According to OECD guideline 106, methanol or acetonitrile is recommended as a solvent, but using acetone probably did not affect the results. **3.2.6** In both the pre test and the advanced test, less soil was used than recommended in the test; 0.2g instead of 1-2g. **3.2.7** The desorption test was performed by adding 0.01 M $CaCl_2$, whereafter deltamethrin was allowed to desorb from the soil while shaking for 16 hours. The aqueous phase was sampled and processed as in the sorption phase. Then a second desorption phase was performed in the same way.
Conclusion	Applicant's version is adopted with the following comments: **5.2** The desorption of 44.9-52.6% was rather high. **5.2** The Freunlich exponents (1/n) and coefficients of determination for each individual soil were: Arkansas: 1/n 1.0; r^2 0.889 Georgia: 1/n 1.13; r^2 0.996 Texas: 1/n 0.848; r^2 0.990. **5.3** Deltamethrin showed a high adsorption to soil with Koc values ranging from 204 000 to 577 000 L/kg.
Reliability	2 The study was not performed according to the new test guideline, but the results are still considered reliable.
Acceptability	The study is acceptable. The Koc of deltamethrin was 204 000 to 577 000 L/kg and 1/n 0.848-1.13.
Remarks	No further remarks

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			Official use only
		1. REFERENCE	
1.1	**Reference**	Wang, W.W. (1991b) Adsorption and Desorption of ^{14}C-Br_2CA in Five Soils XenoBiotic Laboratories Inc, USA Document A72145 **7.2.3.1/03** 16 December 1991 Unpublished See Monograph 91/414 from 1998 – Point B.7.2.1	
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 163-1	X
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Labelled and unlabelled Br_2CA	
3.1.1	Lot/Batch number	X3785A (labelled); 7B0207B (unlabelled)	
3.1.2	Specification	Br_2CA, a soil metabolite of deltamethrin (^{14}C-gem label position)	
3.1.2.1	Description	-	
3.1.2.2	Purity	Labelled: 98.81% (55.4 mCi/mMole) Unlabelled: 100%	
3.1.2.3	Stability	Stable	
3.2	**Test conditions**		
3.2.1	Type of study	Batch equilibrium	
3.2.2	Number of soils	Five	
3.2.3	Description of soils	See Table A7.2.3.1-2.	X
3.2.4	Concentrations	0, 0.053, 0.105, 0.525, 1.050 mg/l	
3.2.5	Vehicle	Acetonitrile	

3.2.6	Test system	Individually-labelled 50 ml centrifuge tubes, each containing ~5 g of soil, were prepared in duplicate as described in the previous section. A total of 60 tubes, 10 tubes per soil type and 10 controls (blank tubes with only 25 ml of treatment solution), were prepared. 22 ml of the treatment solutions of respective concentrations were then added to each soil tube using a pipette. All tubes were capped securely and placed on a wrist-action shaker and shaken under constant ambient conditions. Samples were assayed at 6 hours (the equilibration time determined in the preliminary study) post-treatment. After the 6-hour shaking period, all sample tubes were centrifuged for 10 minutes as described in the previous section. Following centrifugation, the supernatants (adsorption solutions, typically 22 – 25 ml each) were removed using a pipette, their volumes recorded and then aliquoted in duplicate for LSC analysis. Upon completion of the adsorption procedure, 25 ml of fresh, untreated, 0.01 M $CaCl_2$ solution was added to all of the tubes to initiate the desorption process. All tubes were then returned to the shaker and shaken again under constant ambient conditions for an additional 24 hours. At the end of the 24-hour shaking, the soil-solution samples were centrifuged as described above. The supernatants (desorption solutions, approximately 25 ml each) were removed, their volumes recorded and then assayed by LSC. The desorbed soils were air-dried and subsampled for combustion analyses.	
3.2.7	Desorption time	24 hours	
3.2.8	Replicates	Two	
3.3	**Reference substance**		
3.3.1	Analytical method	Combustion followed by scintillation counting; HPLC	
3.3.2	Other	-	
3.4	**Further remarks**	The Freundlich isotherm equation was used for data evaluation	
		4. RESULTS	
4.1	**Equilibrium time**	4 – 6 hours	
4.2	**Material balance**	The average recoveries in the definitive study were 109.36% (control), 112.70% (AZ #2 sandy loam), 109.06% (AZ #3 clay), 104.87% (MS silty clay loam), 110.54% (USA sandy loam), and 112.84% (MI clay loam).	
4.3	**K_{oc}**	The K_{oc} values for the adsorption of Br_2CA in the five soils were as follows: AZ #2 sandy loam, 38.19; AZ #3 clay, 46.78; MS silty clay loam, 43.73; USA sandy loam, 23.00; and MI clay loam, 10.10.	X
4.4	**K_{ads} – K_{des}**	K_{ads} values are as follows: 0.09 (AZ #2 sandy loam); 0.11 (AZ #3 clay); 0.36 (MS silty clay loam); 0.59 (USA sandy loam) and 0.27 (MI clay loam). K_{des} values were as follows: 0.14 (AZ #2 sandy loam); 0.16 (AZ #3 clay); 1.91 (MS silty clay loam); 2.51(USA sandy loam); and 0.40 (MI clay loam).	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Adsorption/desorption of ^{14}C-gem-methyl labelled Br_2CA (decamethrinic acid, radiopurity 98.8%) in five soils was studied, in accordance with US EPA Guideline 163-1. Soil characteristics are presented in Table A7.2.3.1-2. In a preliminary study, 1 mg/l solutions in tubes with soil:solution ratios of 1:5, 1:10 and 1:100 were equilibrated for 4 hours before analysis. To establish the equilibration time, other tubes were assayed after 0, 2, 4, 6 and 24 hours. In the definitive study the soil:solution ratio was 1:5 (25 ml solution and 5 g soil) and the equilibration time 6 hours. The tubes were shaken under constant ambient conditions. After centrifugation, sampling and addition of fresh $CaCl_2$ solution, one desorption step of 24 hours followed. Concentrations of approx. 0.05, 0.1, 0.5 and 1.0 mg/l in 0.01 M $CaCl_2$ were used, with < 1% acetonitrile as co-solvent. Tubes were prepared in duplicate. Soil-less and Br_2CA-free controls were prepared. Analysis of supernatants and residues in soil following combustion was carried out with LSC. Selected samples were analysed with HPLC, for determination of possible degradation. Freundlich isotherm equation was used to determine the adsorption constants, K_d. Adsorption constants based on soil organic carbon, K_{oc}, were also calculated.	
5.2	**Results and discussion**	The average recovery ranged from 105 to 113% in the definitive study. No adsorption to laboratory equipment occurred, and Br_2CA was stable under the test conditions. Adsorption constants ranged from 0.089 (AZII sandy loam) to 0.59 (USA sandy loam). K_{oc} values ranged from 10 (MI clay loam) to 47 (AZIII clay). Coefficients of determination were ≥ 0.93, and the slopes of the lines (1/n) ranged from 0.84 to 1.0. Desorption constants, K_{des}, varied from 0.14 (AZII sandy loam) to 2.5 (USA sandy loam). The author concluded that the results indicate that Br_2CA is very mobile in soil, and readily desorbed.	X
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.2.3.1-2 Characteristics of Soils Used in Study of Adsorption/Desorption of Br_2CA (prior to testing the soils were sieved [∅ 2 mm])

	Sand %	Silt %	Clay %	OM %	pH %	FMC % [1]	CEC meq/100g
Arizona II Sandy loam	66	17	17	0.4	8.1	14.2	15.3
Arizona III Clay	32	25	43	0.4	7.6	26.8	23.9
Mississippi Silty Clay Loam	14	47	39	1.4	6.5	32.1	17.1
USA Sandy loam	76	13	11	4.4	6.4	12.9	9.4
Michigan Clay loam	35	33	32	4.6	6.8	25.9	17.1

[1] = Field Moisture Capacity at 1/3 bar

EVALUATION BY COMPETENT AUTHORITIES
EVALUATION BY RAPPORTEUR MEMBER STATE

Section 7 Annex Point IIIA XII.1.2	**Ecotoxicological Profile Including Environmental Fate and Behaviour** A7.2.3.1 Adsorption and desorption in accordance with the new test guideline EC C18

Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **2.1** The study did not follow the new guideline, but a US EPA guideline. The results are still considered to be useful. **3.2.3** The organic carbon content in Arizona soils II and III was 0.24%, which is lower than the minimum organic carbon content recommended in OECD 106. The guideline states that soils with less than 0.3% organic carbon (OC) content may disturb the correlation between organic content and adsorption. Thus, the results are not reliable. Also the pH values in the Arizona soils were higher than recommended in OECD 106. The characteristics of the other soils are acceptable.
Results	Applicant's version is adopted with the following comment: **4.3** The Koc values for Br_2CA derived in Arizona soils II and III are not considered reliable. Therefore, only the Koc values obtained with the other soils can be used to estimate the adsorption of Br_2CA in soil. **5.2** The Freunlich exponents (1/n) and coefficients of determination for each individual of these soils were: Silty clay loam (MS): 1/n 0.957; r^2 0.999 Sandy loam (USA): 1/n 0.888; r^2 0.999 Clay loam (MICH): 1/n 0.836; r^2 0.998
Conclusion	The results obtained with the Arizona soils are not considered reliable and can therefore not be used. The Koc values obtained with the other soils, 10.10-43.73 L/kg, indicate that Br_2CA is very mobile in soil and readily desorbed.
Reliability	2 for Mississippi, USA and Michigan soils 4 for Arizona soils
Acceptability	The study is regarded as partly acceptable. Two of the soils had an organic content that was too low and the data therefore became unreliable and the test unacceptable. The tests with the other three soils are acceptable, and show that Br_2CA has a Koc of 10.10-43.73 L/kg and 1/n 0.836-0.957.
Remarks	No further remarks

			Official use only
		1. REFERENCE	
1.1	**Reference**	Reynolds, J.L. (1992) Adsorption and Desorption of ^{14}C-m-Phenoxybenzoic Acid in Four Soils XenoBiotic Laboratories Inc, USA Document A71037 **7.2.3.1/04** 18 November 1992 Unpublished See Monograph 91/414 from 1998 – Point B.7.2.1	
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 163-1	X
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Labelled and unlabelled mPBacid	
3.1.1	Lot/Batch number	Labelled: X6975A Unlabelled: 7B0237B	
3.1.2	Specification	m-Phenoxybenzoic acid (mPBacid), a soil metabolite of deltamethrin	
3.1.2.1	Description	^{14}C-labelled at the benzylic carbon	
3.1.2.2	Purity	Labelled: 100% with a specific activity of 20 mCi/mMole Unlabelled: 100 %	
3.1.2.3	Stability	Stable	
3.2	**Test conditions**		
3.2.1	Type of study	Batch equilibrium	
3.2.2	Number of soils	Four	
3.2.3	Description of soils	See Table A7.2.3.1-3	X
3.2.4	Concentrations	0.05, 0.09, 0.68 and 1.36 mg/l	
3.2.5	Vehicle	Acetonitrile	

3.2.6	Test system	Individually-labelled 50 ml Teflon® centrifuge tubes, each containing ~5 g of soil, were prepared as described in the previous section. A total of 12 tubes, 2 tubes per soil type and 2 positive controls (blank tubes with only ~25 ml of treatment solution) and 2 negative control tubes (soil and untreated $CaCl_2$ solution), were prepared for the four treatment rates. Approximately 25 ml of the $CaCl_2$ solution was then added to each soil tube using a pipette. The appropriate amount of radiolabelled chemical was then added to each tube. All tubes were capped securely and placed on a Wrist Action® Shaker and shaken under ambient conditions. Samples were assayed at 48 hours post-treatment (the optimum equilibration time determined from the preliminary study). After the 48-hour shaking period, all sample tubes were centrifuged for about 10 minutes as described in the previous section. Following centrifugation, the supernatants (adsorption solutions, typically ~22 – 25 ml each) were aliquoted in duplicate for LSC. Each supernatant was then decanted to minimize its binding to the glassware and the resultant loss of the chemical; the total volume was recorded. Upon completion of the adsorption procedure, approximately 25 ml of fresh, untreated, 0.01 M $CaCl_2$ solution was added to all of the tubes to initiate the desorption process. All tubes were then returned to the shaker and shaken again under ambient conditions for an additional 48 hours. After shaking, the soil-solution samples were centrifuged as described above. The supernatants (desorption solutions, approximately 25 ml each) were assayed by LSC, decanted, and their volumes recorded. The desorbed soils were removed, air dried, and subsampled for combustion analyses.	
3.2.7	Desorption time	48 hours	
3.2.8	Replicates	Two	
3.3	**Reference substance**		
3.3.1	Analytical method	Combustion followed by scintillation counting; HPLC	
3.3.2	Other	-	
3.4	**Further remarks**	The Freundlich isotherm equation was used for data evaluation	
		4. RESULTS	
4.1	**Equilibrium time**		
4.2	**Material balance**	The average recoveries in the definitive study were 103.33 (control), 100.54% (AZ #3 clay), 100.13% (MS silty clay loam), 97.39% (MD sandy loam), and 101.53% (MI clay loam).	
4.3	**K_{oc}**	The K_{oc} values determined for the adsorption of m-phenoxybenzoic acid in the four soils were as follows: 287.76 (AZ #3), 189.90 (MS), 105.03 (MD), and 50.65 (MI).	X
4.4	**K_{ads} – K_{des}**	K_{ads} values of m-phenoxybenzoic acid based on the total radioactivity in the four soils were as follows: 0.67 (AZ clay); 1.54 (MS silty clay loam); 2.68 (MD sandy loam) and 1.34 (MI clay loam). For the desorption process of m-phenoxybenzoic acid from the soil matrices, the K_{des} values were as follows: 0.87 (AZ #3 clay); 3.00 (MS silty clay loam); 4.21 (MD sandy loam) and 1.85 (MI clay loam).	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Adsorption/desorption of mPBacid (m-phenoxybenzoic acid), ^{14}C-labelled at the benzylic carbon (radiopurity 100%), was studied in accordance with US EPA Guideline 163-1. Characteristics of the four soils used are shown in Table A7.2.3.1-3. A preliminary study was performed to determine the proper soil:solution ratio and equilibration time (assay after 0, 2, 4, 24, 48 and 72 hours). Test concentrations in the definitive study were 0.050, 0.085, 0.68 and 1.4 mg/L, in 0.01 M $CaCl_2$ solution, with < 1% acetonitrile and toluene as co-solvent. Test tubes were prepared in duplicate. Soil:solution ratio was 1:5 (25 ml solution and 5 g soil), and equilibration time 48 hours. After the adsorption step, a 48-h desorption step followed. Soil-less and mPBacid-free controls were included in the study. To minimise binding to centrifuge tubes, these were precoated with unlabelled mPBacid dissolved in methylene chloride. Supernatants were analysed with LSC. After the desorption step soil aliquots were combusted for analysis of $^{14}CO_2$. Selected supernatant samples were also analysed with HPLC. Freundlich isotherm equation was used to determine adsorption constants, K_d. Adsorption was also expressed as K_{oc}.	
5.2	**Results and discussion**	The average recovery in the definitive study ranged from 97 to 103%. In soil-less controls with the higher test concentration approximately 18 – 27% of the test substance adsorbed to the walls or caps of the centrifuge tubes, whereas no adsorption was observed at the lower concentrations. The test substance was the only substance detected with HPLC. Adsorption constants ranged from 0.67 (AZIII clay) to 2.7 (MD sandy loam). K_{oc} values ranged from 51 (MI clay loam) to 288 (AZIII clay). Coefficients of determination were ≥ 0.98, and the slopes of the lines (1/n) ranged from 0.92 to 1.0. Desorption constants, K_{des}, ranged from 0.87 (AZIII clay) to 4.2 (MD sandy loam). The author concluded that the results indicate that mPBacid is mobile and readily desorbed from soil.	X
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Section 7 Annex Point IIIA XII.1.2	Ecotoxicological Profile Including Environmental Fate and Behaviour A7.2.3.1 Adsorption and desorption in accordance with the new test guideline EC C18

Table A7.2.3.1-3 Characteristics of Soils Used in Study on Adsorption/Desorption of mPBacid (prior to testing the soils were sieved [∅ 2 mm])

	Sand %	Silt %	Clay %	OM %	pH %	FMC % [1]	CEC meq/100g
Arizona III Clay	32	25	43	0.4	7.6	26.8	23.9
Mississippi Silty Clay Loam	14	47	39	1.4	6.5	32.1	17.1
Maryland Sandy loam	76	13	11	4.4	6.4	12.9	9.4
Michigan Clay loam	35	33	32	4.6	6.8	25.9	17.1

[1] = Field Moisture Capacity at 1/3 bar

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **2.1** The study did not follow the new guideline, but a US EPA guideline. The results are still considered to be useful. **3.2.3** The organic carbon content in Arizona soil III was 0.24%, which is lower than the minimum organic carbon content recommended in OECD 106. The guideline states that soils with less than 0.3% organic carbon (OC) content may disturb the correlation between organic content and adsorption. Thus, the results are not reliable. Also the pH value in the Arizona soil was higher than recommended in OECD 106. The characteristics of the other soils are acceptable.
Results	Applicant's version is adopted with the following comment: **4.3** The Koc value for mPBacid derived in Arizona soil III is not considered reliable. Therefore, only the Koc values obtained with the other soils can be used to estimate the adsorption of mPBacid in soil. **5.2** The Freunlich exponents (1/n) and coefficients of determination for each individual of these soils were: Silty clay loam (MS): 1/n 1.01; r^2 0.998 Sandy loam (MD): 1/n 0.939; r^2 1.00 Clay loam (MICH): 1/n 0.922; r^2 0.999
Conclusion	The results obtained with the Arizona soil are not considered reliable and can therefore not be used. The Koc values obtained with the other soils, 50.65-189.90 L/kg, indicate that mPBacid is very mobile in soil and readily desorbed.
Reliability	2 for Mississippi, Maryland and Michigan soils 4 for Arizona soil
Acceptability	The study is regarded as partly acceptable. One of the soils had an organic content that was too low for the results to be reliable and the test was therefore unacceptable. The tests with the other three soils are acceptable, and show that mPBacid has a Koc of 50.65-189.90 L/kg, and 1/n 0.922-1.01.
Remarks	No further remarks

7.2.3.2 Mobility in at least three soil types

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	These studies are not required as appropriate PEC modelling indicates no leaching to groundwater.	
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

7.3 Fate and behaviour in air

7.3.1 Phototransformation in air

			Official use only
		1. REFERENCE	
1.1	**Reference**	Meichsner, C. (1999) Calculation of the Indirect Photolysis Reaction Using the Incremental Method of Atkinson and the Program AOPWIN, Version 1.80 InfraServe GmbH & Co. Höchst KG, Germany Document C002214 **7.3.1/01** 19 January 1999 Unpublished See Addendum to the Monograph 91/414 from 2002 – Point B.7.7.2	
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**	Not applicable	
2.2	**GLP**	Not applicable	
2.3	**Deviations**	Not applicable	
		3. MATERIALS AND METHODS	
3.1	**Test material**		
3.1.1	Lot/Batch number	Not applicable	
3.1.2	Specification	As given in Section 2	
3.1.3	Description	Not applicable	
3.1.4	Purity	Not applicable	
3.1.5	Stability	Not applicable	
3.2	**Method of calculation**	Atkinson model	
3.3	**Further remarks**	-	
		4. RESULTS	
4.1	**Summary**	The Atmospheric Oxidation Program (AOPWJN) was used to calculate the rate constants for reaction of deltamethrin with hydroxyl radicals and ozone.	

		Using a concentration of 500 000 hydroxyl radicals the calculation of the indirect photolysis reaction of deltamethrin with hydroxyl radicals using the incremental-method of Atkinson and AOPWIN, version 1.80 resulted in an: Overall OH rate constant = 23.4695 x 10^{-12} cm^3/molecule-sec; Half-Life = 0.684 days (24-hr day; 0.5 x 10^6 OH/cm^3) = 16.407 hours.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The Atmospheric Oxidation program (AOPWIN) was used to calculate the rate constants for reaction of deltamethrin with hydroxyl radicals and ozone. The estimations were based on structure-activity relationship (SAR) methods developed by Atkinson and co-workers and by Syracuse Research Corporation.	
5.2	**Results and discussion**	Half-life for reaction with ozone was calculated to 51.4 days. Half-life for reaction with OH-radicals, given a 24-h concentration of 0.5 x 10^6 OH/cm^3, was calculated to 16.4 hours.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

EVALUATION BY COMPETENT AUTHORITIES	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Not relevant
Materials and methods	Applicant's version is adopted
Conclusion	Half-life for reaction with ozone was calculated to 51.4 days. Half-life for reaction with OH-radicals was calculated to 16.4 hours.
Reliability	1
Acceptability	The submitted calculation of indirect photolysis of deltamethrin is considered acceptable.
Remarks	No further remarks

7.3.2 Fate and behaviour in air, further studies

			Official use only
		1. REFERENCE	
1.1	**Reference**	Rüdel, H. and Waymann, B. (1993) Testing for Volatility of ^{14}C-Deltamethrin (formulated as the product Decis Flüssig EC): Volatilisation from plant surfaces, volatilisation from soil Fraunhofer-Institut für Umweltchemie und Ökotoxikologie – IUCT, Germany Document A53910 **7.3.2/01** 23 April 1993 Unpublished See Addendum to the Monograph 91/414 from 2002 – Point B.7.7.1	
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; BBA Part IV/6-1.	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Labelled deltamethrin applied in a blank formulation 2.5% EC	
3.1.1	Lot/Batch number	Labelled deltamethrin: X8595A	
3.1.2	Specification	-	
3.1.3	Description	-	
3.1.4	Purity	^{14}C-benzyl: > 95% with a specific activity of 2.18 GBq/mMol or 4.32 MBq/mg	
3.1.5	Stability		
3.2	**Test system**		
3.2.1	Plants	Common beans (*Phaseolus vulgaris)*	
3.2.2	Location of trials	Controlled environment room (20°C, 70% humidity, 12 h light)	
3.2.3	Soil type	See Table A7.3.2-1.	
3.2.4	Preparation of solution	Prepared in toluene	
3.2.5	Number of trials	Two	
3.2.6	Application rate	25 g as/l	
3.2.7	Sampling timing	0 – 1 h, 1 – 3 h, 3 – 6 h, 6 – 24h	

3.2.8	Analytical method	LSC	
3.2.9	Other	Air sampling was conducted throughout the study.	
		4. RESULTS	
4.1	**Volatility from plants**	0.6%	
4.2	**Volatility from soil**	0.2%	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Volatilisation was tested in a wind-tunnel, in accordance with the BBA Guideline IV, 6-1. ^{14}C-benzyl-labelled deltamethrin was sprayed in blank formulation "Decis flüssig EC 2.5%" onto common beans (*Phaseolus vulgaris*) or on bare soil. During the experiment, the plants were at the flowering stage with 35-40 cm height and 80-90% ground cover. For the soil experiment, a silty sand with 0.5-1.3% OC was used. Before the experiment, the soil was sieved (≤2 mm) and soil moisture was adjusted to about 60% of the WHC. Immediately after application the treated containers with plants or bare soil were placed in the wind tunnel. Relative humidity was 37 and 43%, temperature 19.8-19.9°C, air velocity was 1.1 m/s and dark:light cycle 12:12. Air was drawn through polyurethane foam filter plugs, subsequently extracted with toluene. ^{14}C was determined by LSC at four intervals. After 24 h the plants were cut and rinsed with methanol before analysis. No complete mass balance was set up. Deltamethrin was shown to adsorb well to polyurethane foam and remaining ^{14}C was assumed to remain in/on plants or soil.	
5.2	**Results and discussion**	The amount applied was calculated as the difference between total amount applied and losses in spraying equipment. In the plant material the calculated application rate was 1.6 mg/m^2 or 16 g a.s./ha. For the soil trial, the application rate was 0.86 mg/m^2, or 8.6 g a.s./ha. Total volatilisation over 24 hours was calculated to 0.6% of applied amount to plants, and 0.2% of applied amount to bare soil. (Table A7.3.2-2)	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table 7.3.2-1 Soil Characteristics

Characteristics	Silty sand
Sand %	> 70
Organic Matter %	0.5 – 1.3

Table A7.3.2-2 Radioactivity Volatilised from Bean Plants and Soil in a Wind-Tunnel

Time (hours)	0 – 1	0 – 3	0– 6	0 – 24
Bean plants Volatilisation (% of applied activity)	0.1	0.2	0.5	0.6
Soil Volatilisation (% of applied activity)	< 0.1	0.1	0.1	0.2

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted
Conclusion	The total volatilisation over 24 hours was calculated to 0.6% of applied amount to plants, and 0.2% of applied amount to bare soil. The volatilisation of deltamethrin therefore seems negligible.
Reliability	1
Acceptability	The study is considered acceptable. Volatilisation of deltamethrin is regarded as negligible.
Remarks	No further remarks

7.4 Effects on aquatic organisms

7.4.1 Aquatic toxicity, initial tests

7.4.1.1 Acute toxicity to fish

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1986) Acute Toxicity of Deltamethrin to Rainbow Trout (*Salmo gairdneri*) [redacted] Document A70935 7.4.1.1/01 6 January 1986 Unpublished See Monograph 91/414 from 1998 – Point B.8.2.1	
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	
2.2	**GLP**	No, the study was conducted prior to the introduction of GLP as a standard requirement, but was conducted in line with good scientific practice.	
2.3	**Deviations**	No checking of the actual concentrations of deltamethrin was performed during the test	
		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	-	X
3.1.6	Method of analysis	Nominal concentrations used	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See Table A7.4.1.1-1	
3.3	**Reference substance**	None	

3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Dilution water	See Table A7.4.1.1-2	
3.4.2	Test organisms	Rainbow trout (*Salmo gairdneri*). See Table A7.4.1.1-3.	
3.4.3	Test system	See Table A7.4.1.1-4.	
3.4.4	Test conditions	See Table A7.4.1.1-5.	
3.4.5	Duration of the test	96 hours	
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	Not applicable	
3.4.8	Monitoring of TS concentration	No	
3.4.9	Statistics	Stephan *et al* computer program	X
		4. RESULTS	
4.1	**Limit test**	A preliminary test was performed	
4.1.1	Concentration	0.1, 1, 10 and 100 µg/l	
4.1.2	Number/ percentage of animals showing adverse effects	0.1 µg/l: 0 / 0% 1.0 µg/l: 4 / 80% 10.0 µg/l: 5 / 100% 100.0 µg/l: 5 / 100%	
4.1.3	Nature of adverse effects	Mortality	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	0.2, 0.40, 0.8, 1.6 and 3.2 µg/l	
4.2.2	Actual concentrations of test substance	Not measured	
4.2.3	Effect data (Mortality)	See Table A7.4.1.1-6	
4.2.4	Concentration / response curve	-	
4.2.5	Other effects	-	
4.3	**Results of controls**		
4.3.1	Number/percentage of animals showing adverse effects	0	
4.3.2	Nature of adverse effects	None	

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 static acute toxicity test rainbow trout (*Salmo gairdneri*) were exposed for 96 hours to deltamethrin (purity 99.3%) at nominal concentrations of 0, 0.20, 0.40, 0.80, 1.6 and 3.2 µg/l. Dimethylformamide was used as a solvent. Ten fish were exposed to each concentration and the control plus a solvent control. The mean fish weight was 0.49 ± 0.17 g and the mean standard length was 33 ± 3.4 mm. The glass aquarias contained 15 l and the loading was 0.32 g/l. The temperature was 11 – 13°C, the pH was 6.9 – 7.5, the dissolved oxygen was 8.0 – 9.7 mg/l (> 75% of saturation), and the hardness and the alkalinity were 40 – 45 and 30 – 35 mg/l as $CaCO_3$, respectively.	
5.2	**Results and discussion**	The 96-hour LC_{50} was 0.91 µg/l (0.66 – 1.3 µg/l, 95% CL), based on nominal concentrations. The NOEC was 0.20 µg/l (see Table A7-4.1.1-7)	
5.3	**Conclusion**		
5.3.1	Other conclusions	-	
5.3.2	Reliability	2	
5.3.3	Deficiencies	No	X

Table A7.4.1.1-1 Preparation of TS Solution for Poorly Stable or Volatile Test Substances

Criteria	Details
Dispersion	No
Vehicle	DMF
Concentration of vehicle	A 60 µg/ml standard was added to 0.05, 0.1, 0.2, 0.4 and 0.8 ml of DMF for final concentrations of 0.2, 0.4, 0.8, 1.6 and 3.2 a.s. µg/l.
Vehicle control performed	Yes
Other procedures	-

Table A7.4.1.1-2 Dilution Water

Criteria	Details
Source	Well water
Alkalinity (mg/l)	30 – 35
Hardness (mg/l)	40 – 45
PH	7.2
Oxygen content	9.7 (> 90% saturation)
Conductance	700 µmhos/cm
Holding water different from dilution water	-

Table A7.4.1.1-3 Test Organisms

Criteria	Details
Species/strain	Rainbow trout (*Salmo gairdneri*)
Source	Trout Lodge, USA
Wild caught	No
Age/size	Mean weight: 0.49 g. Mean size: 33 mm
Kind of food	Standard commercial fish food supplemented with brine shrimp
Amount of food	Not reported
Feeding frequency	Daily
Pretreatment	No
Feeding of animals during test	No

Table A7.4.1.1-4 Test System

Criteria	Details
Test type	Static
Renewal of test solution	No
Volume of test vessels	5 gallons (18.925 litres) containing 15 litres of water
Volume/animal	Loading mass of 0.32 g/l
Number of animals/vessel	10
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.1-5 Test Conditions

Criteria	Details
Test temperature	11 – 13°C
Dissolved oxygen (mg/l)	8.0 – 9.7 (> 75% saturation)
pH	6.9 – 7.5
Adjustment of pH	No
Aeration of dilution water	No
Intensity of irradiation	Not reported
Photoperiod	16 hours

Table A7.4.1.1-6 Mortality Data

Test-Substance concentration (nominal/) [µg/l]	Mortality					
	Number			Percentage		
	24 h	48 h	96 h	24 h	48 h	96 h
Control	0	0	0	0	0	0
Solvent control	0	0	0	0	0	0
0.2	0	0	0	0	0	0
0.4	0	0	1	0	0	10
0.8	3	4	4	30	40	40
1.6	3	6	8	30	60	80
3.2	10	10	10	100	100	100
Temperature [°C]	11	13	13	-	-	-
pH	7.2 – 7.5	6.9 – 7.0	7.1 – 7.2	-	-	-
Oxygen [mg/l]	9.6 –9.7	8.4 – 8.8	8.0 – 8.7	-	-	-

Table A7.4.1.1-7 Effect Data

	48 h [µg/l][1]	95% c.l.	96 h [µg/l][1]	95% c.l.
LC_0*	0.4	-	0.2	-
LC_{50}*	1.1	(0.82 – 1.6)	0.91	(0.66 – 1.3)
LC_{100}*	3.2	-	3.2	-

*: based on nominal concentration

Table A7.4.1.1-8 Validity Criteria for Acute Fish Test According to OECD Guideline 203

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	
Concentration of dissolved oxygen in all test vessels > 60% saturation	X	
Concentration of test substance ≥ 80% of initial concentration during test	-	
Criteria for poorly soluble test substances	X	

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **3.1.5** The water solubility of deltamethrin is <5µg/l and the log Kow is 4.6. **3.4.9** The computer program used for statistic calculations by Stephan et al. is from 1978. The LC_{50} was calculated using the binominal, the moving average, and the probit tests. The method selected for presentation was that which gave the narrowest confidence limits for the LC_{50}.
Conclusion	Applicant's version is adopted with the following comment: **5.3.3** One deficiency of the test was that no actual concentrations were measured, which makes the results uncertain.
Reliability	2 The test was performed according to recommended guidelines, but the lack of measured concentrations is considered a deficiency.
Acceptability	The study is acceptable as an indication of the acute toxicity of deltamethrin to fish based on nominal concentrations, with a 96-hour LC_{50} of 0.91 µg/l.
Remarks	No further remarks

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1990a) Acute Toxicity of Decis 2.5 EC (IS-002A) to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions [redacted] Document A47096 7.4.1.1/02 21 June 1990 Unpublished See Monograph 91/414 from 1998 – Point B.8.2.1	
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 72-1; OECD 203	X
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin formulated as a 2.5% EC	
3.1.1	Lot/Batch number	15X0205	
3.1.2	Specification	As given in Section formulated as a 2.5% EC	X
3.1.3	Purity	-	
3.1.4	Composition of product	Deltamethrin 24.8 g/l	
3.1.5	Further relevant properties	-	X
3.1.6	Method of analysis	GC-ECD (validated method)	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	-	X
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Dilution water	See Table A7.4.1.1-9.	

3.4.2	Test organisms	Rainbow Trout (*Oncorhynchus mykiss*). See Table A7.4.1.1-10.	
3.4.3	Test system	See Table A7.4.1.1-11.	
3.4.4	Test conditions	See Table A7.4.1.1-12.	
3.4.5	Duration of the test	96 hours	
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	Water samples from control and all treatment levels	
3.4.8	Monitoring of TS concentration	Yes (exposure Days 0 and 4).	
3.4.9	Statistics	Moving average angle analysis, probit analysis, nonlinear interpolation	X
		4. RESULTS	
4.1	**Limit test**		
4.1.1	Concentration	0.29, 0.45, 0.69, 1.1, 1.6, 2.5 µg as/l (nominal)	
4.1.2	Number/ percentage of animals showing adverse effects	0.29 µg/l: 40% 0.45 µg/l: 0% 0.69 µg/l: 0% 1.1 µg/l: 80% 1.6 µg/l: 80% 2.5 µg/l: 100%	
4.1.3	Nature of adverse effects	Mortality	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	0.29, 0.45, 0.69, 1.1, 1.6 and 2.5 µg as/l	
4.2.2	Actual concentrations of test substance	0.18, 0.17, 0.25, 0.40, 0.58, 0.97 µg as/l	
4.2.3	Effect data (Mortality)	See Table A7.4.1.1-13	
4.2.4	Concentration / response curve	See Figure A7.4.1.1-1.	
4.2.5	Other effects	-	
4.3	**Results of controls**		
4.3.1	Number/percentage of animals showing adverse effects	1 (5%)	
4.3.2	Nature of adverse effects	Not reported	
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 flow-through test rainbow trout (*Oncorhynchus mykiss*) were exposed for 96 hours to IS-002A, a formulation containing 24.8 g as/l as deltamethrin. The mean measured test concentrations were 0, 0.18, 0.17, 0.25, 0.40, 0.58 and 0.97 µg as/l. There were duplicate aquarias of 15 l containing ten fish for each concentration and the control. The renewal of test solution was approximately 6.4 aquarium volumes per day. The fish had a mean weight and length of 0.66 (0.54 – 0.86) g and 41 (38 – 47) mm, respectively. The loading was 0.44 g/1. The temperature was 12 – 13°C, the pH was 6.7 – 7.4, the dissolved oxygen concentration was > 9.0 mg/1 (> 83% saturation) and the hardness and alkalinity were 30 – 32 and 20 – 22 mg/1 as $CaCO_3$, respectively.	
5.2	**Results and discussion**	The 96-hour LC_{50} was 0.26 (0.24 – 0.29, 95% CL) µg as/l and the 96-hour NOEC was 0.17 µg as/l based on mean measured concentrations. The 72 h LC_{50} was 0.27 µg/l (0.24 – 0.30), while the 24- and 48-hour LC_{50} could not be determined (see Table A7.4.1.1-14).	
5.3	**Conclusion**		
5.3.1	Other conclusions		X
5.3.2	Reliability	1	
5.3.3	Deficiencies	No	

Table A7.4.1.1-9 Dilution Water

Criteria	Details
Source	Well water
Alkalinity (mg/l)	20 – 22
Hardness (mg/l)	25 – 27
pH	7.1 – 7.3
Oxygen content	9.0 – 9.4 mg/l (> 83% saturation)
Conductance	130 – 140 µmhos/cm
Holding water different from dilution water	No

Table A7.4.1.1-10 Test Organisms

Criteria	Details
Species/strain	Rainbow trout (*Onchorhynchus mykiss*)
Source	Mount Lassen Trout Farm, USA
Wild caught	No
Age/size	Mean weight: 0.66 g. Mean size: 41 mm
Kind of food	Dry commercial pelleted food
Amount of food	Not reported
Feeding frequency	Daily
Pretreatment	-
Feeding of animals during test	No

Table A7.4.1.1-11 Test System

Criteria	Details
Test type	Flow-through
Renewal of test solution	6.4 volume replacements/day
Volume of test vessels	15 l
Volume/animal	Loading mass of 0.069 g
Number of animals/vessel	10
Number of vessels/ concentration	2
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.1-12 Test Conditions

Criteria	Details
Test temperature	12 – 13°C
Dissolved oxygen (mg/l)	9.0 – 10.4 (> 83% saturation)
PH	6.7 – 7.4
Adjustment of pH	No
Aeration of dilution water	No
Intensity of irradiation	65 – 100 footcandles
Photoperiod	16 h light

Table A7.4.1.1-13 Mortality Data

Test-Substance concentration (measured) [µg/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
Control	0	0	0	1	0	0	0	5
0.17	0	0	0	0	0	0	0	0
0.18	0	0	6	6	0	0	30	30
0.25	0	0	9	10	0	0	45	50
0.40	0	0	18	18	0	0	90	90
0.58	0	0	20	20	0	0	100	100
0.97	1	7	20	20	5	35	100	100
Temperature [°C]	12	13	12	12	-	-	-	-
PH	6.7	7.1 – 7.4	6.9	6.8 – 6.9	-	-	-	-
Oxygen [mg/l]	10 – 10.4	9.8 – 10.4	10 – 10.6	9.0 – 9.4	-	-	-	-

Table A7.4.1.1-14 Effect Data

	48 h [µg/l][1]	95% c.l.	96 h [µg/l][1]	95% c.l.
LC_0*	0.58	-	0.17	-
LC_{50}*	> 0.97	-	0.26	0.24 – 0.29
LC_{100}*	-	-	0.58	-

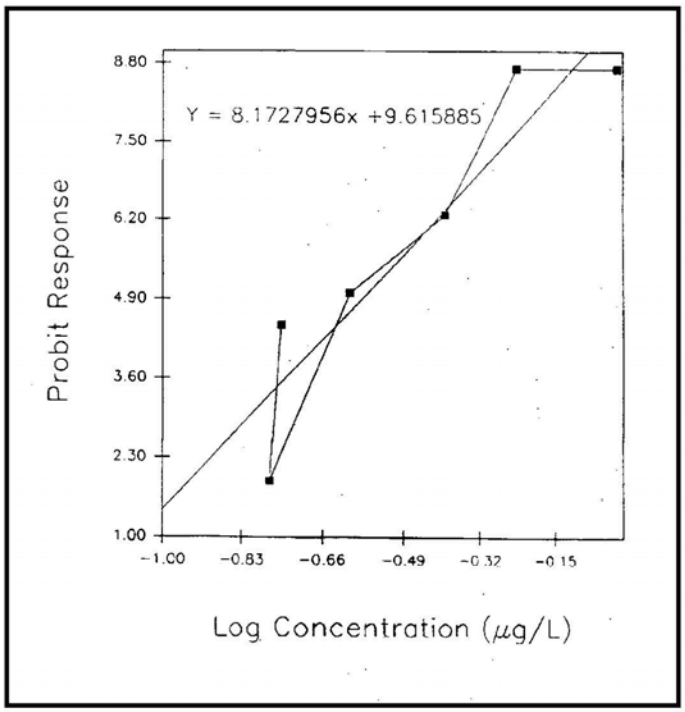
*: based on mean measured concentration of deltamethrin

Table A7.4.1.1-15 Validity Criteria for Acute Fish Test According to OECD Guideline 203

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	
Concentration of dissolved oxygen in all test vessels > 60% saturation	X	
Concentration of test substance ≥ 80% of initial concentration during test	X*	
Criteria for poorly soluble test substances	X	

*: Results based on mean measured concentration

Figure A7.4.1.1-1 96-Hour Concentration-Response Curve for Rainbow Trout (*Oncorhynchus mykiss*) Exposed to IS-002A



EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **3.1.2** The specification is as given in Section 2. **3.1.5** The water solubility of deltamethrin is <5µg/l and the log Kow is 4.6. **3.2** The product was dissolved in distilled water. **3.4.2** The test organisms were fed *ad libitum* and the frequency was daily, except 48 h prior to testing. **3.4.3** The loading mass was ≤ 0.069 g of biomass per liter. **3.4.9** The LC_{50} value was calculated with a computer program by Stephan (1977, 1982) and the method which yielded the smallest 95% confidence interval was selected.
Conclusion	Applicant's version is adopted with the following comment: **5.3.1** One conclusion that can be drawn is that there is a steep response from a NOEC of 0.17 µg/l to a LC_{50} of 0.26 µg/l.
Reliability	1
Acceptability	The study is acceptable and gives a 96h LC_{50} for deltamethrin for fish of 0.26 µg/l, based on mean measured concentrations.
Remarks	No further remarks

			Official use only
		1. REFERENCE	
1.1	**Reference**	Grau, R. and Maus, C. (2006) Position Paper: Aquatic Toxicity of Br_2CA, a Metabolite of Deltamethrin Bayer CropScience AG Document M-264711-01-1 7.4.1.1/03 16 January 2006 Unpublished	
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**	n.a.	
2.2	**GLP**	n.a.	
2.3	**Deviations**	n.a.	
		3. MATERIALS AND METHODS	
3.1	**Test material**		
3.1.1	Lot/Batch number	n.a.	
3.1.2	Specification	n.a.	
3.1.3	Purity	n.a.	
3.1.4	Further relevant properties	n.a.	
3.1.5	Radiolabelling	n.a.	
3.1.6	Method of analysis	n.a.	
3.2	**Reference substance**		
3.2.1	Method of analysis for reference substance	n.a.	
3.3	**Testing/estimation procedure**		
3.3.1	Test system / performance	QSAR modelling was used to predict the acute toxicity of the only major metabolite of deltamethrin, Br_2CA, to fish, daphnids and algae.	
3.3.2	Estimation of bioconcentration	n.a.	
		4. RESULTS	
4.1	**Experimental data**		

4.1.1	Acute toxicity	Predicted acute toxicity data are presented in Table A7.4.1.1-16.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	QSAR modelling was used to predict the acute toxicity of the only major metabolite of deltamethrin, Br_2CA, to fish, daphnids and algae.	
5.2	**Results and discussion**	Predicted acute toxicity data for Br_2CA are presented in Table A7.4.1.1-16. The data show that the predicted toxicity of Br_2CA to sensitive aquatic organisms is several orders of magnitude lower than the toxicity of the parent, deltamethrin.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

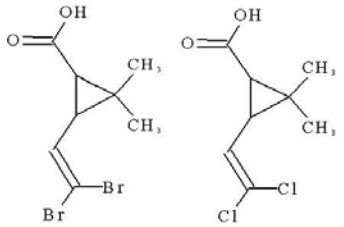
Table A7.4.1.1-16 Acute toxicity data predicted for Br_2CA on the basis of QSAR

Test organism	Endpoint	Value predicted by QSAR calculation (mg a.i./L)
Fish	LC_{50} (96 h)	10.4
Daphnia	EC_{50} (48 h)	84.9
Green algae	EC_{50} (96 h)	74.1

EVALUATION BY COMPETENT AUTHORITIES
EVALUATION BY RAPPORTEUR MEMBER STATE

Section 7 Annex Point IIA 7.1	**Ecotoxicological Profile Including Environmental Fate and Behaviour** A7.4.1.1 Acute toxicity to fish

Date	Not relevant
Materials and methods	Applicant's version is adopted. The following amendment was made on request during peer review: QSARs were performed using US EPAs ECOSAR module (v 0.99h) and the EPI-Suite program (v 3.20). ECOSAR uses SARs to predict the aquatic toxicity of chemicals based on their structural similarity to chemicals for which aquatic toxicity data is available. SARs express the correlations between a compound's physicochemical properties and its aquatic toxicity. SARs measured for one compound can be used to predict the toxicity of similar compounds belonging to the same chemical class. ECOSAR also allows access to over 100 SARs developed for 42 chemical classes. The SARs contained within the program are based on test data. Many of the SAR predictions have been validated. The program assigns the compound to be assessed to one or more chemical classes and uses the appropriate regression equation to calculate toxicity values for a range of organisms based on its lipophilicity (represented by the octanol-water partition coefficient). ECOSAR assigned Br_2CA to the chemical class of vinyl / allyl halides. The regression equations for vinyl / allyl halides used by ECOSAR are: - Log Fish 96-h LC50 (mmoles/L) = -0.367 - 0.657 log Kow (using ClogP) where n=12, R^2=0.55, log Kow < 5, MW<1000 - Log Daphnid 48-h LC50 (mmoles/L) = 2.328 - 1.218 log Kow (using ClogP) where n=5, R^2=0.96, log Kow < 5, MW<1000 - Log Green Algal 96-h EC50 (mmoles/L) = 0.860 - 0.775 log Kow (using ClogP) where n=1, R^2=n/a, log Kow < 6.4, MW<1000 For a closely related compound, DCVA, which differs from Br_2CA only in that the two Br atoms are replaced by Cl, measured toxicity values are available on all three standard species, fish, Daphnia and algae. With this close structural similarity, a "read-across" would suggest that toxicity of both compounds should be equivalent. To test the reliability of the QSAR calculation for Br_2CA, a similar calculation was performed on DCVA. The calculated results for DCVA were checked against measured values. This comparison revealed that calculated and measured values corresponded very well, indicating that the calculated results for Br_2CA can be deemed reliable. Therefore a defensible validation of the applied QSAR algorithm was provided and no further analysis should be required. **At TMI 2010, on MS** pointed out as a general remark, the need to be cautious when including these models in the CARs. In this specific case, looking to the three models provided, the model for fish seemed not to be appropriate (R^2=0.55) and in the algae model there is an insufficient number of data points.

	However they did not consider this as a major issue for the metabolite of Deltamethrin, since reliable experimental data was given by the applicant for another similar compound in with Cl instead of Br. Summarizing, **NO** suggested to include the information on the reliability of the models. TM agreed. Br_2CA DCVA 
Conclusion	Applicant's version is adopted
Reliability	1
Acceptability	The use of QSAR modelling for predicting the acute toxicity of the metabolite Br_2CA to fish is acceptable, and the 96h LC_{50} value is estimated to be 10.4 mg/l.
Remarks	No further remarks

7.4.1.2 Acute toxicity to invertebrates

			Official use only
		1. REFERENCE	
1.1	**Reference**	Putt, A.E. (1999) Deltamethrin (^{14}C-labelled) – Acute Toxicity to Daphnids (*Daphnia magna*) Under Flow-Through Conditions [redacted] Document C003959 7.4.1.2/01 13 May 1999 Unpublished See Addendum to the Monograph 91/414 from 2002 – Point B.8.2.1	
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; OECD 202	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Deltamethrin ^{14}C-benzyl label position	
3.1.1	Lot/Batch number	10562A	
3.1.2	Specification	As given in Section 2	
3.1.3	Purity	> 95%, specific activity of 57.83 mCi/mMole (2.14 GBq/mMole)	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	X
3.1.6	Method of analysis	Liquid Scintillation Counting (LSC). The method was validated.	X
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	The test material was received in toluene contained in sealed ampule. The ampule was opened and the solution was taken to incipient dryness under a gentle stream of nitrogen to remove the toluene. The contents of the ampoule were then quantitatively transferred to a volumetric flask (50.0 ml) via repetitive rinsing with acetone and brought to final volume. A 10 µg/ml diluter stock solution was prepared by adding 6.1 ml of the deltamethrin primary stock (82.73 µg/ml) to 50 ml of acetone.	
3.3	**Reference substance**	None	

3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Dilution water	See Table A7.4.1.2-2.	
3.4.2	Test organisms	See Table A7.4.1.2-3.	
3.4.3	Test system	See Table A7.4.1.2-4.	
3.4.4	Test conditions	See Table A7.4.1.2-5.	X
3.4.5	Duration of the test	48 hours	
3.4.6	Test parameter	Mortality/immobilisation	X
3.4.7	Sampling	0 and 48 hours	X
3.4.8	Monitoring of TS concentration	As above	
3.4.9	Statistics	Moving average angle analysis, probit analysis, nonlinear interpolation.	
		4. RESULTS	
4.1	**Limit test**		
4.1.1	Concentration	0.19, 0.32, 0.54, 0.90 and 1.5 µg/l (nominal)	
4.1.2	Number/ percentage of animals showing adverse effects	Control: 1 / 10% 0.19 µg/l: 0 / 0% 0.32 µg/l: 0 / 0% 0.54 µg/l: 3 / 30% 0.90 µg/l: 9 / 90% 1.5 µg/l: 9 / 90%	
4.1.3	Nature of adverse effects	Immobilisation, lethargy, on bottom of vessel	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	0.13, 0.22, 0.36, 0.61 and 1.0 µg/l (nominal)	
4.2.2	Actual concentrations of test substance	0.11, 0.15, 0.27, 0.49 and 1.3 µg/l	
4.2.3	Effect data	See Table A7.4.1.2-6	
4.2.4	Concentration / response curve	See Figure A7.4.1.2-1.	
4.2.5	Other effects	-	
4.3	**Results of controls**	There were no deaths in the negative or solvent control.	
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**	A flow-through acute toxicity test with *Daphnia magna* was performed, in accordance with OECD Guideline Test No. 202. Nominal concentrations were 0.13, 0.22, 0.36, 0.61 and 1.0 µg ^{14}C-deltamethrin/l. Two replicates were maintained for all treatments and solvent (acetone) and dilution water controls, with ten daphnids in each vessel. At 0 and 48 hours samples were analysed by LSC. The mean measured concentrations were 0.11, 0.15, 0.27, 0.49 and 1.3 µg/l (69 – 130% of nominal). Samples of the highest treatment level were also analysed by HPLC-RAM. The presence of another substance, presumably a metabolite, was indicated, accounting for approximately 25% of the radioactivity in the extracts.	
5.2	**Results and discussion**	Based on the mean measured concentrations, the 48-h EC_{50} was determined to be 0.56 µg/l (0.44 – 0.78, 95% CL), by probit analysis. 24-h EC_{50} was > 1.3 µg/l. Adverse effects (ie lethargy and on bottom of vessels) were observed among daphnids at all treatment levels. NOEC was therefore established as < 0.11 µg/l.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.4.1.2-1 Preparation of TS Solution for Poorly Stable or Volatile Test Substances

Criteria	Details
Dispersion	-
Vehicle	Acetone
Concentration of vehicle	6.1 ml deltamethrin stock solution/50 ml acetone
Vehicle control performed	Yes
Other procedures	-

Table A7.4.1.2-2 Dilution Water

Criteria	Details
Source	Fortified well water
Alkalinity (mg/l)	120
Hardness (mg/l)	180
pH	8.2
Oxygen content (mg/l)	8.2 – 9.5
Conductance	500 µmhos/cm
Holding water different from dilution water	No

Table A7.4.1.2-3 Test Organisms

Criteria	Details
Species/strain	*Daphnia magna*
Source	Laboratory cultures
Age	24 hours
Breeding method	Not reported
Kind of food	Unicellular green algae
Amount of food	4×10^7 cells/ml of algae
Feeding frequency	Once daily
Pretreatment	No
Feeding of animals during test	No

Table A7.4.1.2-4 Test System

Criteria	Details
Renewal of test solution	90% solution replacement rate of 6 h
Volume of test vessels	1.6 l
Volume/animal	Not reported
Number of animals/vessel	10
Number of vessels/ concentration	2
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.2-5 Test Conditions

Criteria	Details
Test temperature	20 – 21°C
Dissolved oxygen (mg/l)	8.2 – 9.5 (92 – 107% saturation)
pH	7.9 – 8.1
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	80 – 100 footcandles
Photoperiod	16 h light

Table A7.4.1.2-6 Immobilisation Data

Test-Substance concentration (measured) [µg/l]	Immobile *Daphnia*				Oxygen [mg/l]	pH	Temperature [°C]
	Number		Percentage				
	24 h	48 h	24 h	48 h	48h	48 h	48 h
Control	0	0	0	0	9.4	8.1	21
Solvent control	0	0	0	0	8.9	8.0	21
0.11	0	1	0	5	8.7 – 8.9	8.0	21
0.15	0	0	0	0	9.0 – 9.1	8.0	21
0.27	1	5	5	25	9.0	8.0	21
0.49	0	6	0	30	8.9	8.0	21
1.3	9	18	45	90	8.8 – 9.0	8.0	21

Table A7.4.1.2-7 Effect Data

	EC_{50}[1]	95% c.l.	NOEC[1]	EC_{100}[1]
24 h [µg/l]	> 1.3	-	0.15	> 1.3
48 h [µg/l]	0.56	0.44 – 0.78	< 0.11	> 1.3

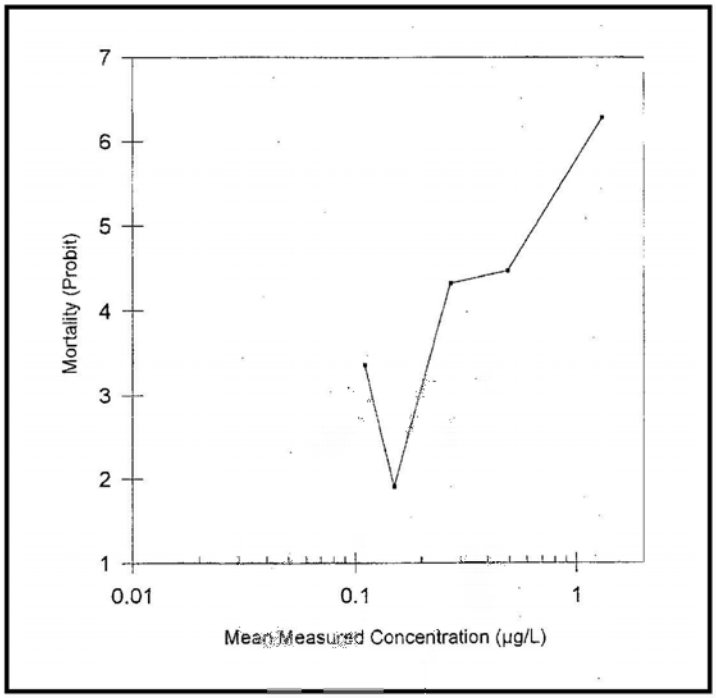
[1] based on measured concentrations

Table A7.4.1.2-8 Validity Criteria for Acute *Daphnia* Immobilisation Test According to OECD Guideline 202

	Fulfilled	Not fulfilled
Immobilisation of control animals < 10%	X	
Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels > 3 mg/l	X	
Concentration of test substance ≥ 80% of initial concentration during test	X*	
Criteria for poorly soluble test substances	X	

* results based on measured concentration

Figure 7.4.1.2-1 The 48-hour Concentration-Response (Mortality) Curve for Daphnids (*Daphnia magna*) Exposed to Deltamethrin Under Flow-Through Conditions During the Definitive Exposure



EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	Not relevant
Materials and methods	Applicant's version is adopted with the following comments: **3.1.6** The highest treatment was also analysed using HPLC-RAM (radio-chemical detection). **3.4.2** The test organisms were from a laboratory culture at Springborn, and the kind of food was green algae of the species *Ankistrodesmus falcatus*. The concentration of algae was 4 x10^7 cells/ml in the food solution. **3.4.4** The pH ranged between 7.9 and 8.1, which is within the limit when hydrolysation of deltamethrin can occur. **3.4.6** The daphnids were defined as immobile if no movement within the water column occurred after gentle prodding. **3.4.7** The number of immobilized daphnids was recorded at 24 and 48 hours.
Results	Applicant's version is adopted with the following comment: **4.2.4** In Figure 7.4.1.2-1, the defined response is mortality, instead of immobilisation. This is also the case in the study report, and it causes some confusion. However, the effect concentration given is based on immobilisation and therefore this is regarded as the response variable.
Conclusion	Applicant's version is adopted with the following comments: **5.2** According to the study report, the HPLC-RAM analysis indicated the presence of an additional radiolabelled substance, probably a degradation product of deltamethrin, in the solution. This material accounted for approximately 25% of the radioactivity. Therefore, the exposure concentrations of deltamethrin may have been about 25% lower than the measured concentrations, but this has not been taken into account when presenting the effect concentrations. However, RMS finds the EC_{50} based on mean measured concentrations acceptable.
Reliability	1
Acceptability	The study is considered acceptable and the estimated EC_{50} of deltamethrin to *Daphnia magna* is 0.56 µg/l.
Remarks	It appears a bit strange that the EC_{50} value for Daphnia is higher than the LC_{50} for fish, but since there are lower effect concentrations used in the risk assessment, this is not further investigated by RMS.

			Official use only
		1. REFERENCE	
1.1	**Reference**	Putt, A.E. (2000a) Decis EC 25 g/l – Acute Toxicity to Gammarids (*Gammarus fasciatus*) Under Flow-Through Conditions [redacted] Document C006608 7.4.1.2/02 7 January 2000 Unpublished See Addendum to the Monograph 91/414 from 2002 – Point B.8.2.1	
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 (draft test guideline OPPTS 850-1020)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	X
3.1	**Test material**	Deltamethrin formulated as a 25 g/l EC and radiolabelled in the ^{14}C-benzyl position	
3.1.1	Lot/Batch number	X10562A (radiolabelled), 7CD11324 (EC formulation)	
3.1.2	Specification	As given in Section 2	
3.1.3	Purity	Radiochemical purity: 96.4%, specific activity of 57.83 mCi/mMole	
3.1.4	Further relevant properties	-	
3.1.5	Radiolabelling	^{14}C-benzyl position	
3.1.6	Method of analysis	Water samples were extracted with hexane then analysed by LSC. The method was validated with recoveries averaging 95.0 ± 4.6% with a minimum detection limit of 0.000138 µg/l.	
3.2	**Reference substance**	None	
3.2.1	Method of analysis for reference substance	Not applicable	
3.3	**Testing procedure**		
3.3.1	Dilution water	See Table A7.4.1.2-9.	
3.3.2	Test organism	See Table A7.4.1.2-10.	
3.3.3	Test system	See Table A7.4.1.2-11.	