		Duplicate samples of each soil type were removed from the incubation system at ten intervals during the 26-week incubation period (0, 1, 3, days, 1, 2, 4, 8, 13, 19 and 26 weeks). The remaining two samples/soil type were kept as spares. At sampling, the soils were transferred to cellulose thimbles and soxhlet extracted first with dichloromethane followed by extraction with acetonitrile:water (80:20 v/v). The radioactivity in the solvent was quantified by LSC. The dichloromethane extracts were concentrated to 3-5 ml for analysis and quantification by thin layer chromatography (TLC) against authentic reference standards. The combined supernatants of representative samples of acetonitrile extracts were analysed by TLC and HPLC against authentic reference standards. Extracted soil samples were combusted using a Packard 307 sample oxidiser. The $^{14}CO_2$ released was adsorbed into 'Carbosorb' mixed with scintillant and quantified by L.S.C. These data were used to calculate the percentage of radioactivity 'bound' to the soil. Portions (10 g) of dried and milled soils incubated for 26 weeks and previously extracted with acetonitrile : water (80:20) were further extracted and radioactivity in the fulvic and humic acid fractions was quantified by LSC.	
3.3	**Reference substance**	Unlabelled bendiocarb and the metabolites NC 7312 and pyrogallol were used as authentic reference substances.	
3.3.1	Method of analysis for reference substance	TLC and HPLC. Radioactivity was quantified by LSC.	
3.4	**Soil types**	Sandy loam and a silty clay loam See Table A7.2.1-1	
3.5	**Testing procedure**		
3.5.1	Test systems	Two soils, a sandy loam and a silty clay loam were used in this study (see Table A7.2.1-1). The soils which came from sites free of previous pesticide treatment were used within two weeks of collection. The soils were sampled to a depth of 15 cm after removal of surface vegetation. The soils were passed through a 2 mm sieve, then stored in plastic buckets with aluminium foil covers at 25°C until used (within two weeks of collection).	

3.5.2	Test solution and Test Conditions	The treatment solution was prepared by dissolving [^{14}C]-bendiocarb (ca. 10 mg) and unlabelled bendiocarb (ca. 110 mg) in acetone (ca. 35 ml). The specific radioactivity of the treatment solution was determined by high performance liquid chromatography (HPLC). Aliquots of moist soil (100 g dry weight equivalent) were weighed into 250 ml Erlenmeyer flasks. Twenty two flasks per soil type were treated with [^{14}C]-bendiocarb (1.880 mg (ca. 15 µCi)/flask, equivalent to 3.71 kg ai/ha). The acetone was allowed to evaporate and the soil gently agitated to incorporate the compound. Similarly, five flasks per soil type were treated with unlabelled bendiocarb (1.684 mg/flask, equivalent to 3.32 kg ai/ha) for determination of soil microbial biomass after 26 weeks incubation. Following application of bendiocarb the moisture content of each soil sample was adjusted to 40 % of its water holding capacity with distilled water. Flasks were incubated in the dark at 25°C ± 2°C, in an enclosed system, through which a continuous stream of CO_2-free air was passed to maintain aerobic conditions. Carbon dioxide was removed by passing the incoming air through 1N sodium hydroxide solution and the air moistened by passing through distilled water. The effluent air stream from each flask was passed through an ethanediol and ethanolamine trap. The moisture content of the soil was checked at up to six weekly intervals and adjusted as required by addition of distilled water.	
		4. RESULTS	
4.1	**Degradation product(s)**	Bendiocarb was rapidly degraded in both soil types. The times for 50 % and 90 % degradation of bendiocarb (DT_{50} and DT_{90} values) were calculated to be 1.1 days and 5.5 days in the sandy loam soil and 3.5 days and 11.7 days in the silty clay loam soil. The primary degradation product was NC 7312 (2,2-dimethyl-1,3-benzodioxol-4-ol) arising from hydrolysis of the parent compound. However this component represented up to only 2 % of applied radioactivity. Subsequent rapid breakdown resulted in the formation of the natural product pyrogallol together with other unidentified polar metabolites, each of which accounted for less than 0.5 % of applied radioactivity.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The degradation of [^{14}C]-bendiocarb (2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate) in soil was investigated under laboratory conditions using a sandy loam and a silty clay loam soil incubated in the dark at 25°C and 40 % soil moisture holding capacity. Soil samples were treated with [^{14}C]-ring labelled bendiocarb at a rate of 3.71 kg ai/ha (dissolved in acetone). Treated soils were incubated under aerobic conditions in a stream of CO_2-free air for up to 26 weeks. At intervals during incubation soil samples were extracted with dichloromethane followed by acetonitrile + water (80+20, by vol) and the proportions of [^{14}C]- degradation products were determined. Radioactivity remaining bound to the soil was quantified by combustion. Radiolabelled volatile products were collected in ethanediol and ethanolamine traps.	
5.2	**Results and discussion**	Recoveries of applied radioactivity averaged 96.3 % and 97 % for sandy loam and silty clay loam soils respectively.	

		Bendiocarb was rapidly degraded in both soil types. The times for 50 % and 90 % degradation of bendiocarb (DT_{50} and DT_{90} values) were calculated to be 1.1 days and 5.5 days in the sandy loam soil and 3.5 days and 11.7 days in the silty clay loam soil (see Appendix A7.2.1-1). The primary degradation product was NC 7312 (2,2-dimethyl-1,3-benzodioxol-4-ol) arising from hydrolysis of the parent compound. However this component represented up to only 2 % of applied radioactivity. Subsequent rapid breakdown resulted in the formation of the natural product pyrogallol together with other unidentified polar metabolites, each of which accounted for less than 0.5 % of applied radioactivity. Further degradation resulted in the formation of unextractable 'bound' residues (ca. 45 % after 26 weeks) and approximately 55 % of the applied radioactivity was mineralised to $^{14}CO_2$ in the same time period. Bendiocarb is very short lived in soil. No major metabolites are likely to accumulate due to the rapid degradation of the hydrolysis product NC 7312. Degradation of NC 7312 via the natural product pyrogallol and its oxidation products results in the formation of soil bound residues and substantial mineralization to carbon dioxide.	
5.3	**Conclusion**		
5.3.1	Reliability	2	
5.3.2	Deficiencies	No	

Table A7.2.1-1 Classification and Physico-Chemical Properties of Soils Used

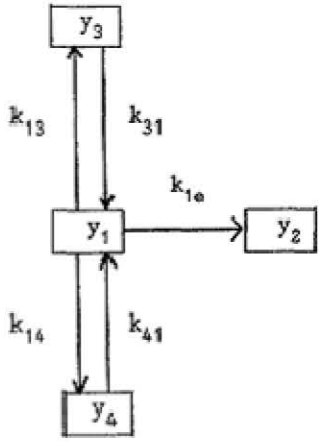
	Soil 1	Soil 2
Soil order	Abington	Terling
Soil series	-	-
Classification	Sandy loam	Silty clay loam
Location	Land Settlement nr. Great Abington, Cambridgeshire, UK. OS TL 518475	Terling Hall, nr. Hatfield Peverel, Essex, UK. OS TQ 774135
Horizon	-	-
Sand [%]	67	15
Silt [%]	19	57
Clay [%]	14	28
Organic carbon [%]	3.2	6.2
Carbonate as $CaCO_3$ (g/kg)	95	<5
insoluble carbonates [%]	-	-
pH (1:1 H_2O)	7.52	7.28
Cation exchange capacity (MEQ/100 g)	12.0	25.4
Extractable cations (MEQ/100 g)		
Ca	-	-
Mg	-	-
Na	-	-
K	-	-
H	-	-
Special chemical/mineralogical features	-	-
Clay fraction mineralogy	-	-

Appendix A7.2.1-1 Rate of bendiocarb and bound residue degredation

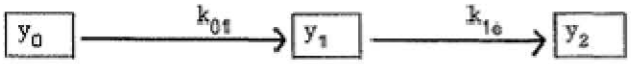
In order to determine the times for 50% (DT50) and 90% (DT90) dissipation of bendiocarb and its 'bound' residues in soil the data have been analysed using multi-compartment models (TOPFIT version IBM.1.57E). The models used can be described as follows:

Bendiocarb degradation in Terling soil (1 compartment model)

Bendiocarb degradation in Abington soil (3 compartment model)



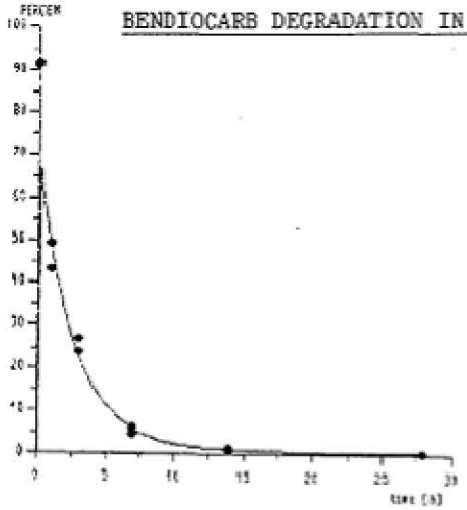
Formation and decline of 'bound' residue in Abington and Terling soils (1 compartment model)



Where y_1 is the concentration of compound available for degradation, y_2 is the concentration of degradation products, y_3 and y_4 are the concentrations of compound in unavailable pools and y_0 is the compound(s) being degraded to form compound y_1 and k_{1e}, k_{13}, k_{31}, k_{14}, k_{41} and k_{01} are first order rate constants.

The 1 compartment models assume simple first order kinetics but the multi-compartment model assumes that following addition of a chemical to soil or its formation following degradation of another, it is all available for degradation, which, in many cases, is shown by a rapid initial degradation. However, chemical is also passing into 'unavailable' compartments where it is not available for degradation. Eventually, the system will reach a steady state condition where decomposition will proceed at a rate that is determined by the reservoir of available chemical maintained by the reservoirs of unavailable chemical.

The results for this study are as follows:



BENDIOCARB DEGRADATION IN ABINGTON SOIL

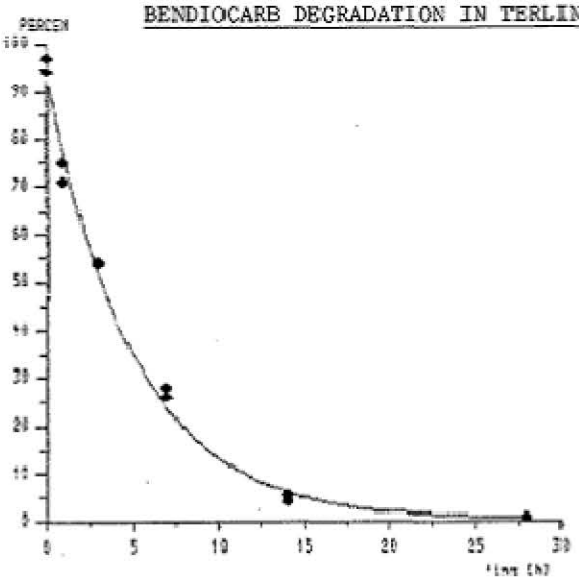
Rate constants	Value	Half-life time (days)
k_{1e}	0.2045	3.4
k_{13}	5.5825	0.12
k_{31}	14.05	0.049
k_{14}	0.3098	2.2
k_{41}	0.0025	274

Model values

time	data	model
0.01	91.1	91.4
0.01	91.7	91.4
1.00	49.2	47.1
1.00	42.6	47.1
3.00	26.7	22.8
3.00	24.0	22.8
7.00	4.1	5.5
7.00	5.7	5.5
14.00	0.8	0.7
14.00	0.6	0.7
28.00	0.3	0.3
28.00	0.3	0.3

Disappearance times (days)

	%	model	time
DT90→	10	9.6	5.39
	20	19.3	3.46
	30	28.9	2.34
	40	38.5	1.55
DT50→	50	48.1	0.94
	60	57.8	0.44
	70	67.4	0.12
	80	77.0	0.05
	90	86.6	0.02



Rate constants	Value	Half-life time (days)
k_{1e}	0.1974	3.5

Model values

time	data	model
0.01	97.0	93.7
0.01	93.9	93.7
1.00	74.7	77.1
1.00	79.9	77.1
3.00	53.7	51.9
3.00	53.8	51.9
7.00	27.5	23.6
7.00	25.9	23.6
14.00	4.0	5.9
14.00	5.5	5.9
28.00	0.5	0.4
28.00	0.6	0.4

Disappearance times (days)

	%	model	time
DT90→	10	9.4	11.66
	20	18.8	8.15
	30	28.2	6.10
	40	37.6	4.64
DT50→	50	47.0	3.51
	60	56.3	2.59
	70	65.7	1.81
	80	75.1	1.13
	90	84.5	0.53

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	03/01/07 **2.1** Inhouse method used, inline with US EPA, reference not given for comparison. UK CA has assumed it to be US EPA 162 – 1. **2.3** Does not make it clear if these are deviations from their in house method or the guideline mentioned. However, the study presented has been evaluated and found to be acceptable to the UK CA.
Materials and methods	Applicant's version is acceptable with the following comments: **3.1.4** Physico – chemical properties such as water solubility (0.28 g/l at pH 7) etc should have been included in the summary.
Conclusion	Applicant's version is acceptable
Reliability	2
Acceptability	Acceptable
Remarks	Study and endpoints robust for use in risk assessments. All endpoints transcribed from study correctly.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

			Official use only
		1. REFERENCE	
1.1	**Reference**	Allen, R. (1989) The Volatilisation of [^{14}C]-Bendiocarb from Soil under Laboratory Conditions Schering Agrochemicals Ltd. Document A90224 7.2.1/02 30 October 1989 Unpublished	X
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**	In house method in line with US EPA Guideline	X
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3. MATERIALS AND METHODS	
3.1	**Test material**	Unlabelled bendiocarb: Turcam 76WP (80 % water dispersible powder formulation used to treat turf in USA against surface and sub-surface insect pests) (^{14}C)-bendiocarb (labelled in the phenyl ring)	X
3.1.1	Lot/Batch number	Unlabelled bendiocarb CR 4944/13 (^{14}C)- bendiocarb CFQ 4944 (Amersham International plc)	
3.1.2	Specification	Unlabelled bendiocarb: 77.5-82.5 % bendiocarb (^{14}C)- bendiocarb (specific activity 102.7 µCi/mg)	
3.1.3	Purity	Unlabelled bendiocarb: not specified (^{14}C)- bendiocarb >96 % (TLC)	
3.1.4	Further relevant properties	-	X
3.1.5	Method of analysis	unlabelled bendiocarb: HPLC (^{14}C)- bendiocarb: TLC and LSC	
3.2	**Degradation products**	Yes	
3.2.1	Method of analysis for degradation products	At intervals during the study and when soil flasks were removed for analysis the polyurethane foam plugs and the liquid trapping solutions were replaced with fresh materials. Radioactivity in those removed was quantified by liquid scintillation counting (LSC).	

		Preliminary studies had shown that [^{14}C]-bendiocarb could be readily extracted from the polyurethane foam using dichloromethane, without significant degradation of the compound. The foam plugs were therefore extracted with cold dichloromethane (90 ml) using a soxhlet extractor to act as a siphon. The extracts were combined and made up to 100ml prior to sampling by LSC. The trapping solutions ethanediol, acid and ethanolamine were analysed directly by LSC. The soil samples were soxhlet extracted in cellulose thimbles with 250ml of dichloromethane followed by 250ml of acetonitrile : water (80:20 v/v). The liquid extracts were transferred to volumetric flasks and sub-samples (1.0ml) taken for LSC. Portions of dichloromethane extracts (50 – 100ml) and acetonitrile:water extracts (100ml) from both replicates of each soil/incubation regime at each sampling time were concentrated by rotary evaporation at a temperature of 30°C under reduced pressure, to near dryness. The residues were dissolved in dichloromethane or acetonitrile:water (3-5ml) for analysis by thin layer chromatography (TLC) and high performance liquid chromatography (HPLC) against authentic reference standards. Extracted soil samples were combusted using a Packard 306 sample oxidiser. The $^{14}CO_2$ released was adsorbed into 'Carbosorb' mixed with scintillant and quantified by LSC. These data were used to calculate the percentage of radioactivity 'bound' to the soil.	
3.3	**Reference substance**	Unlabelled bendiocarb and the metabolites NC 7312 and pyrogallol were used as authentic reference substances.	
3.3.1	Method of analysis for reference substance	TLC and HPLC. Radioactivity was quantified by LSC.	
3.4	**Soil types**	Sand See Table A7.2.1-2	
3.5	**Testing procedure**		
3.5.1	Test systems	The soil, a sand with low organic matter content, was collected fresh from the field, from a site free of previous pesticide treatment. The soils were sampled to a depth of 15cm after removal of the surface vegetation. The moist soil was passed through a 2mm sieve and stored in plastic buckets with loose foil covers at 15°C ± 2°C until used (within 7 days of collection).	
3.5.2	Test solution and Test Conditions	Samples of moist soil (100g dry soil equivalent) were weighed into 250ml volume Erlenmeyer flasks and treated with [^{14}C]-bendiocarb as Turcam$^{(R)}$ 76WP. The application rate was equivalent to a direct overspray of 4 lb product/120 US gallons/acre (3.2 lb a.i./acre; 3.6kg a.i./ha). [^{14}C]-Bendiocarb was formulated with Turcam 76WP and diluted with tap water. Approximately 1.8mg of [^{14}C]-bendiocarb (2.2mg of product) was applied in 545µl of diluted formulation to the surface of each soil sample.	

		Immediately after treatment, the flasks were adjusted for moisture content using distilled water, connected to the incubation system and incubated at one of two temperatures (15°C ± 2°C, 30°C ± 2°C), two moisture contents (20 % and 60 % at both temperatures) and two flow rates (1 L/min at 15°C and 30°C and 0.1L/min at 30°C). Duplicate samples were also taken for extraction approximately 2 hours after treatment. Carbon dioxide-free moist air was passed over the surface of the soils in the flasks. The effluent air stream from each flask was passed through a polyurethane foam plug followed by ethanediol, acid (0.1M H_2SO_4) and ethanolamine. The air flow rate was monitored and adjusted daily using Platon flowbits flow meters. In order to ensure measurement was conducted at atmospheric pressure the flow meters were connected to the outlet of the ethanolamine traps. The moisture content of soils was also checked regularly and adjusted, if necessary, by the addition of distilled water.	
		4. RESULTS	
4.1	**Degradation product(s)**	Bendiocarb was rapidly degraded in soil; times for 50 % and 90 % degradation varied from 0.5 to 5.0 days and from 1.6 to 19.5 days respectively. The principal degradation product resulting from hydrolysis of the parent compound was NC 7312 (2,2-dimethyl-1,3-benzodioxol-4-ol) (up to 14 % of applied radioactivity after 2 hours). This was further degraded leading to the natural product pyrogallol (up to 2.0 % at day 1) and to the formation of unextractable 'bound' residues (ca. 55-65 % of applied radioactivity after 21 days) and $^{14}CO_2$ (ca. 20-35 % after 21 days).	X
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The volatilisation of [^{14}C]-bendiocarb (2,2-dimethyl-1 ,3-benzodioxol-4-yl methylcarbamate) from a soil surface has been investigated under laboratory conditions using a sandy soil (<1.5 % organic matter) at two incubation temperatures (30°C and 15°C) and different moisture contents and air flow rates. Soil samples at 20 % and 60 % moisture holding capacity were treated with [^{14}C] ring-labelled bendiocarb prepared as the TurcamW 76WP formulation at a rate equivalent to 3.2 lb ai/acre (3.6 kg ai/ha). Treated soils were incubated in darkness for up to 21 days during which time they were continuously purged with carbon dioxide free moist air at either 1.0 L/min or 0.1 L/min. Radiolabelled volatile products evolved were collected in a series of traps consisting of a polyurethane foam plug, ethanediol, acid and ethanolamine. At various time intervals during incubation soil samples were extracted with solvents and the proportions of [^{14}C] –degradation products determined. Radioactivity remaining bound to the soil was quantified by combustion.	
5.2	**Results and discussion**	Recoveries of applied radioactivity averaged between 91.5 % and 97.8 % for the different incubation regimes.	

		Less than 1 % of applied radioactivity was evolved as [^{14}C]-bendiocarb or its degradation products from soil regardless of incubation conditions. Bendiocarb was rapidly degraded in soil; times for 50 % and 90 % degradation varied from 0.5 to 5.0 days and from 1.6 to 19.5 days respectively. The principal degradation product resulting from hydrolysis of the parent compound was NC 7312 (2,2-dimethyl-1,3-benzodioxol-4-ol) (up to 14 % of applied radioactivity after 2 hours). This was further degraded leading to the natural product pyrogallol (up to 2.0 % at day 1) and to the formation of unextractable 'bound' residues (ca. 55-65 % of applied radioactivity after 21 days) and $^{14}CO_2$ (ca. 20-35 % after 21 days).	
5.3	**Conclusion**		
5.3.1	Reliability	2	
5.3.2	Deficiencies	No	

Table A7.2.1-2 Classification and Physico-Chemical Properties of Soils Used

	Soil low temperature experiment	Soil high temperature experiment
Soil order	Icklingham	Icklingham
Soil series	-	-
Classification	sand	sand
Location	Weatherhill Farm, Nr. Icklingham, Suffolk, U.K. Ordnance Survey Map Reference TM 785 723	Weatherhill Farm, Nr. Icklingham, Suffolk, U.K. Ordnance Survey Map Reference TM 785 723
Horizon	-	
Sand [%]	89	90
Silt [%]	6	5
Clay [%]	5	5
Organic matter [%]	1.4	1.4
Carbonate as $CaCO_3$ (g/kg)	60	60
insoluble carbonates [%]	-	
pH (1:1 H_2O)	7.1	7.3
Cation exchange capacity (MEQ/100 g)	7.1	4.3
Extractable cations (MEQ/100 g)		
Ca	-	-
Mg	-	-
Na	-	-
K	-	-
H	-	-
Special chemical/mineralogical features	-	-
Clay fraction mineralogy	-	-

Appendix A7.2.1-2 Information regarding recovery rate of radioactivity for the different systems:

Recovery of radioactivity in soil incubated at 15°C, 20% moisture holding capacity and an air flow rate of 1.0 L/min

	Percentage of applied radioactivity									
	Day 0 (2h)		Day 1		Day 3		Day 9		Day 21	
Sample No.	1601	1602	1603	1604	1605	1606	1607	1608	1609	1610
Total	100.3	100.6	98.0	96.5	95.6	95.7	94.7	89.9	94.2	109.4
Overall mean	97.5									

Recovery of radioactivity in soil incubated at 15°C, 60% moisture holding capacity and an air flow rate of 1.0 L/min

	Percentage of applied radioactivity									
	Day 0 (2h)		Day 1		Day 3		Day 9		Day 21	
Sample No.	1611	1612	1613	1614	1615	1616	1617	1618	1619	1620
Total	99.1	96.4	96.7	96.5	90.7	95.4	99.3	99.4	105.2	99.3
Overall mean	97.8									

Recovery of radioactivity in soil incubated at 30°C, 20% moisture holding capacity and an air flow rate of 1.0 L/min

	Percentage of applied radioactivity									
	Day 0 (2h)		Day 1		Day 3		Day 9		Day 21	
Sample No.	2701	2702	2703	2704	2705	2706	2707	2708	2709	2710
Total	94.6	95.5	94.5	103.0	89.8	87.6	88.5	76.4	94.7	90.7
Overall mean	91.5									

Recovery of radioactivity in soil incubated at 30°C, 60% moisture holding capacity and an air flow rate of 1.0 L/min

	Percentage of applied radioactivity									
	Day 0 (2h)		Day 1		Day 3		Day 9		Day 21	
Sample No.	2711	2712	2713	2714	2715	2716	2717	2718	2719	2720
Total	90.7	95.4	99.7	94.3	88.8	87.5	67.3	92.4	94.3	92.2
Overall mean	92.8 (excluding sample 2717)									

Recovery of radioactivity in soil incubated at 30°C, 60% moisture holding capacity and an air flow rate of 0.1 L/min

	Percentage of applied radioactivity									
	Day 0 (2h)		Day 1		Day 3		Day 9		Day 21	
Sample No.	2721	2722	2723	2724	2725	2726	2727	2728	2729	2730
Total	96.2	97.0	90.0	94.5	94.0	82.5	98.4	108.0	99.9	98.9
Overall mean	95.9									

As indicated on page 25 of the study report "The times for 50% (DT50) and 90% (DT90) decomposition of bendiocarb were stimated from Figures 3 to 7 and are given in Table 8.

Figures 3-7 and Table 8 are presented below:

Figure 3. Degradation of bendiocarb at 15 degrees C and 20% MHC

Regime A

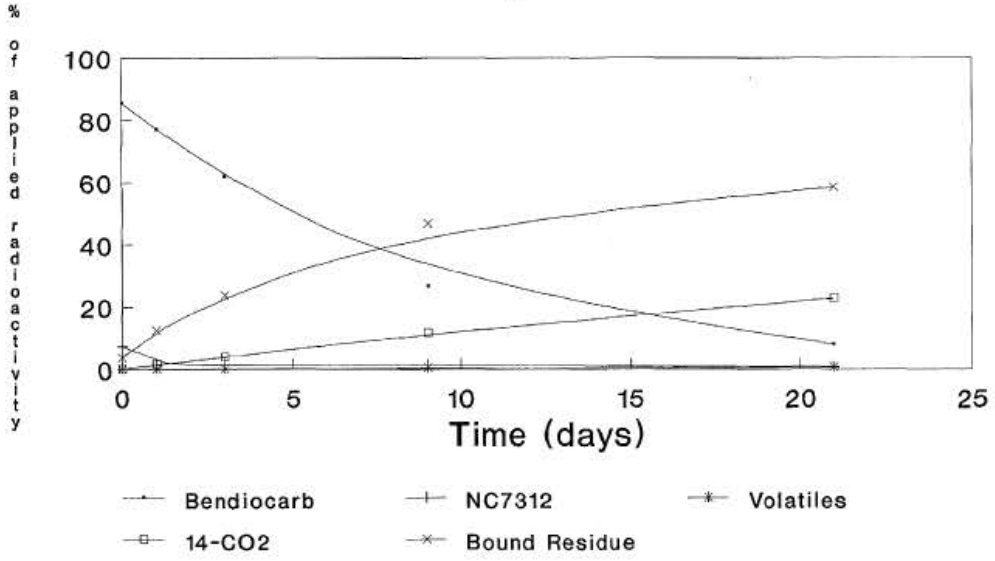


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Figure 4. Degradation of bendiocarb at 15 degrees C and 60% MHC
Regime B

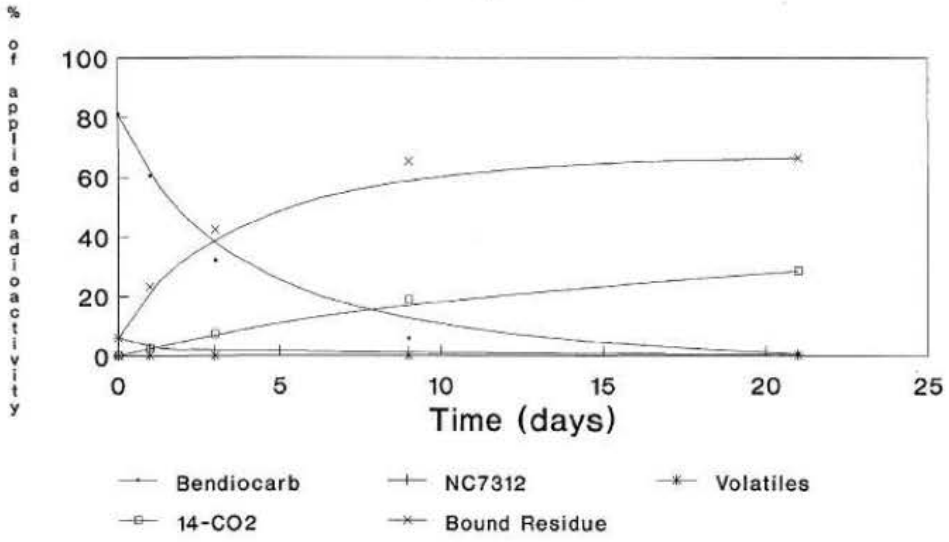

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Figure 5. Degradation of bendiocarb at 30 degrees C, 20% MHC and 1.0L/min
Regime C

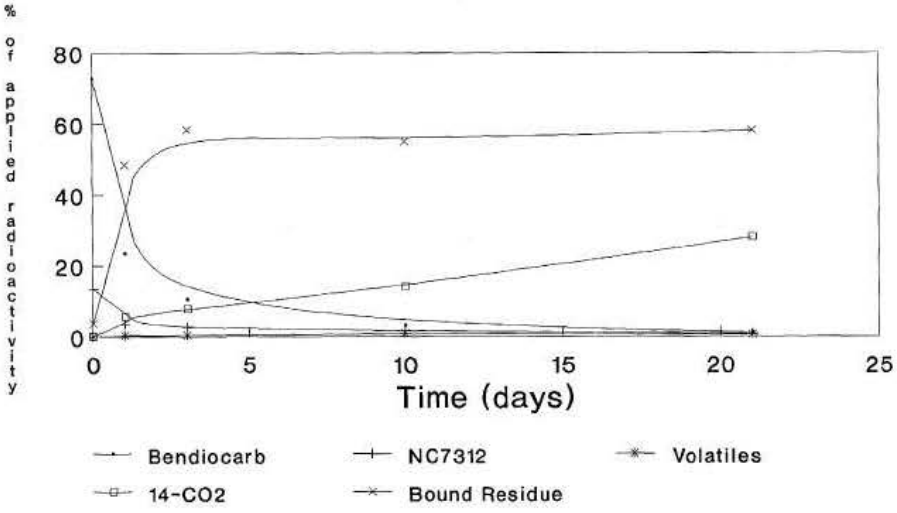

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Figure 6. Degradation of bendiocarb at 30 degrees C, 60% MHC and 1.0L/min
Regime D

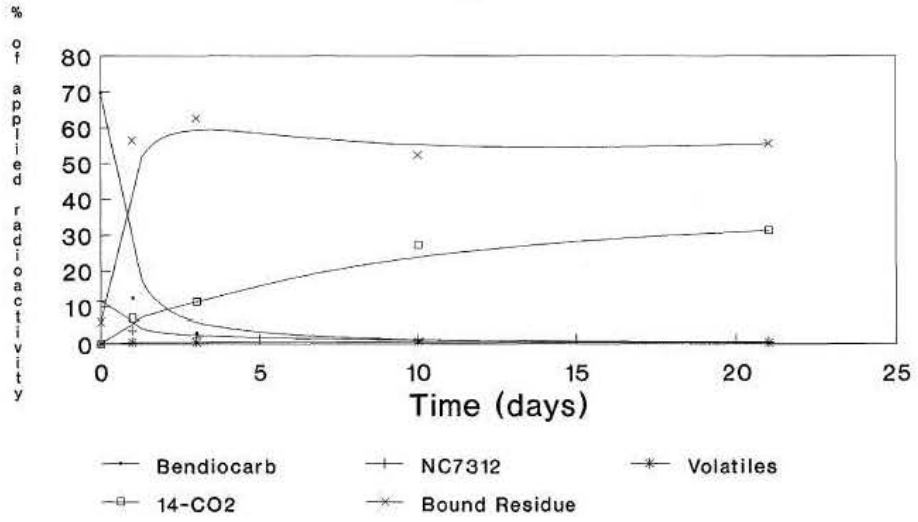

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Figure 7. Degradation of bendiocarb at 30 degrees C, 60% MHC and 0.1L/min
Regime E

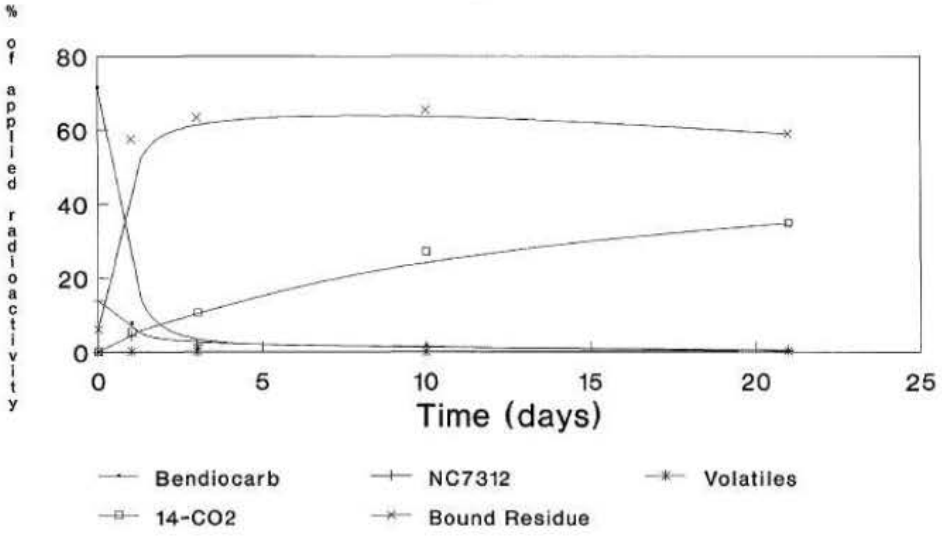

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Table 8

DT50 and DT90 values estimated from Figures 3 to 7

Incubation Regime	DT50 (Days)	DT90 (Days)
A	5.0	19.5
B	1.8	10.1
C	0.7	4.9
D	0.5	1.9
E	0.5	1.6

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/02/08 **1.1** Title suggests that this study is concerned with the removal of the test substance via volatilisation. However, the data within the study also provides information on the biodegradation processes of the test substance. **2.1** Inhouse method used, is stated to be inline with US EPA, but reference not given for comparison. The UK CA has assumed it to be US EPA 162 – 1 **2.3** Does not make it clear if these are deviations from their in house method or the guideline mentioned. However, evaluation of the study suggests that the study has been carried out to an acceptable standard.
Materials and methods	Applicant's version is acceptable with the following comments: **3.1** One of the test materials is a commerical preparation of the active at lower purities than given in Document IIIA Section 2. There is very little additional information regarding the formation of this product. Applicant explained that Radiolabelled bendiocarb was diluted with cold bendiocarb formulated as Turcam 76 WP. The resulting formulation contained 82.5 % of bendiocarb (higher end of the specification limits 77.5 – 82.5 %). Therefore the 82.5 % value does not specify the purity of bendiocard but the total content of bendiocarb in the formulation used in the study (containing cold [^{14}C] – bendiocarb). **3.1.4** Relevant properties of both test substances ie water solubility (i.e. bendiocarb 0.28 g/l at pH 7) should have been provided. **4.1** No further analysis carried out within study on metabolites and transformation products exceeding the 10 % threshold.
Conclusion	Applicant's version is acceptable.
Reliability	2
Acceptability	Acceptable.
Remarks	Study and endpoints robust for use in risk assessments. All endpoints transcribed from study correctly.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

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 degradation studies of bendiocarb in three soil types are summarized under Point 7.2.1. These studies provide information on rate and route of degradation of bendiocarb in soil and show that bendiocarb is very short lived in soil (DT_{50} << 21 days). The results obtain demonstrate that further studies on aerobic degradation of bendiocarb in soil should not be required. These data together with other submitted studies on hydrolysis in water (Point 7.1.1.1.1), photodegradation on soil surfaces (Point 7.2.2.4), adsorption/desorption studies in soil (Point 7.2.3.1) are considered scientifically valid for evaluating the fate and behaviour of bendiocarb in soil.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/06/07
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

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:	The laboratory aerobic degradation studies of bendiocarb in three soil types summarized under Point 7.2.1 show that bendiocarb is very short lived in soil ($DT_{50} \leq 5$ days and $DT_{90} \leq 20$ days). Therefore, the requirement for field soil dissipation and accumulation studies is not triggered. These data together with other submitted studies on hydrolysis in water (Point 7.1.1.1.1), photodegradation on soil surfaces (Point 7.2.2.4), adsorption/desorption studies in soil (Point 7.2.3.1) are considered scientifically valid for evaluating the fate and behaviour of bendiocarb in soil.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/06/07
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

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 laboratory aerobic degradation studies of bendiocarb in soil summarized under Point 7.2.1 indicate the formation of bound residues at levels exceeding 10 % a.s. applied. The extent and nature of the bound residues are characterised and discussed in the study submitted under Point 7.2.1/01. Therefore, further studies on the extent and nature of bound residues should not be required. In the study submitted under Point 7.2.1/01, the soil residues extracted with organic solvent (dichloromethane and acetonitrile + water) were further extracted with calcium chloride solutions and 0.1M sodium hydroxide, and the humic acid and fulvic acid fractions were subsequently extracted with methanol and diethyl ether, respectively. The results show that some bendiocarb was extracted from the 'bound' soil residues and suggest that some bendiocarb is strongly bound to soil organic matter. However, this represents only a small percentage of the radioactivity applied (ca. 2 % or less). The majority of the unextracted radioactivity comprises of highly polar base-soluble compounds, probably a result of pyrogallol oxidation and polymerisation, or material associated with insoluble humin fraction of organic matter.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/06/07
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

7.2.2.4 Other soil degradation studies

		1. REFERENCE	Official use only
1.1	**Reference**	Brehm, M. (1988b) The Photodegradation of Bendiocarb (Schering Code No. ZK 52 020) on Soil Surfaces Schering Agrochemicals Limited, UK Document A90109 7.2.2.4/01 21 October 1988 Unpublished.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	Not applicable	
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**	U.S. Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision N – Chemistry: Environmental Fate, NTIS PB 83 – 153973 – 18th October 1982	X
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Bendiocarb	
3.1.1	Lot/Batch number	Unlabelled bendiocarb, R000174 Radiolabelled bendiocarb – benzene ring-U-^{14}C, CFQ. 4944	
3.1.2	Specification	As given in Section 2	
3.1.3	Purity	Unlabelled bendiocarb, purity 99 % w/w Radiolabelled bendiocarb, purity 99 %, specific activity 3.96 MBq/mg	
3.1.4	Radiolabelling	Uniformly labelled in the benzene ring	
3.1.5	UV/VIS absorption spectra and absorbance value	Absorption spectrum of bendiocarb measured in acetonitrile in the wavelength region 250 – 600 nm shows an absorption band with a maximum at λ = 276.9 nm (ε = 2805 l.mole^{-1}.cm^{-1})	
3.1.6	Further relevant properties	-	
3.2	**Reference substances**	Possible degradation products of bendiocarb: 2,2-dimethyl-1,3-dioxol-4-ol (NC 7312) and pyrogallol	
3.3	**Test solution**	3.23 mg unlabelled bendiocarb plus 0.7mg labelled bendiocarb (~ 2.27 MBq) in 1.5mL dioxane used to treat the soil	
3.4	**Testing procedure**	Soil thin layers (~ 0.5 mm) were treated with bendiocarb at a rate equivalent to about 0.5kg/ha and either irradiated or kept in the dark as a control.	

3.4.1	Test system	20 x 20 cm thin-layer glass plates covered with a layer of sandy loam soil with a thickness of 0.5 mm. Plates were dried at 120°C and, after treatment, either kept in the dark (covered with aluminium foil) or irradiated with a xenon arc lamp with a filter to cut out light wavelengths < 290 nm. The soil plates were cooled to keep the temperature below 30°C. Air was drawn over the irradiated samples and passed through traps (ethyleneglycol and ethanolamine) to trap any volatile components.	
3.4.2	Properties of light source	Xenon arc (Osram XBF 2500 W/l) equipped with a UV-transmissive water jacket (Osram KG 2500 UVQ) and a metallic reflector. The light was filtered by a solarized Duran glass and a glass filter plate (Schott WG 295) to remove wavelengths < 290 nm.	
3.4.3	Determination of irradiance	**Wavelength (nm)** / **Irradiation intensity** / **Solar irradiation** 290 – 320 / 0.3 mWatt/cm² / 0.3 mWatt/cm² 290 – 350 / 2.6 mWatt/cm² / 1.9 mWatt/cm² 290 – 400 / 12.8 mWatt/cm² / 5.5 mWatt/cm² The data show that the light intensity used in the wavelength region 290-320 nm, where bendiocarb absorbs sunlight, is comparable to that of natural sunlight.	
3.4.4	Temperature	≤ 30°C	
3.4.5	pH	Soil pH 7.8	
3.4.6	Duration of the test	3.5, 7.2, 13.7 and 21.1 hours	
3.4.7	Number of replicates	Each soil plate was normally sampled to give three replicates	
3.4.8	Sampling	Soil samples were scraped off from the plates and extracted with acetonitrile (4 times) using an ultrasonic bath. After each extraction step, the suspensions were centrifuged, the extracts combined and brought to a volume of 5 ml of acetonitrile. In addition to this procedure the samples irradiated for 21.1 hours were further extracted once with dichloromethane, twice with HPLC-eluent (acetonitrile + 0.01 M phosphate buffer) and once with 0.1 M sodium hydroxide using the same procedure as described above.	
3.4.9	Analytical methods	The soil, soil extracts and the traps for volatiles were assayed by liquid scintillation counting. In addition the acetonitrile extracts were analysed by HPLC using an ODS Hypersil 5µm column (120 x 4.6 (i.d.) mm).	
3.5	**Transformation products**	No significant amounts (> 10 %) of radioactivity due to conversion products were found. Conversion products were probably polar compounds that were strongly bound to soil.	
		4. RESULTS	
4.1	**Screening test**	Not applicable	

4.2	**Actinometer data**	The actinometer was based on uranyl sulphate/oxalic acid which utilises the photodegradation of oxalic acid which is photosensitised by UO_2^{2+}. This system has a quantum yield of 0.56 molecules oxalic acid degraded per photon absorbed, which can be considered constant in the wavelength range 290-500 nm, see 3.4.3 above.
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 bendiocarb at a rate equivalent to about 0.5 kg/ha
4.4.2	Mass balance	**Irradiated samples**

Time (h)	Acetonitrile Extract (%)	Soil Residue (%)	Volatiles (%)	Total Recovery** (%)
3.5	76.3	15.8	0.7	94.9
7.2	65.7	24.9	1.9	94.6
13.7	61.4	27.3	2.7	93.5
21.1	42.5*	40.5*	5.2	90.2

* mean of two segments, the third one was used for additional extraction steps
** Corrected for recovery from soil plates

Non-irradiated samples

Time (h)	Acetonitrile Extract (%)	Soil Residue (%)	Volatiles (%)	Total Recovery** (%)
3.5	97.9	1.5	-	101.6
7.2	95.3	2.6	-	100.1
13.7	90.2	6.9	-	99.3
21.1	92.1	5.5	-	99.8

** Corrected for recovery from soil plates

4.4.3	Kinetic order	Non-irradiated controls – first order Irradiated samples – two compartment first order (irradiated and non-irradiated)
4.4.4	Half-life ($t_{½E}$)	Non-irradiated 187.3 hours; irradiated 7.8 hours
4.5	**Specification of the transformation products**	The HPLC analyses of soil extracts subjected to an additional extraction procedure (with dichloromethane, HPLC-eluent and sodium hydroxide) showed that the radioactivity was not due to bendiocarb hydrolysis products (NC 7312 and pyrogallol).

		The products of the soil photolysis of bendiocarb are various highly polar compounds whose individual amounts are too low for isolation and identification. They are strongly bound to the soil and therefore not readily extractable. The small amounts of volatile material produced (5.2 %) are considered to be either carbon dioxide or formic acid as they are trapped in basic solution.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A soil photodegradation study has been carried out according to US EPA Guidelines. 20 x 20cm thin-layer glass plates were covered with a layer of sandy loam soil (particle size < 0.2 mm) to a thickness of 0.5 mm using a slurry in a water/methanol mixture and a TLC coating apparatus. Plates were dried at 120°C and then equilibrated at ambient conditions for several days. Soil water content was about 2.7 %. The plates were treated with bendiocarb, using a thin-layer spotter apparatus, to give an application rate equivalent to 0.5kg/ha. After treatment the plates were either kept in the dark (covered with aluminium foil) or irradiated with a xenon arc lamp. The xenon arc lamp (Osram XBF 2500 W/l) was equipped with a UV-transmissive water jacket (Osram KG 2500 UVQ) and a metallic reflector. The light was filtered by a solarized Duran glass and a glass filter plate (Schott WG 295) to remove wavelengths < 290 nm. The soil plates were cooled to keep the temperature below 30°C. Air was drawn over the samples and passed through traps (ethyleneglycol and ethanolamine) to trap any volatile components. After irradiation the soil samples (three replicates per plate) were scraped off from the glass plates and extracted with acetonitrile (1x 2mL and 3 x 1mL), with centrifugation after each extraction. The extracts were combined and assayed by liquid scintillation counting and HPLC. The soil remaining was dried prior to combustion and assay by liquid scintillation counting. The traps for volatiles were also assayed by liquid scintillation counting. The acetonitrile extracts were also analysed by HPLC on a Waters M 6000 A system using an ODS Hypersil 5µm column (120 x 4.6 (i.d.) mm) and equipped with a variable wavelength monitor (Knauer) and a Ramona 6-LS radioactivity detector (Raytest). The eluent was acetonitrile (230mL)/0.01M phosphate buffer (770mL). Additionally, samples irradiated for 21.1 hours were extracted once with dichloromethane, twice with the HPLC eluent and once with 0.1 M sodium hydroxide.	
5.2	**Results and discussion**	Good recoveries of the applied radioactivity were obtained at each sampling point for both irradiated and non-irradiated samples. For the irradiated samples the recovery of radioactivity in the acetonitrile extracts decreased from 76.3 % after 3.5 hours to 42.5 % after 21.1 hours. The corresponding decrease in the non-irradiated samples was from 97.9 % to 92.1 %. In addition, volatile components were formed in the irradiated samples (5.2 % at 21.1 hours), but were not formed in the non-irradiated samples. Soil bound material also significantly increased in the irradiated samples from 15.8 % at 3.5 hours to 40.5 % at 21.1 hours.	

		The disappearance of bendiocarb was first order in the non-irradiated samples with a half-life of 187.3 hours. The kinetics of degradation in the irradiated samples is more complex as not all of the applied bendiocarb will be exposed to light (e.g. any in the soil interstices). Assuming first order kinetics for a two compartment model a half-life of 7.8 hours can be calculated for the photolysis reaction. No significant amounts of degradation products could be detected in the acetonitrile extracts from the irradiated or non-irradiated soil samples. Soil samples at 21.1 hours were also subjected to an additional extraction procedure which was designed to extract neutral, acidic and basic substances. Further radioactivity was extracted and appeared mainly in the HPLC-eluent and 0.1 M sodium hydroxide extracts, indicating polar materials. HPLC analysis showed that the radioactivity was not due to bendiocarb or its hydrolysis products (NC 7312 and pyrogallol). The results indicate that the photolysis products are various highly polar products whose individual amounts are too low for isolation and identification and that they are strongly bound to the soil and not readily extracted. The small amounts of volatile material produced (5.2 %) are considered to be either carbon dioxide or formic acid as they are trapped in basic solution. In conclusion, bendiocarb has a half-life of 7.8 hours when exposed to light equivalent to natural sunlight. The degradation products are highly polar compounds that are strongly bound to the soil.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	None	

Table A7.2.2.4-1 Classification and Physico-Chemical Properties of Soil Used

	Soil
Soil order	Abington
Soil series	-
Classification	Sandy loam
Location	Land Settlement nr. Great Abington, Cambridgeshire, UK. OS TL 518475
Horizon	
Sand [%]	67
Silt [%]	19
Clay [%]	14
Organic carbon [%]	3.2
Carbonate as $CaCO_3$ (g/kg)	85
Insoluble carbonates [%]	
pH (1:1 H_2O)	7.8
Cation exchange capacity (MEQ/100 g)	10.8
Extractable cations (MEQ/100 g)	
Ca	-
Mg	-
Na	-
K	-
H	-
Special chemical/mineralogical features	-
Clay fraction mineralogy	-

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	24/11/06 **2.1** Should state the US EPA guideline as, 161-3
Materials and methods	Applicant's version is acceptable
Conclusion	Applicant's version is acceptable
Reliability	1
Acceptability	Acceptable
Remarks	Study and endpoints robust for use in risk assessments. All endpoints transcribed from study correctly.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

7.2.3 Adsorption and mobility in soil, further studies

7.2.3.1 Adsorption / desorption (3 soil types)

		1. REFERENCE	Official use only
1.1	**Reference**	Allen, R. (1988) [^{14}C]-Bendiocarb: Adsorption/Desorption in Soil Hazleton UK and Schering Agrochemicals Ltd. Document A90217 7.2.3.1/01 14 January 1988 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**	In house method which is similar to EC C18 and OECD 106	X
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3. MATERIALS AND METHODS	
3.1	**Test material**	(^{14}C)- bendiocarb (labelled in the heterocycling ring) and unlabelled bendiocarb	
3.1.1	Lot/Batch number	No data	X
3.1.2	Specification	As given in Section 2 for unlabelled bendiocarb; (^{14}C)- bendiocarb (specific activity 43.39 µCi/mg)	
3.1.3	Purity	Unlabelled bendiocarb: not specified (^{14}C)- bendiocarb >98.8 % (TLC)	
3.1.4	Further relevant properties	-	X
3.1.5	Method of analysis	Radioactivity was measured by LSC and analysis conducted by TLC	
3.2	**Degradation products**	Yes	
3.2.1	Method of analysis for degradation products	TLC	
3.3	**Reference substance**	Unlabelled bendiocarb and the metabolite NC 7312 were used as authentic reference substances.	
3.3.1	Method of analysis for reference substance	As above in 3.1.5 and 3.2.1	

3.4	**Soil types**	Sand, sandy loam, silty clay loam, clay See Table A7.2.3.1-1	
3.5	**Testing procedure**		
3.5.1	Test systems	Four soil types, a sand (designated Icklingham), a sandy loam (designated Abington), a silty clay loam (designated Terling) and a clay (designated Shelford) were used.	
3.5.2	Test solution and Test Conditions	A solution of (^{14}C)-bendiocarb (10.10 µg/ml) was prepared by dissolving the material (2.524 mg) in ethanol (2.5 ml) and diluting to 250 ml with 0.01M aqueous calcium chloride. The solution was serially diluted with calcium chloride to provide solutions of nominally 1.01, 0.10 and 0.01 µg/ml. The solutions were filtered. Duplicate samples were prepared for each of the 4 soil types at each of the concentrations. All soil samples were autoclaved prior to addition of the radiolabelled solutions. Samples were shaken continuously for 24 hr. The tubes were then removed and assayed.	
3.6	**Test performance**		
3.6.1	Preliminary test	Solutions of (^{14}C)-bendiocarb in 0.01M aqueous calcium chloride (nominally 0.01, 0.1, 1.0 and 10µg/ml) were prepared. The radioactivity content of each solution was determined by liquid scintillation counting to confirm or otherwise complete solubilisation of the test article. Incomplete solubilisation at the highest concentration was observed. Therefore the material (1.451 mg) was first dissolved in ethanol (1 ml) and this solution diluted to 100 ml with 0.01M calcium chloride. Complete solubilisation using this procedure was observed. The potential for adsorption to glassware was assessed. A solution of (^{14}C)-bendiocarb in 0.01M calcium chloride (0.0032 µg/ml) was added to 3 screw-capped Pyrex culture tubes containing no soil. The tubes were shaken for 24 hr and the solution reassayed by liquid scintillation counting. No adsorption to the tubes was observed. To establish equilibrium time ten samples were prepared by adding solutions (ca. 25g) of (^{14}C)-bendiocarb in 0.01M calcium chloride (2.85 µg/ml), sterilised by filtration, to autoclaved Icklingham soil (5 g dry weight equivalent) in a screw-capped culture tube using aseptic techniques. The tubes were capped and shaken continuously using a flat bed shaker set at 225 rpm. Duplicate samples were removed at 2, 4, 8, 24 and 48 hr, centrifuged (ca. 400 g, 10 min) and the radioactivity content of weighed aliquots determined by liquid scintillation counting.	

		The stability of (^{14}C)-bendiocarb in the supernatant of samples shaken for 24 and 48 hr, was investigated. Aliquots (3 ml) of the supernatant were diluted to 25 ml and extracted with dichloromethane (3 x 25 ml). The radioactivity content of the aqueous and organic phases were determined by liquid scintillation counting to determine the efficiency of extraction (98.7 %). The pooled dichloromethane extracts were concentrated to approximately 10 ml by rotary evaporation at 35°C. The remaining solvent was removed under a gentle stream of nitrogen at room temperature. Samples were reconstituted in ethanol (2 ml) and sub samples (25 µl) analysed for radioactivity content by liquid scintillation counting. No radioactivity was lost during concentration. Further sub-samples containing approximately 10,000 dpm were analysed by TLC. Non-radiolabelled bendiocarb and NC 7312 were used as authentic standards.	
3.6.2	Screening test: Adsorption	A solution of (^{14}C)-bendiocarb (10.10 µg/ml) was prepared by dissolving the material (2.524 mg) in ethanol (2.5 ml) and diluting to 250 ml with 0.01M aqueous calcium chloride. The solution was serially diluted with calcium chloride to provide solutions of nominally 1.01, 0.10 and 0.01 µg/ml. The solutions were filtered. Duplicate samples were prepared for each of the 4 soil types at each of the concentrations. All soil samples were autoclaved prior to addition of the radiolabelled solutions. Samples were shaken continuously for 24 hr. The tubes were then removed and assayed. An aliquot (3 ml) of each supernatant taken from the 10.10 µg/ml samples of Icklingham soil was submitted to TLC.	
3.6.3	Screening test: Desorption	A portion (7.5 ml) of the supernatant was removed from each sample and replaced with a equal volume of filtered 0.01M calcium chloride. The culture tubes were shaken vigorously to break up the soil packed at the bottom, then shaken continuously for 24 hr and assayed. Sequential desorption steps were carried out by removing 10, 12.5 and finally 15 ml of supernatant and replacing with equal volumes of filtered 0.01M calcium chloride. An aliquot (3 ml) of the supernatant removed after the 2nd and 4th desorption steps from the samples was submitted to TLC. Aseptic techniques were used throughout the adsorption and desorption phases.	
3.6.4	HPLC-method	n.a.	
3.6.5	Other test	-	
		4. RESULTS	
4.1	**Preliminary test**	(^{14}C)-Bendiocarb was rapidly hydrolysed to NC 7312. Only 7 % of the radioactivity present in the supernatant after 24 hr shaking was unchanged test article. The remainder was comprised of NC 7312 (90 %) and unresolved background. The radioactivity present in the supernatant after 48 hr shaking was associated with NC 7312 only.	

4.2	**Screening test: Adsorption**	The adsorption of (^{14}C)-bendiocarb to a sand, sandy loam, silty clay loam and clay soils was studied over 24 hr. At the end of the adsorption period, 87.3 % of (^{14}C)-bendiocarb had been hydrolysed to NC 7312 in the sand (Icklingham) soil. The soil/solution concentration ratios (k_a) ranged from 0.10 to 0.20 for the sand soil (Icklingham), 0.49 to 0.86 for the sandy loam (Abington) soil, 0.93 to 1.72 for the silty clay loam (Terling) soil and 1.09 to 1.85 for the clay (Shelford) soil. In general k_d values decreased with increasing solution concentrations. The Freundlich adsorption coefficients kf and 1/n were 0.14 and 0.96 for Icklingham, 0.60 and 0.93 for Abington, 1.14 and 0.92 for Terling and 1.35 and 0.93 for Shelford soils respectively. The value kf is equivalent to k_d when the equilibrium solution concentration equals 1.0 µg/g. The strength of adsorption of radioactivity to soil increased with soil organic matter content. For example the adsorption coefficient (kf) for Shelford (4.9 % organic carbon) was approximately 10 times greater than that for Icklingham (0.35 % organic carbon). Clay content also increased with organic matter content. However it is considered that it would have little influence on adsorption.	
4.3	**Screening test: Desorption**	Four sequential desorption steps from each of the soils were carried out over the following 96 hr (24 hr/desorption step). At the end of the 2nd and 4th desorption steps, 86.3 and 81.0 % of the radioactivity in solution was present as NC7312 in Icklingham soil respectively. In general, k_d values for individual samples and the Freundlich desorption coefficients for all soils increased with each desorption step. For example k_d values after the 4th desorption step ranged from 0.24 to 3.37 for Icklingham, 0.52 to 3.72 for Abington, 1.23 to 3.77 for Terling and 1.41 to 4.44 for Shelford soils. Freundlich desorption coefficients (kf) after the same time interval increased to 0.87, 0.79, 1.70 and 1.72 in the 4 soils respectively.	
4.4	**Calculations**		
4.4.1	Ka, Kd	K_a (adsorption): the soil/solution concentration ratios (k_d) ranged from 0.10 to 0.20 for the sand soil (Icklingham), 0.49 to 0.86 for the sandy loam (Abington) soil, 0.93 to 1.72 for the silty clay loam (Terling) soil and 1.09 to 1.85 for the clay (Shelford) soil. In general k_d values decreased with increasing solution concentrations. Values for the Freundlich adsorption coefficients k_f and 1/n were 0.14 and 0.96 for a sand soil, 0.60 and 0.93 for a sandy loam, 1.14 and 0.92 for a silty clay loam and 1.35 and 0.93 for a clay soil respectively. K_d (desorption): in general, k_d values for individual samples and the Freundlich desorption coefficients for all soils increased with each desorption step. For example k_d values after the 4th desorption step ranged from 0.24 to 3.37 for Icklingham, 0.52 to 3.72 for Abington, 1.23 to 3.77 for Terling and 1.41 to 4.44 for Shelford soils. After the 4th desorption, the respective values for k_f were 0.87, 0.79, 1.70 and 1.72 for the 4 soils.	
4.4.2	Ka_{oc} , Kd_{oc}	See 5.2.2 for Ka_{oc}	

4.5	**Degradation product(s)**	(^{14}C)-Bendiocarb was hydrolysed during the course of the studies to 2,2-dimethyl-1,3 benzodioxol-4-ol (NC 7312). Analysis of the equilibrium solutions shaken with a sand soil indicated that over 80 % of the radioactivity was present as NC 7312 at the end of the adsorption period.	X
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The adsorption of (^{14}C)-bendiocarb to 4 soil types and its subsequent desorption over successive 24 hour periods have been studied. The studies were carried out with sterilised solutions of (^{14}C)-bendiocarb in 0.01M calcium chloride at nominally 0.01, 0.10, 1.0 and 10 µg/ml and soil in screw-capped culture tubes using aseptic techniques.	
5.2	**Results and discussion**	(^{14}C)-Bendiocarb was hydrolysed during the course of the studies to 2,2-dimethyl-1,3 benzodioxol-4-ol (NC 7312). Analysis of the equilibrium solutions shaken with a sand soil indicated that over 80 % of the radioactivity was present as NC 7312 at the end of the adsorption period. Values for the Freundlich adsorption coefficients k_f and 1/n were 0.14 and 0.96 for a sand soil, 0.60 and 0.93 for a sandy loam, 1.14 and 0.92 for a silty clay loam and 1.35 and 0.93 for a clay soil respectively. In 4 subsequent desorption steps, the Freundlich desorption coefficients for all soils increased with each desorption. After the 4th desorption, the respective values for k_f were 0.87, 0.79, 1.70 and 1.72 for the 4 soils.	
5.2.1	Adsorbed a.s.[%]	See 4.2	
5.2.2	K_a	K_a (adsorption): the soil/solution concentration ratios (k_d) ranged from 0.10 to 0.20 for the sand soil (Icklingham), 0.49 to 0.86 for the sandy loam (Abington) soil, 0.93 to 1.72 for the silty clay loam (Terling) soil and 1.09 to 1.85 for the clay (Shelford) soil. In general k_d values decreased with increasing solution concentrations. Values for the Freundlich adsorption coefficients k_f and 1/n were 0.14 and 0.96 for a sand soil, 0.60 and 0.93 for a sandy loam, 1.14 and 0.92 for a silty clay loam and 1.35 and 0.93 for a clay soil respectively. Based on these values, the following K_{oc} values are obtained:	
5.2.3	K_d	K_d (desorption): in general, k_d values for individual samples and the Freundlich desorption coefficients for all soils increased with each desorption step. For example k_d values after the 4th desorption step ranged from 0.24 to 3.37 for Icklingham, 0.52 to 3.72 for Abington, 1.23 to 3.77 for Terling and 1.41 to 4.44 for Shelford soils. After the 4th desorption, the respective values for k_f were 0.87, 0.79, 1.70 and 1.72 for the 4 soils.	
5.2.4	Ka_{oc}	See 5.2.2	

Soil, soil type	Kf (ads)	1/n	OC (%)	K_{oc}
Icklingham, sand	0.1391	0.9557	0.35	39.7
Abington, sandy loam	0.6034	0.9273	1.9	31.7
Terling, silty clay loam	1.140	0.9180	3.2	35.6
Shelford, clay	1.350	0.9275	4.9	27.6

5.2.5	Ka/Kd	K_a/K_d values were: 0.05 - 0.61, 0.23 - 1.12, 0.33 - 0.92 and 0.42 - 0.78 for the Icklingham, Abington, Terling and Shelford soils, respectively	
5.2.6	Degradation products (% of a.s.)	(^{14}C)-Bendiocarb was hydrolysed during the course of the studies to 2,2-dimethyl-1,3 benzodioxol-4-ol (NC 7312). Analysis of the equilibrium solutions shaken with a sand soil indicated that over 80 % of the radioactivity was present as NC 7312 at the end of the adsorption period.	
5.3	**Conclusion**		
5.3.1	Reliability	1	X
5.3.2	Deficiencies	No	

Table A7.2.3.1-1 Classification and Physico-Chemical Properties of Soils Used as Adsorbents

	Soil 1	Soil 2	Soil 3	Soil 4
Soil order	Icklingham	Abington	Terling	Shelford
Soil series	-	-	-	
Classification	Sand/loamy sand	Sandy loam	Silty clay loam	Clay
Location	Weatherhill Farm Nr. Icklingham, Suffolk, U.K. OS TM 785 723	Land Settlement Nr. Great Abington, Cambridgeshire, UK. OS TL 518475	Terling Hall Nr. Hatfield Peverel, Essex, UK. OS TQ 774135	Great Shelford Nr. Cambridge OS TL 464514
Horizon	-	-	-	-
Sand [%]	88	63	14	39
Silt [%]	6	21	58	19
Clay [%]	6	16	28	43
Organic carbon [%]	0.35	1.9	3.2	4.9
Carbonate as $CaCO_3$	-	-	-	-
insoluble carbonates [%]	-	-	-	-
pH (1:1 H_2O)	6.8	7.4	6.65	6.6
Cation exchange capacity (MEQ/100 g)	1.9	9.2	25.0	39.0

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/07/07 **1.1** Title in dossier refers to adsorption/desorption on 3 soils, yet 4 soil matrices are used. Use of four matrices in the UK CA's opinion makes the study more robust. **2.1** No reference to the validation of the in house method. No details of any deviations from the stated guidelines. **2.3** Does not clearly indicate whether there are no deviations from their in house method or the stated guidelines.
Materials and methods	Applicant's version is acceptable with the following comments: **3.1.1** No lot numbers for the test chemicals. **3.1.4** Physico-chemical properties such as water solubility (0.28 g/l at pH 7) would have been appropriate.
Results	**4.5** Although metabolite (NC7312) accounts for 80 % after adsorption phase, no further work was carried out as to its fate and behaviour in this study. No reference is made to existing data to support this non-testing is provided.
Conclusion	Applicant's version is acceptable with the following comment: **5.3.1** Reliability reduced to a 2 due to lack of detail on deviations and fate of metabolite.
Reliability	2
Acceptability	Acceptable
Remarks	Due to the lack of clarity, the reliability has been reduced to 2. Study and endpoints robust for use in risk assessments. All endpoints transcribed from study correctly.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

7.2.3.2 Mobility in soil

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [✓]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	According to the Guidance on Additional Data Requirements for Active Substances, in most cases the mobility of a substance in soil can be estimated by means of running mathematical model calculations, processing adsorption coefficient and degradation rates of the substance (and its transformation products) but also pedological and climatic parameters. The laboratory aerobic degradation studies of bendiocarb in three soil types are summarized under Point 7.2.1 and the adsorption/desorption study conducted with bendiocarb in four different soil types is summarized under Point 7.2.3.1. The adsorption coefficient and the degradation rates of bendiocarb and its transformation products have been used to calculate Predicted Environmental Concentration in groundwater with the Focus-Pearl model (see Appendix 3 (M-266366-01-1) of the Environmental Risk Assessment – attached to DocIIB). As the PEC calculations indicate that bendiocarb does not trigger concerns regarding the risk for a possible groundwater contamination, no study on mobility of bendiocarb in soil should be required.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/06/07
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

7.3 Fate and behaviour in air

7.3.1 Phototransformation in air

			Official use only
		1. REFERENCE	
1.1	**Reference**	Brehm, M. (1992b) Estimation of the Photochemical-Oxidative Degradation of Bendiocarb (Schering Code No. ZK 52 020) in the Atmosphere Schering AG Agrochemicals Division Document A90133 7.3.1/01 7 June 1992 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**	Estimation method of Atkinson	
2.2	**GLP**	n.a.	
2.3	**Deviations**	n.a.	
		3. MATERIALS AND METHODS	
3.1	**Test material**	As given in Section 2 but no actual test was carried out as this is a calculation method.	
		4. RESULTS	
4.1	**Calculation**	The total OH radical rate constant k_{OH} is given by $k_{OH} = k_{abs} + k_{add} + k_{arom}$ In the case of bendiocarb only the contributions k_{abs} and k_{arom} need to be considered as there are no unsaturated aliphatic groups. A minimum rate constant for k_{abs} of bendiocarb can be estimated to be $k_{abs} = 0.372 \times 10^{-12}$ cm^3 molecule^{-1}s^{-1} and $k_{arom} = 2.88 \times 10^{-11}$ cm^3 molecule^{-1} The total rate constant for the reaction of bendiocarb with OH radicals is $k_{OH} = 2.92 \times 10^{-11}$ cm^3 molecule^{-1}. This value has to be considered as a minimal reactivity value, because the reactivities of the carbamate nitrogen and the methyl group regarding to H-abstraction have not been considered.	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Photochemical degradation processes of chemicals can occur either directly by a chemical reaction after excitation of the compound itself by absorption of light or indirectly by reaction with a second photochemically produced species. It is generally agreed that, in contrast to the processes in aqueous solution, the indirect photochemical reactions are the determining factors for the phototransformation of chemicals in the atmosphere: - reaction with OH radicals - reaction with ozone - reaction with other photochemically generated species (e.g. NO_3, Cl)	
5.2	**Results and discussion**	Reaction with photochemically generated OH radicals can be expected to be the main photo-transformation process for bendiocarb in the atmosphere. The bimolecular OH radical rate constant was estimated according to the incremental method of Atkinson to be $>2.92 \times 10^{-11}$ cm^3 $molecule^{-1}s^{-1}$. Assuming the global 24 hour average for the concentration of OH radicals to be 5×10^5 molecules/cm^3, this value corresponds to a maximum half-life of 13.2 h for the photo-oxidative degradation of bendiocarb in air. The calculated half-life is significantly less than the long-range transport trigger of 2 days.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	30/11/06
Materials and methods	Applicant's version is acceptable
Conclusion	Applicant's version is acceptable
Reliability	1
Acceptability	Acceptable
Remarks	TGD approved QSAR calculation.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

7.3.2 Fate and behaviour in air, further studies

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [✓]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The study requirement is not triggered as the active substance will not be presented as a fumigant or in such a way that it causes risk to the atmospheric environment. Furthermore, as demonstrated under Point 7.3.1, bendiocarb degrades rapidly in air (by photo-oxydative degradation) with a maximum half-life of 13.2 h. Therefore, it is not to be expected that bendiocarb can be transported in the gaseous phase over large distances or can accumulate in the air. Consequently, no further studies on the fate and behaviour of bendiocarb in air should be required.	
Undertaking of intended data submission [ ]		

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/06/07
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

7.4 Effects on aquatic organisms

7.4.1 Aquatic toxicity, initial tests

7.4.1.1 Acute toxicity to fish

		1. REFERENCE	Official use only
1.1	Reference	[redacted] (1989a) Acute Toxicity of Bendiocarb Technical to Sheepshead Minnow (*Cyprinodon variegatus*) under Flow-Through Conditions [redacted] Document A90622 7.4.1.1/01 10 March 1989 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	US EPA Guideline 72-3	X
2.2	GLP	Yes	
2.3	Deviations	No	X
		3. MATERIALS AND METHODS	
3.1	Test material	Bendiocarb	
3.1.1	Lot/Batch number	CR19048/1	
3.1.2	Specification	As given in Section 2	
3.1.3	Purity	98.0 %	
3.1.4	Composition of product	n.a.	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	HPLC	X
3.2	Preparation of TS solution for poorly soluble or volatile test substances	See Table A7.4.1.1-1	
3.3	Reference substance	No	
3.3.1	Method of analysis for reference substance	n.a.	

3.4	**Testing procedure**		
3.4.1	Dilution water	See Table A7.4.1.1-2	X
3.4.2	Test organisms	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	X
3.4.5	Duration of the test	96 h	
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	All concentrations, water control and solvent control prior to initiation, on Day 0 and on Day 4	
3.4.8	Monitoring of TS concentration	Yes, Day 0 and Day 4	
3.4.9	Statistics	Three statistical methods were available in the computer program: moving average angle analysis, probit analysis, and nonlinear interpolation with 95 % confidence intervals calculated by binomial probability. The 96-hour LC_{50} value and 95 % confidence interval were calculated by probit analysis.	
		4. RESULTS	
4.1	**Limit test**	Not performed	X
4.1.1	Concentration	n.a.	
4.1.2	Number/ percentage of animals showing adverse effects	n.a.	
4.1.3	Nature of adverse effects	n.a.	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	3.3, 2.1, 1.4, 0.89 and 0.58 mg ai/L.	
4.2.2	Actual concentrations of test substance	2.6, 1.9, 1.0, 0.64 and 0.45 mg ai/L.	X
4.2.3	Effect data (Mortality)	See Tables A7.4.1.1-6 and A7.4.1.1-7	X
4.2.4	Concentration / response curve	See Figure 2, page 28 in the original report	X
4.2.5	Other effects	At the termination of the exposure surviving fish at all concentrations of bendiocarb technical tested exhibited toxicant-related sublethal effects (e.g., loss of equilibrium).	
4.3	**Results of controls**		
4.3.1	Number/percentage of animals showing adverse effects	No mortalities or adverse effects were observed among the control organisms.	X

4.3.2	Nature of adverse effects	None	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	n.a.	
4.4.2	Results	n.a.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The purpose of this study was to estimate the acute toxicity (LC_{50}) of bendiocarb technical to sheepshead minnow (*Cyprinodon variegatus*) under flow-through conditions. Twenty organisms were exposed in duplicate test aquaria in a flow-through system to five concentrations of bendiocarb technical, a dilution (seawater) water control and a solvent (dimethyl formamide, DMF) control. During the test, nominal concentrations of 3.3, 2.1, 1.4, 0.89 and 0.58 mg ai/L bendiocarb technical were maintained by introducing approximately 7.1 aquarium volumes per day of newly prepared test solution via modified proportional diluter apparatus. Each replicate solution was sampled and analyzed for bendiocarb (as active ingredient) concentration at test initiation and on day 4 of the exposure period. Based on the results of these analyses, the mean measured test concentrations were 2.6, 1.9,1.0, 0.64 and 0.45 mg ai/L bendiocarb technical. Biological observations and observations of the physical characteristics of the exposure solutions were made and recorded at test initiation and every 24 hours thereafter until the test was terminated. During the exposure period, no visible sign of undissolved test material (e.g. precipitate, film on solution surface) was observed in any of the treatment level or control solutions.	
5.2	**Results and discussion**	Following 96 hours of exposure, 100 % mortality was recorded in the highest mean measured concentration of bendiocarb technical tested (2.6 mg ai/L). Mortality ranged from 95 to 15 % in the remaining treatment levels (1.9 – 0.45 mg ai/L) and generally followed the concentration gradient established, decreasing as the concentration of test material decreased. LC_{50} values (based on mean measured concentrations of bendiocarb technical) are reported in the following table.	

LC_{50} (mg a.i./l)			
24 h	48 h	72 h	96 h*
1.2	1.1	0.97	0.86

*: calculated by probit analysis

		Due to sublethal effects (e.g., lethargy, loss of equilibrium), observed at all treatment levels, the No Observed Effect Concentration (NOEC) through 96 hours was <0.45 mg ai/L, the lowest mean measured concentration of bendiocarb technical tested.	
5.2.1	LC_0	<0.45 mg a.i./l	
5.2.2	LC_{50}	0.86 mg a.i./l (96 h)	
5.2.3	LC_{100}	2.6 mg a.i./l (96 h)	
5.3	**Conclusion**		X

5.3.1	Other conclusions		
5.3.2	Reliability	1	X
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	Directly added to dilution water
Vehicle	Dimethylformamide (DMF)
Concentration of vehicle	8.0323 g bendiocarb technical in 50 ml vehicle
Vehicle control performed	Yes
Other procedures	-

Table A7.4.1.1-2 Dilution water

Criteria	Details
Source	The dilution water was prepared by filtering natural seawater collected from the Cape Cod Canal, Bourne, Massachusetts.
Alkalinity	See pH
Hardness	Salinity 31-32‰
pH	7.8 – 8.0
Oxygen content	5.1 – 7.6 mg/L
Conductance	-
Holding water different from dilution water	No

Table A7.4.1.1-3 Test organisms

Criteria	Details
Species/strain	Sheepshead minnow (*Cyprinodon variegatus*)
Source	Commercial supplier, Massachusetts
Wild caught	No
Age/size	Mean wet weight 0.9 g; mean length 37 mm
Kind of food	Dry commercial pelleted food
Amount of food	*Ad libitum*
Feeding frequency	Daily, except during the 48 h prior to testing
Pretreatment	The fish were held in 500L fibreglass tank under a photoperiod of 16 hours light and 8 hours darkness. A closed loop recirculating filtration system provided natural seawater to the holding tank and was characterized as having a salinity range of 32 – 33°/oo, a pH range of 7.5 – 7.6 and a dissolved oxygen concentration range of 82 – 90 % of saturation (Weekly Record of Fish Holding Characteristics). Test fish were maintained under these conditions for a minimum of 14 days prior to testing. The temperature in the holding tank was 21°C during this 14-day period.
Feeding of animals during test	No

Table A7.4.1.1-4 Test system

Criteria	Details
Test type	Flow-through
Renewal of test solution	7.1 volume replacements every 24 h
Volume of test vessels	39 x 20 x 25 cm with a constant test water volume of 11 L
Volume/animal	ca. 1.1 L
Number of animals/vessel	10
Number of vessels/ concentration	2
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.1-5 Test conditions

Criteria	Details
Test temperature	22 ± 1 °C
Dissolved oxygen	82-90 %
pH	7.5-7.6
Adjustment of pH	No
Aeration of dilution water	No
Intensity of irradiation	52 footcandles
Photoperiod	16 h light and 8 h darkness

Table A7.4.1.1-6 Mortality data

Test-Substance concentration (measured)[1] [mg/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
2.6	20	20	20	20	100	100	100	100
1.9	17	17	18	19	85	85	90	95
1.0	6	8	11	12	30	40	55	60
0.64	0	2	3	3	0	10	15	15
0.45	0	1	2	4	0	5	10	20
Water control	0	1	2	2	0	5	10	10
Solvent control	0	0	0	0	0	0	0	0
Temperature [°C]	22	23	22	22				
pH	7.8-7.9	7.8-7.9	7.8-7.9	8.0				
Oxygen [mg/l]	5.5-7.0	5.5-7.1	5.1-6.9	6.0-7.7				

1 indicates if effect data are based on nominal (n) or measured (m) concentrations

Table A7.4.1.1-7 Effect data

	48 h [mg/l][1]	95 % c.l.	96 h [mg/l][1]	95 % c.l.
LC_0	-	-	-	-
LC_{50}	1.1	0.94 – 1.3	0.86	0.72 – 1.0
LC_{100}	-	-	-	-

1 based on measured concentrations

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	X	
Criteria for poorly soluble test substances	n.a.	

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

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	19/02/2007
	2.1 The study report indicates that the study was carried out according to a Springborn Life Sciences test protocol that closely follows the ASTM 'Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macro invertebrates, and Amphibians' (1980) and not US EPA 72-3 as stated. However, the UK CA considers that this is not an issue, and has assessed the study against the requirements within the OECD guideline 203 (Fish, Acute Toxicity Test, 1992). This is consistent with the Applicant's approach of comparing the study against the validity criteria in OECD 203 in this study summary. **2.3** One deviation was reported against the protocol used in this 1989 study - the temperature in the control solution ranged from 21 – 25 °C, whilst the protocol indicated that it would be maintained at 22 ± 1 °C. The UK CA does not consider this would affect the results of this study.
Materials and methods	The Applicant's version is acceptable, noting the following: **3.1.6** The detail given is insufficient. The method of analysis for bendiocarb includes a solid-phase extraction step (using C18 extraction column) prior to HPLC analysis with UV detection at 240 nm **3.4.1** and **3.4.4** The parameters given in Table A7.4.1.1-2 appear to be those of the test conditions rather than the dilution water, whilst those in Table A7.4.1.1-5 appear to be those of the dilution water used during the pre-test conditioning period. For Table A7.4.1.1-2 : Salinity should be 32-33 °/oo and not 31-32 °/oo pH should be 7.5 –7.6 and not 7.8 – 8.0 Oxygen content should be 82 – 90 % saturation and not 5.1 - 7.6 mg l^{-1} For Table A7.4.1.1-5: Salinity should be included as 31- 32 °/oo Oxygen content should be 5.1 - 7.6 mg l^{-1} and not 82 – 90 % saturation pH should be 7.8 – 8.0 and not 7.5 – 7.6

Section A7 Annex Point IIA 7.1	**Ecotoxicological Profile Including Environmental Fate and Behaviour** A7.4.1.1 Acute toxicity to fish
Results and Discussion	The Applicant's version is acceptable, noting the following: **4.1** The UK CA notes that although no limit test was done, a preliminary test had been performed which suggested that the 96 h LC_{50} would occur between 5 mg a.s. l^{-1} (100 % mortality observed) and 3.2 mg a.s. l^{-1} (40 % mortality observed). **4.2.2** The actual concentrations given are mean measured concentrations, which are reported to be, on average, 78 % of the nominal concentrations (range 71.4 – 90.5 % of the nominal). As the test substance concentrations are not all ± 20 % of the nominal concentrations, mean measured concentrations were used to calculate the LC_{50}. **4.2.3** Table A7.4.1.1-6 indicates both the number and percentage mortality during the study. However, the UK CA notes that the numbers are not presented in the study report, but have been correctly back-calculated from the percentages within the report. Table A7.4.1.1-7 reports only LC_{50} values giving the impression LC_0 and LC_{100} values are not available. However LC_0 and LC_{100} values are given by the Applicant in Section 5.2 and should have been included in this table. **4.2.4** Figure 2 is presented on page 26 of the original report, and not page 28 as stated in the study summary. **4.3.1** The study summary incorrectly states that no mortalities were observed in the control, as 10 % mortality was observed in the (water) control after 96 hours. This is acceptable according to the validity criteria in OECD guideline 203. In addition, the UK CA notes that there was 0 % mortaility in the solvent control, which is considered a more representative control as the test vessels contained solvent as a carrier.
Conclusion	The Applicant's version is acceptable, noting the following: **5.3** The validity criteria have not been mentioned here, although a table (Table A7.4.1.1-8) has been included to show the validity of this study against the criteria given in OECD guideline 203. The mortality in the control should be ≤ 10 % and not < 10 %. **5.3.2** The reliability of this study has been reduced to 2, as there was limited characterisation data given on both the bendiocarb technical and source of sheepshead minnows because it was not done to guideline OECD 203. **5.3.3** No deficiencies have been reported compared to the original study protocol. However, when compared to OECD guideline 203, the UK CA noted that feeding was stopped 48 h before the test started, rather than 24 h before as stated in the OECD guideline. The UK CA considers this deficiency does not affect the results of the study.
Reliability	2
Acceptability	Acceptable

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

Remarks	The TNG on Data Requirements indicates that the endpoint of acute toxicity to fish should be studied with one species, with a freshwater species being preferred (but not essential). In addition, the TNG permits a test corresponding to OECD guideline 203 using *Cyprinodon variegatus* (marine species). Hence the UK CA considers this study, which meets the requirements of OECD guideline 203, appropriate to address the acute toxicity to fish endpoint for the freshwater aquatic environment. All endpoints and data presented in the summary have been checked against the original study and are correct.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

			Official use only
		1. REFERENCE	
1.1	**Reference**	[redacted] (1982) The Acute Toxicity of NC 7312 to Rainbow trout (*Salmo gairdneri*) [redacted] Document A90492 7.4.1.1/02 27 January 1982 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**	US EPA Guideline EPA-660/3-75-009	
2.2	**GLP**	No, the study was conducted prior to the introduction of GLP as a standard requirement	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	NC 7312 (major hydrolysis product of bendiocarb)	
3.1.1	Lot/Batch number	20173/1	
3.1.2	Specification	-	
3.1.3	Purity	> 99 %	
3.1.4	Composition of product	n.a.	
3.1.5	Further relevant properties	-	X
3.1.6	Method of analysis	GC-ECD	X
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See Table A.7.4.1.1-9	X
3.3	**Reference substance**	No	
3.3.1	Method of analysis for reference substance	n.a.	
3.4	**Testing procedure**		
3.4.1	Dilution water	See Table A7.4.1.1-10	X
3.4.2	Test organisms	See Table A7.4.1.1-11	X
3.4.3	Test system	See Table A7.4.1.1-12	

3.4.4	Test conditions	See Table A7.4.1.1-13	X
3.4.5	Duration of the test	96 h	
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	Day 0 and at the end of each 24 h exposure period (except for the concentration of 20 mg NC 7312/L for which analysis was performed at Day 0 and after 24 hours only)	
3.4.8	Monitoring of TS concentration	Yes	
3.4.9	Statistics	Method of Litchfield and Wilcoxon	
		4. RESULTS	
4.1	**Limit test**	A range finding trial was performed	
4.1.1	Concentration	0.5, 5.0, 25.0 and 50.0 mg NC 7312/L	
4.1.2	Number/ percentage of animals showing adverse effects	100 % mortality at 24 h for 25.0 and 50.0 mg NC 7312/L	X
4.1.3	Nature of adverse effects	Despite these mortality figures, toxic symptoms, as precipitated by lethal levels of NC 7312, seemed relatively slow to develop. Even at the 50 mg NC 7312/L level, the fish remained in an almost comatose state for several hours before death occurred. In order to determine the possibility of these toxic symptoms being reversible, 5 fish were separately placed in water containing 50 mg NC 7312/L. After 4 h, all the fish were lying on the bottom of the tank, their breathing was shallow and they were near death. When these same fish were transferred to fresh water, although recovery was slow, within 24 h all the fish were swimming normally and feeding readily.	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	5.0, 8.0, 12.0, 15.0 and 20.0 mg NC 7312/L.	
4.2.2	Actual concentrations of test substance	4.2, 7.1, 11.7, 14.1 and 16.6 mg NC 7312/L.	X
4.2.3	Effect data (Mortality)	See Tables A7.4.1.1-14 and A7.4.1.1-15	X
4.2.4	Concentration / response curve	See Figure 1, page 6 in the original report	
4.2.5	Other effects	-	
4.3	**Results of controls**		
4.3.1	Number/percentage of animals showing adverse effects	No mortalities or adverse effects were observed among the control organisms (see Table A7.4.1.1-14)	
4.3.2	Nature of adverse effects	None	

4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	n.a.	
4.4.2	Results	n.a.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The purpose of this study was to estimate the acute toxicity (LC_{50}) of NC 7312 (major hydrolysis product of bendiocarb) to rainbow trout (*Salmo gairdneri*) under renewal conditions. Ten organisms were exposed in test chambers (using a renewal technique) to five concentrations of NC 7312, a dilution water control and a solvent (ethanol) control. During the test, fish were exposed to freshly prepared test solutions (nominal concentrations of 5.0, 8.0, 12.0, 15.0 and 20.0 mg NC 7312/L) every 24 hours by replacing the solutions in the test chambers. Each test solution was sampled and analysed for NC 7312 concentration at test initiation and at the end of each 24 h exposure period. Based on the results of these analyses, the mean measured test concentrations were 4.2, 7.1, 11.7, 14.1 and 16.6 mg NC 7312/L.	
5.2	**Results and discussion**	Following 96 hours of exposure, 100 % mortality was recorded in the highest nominal concentration of NC 7312 tested (20.0 mg NC 7312/L). Mortality ranged from 90 to 20 % in the remaining treatment levels (15.0 – 8.0 mg NC 7312/L). The 96 h LC_{50} was shown to be 10 mg NC 7312/L with a 95 % confidence interval of 8.1 – 12.4 mg NC 7312/L.	
5.2.1	LC_0	5.0 mg NC 7312/L	
5.2.2	LC_{50}	10.0 mg NC 7312./L (96 h)	
5.2.3	LC_{100}	20 mg NC7312/L (96 h)	
5.3	**Conclusion**		X
5.3.1	Other conclusions		
5.3.2	Reliability	1	X
5.3.3	Deficiencies	No	X

Table A7.4.1.1-9 Preparation of TS Solution for Poorly Stable or Volatile Test Substances

Criteria	Details
Dispersion	Directly added to dilution water
Vehicle	Ethanol
Concentration of vehicle	20 % w/v solution
Vehicle control performed	Yes
Other procedures	-

Table A7.4.1.1-10 Dilution water

Criteria	Details
Source	Dechlorinated tap water from the Anglian Water Authority
Alkalinity ($CaCO_3$)	27.5 mg/L
Hardness ($CaCO_3$)	308 mg/L
pH	7.6 – 7.8
Oxygen content	-
Conductance	410 µmkos
Holding water different from dilution water	No

Table A7.4.1.1-11 Test organisms

Criteria	Details
Species/strain	Rainbow trout (*Salmo gairdneri*)
Source	Bibury Trout Farm, Bibury, Gloucestershire, U.K.
Wild caught	No
Age/size	Weight 3.1-5.3 g; length 4.7-8.2 mm
Kind of food	Proprietary food (Trouvit 1)
Amount of food	*Ad libitum*
Feeding frequency	Daily
Pretreatment	The fish were maintained in 250 L fibreglass tanks at 12 ± 1°C in dechlorinated tap water with a flow through of 1L/min. The photoperiod for both maintenance and study was 12 h. The water was aerated continuously. Deaths over the 14 day acclimatisation period were recorded as < 1 %.
Feeding of animals during test	No

Table A7.4.1.1-12 Test system

Criteria	Details
Test type	Renewal of the test solution
Renewal of test solution	Replacement of the solution in the test chamber (40 L) by freshly prepared test solution every 24 hours
Volume of test vessels	40 L (depth of 30 cm)
Volume/animal	ca. 4.0 L
Number of animals/vessel	10
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.1-13 Test conditions

Criteria	Details
Test temperature	11-12°C
Dissolved oxygen	42-66 %
pH	7.5-7.8
Adjustment of pH	No
Aeration of dilution water	No
Intensity of irradiation	Not reported
Photoperiod	12 hours

Table A7.4.1.1-14 Mortality data

Test-Substance concentration (nominal) [mg/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
5.0	0	0	0	0	0	0	0	0
8.0	0	1	2	2	0	10	20	20
12.0	0	4	7	8	0	40	70	80
15.0	2	9	9	9	20	90	90	90
20.0	7	10	10	10	70	100	100	100
Water control	0	0	0	0	0	0	0	0
Solvent control	0	0	0	0	0	0	0	0
Temperature [°C]	11-12							
pH	7.5-7.8							
Oxygen [mg/l]	42-66							

Table A7.4.1.1-15 Effect data

	96 h [mg/l][1]	95 % c.l.
LC_0	-	-
LC_{50}	10.0	8.1 – 12.4
LC_{100}	-	-

[1] based on nominal concentrations

Table A7.4.1.1-16 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	n.a.	

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

EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	22/12/2006
Materials and methods	The Applicant's version is acceptable, noting the following: **3.1.5** No relevant properties of NC 7312 were provided (e.g. water solubility, hydrolytic stability, vapour pressure). The UK CA would have liked to have seen these properties recorded, but notes that as analysis has been provided to confirm NC 7312 levels in the test medium, this additional information is not critical. **3.1.6** The detail given is insufficient. The method of analysis for NC 7312 is based on solvent extraction with diethyl ether, derivatisation with 2,4-dinitro-1-fluorobenzene and GC analysis with electron capture (EC) detection. **3.2** The NC 7312 in ethanol solution was added to the test solutions such that the maximum volume of ethanol was 10 ml per 40 litre (range-finding test) and 4 ml per 40 litre (definitive test). **3.4.1** Although the oxygen content of the dilution water was not given in Table A7.4.1.1-10, it is stated in the study report that the water was aerated continuously during the pre-study period, and the UK CA assumes that the dilution water was adequately oxygenated. **3.4.2** There is error in Table A7.4.1.1-11 – the length of the fish should be 4.7-8.2 cm as given in the study report, and not 4.7 – 8.2 mm as stated in the summary. **3.4.4** In Table A7.4.1.1-13 it states that there was no aeration during the study – the UK CA does not consider this a significant issue, as the dilution water was aerated and no mortalities were observed in the control test vessels during the study.
Results and discussion	The Applicant's version is acceptable, noting the following: **4.1.2** The range-finding test also indicated that no mortality was observed in the 5.0 mg l^{-1} test concentration over 96 h, suggesting that a 96 h LC_{50} would be between 5 and 25 mg l^{-1} **4.2.2** The actual concentrations given are based on the mean of the measured values on Day 0 and after 24, 48, 72 and 96 h for each of the 5, 8, 12 & 15 mg l^{-1} concentrations, and the mean of the measured values on Day 0 and after 24 h for the 20 mg l^{-1} concentration. The mean measured values were within ± 20 % of the nominal concentrations, so the test substance concentrations are considered to have been maintained and nominal values can be used to determine the results, according to the validity criteria given in OECD guideline 203. Nominal values were used determine the 96 h LC_{50} in this study. **4.2.3** Table A7.4.1.1-14 indicates both the number and percentage mortality during the study. However, the UK CA notes that the numbers are not presented in the study report, but have been correctly back-calculated from the percentages within the report.

	Table A7.4.1.1-15 reports only LC_{50} values giving the impression LC_0 and LC_{100} values are not available. However LC_0 and LC_{100} values are given by the Applicant in Section 5.2 and hence should have been included in this table.
Conclusion	The Applicant's version is acceptable, noting the following: **5.3** The validity criteria have not been mentioned here, although a table (Table A7.4.1.1-16) has been included to show the validity of this study against criteria given in OECD guideline 203. The criteria of dissolved oxygen > 60 % saturation is not fulfilled in this study as the dissolved oxygen (DO) varied from 42 - 66 %. However, it should be noted that the dissolved oxygen was measured before and after each replenishment (according to page 4 of the study report), but only prior to replenishment (according to page 7 of the study report). The UK CA does not consider the lower DO values to be an issue as used solutions were being measured. **5.3.2** The reliability of this study has been reduced to 2, since it was not done to guideline OECD 203, and shows some deficiencies compared to this guideline (see below). In addition, no replicates were used and the analytical methodology is missing. **5.3.3** No deficiencies have been reported compared to the original study protocol. However, when compared to OECD guideline 203, the UK CA noted that: - there was a lack of information on the solubility, stability and volatility of the test substance (although measured values confirmed the presence of NC 7312 in the test) - the fish exceeded the recommended total length for these test fish of 5 ± 1 cm (recorded as 4.7 - 8.2 cm for this study) - the fish were maintained at 11 - 12 °C (lower than the recommended test temperature range of 13 - 17 °C) The UK CA considers these deficiencies do not affect the results of the study.
Reliability	2
Acceptability	Acceptable
Remarks	All endpoints and data presented in the summary have been checked against the original study and are correct.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

7.4.1.2 Acute toxicity to invertebrates

		1. REFERENCE	Official use only
1.1	**Reference**	Gries. T. (2005a) Bendiocarb technical: Acute immobilisation test with daphnids (*Daphnia magna*) under flow-through conditions [redacted] Document M-259123-01-1 7.4.1.2/01 13 October 2005 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**	OECD 202, EEC C2, US EPA 72-2.	X
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Bendiocarb	
3.1.1	Lot/Batch number	B930101	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	97.62 %	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	HPCL/UV	X
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See Table A7.4.1.2-1	
3.3	**Reference substance**	None	X
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	X
3.4.2	Test organisms	See Table A7.4.1.2-3	X

3.4.3	Test system	See Table A7.4.1.2-4	X
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	Immobilisation	
3.4.7	Sampling	Prior to test and 24 and 48 hours	
3.4.8	Monitoring of TS concentration	Yes	
3.4.9	Statistics	Moving average angle analysis, probit, non-linear interpolation.	
		4. RESULTS	
4.1	**Limit test**		
4.1.1	Concentration	Not conducted	
4.1.2	Number/ percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	0.0125, 0.025, 0.05, 0.1, 0.2 mg a.s./L	
4.2.2	Actual concentrations of test substance	0.015, 0.029, 0.050, 0.11 and 0.16 mg a.i./L	
4.2.3	Effect data (Immobilisation)	See Tables A7.4.1.2-6 and A7.4.1.2-7.	X
4.2.4	Concentration / response curve	See Figure A7.4.1.2-1.	
4.2.5	Other effects	-	
4.3	**Results of controls**	0 % immobilisation at hour 0, 24 and 48 for the control and solvent control (DMF)	
4.4	**Test with reference substance**	Not applicable	
4.4.1	Concentrations	Not applicable	
4.4.2	Results	Not applicable	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A 48 hour study was conducted with technical bendiocarb (97.62 %) to determine its toxicity to *Daphnia magna* under flow-through conditions. The GLP study was conducted according to guideline OECD 202. It included four replicates at each test concentration, control and solvent control (DMF). Mean measured concentrations were 0.015, 0.029, 0.050, 0.11 and 0.16 mg a.s./L.	

		Observations regarding immobilisation and any sublethal effects resulting from the exposure to the test item were performed at hour 0, 24 and 48. Dissolved oxygen concentration, temperature and pH were measured at hours 0 and 48 in one replicate of the control, solvent control and of the treated test concentrations. The measured parameters were within the acceptable range.	
5.2	**Results and discussion**	Twenty-four hours after start of the exposure, no immobilisation was observed at the control, the solvent control and at the mean measured 0.015 mg a.s./L test group. At mean measured 0.029, 0.050, 0.11 and 0.16 mg a.s./L, 10, 55, 70 and 95 % immobilisation was found, respectively. Lethargic daphnids were observed at mean measured concentrations of 0.015 mg a.s./L and higher. At hour 48, no immobilisation was found at the control, solvent control and at mean measured 0.015mg a.s./L. At mean measured 0.029, 0.050, 0.11 and 0.16 mg a.i/L, 10, 90, 100 and 100 % immobilisation was observed, respectively. Sublethally affected daphnids, i.e. lethargic daphnids, were observed at mean measured 0.029 mg a.s./L. Based on the observed immobilisation, the 48-hour NOEC is 0.0148 mg a.s./L. The 48-hour EC_{50} was determined as 0.0377 mg a.s./L (corresponding 95 % confidence interval: 0.0333 to 0.0427 mg a.s./L).	
5.2.1	EC_0	0.0148 mg a.s./L	X
5.2.2	EC_{50}	0.0377 mg a.s./L (48 h)	X
5.2.3	EC_{100}	0.11 mg a.s./L	
5.3	**Conclusion**		X
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	Directly added to dilution water
Vehicle	Dimethylformamide (DMF)
Concentration of vehicle	0.2047 g test substance in 100 ml vehicle
Vehicle control performed	Yes
Other procedures	-

Table A7.4.1.2-2 Dilution water

Criteria	Details
Source	Modified Elendt M4
Alkalinity	29 mg/L $CaCO_3$/L
Hardness	160 mg/L
pH	8.08
Ca / Mg ratio	Not reported
Na / K ratio	Not reported
Oxygen content	94 % saturation
Conductivity	455 µS/cm
Holding water different from dilution water	No

Table A7.4.1.2-3 Test organisms

Criteria	Details
Species/strain	*Daphnia magna*
Source	In-house culture
Age	≤ 24 h
Breeding method	Not reported
Kind of food	*Ankistrodesmus falcatus* (green algae)
Amount of food	0.5 – 1.5 ml containing 4 x 10^7 cells/ml
Feeding frequency	Daily
Pretreatment	None
Feeding of animals during test	Yes

Table A7.4.1.2-4 Test system

Criteria	Details
Renewal of test solution	Yes (flow rate: 20 mL/min)
Volume of test vessels	Filled to 1 litre
Volume/animal	Not reported
Number of animals/vessel	Five
Number of vessels/ concentration	Four
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.2-5 Test conditions

Criteria	Details
Test temperature	19.7 - 21°C
Dissolved oxygen	6.76 – 8.25 mg/L (77 – 96 % saturation)
pH	7.56 – 7.84
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Not reported
Photoperiod	16 h light, 8 h dark

Table A7.4.1.2-6 Immobilisation data

Test-Substance concentration (mean measured) [mg a.s./l]	Immobile *Daphnia*			
	Number		Percentage	
	24 h	48 h	24 h	48 h
0	0	0	0	0
Solvent control	0	0	0	0
0.015	0	0	0	0
0.029	2	2	10	10
0.050	11	18	55	90
0.11	14	20	70	100
0.16	19	20	95	100

Table A7.4.1.2-7 Effect data

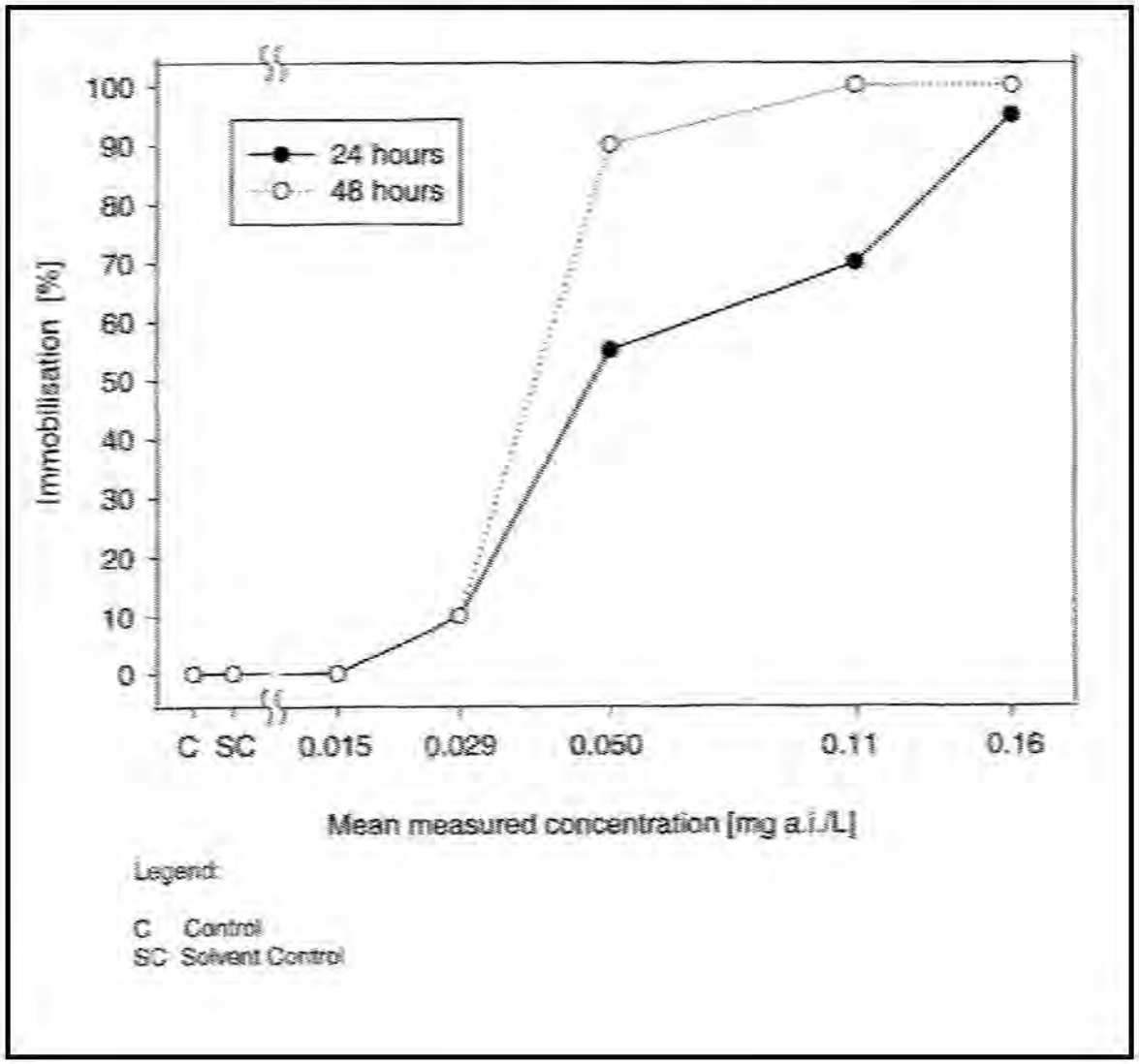
	EC_{50}[1]	95 % c.l.	EC_0[1]	EC_{100}[1]
24 h [mg a.s./l]	0.0593	0.0448 – 0.0758	0.015	-
48 h [mg a.s./l]	0.0377	0.0333 – 0.0427	0.015	0.11

1 based on mean 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	

Figure A7.4.1.2-1 Dose Response Curve During the 48-hour Exposure of Daphnids (*Daphnia magna*) to the Test Item Under Flow-Through Conditions



	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	22/12/2006
	2.1 The study has been done according to OECD 202 (2004). In addition EEC C.2 indicates guideline C.2 from directive 92/69/EC (1992) and US EPA 72-2, refers to guideline FIFRA 72 – 2 (1982).
Materials and methods	The Applicant's version is acceptable, noting the following: **3.1.6** The method of analysis is HPLC-UV (as 213 nm) and not HPCL/UV. **3.3** A reference substance, potassium dichromate, was used to determine the sensitivity of the *Daphnia magna*. The reference test gave a 48 h EC_{50} value of 0.68 mg l^{-1} which is consistent with the 24 h EC_{50} of 0.6 – 2.1 mg l^{-1} quoted in OECD guideline 202. **3.4.1** Table A7.4.1.2-2 gives an oxygen content of 94 % saturation but this is not stated in the study report. The report did state that the dilution water was recirculated so that dissolved gases would reach equilibrium with the atmosphere. The conductivity of 455 µS cm^{-1} appears to be taken from a measurement of the control vessel on Day 0. The dilution water is a modified Elendt M4 although no reason for the modification, compared to the Elendt M4 composition in the OECD 202 guideline, is given in the study report. The UK CA does not consider this to be of concern, as the reference substance test indicated that the effect on daphnids was as expected. **3.4.2** Table A7.4.1.2-3 incorrectly indicates that there was feeding of the animals during the test. The actual study report states (on page 14) that the daphnids were not fed which is in line with the OECD 202 guideline. **3.4.3** Table A7.4.1.2-4 indicates that the volume/animal is not reported, although the UK CA notes that as the test vessels are 1 litre and contain 5 daphnids the volume/animal can be calculated to be 200 ml **3.4.4** Table A7.4.1.2-5 indicates that the test temperature was 19.7 – 21 °C which is consistent with the daily single readings. However, the continuously measured temperature ranged from 19.4 – 21 °C.
Results and discussion	The Applicant's version is acceptable, noting the following: **4.2.3** Table A7.4.1.2-7 gives effect data based on mean measured concentrations. The UK CA notes that the EC_{50} value is based on immobility data presented in Table A7.4.1.2-6, but that no sub lethal effects data are presented in the study summary, although the conclusions are given in Section 5.2.
Conclusion	The Applicant's version is acceptable, noting the following:

	5.2.1 & 5.2.2 The EC_0 and EC_{50} values given are to four decimal places, and the UK CA thinks that this is beyond the limits of accuracy. The applicant has previously reported the EC_0 as 0.015 mg l^{-1} (rather than the 0.0148 mg l^{-1} given here). The UK CA considers that the 48 h EC_{50} should be reported here as 0.038 mg l^{-1} and proposes to take this value forward for use in risk assessment. **5.3** The validity criteria have not been mentioned here, although a table (Table A7.4.1.2-8) has been included to show the validity of this study against criteria given in OECD guideline 202. The applicant has indicated that the test substance concentrations are ≥ 80 % of the initial concentrations, whilst the test concentrations should be ± 20 % of the nominal concentrations, if nominal values are to be used to determine the EC_{50}. This study reported that the measured concentrations ranged from 70.6 -122 % (Day 0) and 92.2 – 115 % (48 hours) of the nominal values, but the UK CA notes for any specific test concentration the mean measured concentration is ± 20 % of the nominal value and hence agrees that the criteria has been fulfilled. However, the applicant has chosen to use mean measured concentrations to determine the EC_{50} and the UK CA considers this acceptable.
Reliability	1
Acceptability	Acceptable
Remarks	All endpoints and data presented in the summary have been checked against the original study and are correct.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

			Official use only
		1. REFERENCE	
1.1	**Reference**	Williams, T.D. and Thompson, R.S. (1982) Determination of the Acute Toxicity (48 hour EC_{50}) of NC 7312 to *Daphnia magna* [redacted] Document A90493 7.4.1.2/02 January 1982 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**	No, but the study was conducted in line with good scientific practice	X
2.2	**GLP**	No, the study was conducted prior to the introduction of GLP as a standard requirement but was conducted to QA	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	NC 7312 (major hydrolysis product of bendiocarb)	
3.1.1	Lot/Batch number	20173/1	X
3.1.2	Specification	-	
3.1.3	Purity	> 99 %	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	X
3.1.6	Method of analysis	GC-ECD	X
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable	
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 A7.4.1.2-9	X
3.4.2	Test organisms	See Table A7.4.1.2-10	X

3.4.3	Test system	See Table A7.4.1.2-11	X
3.4.4	Test conditions	See Table A7.4.1.2-12	X
3.4.5	Duration of the test	48 hours	
3.4.6	Test parameter	Immobilisation	X
3.4.7	Sampling	Prior to test and 48 hours	
3.4.8	Monitoring of TS concentration	Yes	
3.4.9	Statistics	Probit analysis (Finney, 1971) using a computer programme	
		4. RESULTS	
4.1	**Limit test**		
4.1.1	Concentration	Not conducted	
4.1.2	Number/ percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	3.2, 5.6, 10.0, 18.0, 32.0, 56.0 and 100.0 mg NC 7312/L	
4.2.2	Actual concentrations of test substance	2.52, 5.43, 9.22, 18.41, 33.73, 59.65, 99.05 mg NC 7312/L	X
4.2.3	Effect data (Immobilisation)	See Tables A7.4.1.2-13 and A7.4.1.2-14.	
4.2.4	Concentration / response curve	Not reported	
4.2.5	Other effects	-	
4.3	**Results of controls**	0 % immobilisation at 24 and 48 hours for the control	
4.4	**Test with reference substance**	Not applicable	
4.4.1	Concentrations	Not applicable	
4.4.2	Results	Not applicable	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A 48 hour study was conducted with NC 7312 (major hydrolysis product of bendiocarb) (> 99 % purity) to determine its toxicity to *Daphnia magna* under static conditions. The study included four replicates at each test concentration and control. Nominal concentrations were 3.2, 5.6, 10.0, 18.0, 32.0, 56.0 and 100.0 mg NC 7312/L.	

		Observations regarding immobilisation resulting from the exposure to the test item were performed at 24 and 48 hours after commencement of the test. Dissolved oxygen concentration and pH were measured prior to the start of the test and at the end of the test in two replicates of the control and treatment.	
5.2	**Results and discussion**	The EC_{50} values (and 95 % confidence limits) obtained were: 24 hour EC_{50} = 52.1 (43.3 – 63.3) mg NC 7312/L 48 hour EC_{50} = 25.4 (22.1 – 29.2) mg NC7312/L These values were calculated on the basis of the nominal concentrations.	
5.2.1	EC_0	10.0 mg NC 7312/L (48 h)	
5.2.2	EC_{50}	25.4 mg NC 7312/L (48 h)	
5.2.3	EC_{100}	56 mg NC 7312/L (48 h)	
5.3	**Conclusion**		X
5.3.1	Reliability	2	
5.3.2	Deficiencies	No	

Table A7.4.1.2-9 Dilution water

Criteria	Details
Source	Reconstituted water medium
Alkalinity	111 mg/L
Hardness (total as $CaCO_3$)	144 mg/L
pH	8.25 ± 0.25
Ca / Mg ratio	Not reported
Na / K ratio	Not reported
Oxygen content	Not reported
Conductivity	350 µS/cm
Holding water different from dilution water	No

Table A7.4.1.2-10 Test organisms

Criteria	Details
Species/strain	*Daphnia magna*
Source	In-house culture
Age	≤ 24 h
Breeding method	Not reported
Kind of food	Algae *(Chlorella vulgaris)* and yeast
Amount of food	Not specified
Feeding frequency	Not specified
Pretreatment	None
Feeding of animals during test	Yes

Table A7.4.1.2-11 Test system

Criteria	Details
Renewal of test solution	No
Volume of test vessels	200 mL
Volume/animal	Not reported
Number of animals/vessel	Five
Number of vessels/ concentration	Four
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.2-12 Test conditions

Criteria	Details
Test temperature	20.0 ± 1.0°C
Dissolved oxygen	8.60 – 9.10 mg/L
pH	8.10 – 8.60
Adjustment of pH	No
Aeration of dilution water	Yes (for > 2 hours before use)
Quality/Intensity of irradiation	1500 Lux
Photoperiod	16 h light, 8 h dark

Table A7.4.1.2-13 Immobilisation data

Test-Substance concentration (nominal) [mg/L]	Immobile *Daphnia*			
	Number		Percentage	
	24 h	48 h	24 h	48 h
0	0	0	0	0
3.2	0	0	0	0
5.6	0	0	0	0
10	0	0	0	0
18	0	2	0	10
32	4	16	20	80
56	11	20	55	100
100	18	20	90	100

Table A7.4.1.2-14 Effect data

	EC_{50}[1]	95 % c.l.	EC_0[1]	EC_{100}[1]
24 h [mg NC 7312/L]	52.1	43.3 – 63.3	18	-
48 h [mg NC 7312/L]	25.4	22.1 – 29.2	10	56

1 based on nominal concentrations

Table A7.4.1.2-15 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	

	EVALUATION BY COMPETENT AUTHORITIES
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	22/12/2006
	2.1 The study was not carried out to any recognised national/international guidelines. However, the UK CA considers that this is not an issue, and has assessed the study against the requirements within the OECD guideline 202 (*Daphnia* sp., Acute Immobilisation Test, 1992). This is consistent with the Applicant's approach of comparing the study against the validity criteria in OECD 202 in this study summary.
Materials and methods	The Applicant's version is acceptable, noting the following: **3.1.1** The full batch number is CR No. 20173/1 **3.1.5** No relevant properties of NC 7312 were provided (e.g. water solubility, hydrolytic stability, vapour pressure). The UK CA would have liked to have seen these properties recorded, but notes that as analysis has been provided to confirm NC 7312 levels in the test medium, this additional information is not critical. **3.1.6** The detail given in the study summary is insufficient. NC 7312 in the test samples was analysed by solvent extraction with diethyl ether, derivatisation with 2,4-dinitro-1-fluorobenzene and GC analysis with electron capture (EC) detection. The UK CA also notes that no method validation data (recoveries or LOD) or results were presented in the study report, just the measured levels of NC 7312. **3.4.1** Table A7.4.1.2-9 indicates that the oxygen content of the dilution water was not reported. However, the study report indicates that the dissolved oxygen content at 0 hours in the dilution water was 9.10 mg l^{-1}. The dilution water was reconstituted water with a salt composition that differed from that proposed in OECD guideline 2002. However, as the daphnids survived for the length of the study in the control, the UK CA considers this medium adequate for this test. The pH range is stated as 8.25 ± 0.25 °C which represents the pH values observed in the test concentrations during the test and not the dilution water. The study report gives the pH value of the dilution water batch as 8.48 **3.4.2** Table A7.4.1.2-10 indicates that the animals were fed during the test. This is incorrect, as the study report (page 4) states that the *Daphnia* were not fed during the course of the test - this is consistent with the requirements in OECD guideline 202. The species of *Daphnia* has been recorded as *Daphnia magna*, although the study report gives more detail, recording it as *Daphnis magna* Straus. **3.4.3** Table A7.4.1.2-11 indicates that the volume/animal is not reported, although the UK CA notes that as the test vessels are 200 ml and contain 5 daphnids the volume/animal can be calculated to be 40 ml.

	3.4.4 Table A7.4.1.2-12 indicates the test temperature to be 20.0 ± 1.0 °C. The UK CA notes that this is proposed range for the test, and that the actual values range from 19.5 –19.9 °C **3.4.6** In this study a *Daphnia* is considered immobile if it shows no whole body movement relative to the water within a period of 10 seconds, even if movement of individual appendages is visible. This differs from the definition of immobile in the OECD guideline 2002. In the OECD guideline a *Daphnia* is considered immobile if it is not able to swim within 15 seconds after gentle agitation of the test vessel (even if it can still move its antennae). The UK CA considers that the definition of immobile in this study is more likely to define daphnids as immobile than the OECD guideline and hence that the EC_{50} value determined is worst-case.
Results and discussion	The Applicant's version is acceptable, noting the following: **4.2.2** The actual concentrations of test substance i.e. 2.52, 5.43, 9.22, 18.41, 33.73, 59.65, 99.05 mg l^{-1} NC 7312 are mean measured values obtained from the analysis of two replicates at each concentration after 48 hours. The UK CA has calculated the mean measured concentrations from 0 and 48 h for each test concentration and all are ± 20 % of the nominal values. Hence, the UK CA considers the Applicant's use of nominal concentrations for the determination of the EC_{50} to be acceptable.
Conclusion	The Applicant's version is acceptable, noting the following: **5.3** The validity criteria have not been mentioned here, although a table (Table A7.4.1.2-15) has been included to show the validity of this study against criteria given in OECD guideline 202. The UK considers the Applicant's indication that all criteria have been met to be consistent with the study report.
Reliability	2
Acceptability	Acceptable
Remarks	All endpoints and data presented in the summary have been checked against the original study and are correct.
	COMMENTS FROM …
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

7.4.1.3 Growth inhibition test on algae

			Official use only
		1. REFERENCE	
1.1	**Reference**	Gries, T. (2005b) Bendiocarb technical: Alga, Growth Inhibition Test with *Pseudokirchneriella subcapitata* (syn. *Selenastrum capricornutum*) [redacted] Document M-259108-01-1 7.4.1.3/01 13 October 2005 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**	OECD 201.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3. MATERIALS AND METHODS	
3.1	**Test material**	Bendiocarb	
3.1.1	Lot/Batch number	B930101	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	97.62 %	
3.1.4	Composition of product	Not applicable	
3.1.5	Further relevant properties	-	
3.1.6	Method of analysis	HPLC/UV	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See Table A7.4.1.3-1.	
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Culture medium	Algal medium	X
3.4.2	Test organisms	*Pseudokirchneriella subcapitata* (see Table A7.4.1.3-2).	X

3.4.3	Test system	See Table A7.4.1.3-3	
3.4.4	Test conditions	See Table A7.4.1.3-4	X
3.4.5	Duration of the test	72 hours	X
3.4.6	Test parameter	Cell density and growth rate	
3.4.7	Sampling	0, 48 and 72 hours	
3.4.8	Monitoring of TS concentration	Yes	
3.4.9	Statistics	Dunnett's test (NOEC); probit, moving average angle, non-linear interpolation (E_rC_{50})	X
		4. RESULTS	
4.1	**Limit test**	None	X
4.1.1	Concentration	Not applicable	
4.1.2	Number/ percentage of animals showing adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	0.13, 0.32, 0.8, 2.0, 5.0 mg a.s./L	X
4.2.2	Actual concentrations of test substance	0.015, 0.035, 0.087, 0.17, 0.54 mg a.s./L	X
4.2.3	Growth curves	See Figure A7.4.1.3-1.	
4.2.4	Concentration / response curve	See Figure A7.4.1.3-2.	
4.2.5	Cell concentration data	See Table A7.4.1.3-5.	X
4.2.6	Effect data (cell multiplication inhibition)	See Table A7.4.1.3-5.	
4.2.7	Other observed effects	-	
4.3	**Results of controls**	See Table A7.4.1.3-5.	
4.4	**Test with reference substance**	Not applicable	
4.4.1	Concentrations	-	
4.4.2	Results	-	

		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A 72 hour study was conducted with bendiocarb technical (97.62 %) to determine its toxicity to *Pseudokirchneriella subcapitata*. The GLP study was conducted according to Guideline OECD 201. It included three replicates for each test concentration; measured concentrations were 0.015, 0.035, 0087, 0.17 and 0.54 mg a.s./L.	
5.2	**Results and discussion**	From 0 to 48 hours, fast algal growth was observed in the control, solvent control and up to mean measured test concentrations to 0.087 mg a.s./L. From 48 to 72 hours, reduced algal growth was observed in all cultures including the controls. Therefore, the 48 to 72 hours interval was not considered for the evaluation of the biological results. The quality criteria as outlined in the guideline were fulfilled for the test period from 0 to 48 hours since exponential growth was observed for the initial 48 hours exposure interval and the cell density increased by the factor of 66 during that period. Therefore, this time interval is considered to be the most relevant for the evaluation of the results. One deformed algal cell was observed at the geometric mean measured test concentration of 0.087 mg a.s./L at hour 48. Based on geometric mean measured concentrations, the NOEC (0 to 48 hours, growth rate) was 0.087 mg a.s./L. The 0 to 48 hours E_rC_{50} was 0.408 mg a.s./L (corresponding 95 % confidence interval: 0.181 to 1.11 mg a.s./L). Based on nominal concentrations, the 0 to 48 hours E_rC_{50} was 3.96 mg a.s./L (corresponding 95 % confidence interval: 2.60 to 6.31 mg a.s./L). The 48-hour NOEC (growth rate) was 0.8 mg a.s./L based on nominal concentrations.	
5.2.1	NOE_rC	0.087 mg a.s./L (based on geometric mean measured concentrations)	
5.2.2	E_rC_{50}	0.408 mg a.s./L (based on geometric mean measured concentrations)	X
5.2.3	E_bC_{50}	0.227 mg a.s./L (based on geometric mean measured concentrations)	
5.3	**Conclusion**		X
5.3.1	Reliability	1	X
5.3.2	Deficiencies	No	

Table A7.4.1.3-1 Preparation of TS Solution for Poorly Stable or Volatile Test Substances

Criteria	Details
Dispersion	Stock solutions were directly added to the dilution water
Vehicle	Dimethyl formamide (DMF)
Vehicle control performed	Yes
Other procedures	-

Table A7.4.1.3-2 Test organisms

Criteria	Details
Species	*Pseudokirchneriella subcapitata*
Strain	-
Source	In-house culture
Laboratory culture	Yes
Method of cultivation	Not reported
Pretreatment	None
Initial cell concentration	66.8 x 10^4 cells/mL

Table A7.4.1.3-3 Test system

Criteria	Details
Volume of culture flasks	250 ml
Culturing apparatus	Erlenmeyer flasks
Light quality	7000 – 8600 lux (continuous)
Procedure for suspending algae	Continual shaking (90 rpm)
Number of vessels / concentration	Three
Test performed in closed vessels	Yes

Table A7.4.1.3-4 Test conditions

Criteria	Details
Test temperature	23.7 – 25.0°C
pH	7.76 – 9.96
Aeration of dilution water	Yes
Light intensity	7000 – 8600 lux
Photoperiod	Continuous

Table A7.4.1.3-5 Cell Concentration Data After 48 Hours

Test-Substance concentration (mean measured) [mg a.s./l]	Density (x 10^4 cells/mL)	Growth Rate (day^{-1})	Inhibition Growth Rate (%)
Pooled control	66.4	2.08	0.00
0.015	62.8	2.06	1.09
0.035	58.2	2.02	3.12
0.087	65.0*	2.08	0.29
0.17	28.8	1.67**	19.9
0.54	5.4	0.84**	59.6
Temperature [°C]	23.8 – 24.1		
pH	7.76 – 9.96		
Oxygen [mg/l]	-		

*: one deformed algal cell was observed
**: statistically significant reduction when compared to the pooled control (Dunnett's test, 1 tailed, test level = 0.05)

Table A7.4.1.3-6 Validity Criteria for Algal Growth Inhibition Test According to OECD Guideline 201

	Fulfilled	Not fulfilled
Cell concentration in control cultures increased at least by a factor of 16 within 3 days	X	
Concentration of test substance ≥ 80 % of initial concentration during test	X	

Figure A7.4.1.3-1 Algal Growth Curves (density versus time) for *Pseudokirchneriella subcapitata* Exposed to the Test Item

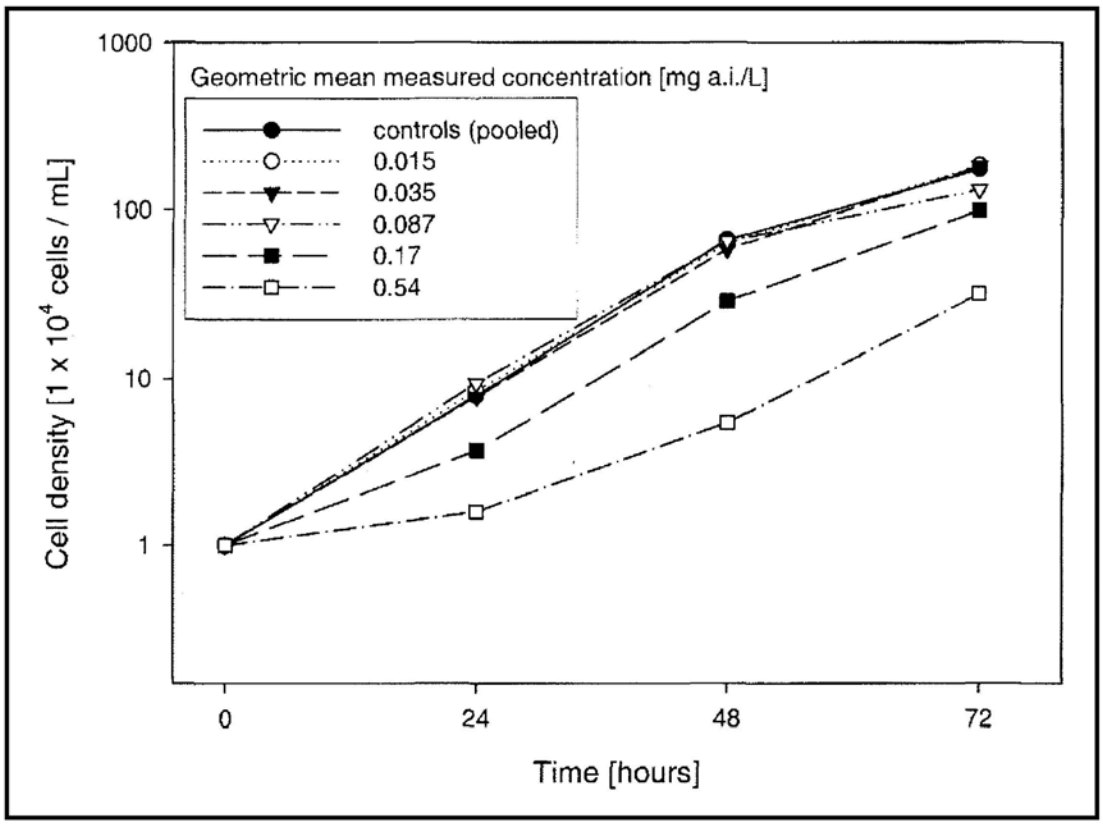
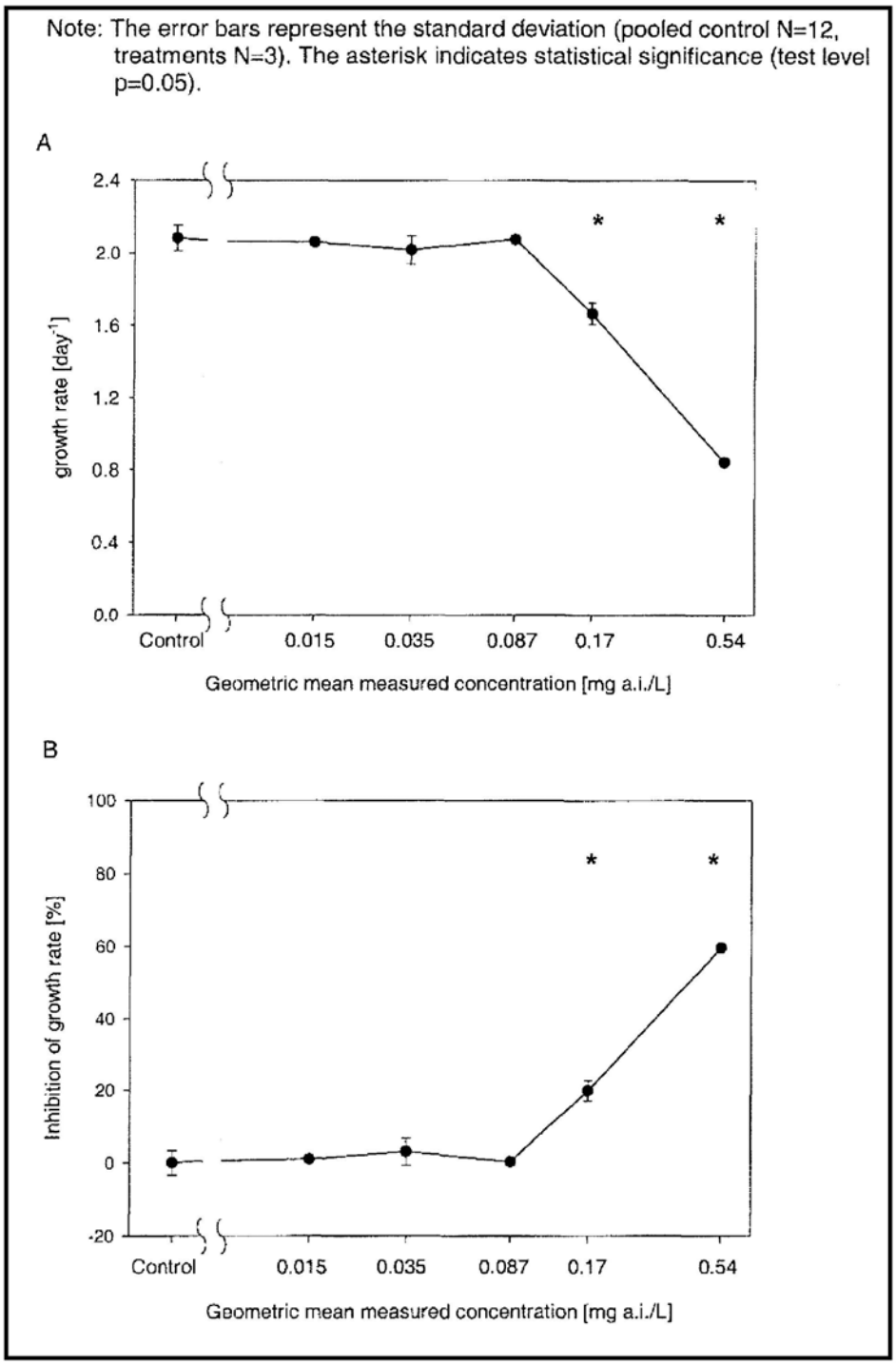


Figure A7.4.1.3-2 **A. Algal Growth Curves (growth rate versus concentration) for 0 to 48 hours for *Pseudokirchneriella subcapitata* Exposed to the Test Item**
B. Percentage Inhibition of the Growth Rate



EVALUATION BY COMPETENT AUTHORITIES	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	04/02/08
	2.3 It is stated in the study report that there is a deviation from the OECD 201 guideline. However, as in this 72 h study the pH increased from 7.76 to 9.96 i.e. more than 1.5 pH units. The Applicant has indicted that this is not an issue as bendiocarb is not detectable at 72 h, and hence EC_{50}/NOEC data have only been presented for 0 - 48 h. Although the pH was not recorded at 48 h, the Applicant notes that the pH increase is expected to be greatest from 48 h to 72 h and hence believes that the pH increase would not have exceeded 1.5 units after 48 h. The UK CA agrees.
Materials and methods	The Applicant's version is acceptable, noting the following: **3.4.1** The algal medium used was the OECD medium given in OECD 201 guideline with a slight modification. In the guideline 0.064 mg l^{-1} $FeCl_3.6H_2O$ was required, whilst in the study 0.08 mg l^{-1} $FeCl_3.6H_2O$ was used. No explanation was given in the study report, but the UK CA considers that this difference should not affect the results of the study. **3.4.2** In Table A7.4.1.3-2 the initial cell concentration was given as 66.8 x 10^4 cells ml^{-1}. This concentration is that prior to dilution down into the test vessels, with the concentration in the test vessels being 1 x 10^4 cells ml^{-1}. **3.4.4** Table A7.4.1.3-4 indicates that there is aeration of the dilution water, which is not indicated in either the study report or the OECD 201 guideline. Irrespective of whether the culture was aerated or not, the control cultures met the criteria for a biomass increase of at least 16-fold in the 72 h period, and hence the UK CA considers this discrepancy does not affect the study results. **3.4.5** The study was conducted over 72 h. However, reduced algal growth was observed in all test concentrations and controls after 48 h and the concentration of bendiocarb was not detectable in any nominal concentration after 72 h. Therefore, the Applicant considered it most appropriate to determine EC_{50}/NOEC values for the 0 - 48 h period. This is consistent with the OECD 201 guideline, where the test period may be shortened to 48 h to maintain unlimited exponential growth as long as the minimum multiplication factor of at least 16 is reached (the study summary indicates a multiplication factor of about 66 was obtained). **3.4.9** The study report indicates that the statistical package included probit, moving average angle and non-linear interpolation. However the UK CA notes that only probit analysis was used to determine the EC_{50} according to the study report.
Results and discussion	The Applicant's version is acceptable, noting the following: **4.1** Although no limit test was done, a non-GLP range-finder was carried out to establish the test concentrations to be used in this study. **4.2.1** These initial concentrations of test substance are nominal concentrations. It

	should be noted that when analysis was done at 0 h the concentrations present varied from 79.2 % - 83.2 % of the nominal concentrations. **4.2.2** These actual concentrations of test substance are the geometric mean of measured concentrations. They have been calculated by taking the measured concentration at 0 h and the measured degradation for the nominal 5.0 mg l^{-1} sample at 48 h. This degradation has then been applied to the lower nominal concentrations (0.13 to 0.8 mg l^{-1}) where the observed concentrations were below LOQ (0.009 mg l^{-1}). The measured concentrations for the nominal 2.0 mg l^{-1} sample at 0 and 48 h were used to calculate its geometric mean. **4.2.5** Table A7.4.1.3-5 states that the temperature range after 48 h was 23.8 - 24.1 °C. This is incorrect and should be 23.8 – 25.0 °C. The pH range given is that for the whole study i.e. 0 - 72 h and not for 0 - 48 h. As the pH was not recorded at 48 h, no range can be given for 0 - 48 h.
Conclusion	The Applicant's version is acceptable, noting the following: **5.2.2** Due to lack of analysis at the 24 and 48 h endpoints, the UK CA does not have confidence in the ErC50 generated. However the UK CA does have confidence in the NOEC and considers this to be a reliable chronic endpoint. **5.3** The validity criteria have not been mentioned here, although a table (Table A7.4.1.3-6) has been included to show the validity of this study against criteria given in OECD guideline 201. The UK CA agrees that the study meets the biological criteria over the 0 - 48 h period: - biomass increased by at least a factor of 16 within test period (actual value was 66.4) - mean coefficient of variation for section-by-section growth rates do not exceed 35 % (actual value was 19.6 %) - coefficient of variation of average specific growth rates in the controls during whole test do not exceed 7 % (actual value was 3.42 %) but not that the test concentrations are ≥ 80 % .The test concentrations are not within ± 20 % of the nominal concentrations, however as geometric mean measured concentrations have been used the UK CA considers the validity criteria met. **5.3.1** The UK CA considers that the reliability of this study should be reduced to 2, since the lower test concentrations are approximate as they have been based on the measured concentrations at 0 h and the measured degradation observed in a higher test concentration. In addition, the pH at 48 h is not known and no EC_{50}/NOEC value has been able to be obtained for longer than 48 h.
Reliability	2
Acceptability	Acceptable
Remarks	All endpoints and data presented in the summary have been checked against the original study and are correct. The UK CA also notes that bendiocarb rapidly hydrolyses (half-life of 48.1 h at pH 7 and 43.8 minutes at pH 9) to NC 7312. Hence, it seems likely that the biological effects seen in the latter part of the test period may be partially contributed to NC 7312.