Table A7_1_1_1_2 (02)-1: Description of test solution and controls

Criteria	Details
Purity of water	Water of resistivity of 17 Mohms-cm from a Milli-Q water system (ion exchange, activated carbon and microfiltration) was used.
Preparation of test chemical solution	pH 5 Buffer- 0.6 mL of conc. acetic acid to 1L of water adjusted to pH 5 by addition of 50% NaOH. pH 7 buffer- 30 mL of 0.067M NaH_2PO_4 and 61 mL of 0.67 M K_2HPO_4 diluted 10-fold and adjusted to pH 7 with 50% NaOH pH 9 Buffer- 0.01 M $Na_2B_4O_7$ adjusted to pH 9 with conc. acetic acid
Test concentrations (mg a.s./L)	0.065 mg a.s./L
Temperature (°C)	25±1°C
Preparation of a.s. solution	1.0 mL of 0.013 mg/mL of AC 303,630 in acetonitrile was added to 200 mL of buffer
Controls	Dark Control – wrapped in tin-foil and stored at 25±1°C
Identity and concentration of co-solvent	Acetonitrile - 0.5% v/v

Table A7_1_1_1_2(02)-2: Description of test system

Criteria	Details
Laboratory equipment	250 mL Erlenmeyer flasks were used for the irradiated samples, and 16 oz. bottles were used for the controls. Both were sterilized by autoclaving for 30 minutes at 120°C. 200 mL of buffer, sterilized by filtration through a 0.22µm nylon filter (Corning Inc., Corning, NY) were transferred to each flask, and the tests substance was added under aseptic conditions. The controls were wrapped with foil and stored in a constant temperature room (QUEUE Mini-room, Queue Systems, Parkersburg, WV) at 25±1°C. Irradiated samples were placed in the photolysis chamber at 25±1°C. The spectrum of the lamp was recorded using a Li-Cor LI-1800 portable spectroradiometer at the point samples were irradiated during the study
Test apparatus	Ci-65 Weather-ometer® photolysis chamber
Properties of artificial light source:	
Nature of light source	[redacted]
Emission wavelength spectrum	See Figure A7_1_1_1_2(02)-1
Light intensity	0.25 w/m^2 at 340 nm
Filters	Borosilicate glass excluded wavelengths of less than 290 nm

Table A7_1_1_1_2 (02)-3.1: Concentration of test substance versus sampling time - pH 5

Phenyl label				Pyrrole label			
Time (Days)	ppm			Time (Days)	ppm		
	Rep A	Rep B	Avg.		Rep A	Rep B	Avg.
0	0.0657	0.0667	0.0662	0	0.0653	0.0657	0.0655
1	0.0475	0.0436	0.0455	1	0.0504	0.0522	0.0513
2	0.0432	0.0413	0.0422	2	0.0356	0.0423	0.0390
3	0.0321	0.0310	0.0315	3	0.0361	0.0372	0.0366
7	0.0180	0.0234	0.0207	7	0.0076	0.0179	0.0127
14	0.0074	0.0040	0.0057	14	0.0072	0.0082	0.0077
21	0.0038	0.0014	0.0026	21	0.0028	0.0029	0.0028
30	0.0019	0.0012	0.0016	30	0.0012	0.0005	0.0009
		k = 0.12832 $t_{1/2}$ = 5.4 days				k = 0.13504 $t_{1/2}$ = 5.1 days	

Table A7_1_1_1_2 (02)-3.2: Concentration of test substance versus sampling time - pH 7

Phenyl label				Pyrrole label			
Time (days)	ppm			Time (days)	ppm		
	Rep A	Rep B	Avg.		Rep A	Rep B	Avg.
0	0.0649	0.0676	0.0663	0	0.0599	0.0590	0.0594
0.166	0.0689	0.0664	0.0676	0.166	0.0599	0.0608	0.0603
0.25	0.0704	0.0585	0.0645	0.25	0.0620	0.0609	0.0615
1	0.0603	0.0580	0.0592	1	0.0562	0.0566	0.0564
1.25	0.0540	0.0558	0.0549	1.25	0.0551	0.0578	0.0564
2	0.0587	0.0561	0.0574	2	0.0525	0.0520	0.0522
3	0.0488	0.0563	0.0525	3	0.0515	0.0503	0.0509
4	0.0434	0.0376	0.0405	4	0.0458	0.0505	0.0482
7	0.0272	0.0365	0.0318	7	0.0255	0.0261	0.0258
14	0.0220	0.0167	0.0193	14	0.0223	0.0242	0.0232
22	0.0048	0.0111	0.0079	22	0.0110	0.0034	0.0072
30	0.0021	0.0039	0.0030	30	0.0056	0.0049	0.0052
		k = 0.09983 $t_{1/2}$ = 6.9 days				k = 0.08607 $t_{1/2}$ = 8.1 days	

Table A7_1_1_1_2 (02)-3.3: Concentration of test substance versus sampling time - pH 9

Phenyl label				Pyrrole label			
Time (days)	ppm			Time (days)	ppm		
	Rep A	Rep B	Avg.		Rep A	Rep B	Avg.
0	0.0616	0.0590	0.0603	0	0.0596	0.0608	0.0602
0.25	0.0569	0.0571	0.0570	0.25	0.0596	0.0571	0.0584
0.251	0.0558	0.0555	0.0566	0.251	0.0551	0.0560	0.0555
1.25	0.0502	0.0508	0.0505	1.25	0.0547	0.0538	0.0542
2	0.0466	0.0488	0.0477	2	0.0460	0.0482	0.0471
3	0.0450	0.0426	0.0438	3	0.0438	0.0423	0.0430
4	0.0374	0.0354	0.0364	4	0.0402	0.0325	0.0364
7	0.0217	0.0323	0.0270	7	0.0304	0.0226	0.0265
14	0.0063	0.0126	0.0095	14	0.0072	0.0111	0.0092
21	0.0023	0.0053	0.0038	21	0.0049	0.0034	0.0042
30	0.0008	0.0006	0.0007	30	0.0007	0.0009	0.0008
		k = 0.14311 $t_{1/2}$ = 4.8 days				k = 0.14149 $t_{1/2}$ = 4.9 days	

Table A7_1_1_1_2 (02)-4: Specification and amount of transformation products

Lab/Report Code, CAS, and/or IUPAC* Chemical Name*(s)	**Amount [%] of parent compound measured at**		
	pH 5	**pH 7**	**pH 9**
CL 357806 Not available 2-bromo-4-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-pyrrole-4-carbonitrile	62% at 21 days 53% at 30 days	62% at 30 days	68% at 21 days 66% at 30 days

Figure A7_1_1_1_2 (02)-1: Spectrum of Xenon Lamp

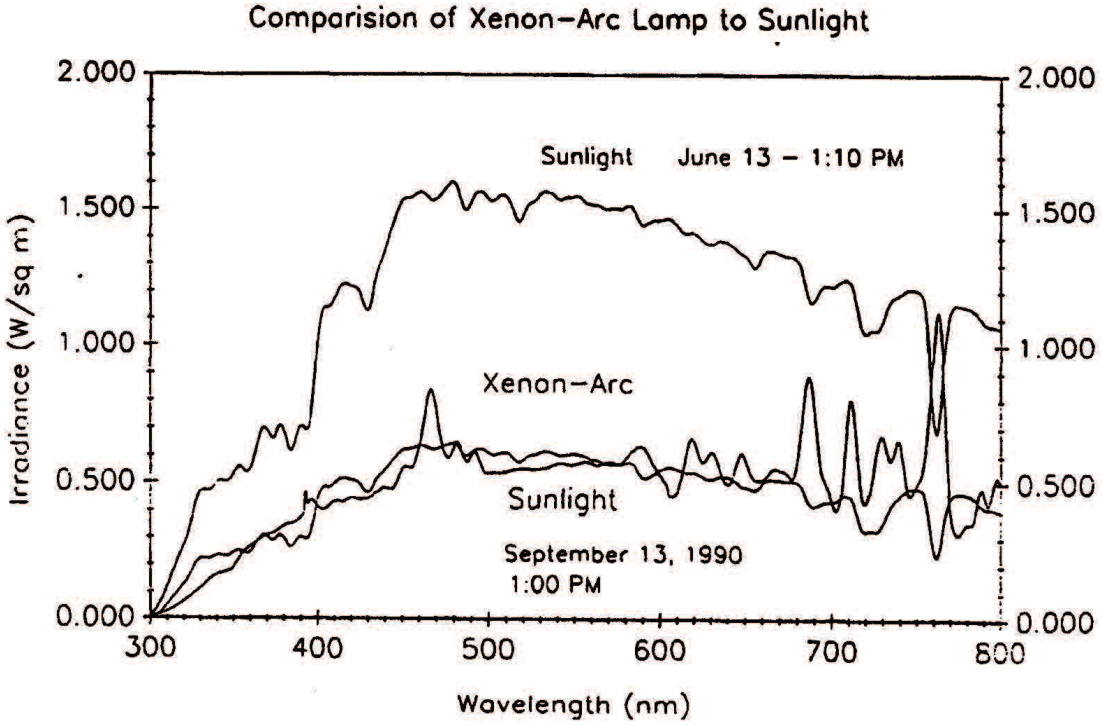
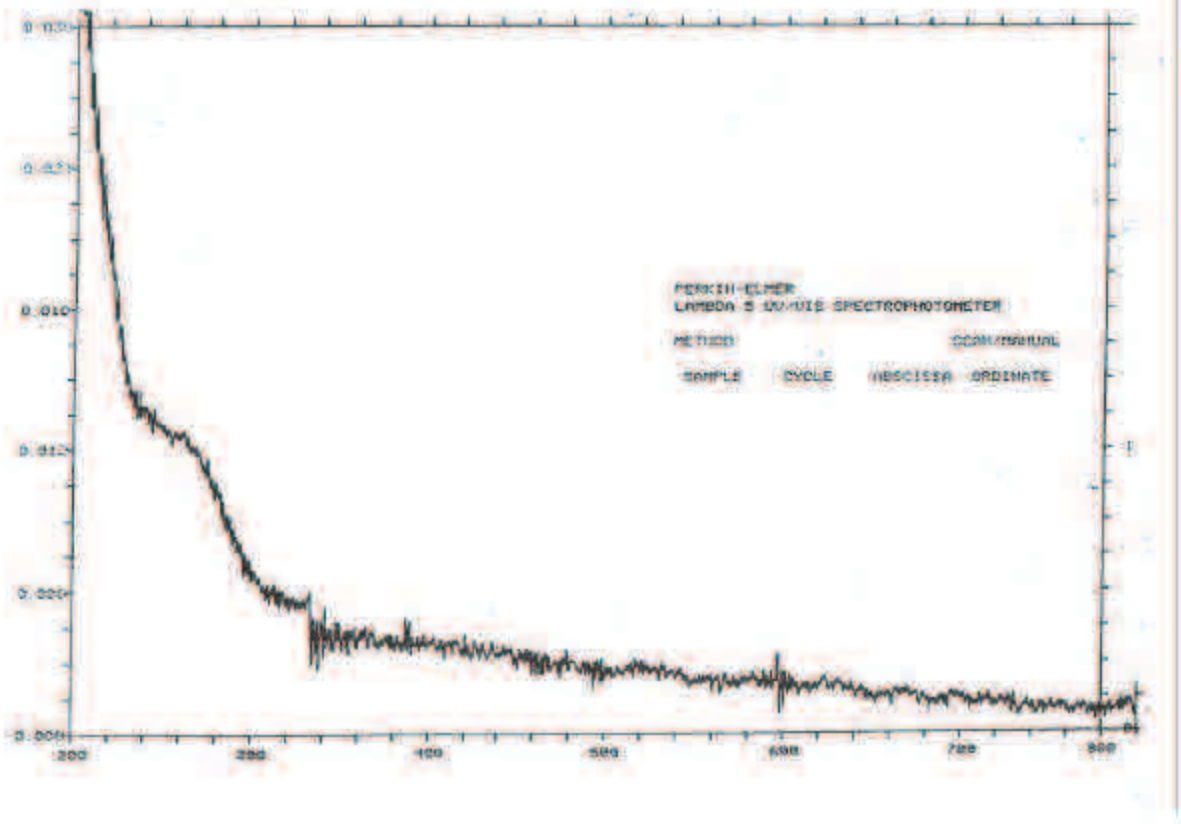


Figure A7_1_1_1_2 (02)-2: UV-vies absorption spectrum of chlorfenapyr



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			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I / authorization	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD 301B	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2	
3.1.1	Lot/Batch number	AC 8710-96D	
3.1.2	Specification	Deviating from specification given in section 2 as follows	
3.1.2.1	Purity	99.0%	
3.1.3	Further relevant properties	The solubility of AC 303,630 in de-ionized water and pH 5, 7, and 9 buffer solutions at 20°C is 0.14, 0.11, 0.11, and 0.14 mg/L, respectively.	X
3.1.4	Composition of Product	pure active ingredient	
3.1.5	TS inhibitory to microorganisms	No	
3.1.6	Specific chemical analysis	No	
3.2	**Reference substance**	sodium benzoate	
3.2.1	Initial concentration of reference substance	10 mg carbon/L	
3.3	**Testing procedure**		
3.3.1	Inoculum / test species	see Table A7_1_1_2_1(01)-2	
3.3.2	Test system	see Table A7_1_1_2_1(01)-3	

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3.3.3	Test conditions	see Table A7_1_1_2_1(01)-4
3.3.4	Method of preparation of test solution	67.9 mg and 67.7 mg of AC303,630 were added to the test replicates (3L)
3.3.5	Initial TS concentration	10 mg carbon/L
3.3.6	Duration of test	29 days
3.3.7	Analytical parameter	CO_2 evolution and loss of total organic carbon
3.3.8	Sampling	Samples were collected at days 1, 4, 6, 8, 11, 15, 20, 25, and 29 for CO_2 evolution, 0 and 29 days for TOC.
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	Not Applicable
3.3.11	Controls	Reference control - with Sodium Benzoate Toxicity control - with test and reference compounds Abiotic control - no inoculum plus sodium azide Blanks - without test or reference substance
3.3.12	Statistics	Inorganic carbon concentrations were calculated by the carbon analyzer as mg carbon/L, based on carbon standards. From the mg carbon/L values, the mg CO2 values were calculated as follows: (mg carbon/L from TOC) x 0.1L x (1mmol C/12 mg C) x (1mmolCO_2/ mmol C) x (44 mg CO_2/mmol CO_2) = mg CO_2 For carboys receiving test or reference chemicals, the net mg CO2 was determined by subtracting the average mg CO2 of the inoculum blank for a given day from the mg CO2 calculated per carboy per day. The net cumulative mg CO2 produced during the study was calculated. Percent theoretical CO2 (% ThCO2) was also calculated and determined as follows: %ThCO_2 = Total mg CO_2 produced/ThCO_2 x 100% where: ThCO_2 = Dosed mg carbon/L x 3L x (1 mmol C/12.01 mg C) x (1mmolCO_2/ mmol C) x (44 mg CO_2/mmol CO_2) The dosed mg carbon/L was determined from the theoretical dosing rate for the test chemical additions due to the insolubility of the test chemical at the concentration tested. The nominal dose value for the reference chemical was also used for calculating the percent theoretical CO2 production for this system.

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4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	The cumulative CO_2 evolved and percent theoretical CO_2 (%$ThCO_2$) from reference, test, and abiotic and toxicity control systems are shown in Figures A7_1_1_2_1(01)-1 and -2, respectively.
4.1.2	Degradation	Only 20% of theoretical carbon was found at the end of the study.
4.1.3	Other observations	The toxicity control system, containing both test and reference substances, exhibited 82.8% of $ThCO_2$. If the reference substance is 100% degraded, then the test substance was approximately 66% degraded versus 20% as in the test system.
4.1.4	Degradation of TS in abiotic control	The abiotic control exhibited a 14.8% $ThCO_2$ evolution, the majority within the first four days of the study, indicating CO_2 derived from the inoculum before inhibition by the sterilant.
4.1.5	Degradation of reference substance	The reference control system (sodium benzoate) exhibited a final %$ThCO_2$ of 113%.
4.1.6	Intermediates/ degradation products	No degradates were identified.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A ready biodegradability test was conducted according to OECD 301B using a microbial inoculum obtained from municipal sewage sludge. A reference control system used sodium benzoate to monitor the viability of the microbial population. A test system containing both the test and reference chemicals as the sole sources of carbon was used to evaluate the toxicity of the test compound. An abiotic control was dosed with only the test chemical but no inoculum to evaluate any abiotic transformation of the test chemical. Duplicate blank systems containing the microbial inoculum without added test or reference chemicals were used to determine the endogenous microbial respiration. A total of seven systems were prepared and analyzed for CO2 evolution after 1, 4, 6, 8, 11, 15, 20, 25, and 29 days of incubation. The loss of total organic carbon (TOC) in the reference control, toxicity control, and inoculum blank systems was determined from analysis of samples on days 0 and 29.
5.2	**Results and discussion**	The test systems amended with only AC 303,630 yielded %$ThCO_2$ values of 17.4% and 23.4% for the first and second replicate, respectively, which indicated that the test chemical is not readily biodegraded. The %$ThCO_2$ observed for the reference chemical was 113 %, which indicated that the microbial inoculum was viable and active. The toxicity control system, which was amended with test and reference chemicals, exhibited 82.8 % $ThCO_2$ evolution, indicating no toxicity effects due to the test chemical on CO_2 evolution by the readily degradable sodium benzoate.

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		The abiotic control exhibited 14.8 % $ThCO_2$ evolution. It is likely that the CO_2 evolution observed represents CO_2 which was derived from the inoculum prior to full inhibition of microbial viability by the sterilizing agent since the majority of CO_2 evolved from the abiotic system was observed during the first four days of the study.
5.3	**Conclusion**	AC 303,630 does not meet the criteria for ready biodegradability.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/05/2005
Materials and Methods	**Comments:** In **3.1.3,** the solubility of AC 303,630 in de-ionized water and pH 5, 7 and 9 buffer solutions at 20°C was 0.11, 0.11 and 0.14 mg/L respectively, instead of 0.14, 0.11, 0.11 and 0.14 mg/L.
Results and discussion	The RMS adopt the applicant's results and discussion.
Conclusion	The RMS adopt the applicant's conclusion.
Reliability	**1**
Acceptability	**Acceptable**
Remarks	No
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_1_2_1(01)-1: Guideline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
CO_2 Evolution-Test (Modified Sturm Test)	C.4-C	301B	ready

Table A7_1_1_2_1(01)-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Source	[redacted]
Sampling site	Activated sludge return
Laboratory culture	No
Preparation of inoculum for exposure	The activated sludge was adjusted to a total suspended solids concentration of approximately 1.5 g/L with well water. The sludge was blended and then allowed to settle for half an hour. The supernatant from this prepared sludge was then utilized as the inoculum (1%) for the test system.
Pretreatment	None
Initial cell concentration	Not determined

Table A7_1_1_2_1(01)-3: Test system

Criteria	Details
Culturing apparatus	4-L glass carboys with 3 L of test solution. Incoming air was passed over Ascarite to remove CO_2 and introduced to the carboy via glass tube. Flow rates were monitored by flow meters and the outlet was connected to three CO_2 absorber gas-washing bottles in series, each filled with 100 mL of 0.2 N KOH. The carboys were kept in the dark in a temperature-controlled room at 20-22°C for 29 days with constant stirring by magnetic stirrer and stir bar.
Number of culture flasks/concentration	2 test flasks + controls and blanks
Aeration device	unspecified air pump and flow meters
Measuring equipment	Shimadzu Model 5050 total organic carbon analyzer
Test performed in closed vessels due to significant volatility of TS	No

Table A7_1_1_2_1(01)-4: Test conditions

Criteria	Details
Composition of medium	Each liter of test medium contained: 1 mL of 0.25 g/L $FeCl_3 \cdot H_2O$ 1 mL of 22.50 g/L $MgSO_4 \cdot 7H_2O$ 1 ml of 27.50 g/L $CaCl_2$ 10 mL of 8.5 g/L KH_2PO_4, 21.75 g/L K_2HPO_4, 27.40 g/L Na_2HPO_4, and 0.50 g/L NH_4Cl
Additional substrate	No
Test temperature	20-22°C
pH	Not Reported
Aeration of dilution water	Yes, Ascarite treated air at 100 mL/min.
Suspended solids concentration	TOC = 0.026 mg carbon/L

Table A7_1_1_2_1(01)-5: Pass levels and validity criteria for tests on ready biodegradability

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$		X
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test		X
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	X	
Percentage of removal of reference substance reaches pass level by day 14		X

Figure A7_1_1_2_1(01)-1: Cumulative CO_2 evolved from reference, test, and abiotic and toxicity control systems

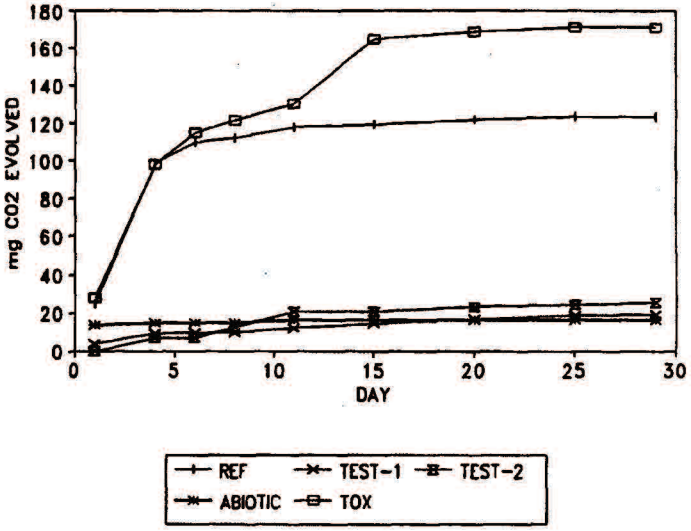
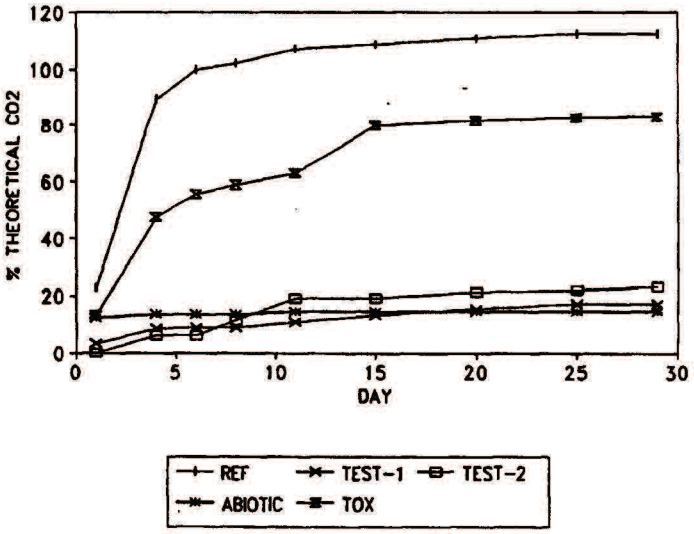


Figure A7_1_1_2_1(01)-2: Percent Theoretical CO_2 (%ThCO_2) from reference, test, and abiotic and toxicity control systems



Section A7.1.1.2.1(02) Ready Biodegradability

Annex Point IIA, VII.7.6.1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I / authorization	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD 301C Ready Biodegradability, Modified MITI test	
2.2	**GLP**	Yes	
2.3	**Deviations**	After 3 days of exposure, leak of air from closed system occurred by damage of bottle cap in bottle 1. The damaged cap was exchanged for new one and the BOD value was returned to the original value. The test results obtained from bottle 1 showed that the oxygen consumption rate of aniline was 60% after 7 days and 73% after 14 days. These values satisfied the guideline requirements of exceeding 40% after 7 days and 65% after 14 days and demonstrated good microbial activity of the sludge used. Thus, the leak did not affect the reliability of the test. There were no specific circumstances that might have affected the reliability of the test results.	
		3 MATERIALS AND METHODS	
3.1	**Test material**	AC303,630	
3.1.1	Lot/Batch number	Lot No. AC9389-90	
3.1.2	Specification	Deviating from specification given in section 2 as follo ws:	
3.1.2.1	Purity	99.7%	
3.1.3	Further relevant properties	The solubility of AC 303,630 in de-ionized water and pH 5, 7, and 9 buffer solutions at 20°C is 0.14, 0.11, 0.11, and 0.14 mg/L, respectively.	
3.1.4	TS inhibitory to microorganisms	No	X
3.1.5	Specific chemical analysis	By reversed phase HPLC w/ UV-VIS detection	
3.2	**Reference substance**	Aniline	
3.2.1	Initial concentration of reference substance	100 mg/L, 300 mg/L ThOD	

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3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Activated Sludge , See Table A7_1_1_2_1(02)-2
3.3.2	Test system	See Table A7_1_1_2_1(02)-3
3.3.3	Test conditions	See Table A7_1_1_2_1(02)-4
3.3.4	Method of preparation of test solution	30 mg of test substance was added to each bottle with 300 mL of medium or water.
3.3.5	Initial TS concentration	100 mg/L, 151 mg/L ThOD,
3.3.6	Duration of test	28 days
3.3.7	Analytical parameters	BOD and analysis of test substance. DOC measurements were made but not used as the test substance was not dissolved in the test system.
3.3.8	Sampling	BOD analyses were made at 7, 14, 21, and 28 days. The residual test substance was determined by reversed phase HPLC w/ UV-VIS detection at the end of the test.
3.3.9	Intermediates/ degradation products	No intermediates/degradates were identified.
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	A blank with inoculum and medium and a sterile control with test substance and ultra-pure water were included in the study.
3.3.12	Statistics	Degradability based on BOD was calculated
	4 RESULTS	
4.1	**Degradation of test substance**	
4.1.1	Graph	Based on BOD measurements and analysis of the residual test substance, there was no degradation of the test substance during the test.
4.1.2	Degradation	Based on BOD measurements and analysis of the residual test substance, there was no degradation of the test substance during the test.
4.1.3	Other observations	DOC measurements at the end of the study indicated the test substance was not dissolved in the medium.
4.1.4	Degradation of TS in abiotic control	No degradation was observed in the abiotic control.
4.1.5	Degradation of reference substance	The test substance, aniline, was 60%, 70%, and 80% degraded at 7, 14 and 28 days, respectively, indicating an active biological system.
4.1.6	Intermediates/ degradation products	No degradation occurred, therefore no degradation products were found.

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		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The test was conducted according to OECD 301C Ready Biodegradability, Modified MITI test. Aniline was used as a reference substance, and BOD was used to follow the degradation of the test and reference substances. In addition, the residual test substance was analyzed by HPLC at the end of the study. DOC measurements were made, but showed that the test substance was not dissolved in the medium.
5.2	**Results and discussion**	Based on BOD measurements and by HPLC analysis of residual test substance at the end of the test, no degradation of the test substance was observed. The degradation of the reference substance indicated an active biological system.
5.3	**Conclusion**	AC 303,630 does not meet the criteria for ready degradability.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/05/2005
Materials and Methods	**Comments:** In **3.1.3,** the solubility of AC 303,630 in de-ionized water and pH 5, 7 and 9 buffer solutions at 20°C was 0.11, 0.11 and 0.14 mg/L respectively, instead of 0.14, 0.11, 0.11 and 0.14 mg/L. ***Note:*** the following subheadings proposed by the applicant, **3.1.2.1, 3.1.3, 3.1.4; 3.1.5** corresponds respectively to 3.1.3, 3.1.4, 3.1.6 and 3.1.7, from standard formats of TNsG.
Results and discussion	The RMS adopt the applicant's results and discussion.
Conclusion	The RMS adopt the applicant's conclusion.
Reliability	**1**
Acceptability	**Acceptable**
Remarks	No
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Section A7.1.1.2.1(02) Ready Biodegradability

Annex Point IIA, VII.7.6.1.1

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_1_1_2_1(02)-1: Guideline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
MITI-I-Test	C.4-F	301C	ready

Table A7_1_1_2_1(02)-2: Inoculum / Test organism

Criteria	Details
Nature	activated sludge, mixed liquor suspended solids - 4000 mg/L
Source	[redacted]
Laboratory culture	No
Preparation of inoculum for exposure	None
Pretreatment	None
Initial cell concentration	30 mg/L suspended solids

Table A7_1_1_2_1(02)-3: Test system

Criteria	Details
Culturing apparatus	Closed system oxygen measuring apparatus
Number of culture flasks/concentration	3 + controls and blanks
Aeration device	None
Measuring equipment	Closed system oxygen measuring apparatus, Ohkura Electric Co., Model OM-2001 pH meter, Orion Research, Model 720A TOC analyzer, Shimadzu Co. model TOC-5000 Shimadzu HPLC system w/ UV-VIS detector and Inertsil ODS-3V column
Test performed in closed vessels due to significant volatility of TS	No Closed system used to exclude oxygen

Table A7_1_1_2_1(02)-4: Test conditions

Criteria	Details
Composition of medium	As per 301 C
Additional substrate	No
Test temperature	25±1°C
pH	At the end of the 28 day incubation period the pH was 7.2 for all three replicates of test substance
Aeration of dilution water	No
Suspended solids concentration	30 mg/L

Table A7_1_1_2_1(02)-5: Pass levels and validity criteria for tests on ready biodegradability

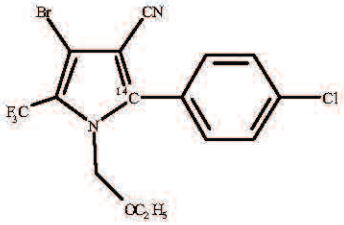
	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$		X
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test		X
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	X	
Percentage of removal of reference substance reaches pass level by day 14		X

Section 7.1.1.2.2. Annex Point IIA, VII 7.6.1.2	Inherent biodegradability	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	Studies on the ready biodegradability of the substance submitted with this dossier demonstrate that chlorfenapyr is not readily biodegradable. Studies on the physical chemical characteristics of the substance demonstrate a low vapor pressure, low water solubility, and strong binding to soil which indicates that the substance will not leach from the application site. In addition, the intended biocidal uses for the substance limit the range of exposure to the environment. Therefore, a waiver from additional data on the inherent biodegradability is justified since chlorfenapyr will not enter sewage treatment facilities.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	20/05/2005	
Evaluation of applicant's justification	According to the data requirements this study should be preformed if the compound is not readily degradable unless a simulation test is preformed. So, the proposed justification for non-submission data doesn't match the requirements.	
Conclusion	For previous reasons, the applicant's justification is not acceptable. However, in agreement with TNsG, this test doesn't provide adequate information for risk asses sment, for that reason the submission of inherent biodegradability test may not be preformed.	
Remarks	No	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.1.2.3.	Biodegradation in seawater	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [✓]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [✓]	**Other justification** [ ]	
Detailed justification:	Studies submitted with this dossier on the physical chemical characteristics of the substance demonstrate a low vapor pressure, low water solubility, and strong binding to soil which indicates that the substance will not leach from the application site. In addition, the intended biocidal uses for the substance limit the range of exposure to the environment from runoff. Therefore, a waiver from biodegradation in seawater data is justified since chlorfenapyr will not enter seawater.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	20/05/2005	
Evaluation of applicant's justification	In agreement with data requirements of TnsG this study only applies to substance that can be used or released in marine environments in considerable amounts. Since this is not the intended use for chlorfenapyr, There is no need of a biodegradation in seawater study.	
Conclusion	Justification for non-submission data accepted.	
Remarks	No	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.2(01) Rate and route of degradation in aquatic systems

Annex Point IIIA XII.2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I / authorization	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes BBA Guideline, Part IV, 5-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	^{14}C-pyrolle-ring labeled AC 303,630	X
3.1.1	Lot/Batch number	AC 8877-81	
3.1.2	Specification	Deviating from specification given in section 2 as follows:	
3.1.2.1	Radiolabeling		
3.1.2.2	Purity	96.8% Radiopure, 97.3% chemically pure	
3.1.2.3	Specific Activity	41.8 µCI/mg	
3.1.1	Further relevant properties	The solubility of AC 303,630 in de-ionized water at 20°C is 0.14 mg/L.	
3.1.2	Composition of Product	Not applicable	
3.1.3	TS inhibitory to microorganisms	No	
3.2	**Reference substance**	Reference substances used for co-chromatography are shown in Table A7_1_2(01)-1.	
3.3	**Testing procedure**		

Section A7.1.2(01) Rate and route of degradation in aquatic systems

Annex Point IIIA XII.2.1

3.3.1	Test system	The distribution and degradation of chlorfenapyr was studied in two natural systems of water and sediment. The water/sediment systems were taken from the "Altensenner" lake near Paderborn and the "Mülenteich" brooklet near Scmallenberg-Grafschaft. Characteristics of the water/sediment systems are given in Table A7_1_2(01)-2. The study was performed using an open gas flow system with a trapping device for volatiles. The test vessels were filled with a 2 – 2.5 cm sediment layer (ca. 30g dry weight for loamy sediment, 82 g dry weight for sandy sediment) and a 6 cm water layer (ca 145 mL), which were allowed to equilibrate for six to eight weeks before treatment. ^{14}C-pyrrole-ring labeled AC 303,630 in 100 µL of acetone (<0.1% in the system) was applied to the water at a rate of 20 µg a.s. per test vessel. Two flasks per system were heat sterilized (121°C, 30 min) prior to application of the test substance. Incubation was done in the dark at a temperature of 20 ± 2°C for up to 100 days after treatment. Duplicate samples were taken from each water/sediment system at 0h, 6h, and 1, 2, 7, 14, 30, 60, and 100 or 101 days after treatment.	X
3.3.2	Analytical procedures	The entire water/sediment system was transferred to centrifuge tube and centrifuged at 650 G for 20 minutes. The water was decanted and analyzed by LSC. Water samples that contained more than 10% of the applied radiocarbon were extracted with methylene chloride and the extract was analyzed by LSC, TLC, and HPLC using the conditions in Table A7_1_2(02)_3 and Table A7_1_2(02)_4. The sediment was extracted with MeOH and the extract was analyzed by LSC, TLC, and HPLC. Unextractable radiocarbon remaining in the soil was determined by combustion and LSC.	
3.3.3	Intermediates/ degradation products	Metabolites were identified by co-chromatography using HPLC with radiodetection.	
3.3.4	Controls	Two flasks per system were heat sterilized (121°C, 30 min) prior to application of the test substance.	
3.3.5	Statistics	The best-fit functions for the decrease in AC 303,630 in the water, sediment, and whole system were determined and DT^{50} values were calculated.	
		4 RESULTS	
4.1	**Degradation of test substance**		
4.1.1	Distribution of Radiocarbon and Mass Balance	The distribution of radiocarbon and mass balance for each interval is shown in Table A7_1_2(01)-5 for the sand/water system and Table A7_1_2(01)-6 for the loam/water system. The overall mass balance ranged from 85% to 96% with an average of 91% for the sand system and from 86% to 104% with an average of 96% for the loam system.	