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TRANSFLUTHRIN

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Section 7 Environment
Study Summaries
Active Substance

Rapporteur Member State: The Netherlands
August 2013

CA-report and Proposed Decision of The Netherlands in the context of the
Possible inclusion of Transfluthrin in Annex I of Council Directive 98/8/EC

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Document IIIA — Hydrolysis as a function of pH and identification of breakdown products

SECTION A7.1.1.1.1

BPD Data set IIA/ Annex Point VII7.6.2.1

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1 REFERENCE

1.1	**Reference**	Hellpointer, E. (1989). Benfluthrin: Hydrolysis in Buffers, Bayer AG, Pflanzenschutz-Forschung, Chemische Produktentwicklung und Ökobiologie, Institut für Metabolismusforschung, FRG, Germany Bayer AG Report No.: M 111 0290-4 [BES Ref: MO-03-009363] Report date: August 31, 1989 Unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience
1.2.2	Companies with letters of access	
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 inclusion on Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes EPA Pesticide Assessment Guidelines, Subdivision N: § 161-1 (1982)
2.2	**GLP**	Yes
2.3	**Deviations**	The method is generally in compliance with the prescribed EU method C.7. Differences included: Rather than using individual hydrolysis vessels, due to the low solubility of the test material and problems encountered in the preliminary experiment with adsorption to the small test vessel walls, a single large reaction vessel was used at each pH. Details of the preliminary study were not reported. The preliminary test only serves as a screen for molecules that are rapidly hydrolysed, therefore the lack of reported detail is not considered to be a significant deficiency. No replication of the hydrolysis experiment was conducted. No deviations are considered sufficient to affect the overall scientific validity of the results obtained.

3 MATERIALS AND METHODS

3.1	**Test material**	Transfluthrin (cited as benfluthrin in this report) 2,3,5,6-tetrafluorphenyl)methyl ester 3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylic acid

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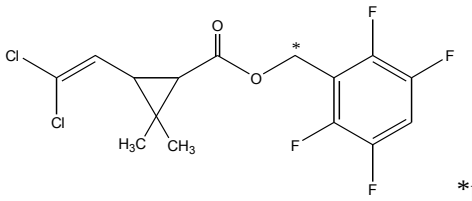
3.1.1	Lot/Batch number	 *position of radiolabel Specific activity: 3.90 MBq/mg Tetrafluorophenyl-[^{14}C-methylene]-transfluthrin: / Batch no.: not given	X
3.1.2	Specification	See purity (Section 3.1.3).	
3.1.3	Purity	Radiochemical purity of the test substance was confirmed by radio-HPLC (98.7%) and radio-TLC (>99%) The chemical purity and identity of the chemical substance were verified by GC-MS.	
3.1.4	Further relevant properties	Water solubility is low: 57 µg/L, therefore a co-solvent, acetonitrile, was used at 1% v/v.	
3.2	**Reference substance**	Transfluthrin (NAK 4455); batch 880325ELB01 (Bayer AG, Elberfeld). Purity: 97.8% (GC), cis-transfluthrin (NAK 4711), trans-transfluthrin (NAK 5368), 2,3,5,6-tetrafluorobenzyl alcohol (NAK 4452), trans-permethrinic acid.	
3.3	**Test solution**	The preparation detail and experimental conditions are summarised in Tables A7.1.1.1.1-1 to A7.1.1.1.1-3. Batches (250 ml) of 0.01M pH 5 acetate buffer, 0.02M pH 7 phosphate buffer and 0.01M pH 9 borate buffer were prepared and steam sterilised. The test material was prepared in acetonitrile at a concentration of 0.391 mg/ml (= 1.524 MBq/ml). Note: The report also cites the buffer concentration as 0.01M, but the description of the buffer preparation in Appendix 3 cites 0.02M, so this value has used through out the summary.	
3.4	**Testing procedure**		
3.4.1	Test system	The test system is detailed in Table A7.1.1.1.1-3. Based on the results of a preliminary experiment, in which pronounced adsorption of the active substance to the walls of the test vessels was observed, single batches of pH 5, 7 and 9 buffer (200 ml) were prepared and treated with ^{14}C-transfluthrin in large vessels. To minimise the risk of microbial contamination, subsamples were taken at only 6 time points. 200 ml of each of the steam sterilised buffers were transferred into three 250 Erlenmeyer flasks. 2ml of each buffer was removed and replaced with acetonitrile to give a co-solvent concentration of 1% v/v. The solutions were sonicated (15 mins) and left overnight at room temperature. ^{14}C-transfluthrin was then added to each test vessel at a rate of 19.6 µg (76 kBq) in 50 µl of acetonitrile (i.e. final solution	

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		concentration of 98 µg/l). The solutions were wrapped in aluminium foil, sonicated before incubating at 25ºC in the dark for three hours (the time required for uniform distribution of the test material and considered to be time zero, T=0). Subsamples of the buffered test solution were taken for analysis (as described in 3.4.6) at 0, 7, 15, 22/23, 29/30 and 36 (at pH 7 and 9 only) days. Note: due to microbial contamination and loss of sterility in the pH 7 and 9 test solutions, these incubations were repeated.	X
3.4.2	Temperature	25 ± 0.1°C	
3.4.3	pH	pH 5: 5.09 (Day 15), 5.11 (Day 30) pH7: 7.09 (Day 15), 7.09 (Day 29), 7.06 (Day 36) pH9: 9.03 (Day 15), 8.96 (Day 29), 8.98 (Day 36)	
3.4.4	Duration of the test	Up to 36 days	
3.4.5	Number of replicates	One	
3.4.6	Sampling	Details of sampling times give in Table A7.1.1.1.1-4. At each sample point, triplicate 5 ml aliquots were removed from the buffered treated solutions under sterile conditions. One aliquot was frozen, one taken for pH measurement and the other for "mass balance" and analysis. From the "mass balance" subsample, a 1ml subsample was taken for quantification by LSC. The remaining solution (4ml) was extracted with 5ml of dichloromethane.	
3.4.7	Analytical methods	Quantification of the dichloromethane extracts was by normal phase TLC using two solvent systems (toluene/methanol, 9/1; chloroform/diisopropylether/acetone, 5/4/1) with evaluation by radio thin-layer analyser. Identification of degradation products was by co-chromatograph with authentic reference standards. GC-MS was also used to identify products isolated by preparative TLC. GC-MS system: HP 5970 (MSD) with GC 5880 A; column: 25m ULTRA, i.d. 0.2 mm, film thickness: 0.25 µm; column head pressure: 10 psi He, injector temp: 200ºC; splitless injection; temp program: 80ºC isothermal (1 min) then to 280ºC at 10ºC/min.	
3.5	**Preliminary test**	Yes Buffer solutions summarised in Table A7.1.1.1.1-1. The preliminary test demonstrated that the solubility of NAK 4455 was below 100 µg/l even when the maximum concentration of co-solvent is used. Pronounced adsorption of the test material to the walls of the test vessels was observed in the preliminary experiment, which dictated the design of the main incubation.	

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4 RESULTS

4.1 Mass balance results

At pH 5, relative to the total recovered radioactivity in the T=0 sample, 98.8 - 102.1% of the radioactivity was recovered. X

At pH 7, relative to the total content of the T=0 sample, at least 93.5% of the radioactivity were recovered in samples taken up to day 29. Recovery of radioactivity in the terminal day 36 sample was only 80.2%. It was assumed that this loss was due to incomplete recovery of adsorbed radioactivity at this particular time point. X

At pH 9, relative to the T=0 sample, 98.7 – 103.2% AR relative to the T=0 samples was recovered. X

Sterility of the samples was maintained at pH 5, but was compromised on Day 15 in the pH 7 and 9 solutions. Theses incubations were repeated. The sterility was maintained in these latter incubations.

4.2 Hydrolysis rate constant

The concentration of transfluthrin determined at T=0 was equated to 100%, the degradation rates were calculated relative to this point.

Sample set	Degradation rate constant ($days^{-1}$)	Half-life (days)	r^2
pH 5	0.0001	> 1 year	-
pH 7	0.0007	> 1 year	-
pH 9	0.049	14	0.9818

4.3 Dissipation time

DT_{50} values are summarised in 4.2

4.4 Concentration – time data

See table A7.1.1.1.1-4.

4.5 Specification of the transformation products

See table A7.1.1.1.1-4. At pH 5 no degradation products were present at > 1% AR (applied radioactivity) during the 30 day hydrolysis period.

At pH 7 and 9 there was formation of one degradate (maxima: 3.5% AR pH 7; 81.9% AR pH 9). Analysis by co-chromatograph and GC-MS of the isolated degradate identified the only major product as 2,3,5,6-tetrafluorobenzylalcohol (denoted as NAK 4452 in the original report).

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Based on the results of a preliminary experiment, single batches of sterile pH 5, 7 and 9 buffer (with 1% co-solvent (acetonitrile)) were treated with tetrafluorophenyl-[^{14}C-methylene]-transfluthrin at a nominal rate of

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98µg/l and incubated at 25 ± 0.1ºC for periods of up to 36 days. At days 0, 7, 15, 22/23, 29/30 and 36 (pH 7 and 9 only), triplicate 5 ml subsamples were removed from each treated buffer solution. One replicate was analysed for pH, one frozen and the other quantified by direct LSC and checked for sterility. After quantification by LSC, the remaining sample was extracted with dichloromethane and the organic phase analysed by TLC. The major degradate was isolated at pH 9 and identified by co-chromatography and GC-MS.

5.2 Results and discussion

The radiochemical purities of the test substances were determined to be >98% by TLC prior to experimental start and time zero samples showed that the test material was stable under the conditions of administration.

The pH of the samples was measured at each sampling time. The results for all sets of samples indicated that the buffering capacity was maintained in the solution during the study period.

Sterility assays at pH confirmed sterility over the 30 – 36 day incubation period. At pH 7 and 9, the sterility was compromised at day 15, so these incubations were repeated. Subsequent sterility checks confirmed sterility at pH 7 and 9 over 36 days.

Total material balance recoveries ranged from 80.2 to 103.2% AR. Degradation of tetrafluorophenyl-[^{14}C-methylene]-transfluthrin was minimal at pH 5 and 7 at 25 ±0.1°C. At pH 5, benfluthirn (transfluthrin) degraded from an initial 95.79% AR to 94.12% AR. At pH 7, transfluthrin degraded from 97.41% AR to 75.21% after 35 days. The latter value was due to poor recovery of radioactivity rather than degradation, as only one degradate was present, accounting for a maximum of 3.5% AR.

At pH 9, transfluthrin degraded from an initial 97.92% AR to 17.8% AR over 35 days. One major degradate was formed, which accounted for a maximum of 81.88% AR after 35 days. This was identified by co-chromatography and GC-MS as 2,3,5,6-tetrafluorobenzylalcohol.

5.2.1 $k_{H,}$ DT_{50}, r^2

Sample set	Degradation rate constant ($days^{-1}$)	Half-life (days)	R^2
pH 5	0.0001	> 1 year	-
pH 7	0.0007	> 1 year	-
pH 9	0.049	14	0.9818

5.3 Conclusion

Hydrolysis studies showed that transfluthrin was stable to hydrolysis at pH 5 and pH 7 at 25°C with half-lives estimated to greater than one year.

The half-life of transfluthrin at 25°C at pH 9 was determined to be 14 days, using pseudo first order kinetics. The major degradate observed was 2,3,5,6-tetrafluorobenzylalcohol.

5.3.1 Reliability 2

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5.3.2 Deficiencies	Due to technical difficulties, one batch of each test buffer was prepared, rather than individual test vessels and no repetition of the hydrolysis was conducted. Quantification of the hydrolysis product at pH 7 lacked detail, but as this product was the major product at pH 9 and was subsequently identified by co-chromatography and GC-MS, this lack of detail is not considered to be a significant deficiency. Considering the hydrolytic stability of transfluthrin at the environmentally relevant pHs of 5 and 7, it is considered that the study is adequate to assess its hydrolytic behaviour.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	08-02-2007
Materials and Methods	Applicant's summary is adopted with the following additions: 3.4.1 time 0 is 3 hours after addition of the test substance 4.1 recovery by adding up radioactivity of all samples taken and of the remaining batch was 100, 88 and 102 % of the theoretically applied amount.
Results and discussion	Applicant's version is adopted.
Conclusion	Applicant's version is adopted. The results no hydrolysis within 30 days at pH 5 and 36 days at pH 7, and DT_{50} 14 days at pH 9 are accepted for risk assessment. Recalculated to 12°C the DT_{50} is 40 days at pH 9, with no hydrolysis at lower pH.
Reliability	2 See applicant's summary for deficiencies.
Acceptability	Acceptable Most of the deficiencies are considered to be inevitable due to the specific characteristics of the test substance.
Remarks	Batch differs from those included in the batch analysis (Doc III A.2 confidential), but purity is acceptable.
	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*

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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 A7.1.1.1.1-1: Type and composition of buffer solutions

pH	Type of buffer (final molarity)	Composition
5	0.02 M	Sodium acetate: 125 ml of a 0.04 M sodium acetate solution (5.44 g $NaC_2H_3O_2$ x 3 H_2O/l) was brought to a volume of 250 ml with purified water (see Table A7.1.1.1.1-2 for water specification). The pH was adjusted to pH 5 at 25 ± 2°C using 0.04M sodium hydroxide or acetic acid.
7	0.02 M	Potassium dihydrogen phosphate: To 125 ml of a 0.04 M Potassium dihydrogen phosphate solution (5.44 g KH_2PO_4/l) 74 ml of a 0.04M sodium hydroxide solution was added (1.6 g NaOH/l) and diluted to 250 ml with water). The pH of this solution was adjusted to pH 7 at 25 ± 2°C using 0.04M sodium hydroxide solution or phosphoric acid.
9	0.02 M	0.04 mole boric acid (2.48 g H_3BO_4) are dissolved in 1 litre of a 0.04M potassium chloride solution (2.98 g KCl/l). To 125 ml of this solution was added 53 ml of a 0.04 M sodium hydroxide solution (1.6g NaOH/l) and diluted with water to 250ml. the pH of this solution was adjusted to pH 9 at 25 ± 2°C using 0.04M sodium hydroxide solution or boric acid.

Buffered solutions were sterilised using steam sterilisation prior to incubation.

Table A7.1.1.1.1-2: Description of test solution

Criteria	Details
Purity of water	Water was purified through a Milli-Q unit (MILLIPORE) with a bacterial filter. All other chemical were reagent quality.

Preparation of test medium	50 µL of dose solution was added to 200 mL of buffer solution. Dosing was undertaken under aseptic conditions in a biological hood flow cabinet.
Test concentrations (mg a.i./L)	Nominal dose rate of 98 µg/L. Measured: 82 – 95 µg/L
Temperature (°C)	25°C ± 0.1 for up to 36 days.
Controls	Not applicable.
Identity and concentration of co-solvent	Acetonitrile at 1% v/v to enable preparation of a homogenous solution, avoiding high adsorption to glass surfaces.
Replicates	Due to technical difficulties, dingle replicate were used.

Table A7.1.1.1.1-3: Description of test system

Glassware	Sterile 250 mL glass Erlenmeyer flasks with glass stoppers.
Other equipment	pH of all buffer solutions measured with an Orion 501 pH meter. Dosing under aseptic conditions in a biological hood flow cabinet. Mixing of dosed solution using a Wrist Action Shaker. Test systems were maintained in a temperature controlled room or water bath in the dark (wrapped with aluminium foil to minimise light exposure). TLC (2 solvent systems) used to analyse sample solutions (parent and metabolites quantification). Preparative TLC was used to isolate degradates of interest which were analysed by GC-MS
Method of sterilization	Steam sterilisation

Table A7.1.1.1.1-4: Hydrolysis products of tetrafluorophenyl-[^{14}C-methylene]-transfluthrin (expressed as % AR)

Sample time (days)					
	0	**7**	**15**	**22**	**30**
pH 5					

Transfluthrin	95.79	93.56	97.05	94.67	94.12
NAK 4452	*	*	*	*	0.25

Sample time (days)						
	0	**7**	**15**	**23**	**29**	**36**
pH 7						
Transfluthrin	97.41	92.00	92.96	91.05	89.38	75.21
NAK 4452	*	*	*	*	*	3.56
pH 9						
Transfluthrin	97.92	89.77	49.00	35.57	27.59	17.80
NAK 4452	*	7.69	46.46	60.65	70.86	81.88

NAK 4452 - 2,3,5,6-tetrafluorobenzylalcohol

* Values not reported

Table A7.1.1.1.1-5: Dissipation times of at pH 5, pH 7 and pH 9

	DT50		
	pH5	**pH 7**	**pH 9**
Transfluthrin	estimated > 1 year	estimated > 1 year	14 days

Document. IIIA — Phototransformation in water including identity of transformation products

SECTION A7.1.1.1.2/01

BPD Data set IIA/ Annex Point VII7.6.2.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	Anderson, C. (1987) Preliminary study on abiotic degradation of NAK 4455, Bayer AG, Institut für Metabolismusforschung, Leverkusen, Germany Bayer AG Report No.: 2888 [BES Ref: MO-04-007423] Report date: October 28, 1987 Unpublished Note: The study addresses the hydrolysis, aqueous photolysis and adsorption characteristics of transfluthrin (also known as NAK 4455). Only the aqueous photolysis portion of the report has been summarised below.	X
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience	
1.2.2	Companies with letters of access		
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 inclusion on Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No. No guidelines available	
2.2	**GLP**	No. GLP was not compulsory at the time the study was performed	
2.3	**Deviations**	Not applicable	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Transfluthrin (cited as NAK 4455 in the report)	
3.1.1	Lot/Batch number	Batch No.: 11088650	
3.1.2	Specification	See purity (Section 3.1.3).	X
3.1.3	Purity	97.8% (GLC) and 98.8% (HPLC)	
3.1.4	Radiolabelling	Non-radiolabelled test material used.	
3.1.5	UV/VIS absorption spectra and absorbance value	Due to the low solubility of transfluthrin in water, it was not possible to obtain a UV absorption spectrum in water. An absorption spectrum in methanol was produced which showed a main maximum at 210 nm, (ϵ = 22,000) and a weaker maximum at 269 nm, (ϵ = 1800). The residual extinction at 290 and 300 nm had coefficients of 69 and 34 and flattened off very slowly.	
3.1.6	Further relevant	The water solubility of transfluthrin is low, 57 µg/L, therefore a co-	X

	properties	solvent, acetonitrile, was used at 2% v/v.
3.2	**Reference substances**	NAK 5368 (aldehyde of transfluthrin), NAK 5366 (alkyne of transfluthrin) NAK 4711 (*cis* form of transfluthrin)
3.3	**Test solution**	See table A7.1.1.1.2(01)-1.
3.4	**Testing procedure**	
3.4.1	Test system	See table A7.1.1.1.2(01)-1 and 2.
3.4.2	Properties of light source	See table A7.1.1.1.2(01)-2.
3.4.3	Determination of irradiance	A mercury vapour lamp generated light spectrum of wavelength 200 – 600 was used. The spectral energy distribution of the mercury lamp was measured over the range 200 – 580 nm. Light intensity measurements were also taken through the quartz filter over the same wavelength range to reproduce the light actually reaching the test solutions.
3.4.4	Temperature	Not stated in the report whether the photolysis chamber was temperature controlled, but the usual design of the merry-go-round photolysis exposure chamber incorporates a means of temperature regulation.
3.4.5	pH	Test material was prepared in high-purity, sterile filtered water. The solutions were not buffered and pH measurements were not conducted.
3.4.6	Duration of the test	Up to 8 hours continuous irradiation.
3.4.7	Number of replicates	Assumed to be duplicate samples
3.4.8	Sampling	0, 1, 2, 3, 4, 6 and 8 hours
3.4.9	Analytical methods	After irradiation, a spatula of sodium sulphate was added to each solution and the mixtures shaken thoroughly with 0.5 ml hexane. The organic phase was removed and analysed by GC. The GC method was as follows: Instrument: Hewlett Packard 5880 Column: High performance capillary column, cross linked methyl silicone, (12 m x 0.2 mm 9i.d.), film thickness: 0.33 µm Carrier gas: Nitrogen Flow: 1 ml/min Detector: ECD The limit of detection was 1 µg/l. Photodegradation products were identified using GC-MS and comparison with authentic referenced standards.

Document. IIIA **Phototransformation in water including identity of transformation products**

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3.5	**Transformation products**	Yes
3.5.1	Method of analysis for transformation products	See 3.4.9
		4 RESULTS
4.1	**Screening test**	Not performed.
4.2	**Actinometer data**	Not performed.
4.3	**Controls**	No data for dark controls presented.
4.4	**Photolysis data**	
4.4.1	Mass balance	No mass balance data presented.
4.4.2	k^c_p	Measured photolysis rate constants for the test substance: 0.0407 h^{-1}. Results from the quantification of transfluthrin are presented in A7.1.1.1.1.2(01)-3.
4.4.3	Kinetic order	Pseudo first order.
4.4.4	k^c_p / k^a_p	Not calculated
4.4.5	Reaction quantum yield (ϕ^c_E)	Not calculated
4.4.6	k_{pE}	Not calculated
4.4.7	Half-life ($t_{1/2E}$)	The half-life of transfluthirn was calculated to be 17 hours (r^2 = 0.9552)
4.5	**Specification of the transformation products**	Three degradation products were identified: NAK 4711, NAK 5368 and NAK 5366. NAK 4711 is the cis-isomer of transfluthrin. NAK 5368 is an aldehyde formed by oxidative cleavage of the dichlorovinyl group. NAK 5366 is an alkyne formed by elimination of HCl from the transfluthrin molecule. The photolysis products were not determined quantitatively.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The photolysis of transfluthrin was examined in a non-guideline study using samples prepared in sterile-filtered water. Samples (in quartz cells) were irradiated using a mercury vapour light source using a carousel apparatus for periods of up to 8 hours. At each time point, a sample was taken and sodium acetate added, the mixture shaken and extracted with hexane. The organic phase was removed and analysed by GC. Photodegradation products were identified using GC-MS and comparison with authentic referenced standards. Photolysis in the presence of humic acids was also conducted. A solution of 110 mg humic acids (Roth) in 100 ml of high purity water was prepared, filtered and diluted (0.4 ml in 10 ml water). 600 µl

Document. IIIA **Phototransformation in water including identity of transformation products**

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BPD Data set IIA/ Annex Point VII7.6.2.2

		portions of the diluted humic acid solution was added to 2 ml portion of the transfluthrin solution before irradiation as per the main experiment.
5.2	**Results and discussion**	Transfluthrin degraded photolytically with a half life of 17 hours. Three photodegradation products were identified by GC-MS: NAK 4711, NAK 5368 and NAK 5366. NAK 4711 is the *cis*-isomer of transfluthrin. NAK 5368 is an aldehyde formed by oxidative cleavage of the dichlorovinyl group. NAK 5366 is an alkyne formed by elimination of HCl from the transfluthrin molecule. The photolysis products were not determined quantitatively. Humic acids did not significantly affect the rate of photodegradation under laboratory conditions.
5.2.1	k^c_p	Measured photolysis rate constants for the test substance: 0.0407 h^{-1}
5.2.2	K_{pE}	Not calculated
5.2.3	ϕ^c_E	Not calculated
5.2.4	$t_{1/2E}$	The half-life of transfluthrin was calculated to be 17 hours. No extrapolation to equivalent days of sunlight at EU latitudes was made.
5.3	**Conclusion**	Transfluthrin degraded when exposed to artificial light with a half-life of 17 hours.
5.3.1	Reliability	2
5.3.2	Deficiencies	Yes The use of mercury vapour lamp rather than a polychromatic light source. Sterility of the test vessels was not confirmed. Low concentration of active substance in solution No indication as to whether the photolysis was temperature controlled. No collection of volatiles components. Use of a co-solvent, acetonitrile was at 2% v/v rather than at the prescribed limit of 1% v/v. No quantification of degradation products. Although there are considerable deficiencies, the study is sufficient to provide an indication of the qualitative photolytic behaviour of transfluthrin when used in conjunction with other supporting data.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09-02-07
Materials and Methods	Applicant's version adequately reflects the study report, with the following addition: 3.1.2: Batch differs from those included in the batch analysis (Doc III A.2 confidential), but purity is acceptable.
Results and discussion	Applicant's version adequately reflects the study report.
Conclusion	Applicant's version adequately reflects the study report. However, the $DT_{50,photolysis}$ cannot be accepted for risk assessment because of serious deficiencies, see below.
Reliability	3 In addition to the deficiencies reported by the applicant, the following comments can be made: pH of the test solutions was not checked. No mass balance was established, which in view of the possible adsorption to the test vials is a deficiency. It is not clear whether dark controls were included in the main experiment. Only for the experiment with addition of humic acid, it is stated that one sample was kept in the dark and analysed in comparison with the irradiated samples at the end of the study. Results are, however, not reported, which makes it impossible to judge the value of the reported results for the irradiated samples.
Acceptability	Not acceptable In view of the deficiencies listed above, of which the absence of results for dark controls is the most prominent, the study is not considered valid for risk assessment.
Remarks	Since photolysis data are not necessary for the estimation of environmental concentrations, additional studies are not considered necessary. Report also contains hydrolysis and adsorption experiments. Hydrolysis: The column generated standard solution of transfluthrin (see Table A7.1.1.1.2(01)-1) was diluted 1:1 with sterile buffers (pH 4, 7 and 9), 5 mL samples were incubated at 50 °C, and samples were removed regularly for analysis. $DT_{50,hydrolysis}$ was determined as 9, 8 and 0.75 days, respectively. Extrapolation to 20 °C applying a Q_{10} of 2.2 yields 235, 227 and 20 days, respectively. It is well possible that adsorption to the vials has influenced the results. The study submitted under A.7.1.1.1.1 is considered to be more reliable, and the present results are not used for risk assessment. Adsorption: Portions of two soils (2 g) were shaken with 20 mL of column generated solution (see Table A7.1.1.1.2(01)-1), samples were taken after 1, 2, 4, 6 and 24 h, centrifuged and the water phase was analysed for transfluthrin after extraction with hexane. Concentrations in the water phase were < LOD and a quantitative estimation of the adsorption could not be made.
	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 A7.1.1.1.2(01)-1: Description of test solution and controls

Criteria	Details
Purity of water	All water used was high purity passed through a Milli-Q unit (Waters) with a bacterial filter.
Preparation of test chemical solution	*Ca* 50 mg transfluthrin was dissolved in 2 ml of hexane and mixed with approximately 10 g silica gel (particle size 0.063 – 0.2 mm). The silica gel was packed into a glass column and eluted with high-purity, sterile filtered water. The initial 300 ml of the eluate was discarded. Subsequent 5 ml fractions were diluted with 93 ml of high-purity, sterile filtered water and 2 ml of acetonitrile. 2.5 ml subsamples of this solution were used transferred to 7 quartz cells for the irradiation. For the photolysis in the presence of humic acids, a solution of 110 mg humic acids (Roth) in 100 ml of high purity water was prepared, filtered and diluted (0.4 ml in 10 ml water). 600 µl portions of the diluted humic acid solution was added to 2 ml portion of the transfluthrin solution before irradiation as per the main experiment.
Test concentrations (mg a.s./L)	10 – 30 µg transfluthrin/l
Temperature (°C)	Not stated
Preparation of actinometer solution	Not conducted.
Controls	One dark control samples for each time point.
Identity and concentration of co-solvent	Acetonitrile at 2% to enable preparation of a homogenous solution.
Sterilisation	Sterile filtered water was used.

Table A7.1.1.1.2(01)-2: Description of test system

Criteria	Details
Laboratory equipment	Quartz sample tubes. Mercury vapour lamp.
Emission wavelength spectrum	Mercury vapour lamp generated light spectrum of wavelength 200 – 600. The use of a quartz immersion cell filters out light of wavelengths < 290 nm.
Light intensity	200 – 600 nm: 47 W
Filters	Quartz

Table A7.1.1.1.1.2(01)-3: Quantification of transfluthrin in irradiated test solutions (results expressed as µg/l)

Time (hours)						
0	**1**	**2**	**3**	**4**	**6**	**8**

Transfluthrin	26.5	24.4	24.8	23.3	21.4	20.2	19.2

Document. IIIA — Phototransformation in water including identity of transformation products

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		6 REFERENCE
6.1	**Reference**	Hellpointner, E. (1991). Experiments concerning the indirect photodegradation of BENFLUTHRIN in aqueous solution, Bayer AG, Crop Protection-Research, Leverkusen, Germany Bayer AG Report No.: HPO/046 (PF-report No.: 3467) [BES Ref: MO-03-009362] Report date: February 19, 1991 Unpublished
6.2	**Data protection**	Yes
6.2.1	Data owner	Bayer CropScience
6.2.2	Companies with letters of access	
6.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I
		7 GUIDELINES AND QUALITY ASSURANCE
7.1	**Guideline study**	No. No guidelines available
7.2	**GLP**	No. GLP was not compulsory at the time the study was performed
7.3	**Deviations**	Not applicable
		8 MATERIALS AND METHODS
8.1	**Test material**	Benfluthrin (NAK 4455) - also known as transfluthrin
8.1.1	Lot/Batch number	Batch No.: 880325ELBO1
8.1.2	Specification	See purity (Section 3.1.3).
8.1.3	Purity	97.8% (GC)
8.1.4	Radiolabelling	Non-radiolabelled test material used.
8.1.5	UV/VIS absorption spectra and absorbance value	An absorption spectrum in water/acetonitrile 1:1 was produced which showed a main maximum at 210 nm, (ϵ = 18,200, band width up to 226 nm) and a secondary maximum at 265 nm, (ϵ = 1277, band width up to 275 nm). Above 279 nm, ϵ <10 l/mol cm.
8.1.6	Further relevant properties	The water solubility of transfluthrin is low, 57 µg/L, therefore a co-solvent, acetonitrile, was used at 50% v/v (i.e. 1:1, v/v).
8.2	**Reference substances**	Not applicable. Identification of degradation products was not conducted.

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8.3	**Test solution**	See table A7.1.1.1.2(02)-1
8.4	**Testing procedure**	
8.4.1	Test system	See table A7.1.1.1.2(02)-1 and 2.
8.4.2	Properties of light source	See table A7.1.1.1.2(02)-2.
8.4.3	Determination of irradiance	Spectral energy distribution of the mercury lamp was measured by means of a 0.01M uranyloxalate actinometer. Measurements were taken over the range 295 – 490 nm, resulting in an average of 0.7 x 10^{17} photons (per second and 3.0 ml).
8.4.4	Temperature	Temperature of photolysis regulated to 25 ºC using a circulating condenser.
8.4.5	pH	The solutions were not buffered and pH measurements were not conducted.
8.4.6	Duration of the test	Up to 8.5 hours continuous irradiation.
8.4.7	Number of replicates	Not stated in the report, but assumed to be single samples only.
8.4.8	Sampling	At each of the following sample points, a single replicate was removed (one cuvette containing 3 ml of solution) and analysed as detailed in Section 3.4 9: Water:acetonitrile 1:1 photolysis: 0, 0.5, 1, 1.5, 2.85, 3.55, 4.23, 4.91, 4.73 and 6.43 hours Humic acid in water/acetonitrile: 0, 0.5, 1, 2, 3, 4, 5, 6, 7, 8 and 8.5 hours. 10 ppm nitrate solution/acetonitrile: 0, 0.5, 1, 1.5, 2, 3.16, 4, 5, 6 and 7 hours. 50 ppm nitrate solution/acetonitrile: 0, 0.5, 1, 1.5, 2, 2.83, 3.66, 4.5, 5.25, 6 and 6.73 hours
8.4.9	Analytical methods	After irradiation, the aqueous samples were extracted with hexane (1:1, v/v). The organic phase was removed and analysed by GC. The GC method was as follows: Instrument: Hewlett Packard 5890 Column: High performance capillary column, cross linked methyl silicone, 25 m Carrier gas: Nitrogen, 60 ml/min Flow: 1 ml/min Detector: ECD Injector/detector temperature: 220ºC/260ºC Oven temperature: 120ºC (4 min), then to 220ºC at 5ºC per minute (3 min).

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8.5	**Transformation products**	No
8.5.1	Method of analysis for transformation products	Not applicable
	9 RESULTS	
9.1	**Screening test**	Not performed.
9.2	**Actinometer data**	Spectral energy distribution of the mercury lamp was measured by means of a 0.01M uranyloxalate actinometer. Measurements were taken over the range 295 – 490 nm, resulting in an average of 0.7 x 10^{17} photons (per second and 3.0 ml).
9.3	**Controls**	No control incubations
9.4	**Photolysis data**	
9.4.1	Mass balance	No mass balance data presented.
9.4.2	k^c_p	Quantification of transfluthrin was by GC. See tables 7.1.1.1.2(02)-3 to 6. Measured photolysis rate constants for the test substance: Direct photodegradation (water:acetonitrile, 1:1 system): 0.0268/hr Indirect photodegradation (1mg/l humic acid in water/acetonitrile system): 0.1609/hr Indirect photodegradation (10 mg/l sodium nitrate in water /acetonitrile, 1:1 system): 0.0599/hr Indirect photodegradation (50 mg/l sodium nitrate in water/acetonitrile, 1:1 system): 0.0793/hr
9.4.3	Kinetic order	Pseudo first order. Half lives calculated by means of linear regression.
9.4.4	k^c_p / k^a_p	Not calculated as no sunlight measurements were recorded.
9.4.5	Reaction quantum yield (ϕ^c_E)	Not calculated
9.4.6	k_{pE}	Not calculated
9.4.7	Half-life ($t_{1/2E}$)	The half-life of transfluthirn was calculated in the following systems: Direct photodegradation (water:acetonitrile, 1:1 system): 26 hours Indirect photodegradation (1 mg/l humic acid in water/acetonitrile system): 4.3 hours Indirect photodegradation (10 mg/l sodium nitrate in water/acetonitrile, 1:1 system): 11.6 hours Indirect photodegradation (50 mg/l sodium nitrate in water/acetonitrile, 1:1 system): 8.7 hours
9.5	**Specification of the transformation**	No quantification of degradation products was conducted.

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	products	
		10 APPLICANT'S SUMMARY AND CONCLUSION
10.1	**Materials and methods**	The direct and indirect photolysis of transfluthrin was examined in a non-guideline study using samples prepared in either acetonitrile/water (1:1, v/v), humic acid (1mg/l)/acetonitrile (1:1, v/v), sodium nitrate (10 ppm)/acetonitrile (1:1, v/v) or sodium nitrate (50 ppm)/acetonitrile (1:1, v/v). Samples (3 ml of solution in quartz cells) were irradiated using a mercury vapour light source in a merry-go-round carousel apparatus at 25ºC for periods of up to 7 hours. At each time point, a single sample was taken and extracted with hexane (1:1, v/v). The organic phase was removed and analysed by GC for the quantification of transfluthrin.
10.2	**Results and discussion**	Transfluthrin degraded photolytically with a half life of 4.3 – 26 hours.
10.2.1	k^c_p	Measured photolysis rate constants for the test substance: Direct photodegradation (water:acetonitrile, 1:1 system): 0.0268/hr Indirect photodegradation (1mg/l humic acid in water/acetonitrile system): 0.1609/hr Indirect photodegradation (10 mg/l sodium nitrate in water/acetonitrile, 1:1 system): 0 0599/hr Indirect photodegradation (50 mg/l sodium nitrate in water/acetonitrile, 1:1 system): 0.0793/hr
10.2.2	K_{pE}	Not calculated
10.2.3	ϕ^c_E	Not calculated
10.2.4	$t_{1/2E}$	The half-life of transfluthrin was calculated in the following systems: Direct photodegradation (water:acetonitrile, 1:1 system): 26 hours Indirect photodegradation (humic acid/acetonitrile system): 4.3 hours Indirect photodegradation (10 ppm sodium nitrate/acetonitrile, 1:1 system): 11.6 hours Indirect photodegradation (50 ppm sodium nitrate/acetonitrile, 1:1 system): 8.7 hours No extrapolation to equivalent days of sunlight at EU latitudes was made.
10.3	**Conclusion**	Transfluthrin degraded when exposed to artificial light with a half life for direct photolysis of 26 hours indicating that direct photolysis is unlikely to be a significant route of elimination in aqueous environmental compartments. Indirect photolysis of transfluthrin was more rapid, with half lives in the range 4.3 – 11.6 hours, indicating that transfluthrin is susceptible to natural photochemical and/or radical-induced oxidations and therefore its

		persistence it aqueous compartments is unlikely.
10.3.1	Reliability	2
10.3.2	Deficiencies	Yes

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09-02-2007
Materials and Methods	Applicant's version adequately reflects the study report, with the following addition: 3.1.2: Batch differs from those included in the batch analysis (Doc III A.2 confidential), but purity is acceptable.
Results and discussion	Applicant's version adequately reflects the study report.
Conclusion	Applicant's version adequately reflects the study report. However, the $DT_{50,photolysis}$ cannot be accepted for risk assessment because of serious deficiencies, see below.
Reliability	3 Deficiencies: The concentration of acetonitrile was very high (1:1 v/v). According to the author, acetonitrile at this concentration may have acted as competitor with transfluthrin for the developing OH-radicals. pH of the test solutions was not checked. No mass balance was established, which in view of the possible adsorption to the test vials is a deficiency. It is not reported whether dark controls were included, no results are presented. This makes it impossible to judge the value of the reported results for the irradiated samples.
Acceptability	Not acceptable In view of the deficiencies listed above, of which the absence of results for dark controls is the most prominent, the study is not considered valid for risk assessment.
Remarks	Since photolysis data are not necessary for the estimation of environmental concentrations, additional studies are not considered necessary.
	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(02)-1: Description of test solution and controls

Criteria	Details
Purity of water	All water used was high purity passed through a Milli-Q unit (Waters) with a bacterial filter.
Preparation of test chemical solution	For the irradiation, 3ml samples of the following solutions were transferred to quartz cuvettes: Test with humic acid: Transfluthrin (47.9 mg) was dissolved in 2 ml hexane and mixed into 10 g silica gel. A filter column was prepared using this treated silica and eluted 5 times with 100 ml of high purity water. The initial 4 elutates were discarded and the 5th fraction was diluted 1:1 v/v with high purity water containing humic acid salt (2.06 mg/l). Test solutions in water/acetonitrile 1:1 (v/v) Using the silica gel filtration method it was not possible to prepare solutions of transfluthrin in highly pure water or nitrate containing water with stable concentrations, therefore a test solution was prepared in acetonitrile 1:1 v/v.
Test concentrations (mg a.s./L)	Test with humic acid: 0.15 mg transfluthrin/l (confirmed by GC-analysis using an external standard in hexane) Test solutions in water/acetonitrile 1:1 (v/v): Direct photolysis 0.44 mg/l benfluthin in 1:1 v/v water: acetonitrile. Indirect photolysis: 0.41 mg/l transfluthrin in 1:1 v/v 10 mg/l nitrate water:acetonitrile or 0.45 mg/l transfluthrin in 1:1 v/v 50 mg/l nitrate water:acetonitrile. UV-absorption spectrum: 4.65 mg transfluthrin/l in 1:1 v/v water: acetonitrile.
Temperature (°C)	25ºC
Preparation of actinometer solution	Actinometry conducted with 0.01M uranyloxalate. No experimental details provided within the report.
Controls	No control incubations
Identity and concentration of co-solvent	Acetonitrile at 1:1 v/v to enable preparation of a homogenous solution.
Sterilisation	Sterile conditions were not used.

Table A7.1.1.2(02)-2: Description of test system

Criteria	Details
Laboratory equipment	UV-vis spectrophotometer DMS (Varian Co.). Quartz cuvettes (optical path length = 1 cm, height = 4.4 cm) with Teflon plug Merry-go-round irradiation apparatus 13/150 (Mangels Co.) with TQ 150 immersion lamp (Original Hanan Co.). Figure A7.1.1.1.2(02)-1 Thermostatization of the samples was achieved by the use of a circulating condenser 7007 (Huber Co.)
Emission wavelength spectrum	Mercury vapour lamp generated light spectrum of wavelength 200 – 600. The use of a quartz immersion cell filters out light of wavelengths < 290 nm.
Light intensity	
Filters	Filter finger made of Duran 50 glass

Table A7.1.1.1.2(02)-3: Quantification of transfluthrin in irradiated test solutions (water:acetonitrile, 1:1 test system) (results expressed as mg/l)

	Time (hours)									
	0	**0.5**	**1**	**1.5**	**2.85**	**3.55**	**4.23**	**4.91**	**5.73**	**6.43**
Transfluthrin	0.44	0.44	0.43	0.42	0.40	0.40	0.39	0.39	0.38	0.37

Table A7.1.1.1.2(02)-4: Quantification of transfluthrin in irradiated test solutions (1 mg/l humic acid in water:acetonitrile, 1:1 test system) (results expressed as mg/l)

	Time (hours)										
	0	**0.5**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**8.5**
Transfluthrin	0.15	0.14	0.13	0.12	0.09	0.09	0.07	0.06	0.05	0.04	0.04

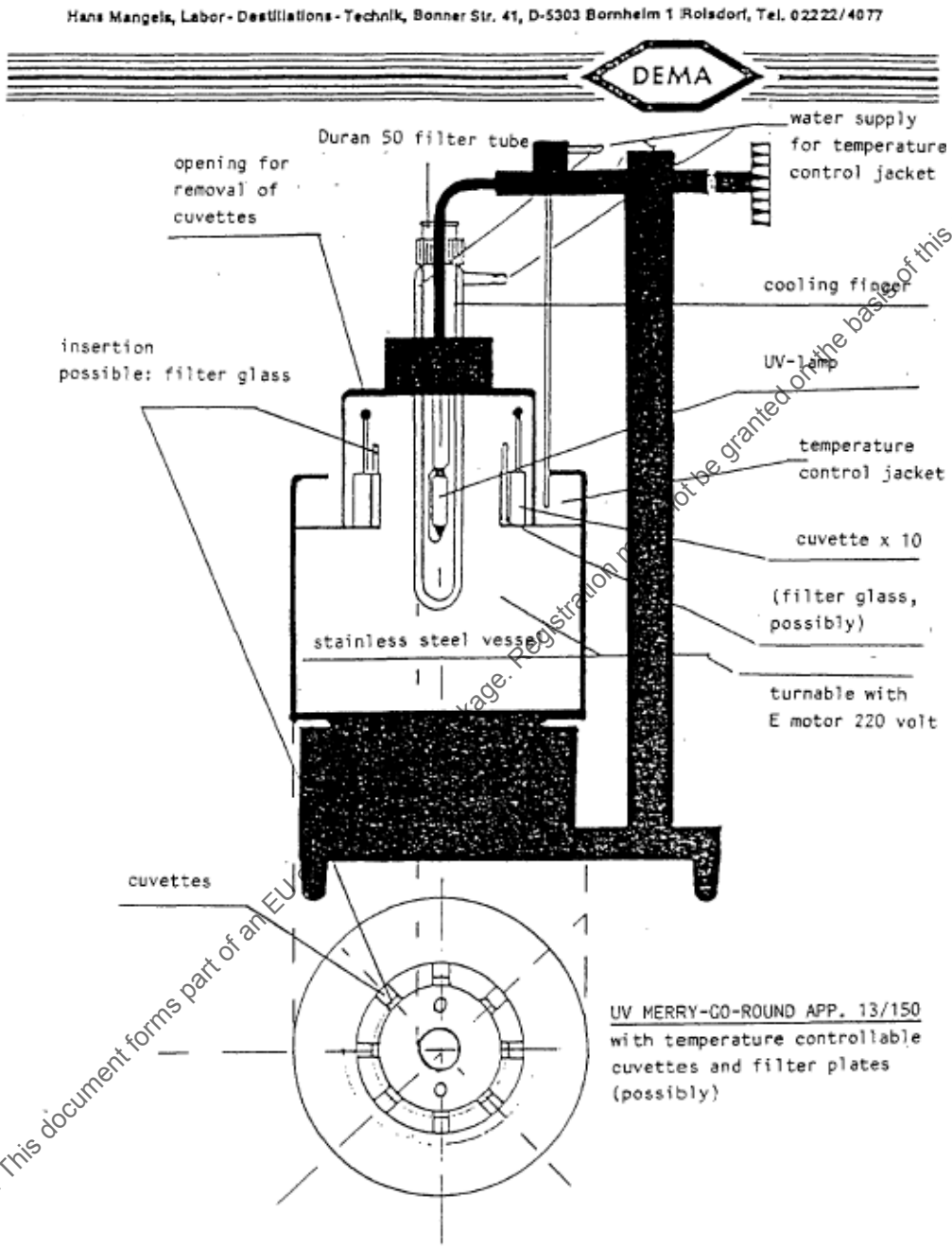
Table A7.1.1.1.2(02)-5: Quantification of transfluthrin in irradiated test solutions (10 mg/l sodium nitrate in water:acetonitrile, 1:1 test system) (results expressed as mg/l)

	Time (hours)									
	0	**0.5**	**1**	**1.5**	**2**	**3.16**	**4**	**5**	**6**	**7**
Transfluthrin	0.41	0.42	0.4	0.39	0.37	0.33	0.33	0.31	0.28	0.29

Table A7.1.1.1.2(02)-6: Quantification of transfluthrin in irradiated test solutions (50 mg/l sodium nitrate in water:acetonitrile, 1:1 test system) (results expressed as mg/l)

	Time (hours)										
	0	**0.5**	**1**	**1.5**	**2**	**2.83**	**3.66**	**4.5**	**5.25**	**6.0**	**6.73**
Transfluthrin	0.45	0.46	0.44	0.44	0.44	0.40	0.35	0.33	0.31	0.30	0.28

Figure A7.1.1.1.2(02)-1 - Merry-go-round irradiation apparatus



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	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure []	**Other justification [✓]**	
Detailed justification:	**Justification for not repeating an aqueous photolysis study on transfluthrin in the frame of the Biocidal Product Directive**	

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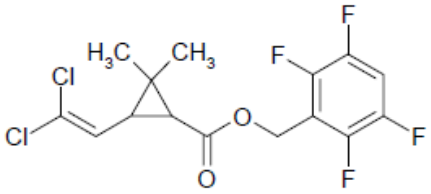
1 Introduction.

Transfluthrin, [(2,3,5,6-tetrafluorophenyl)methyl]1R,3R-(2,2-dichloroethenyl)-2,2-dimethyl cyclo-propanecarboxylate (see Figure 1), is a photo stable Class 1 synthetic pyrethroid developed by Bayer in the 1980s for control of various flying and crawling insects found in and around the home.

Figure 1:



Due to the fact the majority of transfluthrin containing products sold in Europe historically have been used for indoor application (the exception being a low concentration mosquito coil product); direct exposure of water to transfluthrin has been qualitatively considered very low. Therefore, less information on transfluthrin environmental fate and effects has been generated than for the various synthetic pyrethroids used in field crop protection.

Transfluthrin is now regulated in Europe as a Biocidal Product - PT-18, Insecticides, acaricides and products to control other arthropods - under

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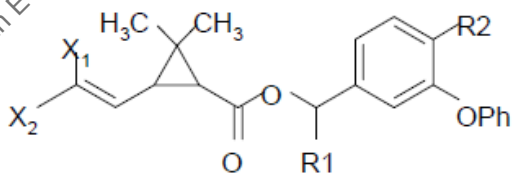
Directive 98/8 EC. In order to be granted re-registration, transfluthrin must be shown to be safe for all exposed environmental compartments.

A respective data package in order to risk assess the aqueous environment is available, i.e. on abiotic degradation (hydrolysis, photolysis) and biodegradation in water/sediment system. However, during the evaluation and the peer-review of the dossier, the request for a new aqueous photolysis study was raised by some member states.

This paper aims to demonstrate that repeating a new guideline study on direct photo-transformation in water would not add relevant information for the risk assessment.

In fact the photodegradation of transfluthrin in water was not yet investigated by a study performed according to currently available test guidelines. However, there exists a significant body of studies on Class 1 and Class 2 synthetic pyrethroid environmental fate and effects within Bayer CropScience, and in the open literature as well. A large proportion of photo stable synthetic pyrethroids used in crop protection contain a 3-vinyl substituted cyclopropyl acid moiety linked through a central ester bond to a substituted benzyl alcohol moiety. Bayer CropScience is a data owner for 3 synthetic pyrethroids in addition to transfluthrin: cyfluthrin, deltamethrin, and permethrin (see Figure 2). Furthermore, extensive published data is available on several pyrethroids including permethrin and its cyano-analogue cypermethrin as well as on a pyrethroid containing a 3-vinyl substituted cyclopropyl acid moiety linked through a central ester bond to a para-substituted tetrafluorobenzyl (see Figure 3).

Figure 2:



	CAS No.	Xi	x2	Ri	R2
Cyfluthrin	68359-37-5	Cl	Cl	CN	F
Cypermethrin	52315-07-8	Cl	Cl	CN	H
Deltamethrin	52918-63-5	Br	Br	CN	H
Permethrin	52645-53-1	Cl	Cl	H	H

Figure 3:

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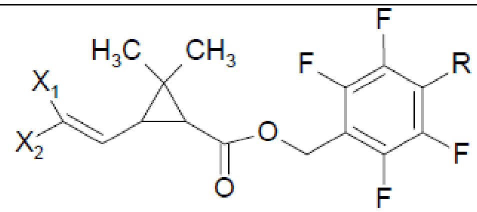

	CAS No.	Xi	x2	R
Transfluthrin	118712-89-3	Cl	Cl	H
Tefluthrin	79538-32-2	Cl	CF3	CH3

A significant proportion of photo stable synthetic pyrethroids used in crop protection contain a 3-vinyl substituted cyclopropyl acid moiety linked through a central ester bond to a substituted benzyl alcohol moiety. The following sections will demonstrate that for pyrethroids of similar structure to transfluthrin, the degradation pattern is consistent across Class 1 and Class 2 pyrethroids.

2 Hydrolysis.

Abiotic hydrolysis studies provide information on the potential stability of compounds in water at pH values expected in the environment (pH 5, 7, and 9). Under abiotic hydrolysis conditions at 25°C, transfluthrin was found to be stable at pH 5 and 7 (T½ > 1 year) but was degraded by ester cleavage to 2,2',3,3'-tetrafluorobenzyl alcohol and 3-(2,2-dichloroethynyl)-2,2-dimethylcyclo-propane carboxylic acid (a.k.a. permethrinic acid or DCVA) at pH 9 with a half-life of 14 days.

It should be considered that an alkaline pH showing the highest instability of the pyrethroids is most common in surface waters exposed to sunlight. Due to the fact that via photosynthesis of algae and aquatic plants the dissolved carbonate is consumed during the day the pH is increasing to alkaline pH, always.

Hydrolysis studies on other pyrethroids show similar results (see Table 1 and Table 2).

Conclusion: Based upon the results presented, it can be concluded that Class 1 and Class 2 pyrethroids similar in structure to transfluthrin are susceptible to hydrolytically cleavage of the ester bond under alkaline conditions in water, which are most common in surface water bodies exposed to sunlight.

3 Photolysis.

In an experiment on transfluthrin (Hellpointner, 1991), the UV-absorption spectrum of 4.65 mg transfluthrin per liter of

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water/acetonitrile[1] 1:1 (v:v) showed an absorption maximum at 210 nm (ε = 18200: band width up to 226 nm) and a secondary maximum at 265 nm (ε = 1277; band width up to 275 nm). The absorption of transfluthrin ended at 279 nm with ε <10 I/mole cm. Therefore, the direct interaction of transfluthrin with the sunlight is not expected to be a relevant route of degradation in water. Even when assuming a theoretical quantum yield of 1.0, not any direct phototransformation is possible in the environment in such a case.

For crop protection products to be registered in the EU or NAFTA currently, this type of study can be waived if the UV-VIS absorption spectra of the test item do not indicate absorption of environmental sunlight (i.e. molar absorption coefficient of ε ≥ 10 L mol-1 cm-1 at wavelengths above 295 nm. Exactly that is the case for transfluthrin as described above.

[References: Draft of revised version of Annex II to Council Directive 91/414/EEC Rev.7.0, May 2007). OECD Guideline 316: Phototransformation of Chemicals in Water – Direct Photolysis (adopted October 2008)]

Despite the before-mentioned fact direct phototransformation of transfluthrin was examined historically, e.g. in a non-guideline study (Anderson, 1987) using samples prepared in sterile-filtered water. Samples (in quartz cells) were irradiated using a mercury vapour light source using a carousel apparatus for periods of up to 8 hours. Indirect photolysis in the presence of humic acids was also conducted.

Whenever evaluating results of phototransformation studies with organic compounds, e.g. of pyrethroids (see a compilation of data in and Table 4) the respective purpose and detailed parameters of study (light source, light intensity, cut-off filters of wavelengths, as well as the ingredients and impurities of test solutions) should be considered carefully, always.

Conclusion: Based upon the results presented, it can be concluded that Class 1 and Class 2 pyrethroids similar in structure to transfluthrin are susceptible to cis/trans-photo isomerisation and to ester cleavage leading to the formation of phenoxybenzoic acid, phenoxybenzoic aldehyde, or phenoxybenzoic alcohol and the corresponding vinyl acid under aqueous conditions.

The tests where transfluthrin degraded photolytically with a half life of 17 hours were set up in order to determine the quantum yield of direct phototransformation, but not to simulate real environmental outdoor sunlight conditions. Experience shows that a DT50 of 17 hours in such equipment is regarded comparatively long, and the product formation might have been rather artificial as well. The other photodegradation tests, i.e. including natural waters or humic acids, did have the purpose to investigate the potential of indirect phototransformation and to

[1] The solubility of tansfluthrin in water was given to be 57 µg/L at 20°C while its solubility in a mixture of water/acetonitrile (99:1) raised up to 100 µg/L

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identify its degradates, but not testing the direct phototransformation.

A further fact to be considered i.e. for pyrethroids is their commonly very low water solubility and, on the other hand, their high sorption potential to organic matter (indicated by the high Kd or Koc values). If entries into surface water might occur, this leads to a very fast disappearance from the water body to any surfaces. In consequence, the compound will not be accessible for direct phototransformation in water for a longer time period.

4 Conclusion.

For the following reasoning direct photolytic degradation in water is not expected to be a relevant route of degradation of transfluthrin in water:

a) As for a crop protection product to be registered in the EU or NAFTA, this type of study can be waived for a compound like transfluthrin showing not any UV-absorption in the environmentally relevant wavelengths occurring on earth's surface. Such compounds are regarded as stable with respect to direct phototransformation in water.

b) Due to the hydrophobic nature of transfluthrin residues entering into water will rapidly be adsorbed on sediment and transfluthrin will undergo a rapid degradation in a microbial active system (Hellpointner, 1993). Thus, transfluthrin will never be accessible to phototransformation for a longer time period.

c) Transfluthrin indicates lowest hydrolytic stability in alkaline water, which is most prominent whenever natural surface waters are exposed to sunlight.

Table 1: Hydrolysis Results for Synthetic Pyrethroids, Bayer data

		pH 9, <2 day
Cyfluthrin	20	pH 5, stable pH 7, 270da diast I+II, 16(diast III+IV pH 9, 42h dia 33h diast III+
Deltamethrin	25	pH 5, stable pH 7, stable pH 9, 2.5 day
Permethrin	25	pH 5.7, >200 pH 7.6, >200 pH 9.6: 40-6(

Document. IIIA **Phototransformation in water including identity of transformation products**

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Table 2: Hydrolysis Results for Synthetic Pyrethroids, published data

(cis:trans)	25 °C	pH 7, stable pH 9, 1.8-2.5
Tefluthrin	25°C,	pH 5- pH 7: hydrolytically pH 9: > 30 d

Table 3: Aqueous photolysis results for synthetic pyrethroids, Bayer data

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deltamethrin	under sterilised buffer solution at 25°C. Xenon Arc lamp	
Permethrin		

Table 4: Aqueous photolysis results for synthetic pyrethroids, published data

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benzyl ring positions	solution; natural sunlight for 10 days (ca 8 hours per day).
Tefluthrin Cyclopoipyl and phenyl labelled	25°C, at the solubility limit of tefluthrin – 20µg/L

Study References:

Alvarez, M. & Dziedzic, J.E.; 1977; Hydrolysis of FMC 33297. FMC Corporation. Report No. CGP-77-12; Not GLP; Unpublished

Amos, R. and Donelan, R. B; 1987; Permethrin: Photolysis in sterile water at pH5. Report No. RJ0577B, 15 June 1987; Not GLP; Unpublished

Anderson, C. (1987). Preliminary study on abiotic degradation of NAK 4455, Bayer AG, Institut für Metabolismusforschung, Leverkusen, Germany. Bayer AG Report No.: 2888. BES Ref: M-103201-01-2. Report date: October 28, 1987. Unpublished

Bowman, B. and Carpenter, M. (1987) Determination of Photodegradation of 14C-Deltamethrin in Aqueous Solution. Analytical Bio-Chemistry Laboratories Inc, USA. ABC Project No.35491. BES Ref.: M-124981-01-1. Report date: 25 June 1987. Unpublished

Gronberg, R.R. (1987). Photodecomposition of [phenyl-UL-14C]Baythroid in aqueous solution by sunlight. Mobay Chemical Corporation, Agricultural Chemicals Division. Bayer Report No.: 88598. BES Ref.: M-040090-01-1. Report date: Original report 18 October 1984; revised report April 30 1987. Unpublished

Hellpointer, E. (1989). Benfluthrin: Hydrolysis in Buffers, Bayer AG, Pflanzenschutz-Forschung, Chemische Produktentwicklung und Ökobiologie, Institut für Metabolismusforschung, FRG, Germany Bayer AG Study No. PF3343. Report No.: M 111 0290-4. BES Ref: M-

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BPD Data set IIA/ Annex Point IIA7.6.2.2

102618-01-1. Report date: August 31, 19. Unpublished

Hellpointner, E. (1993), Aerobic metabolism of 14C-Benfluthrin in an aquatic model ecosystem, Bayer AG Crop Protection, Development Institute for Metabolism Research, Leverkusen, Germany. Bayer AG Study No. PF3920. Report No.: M 151 0481-0. BES Ref: (M-102622-01-1. Report date: 14 July 1993. Unpublished (GLP)

Krohn, J. (1997) Hydrolysis of cyfluthrin and beta-cyfluthrin as a function of pH. Bayer AG, Institute for Formulation development and Analysis. D-51368 Leverkusen, Germany. Bayer Report No.: 14 500 0926 BES Ref.: M-043171-01-1 Report date: 2 October 1997. Unpublished

Puhl, R.J., Hurley, J. B. and Dime R. A. (1983). Photodecomposition of BAYTHROID-14C in Aqueous Solution and on Soil. Mobay Chemical Corporation, Agricultural Chemicals Division. Report No.: 86182. BES N° M-072776-01-1 December 2, 1983. unpublished

Sandie, F.E. (1983) Hydrolysis of Baythroid in sterile aqueous buffered solutions. Mobay Chemical Corporation, Agricultural Chemicals Division. Bayer Report No.: 86051. BES Ref.: M-073571-01-1 Report date: 7 October 1983. Unpublished

Smith, A.M. (1990) Determination of Aqueous Hydrolysis Rate Constant and Half-Life of Deltamethrin. Springborn Laboratories Inc, USA. SLI Report No.: 90-4-3310. BES Ref: M-129026-01-1.Report date: 2 July 1990. Unpublished

Wang, W.W. and Reynolds, J.L. (1991). Aqueous Photolysis of 14C-Deltamethrin. XenoBiotic Laboratories Inc, USA. Report No.: XLB90035. BES Ref: M-136754-01-1. Report date: 18 July 1991. Unpublished

Publications:

DAR (2006). Draft Assessment Report of Tefluthrin. Rapporteur Member State: Germany: August 2006

Pesticide residuesin food 2008. EVALUATIONS - PART I – RESIDUES. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 9–18 September 2008. FAO Plant Production and Protection Paper 194

Takahashi, N., Mikami, N., Matsuda, T. and Miyamoto, J (1985a).Hydrolysis of the pyrethroid insecticide cypermethrin in aqueous media. J. Pestic. Sci, 10:643-648.

Takahashi, N., Mikami, N., Matsuda, T. and Miyamoto, J (1985b). Photodegradation of the pyrethroid insecticide cypermethrin in water and on soil surface. J. Pestic. Sci., 10, 629-642. Laboratory of Biochemistry and Toxicology, Sumitomo Chemical Co., BES Ref.: M-072742-01-1 Published paper

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BPD Data set IIA/ Annex Point IIA7.6.2.2

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	01-08-2013
Evaluation of applicant's justification	Information on photolysis in water is not required in order to perform the risk assessment for surface water.
Conclusion	Further information is not required.
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	

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Annex Point VII.7.6.1.1

Official use only

11 REFERENCE

11.1	**Reference**	Kanne (1990) Biodegradation of transfluthrin. Bayer AG, WD-UWS, Institute of Environmental Analysis, Leverkusen, Germany. Bayer AG Report No.: 90104217 [BES Ref: MO-03-010179] Report date: March 8, 1990 Unpublished
11.2	**Data protection**	Yes
11.2.1	Data owner	Bayer CropScience
11.2.2	Companies with letters of access	
11.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I

12 GUIDELINES AND QUALITY ASSURANCE

12.1	**Guideline study**	Yes OECD 301 F Manometric Respirmetry
12.2	**GLP**	No. GLP was not compulsory at the time the study was performed
12.3	**Deviations**	The report lacks experimental detail to determine the methodology used in the test. The study claims compliance with OECD 301F, so it can be assumed that the correct methodology was used. Several deficiencies are apparent including: Purity/batch of test material not stated Details on mineral medium used in test lacking. No abiotic control included. No indication if the incubations were replicated or not. pH not measured. Although the study lacks experimental and reporting detail, it has been conducted according to a recognised guideline and can be considered a valid for risk assessment purposes.

13 MATERIALS AND METHODS

13.1	**Test material**	Transfluthrin
13.1.1	Lot/Batch number	Not stated
13.1.2	Specification	Presumably as given in section 2 of Doc IIIA.
13.1.3	Purity	Not stated
13.1.4	Further relevant	Low water solubility: 0.057 mg/l

	properties		
13.1.5	Composition of Product	Not applicable.	
13.1.6	TS inhibitory to microorganisms	No information	X
13.1.7	Specific chemical analysis	None	
13.2	**Reference substance**	Yes, Aniline	
13.2.1	Initial concentration of reference substance	100 mg /l	
13.3	**Testing procedure**		
13.3.1	Inoculum / test species	See table A7.1.1.2-2	
13.3.2	Test system	See table A7.1.1.2-3	
13.3.3	Test conditions	See table A7.1.1.2-4	
13.3.4	Method of preparation of test solution	Test substance used as supplied and added by direct weighing.	
13.3.5	Initial TS concentration	100 mg test substance/L.	
13.3.6	Duration of test	28 days	
13.3.7	Analytical parameter	Oxygen consumption (this was related to the Theoretical Oxygen Demand (TOD) and concentration of the test substance and expressed as per cent biodegradation rate.	
13.3.8	Sampling	4, 6, 8, 12, 14, 20, 22, 26 and 28 days.	
13.3.9	Intermediates/ degradation products	Not identified.	
13.3.10	Nitrate/nitrite measurement	No	
13.3.11	Controls	Control without test substance and procedure control (aniline reference).	
13.3.12	Statistics	Not stated	
		14 RESULTS	
14.1	**Degradation of test substance**		

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14.1.1	Graph	Zero degradation was observed after 28 days, therefore no graphical plot is considered necessary.
14.1.2	Degradation	Zero degradation (calculated to the theoretical oxygen demand of 1336 mg O_2/g) was observed after 28 days. See table A7.1.1.2-5
14.1.3	Other observations	None
14.1.4	Degradation of TS in abiotic control	Not determined.
14.1.5	Degradation of reference substance	Percentage degradations of Aniline are presented below;
14.1.6	Intermediates/ degradation products	Not identified.

Day No.	% Biodegradation of Aniline
4	0
6	20
8	70
12	77
14	78
20	79
22	80
26	80
28	80

15 APPLICANT'S SUMMARY AND CONCLUSION

15.1 Materials and methods

Test substance: Transfluthrin (batch and purity not given). The test was conducted according to OECD Guideline 301F Manometric Respirometry Test.

Transfluthrin was suspended in a mineral medium, inoculated with a mixed population of aquatic organisms (activated sludge conc in flasks: 30 mg ss/l) at a rate of 100 mg/L. The reference material (aniline) was added to the same rate of 100 mg/L.

Test bottles for control, procedure control (aniline reference) and test substance were incubated in the dark at 20 ± 1ºC for periods of up to 28 days. Oxygen concentration was measured at days 4, 6, 8, 12, 14, 20, 22, 26 and 28 using a respirometer. This was then related to Theoretical Oxygen Demand (1336 mg O_2/g) and concentration of the test substance or reference material and expressed as per cent biodegradation rate.

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15.2	**Results and discussion**	The degradation rate calculated for oxygen consumption was zero percent in the test suspension after 28 days under the test conditions. From these results it is considered that transfluthrin was not readily biodegradable under the conditions of the test. Degradation of reference material (aniline) calculated from oxygen consumption was 78% within 14 days exposure.	
15.3	**Conclusion**	Transfluthin was not readily biodegradable under the conditions of the test. The test met all validity criteria.	X
15.3.1	Reliability	2	
15.3.2	Deficiencies	Yes Report lacks experimental detail to determine methodology used. Study claims compliance with OECD 301F, so it can be assumed that the correct methodology was used. Several deficiencies are apparent including: Purity/batch of test material not stated Mineral medium details lacking, toxicity control not included, whether the incubations were replicated or not. Although the study lacks experimental and reporting detail, it has been conducted according to a recognised guideline and can be considered a valid for risk assessment purposes.	

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
EVALUATION BY RAPPORTEUR MEMBER STATE
Date 09-02-07

Document IIIA Biodegradability (ready)

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Annex Point VII.7.6.1.1

Materials and Methods	Applicant's version adequately reflects the study report.with the following additional information submitted by the applicant: 1. The oxygen consumption in the blank vessel is higher than in the vessel containing the test substance, which potentially indicates a microbial inhibitory effect of transfluthrin. This is contradicted by the results shown in an activated sludge respiration test (Doc IIIA7.4.1.4), which demonstrates that transfluthrin was not inhibitory at concentrations up to 10 000 mg/L. At present there is no scientific explanation for the observed effect at 100 mg/L in the underlying study. There was no assessment of the toxicity of the test substance towards the bacteria (no toxicity test, containing both the test substance and a reference compound, was included in the experiment). In addition no measure of pH is available at the start or the end of the experiment. It can be noted that lower oxygen consumption is observed in only one of the 2 bottles for the test substance. In this bottle the oxygen consumtion reached a maximum at day 12 and then remained stable until the end of the experiment. However the conclusion that transfluthrin is not readily biodegradable remains. 2. Two bottles were used for each test substance, the reference substance and the control. 3. Only one measure was performed for each bottle.
Results and discussion	Applicant's version adequately reflects the report, but the following remark should be made: The study was performed at 100 mg/L, which is > 1750 x the reported water solubility (57 µg/L). It is possible that strong sorption to particles and/or vessels has influenced the results.. The test was performed according to the guidelines, and the test concentration itself is thus not a reason to consider the test as not reliable. However, it is not possible to draw a definitive conclusion with as to whether the classification *not readily biodegradable* is correct or is due to the test conditions.
Conclusion	It is recognised that the study does not meet the current standards with respect to reporting materials and methods and results. However, since the result *not readily biodegradable* reflects a *worst case* classification regarding the risk assessment, repetition of the experiment is not considered necessary.
Reliability	2 The following deficiencies were noted in addition to those reported by the applicant: The study was performed at 100 mg/L, which is far above the reported water solubility (57 µg/L).
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...

Document IIIA Biodegradability (ready)

SECTION A7.1.1.2.1
BPD Data set IIA/
Annex Point VII.7.6.1.1

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: 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
Manometric Respirometry	C.4-D	301F	ready

Table A7.1.1.2-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge.
Species	Not stated.
Strain	Not stated
Source and sampling site	Laboratory scale unit receiving sewage from the south Wupper area water authority (predominantly domestic sewage)
Laboratory culture	No
Method of cultivation	N/a
Preparation of inoculum for exposure	Not stated.
Pretreatment	No
Initial cell concentration	Concentration of activated sludge in test flasks: 33 mg ss/L.

Table A7.1.1.2-3: Test system

Criteria	Details
Culturing apparatus	Test bottles
Number of culture flasks/concentration	Number of replicates not stated. At least one flask for the test suspension and one each for the procedure control and blank control.
Aeration device	None
Measuring equipment	Oxygen consumption was measured using a respirometer.
Test performed in closed vessels due to significant volatility of TS	No

Table A7.1.1.2-4: Test conditions

Criteria	Details
Composition of medium	Not stated, but assumed to be of a composition stated within OECD 301F.
Additional substrate	None.
Test temperature	20 ± 1ºC
pH	Not stated
Aeration of dilution water	Not stated.
Suspended solids concentration	Not stated.
Other relevant criteria	None

Table A7.1.1.2-5: Results for degradation

Day	Oxygen consumption (mg O_2/g)		Biodegradation (%)
	Transfluthrin	Blank	
4	19	19	0
6	23	25	0
8	26	28	0
12	30	35	0
14	32	36	0
20	36	43	0
22	37	45	0
26	38	47	0
28	39	49	0

Table A7.1.1.2-6: 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 $ThCO_2$		No
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		No
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%		No (no replication)
Percentage of removal of reference substance reaches pass level by day 14	Yes	

Document IIIA	**Inherent Biodegradability**	
SECTION 7.1.1.2.2 **BPD Data Set IIA/ Annex Point VII.7.6.1.2**		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Transfluthrin was subject to a ready biodegradation test (equivalent to OECD Guideline 301F) and was found not to be readily biodegradable under the conditions of the test (Document III-A, section 7.1.1.2.1). Inherent biodegradability tests allow prolonged exposure of the test compound to microorganisms, or more favourable conditions for biodegradation, however as such, biodegradation under environmental conditions may not be assumed and the tests are not considered to provide adequate information for risk assessment purposes (TGD, Chapter 3, section 7.0.2.2.2). Manufacture and formulation of transfluthrin will be outside the EU therefore it is expected that exposure of the environment will only arise from the use and disposal of transfluthrin products. The proposed uses of the transfluthrin in the EU are for small scale localised use, as domestic (amateur) insecticides both indoors and outdoors e.g. patio use; no direct exposure/contamination of the outdoor environment is anticipated (see Doc IIB, section 3.3). Detailed environmental exposure assessments have been carried out, assuming a worst case scenario of no biodegradation in water/sediment systems (although biodegradability under biotic conditions was observed in the submitted water/sediment study). Exposure of the outdoor environment from the proposed uses of transfluthrin is negligible (see Doc IIB, Section 3.3). The amateur indoor use of transfluthrin (from use of Raid Portable Electric), with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in STP (8.8×10^{-10} – 8.8×10^{-7} mg/l) and surface water (1.9×10^{-11} – 8.2×10^{-8} mg/l). Worst case local contamination of outdoor air (from use of Raid Portable Electric) assuming standard room ventilation rates has been estimated to be 1.31×10^{-10} mg/m^3 (100m from source). Worst case contamination of soil *via* atmospheric deposition from use of one coil (Baygon mosquito coil) is estimated to be 6.8×10^{-11} mg/kg (this is considered to negligible and is analytically non-determinable). The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours (12 hr day) and with ozone 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode (8 hours) some degradation of transfluthrin maybe expected (with up to 25% reduction in concentration). Due to the fact that transfluthrin is not directly emitted to water or soil	

Document IIIA SECTION 7.1.1.2.2 BPD Data Set IIA/ Annex Point VII.7.6.1.2	Inherent Biodegradability
	and importantly there is extremely limited exposure to terrestrial and aquatic environmental compartments, even assuming zero biodegradation in the case of water, the need to conduct a study on inherent biodegradability is considered to be scientifically unjustified.
Undertaking of intended data submission [ ]	Not applicable
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11-02-2007
Evaluation of applicant's justification	Applicant's justification is accepted. In view of the presence of acceptable data on degradation in water/sediment systems, there is no need to perform a study on inherent biodegradability.
Conclusion	No additional data needed.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Document IIIA **SECTION 7.1.1.2.3** **BPD Data Set IIA/ Annex Point XII.2.1**	**Biodegradation in seawater**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Detailed human and environmental exposure assessments have been carried out (Document II-B, sections 3.2 and 3.3), taking into account the frequency and duration of use, the emission rate of the active substance from the product. Since there is no direct emission to water and the product uses are small scale and localized, i.e. uses as domestic insecticides for use indoors and outdoors (patio use), no direct exposure/contamination of the environmental compartments is anticipated so the only possible route of entry to water is via cleaning of residues deposited on indoor surfaces, with washings entering a sewerage system via a sink (e.g. washing of the cloth used for cleaning the surface under the tap). The use of transfluthrin in a vapouriser, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in concentrations in STP (8.8×10^{-10} – 8.8×10^{-7} mg/l) and surface water (1.9×10^{-11} – 8.2×10^{-8} mg/l). According to the TGD on risk assessment, the dilution factor for discharges to the coastal zone (100) is greater than that applied to the freshwater environment. The estimated Clocal seawater is 8.2×10^{-9} to 8.2×10^{-12} mg/l. Due to limited exposure to the marine environmental compartment, the need to conduct studies on biodegradation in seawater is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11-02-2007	
Evaluation of applicant's justification	Applicant's justification is accepted.	
Conclusion	No additional data needed.	
Remarks		

Document IIIA	**Biodegradation in seawater**
SECTION 7.1.1.2.3 **BPD Data Set IIA/ Annex Point XII.2.1**	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Document IIIA **SECTION 7.1.2.1.1** **BPD Data Set IIIA/ Annex Point XI.2.1**	**Aerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Manufacture and formulation of transfluthrin will be outside the EU therefore it is expected that exposure of the aquatic environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for small scale localised use as domestic (amateur) insecticides both indoors and outdoors e.g. patio use; no direct exposure/contamination of water bodies is anticipated. Detailed human and environmental exposure assessments have been carried out (Document II-B, sections 3.2 and 3.3), taking into account the frequency and duration of use, the emission rate of the active substance from the product, assuming that the airborne fraction of emitted residues is 100% and using standard room volume and ventilation rates. Environmental exposure from use and disposal is considered to be negligible. The amateur indoor use of transfluthrin (from use of Raid Portable Electric), with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in STP ($8.8 \times 10^{-10} – 8.8 \times 10^{-7}$ mg/l) and surface water ($1.9 \times 10^{-11} – 8.2 \times 10^{-8}$ mg/l). In fact the relatively high log Kow (5.46) and low water solubility (0.0575 mg/L) mean that it is unlikely that transfluthrin will be present in wastewater (Doc IIB, section 3.3). Indirect photolysis studies (in the presence of humic acid – see Section 7.1.1.1.2) and water-sediment study (see Section 7.1.2.2.2) indicate the rapid removal and abiotic degradation of transfluthrin. Due to limited exposure to aquatic environmental compartments and the biotic degradation demonstrated in the water sediment study (degradation half-life total biotic system in the dark ca. 7-15 days), the need to conduct aerobic biodegradation studies is considered to be scientifically unjustified.	X
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11-02-2007	

Document IIIA	Aerobic biodegradation
SECTION 7.1.2.1.1 **BPD Data Set IIIA/ Annex Point XI.2.1**	
Evaluation of applicant's justification	Applicant's justification is accepted, except for the statement on photolysis because the photolysis studies are considered not reliable. In view of the presence of acceptable data on degradation in water/sediment systems, there is no need to perform a study on aerobic degradation.
Conclusion	No additional data needed.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Document IIIA	**Anaerobic biodegradation**	
SECTION 7.1.2.1.2 **BPD Data Set IIIA/ Annex Point XI.2.1**		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Exposure to anaerobic conditions through the use of transfluthrin based products is not expected. The amateur indoor use of transfluthrin (from use of Raid Portable Electric (highest exposures), with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in STP (8.8×10^{-10} – 8.8×10^{-7} mg/l) and surface water (1.9×10^{-11} – 8.2×10^{-8} mg/l). In fact the relatively high log Kow (5.46) and low water solubility (0.0575 mg/L) mean that it is unlikely that transfluthrin will be present in wastewater (Doc IIB, section 3.3). Biotic degradation of transfluthrin has been observed in a water-sediment study (Section 7.1.2.2) with a half life in the total system of 7-15 days (incubated in the dark) and also in an aqueous photolysis study, when the sensitizer humic acid was used. Therefore, any transfluthrin released into the aquatic environment will be subsequently degraded, at least under aerobic conditions. Exposure under anaerobic conditions, possibly caused due to leaching into deeper anaerobic soil layers is excluded due to the immobility in soil (high Koc values). Due to limited exposure to aquatic environmental compartments and the biotic degradation demonstrated in the water sediment study, the need to conduct studies on the anaerobic biodegradation of transfluthrin is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11-02-2007	
Evaluation of applicant's justification	Applicant's justification is accepted.	
Conclusion	No additional data needed.	
Remarks		

Document IIIA	**Anaerobic biodegradation**
SECTION 7.1.2.1.2 **BPD Data Set IIIA/ Annex Point XI.2.1**	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Document IIIA **SECTION 7.1.2.2.1** **BPD Data Set IIIA/ Annex Point XI.2.1**	**Aerobic aquatic degradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	The biotic degradation of transfluthrin in aquatic systems has been thoroughly evaluated in a water/sediment study (Hellpointner, (1993) – See Doc IIIA, Section 7.1.2.2.2). This study demonstrated the rapid removal and degradation of transfluthrin under aerobic-aquatic conditions (DT_{50} (whole system, dark): 7 – 15 days). Further confirmatory data from indirect aquatic photolysis (See Doc IIIA Section 7.1.1.1.2) demonstrated that in the presence of photosensitisers (humic acid), transfluthrin degrades rapidly in the aquatic environment. The amateur indoor use of transfluthrin (from use of Raid Portable Electric (highest exposures), with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in STP (8.8×10^{-10} – 8.8×10^{-7} mg/l) and surface water (1.9×10^{-11} – 8.2×10^{-8} mg/l). In fact the relatively high log Kow (5.46) and low water solubility (0.0575 mg/L) mean that it is unlikely that transfluthrin will be present in natural water (Doc IIB, section 3.3). Due to limited exposure to aquatic environmental compartments and the biotic degradation demonstrated in the water sediment study the need to conduct studies on the aerobic aquatic degradation in aquatic systems is considered to be scientifically unjustified.	X
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11-02-2007	
Evaluation of applicant's justification	Applicant's statement on photolysis is not considered justified because the photolysis studies are not considered reliable. However, in view of the presence of acceptable data on degradation in water/sediment systems, further studies are not necessary.	
Conclusion	No further information needed.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Document IIIA	Aerobic aquatic degradation
SECTION 7.1.2.2.1 **BPD Data Set IIIA/ Annex Point XI.2.1**	
Date **Evaluation of applicant's justification** **Conclusion** **Remarks**	

Doc IIIA Water/sediment degradation study

SECTION A7.1.2.2.2
BPD Data set IIIA/
Annex Point XII.2.1

Official use only

16 REFERENCE

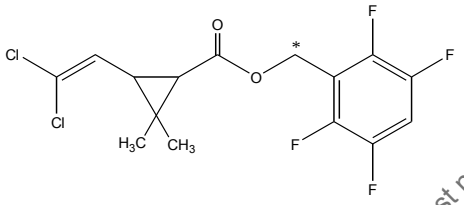
16.1	**Reference**	Hellpointner, E. (1993), Aerobic metabolism of ^{14}C-Benfluthrin in an aquatic model ecosystem, Bayer AG Crop Protection, Development Institute for Metabolism Research, Leverkusen, Germany. Bayer AG Report No.: M 151 0481-0 (MO-03-009370) Report date: 14 July 1993 Unpublished (GLP) With Kinetic evaluation of these data from: Buerkle, L. (2005), Transfluthrin (Benfluthrin), Kinetic Evaluation of the Data in Report PF 3920 (MO-03-009370): "Aerobic Aquatic Metabolism of E. Hellpointner (July 14, 1993)", Bayer CropScience AG, Research & Development – Development Metabolism and Environmental Fate, Monheim, Germany. Bayer AG Report No.: MEF-05/530 (M-26171-01-1) Report date: 30 November 2005 Unpublished (non-GLP)
16.2	**Data protection**	Yes
16.2.1	Data owner	Bayer CropScience
16.2.2	Companies with letters of access	
16.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I

17 GUIDELINES AND QUALITY ASSURANCE

17.1	**Guideline study**	Yes EPA Pesticide Assessment Guidelines, Subdivision N: § 161-4 (1982) Netherlands Guidelines G 2.1 (1981) Germany, BBA IV, 5-1 (1990)
17.2	**GLP**	Yes
17.3	**Deviations**	No The method does not significantly differ from the prescribed method for biocides, OECD 308 (draft)

Doc IIIA Water/sediment degradation study

SECTION A7.1.2.2.2
BPD Data set IIIA/
Annex Point XII.2.1

		18 MATERIALS AND METHODS	
18.1	**Test material**	Transfluthrin (Benfluthrin) 2,3,5,6-tetrafluorophenyl)methyl ester 3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropane carboxylic acid	
18.1.1	Lot/Batch number	 *position of radiolabel ^{14}C-Transfluthrin: Batch no.: not given Specific activity: 3.90 MBq/mg (105 µCi/mg)	
18.1.2	Specification	As given in section 2 of Doc IIIA	X
18.1.3	Purity	Radiochemical purity of the test substance was confirmed by radio-HPLC (98.7%) and radio-TLC (>99%)	
18.1.4	Further relevant properties	<u>Water solubility:</u> 0.057 ± 2.94 mg/L at 20 °C (Krohn, J - See Doc IIIA Section 3.5) <u>Dissociation Constant</u> Based on its chemical structure, transfluthrin will not dissociate in water (Bogdoll, B and Lemke, G – See Doc IIIA, Section 3.6) <u>Aqueous hydrolysis study</u> The half life of transfluthrin was 14 days at pH 9 and greater than 1 year at pH 5 and 7, assuming pseudo first order kinetics. (Hellpointer, E. – See Document IIIA, Section 7.1.1.1.1), <u>Vapour pressure</u> 20°C $9x10^{-4}$ Pa 25°C $2x10^{-3}$ Pa (Weber, R and Krohn, J – See Document IIIA, Section 3.2)	X
18.2	**Reference substances**	Transfluthrin (NAK 4455), 2,3,5,6-tetrafluorobenzoic acid (NAK 4723), 2,3,5,6-tetrafluorobenzyl alcohol (NAK 4452)	

Doc IIIA Water/sediment degradation study

SECTION A7.1.2.2.2
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18.3	**Test solution**	190 µl of a solution of transfluthrin (41.8 µg) dissolved in ethanol	
18.4	**Testing procedure**		
18.4.1	Test system	Natural sediment (2mm sieved) sourced from Laacherhof (Monheim) and Hönniger Weiher (Wipperfürth), Germnay (physico-chemical details are shown in Table A7.1.2.2.2-1) were placed in glass vessels	X
		of 10 cm internal diameter to a depth of 2 cm (ca 200g) and overlain	X
		with 6cm (ca 500 ml) depth of 2mm sieved natural water. The surface of the water was stirred/shaken to induce movement, whilst the sediment remained still. Flasks were fitted with appropriate traps containing a polyurethane plug and soda lime to collect volatile compounds and incubated at 20°C ± 2ºC for periods of up to 100 days.	
		The system was equilibrated for 2 weeks under test conditions. The redox potential in the water remained relatively steady over this period (166-174 mV at start to 178 -225mV after pre-incubation;	X
		oxygen content stable at 79-85%). The redox potential in the sediment decreased from 157 to 163 mV at the start to 1 to -177mV after pre-incubation, hence the sediment can be considered to	X
		anaerobic.	
		The redox potentials during the study are shown in table A7.1.2.2.2-2.	
18.4.2	Properties of light source	One set of incubations occurred under light conditions using a mixture of natural sunlight and standard growth lamps. The vessel was fitted with a quartz glass lid (to filter out light of <290 nm). Other incubations were carried out under dark conditions.	
18.4.3	Determination of irradiance	Not stated	
18.4.4	Temperature	20 ± 2 ºC	
18.4.5	pH	The pH values during the study are shown in table A7.1.2.2.2-2.	
18.4.6	Duration of the test	100 days	
18.4.7	Number of replicates	Two replicates per sampling day in dark experiments. One replicate per sampling day in light exposed experiments.	
18.4.8	Sampling	1, 7, 28, 70 and 100 day	
18.4.9	Analytical methods	Water was phase was separated, centrifuged (15 mins, 3300 g), filtered and aliquots taken for LSC. Samples from days 1, 7 and 28 were extracted with dichloromethane. The dichloromethane phase were analysed by TLC. The extracted water phases were freeze dried, the residue reconstituted in methanol and analysed by TLC.	

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		Water samples from day 70 and 100 were freeze dried directly after filtration and analysed by LSC (however results suggest that these were also subject to TLC analysis). Sediment was extracted three times with acetonitrile, the extracts filtered, combined and analysed by TLC. The filter residue and extracted sediment residue were air dried prior to combustion and radioassay. Radioactivity in the polyurethane bung was extracted with acetonitrile and then subjected to LSC and TLC analysis. Radioactivity in the soda lime was released with acid, trapped in carbosorb/permafluor and measured by LSC. TLC was undertaken on silica gel plates which were developed with toluene:methanol (9:1) or toluene:hexane (2:1).	
		19 RESULTS	
19.1	**Screening test**	Not performed	
19.2	**Radioactive distribution after degradation in test system**	Results are shown in Tables A7.1.2.2.2-3, A7.1.2.2.2-4 and A7.1.2.2.2-5 for the systems Laacherhof (dark), Honniger weiher (dark) and Honniger Weiher (light), respectively. In all cases the results were re-presented to include the filter extract that contained transfluthrin adsorbed to the suspended particles, as part of the sediment load.	X
19.3	**Mean balance of radioactivity**	The radioactivity balance was 81.5-106.4% (with one exception where the sample was lost part of the way through processing). Bound residues were 4.4%, 7.9 and 21.8% after 100 days in the Laacherhof, Honniger Weiher (referred to as Hofchen in the kinetic analysis report) and Honniger Weiher (light), systems respectively. Carbon dioxide levels were 3.0, 12.6 and 7.3% after 100 days in the Laacherhof, Honniger Weiher and Honniger Weiher (light), systems respectively. The vast majority of the radioactivity was accounted for by transfluthrin (NAK 4455), NAK 4452, and NAK 4723. The unidentified remaining radioactivity was always <10%.	X
19.4	**Effects of pH**	None observed. However both systems had similar pH.	
4.5	**Half-life**	Transfluthrin partitioned extremely rapidly into the sediment phase (ca 20% remaining in water after 1 day) and also degraded rapidly in the overall system. First order non-linear regression analysis was used to obtain the DT_{50}/DT_{90} values of transfluthrin in the system from the incubations in darkness. First order non-linear regression analysis was also used to obtain a conservative estimate of the DT_{50}/DT_{90} values of the major metabolite, NAK 4723. This estimation was only based on the decline in amounts over final three time points (28, 77, 100 days) and hence does not consider the effects of ongoing formation of the molecule. All DT_{50}/DT_{90} values obtained are shown in Table A7.1.2.2.2-6.	

Doc IIIA Water/sediment degradation study

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19.5	**Formation and identity of transformation products**	Code	% radioactive recovery	Pathway	X
		NAK 4452 (TFB-OH)	Max. 38% in water phase at day 7	Via ester cleavage	
		NAK 4723 (TBF-COOH)	Max. 59% in water phase and 81.2% in system at 70 day	formed by oxidation of NAK 4452	
19.6	**Degradation pathway**	The proposed degradation pathway is shown in figure 7.1.2.2.2-01.			

20 APPLICANT'S SUMMARY AND CONCLUSION

20.1 Materials and methods

The behaviour of ^{14}C-transfluthrin in two natural water/sediment systems was investigated under dark and light conditions at 20ºC.

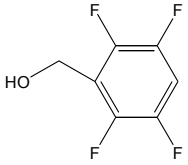
Analysis of transfluthrin and transformation products was by one-dimensional thin-layer chromatography. Trapped CO_2 radioactivity was determined by LS measurement.

20.2 Results and discussion

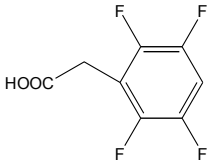
Transfluthrin was degraded rapidly under the conditions of the test and the first order DT_{50} in the whole system was 7-15 days (under dark conditions). The main metabolites were NAK-4455 (maximum 37.8% in the water phase after 7 days) and NAK-4723 (maximum 59.% in the water phase and 81.2% in the whole system after 70 days). The first order DT_{50} for NAK-4723 was conservatively calculated to be 437-485 days.

Structure of transformation products:

NAK 4452



NAK-4723



20.3 Conclusion

Transfluthrin was degraded rapidly under the conditions of the test and the first order DT_{50} in the whole system was 7-15 days (under dark conditions). The main metabolites were NAK-4455 (maximum 37.8% in the water phase after 7 days) and NAK-4723 (maximum 59% in the water phase and 81.2% in the whole system after 70 days). The first order DT_{50} for NAK-4723 was conservatively calculated to be 437-485 days.

20.3.1 Reliability 2

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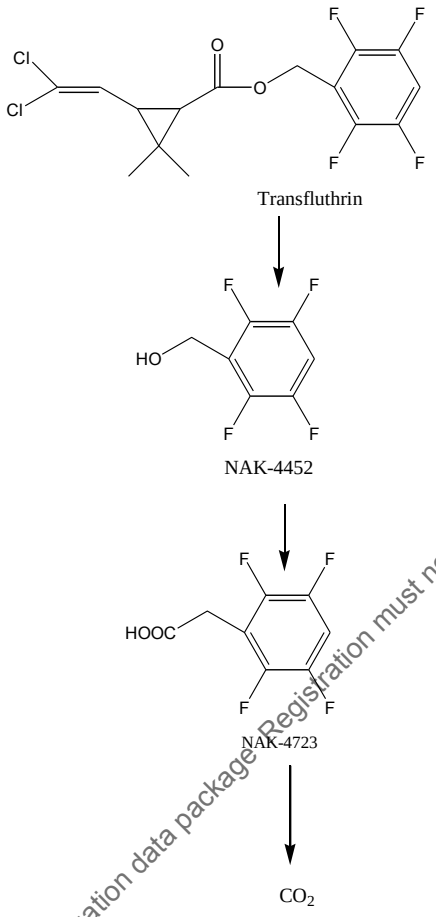
20.3.2	Deficiencies	None.

Figure 7.1.2.2.2-01: Degradation pathway of ^{14}C-transfluthirn in aerobic aquatic sediment systems



Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12-02-2007

Materials and Methods

Applicant's version is adopted with the following additions/amendments:

3.1.2 Batch differs from those included in the batch analysis (Doc III A.2 confidential), but purity is acceptable.

3.1.4 0.057 ± **0.00294** mg/L at 20 °C (Krohn, J - See Doc IIIA Section 3.5)

3.3 The amount of ethanol and application rate to test medium are 5.5 ml ethanol in vessel; content approx 700 ml, water phase 200 ml.

3.4.1 The tests were carried out with two different water-sediment systems, which were taken fresh from their natural locations. The water and sediment of Laacherhof origin was taken from a pond in natural state of approx. 500 m^2 without inflow or outflow. The water and sediment of Honniger Weiher origin was taken from an artificially dammed pond in the course of the Honniger Bach river. The pond is approx. 1000 m^2 in size, and has a strong current due to the inflow and outflow. The water passes through the pond into the Dhiinn Valley Dam, which is a drinking water reservoir.

Textural class according to USDA is silt loam

Sediment content is equivalent to 10 % dwt (0.1 g dwt/mL) for Laacherhof, 14.3 % dwt (0.143 g/mL) for Hönniger Weiher (dark) and 14.6 % dwt (0.146 g/mL) for Hönniger Weiher (light).

Applicant gives -177 mV for Hönniger Weiher sediment at end of equilibration, correct value is -117 mV. Redox potential during equilibration specified per system:

	Laacherhof			Hönniger Weiher	
	start	end		start	end
water	166/168	178		167/174	225
sediment	158/159	1		157/163	-117

Applicant states that sediment was anaerobic by the end of the equilibration, but Laacherhof (1 mV) is not.

Organic carbon content and texture of both selected sediments is quite similar. Organic carbon content was 5.0% and 3.7%; clay + silt was 70.1% and 75.6% for Laacherhof and Hönniger Weiher, respectively.

3.4.9 Water phase was also analysed for dissolved CO_2, carbonic acid or their salts after addition of HCl.

4.2 Results tables originate from report of Buerkle (2005), and are composed from the data in the original study report.

No measured data are available for day 0. In the kinetic evaluation by Buerkle, it is clearly stated that "with only five sampling intervals each suggests that a detailed calculation of the formation/degradation kinetics for each compartment would result in a very high uncertainty of the resulting rate constants and degradation half lives due to the too high number of degrees of freedom"

4.3 Total recovery in individual replicates ranges from **80.9** to 106.4 % of AR; Recovery of radiolabelled material was below the range of 90% to 110% for labelled chemicals.

NAK 4452 = 2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH)

NAK 4723 = 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH)

4.3 Analysis on degradation pathways and transformation products focussed on the benzylmethylene moiety. Information on transformation of the tetrafluorophenyl moiety is limited

4.4 Estimated $DT_{50,system}$ of NAK 4452 (TFB-OH) of < 7 days is based on rapid decline from 2.61 % of AR (Laacherhof) and 39 % of AR (Hönniger Weiher) on day 7 to n.d. on day 28.

4.5 TBF-COOH in text applicant should be changed to TFB-COOH

Maximum formation percentages of metabolites:

NAK 4452 (TFB-OH):

Laacherhof: 4.7 % in water (day 1); 2.5 % in sediment (day 7); 2.5 % in total system (day 7)

Hönniger Weiher: 38 % in water (day 7; large difference between replicates), 2.9 % in sediment (day 7), 39 % in total system (day 7)

NAK 4723 (TFB-COOH):

Laacherhof: 59 % in water (day 70); 24 % in sediment (day 28); 81 % in total system (day 70)

Hönniger Weiher: 55 % in water (day 28); 26 % in sediment (day 28); 82 % in total system (day 28)

Results and discussion	Applicant's version is accepted with the following remarks/additions: - The estimated DT_{50} of 437-485 d for metabolite NAK 4723 (TFB-COOH) is not considered reliable, on the basis of the available time points no quantitative estimate is possible. A quantitative estimate for the degradation of this metabolite can not be obtained from the present study. - The results for Hönniger Weiher are considered less reliable because of the relatively large difference between the replicates. - The $DT_{50,sediment}$ for transfluthrin is estimated by RMS applying non-linear regression of first-order kinetics, using the data as reported by Buerkle (2005): Laacherhof: 17.7 days, r^2 0.9407 Hönniger Weiher: 10.5 days, r^2 0.7592 - No additional metabolites are formed in the light exposed systems.
Conclusion	The following results are used for risk assessment: - transfluthrin: $DT_{50,water}$ < 7 days, values refers to disappearance due to rapid sorption, $DT_{50,system}$ 14.8 and 7.3 days; $DT_{50,sediment}$ 17.7 and 10.5 days - NAK 4452 (TFB-OH): transient in water (max. 38 %), sediment (max. 2.0 %), and total system (max. 39 %). $DT_{50,system}$ < 14 days - NAK 4723 (TFB-COOH): maximum formation between day 28 and 70 (59 % in water, 26 % in sediment, 82 % in total system; decline towards end of study (100 days) - Bound residues 4.4 and 7.9 % of AR after 100 days for Laacherhof and Hönniger Weiher, respectively. - Mineralisation after 100 days was 3.0 and 12.6 % of AR for the respective systems.
Reliability	2 Applies to the combination of both complementary reports. Deficiencies: No information on LOD/LOQ is given. Number of time points (total 5) is small, too small to estimate half-life for major metabolite NAK 4723 (TFB-COOH). For exposure modeling a conservative DT50 of 1000 days can be used Large differences between replicates of Hönniger Weiher.
Acceptability	Acceptable
Remarks	Batch differs from those included in the batch analysis (Doc III A.2 confidential), but purity is acceptable.
	COMMENTS FROM APPLICANT
Date	*7 April 2011*
Materials and Methods	
Results and discussion	The uncertainties in the pathway with respect to the used methylene label position at the tetrafluorophenyl-part are rather limited since the metabolism of the used radiolabel leads to 3 to 13% of $^{14}CO_2$ at the end of study (100 days). Remaining portions are thus not expected as major metabolites, and are probably either bound residues from a remaining phenol moiety or are released into the air since such compounds might be rather volatile, like it was found for the identified tetrafluorobenzyl alcohol
Conclusion	

Reliability
Acceptability
Remarks

Table A7.1.2.2.2-1 Physicochemical parameters of natural sediments

Sample:	Laacherhof	Honniger Weiher
Textural Analysis (%)		
Sand (63-2000 µm)	29.9	24.4
Silt (2-63 µm)	64.7	72.0
Clay (<2 µm)	5.4	3.6
Class (DIN 19682)	Sandy sludge	Sandy sludge
Organic Carbon (%)	5.0	3.7
pH (in 0.01 M $CaCl_2$)	6.5	5.4
Microbial biomass at study end (mg CO_2/hour/kg sediment)	9	13

Table A7.1.2.2.2-2 pH and Redox potential of the systems during incubation

Day	ID	Laacherhof				Hönniger Weiher			
		pH	Oxygen Content [%]	Redox Potential [mV]		pH	Oxygen Content [%]	Redox Potential [mV]	
				Water	Sediment			Water	Sediment
0	A	8.2	82	178	1	7.8	83	225	-117
	B								
	L								
1	A	8.5	78	119	-14	8.3	74	174	-116
	B	8.5	80	121	-30	8.0	70	205	-99
	L					8.6	95	201	-125
7	A	7.9	56	137	-11	5.5	57	245	-85
	B	7.9	55	199	-31	5.5	55	228	-116
	L					8.1	80	190	-85
28	A	7.9	69	201	70	6.3	66	270	-40
	B	7.9	68	187	59	6.1	60	240	-50
	L					6.2	79	220	-37
70	A	7.3	43	168	-69	5.9	45	180	-85
	B								
	L								
100	A	4.8	85	292	51	7.0	95	230	-29
	B	5.1	79	322	-4	7.4	94	247	-44
	L					6.7	98	255	16

A and B are replicates. L= light exposed

Table A7.1.2.2.2.3 **Transfluthrin and its degradates in the water and sediment phases of the system "Laacher Hof" as percentage of applied radioactivity (mean of two replicates)**

Water					
Day	transfluthrin in filtered water	Transfluthrin extracted from suspended part (filter)	NAK-4452 in filtered water	NAK-4723 in filtered water	Total CO_2*
1	19.65	5.90	4.74	1.37	0.03
7	0.76	0.42	-	27.45	0.04
28	-	-	-	52.28	0.71
70	-	-	-	59.39	2.05
100	-	-	-	49.88	2.98
Sediment					
	transfluthrin in extracted from sediment	Transfluthrin extracted from sediment and suspended part (filter)	Extracted NAK-4452	Extracted NAK-4723	Non extractable residues*
1	47.05	52.95	-	-	8.08
7	52.36	52.78	2.46	5.68	6.84
28	14.94	14.94	-	23.85	5.31
70	-	7.66	-	21.85	5.45
100	2.27	2.27	-	18.81	4.44

* CO_2 is the sum of that from the sediment and the filtered water. Non-extractable residues is the sum of that from sediment and that in the suspended part (filter)

Table A7.1.2.2.2-4 **Transfluthrin and its degradates in the water and sediment phases of the system "Honniger Weiher" as percentage of applied radioactivity (mean of two replicates)**

Water					
Day	transfluthrin in filtered water	Transfluthrin extracted from suspended part (filter)	NAK-4452 in filtered water	NAK-4723 in filtered water	Total CO_2*
1	19.72	4.06	6.31	0.85	0.02
7	2.97	0.48	37.67	3.76	0.03
28	-	-	-	55.48	1.52
70	-	-	-	51.27	5.14
100	-	-	-	51.44	12.55
Sediment					
	transfluthrin in extracted from sediment	Transfluthrin extracted from sediment and suspended part (filter)	Extracted NAK-4452	Extracted NAK-4723	Non extractable residues*
1	42.82	46.88	-	-	8.56
7	26.63	27.11	2.94	5.63	4.21
28	10.31	10.31	-	26.12	6.10
70	-	-	-	24.70	7.08
100	2.31	2.31	-	21.16	7.94

* CO_2 is the sum of that from the sediment and the filtered water. Non-extractable residues is the sum of that from sediment and that in the suspended part (filter)

Table A7.1.2.2.2-5 **Transfluthrin and its degradates in the water and sediment phases of the system "Honniger Weiher" under light conditions as a percentage of applied radioactivity**

Water					
Day	transfluthrin in filtered water	Transfluthrin extracted from suspended part (filter)	NAK-4452 in filtered water	NAK-4723 in filtered water	Total CO_2*
1	12.94	1.27	12.00	2.31	0.03
7	-	-	-	56.73	0.07
28	-	-	-	58.04	0.54
100	-	-	-	42.30	7.27
Sediment					
	transfluthrin in extracted from sediment	Transfluthrin extracted from sediment and suspended part (filter)	Extracted NAK-4452	Extracted NAK-4723	Non extractable residues*
1	46.82	48.09	-	0.00	7.00
7	9.86	9.86	-	9.51	5.02
28	2.50	2.50	-	27.17	7.20
100	0.40	0.40	-	22.85	21.78

* CO_2 is the sum of that from the sediment and the filtered water. Non-extractable residues is the sum of that from sediment and that in the suspended part (filter)

Table A7.1.2.2.2-6 **DT_{50} and DT_{90} values for transfluthrin and its degradates in the whole system of flasks incubated in darkness**

Compound	**System**	**DT_{50} (days)**	**DT_{90} (days)**	**Quality criterion r^2**
Parent	Laacher Hof	14.8	49.18	0.9918
	Honniger Weiher	7.3	24.2	0.9403
NAK-4452	Laacher Hof	< 14	< 47	estimated
	Honniger Weiher	< 14	< 47	estimated
NAK-4723	Laacher Hof	485	1611	0.9990
	Honniger Weiher	437	1453	0.9998

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			Official use only
		21 REFERENCE	
21.1	**Reference**	Jungheim (2001) Transfluthrin: Adsorption/desorption. Bayer AG, ZF-Zentrale Analytik, Leverkusen, Leverkusen, Germany. Bayer AG Report No.: N 01/0081/00 LEV, [BES Ref: MO-03-013152] Report date: 30 March 2001 Unpublished	
21.2	**Data protection**	Yes	
21.2.1	Data owner	Bayer CropScience	
21.2.2	Companies with letters of access		
21.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		22 GUIDELINES AND QUALITY ASSURANCE	
22.1	**Guideline study**	Yes OECD Guideline for Testing of Chemicals 121	
22.2	**GLP**	Yes	
22.3	**Deviations**	No	
		23 MATERIALS AND METHODS	
23.1	**Test material**	Transfluthrin: cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-,(2,3,5,6-tetrafluorophenyl)methyl ester, (1R-trans)-	
23.1.1	Lot/Batch number	816779502	
23.1.2	Specification	As given in section 2 of Doc IIIA	X

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23.1.3	Purity	Not stated
23.1.4	Further relevant properties	Water solubility: 0.057 ± 2.94 mg/L at 20 °C (Krohn, J - See Doc IIIA Section 3.5) Dissociation Constant Based on its chemical structure, transfluthrin will not dissociate in water (Bogdoll, B and Lemke, G – See Doc IIIA, Section 3.6) Aqueous hydrolysis study The half life of transfluthrin was 14 days at pH 9 and greater than 1 year at pH 5 and 7, assuming pseudo first order kinetics. (Hellpointer, E. – See Document IIIA, Section 7.1.1.1.1), Vapour pressure 20°C $9x10^{-4}$ Pa 25°C $2x10^{-3}$ Pa (Weber, R and Krohn, J – See Document IIIA, Section 3.2) Octanol/water partition coefficient Log Pow = 5.46 at 20ºC (Krohn, J – See Document IIIA, Section 3.9)
23.1.5	Method of analysis	Analysis was by the standard HPLC estimation detailed in OECD Guidelines for the Testing of Chemicals 121. The test material was dissolved in mobile phase and analysed at pH 4 and 6 using the following conditions: **pH 4:** Column type: length 250 mm; i.d. 4.6 mm Stationary phase: Ultrasphere Cyano, particle diameter: 5 µm Mobile phase: 500 mL acetonitrile : 100 mL buffer solution pH 4 : 400 mL water Flow rate: 0.7 ml/min, isocratic Column temperature: 40ºC Detection: UV, 220 nm Injection volume: 10µl **pH 6:** Column type: length 250 mm; i.d. 4 mm Stationary phase: LiChrospher 100 CN, particle diameter: 5 µm Mobile phase: 500 mL acetonitrile : 85 mL buffer solution pH 6 : 415 mL water Flow rate: 0.7 ml/min, isocratic Column temperature: 40ºC Detection: UV, 220 nm Injection volume: 10µl
23.2	**Degradation**	Degradation products tested: No

	products	
23.2.1	Method of analysis for degradation products	Not applicable.
23.3	**Reference substance**	Yes N,N-dimethylbenzamide, methylbenzoate, naphthalene, 1,2,3-trichlorobenzene, phenanthren, diclofop-methyl.
23.3.1	Method of analysis for reference substance	Analysis was by the standard HPLC estimation detailed in OECD Guidelines for the Testing of Chemicals 121 and as detailed in Section 3.1.5.
23.4	**Soil types**	Not relevant as the standard HPLC estimation method was used.
23.5	**Testing procedure**	
23.5.1	Test system	Adsorption of transfluthrin was measured using the standard HPLC estimation method (OECD Guidelines for the Testing of Chemicals 121) at pH 4 and 6. There were no deviations from the guidelines. The test and reference material were analysed by HPLC (pH 4: column Ultrasphere Cyano, 5 µm, 250 x 4.6 mm; pH 6: column LiChrospher 100 CN, 5 µm, 250 x 4 mm) with isocratic elution (pH 4: acetonitrile/pH 4 buffer/water, 50/10/40 v/v; pH 6: acetonitrile/pH 6 buffer/water, 50/8.5/41.5, v/v) and UV detection (220 mm). Test and reference compounds were analysed individually and in a mixture to determine relative retention times. The mixture was analysed in triplicate. Capacity factors, K', were calculated from the dead time (t_o) and retention times of the reference substances (t_R) by the following equation: $k' = \frac{t_R - t_o}{t_o}$ A correlation of log k' (capacity factor) versus known values of log Koc was plotted for the reference substances (calibration). The adsorption coefficient, mean and standard deviation were determined for the test and reference materials. The log Koc for transfluthrin was determined by comparison of its k' value to the calibration using least squares regression.
23.5.2	Test solution and Test conditions	Not stated
23.6	**Test performance**	
23.6.1	Preliminary test	No
23.6.2	Screening test: Adsorption	No
23.6.3	Screening test: Desorption	No

23.6.4	HPLC-method	According to (a)" OECD-HPLC-method"[2]: Yes
23.6.5	Other test	None

24 RESULTS

24.1	**Preliminary test**	No preliminary test was conducted
24.2	**Screening test: Adsorption**	Measured values for log k' are given in Table A7.1.3-01. At pH 6, the resulting regression for the test and reference substances was: Log k' = a + b logKoc Where a = -0.30094 b = 0.16739 r = 0.9549, indicating a good fit At pH 4, the resulting regression for the test and reference substances was: Log k' = a + b logKoc Where a = -0.57446 b = 0.16837 r = 0.97021, indicating a good fit
24.3	**Screening test: Desorption**	Not performed.
24.4	**Calculations**	
24.4.1	Ka , Kd	Not relevant for HPLC method
24.4.2	Ka_{oc} , Kd_{oc}	Measured values for log k' are given in Table A7.1.3-01 below. At pH 4 and 6, log k' values were 0.242 and 0.490 respectively. Measured values for log Koc are given in Table A7.1.3-01 below. At pH 4 and 6, log Koc values were 4.7 and 4.9 respectively.
24.5	**Degradation product(s)**	No degradation products were detected during the course of the study as indicated by the HPLC chromatograms.

25 APPLICANT'S SUMMARY AND CONCLUSION

25.1	**Materials and methods**	Adsorption of transfluthrin was measured using the standard HPLC estimation method (OECD Guidelines for the Testing of Chemicals 121) at pH 4 and 6. There were no deviations from the guidelines. The test

[2] OECD (1999) OECD-Guidelines for the Testing of Chemicals. Proposal for a new guideline 121: Estimation of the adsorption coefficient (K_{OC}) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC), Draft Document (August 1999).

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		and reference material were analysed by HPLC (pH 4: column Ultrasphere Cyano, 5 µm, 250 x 4.6 mm; pH 6: column LiChrospher 100 CN, 5 µm, 250 x 4 mm) with isocratic elution (pH 4: acetonitrile/pH 4 buffer/water, 50/10/40 v/v; pH 6: acetonitrile/pH 6 buffer/water, 50/8.5/41.5, v/v) and UV detection (220 mm). Test and reference compounds were analysed individually and in a mixture to determine relative retention times. The mixture was analysed in triplicate. A correlation of log k' (capacity factor) versus known values of log Koc was plotted for the reference substances (calibration). The mean adsorption coefficients were determined for the test and reference materials. The log Koc for transfluthrin was determined by comparison of its k' value to the calibration using least squares regression.
25.2	**Results and discussion**	At pH 6, the resulting regression for the test and reference substances was: Log k' = a + b logKoc Where a = -0.30094 b = 0.16739 r = 0.9549, indicating a good fit At pH 4, the resulting regression for the test and reference substances was: Log k' = a + b logKoc Where a = -0.57446 b = 0.16837 r = 0.97021, indicating a good fit
25.2.1	Ka_{oc}	The following values of log Koc and Koc were determined for transfluthrin: At pH 4: Log Koc 4.85 (4.9) (Koc = 79433) At pH 6: Log Koc 4.73 (4.7) (Koc = 50119) These Koc values indicate that transfluthrin is not likely to be mobile in soil. The high Koc values correlate with its relatively low water solubility. No degradation products were observed during the study.
25.2.2	Degradation products (% of a.s.)	None
25.3	**Conclusion**	The Koc values for transfluthrin at pH 4 and 6 were determined by the standard OECD HPLC method 121 to be 79,433 and 50,119 respectively. Transfluthrin is therefore classified as immobile.
25.3.1	Reliability	1
25.3.2	Deficiencies	Yes The reference Koc values in the OECD 121 guideline presumable refer to 25ºC. However the column temperature was 40ºC, this temperature is not considered to affect the values obtained.

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Annex Point VII.7.7

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12-02-2007
Materials and Methods	Applicant's version is adopted with the following additions/amendments: 3.1.2: Specification of batches. Batches included in Doc III A.2 (confidential) are different from the batch used here and were produced in 2002/2004; the adsorption study was performed in 2001. Specification and purity are thus unknown
Results and discussion	Applicant's version is adopted.
Conclusion	The results log Koc 4.9 at pH 4 and 4.7 at pH 6 are accepted for risk assessment
Reliability	2 Deficiency: Purity of test substance unknown Retention of transfluthrin was outside the range of reference substances. OECD 121 gives two possible reference substances with Koc at or above that of transfluthrin (Basic Blue 41, Koc 79,433; DDT log Koc 50,119).
Acceptability	Acceptable
Remarks	
	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_3-1: Results of screening test – adsorption coefficients

Compound	Retention Time (min) Inj 1	Inj 2	Inj 3	Retention Time (t_r) Average	k' $k' = (t_r - t_0) / t_0$	log k'	log Koc*	Koc
pH 4								
Sodium nitrate	3.260	3.258	3.259	3.259				
N,N-dimethylbenzamide	4.595	4.596	4.595	4.595	0.410	-0.387	1.52	
Methylbenzoate	5.141	5.143	5.142	5.142	0.578	-0.238	1.80	
Naphthalene	6.101	6.102	6.101	6.101	0.872	-0.059	2.75	
1,2,3-trichlorobenzene	6.426	6.427	6.425	6.426	0.972	-0.012	3.16	
Phenanthren	7.124	7.127	7.126	7.126	1.186	0.074	4.09	
Diclofop-methyl	7.605	7.609	7.608	7.608	1.334	0.125	4.20	
Transfluthirn	8.949	8.952	8.950	8.950	1.746	0.242	4.85	79433
pH 6								
Sodium nitrate	2.433	2.439	2.426	2.433				
N,N-dimethylbenzamide	4.225	4.225	4.224	4.225	0.737	-0.133	1.52	
Methylbenzoate	5.141	5.141	5.141	5.141	1.113	0.046	1.80	
Naphthalene	6.512	6.512	6.510	6.511	1.677	0.225	2.75	
1,2,3-trichlorobenzene	6.852	6.852	6.850	6.851	1.816	0.259	3.16	
Phenanthren	7.726	7.725	7.722	7.724	2.175	0.337	4.09	
Diclofop-methyl	8.447	8.448	8.447	8.447	2.472	0.393	4.20	
Transfluthirn	9.954	9.955	9.951	9.953	3.092	0.490	4.73	50119

* Estimated from linear regression analysis

The average retention time for sodium nitrate = t_0

Document IIIA **Section 7.1.4** **BPD Data Set IIIA/ Annex Point XII.2.2**	**Further studies on adsorption/desorption in water/sediment systems, (including adsorption/desorption of metabolites and degradation products)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	The amateur indoor use of transfluthrin (from use of Raid Portable Electric (highest exposures), with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in STP (8.8×10^{-10} – 8.8×10^{-7} mg/l) and surface water (1.9×10^{-11} – 8.2×10^{-8} mg/l). In fact the relatively high log Kow (5.46) and low water solubility (0.0575 mg/L) mean that it is unlikely that transfluthrin will be present in wastewater (Doc IIB, section 3.3). In sediment, predicted exposures were minimal, with concentrations via an STP of 2.1×10^{-8} - 2.1×10^{-5} mg/kg and from discharge of sewer water direct to river of 8.9×10^{-8} – 8.9×10^{-5} mg/kg An adsorption/desorption study is available (Section 7.1.3) which indicates that transfluthrin will be immobile, this was confirmed by the water-sediment study (Section 7.1.2.2.2) in which a rapid partitioning from the water to the sediment was observed. Due to limited exposure to aquatic environmental compartments, the need to conduct further studies on adsorption/desorption in aquatic systems, (including adsorption/desorption of metabolites and degradation products) is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	12-02-2007	
Evaluation of applicant's justification	Because of the high log Kow, a sorption study is not considered technically feasible. The available information from the HPLC-study is considered sufficient for risk assessment.	
Conclusion	No additional data needed.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		

Document IIIA Section 7.1.4 BPD Data Set IIIA/ Annex Point XII.2.2	Further studies on adsorption/desorption in water/sediment systems, (including adsorption/desorption of metabolites and degradation products)
Evaluation of applicant's justification **Conclusion** **Remarks**	

Document IIIA **SECTION 7.1.4.1** **BPD Data Set IIIA/ Annex Point XII.2.1**	**Field study on accumulation in the sediment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	The amateur indoor use of transfluthrin (from use of Raid Portable Electric (highest exposures), with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in STP (8.8×10^{-10} – 8.8×10^{-7} mg/l) and surface water (1.9×10^{-11} – 8.2×10^{-8} mg/l). In fact the relatively high log Kow (5.46) and low water solubility (0.0575 mg/L) mean that it is unlikely that transfluthrin will be present in wastewater (Doc IIB, section 3.3). In sediment, predicted exposures were minimal, with concentrations via an STP of 2.1×10^{-8} - 2.1×10^{-5} mg/kg and from discharge of sewer water direct to river of 8.9×10^{-8} – 8.9×10^{-5} mg/kg No accumulation of transfluthrin was observed in the laboratory water-sediment study (Section 7.1.2.2.2) Therefore, due to limited exposure to aquatic environmental compartments, the need to accumulation studies in water-sediment systems is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	12-02-2007	
Evaluation of applicant's justification	The available information from the water/sediment study is considered sufficient to address the persistence in sediment.	
Conclusion	No additional data needed.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		

Document IIIA	Field study on accumulation in the sediment
SECTION 7.1.4.1 **BPD Data Set IIIA/ Annex Point XII.2.1**	
Conclusion **Remarks**	

Document IIIA **SECTION 7.2.1** **BPD Data Set IIIA/ Annex Point VII.4, XII.1.1**	**Aerobic degradation in soil, initial study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Manufacture and formulation of transfluthrin will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for small scale localised use as domestic (amateur) insecticides both indoors and outdoors e.g. patio use; no direct exposure/contamination of soil is anticipated. Detailed human and environmental exposure assessments have been carried out (Document II-B, sections 3.2 and 3.3), taking into account the frequency and duration of use, the emission rate of the active substance from the product, assuming that the airborne fraction of emitted residues is 100% and using standard room volume and ventilation rates. Environmental exposure from use and disposal is considered to be negligible. (Worst case exposure values for the soil compartment result from use of the 'Baygon Coil' product, see Doc IIB, section 3.3). The amateur outdoor use of transfluthrin (from use of Baygon Coils), with subsequent deposition into the terrestrial compartment of 6.8×10^{-11} mg/kg i.e. negligible concentrations in soil. There is no aerobic soil metabolism study with transfluthrin. However, Bayer possesses laboratory studies for the aerobic degradation of similar pyrethroids, acrinithrin, cyfluthrin and deltamethrin, which are summarised in Table 7.2.1-01. The open literature contains considerable information on permethrin degradation in soils. In addition, publications on cypermethrin (the Class II counterpart of permethrin, i.e. having an alphacyano group) aerobic soil degradation in soils are also available. Both permethrin and cypermethrin studies are valuable both to further demonstrate consistency of degradation of the pyrethroid as well as to estimate the rate of degradation of common degradation product dichloro vinyl dimethyl cyclopropane carboxylic acid (DCVA, permethric acid). An overview of pertinent studies for estimating parent degradation rates is shown in Table 7.2.1-02. The results of Bayer studies show that the degradation pathway is consistent across all molecules and the same as observed in transfluthrin water sediment study. Cypermethrin and permethrin literature reports also confirm the consistency of the degradation pathway. The fate of transfluthrin in soil can be predicted without conducting an aerobic soil metabolism study. Under aerobic conditions, transfluthrin will degrade in soil to DCVA and tetrafluorobenzyl alcohol which in turn will oxidize to tetrafluorobenzoic acid (TFBA). Both DCVA and TFBA will further degrade in soil. Looking at the typical DT_{50} values across the various reports, the longest reported DT_{50} in any one soil is approximately 12 weeks from a	

Document IIIA SECTION 7.2.1 BPD Data Set IIIA/ Annex Point VII.4, XII.1.1	Aerobic degradation in soil, initial study
	published report for cis-cypermethrin. It is possible to conclude that this class of compounds, which includes transfluthrin, do not have the potential for accumulation and persistence in soil. Therefore, due to limited exposure to the terrestrial compartment and the fate of transfluthrin being confidently predicted by the fate documented for other pyrethroids of comparative structure and function, the need to conduct aerobic soil degradation studies is considered to be scientifically unjustified.
Undertaking of intended data submission [ ]	Not applicable
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13-02-2007
Evaluation of applicant's justification	*Comments on the report* It is stated in the report that metabolite permethrinic acid (DCVA; also named trans-permethric acid) was identified as a hydrolysis product of transfluthrin in the hydrolysis study of Hellpointner, 1989 (A7.1.1.1.1), DCVA was not positively identified, although the compound was mentioned in the conclusion. Only NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) was found, and only at pH 9. DCVA, and not TFB-OH, was identified as a hydrolysis product at pH 9 in the study of Hellpointner, 1989 (A7.1112/01), but this study is not accepted due to major deficiencies. It is stated in the report that in the water/sediment study of Hellpointner (1993; A7.1.2.2.2), presumably DCVA was found. This compound was not included as a reference substance in that study and is not mentioned in the report at all. The metabolites identified in the water/sediment study are 2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH; NAK 4452) and 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH; NAK 4723). *Evaluation of applicant's conclusions* For those compounds for which data from both water/sediment studies and soil are available, it appears that the **route** of degradation is similar in water/sediment and soil. It is considered justified to assume that the degradation pathway of transfluthrin in soil is similar to that observed in water/sediment systems, i.e. main metabolites to be expected in soil are 2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH; NAK 4452) and 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH; NAK 4723). The proposed metabolic pathway of transfluthrin is given at the end of this document. With respect to the **rate** of degradation, the following comments are made: Chemical hydrolysis of transfluthrin is possible at pH 9. At pH 5 and 7, the compound is stable. Hydrolysis of the pyrethroids mentioned in the report is also pH-dependent. Representative soil pH is 4 to 8, and any hydrolysis occurring will be microbially mediated (i.e. micro-organisms creating a micro-climate in which

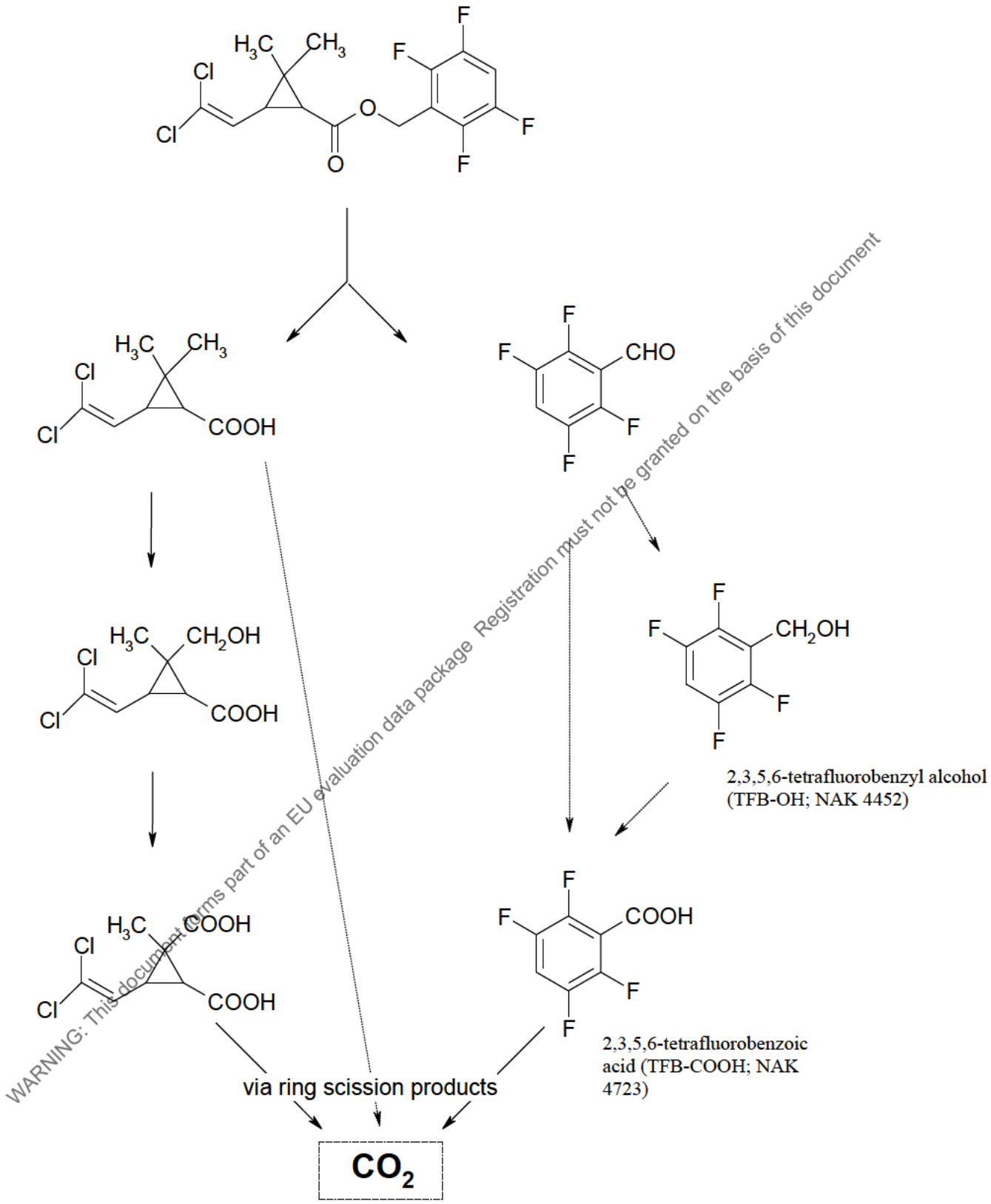
Document IIIA SECTION 7.2.1 BPD Data Set IIIA/ Annex Point VII.4, XII.1.1	Aerobic degradation in soil, initial study
	hydrolysis occurs). Because in the report the pH of the soils is not reported, it is not known to what extent this will have contributed to the degradation of the compounds. The influence of the tetrafluorophenyl-group of transfluthrin on the degradation rate cannot be evaluated. The influence of this group on biological processes (i.e. due to toxicity, spherical effects) cannot be assessed. The tetrafluorophenyl-group is different from the phenoxy-phenyl group of the other pyrethroids under consideration. The fluoro-groups will strongly attract electrons and the presence of one fluoro-substituent to the phenoxyphenyl-group seems to result in a substantial increase of the DT_{50}. To adequately assess the effect of fluoro-substituted phenyl-groups, data on tefluthrin, profluthrin, metofluthrin, fenfluthrin, dimefluthrin would be helpful. It should further be noted that the tetrafluorophenyl-fragment can lead to potentially persistent and toxic metabolites..
Conclusion	From the above, it is concluded that the similarity of transfluthrin with the pyrethroids in the report is too limited to allow the use of a DT_{50} of 60 days on the basis of read-across. However, for the proposed uses of transfluthrin, direct emission to soil is considered negligible and no risks for the terrestrial compartment are identified as a result of indirect emissions. Further information is not required.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Table 7.2.1-01: Laboratory Aerobic Soil Metabolism Study Results for Synthetic Pyrethroids, Bayer data

Pyrethroid	Guideline	°C	DT_{50}	Main Degradates	Reference
Acrinathrin cyclopropyl and benzyl labelled	OECD draft; US EPA 161-2	20	4 soils tested B-labelled 8.5, 16.1, 20.3, 38.9 d C-labelled 8.5, 19.0, 34.1, 16.2 d	Terminal vinyl acid of acrinathrin; 3-phenoxy-benzoic acid; 3-(2-carboxyethynyl)-2,2-dimethylcyclopropyl carboxylic acid; CO2	Diehl, 2002
Cyfluthrin benzyl labelled	No specific guideline given	20	2 soils tested 54 d both soils	4-Fluoro-3-phenoxy-benzoic acid; CO2; presumed DCVA	Wagner at.al, 1983
Deltamethrin Benzyl and cyclopropyl labelled	No specific guideline given	25	2 soils tested 11 - 19 d	3-phenoxybenzoic acid; 3-(2,2-dibromo-ethynyl)-2,2-dimethyl-cyclopropane carboxylic acid ; CO2	Kaufman, et.al., USDA, 1980s (precise year not given)
Deltamethrin Benzyl and cyclopropyl labelled	US EPA 162-1	25	1 soil tested B-labelled 21.6 d C-labelled 25.5 d	As above	Wang, 1991
Permethrin Benzyl and cyclopropyl labelled	No specific guideline given	20	1 Soil 37d	DCVA; 3-phenoxy-benzoic acid; CO2	Hawkins, 1992 (Syngenta study, access to BES for BPD PT08)

Table 7.2.1-02: Laboratory Aerobic Soil Metabolism Study Results for Synthetic Pyrethroids, Published

Pyrethroid	**°C**	**DT_{50} cis isomer**	**DT_{50} tr's isomer**	**Main Degradates**	**Publication**
Cypermethrin Benzyl and cyclopropyl labelled	25	3 Soils B-labelled ~4w, ~3w, ~12w C-labelled, Soil 1 ~4w	3 Soils B-labelled 1-2w, <2w, ~3w C-labelled, Soil 1 ~2w	DCVA; 3-phenoxy-benzoic acid; CO2	Roberts and Standen, *Pestic. Sci*, **8**, 305-319 (1977) (also see Roberts & Standen, *Pestic. Sci*., **12**, 285-296, (1981))
Cypermethrin Benzyl and cyclopropyl labelled	25	2 Soils 12.5d, 56.4d	2 Soils 4.1d, 17.6d	As above	Sakata, et.al., *J. Pesticide Sci*., **11**, 71-79 (1986)
Permethrin Benzyl and cyclopropyl labelled	25	2 Soils 12d, 12d	2 Soils 6d, 9d	DCVA; 3-phenoxy-benzoic acid; CO2	Kaneko et.al., *J. Pesticide Sci*., **3**, 43-51 (1978)
Permethrin Cyclopropyl labelled	25	1 Soil 12d	1 Soils 5d	DCVA; CO2, presumed 3-phenoxybenzoic acid	Jordan et.al., *J. Environ. Sci. Health.*, **B17 1**, 1-17 (1982)



Document IIIA **SECTION 7.2.2** **BPD Data Set IIIA/ Annex Point XII.1.1**	**Aerobic degradation in soil, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Refer to 7.2.1 for detailed justification. A detailed justification for the non-submission of further aerobic soil degradation studies has been presented within section 7.2.1.3 based upon the negligible exposure to the terrestrial compartment (PECsoil of 6.8 x 10^{-11} mg/kg) and the fate of transfluthrin being confidently predicted by the fate documented for other pyrethroids of comparative structure and function. Therefore the need to conduct further aerobic soil degradation studies is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	The statement that the fate of transfluthrin can be confidently predicted from that of other pyrethroids is not agreed upon (see Doc IIIA 7.2.1). However, for the proposed uses of transfluthrin, direct emission to soil is considered negligible. Since no risks for the terrestrial compartment are identified as a result of indirect emissions, it is not considered necessary to perform additional studies.	
Conclusion	Further information is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Document IIIA **SECTION 7.2.2.1** **BPD Data Set IIIA/ Annex Point VII.4, XII.1.1, XII.1.4**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Refer to 7.2.1 for detailed justification. A detailed justification for the non-submission of further aerobic soil degradation studies has been presented within section 7.2.1 based upon the negligible exposure to the terrestrial compartment (PECsoil of 6.8 x 10^{-11} mg/kg) and the fate of transfluthrin being confidently predicted by the fate documented for other pyrethroids of comparative structure and function. Therefore the need to conduct further aerobic soil route and rate of degradation studies (including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions) is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	The statement that the fate of transfluthrin can be confidently predicted from that of other pyrethroids is not agreed upon (see Doc IIIA 7.2.1). However, for the proposed uses of transfluthrin, direct emission to soil is considered negligible. Since no risks for the terrestrial compartment are identified as a result of indirect emissions, it is not considered necessary to perform additional studies.	
Conclusion	Further information is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		

Document IIIA **SECTION 7.2.2.1** **BPD Data Set IIIA/ Annex Point VII.4, XII.1.1, XII.1.4**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**
Conclusion **Remarks**	

Document IIIA SECTION 7.2.2.2 BPD Data Set IIIA/ Annex Point XII.1.1	Field soil dissipation and accumulation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Refer to 7.2.1 for detailed justification. A detailed justification for the non-submission of further aerobic soil studies has been presented within section 7.2.1 based upon the negligible exposure to the terrestrial compartment (PECsoil of 6.8 x 10^{-11} mg/kg) and the fate of transfluthrin being confidently predicted by the fate documented for other pyrethroids of comparative structure and function. It is predicted that under normal agricultural practice, transfluthrin will not persist or accumulation in the terrestrial compartment. Therefore the need to conduct further soil dissipation and accumulation studies is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	The statement that the fate of transfluthrin can be confidently predicted from that of other pyrethroids is not agreed upon (see Doc III 7.2.1). However, for the proposed uses of transfluthrin, direct emission to soil is considered negligible. Since no risks for the terrestrial compartment are identified as a result of indirect emissions, it is not considered necessary to perform additional studies.	
Conclusion	Further information is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		

Document IIIA	Field soil dissipation and accumulation
SECTION 7.2.2.2 **BPD Data Set IIIA/ Annex Point XII.1.1**	
Remarks	

Document IIIA **SECTION 7.2.2.3** **BPD Data Set IIIA/ Annex Point XII.1.4**	**Extent and nature of bound residues**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Refer to 7.2.1 for detailed justification. A detailed justification for the non-submission of further aerobic soil studies (including those to examine the extent and nature of bound residues) has been presented within section 7.2.1 based upon the negligible exposure to the terrestrial compartment (PEC soil of 6.8 x 10^{-11} mg/kg) and the fate of transfluthrin being confidently predicted by the fate documented for other pyrethroids of comparative structure and function. As the predicted concentration of transfluthrin in soil is negligible, the extent of any bound residue will also be negligible. Therefore the need to conduct studies to examine the extent and nature of bound residues in soil is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	The statement that the fate of transfluthrin can be confidently predicted from that of other pyrethroids is not agreed upon (see Doc III 7.2.1). However, for the proposed uses of transfluthrin, direct emission to soil is considered negligible. Since no risks for the terrestrial compartment are identified as a result of indirect emissions, it is not considered necessary to perform additional studies.	
Conclusion	Further information is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		

Document IIIA	Extent and nature of bound residues
SECTION 7.2.2.3 **BPD Data Set IIIA/ Annex Point XII.1.4**	
Conclusion **Remarks**	

Document IIIA **SECTION 7.2.2.4** **BPD Data Set IIIA/ Annex Point XII.1.1**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Refer to 7.2.1 for detailed justification. A detailed justification for the non-submission of further aerobic soil degradation studies has been presented within section 7.2.1 based upon the negligible exposure to the terrestrial compartment (PECsoil of 6.8 x 10^{-11} mg/kg) and the fate of transfluthrin being confidently predicted by the fate documented for other pyrethroids of comparative structure and function. Therefore the need to conduct further aerobic soil studies is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	The statement that the fate of transfluthrin can be confidently predicted from that of other pyrethroids is not agreed upon (see Doc III 7.2.1). However, for the proposed uses of transfluthrin, direct emission to soil is considered negligible. Since no risks for the terrestrial compartment are identified as a result of indirect emissions, it is not considered necessary to perform additional studies.	
Conclusion	Further information is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		

Document IIIA **SECTION 7.2.2.4** **BPD Data Set IIIA/ Annex Point XII.1.1**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**
Remarks	

Document IIIA **SECTION 7.2.3 (INCLUDING 7.2.3.1 AND 7.2.3.2)** **BPD Data Set IIIA/ Annex Point XII.12-1.3**	**Adsorption and mobility in soil, further studies** **Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products.** **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	An adsorption/desorption study of adequate quality has been presented in Section 7.1.3. The Koc of 50119 - 79433 indicates that transfluthrin will be immobile and would not leach through the soil profile to contaminate groundwater. The outdoor coil amateur indoor use of transfluthrin (from use of Baygon Coils), with subsequent deposition and transference of residues to soil, predicts worst case PECsoil for the transfluthrin products of 6.8 x 10^{-11} mg/kg i.e. negligible concentrations in soil. The PEClocalsoil, porew (i.e. the amount of transfluthrin in the soil pore water) is also very low, 7.7 x 10^{-14} mg/l (7.7 x 10^{-11} µg/l). This is significantly less than the 0.1 µg/l considered to be an unacceptable level of groundwater contamination in the EU. If the transfluthrin reaching the soil through use of Baygon Coils was completely metabolised to its metabolites and these are further assumed not to absorb to the soil (i.e. Koc = 1), the PEClocalsoil, porew would be 5.02 x 10^{-11} mg/l. This negligible concentration in pore water is considerably less than the 0.1µg/l cut off value for groundwater contamination. Therefore based on the high Koc from the laboratory study and the negligible exposure of transfluthrin and its metabolites to the terrestrial compartment and porewater, it is considered to be scientifically unjustified to conduct further adsorption and mobility studies in soil.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	Because of the high log Kow, a sorption study according to OECD 106 is not considered technically feasible. The available information from the HPLC-study is considered sufficient for risk assessment.	

Document IIIA **SECTION 7.2.3 (INCLUDING 7.2.3.1 AND 7.2.3.2)** **BPD Data Set IIIA/ Annex Point XII.12-1.3**	**Adsorption and mobility in soil, further studies** **Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products.** **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**
Conclusion **Remarks**	Further information is not required.
Date **Evaluation of applicant's justification** **Conclusion** **Remarks**	**COMMENTS FROM OTHER MEMBER STATE** *(specify)*

Document. IIIA — Phototransformation in air (estimation method), including identification of breakdown products

SECTION A7.3.1

BPD Data set IIIA/ Annex Point VII.5

Official use only

	26 REFERENCE	
26.1	**Reference**	Hellpointer, E. (2005) Transfluthrin: Calculation of the chemical lifetime in the troposphere, Bayer CropScience AG, Research & Development, Monheim, Germany Bayer AG Report No. MEF-05/118 [BES study No.: MO-05-005448] Report date: 9 March 2005 Unpublished
26.2	**Data protection**	Yes
26.2.1	Data owner	Bayer CropScience
26.2.2	Companies with letters of access	
26.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I
	27 GUIDELINES AND QUALITY ASSURANCE	
27.1	**Guideline study**	Yes Guideline EC Directive 94/37/EC Guideline EC Directive 95/36/EC
27.2	**GLP**	Not applicable for the modelling report.
27.3	**Deviations**	None
	28 MATERIALS AND METHODS	
28.1	**Estimation procedure**	
28.1.1	Estimation method	Based on an estimation according to structure-activity relationship (SAR) methods developed by Dr. Roger Atkinson and co-workers, the half life time in air of transfluthrin was assessed by the Atmospheric Oxidation Program, AOPWIN (v1.91). The Atmospheric Oxidation Program for Microsoft Windows (AOPWIN version 1.9, US EPA) estimates the rate constant for the atmospheric, gas-phase reaction between photochemically produced hydroxyl radicals and organic chemicals. It also estimates the rate constant for the gas-phase reaction between ozone and olefinic/acetylenic compounds. The rate constants estimated by the program are then used to calculate atmospheric half-lives for organic compounds based upon average atmospheric concentrations of hydroxyl radicals and ozone.
28.2	**Test performance**	
28.2.1		The accuracy of the estimation methods used by the Atmospheric Oxidation Program has been examined by comparing a list of more than

Document. IIIA

SECTION A7.3.1

BPD Data set IIIA/ Annex Point VII.5

Phototransformation in air (estimation method), including identification of breakdown products

640 experimentally determined hydroxyl radical rate constants to the program's estimated rate constants. Over 90 percent of the estimated rate constants for the 647 different chemicals are within a factor of two of the experiment value (AOPWIN version 1.9, US EPA).

29 RESULTS

29.1 Calculations

29.1.1

Scenarios, half-lives and chemical lifetimes of transfluthrin in air, as estimated by AOPWIN (v1.91) are detailed in Table A7.3.1-01. the following is the output generated by AOPWIN:

SMILES : Fc1c(F)cc(F)c(F)c1COC(=O)C2C(C)(C)C2C=C(CL)CL
CHEM : Transfluthrin
MOL FOR: C15 H12 CL2 F4 O2
MOLWT:371.16

SUMMARY (AOP vl.91): HYDROXYL RADICALS

Hydrogen Abstraction = 1.9059 E-12 cm3/molecule-sec
Reaction with N, S and -OH = 0.0000 E-12 cm3/molecule-sec
Addition to Triple Bonds = 0.0000 E-12 cm3/molecule-sec
Addition to Olefinic Bonds = 3.8323 E-12 cm3/molecule-sec
**Addition to Aromatic Rings = 0.8661 E-12 cm3/molecule-sec
Addition to Fused Rings = 0.0000 E-12 cm3/molecule-sec

OVERALL OH Rate Constant = 6.6043 E-12 cm3/molecule-sec
HALF-LIFE = 2.429 Days = 58.304 Hrs (24-hr day; 0.5E6 OH/cm3)
HALF-LIFE = 1.620 Days = 19.435 Hrs (12-hr day; 1.5E6 OH/cm3)

** Designates Estimation(s) Using ASSUMED Value(s)

SUMMARY (AOP vl.91): OZONE REACTION

OVERALL OZONE Rate Constant = 0.023261 E-17 cm3/molecule-sec
HALF-LIFE = 49.268 Days (at 7E11 mol/cm3)

Experimental Database: NO Structure Matches

29.2 Degradation product(s)

Not determined by this theoretical estimation method. However this is a standard and widely accepted method.

Document. IIIA **Phototransformation in air (estimation method), including identification of breakdown products**

SECTION A7.3.1

BPD Data set IIIA/ Annex Point VII.5

30 APPLICANT'S SUMMARY AND CONCLUSION

30.1 Materials and methods

The Atmospheric Oxidation Program for Microsoft Windows (AOPWIN version 1.9, US EPA), based upon the structure-activity relationship (SAR) methods developed by Dr. Roger Atkinson and co-workers, was used to estimate the rate constant for the atmospheric, gas-phase reaction between transfluthrin and photochemically produced hydroxyl radicals and with ozone. The estimated rate constants are then used within the program to calculate the atmospheric half-lives based upon average atmospheric concentrations of hydroxyl radicals and ozone.

30.2 Results and discussion

The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals ranged between 19.4 hours (equivalent to 1.6 days, based upon typical OH radical concentration during daylight hours) and 58.3 hours (equivalent to 2.4 days, based upon typical OH radical concentration averaged over day and night times). It should be noted that the OH radicals are very reactive after being generated due to irradiation of certain atmospheric constituents by the sunlight. In reality, their concentration is 0 during the night. Therefore, the scenario with 1.5×10^6 radicals cm^{-3} during the daytime (and a corresponding concentration of 0 during the night) and a tropospheric half life of 1.6 days for transfluthrin is the more realistic estimation. This scenario is also favoured by the US Environment Protection Agency mentioned in the legend of AOPWIN.

Ozone reactions can also contribute to the disappearance of transfluthrin in the troposphere, but at a minor extent, only ($t_{½}$ = 49 days at 7×10^{11} mol ozone cm^{-3}). Results are summarised in Table 7.3.1-01.

Transfluthrin may be expected to be highly susceptible for reactions with hydroxyl radicals, which will contribute significantly to the overall degradation of the substance in the atmosphere. Various moieties of the molecule were identified as possible targets for radical reactions. Attack by hydroxyl radicals should result in the formation of multiple primary radicals. These may lead to secondary oxidation products, which can be eliminated from the air by wet and/or dry deposition. The degradation by ozone is possible, but to a minor extent. Reactions with other reactive species and direct gasphase or liquid-phase photolysis are not considered in the employed model calculation, but will also contribute to the overall atmospheric elimination of transfluthrin.

30.3 Conclusion

From the short half-life time in air, it is to be expected that transfluthrin cannot be transported in gaseous phase over large distances and cannot accumulate in the atmosphere.

30.3.1 Reliability 1

30.3.2 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	23-03-2007
Materials and Methods	Applicant's version adequately reflects the report.
Results and discussion	Applicant's version is adopted
Conclusion	Applicant's version is adopted. Half-life = 2.429 days (24-hr day; 0.5E6 OH/cm3); Half-life = 1.620 days (12-hr day; 1.5E6 OH/cm3)]. The atmospheric half-life of 2.4 days (calculated conform TGD) will be used for risk assessment.
Reliability	1
Acceptability	Acceptable
Remarks	
	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 7.3.1-01: Scenarios, half-lives and chemical lifetimes of transfluthrin in air, as estimated by AOPWIN (v1.9.1.)

Scenario of OH concentration used		**Long term**	**Short term**
Time frame	[hours/day]	24	12
OH concentration	[radicals/cm^3]	0.5 x 10^6	1.5 x 10^6
OH rate constant	[cm^3 x $molecule^{-1}$ x s^{-1}]	6.6043 x 10^{-12}	
Half life (t½) due to reaction with OH	[hours]	58.3	19.4
	[days]	2.4	1.6
Chemical lifetime (τ) due to reaction with OH	[hours]	84.1	28.0
	[days]	3.5	2.3
Ozone concentration	[mol cm^{-3}]	7 x 10^{11}	
Ozone rate constant	[cm^3 x $molecule^{-1}$ x s^{-1}]	0.023261 x 10^{-17}	
Half life (t½) due to reaction with ozone	[days]	49	

Document IIIA **SECTION 7.3.2** **BPD Data Set IIIA/ Annex Point XII.3**	**Fate and behaviour in air, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals ranged between 19.4 hours (equivalent to 1.6 days, based upon typical OH radical concentration during daylight hours) and 58.3 hours (equivalent to 2.4 days, based upon typical OH radical concentration averaged over day and night times) (see Document IIIA, section 7.3.1). It should be noted that the OH radicals are very reactive after being generated due to irradiation of certain atmospheric constituents by the sunlight. In reality, their concentration is 0 during the night. Therefore, the scenario with 1.5 x 10^6 radicals cm^{-3} during the daytime (and a corresponding concentration of 0 during the night) and a tropospheric half life of 1.6 days for transfluthrin is the more realistic estimation. This scenario is also favoured by the US Environment Protection Agency mentioned in the legend of AOPWIN. The representative uses of transfluthrin products (Raid Portable Electric, Baygon Mosquito coil and Turbo 4 Seasons) result in negligible predicted local concentration in air (100m from source) of < 1.31 x 10^{-10} mg/m^3. Due to the fact that the products are not classified as fumigants and the fact that use results in relatively limited exposure to the atmospheric compartment and negligible concentrations in air, the need to conduct studies on the fate and behaviour in air is considered to be scientifically unjustified.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	Under the proposed conditions of use, transfluthrin will be emitted to air. According to the ESD, the concentration in air upon outdoor use will be not relevant because of instant dilution. This also applies to indoor use.	
Conclusion	Further information is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Document IIIA	Fate and behaviour in air, further studies
SECTION 7.3.2 **BPD Data Set IIIA/ Annex Point XII.3**	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Document IIIA — Acute toxicity to fish

Rainbow trout (*Salmo gairdneri*)

SECTION A7.4.1.1/01

BPD Data Set IIA / Annex Point VII.7.1

			Official use only
		31 REFERENCE	
31.1	**Reference**	[redacted] Acute Toxicity of NAK 4455 to Rainbow trout (*Salmo gairdneri*) in a flow-through test, [redacted] [redacted]Report No.: FF-220, [BES Ref: MO-03-010110] Report date: June 10, 1988 Unpublished	
31.2	**Data protection**	Yes	
31.2.1	Data owner	Bayer CropScience	
31.2.2	Companies with letters of access		
31.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		32 GUIDELINES AND QUALITY ASSURANCE	
32.1	**Guideline study**	Yes "EEC Directive 79/831, Annex V, Methods for Determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish" (published in Amtsblatt der Europaischen Gemeinschaften, Dated 19.09.1984) OECD "Guideline for Testing of Chemicals, No. 203, Fish, Acute Toxicity Test".	
32.2	**GLP**	Yes	
32.3	**Deviations**	None	
		33 MATERIALS AND METHODS	
33.1	**Test material**	NAK 4455 technical (transfluthrin)	
33.1.1	Lot/Batch number	Mixed pt. 250987	
33.1.2	Specification	As given in section 2	X
33.1.3	Purity	94.5%	X
33.1.4	Composition of Product	Not applicable	
33.1.5	Further relevant properties	Brown solid material	
33.1.6	Method of analysis	Not stated	
33.2	**Preparation of TS solution for poorly**	See table A7_4_1_1(01)-1	

	soluble or volatile test substances	
33.3	**Reference substance**	No
33.3.1	Method of analysis for reference substance	N/A
33.4	**Testing procedure**	
33.4.1	Dilution water	See table A7_4_1_1(01)-2
33.4.2	Test organisms	See table A7_4_1_1(01)-3
33.4.3	Test system	See table A7_4_1_1(01)-4
33.4.4	Test conditions	See table A7_4_1_1(01)-5
33.4.5	Duration of the test	96-hour
33.4.6	Test parameter	Mortality
33.4.7	Sampling	Fish were observed twice on the first day of exposure and daily thereafter (at 24, 48, 72 and 96 hours) for mortalities and signs of intoxication. Dissolved oxygen and pH were determined daily, temperature was measured hourly. Water hardness was determined at the beginning and at the end of the test.
33.4.8	Monitoring of TS concentration	Yes, Analytical measurements of the active ingredient were done at 0, 24, 48 and 96 hours. Concentrations of 1.58 and 2.81 µg a.i./l were analysed at 0 and 24 hours.
33.4.9	Statistics	The LC_{50} values with 95%-confidence intervals were calculated by the method of THOMPSON and WEIL (On the Construction of Tables for Moving Average Interpolation, Biometrics, Vol. 8, pp. 51 - 54, 1952) for each 24-hour period if possible. Where the data were inadequate to use statistical methods (0 and 100 % mortality in two adjacent concentrations spaced by a factor of less than 1.8) the LC_{50} is given as the geometric mean of the two concentrations and the range between the two respective concentrations is given as 95%-confidence interval.
		34 RESULTS
34.1	**Limit Test**	Not performed
34.1.1	Concentration	N/A
34.1.2	Number/	N/A

	percentage of animals showing adverse effects		
34.1.3	Nature of adverse effects	N/A	
34.2	**Results test substance**		
34.2.1	Initial concentrations of test substance	The concentrations tested were: 0.16, 0.28, 0.50, 0.89, 1.58 and 2.81 µg a.i./l (nominal) plus control and solvent control (acetone 0.1 ml/1).	X
34.2.2	Actual concentrations of test substance	Analytical results showed that test concentrations were maintained at >80% of the nominal values. Only in the highest concentration the initial measured concentration was 75% of the nominal value but the geometric mean over 24h was above 80% nominal.	

Sample timepoints (hours)	Nominal concentrations (µg a.i./l)					
	0.16	0.28	0.50	0.89	1.58	2.81
	Measured concentrations (µg a.i./l)					
0	0.13	0.25	0.52	0.79	1.35	2.12
24	0.14	0.27	0.50	0.84	1.50	2.40
48	0.13	0.29	0.52	0.95	-	-
96	0.13	0.29	0.53	0.90	-	-

The analytical results indicated that the active ingredient was stable in the stock solutions.

34.2.3	Effect data (Mortality)	See tables A7_4_1_1(01)-6 and A7_4_1_1(01)-7.	
34.2.4	Concentration / response curve	Not reported.	
34.2.5	Other effects	Symptoms of intoxication such as swimming on side and/or inverted and staggering were noted in fish at dose levels of 0.89 and 2.81 µg a.i./l.	
34.3	**Results of controls**		
34.3.1	Number/ percentage of animals showing adverse effects		

Nominal Conc. (µg a.i./l)	% mortality				
	4hrs	24hrs	48hrs	72hrs	96hrs
Control	0	0	0	0	0
Solvent control	0	0	0	0	0

Document IIIA

SECTION A7.4.1.1/01

BPD Data Set IIA / Annex Point VII.7.1

Acute toxicity to fish

Rainbow trout (*Salmo gairdneri*)

34.3.2	Nature of adverse effects	N/A
34.4	**Test with reference substance**	Not performed
34.4.1	Concentrations	N/A
34.4.2	Results	N/A

35 APPLICANT'S SUMMARY AND CONCLUSION

35.1 Materials and methods

The study was conducted according to "EEC Directive 79/831, Annex V, Methods for Determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish" (published in Amtsblatt der Europaischen Gemeinschaften, Dated 19.09.1984) and OECD "Guideline for Testing of Chemicals, No. 203, Fish, Acute Toxicity Test". Validity criteria were fulfilled and no deviations were noted. Dates of experimental work: 21/03/1987 to 25/03/1987.

Rainbow trout were exposed under flow-through conditions for 96 hours to NAK 4455 technical at nominal concentrations tested of 0.16, 0.28, 0.50, 0.89, 1.58 and 2.81 µg a.i./l. Control and solvent controls (acetone 0.1 ml/1) were also included in the study.

Fish were observed twice on the first day of exposure and daily thereafter (at 24, 28, 72 and 96 hours) for mortalities and signs of intoxication. Dissolved oxygen and pH were determined daily, temperature was measured hourly. Water hardness was determined at the beginning and at the end of the test.

Analytical measurements of the active ingredient were done at 0, 24, 48 and 96 hours in the concentrations 0.16, 0.28, 0.50 and 0.89 µg a.i./1. The concentrations 1.58 and 2.81 µg a.i./l were analysed at 0 and 24 hours.

Water flow and dosing system were controlled twice daily and water flow was adjusted if necessary.

35.2 Results and discussion

Analytical results showed that test concentrations were maintained at >80% of the nominal values. In the highest test concentration, the mean value over 24 h was greater 80% of the nominal concentration with slightly lower values at start of the test. Hence, results refer to nominal values.

Mortalities in the control, solvent control, 0.16, 0.28 and 0.50 µg a.i./l concentrations were 0%, respectively. 90% mortality was observed at 0.89 µg a.i./l and 100% mortality was observed at 1.58 and 2.81 µg a.i./l. Symptoms of intoxication such as swimming on side and/or inverted and staggering were noted in fish at dose levels of 0.89 and 2.81 µg a.i./l.

Water quality and environmental parameters were within acceptable limits.

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Rainbow trout (*Salmo gairdneri*)

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35.2.1	LC_0	Not determined, (NOEC 0.5 µg ai/L)
35.2.2	LC_{50}	96 hour value - 0.7 µg a.i./l (95 % confidence intervals 0.62-0.79)
35.2.3	LC_{100}	Not calculated, 100 % observed at 1.58 µg ai/L
35.3	**Conclusion**	The 96-hour LC_{50} of the test substance was calculated to be 0.7 µg a.i./l with a 95%-confidence interval from 0.62 to 0.79 µg a.i./l. The lowest observed effect concentration (LOEC) was 0.89 µg a.i./l. The no-observed effect concentration (NOEC) was 0.50 µg a.i./l. See also validity criteria summarized in table A7_4_1_1(01)-8.
35.3.1	Other Conclusions	The LC_{50} did not decrease significantly with time, the LC50 value after 24 h in flow through was 0.88 µg/L.
35.3.2	Reliability	1
35.3.3	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version is adopted
Results and discussion	Applicant's version is adopted with the following addition: 3.1.2/3.1.3 Batch differs from those included in the batch analysis (Doc III A.2 confidential). Purity of test substance is low (94.5%), but analytical verification shows acceptable recovery.
Conclusion	Applicant's version is adopted The result 96-hours LC_{50} 0.7 µg as/L is used for risk assessment.
Reliability	1
Acceptability	acceptable
Remarks	
	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*

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Rainbow trout (*Salmo gairdneri*)

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Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_4_1_1(01)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes
Vehicle	Yes, solvent (acetone) (Stock solution at concentrations of 1.6, 2.8, 5.0, 8.9, 15.8 and 28.1 mg NAK 4455 techn./l. acetone were prepared).
Concentration of vehicle	100 µl acetone/l water in test aquarium
Vehicle control performed	Yes, acetone control
Other procedures	All stock preparations were mixed by a magnetic stirrer during the test.

Table A7_4_1_1(01)-2: Dilution water

Criteria	Details
Source	Reconstituted water aerated to saturation with the following ionic concentrations was used: Ca^{++} : 0.384 mMol/1 Mg^{++} : 0.096 mMol/1 Na^{+} : 0.148 mMol/1 K^{+} : 0.015 mMol/1 Cl^{-} : 0.783 mMol/1 $HC0_3^{-}$: 0.148 mMol/1 SO^{--} : 0.096 mMol/1 The test water was analysed in intervals of ca. 6 months for unwanted contaminants and checked for its suitability by breeding of Daphnia, known to be very sensitive to pollutants.
Alkalinity	Not stated
Hardness	48 (40 - 60) mg $CaC0_3$/l
pH	7.5 to 8.0
Oxygen content	10.6 to 12.7 mg/1
Conductance	Not stated.
Holding water different from dilution water	No

Table A7_4_1_1(01)-3: Test organisms

Criteria	Details
Species/strain	Rainbow Trout (*Salmo gairdneri*)
Source	[redacted]
Wild caught	No
Age/size	Mean body weight at the beginning of the test was 1.2 ± 0.4 (SD) g, mean body length was 4.8 ± 0.4 (SD) cm.
Kind of food	Commercial trout diet
Amount of food	Not stated
Feeding frequency	Not stated
Pretreatment	Fish were acclimated to the test water and temperature for at least 14 days
Feeding of animals during test	No, fish were not fed 48 hours before and during the study.

Table A7_4_1_1(01)-4: Test system

Criteria	Details
Test type	Flow-through
Renewal of test solution	Water flow was controlled by a flow meter at a rate of 25 ± 1 1/h. Stock preparations were dosed by HAMILTON Microlab MT dispensers controlled by an EPSON HX-20 computer at a rate of 50 ul/cycle and 72 sec/cycle (ca. 0.1 ml stock preparation/1 water).
Volume of test vessels	100-L-aquaria
Volume/animal	10 fishes per dose level equals 10 L/fish
Number of animals/vessel	10
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	Not stated

Table A7_4_1_1(01)-5: Test conditions

Criteria	**Details**
Test temperature	Temperature was measured hourly and maintained to 12 ºC throughout test.
Dissolved oxygen	

Nominal conc. (µg a.i./l)	Timepoint (hrs)				
	0	24	48	72	96
Control	12.7	12.4	12.0	11.8	10.6
Solvent control	12.5	12.3	11.9	12.0	10.9
0.16	12.3	12.0	11.6	11.6	10.8
0.28	12.3	11.9	11.7	11.6	10.9
0.50	12.3	11.9	11.7	11.6	11.1
0.89	12.3	11.9	11.7	11.8	11.2
1.58	12.3	11.9	-	-	-
2.81	12.2	11.8	-	-	-

pH	

Nominal conc. (µg a.i./l)	Timepoint (hrs)				
	0	24	48	72	96
Control	8.0	7.6	7.5	7.5	7.6
Solvent control	8.0	7.6	7.5	7.5	7.6
0.16	8.0	7.6	7.5	7.6	7.6
0.28	8.0	7.6	7.5	7.6	7.7
0.50	8.0	7.6	7.5	7.6	7.7
0.89	8.0	7.6	7.5	7.6	7.7
1.58	8.0	7.6	-	-	-
2.81	8.0	7.6	-	-	-

Adjustment of pH	No
Aeration of dilution water	Not stated, although oxygen content recorded
Intensity of irradiation	Not stated
Photoperiod	16 hours light / 8 hours dark

Table A7_4_1_1(01)-6: Mortality data

Test-Substance Concentration	**Mortality and Intoxication**

(nominal)[1] [µg a i./l]	Number (dead/affected)[2]				Percentage Mortality			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
Control	0/0	0/0	0/0	0/0	0	0	0	0
Solvent control	0/0	0/0	0/0	0/0	0	0	0	0
0.16	0/0	0/0	0/0	0/0	0	0	0	0
0.28	0/0	0/0	0/0	0/0	0	0	0	0
0.50	0/0	0/0	0/0	0/0	0	0	0	0
0.89	5/10	9/10	9/10	9/10	50	90	90	90
1.58	10/10	10/10	10/10	10/10	100	100	100	100
2.81	10/10	10/10	10/10	10/10	100	100	100	100
Temperature [°C]	12							
***pH**	7.6	7.5	7.6	7.7				
***Oxygen [mg/l]**	12.0	11.8	11.7	10.9				

[1] TS concentrations were nominal

[2] Number exposed 10

* mean values

Table A7_4_1_1(01)-7: Effect data

Time	LC 50 [µg/L]	95 % c l.
24 h	0.88	0.73-1.07
48 h	0.7	0.62-0.79
96 h	0.7	0.62-0.79
	0.7	0.62-0.79

[1] effect data are based on nominal (n) concentrations

Table A7_4_1_1(01)-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	
Concentration of dissolved oxygen in all test vessels > 60% saturation	**yes**	
Concentration of test substance ≥80% of initial concentration during test	**yes**	

Criteria for poorly soluble test substances	**yes**	

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Golden Orfe (*Leuciscus idus melanotus*)

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Official use only

36 REFERENCE

36.1	**Reference**	[redacted] Acute Toxicity of NAK 4455 to Golden Orfe (*Leuciscus idus melanotus*) in a flow-through test [redacted] [redacted] Report No.: F0-1108, MO-03-010113 Report date: June 10, 1988 Unpublished
36.2	**Data protection**	Yes
36.2.1	Data owner	Bayer CropScience
36.2.2	Companies with letters of access	
36.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I

37 GUIDELINES AND QUALITY ASSURANCE

37.1	**Guideline study**	Yes "EEC Directive 79/831, Annex V, Methods for Determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish" (published in Amtsblatt der Europäischen Gemeinschaften, Dated 19.09.1984) OECD "Guideline for Testing of Chemicals, No. 203, Fish, Acute Toxicity Test".
37.2	**GLP**	Yes
37.3	**Deviations**	Yes In the lowest test concentration (0.50 µg a.i/l) only 58 to 74 % of the nominal concentration was found following analysis. Although the concentration of the test substance is <80% of nominal it is considered that there is no influence on the validity of the study, because in the next highest concentration (0.89 µg a.i./l) no effects were observed and mean measured concentrations were >80%.

38 MATERIALS AND METHODS

38.1	**Test material**	NAK 4455 technical (transfluthrin)
38.1.1	Lot/Batch number	Mixed pt. 250987
38.1.2	Specification	Identified by Batch Number As given in section 2
38.1.3	Purity	94.5%
38.1.4	Composition of	Not applicable

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	Product	
38.1.5	Further relevant properties	Brown solid material
38.1.6	Method of analysis	Test concentrations were determined by gas chromatography.
38.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_1(02)-1
38.3	**Reference substance**	No
38.3.1	Method of analysis for reference substance	N/A
38.4	**Testing procedure**	
38.4.1	Dilution water	See table A7_4_1_1(02)-2
38.4.2	Test organisms	See table A7_4_1_1(02)-3
38.4.3	Test system	See table A7_4_1_1(02)-4
38.4.4	Test conditions	See table A7_4_1_1(02)-5
38.4.5	Duration of the test	96-hour
38.4.6	Test parameter	Mortality
38.4.7	Sampling	Fish were observed twice on the first day of exposure and daily thereafter (at 24, 48, 72 and 96 hours) for mortalities and signs of intoxication. Dissolved oxygen and pH were determined daily, temperature was measured hourly. Water hardness was determined at the beginning and at the end of the test.
38.4.8	Monitoring of TS concentration	Yes, Analytical measurements of the active ingredient were done at 0, 24, 48 and 96 hours at concentrations of 0.50, 0.89 and 2.81 µg a.i./l. Concentrations of 1.58 and 5.00 µg a.i./l were only analysed at 0 and 24 hours.
38.4.9	Statistics	The LC_{50} values with 95%-confidence intervals were calculated by the method of THOMPSON and WEIL (On the Construction of Tables for Moving Average Interpolation, Biometrics, Vol. 8, pp. 51 - 54, 1952) for each 24-hour period if possible. Where the data were inadequate to use statistical methods (0 and 100 % mortality in two adjacent concentrations spaced by a factor of less than 1.8) the LC_{50} is given as the geometric mean of the two concentrations and the range between the two respective concentrations is given as 95 %-confidence interval.

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39 RESULTS

39.1	**Limit Test**	Not performed
39.1.1	Concentration	N/A
39.1.2	Number/ percentage of animals showing adverse effects	N/A
39.1.3	Nature of adverse effects	N/A
39.2	**Results test substance**	
39.2.1	Initial concentrations of test substance	The concentrations tested were: 0.50, 0.89, 1.58, 2.81 and 5.00 µg a.i./l (nominal) plus control and solvent control (acetone 0.1 ml/1).
39.2.2	Actual concentrations of test substance	Analytical results showed that test concentrations of 0.89, 1.58 and 2.81 µg a.i./l were maintained at a mean level of >80% of the nominal values. In the highest concentration (5.00 µg a.i./l) the initial measured concentration was slightly below 80% of the nominal value. In the lowest concentration only 58-74% of the nominal concentration was recovered by analysis. It is considered that this had no influence on the study validity as at the next highest concentration 0.89 µg a.i./l no effects were observed. X

Sample timepoints (hours)	Nominal concentrations (µg a.i./l)				
	0.50	0.89	1.58	2.81	5.00
	Measured concentrations (µg a.i./l)				
0	0.34	0.73	1.40	2.38	3.15
24	0.35	0.65	1.54	2.48	4.26
48	0.29	0.75	-	2.55	-
96	0.37	0.76	-	2.50	-

39.2.3	Effect data (Mortality)	See tables A7_4_1_1(02)-6 and A7_4_1_1(02)-7.
39.2.4	Concentration / response curve	Not reported.
39.2.5	Other effects	Symptoms of intoxication such as swimming on side and/or inverted,

red marks on the skin and swimming behaviour slightly irregular (only at 1.58 µg a.i/l) were noted in fish at dose levels of 1.58, 2.81 and 5.00 µg a.i./l.

39.3 Results of controls

39.3.1 Number/ percentage of animals showing adverse effects

Test system	% mortality				
	4hrs	24hrs	48hrs	72hrs	96hrs
Control	0	0	0	0	0
Solvent control	0	0	0	0	0

39.3.2 Nature of adverse effects: N/A

39.4 Test with reference substance: Not performed

39.4.1 Concentrations: N/A

39.4.2 Results: N/A

40 APPLICANT'S SUMMARY AND CONCLUSION

40.1 Materials and methods

The study was conducted according to "EEC Directive 79/831, Annex V, Methods for Determination of Ecotoxicity, Method 5.1.1. Acute Toxicity for Fish" (published in Amtsblatt der Europaischen Gemeinschaften, Dated 19.09.1984) and OECD "Guideline for Testing of Chemicals, No. 203, Fish, Acute Toxicity Test". Validity criteria were fulfilled and minor deviations were noted. Dates of experimental work: 21/03/1988 to 25/03/1988.

Golden orfe were exposed under flow-through conditions for 96 hours to NAK 4455 technical at nominal concentrations tested of 0.50, 0.89, 1.58, 2.81and 5.00 µg a.i./l. Control and solvent controls (acetone 0.1 ml/1) were also included in the study. Analytical measurements of the active ingredient were done at 0, 24, 48 and 96 hours in the concentrations 0.50, 0.89 and 2.81µg/1. The concentrations 1.58 and 5.00 µg/1 were only analysed at 0 and 24 hours. Analytical results showed that test concentrations of 0.89, 1.58 and 2.81 µg a.i./l were maintained at a mean level of >80% of the nominal values. In the highest concentration (5.00 µg a.i./l) the initial measured concentration was slightly below 80 % of the nominal value. In the lowest concentration only 58-74% of the nominal concentration was recovered by analysis. It is considered that this had no influence on the study validity as at the next highest concentration 0.89 µg a.i./l no effects were observed. Hence, results of the study are reported as nominal concentrations.

Fish were observed twice on the first day of exposure and daily

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		thereafter (at 24, 28, 72 and 96 hours) for mortalities and signs of intoxication. Dissolved oxygen and pH were determined daily, temperature was measured hourly. Water hardness was determined at the beginning and at the end of the test. Water flow and dosing system were controlled twice daily and water flow was adjusted if necessary.
40.2	**Results and discussion**	Mortalities in the control, solvent control, 0.50 and 0.89 µg a.i./l concentrations were 0%, respectively. 90% mortality was observed at 2.81 µg a.i./l and 100% mortality was observed at 1.58 and 5.00 µg a.i./l. Symptoms of intoxication such as swimming on side and/or inverted, red marks on the skin and swimming behaviour slightly irregular (only at 1.58 µg a.i./l) were noted in fish at dose levels of 1.58, 2.81 and 5.00 µg a.i./l. Water quality and environmental parameters were within acceptable limits.
40.2.1	LC_0	Not determined.
40.2.2	LC_{50}	96 hour value -1.25 µg a.i./l (95 %-confidence intervals 1.1-1.4)
40.2.3	LC_{100}	Not determined.
40.3	**Conclusion**	The 96-hour LC_{50} based upon nominal concentrations of the test substance was calculated to be 1.25 µg a.i./l with a 95 %-confidence interval from 1.1 to 1.4 µg a.i./l. The lowest observed effect concentration (LOEC) was 1.58 µg a.i./l. The no-observed effect concentration (NOEC) was 0.89 µg a.i./l. See also validity criteria summarized in table A7_4_1_1(02)-8.
40.3.1	Other Conclusions	Mortality did not increase from 24h to 96 hours, the LC50 at 24 h equals that of 96h
40.3.2	Reliability	1
40.3.3	Deficiencies	Minor. The test organism used is not a standard fish species suggested acc. to OECD 203 but the presented result gives a valid endpoint for an additional fish species.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version is adopted with the following addition: 3.1.2/3.1.3 Batch differs from those included in the batch analysis (Doc III A.2 confidential). Purity of test substance is low (94.5%), but analytical verification shows acceptable recovery.

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Results and discussion	Applicant's version is adopted with the following addition: 4.2.2: recovery at the lowest and highest concentration is < 80%, but since at the level of the LC50 recovery was acceptable, expression on the basis of nominal concentrations is accepted.
Conclusion	Applicant's version is adopted The result 96-hours LC_{50} 1.25 µg as/L is used for risk assessment.
Reliability	1
Acceptability	acceptable
Remarks	

	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_4_1_1(02) -1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes
Vehicle	Yes, solvent (acetone) (Stock solution at concentrations of 5.0, 8.9, 15.8, 28.1 and 50 mg NAK 4455 techn./l. acetone were prepared).
Concentration of vehicle	see above, dose to 100 µl acetone/l aquarium water
Vehicle control performed	Yes, acetone control
Other procedures	All stock preparations were mixed by a magnetic stirrer during the test.

Table A7_4_1_1(02) -2: Dilution water

Criteria	Details
Source	Reconstituted water aerated to saturation with the following ionic concentrations was used: Ca^{++}: 0.384 mMol/1 Mg^{++}: 0.096 mMol/1 Na^{+} : 0.148 mMol/1 K^{+} : 0.015 mMol/1 Cl^{-} : 0.783 mMol/1 $HC0_3^{-}$: 0.148 mMol/1 SO_4^{--} : 0.096 mMol/1 The test water was analysed in intervals of ca. 6 months for unwanted contaminants and checked for its suitability by breeding Daphnia as a very sensitive species for pollutants.
Alkalinity	Not stated
Hardness	48 -50 mg $CaC0_3$/l
pH	7.4 to 8.1
Oxygen content	9.1 to 11.5 mg/1
Conductance	Not stated
Holding water different from dilution water	No

Table A7_4_1_1(02) -3: Test organisms

Criteria	Details
Species/strain	Golden orfe (*Leuciscus idus melanotus*)
Source	[redacted]
Wild caught	No
Age/size	Mean body weight at the beginning of the test was 3.5 ± 0.5 (SD) g, mean body length was 7.2 ± 0.3 (SD) cm.
Kind of food	Commercial trout diet
Amount of food	Not stated
Feeding frequency	Not stated
Pretreatment	Fish were acclimated to the test water and temperature for at least 14 days
Feeding of animals during test	No, fish were not fed 48 hours before and during the study.

Table A7_4_1_1(02) -4: Test system

Criteria	Details
Test type	Flow-through
Renewal of test solution	Water flow was controlled by a flow meter at a rate of 25 ± 1 1/h. Stock preparations were dosed by HAMILTON Microlab MT dispensers controlled by an EPSON HX-20 computer at a rate of 50 µl/cycle and 72 sec/cycle (ca. 0.1 ml stock preparation/1 water).
Volume of test vessels	100-L-aquaria
Volume/animal	10 fishes per 100 L aquarium refers to 10L/fish
Number of animals/vessel	10
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	Not stated

Table A7_4_1_1(02) -5: Test conditions

Criteria	Details
Test temperature	19 - 20 ºC

Dissolved oxygen	

Nominal conc. (µg a.i./l)	Timepoint (hrs)				
	0	24	48	72	96
Control	11.0	10.7	10.3	10.3	9.2
Solvent control	11.0	10.6	10.2	10.2	9.1
0.50	11.1	10.6	10.3	10.2	9.1
0.89	11.1	10.6	10.3	10.2	9.2
1.58	11.5	10.8	-	-	-
2.81	11.4	11.0	10.6	10.6	9.9
5.00	11.3	11.0	-	-	-

pH	

Nominal conc. (µg a.i./l)	Timepoint (hrs)				
	0	24	48	72	96
Control	8.1	7.4	7.5	7.6	7.6
Solvent control	8.1	7.4	7.5	7.6	7.6
0.50	8.1	7.4	7.5	7.6	7.6
0.89	8.1	7.4	7.5	7.6	7.6
1.58	8.1	7.4	-	-	-
2.81	8.1	7.4	7.5	7.6	7.6
5.00	8.1	7.4	-	-	-

Adjustment of pH	No
Aeration of dilution water	Not stated, flow rate was 25 ± 1 L/h
Intensity of irradiation	Not stated
Photoperiod	16 hours light / 8 hours dark

Table A7_4_1_1(02) -6: Mortality data

Test-Substance Concentration (nominal)[1] [µg a i./l]	**Mortality and Symptoms of Intoxication**							
	Number (dead/affected)[2]				**Percentage mortality**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
Control	0/0	0/0	0/0	0/0	0	0	0	0

Solvent control	0/0	0/0	0/0	0/0	0	0	0	0
0.50	0/0	0/0	0/0	0/0	0	0	0	0
0.89	0/0	0/0	0/0	0/0	0	0	0	0
1.58	10/10	10/10	10/10	10/10	100	100	100	100
2.81	9/10	9/10	9/10	9/10	90	90	90	90
5.00	10/10	10/10	10/10	10/10	100	100	100	100
Temperature [°C]	19-20							
***pH**	7.4	7.5	7.6	7.6				
***Oxygen [mg/l]**	10.8	10.3	10.3	9.3				

[1] TS concentrations were nominal

[2] Number exposed 10, effects were swimming on side and/or inverted and, red marks on the skin at 24 h in the 2.81 µg/L dose

* mean values

Table A7_4_1_1(02) -7: Effect data

Time	LC_{50} [µg/l][1]	95 % c l.
24h	1.25	1.1-1.4
48h	1.25	1.1-1.4
96h	1.25	1.1-1.4

[1] effect data are based on nominal (n) concentrations

Table A7_4_1_1(02) -8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	
Concentration of dissolved oxygen in all test vessels > 60% saturation	**yes**	
Concentration of test substance ≥80% of initial concentration during test	**in part**	

Criteria for poorly soluble test substances	**yes**	

Document IIIA — Acute toxicity to fish (metabolite toxicity)

Rainbow trout (*Oncorhynchus mykiss*)

SECTION A7.4.1.1/03

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			Official use only
		41 REFERENCE	
41.1	**Reference**	[redacted] Acute toxicity of AE 1371427 to fish (*Oncorhynchus mykiss*) under static conditions (product code: AE 1371427 00 1B) [redacted] [redacted]Report No.: EBTBX003, M-258445-01-1 Report date: 06 October 2005 Unpublished	
41.2	**Data protection**	Yes	
41.2.1	Data owner	Bayer CropScience	
41.2.2			
41.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		42 GUIDELINES AND QUALITY ASSURANCE	
42.1	**Guideline study**	Yes EPA §72-1, Acute Toxicity Test for Freshwater Fish (Oct. 1982) / SEP-EPA-540/9-85-006 (June 1985). OPPTS Test Guideline 850.1075, Public Draft (April 1996), Fish Acute Toxicity Test, Freshwater and Marine. Commission Directive 92/69/EEC, C.1: Acute Toxicity for Fish, 1992. OECD Guideline for Testing of Chemicals, No. 203, Fish, Acute Toxicity Test, rev. 1992.	
42.2	**GLP**	Yes	
42.3	**Deviations**	None	
		43 MATERIALS AND METHODS	
43.1	**Test material**	AE 1371427 (metabolite of Transfluthrin)	X
43.1.1	Lot/Batch number	950627ELB01	
43.1.2	Specification	As given in section 2	
43.1.3	Purity	99.0%	
43.1.4	Composition of Product	N/A	
43.1.5	Further relevant properties	Appearance: white crystals Stability in water: 30 days	

Document IIIA **Acute toxicity to fish (metabolite toxicity)**

Rainbow trout (*Oncorhynchus mykiss*)

SECTION A7.4.1.1/03

BPD Data Set IIA / Annex Point VII.7.1

		log P_{ow}: 1.58
43.1.6	Method of analysis	Not stated
43.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_1(03)-1
43.3	**Reference substance**	No
43.3.1	Method of analysis for reference substance	N/A
43.4	**Testing procedure**	
43.4.1	Dilution water	See table A7_4_1_1(03)-2
43.4.2	Test organisms	See table A7_4_1_1(03)-3
43.4.3	Test system	See table A7_4_1_1(03)-4
43.4.4	Test conditions	See table A7_4_1_1(03)-5
43.4.5	Duration of the test	96-hour
43.4.6	Test parameter	Mortality
43.4.7	Sampling	During the test, fish were examined after four hours and then daily for mortalities and signs of poisoning. Dissolved oxygen, water temperature and pH values were determined daily in each aquarium, water temperature was additionally measured in the control aquarium and recorded hourly with a data logger.
43.4.8	Monitoring of TS concentration	Analytical determinations of the pure metabolite concentrations were made in the test medium at the beginning of the test, after 48h and at test termination. Immediately prior to the test, water samples were taken from the centre of the aquaria for analytical determination of the active ingredient concentration.
43.4.9	Statistics	The statistical evaluation of the data was not necessary as no symptoms of intoxication and no mortalities occurred at the highest dose tested (100 mg pure metabolite/l).

44 RESULTS

44.1	**Results test substance**	
44.1.1	Initial concentrations of test substance	Based on a range finder test, the definitive test concentration was set at 100 mg pure metabolite/l (nominal). The study was conducted as limit test.
44.1.2	Actual	Based on analytical determination of AE 1371427 (in water by HPLC-

concentrations of test substance

UV) measured values between 106% and 107% (mean 107%) of nominal were found.

Nominal concentration mg test item (pure metabolite)/l	Measured Concentration (mg pure metabolite/l)				Percent of nominal
	*day 0	*day 2	*day 4	Mean	
Control	< 0.515	< 0.515	< 0.515	-	-
101 (100)	107	107	106	107	107

* average of 2 detections

44.1.3 Effect data (Mortality)

No mortality occurred (0%), see tables A7_4_1_1(03)-6 and A7_4_1_1(03)-7.

44.1.4 Concentration / response curve

N/A

44.1.5 Other effects

None

44.2 Results of controls

44.2.1 Number/ percentage of animals showing adverse effects

Nominal Conc. (mg pure metabolite/l)	% mortality				
	4hrs	24hrs	48hrs	72hrs	96hrs
Control	0	0	0	0	0

44.2.2 Nature of adverse effects

N/A

44.3 Test with reference substance

Not performed

44.3.1 Concentrations

N/A

44.3.2 Results

N/A

45 APPLICANT'S SUMMARY AND CONCLUSION

45.1 Materials and methods

The study was conducted in accordance with: EPA §72-1, Acute Toxicity Test for Freshwater Fish (Oct. 1982) / SEP-EPA-540/9-85-006 (June 1985); OPPTS Test Guideline 850.1075, Public Draft (April 1996), Fish Acute Toxicity Test, Freshwater and Marine; Commission Directive 92/69/EEC, C.1: Acute Toxicity for Fish, 1992 and OECD Guideline for Testing of Chemicals, No. 203, Fish, Acute Toxicity Test, rev. 1992. Validity criteria were fulfilled and no deviations were noted. Dates of experimental work: 30/05/2005 – 23/08/2005.

Thirty rainbow trout were exposed to AE 1371427 (metabolite of transfluthrin) in a limit test for 96 hours under static test conditions at a nominal concentration of 100 mg test item (pure metabolite)/l. An

Document IIIA — Acute toxicity to fish (metabolite toxicity)

Rainbow trout (*Oncorhynchus mykiss*)

SECTION A7.4.1.1/03

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		untreated water control was also included in the study. During the test, fish were examined after four hours and then daily for mortalities and signs of poisoning. Dissolved oxygen, water temperature and pH values were determined daily in each aquarium, water temperature was additionally measured in the control aquarium and recorded hourly with a data logger. Analytical determinations of the pure metabolite concentrations were made in the test medium at the beginning of the test, after 48h and at test termination.
45.2	**Results and discussion**	No mortality or sub-lethal effects were observed in the control group or at the 100 mg pure metabolite/l test concentration. Analytical determination of AE 1371427 (in water by HPLC-UV) showed that the test concentration (100 mg pure metabolite/l) was maintained at >80% of the nominal value. Measured values ranged from 106% and 107% (mean 107%) of nominal. Test results are therefore based on nominal concentrations. Water quality and environmental parameters were within acceptable limits.
45.2.1	LC_{50}	> 100 mg pure metabolite/l (based on nominal)
45.2.2	NOEC	≥ 100 mg pure metabolite/l (based on nominal)
45.3	**Conclusion**	Based on nominal concentrations the 96h-LC_{50} of AE 1371427 to Rainbow trout (*Oncorhynchus mykiss*) under static test conditions was > 100 mg pure metabolite/l. See also validity criteria summarized in table A7_4_1_1(03)-8.
45.3.1	Other Conclusions	None
45.3.2	Reliability	1
45.3.3	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version is acceptable with the following addition: 3.1 AE 1371427 = NAK 4723 = 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH)
Results and discussion	Applicant's version is adopted
Conclusion	Applicant's version is adopted The result 96-hours LC_{50} > 100 mg/L is used for risk assessment

Document IIIA — Acute toxicity to fish (metabolite toxicity)

Rainbow trout (*Oncorhynchus mykiss*)

SECTION A7.4.1.1/03

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Reliability	1
Acceptability	acceptable
Remarks	

	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_4_1_1(03)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, the test media was prepared by weighing an adequate amount (4.04 g) of the test item into a 4 litre glass with test water and dissolving it by using a magnetic stirrer and an ultrasonic bath.
Vehicle	No
Concentration of vehicle	N/A
Vehicle control performed	N/A
Other procedures	None

Table A7_4_1_1(03)-2: Dilution water

Criteria	Details
Source	Reconstituted water was used for the test. It was prepared by adding salt stock solutions to demineralised water (conductivity < 0.2 µS/cm) to yield the following ionic concentrations (according to ISO): Ca^{++}: 0.384 mmole/L Mg^{++}: 0.096 mmole/L Na^{+} : 0.148 mmole/L K^{+}: 0.015 mmole/L Cl^{-}: 0.783 mmole/L $HCO3^{-}$: 0.148 mmole/L $SO4^{--}$: 0.096 mmole/L The water was then aerated to reach the oxygen saturation point. The test water was periodically analysed for undesired impurities. In addition, the suitability for aquatic tests was examined by breeding *Daphnia magna* in water from the same source.
Alkalinity	Not stated
Hardness	40 - 60 mg $CaCO_3$/L
pH	> 6.0 and < 8.0
Oxygen content	> 60% oxygen saturation
Conductance	<0.2 µS/cm
Holding water different from dilution water	No

Table A7_4_1_1(03)-3: Test organisms

Criteria	Details
Species/strain	Rainbow Trout (*Oncorhynchus mykiss*)
Source	[redacted]
Wild caught	No
Age/size	Mean body wet weight of the fish at the beginning of the test was 1.0 ± 0.3 g (Mean ± SD); mean body total length was 4.6 ± 0.5 cm (Mean ± SD).
Kind of food	Commercial trout food
Amount of food	Not stated
Feeding frequency	During the acclimation period fish were fed daily.
Pretreatment	All test fish were held in culture tanks on a 16/8 hour light/dark photoperiod and observed for at least 14 days prior to testing. In the 48-hour acclimation period prior to test initiation less than 5% mortality was noted and all unsuitable fish (e.g. injured, deformed, etc.) were eliminated from the test prior to the assignment of test groups.
Feeding of animals during test	Fish were not fed 48h before and during the study.

Table A7_4_1_1(03)-4: Test system

Criteria	Details
Test type	Static
Renewal of test solution	N/A
Volume of test vessels	40 litres (the aquaria were made of glass and had a size of 32 x 36 x 38 cm (l x d x h)).
Volume/animal	The biomass loading was 0.75 g fish /l test medium
Number of animals/vessel	30
Number of vessels/concentration	1
Test performed in closed vessels due to significant volatility of TS	Not stated

Table A7_4_1_1(03)-5: Test conditions

<table>
<tr><th>Criteria</th><th>Details</th></tr>
<tr><td>Test temperature</td><td>Temperature ranged from 11.7°C to 12.8°C.
<table>
<tr><td>Nominal conc. (mg pure metabolite/l</td><td>0 hrs</td><td>24 hrs</td><td>48 hrs</td><td>72 hrs</td><td>96 hrs</td></tr>
<tr><td>Control</td><td>12.0</td><td>11.8</td><td>11.7</td><td>11.8</td><td>11.8</td></tr>
<tr><td>100</td><td>12.8</td><td>11.9</td><td>11.7</td><td>11.8</td><td>11.7</td></tr>
</table></td></tr>
<tr><td>Dissolved oxygen</td><td>Dissolved oxygen concentrations ranged from 91 to 98% oxygen saturation.
<table>
<tr><td>Nominal conc. (mg pure metabolite/l</td><td>0 hrs</td><td>24 hrs</td><td>48 hrs</td><td>72 hrs</td><td>96 hrs</td></tr>
<tr><td>Control</td><td>96</td><td>91</td><td>93</td><td>92</td><td>93</td></tr>
<tr><td>100</td><td>98</td><td>94</td><td>91</td><td>93</td><td>93</td></tr>
</table></td></tr>
<tr><td>pH</td><td>pH values ranged from 6.9 to 7.4.
<table>
<tr><td>Nominal conc. (mg pure metabolite/l</td><td>0 hrs</td><td>24 hrs</td><td>48 hrs</td><td>72 hrs</td><td>96 hrs</td></tr>
<tr><td>Control</td><td>7.4</td><td>7.0</td><td>6.9</td><td>7.0</td><td>7.0</td></tr>
<tr><td>100</td><td>7.4</td><td>7.0</td><td>6.9</td><td>7.0</td><td>7.0</td></tr>
</table></td></tr>
<tr><td>Adjustment of pH</td><td>No</td></tr>
<tr><td>Aeration of dilution water</td><td>Not stated</td></tr>
<tr><td>Intensity of irradiation</td><td>Not stated</td></tr>
<tr><td>Photoperiod</td><td>16 hours light / 8 hours dark</td></tr>
</table>

Table A7_4_1_1(03)-6: Mortality data

Test-Substance Concentration (nominal)[1] [mg pure metabolite/l]	**Mortality**									
	Number[2]					**Percentage**				
	4h	**24 h**	**48 h**	**72 h**	**96 h**	**4h**	**24 h**	**48 h**	**72 h**	**96 h**

Control	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0
***Temperature [°C]**	†12.4	11.9	11.7	11.8	11.8					
***pH**	†7.4	7.0	6.9	7.0	7.0					
***Oxygen [%]**	†97	93	92	93	93					

[1] TS concentrations were nominal

[2] Number exposed 30

* mean values

† - 0 hour value

Table A7_4_1_1(03)-7: Effect data

	48 h [mg pure metabolite/l][1]	95 % c l.	96 h [mg pure metabolite/l][1]	95 % c l.
LC_{50}	>100	-	>100	-

[1] effect data are based on nominal (n) concentrations

Table A7_4_1_1(03)-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	
Concentration of dissolved oxygen in all test vessels > 60% saturation	**yes**	
Concentration of test substance ≥80% of initial concentration during test	**yes**	

Criteria for poorly soluble test substances	**yes**	

Document IIIA — Acute toxicity to invertebrates

Daphnia magna

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			Official use only
		46 REFERENCE	
46.1	**Reference**	[redacted] Acute Toxicity of NAK 4455 to water fleas, [redacted] [redacted] Report No.: HBF/Dm 69, MO-03-009344 Report date: July 10, 1987 Unpublished	
46.2	**Data protection**	Yes	
46.2.1	Data owner	Bayer CropScience	
46.2.2	Companies with letters of access		
46.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I.	
		47 GUIDELINES AND QUALITY ASSURANCE	
47.1	**Guideline study**	Yes OECD Guideline No. 202 'Guideline for Testing of Chemicals', *'Daphnia sp.*, Acute Immobilisation Test and Reproduction Test, Part I, Adopted 4 April 1984'.	
47.2	**GLP**	Yes	
47.3	**Deviations**	None	
		48 MATERIALS AND METHODS	
48.1	**Test material**	NAK 4455 (transfluthrin technical)	
48.1.1	Lot/Batch number	130187	X
48.1.2	Specification	As given in section 2	X
48.1.3	Purity	95.0%	
48.1.4	Composition of Product	N/A	
48.1.5	Further relevant properties	Appearance: brown liquid	
48.1.6	Method of analysis	Not stated	
48.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_2(01)-1	
48.3	**Reference**	Yes, potassium dichromate (test conducted in a separate test on	

Document IIIA — Acute toxicity to invertebrates

Daphnia magna

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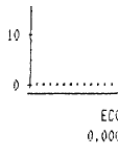
	substance	15/01/1987)
48.3.1	Method of analysis for reference substance	Not stated
48.4	**Testing procedure**	
48.4.1	Dilution water	See table A7_4_1_2(01)-2
48.4.2	Test organisms	See table A7_4_1_2(01)-3
48.4.3	Test system	See table A7_4_1_2(01)-4
48.4.4	Test conditions	See table A7_4_1_2(01)-5
48.4.5	Duration of the test	48 hours
48.4.6	Test parameter	Immobility
48.4.7	Sampling	Visual observations of immobility were made at 24 and 48 hour (unconfirmed immobilisation was verified by use of a microscope).
48.4.8	Monitoring of TS concentration	No
48.4.9	Statistics	Probit Analysis -"Maximum Likelihood "Method.
	49 RESULTS	
49.1	**Limit Test**	Not performed
49.1.1	Concentration	N/A
49.1.2	Number/ percentage of animals showing adverse effects	N/A
49.1.3	Nature of adverse effects	N/A
49.2	**Results test substance**	
49.2.1	Initial concentrations of test substance	0.010, 0.0056, 0.0032, 0.0018 and 0.0010 mg a.i./l (control and solvent controls were also included).
49.2.2	Actual concentrations of test substance	Test reported in nominal concentrations.
49.2.3	Effect data (Immobilisation)	See tables A7_4_1_2(01)-6 and A7_4_1_2(01)-7

49.2.4	Concentration / response curve	
49.2.5	Other effects	Sub-lethal effects reported were rapid trembling of antennae, stagnation at water surface, animals on bottom of vessel and/or almost immobile as given in Table A7_4_1_2(01)-6.
49.3	**Results of controls**	0% mortality was observed in the control (dilution water only) and 3% mortality was observed in the solvent control (0.1 ml/l acetone) after 24h.
49.4	**Test with reference substance**	Performed in a separate test (GLP, E 320 0017-3)
49.4.1	Concentrations	0.75, 1.00, 1.33, 1.73, 2.37 and 3.16 mg/1
49.4.2	Results	24-hour EC_{50} value was 1.72 mg/L (95% confidence intervals 1.54 – 1.91 mg/l).

50 APPLICANT'S SUMMARY AND CONCLUSION

50.1	**Materials and methods**	The study was conducted in accordance with OECD Guideline No. 202 'Guideline for Testing of Chemicals', *'Daphnia sp*., Acute Immobilisation Test and Reproduction Test, Part I, Adopted 4 April 1984'. Juvenile *Daphnia magna* (6 -24 hours old) were exposed for 48 hours under static test conditions to NAK 4455 (transfluthrin technical) at nominal concentrations of 0.0010, 0.0018, 0.0032, 0.0056 and 0.010 mg a.i./l. Control and solvent controls were also included in the study. Daphnids were observed for immobilisation and sublethal effects at 24 and 48 hours. Dissolved oxygen, temperature and pH were measured at the start and end of the study.

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Daphnia magna

SECTION A7.4.1.2/01
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50.2	**Results and discussion**	Mortalities in the control and solvent control were 0 and 3%, respectively. After 24 h, 3%, 7% and 10 % of the daphnids were immobile at the test concentration of 0.0018, 0.0032, 0.0056 mg a.i./L. No effects were observed at 0.01 mg a.i./L at this time point. 7, 70 and 90% immobilisation was observed at the 0.0010, 0.00018 and 0.0032 mg a.i/l test concentrations after 48 h; 97% mortality was observed at the 0.0056 and 0.010 mg a.i./l test concentrations respectively. Water quality and environmental parameters were within acceptable limits.
50.2.1	EC_{50}	The EC_{50} at 24h was 0.039 mg a.i./L (95% confidence intervals of 0.0003-0.003 mg a.i./l), the 48 hour value was 0.0017 mg a.i./l (95% confidence intervals of 0.0003-0.003 mg a.i./l).
50.3	**Conclusion**	The 48-hour EC_{50} of NAK 4455 to Daphnia magna was calculated to be 0.0017 mg a.i./l with 95%-confidence intervals of 0.0003 to 0.003 mg a.i./l. The 'no-observed-effect-concentration' (NOEC) (48 hours) was 0.0001 mg a.i./l. The 'lowest lethal concentration' (LLC) was 0.001 mg a.i./l. See also validity criteria summarized in table A7_4_1_2(01)-8.
50.3.1	Reliability	2
50.3.2	Deficiencies	No analysis of the actual test concentration.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version is adopted with the following addition: 3.1.2/3.1.3 Batch differs from those included in the batch analysis (Doc III A.2 confidential). Purity of test substance is low (95%), but this was most likely accounted for when preparing the test solutions (EC_{50} reported as 0.0017 mg a.i./L).
Results and discussion	Applicant's version is adopted
Conclusion	Applicant's version is adopted The result 48-hours EC_{50} 1.7 µg as/L is used for risk assessment.
Reliability	2 no verification of test concentrations
Acceptability	acceptable
Remarks	
	COMMENTS FROM ...

Document IIIA

SECTION A7.4.1.2/01
BPD Data Set IIA / Annex Point VII.7.2

Acute toxicity to invertebrates

Daphnia magna

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_4_1_2(01)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, magnetic stirrer (approx. 60 minutes)
Vehicle	Yes, solvent (acetone)
Concentration of vehicle	0.1 ml/l
Vehicle control performed	Yes (acetone control)
Other procedures	None

Table A7_4_1_2(01)-2: Dilution water

Criteria	Details
Source	Deionised water
Alkalinity	Not stated
Hardness	Not stated
pH	8.00
Ca / Mg ratio	$CaCl_2$ x 2 H_20 p.a. (0.08 mol/1)/ $MgSO_4$ x 7 H_20 p.a. (0.02 mol/1)
Na / K ratio	$NaHCO_3$ p.a. (0.03 mol/1) / KC1 p.a. (0.003 mol/l)
Oxygen content	95.9%
Conductance	Not stated
Holding water different from dilution water	No

Table A7_4_1_2(01)-3: Test organisms

Criteria	Details
Strain	*Daphnia maqna*
Source	[redacted]
Age	6-24 hours old
Breeding method	Not stated (strain bred in laboratory for a long period of time).
Kind of food	Algae (*Scenedesmus subspicatus*) and fish flake (TetraMin®).
Amount of food	Not stated
Feeding frequency	Not stated
Pretreatment	*Daphnia* were held in the laboratory under standard conditions i.e. 20 ± °C, 16:8 light/dark cycle, which are identical to the test conditions.
Feeding of animals during test	No

Table A7_4_1_2(01)-4: Test system

Criteria	Details
Renewal of test solution	Static test
Volume of test vessels	100 mL (containing 50 mL of test medium)
Volume/animal	5ml/1 organism
Number of animals/vessel	10
Number of vessels/ concentration	3
Test performed in closed vessels due to significant volatility of TS	Yes, test vessels were covered with watch glass lids (60 mm in diameter).

Table A7_4_1_2(01)-5: Test conditions

Criteria	Details
Test temperature	19.6 °C
Dissolved oxygen	98.8 – 99.9%
pH	7.93 – 8.00
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Not stated
Photoperiod	16:8 hours light:dark cycle

Table A7_4_1_2(01)-6: Immobilisation and sublethal effects data

Test-Substance Concentration (nominal) [1] **[mg a.i./l]**	**Immobile *Daphnia****						
	Number		**Percentage**		**Oxygen [%]**	**pH**	**Temperature [°C]**
	24 h	**48 h**	**24 h**	**48 h**	**48 h**	**48 h**	**48 h**
Control	0	0	0	0	99.9	8.00	19.6
Solvent control	0	1	0	3	99.9	7.97	
0.0010	0[3,4]	2[3,4]	0	7	98.9	7.94	
0.0018	1[3,4]	21[3,4]	3	70	-	-	
0.0032	2[2,3,4,5]	27[3,4]	7	90	-	-	
0.0056	3[2,3,4,5]	29[3,4]	10	97	-	-	
0.010	0[2,3,4,5]	29[3,4]	0	97	99.5	7.93	

[1] TS concentrations are based on nominal

[2] stagnation of animals on water surface

[3] animals on bottom of test vessels

[4] almost immobile

[5] rapid trembling of antenna

*(30 organisms exposed in total per concentration)

Table A7_4_1_2(01)-7: Effect data

	EC_{50}[1]	**95 % c l.**
24 h [mg a i./l]	0.039	0.017-0.17
48 h [mg a i./l]	0.0017	0.0003-0.003

[1] effect data are based on nominal (n) concentrations

Table A7_4_1_2(01)-8: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

	fulfilled	**Not fulfilled**
Immobilisation of control animals <10%	**Yes**	
Control animals not staying at the surface	**Yes**	
Concentration of dissolved oxygen in all test vessels >3 mg/l	**Yes**	
Concentration of test substance ≥80% of initial concentration during test	**N.D.**	

Criteria for poorly soluble test substances	**Yes**	

N.D. – Not determined

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Acute toxicity to invertebrates

Daphnia magna

			Official use only
		51 REFERENCE	
51.1	**Reference**	[redacted] (2001) NAK4455 (Bayothrin) Acute *Daphnia* Toxicity, [redacted] [redacted] Report No.: 1091 A/01 D, [BES Ref: MO-03-009813] Report date: July 6, 2001 Unpublished	
51.2	**Data protection**	Yes	
51.2.1	Data owner	Bayer CropScience	
51.2.2	Companies with letters of access		
51.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		52 GUIDELINES AND QUALITY ASSURANCE	
52.1	**Guideline study**	Yes EEC Methods for Determination of Ecotoxicity Annex to Directive 92/69/EEC (O.J. No. L383A, 29.12.92) Part C, Method 2 'Acute toxicity for *Daphnia*' which is in most parts equivalent to the OECD Guideline for Testing of Chemicals No. 202 'Daphnia sp., Acute Immobilisation Test and Reproduction Test, Part I.	
52.2	**GLP**	Yes	
52.3	**Deviations**	None	
		53 MATERIALS AND METHODS	
53.1	**Test material**	NAK 4455 (transfluthrin technical)	
53.1.1	Lot/Batch number	816779502	X
53.1.2	Specification	As given in section 2	X
53.1.3	Purity	95.7%	
53.1.4	Composition of Product	N/A	
53.1.5	Further relevant properties	Molecular weight: 371 g/mol Water solubility: 5.7 x 10^{-5} g/l Vapour pressure: 4.0 x 10^{-6} hPa (20°C)10^{-5}	
53.1.6	Method of analysis	Stability of test concentrations was verified by chemical analysis using Gas Chromatography (GC).	

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53.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_2(02)-1	
53.3	**Reference substance**	No	
53.3.1	Method of analysis for reference substance	N/A	
53.4	**Testing procedure**		
53.4.1	Dilution water	See table A7_4_1_2(02)-2	
53.4.2	Test organisms	See table A7_4_1_2(02)-3	
53.4.3	Test system	See table A7_4_1_2(02)-4	
53.4.4	Test conditions	See table A7_4_1_2(02)-5	
53.4.5	Duration of the test	48 hours	
53.4.6	Test parameter	Immobility	
53.4.7	Sampling	Visual observations of immobility were made at 24 and 48 hours.	
53.4.8	Monitoring of TS concentration	Yes, samples from test concentrations above 0.0008 mg/L were taken at 0 and 48 hours and analysed using Gas Chromatography (GC). GC values were calculated (corresponding to the analytical recovery rate of the highest test concentration) at 0.0002, 0.0004 and 0.0008 mg a.i./1 as the concentrations were below the quantitation limit of the GC method (0.001 mg a.i./1).	X
53.4.9	Statistics	Probit Analysis	
		54 RESULTS	
54.1	**Limit Test**	Not performed	
54.1.1	Concentration	N/A	
54.1.2	Number/ percentage of animals showing adverse effects	N/A	
54.1.3	Nature of adverse effects	N/A	
54.2	**Results test substance**		
54.2.1	Initial concentrations of test substance	Control, 0.0002, 0.0004, 0.0008, 0.002, 0.004, 0.008, 0.02 and 0.04 mg a.i./l .	
54.2.2	Actual	Measured concentrations ranged from 75 - 123% of nominal values at 0	X

concentrations of test substance

hours and from 38 - 50% of nominal values at 48 hours, respectively. At test concentrations of 0.0002, 0.0004 and 0.0008 mg a.i./1 GC values were calculated (corresponding to the analytical recovery rate of the highest test concentration) as the concentrations were below the quantitation limit of the GC method (0.001 mg a.i./1).

Test concentration (mg a.i/l)	0 hours	48 hours
Control	<0.001	<0.001
0.0002	0.000245	0.00008
0.0004	0.00049	0.00016
0.0008	0.00098	0.00032
0.002	0.002	0.001
0.004	0.004	0.002
0.008	0.006	0.003
0.02	0.022	0.008
0.04	0.049	0.016

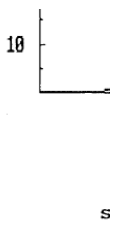
54.2.3 Effect data (Immobilisation)

See tables A7_4_1_2(02)-6 and A7_4_1_2(02)-7

54.2.4 Concentration / response curve

Concentration-immobilisation curve for *Daphnia magna* exposed for 48h to NAK 4455 (Bayothrin):

Correlation coefficient: 0.665



54.2.5 Other effects

None

54.3 Results of controls

0% mortality was observed in the controls (dilution water only).

54.4 Test with reference

Not performed

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	substance		
54.4.1	Concentrations	N/A	
54.4.2	Results	N/A	
		55 APPLICANT'S SUMMARY AND CONCLUSION	
55.1	**Materials and methods**	The study was conducted in accordance with EEC Methods for Determination of Ecotoxicity Annex to Directive 92/69/EEC (O.J. No. L383A, 29.12.92) Part C, Method 2 'Acute toxicity for *Daphnia*' which is in most parts equivalent to the OECD Guideline for Testing of Chemicals No. 202 *'Daphnia sp.*, Acute Immobilisation Test and Reproduction Test, Part I. Dates of experimental work: 27/06/2001 to 29/06/2001. Juvenile *Daphnia magna* (<24 hours old) were exposed for 48 hours under static test conditions to NAK 4455 (transfluthrin technical) at nominal concentrations of 0.0002, 0.0004, 0.0008, 0.002, 0.004, 0.008, 0.02 and 0.04 mg a.i./l. An untreated control was also included in the study. Daphnids were observed after 24 and 48 hours for alteration of mobility and loss of locomotory actions. Dissolved oxygen, temperature and pH were measured at the end of the study. Water hardness was determined at the beginning of the test. Analytical samples were taken from the controls and the 0.002, 0.004, 0.008, 0.02 and 0.04 mg a.i./l test concentrations at 0 and 48 hours and analysed using GC. The test concentrations 0.0002, 0.0004 and 0.0008 mg a.i./1 were not analytically determined as they were below the quantitation limit of the GC analysis method (0.001 mg/1). However at these test concentrations GC values were calculated (corresponding to the analytical recovery rate of the highest test concentration).	X
55.2	**Results and discussion**	Mean measured concentrations ranged from 75 - 123% of nominal values at 0 hours and from 38 - 50% of nominal values at 48 hours, respectively. The results are expressed as nominal values for the 24h effect and as mean measured concentrations for the 48h EC50 value. No immobilisation was recorded in the control, 0.0002 or 0.0004 mg a.i./l test concentrations. 20, 75, 80, 90 and 100% mortality was observed at the 0.0008, 0.002, 0.004, 0.008, 0.02 and 0.004 mg a.i/l test concentrations, respectively. The EC50 at 24 h was > 0.013 mg/L, the EC50 at 48h was 0.0012 mg/L (probit analysis). Water quality and environmental parameters were within acceptable limits.	X
55.2.1	EC_0	(based on mean measured) 48 hour value - 0.00033 mg a.i./l	
55.2.2	EC_{50}	(based on mean measured) 48 hour value - 0.0012 mg a.i./l (95% confidence intervals of 0.0008-0.0016).	
55.2.3	EC_{100}	(based on mean measured) 48 hour value - 0.019 mg a.i./l	

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55.3	**Conclusion**	The 48-hour EC_{50} of NAK 4455 to *Daphnia magna* was calculated to be 0.0012 mg a.i./l with 95%-confidence intervals of 0.0008 to 0.0016 mg a.i./l. See also validity criteria summarized in table A7_4_1_2(02)-8.
55.3.1	Reliability	1
55.3.2	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version adequately reflects the report. The following comments can be made: 3.1.2/3.1.3 Batch differs from those included in the batch analysis (Doc III A.2 confidential). Purity of test substance is low (94.5%), but concentrations were measured. 3.4.8 For the analytical measurements, only the resulting figures are given. Method and results are not described in detail (i.e. it is not clear whether samples were analysed in duplicate, recovery is given as 98 %, but spiking level and individual data are not given).
Results and discussion	Applicant's version adequately reflects the report. The following comments can be made: 4.2.2 Actual concentrations at t = 0 were 100, 100, 75, 110 and 123 % of nominal at 2 to 40 µg as/L (average 102 %). At 48 hours, actual concentrations were 50, 50, 37.5, 40 and 40 % of nominal (average 43.5 %). The 24- and 48-hours concentrations at 0.2, 0.4 and 0.8 µg/L nominal were calculated by correction with the recovery of the highest exposure level, i.e. 123 and 40 %, respectively. Since the range of recoveries is relatively small, it is more appropriate to use the average recoveries of 102 and 43.5 %. 5.2 The 48-hours EC_{50} on the basis of nominal concentrations is 1.6 µg/L (trimmed Spearman-Kärber method). Using the average recovery at 24 and 48 hours, the estimated concentration over the duration of the test is 1.2 µg/L. This value is the same as derived by the authors, although slightly differently calculated.
Conclusion	The result 48-hours EC_{50} 1.2 µg/L (estimated concentration during the test) is used for risk assessment
Reliability	2 Actual concentrations at lower exposure levels estimated instead of measured.
Acceptability	acceptable

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Daphnia magna

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Remarks	
	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_4_1_2(02)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, A stock solution was prepared to give the desired series of test concentrations. To achieve this 1.5 mg of the test substance were added to 3 litres of dilution water and treated for 60 seconds with an ultra turrax and afterwards stirred for 24 h on a magnetic stirrer. Finally undissolved particles of the test substance were removed by filtration.
Vehicle	No (dilution water only)
Concentration of vehicle	n/a
Vehicle control performed	n/a
Other procedures	None

Table A7_4_1_2(02)-2: Dilution water

Criteria	Details
Source	Reconstituted water ('M4 medium', originally described in Water Research 24 (9): 1157-1167), prepared according to the recommendations of Bundesgesundheitsamt Berlin.
Alkalinity	Not stated
Hardness	273.1 mg/l $CaCO_3$
pH	8.0
Ca / Mg ratio	Not stated

Na / K ratio	Not stated
Oxygen content	8.5 mg/L (93.1% saturation)
Conductance	Not stated
Holding water different from dilution water	No

Table A7_4_1_2(02)-3: Test organisms

Criteria	Details
Strain	*Daphnia magna* STRAUS
Source	[redacted]
Age	Neonates <24 hours old
Breeding method	A population of parthenogenetic females of synchronized age structure has been maintained for more than 15 years in the test facility under constant temperature conditions (20 ± 1 °C) at a 16:8 hour light-dark photoperiod (illumination: <1000 lux). The culture water ('M4 medium') is partly renewed once a week. The mortalities of parent *Daphnia* during the culture period are recorded daily. The neonates are separated from their parent *Daphnia* by filtration prior to an acute test.
Kind of food	*Daphnia* were exclusively fed with unicellular green algae (*Scenedesmus subspicatus* CHODAT).
Amount of food	'*ad libitum*'
Feeding frequency	Not stated
Pretreatment	*Daphnia* were held in the laboratory under standard conditions i.e. 20 ± 1 °C, 16:8 light/dark cycle, which are identical to the test conditions.
Feeding of animals during test	No

Table A7_4_1_2(02)-4: Test system

Criteria	Details
Renewal of test solution	Static test
Volume of test vessels	50 mL (containing 20 mL of test medium)
Volume/animal	2ml/1 organism
Number of animals/vessel	10
Number of vessels/ concentration	2
Test performed in closed vessels due to significant volatility of TS	Not stated

Table A7_4_1_2(02)-5: Test conditions

Criteria	Details
Test temperature	Range 19.9 -20 °C
Dissolved oxygen	8.4 – 8.5 mg/l (approx. 90 -93% saturation)
pH	7.9 – 8.0
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	< 1000 lux
Photoperiod	16:8 hours light:dark cycle

Table A7_4_1_2(02)-6: Immobilisation data

Test-Substance Concentration (nominal) [1] [mg a.i./l]	Immobile *Daphnia**						
	Number		Percentage		Oxygen [mg/l]	pH	Temperature [°C]
	24 h	48 h	24 h	48 h	48 h	48 h	48 h
Control	0	0	0	0	8.5	8.0	20.0
0.0002	0	0	0	0	8.4	8.0	20.0
0.0004	0	0	0	0	8.5	8.0	19.9
0.0008	0	4	0	20	8.4	8.0	19.9
0.002	0	15	0	75	8.5	7.9	20.0
0.004	5	16	25	80	8.4	7.9	20.0
0.008	7	18	35	90	8.4	7.9	19.9
0.02	10	20	50	100	8.4	7.9	19.9
0.04	17	20	85	100	8.4	7.9	19.9

[1] TS concentrations are based on nominal

*(20 organisms exposed in total per concentration)

Table A7_4_1_2(02)-7: Effect data

	EC_{50}[1]	95 % c l.	EC_0[1]	EC_{100}[1]
24 h [mg a i./l]	0.013	0.0071 – 0.023	0.002	>0.04
48 h [mg a i./l]	0.0012	0.0008 – 0.0016	0.00033	0.019

[1] effect data are based on nominal (n) concentrations at 24 hours and mean measured concentrations at 48 hours.

Table A7_4_1_2(02)-8: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

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

Document IIIA — Acute toxicity to invertebrates (metabolite toxicity)

Daphnia magna

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56 REFERENCE

56.1	**Reference**	[redacted] (2005) Acute Toxicity of Tetrafluorobenzoic acid to the Waterflea *Daphnia magna* in a Static Laboratory Test System, Limit Test, [redacted] [redacted] Report No.: E 320 2953-4, [BES Ref: M-260372-01-1] Report date: November 9, 2005 Unpublished
56.2	**Data protection**	Yes
56.2.1	Data owner	Bayer CropScience
56.2.2	Companies with letters of access	
56.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I

57 GUIDELINES AND QUALITY ASSURANCE

57.1	**Guideline study**	Yes, OECD -202, April 4, 1984 and corresponding revised draft proposal, dated February 01, 2004. U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72 2 (1982). EEC Directive 92/69/EEC, part C.2 (1992). OPPTS Guideline 850.1010 Draft 1996 (modified). JMAFF 12 Nousan No. 8147 (2000).
57.2	**GLP**	Yes
57.3	**Deviations**	None

58 MATERIALS AND METHODS

58.1	**Test material**	Tetrafluorobenzoic acid (tech.) (Transfluthrin metabolite) Product Code: AE 1371427 00 1B (NAK 4723)
58.1.1	Lot/Batch number	950627ELB01
58.1.2	Specification	As given in section 2
58.1.3	Purity	99.0%
58.1.4	Composition of Product	N/A
58.1.5	Further relevant	Appearance: white crystals

Document IIIA **Acute toxicity to invertebrates (metabolite toxicity)**

Daphnia magna

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	properties	
58.1.6	Method of analysis	Not stated.
58.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_2(03)-1
58.3	**Reference substance**	Yes For quality control of the breeding stock, an acute non-GLP toxicity test was performed on January 10, 2005 using the reference substance $K_2Cr_2O_7$, p.a. grade.
58.3.1	Method of analysis for reference substance	N/A
58.4	**Testing procedure**	
58.4.1	Dilution water	See table A7_4_1_2(03)-2
58.4.2	Test organisms	See table A7_4_1_2(03)-3
58.4.3	Test system	See table A7_4_1_2(03)-4
58.4.4	Test conditions	See table A7_4_1_2(03)-5
58.4.5	Duration of the test	48 hours
58.4.6	Test parameter	Immobility
58.4.7	Sampling	Visual observations of immobility were made at 24 and 48 hours. Additionally sublethal effects were recorded. Prior to test initiation, conductivity, total hardness and alkalinity of the dilution media (Elendt M7) were determined. Dissolved oxygen and pH were measured at test initiation (in freshly prepared test solutions at each treatment level and the control) and at test termination (day 2) (in pooled replicates of the aged media). Light intensity was measured at the start of the study as “diffuse light" immediately above the exposure vessels. Environmental temperature was recorded continuously during the test. Additionally temperature of the test media was measured inside one vessel of the untreated control and of the highest test concentration at start and end of the study.
58.4.8	Monitoring of TS concentration	For analytical verification of the test item concentrations, duplicate samples (20 ml) of the freshly prepared test media were taken at start of exposure from the treatment group and untreated control. For additional stability measurements samples were taken at 48 hours from the aged test media of each treatment group (pooled).
58.4.9	Statistics	The statistical evaluation of the data was not necessary as no treatment related effects occurred at the highest dose tested (100 mg pure metabolite/L).

59 RESULTS

Document IIIA — Acute toxicity to invertebrates (metabolite toxicity)

Daphnia magna

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59.1	**Limit Test**	
59.1.1	Concentration	Based on the results of a non-GLP pre-test Daphnids were exposed to a single exposure concentration of 100 mg pure metabolite/L. The study was conducted as a limit test.
59.1.2	Number/ percentage of animals showing adverse effects	See point 4.2.3.
59.1.3	Nature of adverse effects	N/A
59.2	**Results test substance**	
59.2.1	Initial concentrations of test substance	100 mg pure metabolite/L.
59.2.2	Actual concentrations of test substance	Based on analytical determination of AE 1371427 00 1B (in water by HPLC-UV) measured values of 109% of nominal were found.

Nominal test concns (mg pure metabolite/L	Measured concns of the freshly prepared solutions		Measured concns of the aged solutions after 48 hrs.	
	mg pure metabolite/L	% of nominal	mg pure metabolite/L	% of nominal
Control	<0.515 *)	-	<0.515 *)	-
100	109	109	109	109

*) lowest concentrations of the calibration standard during analytical measurement

59.2.3	Effect data (Immobilisation)	No immobility occurred (0%), see tables A7_4_1_2(03)-6 and A7_4_1_2(03)-7.
59.2.4	Concentration / response curve	N/A
59.2.5	Other effects	None
59.3	**Results of controls**	0% immobilisation was observed in the untreated controls (test media only).
59.4	**Test with reference substance**	
59.4.1	Concentrations	0.75, 1.00, 1.33, 1.78, 2.37 and 3.16 mg/L
59.4.2	Results	24 hour EC_{50} = 1.2 mg/L (95% confidence limits 1.1 -1.3 mg/L). The value determined meets the range required by OECD 202 (0.6 mg/L - 2.1 mg/L).

Document IIIA — Acute toxicity to invertebrates (metabolite toxicity)

Daphnia magna

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60 APPLICANT'S SUMMARY AND CONCLUSION

60.1 Materials and methods

The study was conducted in accordance with: OECD -202, April 4, 1984 and corresponding revised draft proposal, dated February 01, 2004; U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72 2 (1982); EEC Directive 92/69/EEC, part C.2 (1992); OPPTS Guideline 850.1010 Draft 1996 (modified) and JMAFF 12 Nousan No. 8147 (2000). Validity criteria were fulfilled and no deviations were noted. Dates of experimental work: 27/06/2005 – 23/08/2005.

Juvenile *Daphnia magna* (<24 hours old), were exposed (30 per treatment group) in a limit test for 48 hours under static test conditions to Tetrafluorobenzoic acid (AE 1371427 00 1B) (=NAK 4723) - metabolite of transfluthrin) at a nominal concentration of 100 mg pure metabolite/L. Untreated controls were also included in the study.

Daphnids were observed for immobility and sub-lethal effects after 24 and 48 hours.

Prior to test initiation, conductivity, total hardness and alkalinity of the dilution media (Elendt M7) were determined. Dissolved oxygen and pH were measured at the start and end of the study. Light intensity (immediately above the exposure vessels) was also measured at start of the study. Environmental temperature was recorded continuously during the test. Additionally the temperature of the test media was measured inside one vessel of the untreated control and of the highest test concentration at start and end of the study.

Analytical determinations of the pure metabolite concentrations were made in the test medium (100 mg/L treatment group and control) at the beginning of the test and after 48h at test termination.

60.2 Results and discussion

No immobility or sub-lethal effects were observed in the control group or at the 100 mg pure metabolite/L test concentration.

Analytical determination of Tetrafluorobenzoic acid (AE 1371427 00 1B) (in water by HPLC-UV) showed that the test concentration (100 mg pure metabolite/L) was maintained at >80% of the nominal value. Measured values were 109% of nominal. Test results are therefore based on nominal concentrations.

Water quality and environmental parameters were within acceptable limits.

60.2.1 EC_0 -

60.2.2 EC_{50} > 100 mg pure metabolite/l (based on nominal concentrations)

60.2.3 EC_{100} -

60.3 Conclusion

Based on nominal concentrations the 48h-EC_{50} of Tetrafluorobenzoic acid (AE 1371427 00 1B) to *Daphnia magna* under static test conditions was > 100 mg pure metabolite/l. The 48 hour NOEC is ≥ 100 mg pure metabolite/L. See also validity criteria summarised in table A7_4_1_2(03)-8.

60.3.1 Reliability 1

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60.3.2 Deficiencies None

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16-04-2007
Materials and Methods	Applicant's version is adopted
Results and discussion	Applicant's version is adopted
Conclusion	Applicant's version is adopted The result 48-hours EC_{50} > 100 mg/L is used for risk assessment.
Reliability	1
Acceptability	acceptable
Remarks	
	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_4_1_2(03)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, the test solution was prepared by dissolving 101 mg of the test item (purity: 99.0 %) in 1.0 L test water (=100 mg pure metabolite/ L). The solution was alternately ultrasonified whilst carefully heating up to 30°C and stirred on a magnetic stirrer (in total 30 minutes of ultrasonification and 110 minutes of stirring).
Vehicle	No (dilution water only)
Concentration of vehicle	N/A
Vehicle control performed	N/A
Other procedures	None

Table A7_4_1_2(03)-2: Dilution water

Criteria	Details
Source	Reconstituted water ('M7 medium', as documented in the "Original Draft" of an EEC *Daphnia magna* Pilot Ring Test).
Alkalinity	3° dH (= 53 mg/L $CaCO_3$ equivalent to 1 ml 0.1 N HCl)
Hardness	13° dH (= 257 mg/L $CaCO_3$)
pH	8.1
Ca / Mg ratio	7:1
Na / K ratio	6:1
Oxygen content	8.1 mg/L (91% saturation)
Conductance	591 µS/cm
Holding water different from dilution water	No

Table A7_4_1_2(03)-3: Test organisms

Criteria	Details
Strain	*Daphnia magna*
Source	[redacted]
Age	First instars <24 hours old
Breeding method	Not stated. However, this breeding strain has been maintained in the test facility successfully for more than fifteen years in weekly-renewed aqueous media.
Kind of food	Deep-frozen cells of the green algae *Desmodesmus subspicatus*, supplemented by a commercial fish food (trade name: TetraMin®) in aqueous suspension.
Amount of food	Not stated
Feeding frequency	3 times per week
Pretreatment	*Daphnia* were held in the laboratory under standard conditions in 2L glass containers (50 –100 daphnids per container) at 20 ± 1 °C, 16:8 light/dark cycle.
Feeding of animals during test	No

Table A7_4_1_2(03)-4: Test system

Criteria	Details
Renewal of test solution	Static test
Volume of test vessels	100 mL (containing 50 mL of test medium)
Volume/animal	10ml per daphnid
Number of animals/vessel	5
Number of vessels/ concentration	6
Test performed in closed vessels due to significant volatility of TS	Yes, test vessels were covered with transparent glass plates.

Table A7_4_1_2(03)-5: Test conditions

Criteria	Details
Test temperature	Range 20.5 –20.9 °C

Dissolved oxygen	7.3 – 8.1 mg/l (approx. 83 -91% saturation)
pH	6.8 – 8.1
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Cool-white fluorescent bulbs at a light intensity of max. 1500 lux
Photoperiod	16:8 hours light:dark cycle

Table A7_4_1_2(03)-6: Immobilisation data

Test-Substance Concentration (nominal) [1] [mg pure metabolite/l]	**Immobile *Daphnia****						
	Number		**Percentage**		**Oxygen [mg/l]**	**pH**	**Temperature [°C]**
	24 h	**48 h**	**24 h**	**48 h**	**48 h**	**48 h**	**48 h**
Control	0	0	0	0	7.3	8.1	20.5
100	0	0	0	0	7.3	7.7	20.6

[1] TS concentrations are based on nominal; *(30 organisms exposed in total per treatment group)

Table A7_4_1_2(03)-7: Effect data

	EC_{50}[1]	**95 % c l.**	**EC_0[1]**	**EC_{100}[1]**
24 h [mg pure metabolite/l]	>100	N/A	-	-
48 h [mg pure metabolite/l]	>100	N/A	-	-

[1] effect data are based on nominal (n) concentrations

Table A7_4_1_2(03)-8: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

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

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			Official use only
		61 REFERENCE	
61.1	**Reference**	[redacted] (1987) Growth inhibition of green algae (*Scenedesmus subspicatus*) caused by NAK 4455 (techn.), [redacted] [redacted] Report No.: HBF/A1 38, [BES Ref: MO-03-009348] Report date: August 20, 1987 Unpublished	
61.2	**Data protection**	Yes	
61.2.1	Data owner	Bayer CropScience	
61.2.2	Companies with letters of access		
61.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		62 GUIDELINES AND QUALITY ASSURANCE	
62.1	**Guideline study**	Yes ISO-Guideline ISO/TC 147/SC 5/WG 5 N 84 (Algal Growth Inhibition Test) from 19.06.84 and OECD-Guideline No. 201 "OECD-Guideline for Testing of Chemicals", "Alga, Growth Inhibition Test" (07.06.84).	
62.2	**GLP**	Yes	
62.3	**Deviations**	None	
		63 MATERIALS AND METHODS	
63.1	**Test material**	NAK 4455 (transfluthrin technical)	
63.1.1	Lot/Batch number	130187	X
63.1.2	Specification	As given in section 2	X
63.1.3	Purity	95.0%	X
63.1.4	Composition of Product	N/A	
63.1.5	Further relevant properties	Appearance: brown liquid	
63.1.6	Method of analysis	Not stated	
63.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_3(01)-1	

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63.3	**Reference substance**	Yes, potassium dichromate (tested performed 11/02/1987).
63.3.1	Method of analysis for reference substance	Not stated
63.4	**Testing procedure**	
63.4.1	Culture medium	Mineral composition: (based on 1 litre) - 15 mg NH_4Cl, 12 mg $MgCl_2$ x $6H_20$, 18 mg $CaCl_2$ x $2H_20$, 15 mg $MGS0_4$ x $7H_20$, 1.6 mg KH_2P0_4, 80 µg $FeCl_3$ x $6H_20$, 100 µg Na_2EDTA x $2H_20$, 185 µg H_3BO_3, 415 µg $MnCl_2$ x $4H_20$, 3 µg $ZnCl_2$, 1.5 µg $CoCl_2$ x $6H_20$, 0.01 µg $CuCl_2$ x $2H_20$, 7 µg Na $Mo0_4$ x $2H_20$ and 50 mg $NaHCO_3$. pH: 8.19
63.4.2	Test organisms	See table A7_4_1_3(01)-2
63.4.3	Test system	See table A7_4_1_3(01)-3
63.4.4	Test conditions	See table A7_4_1_3(01)-4
63.4.5	Duration of the test	96 hours
63.4.6	Test parameter	Cell multiplication inhibition
63.4.7	Sampling	Cell counts were determined after 24, 48, 72 and 96 hours
63.4.8	Monitoring of TS concentration	No
63.4.9	Statistics	Cell count inhibition was determined using the following equation: $y = 0.00495\ x - 0.00000189\ x^2$ with $x = \frac{\text{cell count / ml}}{10^4}$ and y = extinction.

64 RESULTS

64.1	**Preliminary test**	Performed
64.1.1	Concentration	0.01 and 0.1 mg a.i./l (due to the low solubility of NAK 4455 (techn.) in water, the highest test concentration was 0.1 mg a.i./l). Control and solvent controls (0.1 ml/l) were also included in the study.
64.1.2	Preliminary Test results	After 96 hours:

Concentration (mg a.i./l)	*cell counts (x 10^4/ml)
Control	301.17
Solvent control	298.73
0.01	276.52
0.1	284.35

* mean value of 3 flasks

64.2	**Results test substance**	

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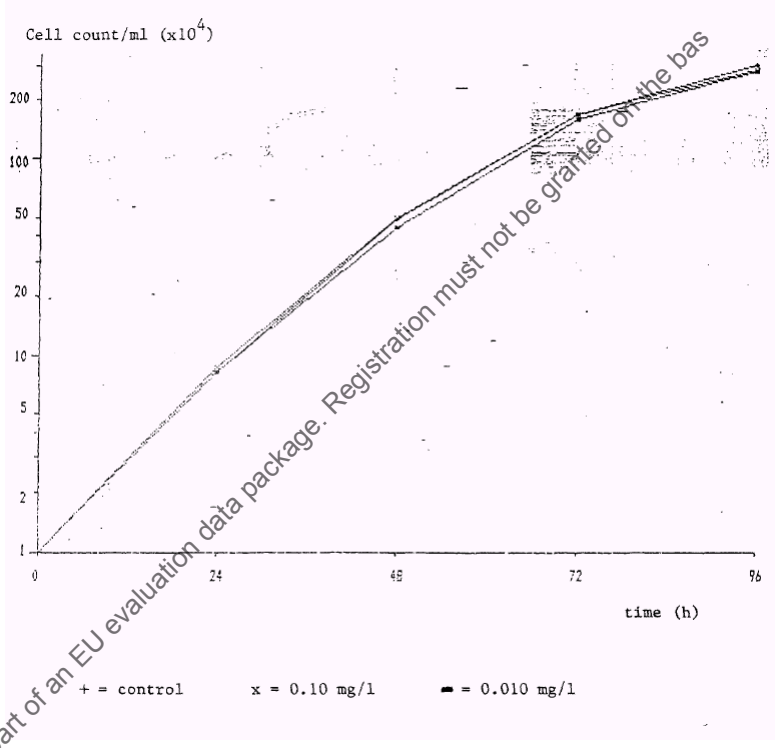
64.2.1	Initial concentrations of test substance	Control, solvent control and 0.1 mg a.i./l.	X
64.2.2	Actual concentrations of test substance	Test reported in nominal concentrations.	
64.2.3	Growth curves		
64.2.4	Concentration / response curve	Not presented	
64.2.5	Cell concentration data	See table A7_4_1_3(01)-5	
64.2.6	Effect data (cell multiplication inhibition)	See tables A7_4_1_3(01)-6 and A7_4_1_3(01)-7 for areas below the growth curve and growth rate effects. The EC_{50} of NAK 4455 determined for the biomass growth (E_bC_{50}) after 72 and 96 hours is > 0.1 mg a.i./l and the EC_{50} of the growth rate of the algae (E_rC_{50}) after 72 and 96 hours is also >0.1 mg a.i./l, based on nominal concentrations. The "no-observed-effect-concentration" (NOEC) for the biomass and the growth rate is ≥0.1 mg a.i./l. No toxic effects were observed for biomass and growth rate even at the highest tested concentration of 0.1 mg a.i./l.	
64.2.7	Other observed effects	None	

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64.3 Results of controls

After 96 hours:

Concentration (mg a.i./l)	*cell counts (x 10^4/ml)
Control	261.05
Solvent control	260.73

* mean value of 3 flasks

64.4 Test with reference substance

Performed

64.4.1 Concentrations

0.18, 0.32, 0.56, 1.0, 1.80 mg/1

64.4.2 Results

An EC_{50} of 0.44 mg/1 was determined (based on biomass growth (E_bC_{50}) after 96 hours). This value is within acceptable limits (i.e. a ring test in which the test results varied from 0.20 to 0.75 mg/1).

65 APPLICANT'S SUMMARY AND CONCLUSION

65.1 Materials and methods

The study was conducted in accordance with ISO Guideline ISO/TC 147/SC 5/WG 5 N 84 (Algal Growth Inhibition Test), dated June 19, 1984 and the OECD Guideline No. 201 "OECD Guideline for Testing of Chemicals", "Alga, Growth Inhibition Test" dated June 7, 1984.

The green algae *Scenedesmus subspicatus* was exposed to NAK 4455 for a period of 96 hours, under static conditions (at 23 ± 1°C and 8000 lux constant illumination) at a nominal concentration of 0.1 mg a.i./l. Control and solvent controls were also included in the study. After 24, 48, 72 and 96 hours cell counts were photometrically (at a wave length of 578 nm) determined in individual test vessels. In addition modifications of the cell structure were monitored; additional cell samples were taken at random from one flask at each of the treatment levels and the controls at each time-point and examined microscopically for abnormalities.

Temperature and pH were monitored daily.

65.2 Results and discussion

No inhibition of cell biomass or growth rate was observed at the test concentration 0.1 mg a.i./l compared to the controls. No abnormalities such as alterations of the cell structure were observed.

Water quality and environmental parameters were within acceptable limits.

65.2.1 NOEC

≥0.1 mg a.i./l.

65.2.2 E_rC_{50}

After 72 and 96 hours >0.1 mg a.i./l.

65.2.3 E_bC_{50}

After 72 and 96 hours >0.1 mg a.i./l.

65.3 Conclusion

The EC_{50} of NAK 4455 to *Scenedesmus subspicatus* was determined to be > 0.1 mg a.i./l for both biomass growth (E_bC_{50}) and growth rate (E_rC_{50}) after 72 and 96 hours. The "no-observed-effect-concentration" (NOEC) for the biomass and the growth rate is also ≥0.1 mg a.i./l. No toxic effects were observed for biomass and growth rate at the highest tested concentration of 0.1 mg a.i./l. Validity criteria were considered to

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		be fulfilled.
65.3.1	Reliability	2
65.3.2	Deficiencies	Initial test concentration was not analytically confirmed, but this is not a stringent testing requirement.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version is adopted with the following addition: 3.1.1/3.1.2 Batch differs from those included in the batch analysis (Doc III A.2 confidential). Purity of test substance is low (95%), but this was most likely accounted for when preparing the test solution (concentrations in tables given as mg a.i./L). .
Results and discussion	Applicant's version is adopted.
Conclusion	Applicant's version is adopted. The results 96-hours $NOE_rC \geq 0.1$ mg/L and $E_rC_{50} > 0.1$ mg as/L are used for risk assessment.
Reliability	1
Acceptability	acceptable
Remarks	The highest test concentration of 0.1 mg/L is above the water solubility of 0.057 mg/L, but since the difference is < a factor of 2 and a solvent is used, the study is considered reliable.
	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_4_1_3(01)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, magnetic stirrer
Vehicle	Yes, solvent (acetone)
Concentration of vehicle	1.316 mg a.i./l stock, diluted 1:10 000 in water
Vehicle control performed	Yes, acetone control with 0.1 ml/L test solution
Other procedures	None

Table A7_4_1_3(01)-2: Test organisms

Criteria	Details
Species	*Scenedesmus subspicatus*
Strain	SAG 86/81
Source	Not stated
Laboratory culture	Yes
Method of cultivation	Stock cultures of algae were incubated at 16 hours illumination daily and 20° C in an autoclaved nutrient solution in accordance with BRINGMANN & KUHN (1980, Water Research 14: 231-241). Once a week the stock cultures are inoculated into fresh nutrient solution. All nutrient solutions are prepared with aseptically filtered, deionised water.
Pretreatment	Precultures were inoculated with 1 x 10^4 cells/ml 3 days prior to test start. Exponentially growing precultures were selected for the test.
Initial cell concentration	Approximately 1 x 10^4 cells/ml

Table A7_4_1_3(01)-3: Test system

Criteria	Details
Volume of culture flasks	300 ml with 100 ml test suspension
Culturing apparatus	Erlenmeyer flasks were exposed in a controlled-environment cabinet at 23±1°C and 8000 lux constant light.
Light quality	For illumination 2 x 4 fluorescent lamps (Osram L 140 W/20 Sa) were attached to the side of the controlled environment cabinet.
Procedure for suspending algae	Shaking
Number of vessels/ concentration	3
Test performed in closed vessels due to significant volatility of TS	Not specified

Table A7_4_1_3(01)-4: Test conditions (main test only)

Criteria	Details
Test temperature	22.5 – 22.7 ° C
pH	Start: 7.74 – 8.14 End: 8.36 – 8.40
Aeration of dilution water	No
Light intensity	Approximately 8000 lux
Photoperiod	Constant light

Table A7_4_1_3(01)-5: Cell concentration data (main study)

Test-Substance Concentration (nominal) [mg a i./l]	Cell concentrations (mean values) [x 10^4cells/ml]									
	measured					Percent of solvent control				
	0 h	24 h	48 h	72 h	96 h	0 h	24 h	48 h	72 h	96 h
Control	1.0	6.75	29.01	101.48	261.05	-	-	-	-	-
Solvent control	1.0	6.75	27.91	98.68	260.73	-	-	-	-	-
0.1	1.0	6.48	26.74	102.24	245.18	-	96	96	104	94

Table A7_4_1_3(01)-6: Area below the growth curves (main study)

Test-Substance Concentration (nominal) [mg a i./l]	Areas (A) below the growth curves									
	measured					Percent of solvent control				
	0 h	24 h	48 h	72 h	96 h	0 h	24 h	48 h	72 h	96 h
Control	n.a.	69	474	2016	6342	-	-	-	-	-
Solvent control	n.a.	69	461	1956	6245	-	-	-	-	-
0.1	1.0	66	440	1964	6109	-	95.3	95.5	100.4	97.8

Table A7_4_1_3(01)-7: Growth rates and % deviation (main study)

Test-Substance Concentration (nominal) [mg a i./l]	Growth rates (μ)				Percent of Control			
	0-24h	0-48h	0-72h	0-96h	0-24h	0-48h	0-72h	0-96h
Control	7.96	7.02	6.42	5.80	100.0	101.2	100.6	100.0
Solvent control	7.96	6.94	6.38	5.80	100.0	100.0	100.0	100.0
0.1	7.79	6.85	6.43	5.73	97.9	98.7	100.8	98.9

Table A7_4_1_3(01)-8: 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	**yes**	
Concentration of test substance ≥80% of initial concentration during test	**N.D.**	

N.D. Not determined (results based on nominal concentrations)

Criteria for poorly soluble test substances	**yes**	

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		66 REFERENCE	
66.1	**Reference**	[redacted] (2001) NAK4455 (Bayothrin) Alga, Growth Inhibition Test, [redacted] [redacted]Report No.: 1091 A/01 A1, [BES Ref: MO-03-009814] Report date: 20 June 2001 Unpublished	
66.2	**Data protection**	Yes	
66.2.1	Data owner	Bayer CropScience	
66.2.2	Companies with letters of access		
66.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		67 GUIDELINES AND QUALITY ASSURANCE	
67.1	**Guideline study**	Yes EEC Methods for Determination of Ecotoxicity Annex to Directive 92/69/EEC (O.J. No. L383A, 29.12.92) Part C, Method 3 'Algal inhibition test' which is in most parts equivalent to the OECD Guideline for Testing of Chemicals No. 201 'Alga, Growth Inhibition Test'.	
67.2	**GLP**	Yes	
67.3	**Deviations**	None	
		68 MATERIALS AND METHODS	
68.1	**Test material**	NAK 4455 (transfluthrin technical)	
68.1.1	Lot/Batch number	816779502	X
68.1.2	Specification	As given in section 2	X
68.1.3	Purity	95.7%	
68.1.4	Composition of Product	N/A	
68.1.5	Further relevant properties	Molecular weight: 371 g/mol Water solubility: 5.7 x 10^{-5} g/l Vapour pressure: 4.0 x 10^{-6} hPa (20°C)10^{-5}	
68.1.6	Method of analysis	Stability of test concentrations was verified by chemical analysis using Gas Chromatography (GC).	
68.2	**Preparation of TS**	See table A7_4_1_3(02)-1	

	solution for poorly soluble or volatile test substances	
68.3	**Reference substance**	No
68.3.1	Method of analysis for reference substance	N/A
68.4	**Testing procedure**	
68.4.1	Culture medium	Mineral composition:

Nutrient	Concⁿ in stock solution	Final concⁿ in the solution of the precultures & test cultures
$NaHCO_3$	solid	50 mg/L
Stock solution 1: macro-nutrients		
NH_4C1	1.5g/l	15 mg/1
$MgCl_2$ x 6 H_2O	1.2 g/1	12 mg/1
$CaCl_2$ x 2 H_2O	1.8 g/1	18 mg/1
$MgS0_4$ x 7 H_20	1.5 g/1	15 mg/1
KH_2PO_4	0.16 g/1	1.6 mg/I
Stock solution 2: Fe-EDTA		
$FeCl_3$ x 6 H_20	80 mg/l	80 µg/1
Na_2EDTA x 2 H_20	100 mg/l	100 µg/1
Stock solution 3: trace elements		
H_3B0_3	185 mg/l	185 µg/1
$MnCl_2$ x 4 H_20	415 mg/1	415 µg/1
$ZnCl_2$	3 mg/l	3 µg/1
$CoCl_2$ x 6 H_20	1.5 mg/1	1.5 µg/1
$CuCl_2$ x 2 H_20	0.01 mg/1	0.01 µg/1
Na_2Mo0_4 x 2 H_20	7 mg/1	7 µg/1

68.4.2	Test organisms	See table A7_4_1_3(02)-2
68.4.3	Test system	See table A7_4_1_3(02)-3
68.4.4	Test conditions	See table A7_4_1_3(02)-4
68.4.5	Duration of the test	72 hours
68.4.6	Test parameter	Cell multiplication inhibition
68.4.7	Sampling	Cell counts were determined after 24, 48 and 72 hours
68.4.8	Monitoring of TS concentration	Yes, samples were taken at 0 and 72 hours and analysed using Gas Chromatography (GC).
68.4.9	Statistics	Analysis of the growth (biomass) and growth rate of the algal population was performed using multiple t-Test according to Dunnett (1955).

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69 RESULTS

69.1	**Limit test**	Not performed
69.1.1	Concentration	N/A
69.1.2	Number/ percentage of animals showing adverse effects	N/A
69.2	**Results test substance**	
69.2.1	Initial concentrations of test substance	Control, 0.003, 0.006, 0.013, 0.025, 0.05 and 0.1 mg a.i./1, an additional sample of 0.1 mg a.i./l was prepared without algae to determine loss of substance due to algal uptake.
69.2.2	Actual concentrations of test substance	Measured concentrations ranged from 50 - 80% of nominal values at 0 hours, and from 4.0-16.8% of nominal values at 72 hours, respectively. The highest test concentration was limited by the maximum water solubility of the test substance under exposure conditions.

Test concentration (mg a.i./l)	0 hours	72 hours
Control	<0.001	<0.001
0.003	0.002	<0.001*
0.006	0.003	<0.001*
0.013	0.007	0.001
0.025	0.015	0.001
0.05	0.031	0.003
0.1	0.080	0.007
0.1 (no algae)	0.081	0.075

*Values below the quantitation limit (0.001mg/1) regarded as 0.0005 mg/1, i.e. half of the quantitation limit.

The measured concentration in the parallel sample of 0.1 mg a.i./L incubated without algae revealed 81 to 75% of the initial concentration.

X

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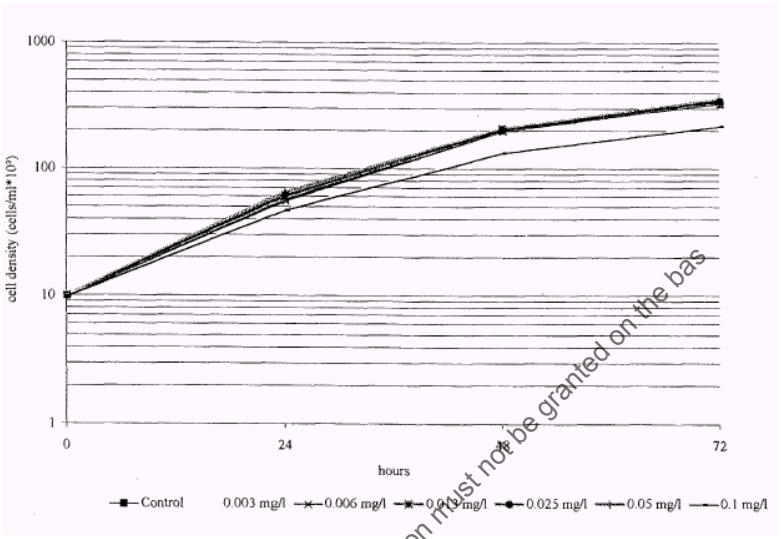
69.2.3 Growth curves



69.2.4 Concentration / response curve — Not presented

69.2.5 Cell concentration data — See table A7_4_1_3(02)-5

69.2.6 Effect data (cell multiplication inhibition) — Based on mean measured concentrations the EC_{50} of NAK 4455 determined for the biomass growth (E_bC_{50}) after 72 hours is > 0.044 mg a.i./l and the EC_{50} of the growth rate of the algae (E_rC_{50}) after 72 hours is also >0.044 mg a.i./l. X

The "no-observed-effect-concentration" (NOEC) for the biomass and the growth rate is 0.017 mg a.i./l.

69.2.7 Other observed effects — The test compound disappeared faster from test vessels including algae. This suggests uptake of the a.i. and hence, significant exposure.

69.3 Results of controls

Concentration (mg a.i./l)	*cell density (cells/ml) (initial cell density = 10^4 cells/ml		
	24 h	48 h	72h
Control	58333	210556	336667

* mean value of 6 replicates

69.4 Test with reference substance — Not performed

69.4.1 Concentrations — N/A

69.4.2 Results — N/A

70 APPLICANT'S SUMMARY AND CONCLUSION

70.1 Materials and methods — The study was conducted in accordance with EEC Methods for Determination of Ecotoxicity Annex to Directive 92/69/EEC (O.J. No.

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		L383A, 29.12.92) Part C, Method 3 'Algal inhibition test' which is in most parts equivalent to the OECD Guideline for Testing of Chemicals No. 201 'Alga, Growth Inhibition Test'. Dates of experimental work: 05/06/2001 to 08/06/2001. The green algae *Scenedesmus subspicatus* was exposed to NAK 4455 for a period of 72 hours; under static conditions (at 23 ± 2°C and 6000 - 10000 lux constant illumination) at nominal concentrations of 0.003, 0.006, 0.013, 0.025, 0.05 and 0.1 mg a.i./l. Controls for analysis of the stability of the test substance as well as effects without treatment were also included in the study. After 24, 48 and 72 hours cell densities were measured in a microcell counter or alternatively by means of a microscopic counting chamber. Temperature and pH were measured at the start and end of the study. Analytical samples were taken from the controls and each test concentration at 0 and 72 hours and analysed using GC.	
70.2	**Results and discussion**	Significant inhibition of cell multiplication (66%), cell biomass (34.4%) and growth rate (11.8 %) was observed after 72 hours at a nominal concentration of 0.1 mg a.i./l (compared to the controls). No negative effects were observed at the remaining test concentrations, only 1.1% inhibition was observed at 0.006 mg/L. The 72-hour E_rC_{50} and E_bC_{50} were calculated to be >0.044 mg a.i./l (based on mean measured concentrations). Measured concentrations ranged from 50 - 80% of nominal values at 0 hours, and from 4.0-16.8% of nominal values at 72 hours, respectively in test vessels containing algal suspensions The highest test concentration was limited by the maximum water solubility of the test substance under exposure conditions. The analysis of the test concentration of 0.1 mg a.i./L, incubated in parallel without algae showed 81% and 75% of the nominal concentration at 0 and 72h, respectively. Water quality and environmental parameters were within acceptable limits.	
70.2.1	NOEC/LOEC	0.017 mg a.i./L and 0.044 mg a.i./l (based on mean measured concentrations), respectively	X
70.2.2	E_rC_{50}	After 72 hours >0.044 mg a.i./l (based on mean measured concentrations).	X
70.2.3	E_bC_{50}	After 72 hours >0.044 mg a.i./l (based on mean measured concentrations).	X
70.3	**Conclusion**	The EC_{50} of NAK 4455 to *Scenedesmus subspicatus* was determined to be > 0.044 mg a.i./l for both biomass growth (E_bC_{50}) and growth rate (E_rC_{50}) after 72 hours. The "no-observed-effect-concentration" (NOEC) for the biomass and the growth rate was determined to be 0.017 mg a.i./l.	X
70.3.1	Reliability	1	
70.3.2	Deficiencies	None	

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Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-02-2007
Materials and Methods	Applicant's version is adopted with the following addition: 3.1.1/3.1.2 Batch differs from those included in the batch analysis (Doc III A.2 confidential). Purity of test substance is low (95.7%), but concentrations were measured. 3.4.8 For the analytical measurements, only the resulting figures are given. Method and results are not described in detail (i.e. it is not clear whether samples were analysed in duplicate, recovery is given as 96 %, but spiking level and individual data are not given).
Results and discussion	Applicant's version adequately reflects the report. The following comments can be made: 4.2.2 Actual concentrations at t = 0 and t = 72 hours were 50 – 80 and 4.0 – 17 %, respectively. In the medium without algae, recovery was 81 and 75 % of nominal after 0 and 72 hours, indicating that measurement in the other test concentrations were highly influenced by the presence of the algae. This is not unexpected in view of the strong sorptive characteristics of transfluthrin. Since the average measured concentration in the medium without algae is close to 80 %, it is considered justified to evaluate the effects on the basis of nominal concentrations. 5.2 The 72-hours E_rC_{50} based on nominal concentrations is > 0.1 mg/L.
Conclusion	The results 72-hours NOE_rC 0.05 mg/L and E_rC_{50} > 0.1 mg/L (nominal) are used for risk assessment
Reliability	2 The highest test concentration is above the reported water solubility of 0.057 mg/L, recovery in test media without algae was slightly lower than 80 %.
Acceptability	acceptable
Remarks	
	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*

Document IIIA Growth inhibition test on algae

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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_4_1_3(02)-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, A stock solution was prepared to give the desired series of test concentrations. 0.9 mg of the test substance was added to 2 litres of dilution water and treated for 60 seconds with an ultra turrax and afterwards stirred for 24 h on a magnetic stirrer. Finally undissolved particles of the test substance were removed by filtration.
Vehicle	No (dilution water only)
Concentration of vehicle	N/A
Vehicle control performed	N/A
Other procedures	None

Table A7_4_1_3(02)-2: Test organisms

Criteria	Details
Species	*Scenedesmus subspicatus* CHODAT
Strain	Non-axenic strain
Source	The Collection of Algal Cultures' of the Institute of Plant Physiology at the University of Gottingen (Germany)
Laboratory culture	Yes
Method of cultivation	Exponentially-growing stock cultures are maintained in the test facility under constant temperature conditions (23 ± 2°C) at a light intensity in the range 60 – 120 µE. x m^{-2} x s^{-1} (measured in the range 400 to 700 nm using a spherical quantum flux meter). The nutrient medium (according to BRINGMANN & KÜHN; 1977) is renewed once a week. Cell density measurements are made using a microcell counter.
Pretreatment	Pre-cultures are set up three days before the start of a test. They are grown under identical exposure conditions as the stock cultures, except from the use of a different nutrient medium.
Initial cell concentration	Approximately 1 x 10^4 cells/ml

Table A7_4_1_3(02)-3: Test system

Criteria	Details
Volume of culture flasks	300 ml
Culturing apparatus	Erlenmeyer flasks were exposed in a light chamber in which a temperature in the range 21 °C to 25°C can be maintained at ± 2°C, and continuous uniform illumination is provided in the spectral range 400 to 700 nm.
Light quality	A light intensity in the range 60 to 120 µE. x m^{-2} x s^{-1}, or an equivalent range of 6000 to 10000 lux, is recommended for use. Light source not stated.
Procedure for suspending algae	Not stated
Number of vessels/ concentration	3 replicates per test concentration and 6 replicates per control
Test performed in closed vessels due to significant volatility of TS	Yes, stoppers

Table A7_4_1_3(02)-4: Test conditions (main test only)

Criteria	Details
Test temperature	23 ± 2° C
pH	Start: 7.7 – 8.3 End: 9.4 – 10.4
Aeration of dilution water	No
Light intensity	Approximately 6000 - 10000 lux
Photoperiod	Constant light

Table A7_4_1_3(02)-5: Cell concentration data

Test-Substance Concentration (nominal)[1] [mg a.i./l]	Cell concentrations (mean values) [cells/ml]							
	measured				Percent of control			
	0 h	24 h	48 h	72 h	0 h	24 h	48 h	72 h
Control	1000	58333	210556	336667	-	-	-	-
0.003	1000	63333	201111	350000	-	109	96	104
0.006	1000	56667	204444	343333	-	97	97	102
0.013	1000	60000	210000	344444	-	103	99	102
0.025	1000	61111	205556	350000	-	105	98	104
0.05	1000	65556	210000	361111	-	112	99	107
0.1	1000	47778	136667	222222	-	82	65	66

[1] TS concentrations were nominal

Table A7_4_1_3(02)-6: Growth (biomass) and growth rate of algae

Test-Substance Concentration (nominal)[1]	Growth (b)	Percent inhibition of Control (b)*	Growth rate (r)	Percent inhibition of Control (r)

[mg a.i./l]				
Control	412222	0.0	1.17	0.0
0.003	414444	-0.5	1.19	-1.1
0.006	407778	1.1	1.18	-0.6
0.013	417222	-1.2	1.18	-0.6
0.025	416667	-1.1	1.19	-1.1
0.05	431111	-4.6	1.20	-2.0
0.1	270556	34.4	1.03	11.8

(b), biomass, (r), growth rate

* negative values indicate growth greater than control algae

Table A7_4_1_3(02)-7: 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	**yes**	
Concentration of test substance ≥80% of initial concentration during test	**No***	
Criteria for poorly soluble test substances	**yes**	

* Results based on mean measured concentrations

‚Document IIIA Inhibition to microbial activity (aquatic)

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			Official use only
		71 REFERENCE	
71.1	**Reference**	[redacted] (2001), NAK4455 (Bayothrin) Toxicity to Bacteria, [redacted] [redacted] Report No.: 1091 A/01 B, [BES Ref: MO-03-010384] Report date: April 26, 2001 Unpublished	
71.2	**Data protection**	Yes	
71.2.1	Data owner	Bayer CropScience	
71.2.2	Companies with letters of access		
71.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		72 GUIDELINES AND QUALITY ASSURANCE	
72.1	**Guideline study**	Yes Commission Directive 88/302/EEC; Official Journal of the EC L 133 Part C (1988). This test method is in most parts identical with OECD Guideline 209.	
72.2	**GLP**	Yes	
72.3	**Deviations**	None	
		73 MATERIALS AND METHODS	
73.1	**Test material**	NAK 4455 (transfluthrin technical)	
73.1.1	Lot/Batch number	816779502	X
73.1.2	Specification	As given in section 2	X
73.1.3	Purity	95.7%	
73.1.4	Composition of Product	N/A	
73.1.5	Further relevant properties	Molecular weight: 371 g/mol	
73.1.6	Method of analysis	Not stated	
73.2	**Preparation of TS solution for poorly soluble or volatile test substances**	See table A7_4_1_4-1	

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73.3	**Reference substance**	Yes, 3,5-Dichlorophenol (97%)
73.3.1	Method of analysis for reference substance	Not stated
73.4	**Testing procedure**	
73.4.1	Culture medium	Activate sludge obtained from sewage treatment plant (Wupperverband)
73.4.2	Inoculum / test organism	See table A7_4_1_4-2
73.4.3	Test system	See table A7_4_1_4-3
73.4.4	Test conditions	See table A7_4_1_4-4
73.4.5	Duration of the test	3 hours contact time
73.4.6	Test parameter	Respiration inhibition
73.4.7	Analytical parameter	Oxygen measurement
73.4.8	Sampling	Respiration rate was determined after an aeration period of 3 hours.
73.4.9	Monitoring of TS concentration	No
73.4.10	Controls	Control without test substance, abiotic control (without activated sludge) and reference substance 3,5-Dichlorophenol
73.4.11	Statistics	Probit analysis (EC_{50} determination of reference substance).
		74 RESULTS
74.1	**Preliminary test**	Not performed
74.1.1	Concentration	N/A
74.1.2	Effect data	N/A
74.2	**Results test substance**	
74.2.1	Initial concentrations of test substance	100, 1000 and 10000 mg a.i./l
74.2.2	Actual concentrations of test substance	Not determined
74.2.3	Growth curves	N/A
74.2.4	Cell concentration data	Concentration of activated sludge – 400 mg/l suspended solids

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74.2.5	Concentration/ response curve	N/A
74.2.6	Effect data	EC_{50} >10000 mg a.i./l (highest concentration tested).
74.2.7	Other observed effects	None
74.3	**Results of controls**	Control without test substance: 30.8 mg/l·h (mean value n=2). Abiotic control: The physico chemical oxygen consumption was determined at 10000 mg/1 test substance concentration. No physico-chemical oxygen consumption has been determined. Therefore lower concentrations of the test substance equally cause no physico chemical oxygen consumption (deduced values).
74.4	**Test with reference substance**	Performed
74.4.1	Concentrations	5, 10 and 20 mg/l
74.4.2	Results	EC_{50} = 9.7 mg/l

75 APPLICANT'S SUMMARY AND CONCLUSION

75.1	**Materials and methods**	The study was conducted in accordance with Commission Directive 88/302/EEC; Official Journal of the EC L 133 Part C (1988). This test method is in most parts identical with OECD Guideline 209. The inhibitory effect of NAK 4455 (transfluthrin) on the respiration rate of aerobic wastewater microorganisms of activated sludge was investigated in a 3 hour respiration inhibition test. A mixed population of microorganisms were exposed to NAK 4455 at nominal concentrations of 100, 1000, 10000 mg/L. Two untreated controls, an abiotic control and three different concentrations of the reference item 3,5-dichlorophenol were tested in parallel. A defined amount of activated sludge was treated with synthetic nutrient medium and the respiration rate measured. This was compared with those measured in test batches containing different concentrations of the test substance. The sensitivity of the activated sludge being used was checked with 3,5-dichlorophenol.

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75.2 Results and discussion

The respiration rate and % inhibition are given below:

Test concentration (mg a.i./l)	Respiration rate - O_2 consumption (mg/l $^{-}$h)	Inhibition (%)
100	31.5	0
1000	31.5	0
10000	32.0	0
Control 1	30.0	-
Control 2	31.5	-
Reference substance (mg/l 3,5-dichlorophenol)		
5	23.3	24.4
10	16.0	48.1
20	6.0	80.5

75.2.1 EC_{20} N/A

75.2.2 EC_{50} >10000 mg a.i/l

75.2.3 EC_{80} N/A

75.3 Conclusion NAK 4455 (transfluthrin) showed 0% respiration inhibition of activated sludge at a test substance concentration of 10000 mg/1. EC_{50} > 10000 mg/1. NOEC ≥ 10000 mg/L. The results of the test with the reference substance demonstrated sufficient sensitivity of the activate sludge.

75.3.1 Reliability 1

75.3.2 Deficiencies None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02-03-2007
Materials and Methods	Applicant's version adequately reflects the report.

‚Document IIIA Inhibition to microbial activity (aquatic)

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Results and discussion	Applicant's version adequately reflects the report, but the following remark should be made: 3.1.2/3.1.3 Batch differs from those included in the batch analysis (Doc III A-2 confidential). The study was performed at 100 - 10000 mg/L, which is far (> 1750 x) above the reported water solubility (57 µg/L). It is well possible that the results of the test were influenced by the strong sorptive capacity of transfluthrin, i.e. that sorption to particles and/or vessels caused the available concentration of transfluthrin to drop below a toxic level. The test was performed according to the guidelines, and the test concentration itself is thus not a reason to consider the test as not reliable. However, it is not possible to draw a definitive conclusion as to whether the absence of effects is due to the fact that transfluthrin is indeed not toxic to bacteria or is caused by the absence of exposure. The absence of respiratory inhibition, however, possibly reflects the natural situation of transfluthrin when bacteria are exposed in the STP. Because the lipophilicity is likely to force distribution to bacterial membranes, the absence of inhibition shows that there is no intrinsic toxicity even at the highest tested doses. Therefore next to the maximum solubility also the EC_{50} > 10000 mg/l is used for risk assessment.
Conclusion	In view of the above, the test is not considered useful for risk assessment.
Reliability	2
Acceptability	useful for risk assessment
Remarks	

	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_4_1_4-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	Yes, the test substance was added to about 130 ml deionized water and stirred overnight before testing (equilibration phase).
Vehicle	No
Concentration of vehicle	N/A
Vehicle control performed	No
Other procedures	None

Table A7_4_1_4-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Species	Mixed population of aquatic organisms
Strain	N/A
Source	Aeration tank of a waste water treatment plant treating predominantly domestic sewage.
Sampling site	Wupper water (Western Germany)
Laboratory culture	Not stated
Method of cultivation	Not stated
Preparation of inoculum for exposure	Not stated
Pretreatment	Aeration of the activated sludge; daily feed with synthetic medium.
Initial cell concentration	400 mg suspended solids/l

Table A7_4_1_4-3: Test system

Criteria	Details
Culturing apparatus	Not stated - assumed to be flasks
Number of culture flasks/concentration	1
Aeration device	Yes
Measuring equipment	Not stated – assumed to be pH-electrode and O_2-electrode
Test performed in closed vessels due to significant volatility of TS	Not stated

Table A7_4_1_4-4: Test conditions

Criteria	Details
Test temperature	18.4 – 18.9ºC
pH	Start of test: 6.8 End of test: 7.2 -8.0
Aeration of dilution water	Yes
Suspended solids concentration	400 mg/l

Table A7_4_1_4-5: Validity criteria

Criteria	Fulfilled	Not fulfilled
Respiratory rate of controls differs less than 15%	yes	
Respiratory rate of the controls < 60 mg oxygen/lxh	yes	
EC50 of reference substance between 5-30 mg/L	yes	

Document IIIA — Bioconcentration in aquatic organisms

SECTION A7.4.2
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			Official use only
		76 REFERENCE	
76.1	**Reference**	[redacted] (2006). [Methylene-^{14}C]–Transfluthrin - Bioconcentration and Biotransformation in Fish (*Lepomis macrochirus*) [redacted]. [redacted] report No.: METBS004 [BES ref: M-264658-01-1] Report date: January 18, 2006 Unpublished	
76.2	**Data protection**	Yes	
76.2.1	Data owner	Bayer CropScience	
76.2.2	Companies with letters of access		
76.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		77 GUIDELINES AND QUALITY ASSURANCE	
77.1	**Guideline study**	Yes OECD 305 (1996) EPA-FIFRA § 72-6 (1982) EPA-FIFRA § 165-4 (1982) OPPTS 850.1730 (1996)	
77.2	**GLP**	Yes	
77.3	**Deviations**	None	
		78 MATERIALS AND METHODS	
78.1	**Test material**	[Methylene-^{14}C]- Transfluthrin	
78.1.1	Lot/Batch number	Sample ID: BECH 1738	X
78.1.2	Specification	As given in section 2 of Doc IIIA.	X
78.1.3	Purity	Radiochemical purity: > 99% (HPLC, TLC) Chemical purity: > 99% (HPLC, UV)	
78.1.4	Further relevant properties	Specific radioactivity: 3.67 MBq/mg Water solubility: 57 µg/L log partition coefficient octanol/water: 5.46	
78.1.5	Radiolabelling	[Methylene-^{14}C]	
78.1.6	Method of analysis	HPLC and LSC	

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78.2 Reference substance — No

78.2.1 Method of analysis for reference substance — Not applicable.

78.3 Testing/estimation procedure

78.3.1 Test system/ performance

The study was performed in 2 parts; Part 1 was a 42-day phase to examine the bioconcentration and depuration of [methylene-^{14}C]-Transfluthrin by bluegill sunfish *(Lepomis macrochirus)*, and Part 2 was a 7 to 14-day exposure to investigate the biotransformation of [methylene-^{14}C]-Transfluthrin in fish.

Part 1 (bioconcentration): Groups of 60 young bluegill sunfish were exposed in glass aquaria (100 L) under flow-through conditions to nominal concentrations of 0 (DMF solvent control) 65 and 198 ng [^{14}C]-Transfluthrin/L for a period of 28 days (these levels were determined based on the results of previously conducted fish toxicity tests and on the detection limit in water). On day 28 of the exposure period the application of [^{14}C]- Transfluthrin was stopped. The depuration phase was initiated (the aquaria were drained to a water height of ca. 5 cm, and then filled with uncontaminated dilution water); the fish were then exposed to flowing, uncontaminated, dilution water for further 14 days. The test aquaria were maintained at a mean water temperature of 22.0-22.2°C. The mean body wet weight of the fish at the beginning of the test was 1.1 ± 0.25 g (Mean ± S.D.), the mean body length was 4.2 ± 0.16 cm (Mean ± S.D.). The initial loading of 0.66 g fish/L and 0.11 g fish/L/day was in accordance with ASTM standard guidance.
The fish were observed initially and every 24 hours on working days for mortality and/or adverse behaviour. Fish were sampled during the exposure period on days 2, 3, 7, 10, 14, 21 and 28 and during the depuration period on days 29, 31 35, 38 and 42. On these days, four fish from each chamber were collected and processed (dissected) individually for *radioassay (LSC). Radioactivity in water samples was measured during the same intervals. On days 0, 28 and 42 of the study four additional fish were taken from each aquarium to determine the lipid content (using a modified method based on Bligh & Dyer (1959)).

*(*Analysis of Fish samples on days 2, 3, 7 and 10 showed inconsistencies therefore the method of fish sample preparation was changed for remaining fish to minimize inconsistencies based on the assumed volatility of the test item, which did not allow using the standard procedures for processing of fish samples).*

Part 2 (biotransformation): Groups of 15 (30 in total) bluegill sunfish were exposed in glass aquaria (100 L) under flow-through conditions to a nominal concentration of 132 ng [^{14}C]- Transfluthrin/L for a period of

7 and 14 days. The test aquaria were maintained at a mean water temperature of 22.0-22.2°C. The mean body wet weight of the fish at the beginning of the test was 18.2 ± 5.76 g (Mean ± S.D.), the mean body length was 10.5 ± 0.85 cm (Mean ± S.D.). The initial loading was 0.91 g/fish/L/day.
The fish were observed initially and every 24 hours on working days for mortality and/or adverse behaviour. Fish were sampled and divided into edible and viscera tissues on days 7 and 14; on each sampling day fifteen fish were collected and processed (dissected) individually for radioassay (LSC and combustion analysis).
Water samples (3 x 10 ml) were taken from each aquarium during the same intervals and analysed.

For the determination of metabolites in water samples 500 ml were taken from the high concentration level of part 1 (198 ng/L) and from part 2 (132 ng/L). The samples were deep-frozen up to the analysis by HPLC. In addition stock solutions (all concentrations) and water samples were analysed for content and stability in the beginning and the end of the exposure period (by HPLC).

Stock solutions of test material (in 2 L brown glass bottles) were prepared using dimethylformamide (DMF) as solvent. Stock solutions at concentrations of 0.65 mg/L, 1.98 mg/L and 1.32 mg/L were prepared to achieve test dose levels of 65 ng/L, 198 ng/L and 132 ng/L (nominal) respectively. 100 µl DMF/L dilution water (= 0.01 vol.-%) were used in this study as solvent carrier. Stock solutions and dilution water were supplied to the test aquaria at a rate of 2.5 mL/h and 25 L/hour respectively. The control aquarium also received an amount of dimethylformamide, which was equivalent to the exposure aquaria.
A dosing system was used to maintain mean water concentrations; a ProMinentR mikro g/5a dispenser (for dosing of stock solutions) and flow-meters (for water flow control) were used for the introduction of [14C]-Transfluthrin and diluent water in 2000 ml-mixing cells. The mixture was running continuously into the 100 L test aquaria.
The diluter system was calibrated by volumetric measurements of dispenser aliquots and the flow-rate of flow meters.

Water quality parameters of dissolved oxygen; temperature and pH were measured initially and throughout the study in each aquarium once a week. In addition, the daily temperature-fluctuation was measured continuously in the control tank and recorded as hourly mean values.
TOC was measured at the beginning of the test and then once a week.

For further details of dilution water, test organisms, test system and test conditions see tables A7_4_2-2 to A7_4_2-5.

78.3.2 Estimation of bioconcentration

As experimental data are available no estimates of BCF are required.

Document IIIA Bioconcentration in aquatic organisms

SECTION A7.4.2
BPD Data Set IIA / Annex Point VII.7.5

79 RESULTS

79.1 Experimental data

79.1.1	Mortality/behaviour	The fish showed no mortalities or abnormal behaviour throughout the study in all test vessels.
79.1.2	Lipid content	The mean lipid content (day 0-28) for the fish used in the study was calculated to be 6.95 % (see table A7_4_2-6).

Document IIIA Bioconcentration in aquatic organisms

SECTION A7.4.2
BPD Data Set IIA / Annex Point VII.7.5

79.1.3 Concentrations of test material during test

During the 28-day bioconcentration (uptake) phase water concentrations ranged from 61.9 ng/L to 70.0 ng/L for the nominal concentration of 65.0 ng/L and from 171 ng/L to 191 ng/L for the nominal concentration of 198 ng/L. The average water concentration (using the mean value for each sample) during the uptake phase was 66.2 ng/L (standard deviation: 2.26) ng/L for the nominal concentration of 65.0 ng/L and 178 ng/L (standard deviation: 7.44) ng/L for the nominal concentration of 198 ng/l. The parent compound Transfluthrin accounted for ca. 67 % to 100 % of the radioactivity in the profiles of water samples. X

During the 7 and 14 day biotransformation phase water concentrations ranged from 102 ng/L to 126 ng/L for the nominal concentration of 132 ng/L. The average water concentration (using the mean value for each sample) was 114 ng/L (standard deviation: 8.14) for the nominal concentration of 132 ng/L. The parent compound Transfluthrin accounted for ca. 79 % to 84 % of the radioactivity in the profiles of water samples. X

The analysis of stock solutions of the test compound from all tests revealed that [Methylene-^{14}C] - Transfluthrin was completely stable in stock solutions in the time range of up to 28 days.

Characterisation of the radioactivity (based on TRR) in fish sampled during 28 days of constant exposure and 14 days of depuration is summarized below:

Conc. (ng/L)	Sampling day	Range of mean values (dpm/g dry weight)		
		Edible parts	Viscera	Whole fish
Control	2 -10	4670.5 - 7767.8	8624.9 - 12777.4	6584.8 - 9978.9
65	2 -10	10683.5 - 15425.1	47260.3 - 66852.9	27952.2 - 38785.2
198	2 -10	18479.2 - 53735.6	92325.0 - 226238.6	52889.9 - 139070.7

Conc. (ng/L)	Sampling day	Range of mean values (dpm/g fresh weight)		
		Edible parts	Viscera	Whole fish
Control	2 –10	1130.1- 1767.1	2650.0 – 3610.6	1773.1 – 2493.5
	14 - 42	165.6 – 365.6	314.2 – 549.7	218.0 – 436.3
65	2 –10	2280.9 – 3492.2	13442.2 – 18700.0	6775.6 – 9629.6
	14 - 42	1500.3 – 9938.5	7265.1 – 59086.6	3732.9 – 28302.4
198	2 –10	3939.2 – 18415.8	24998.4 – 108513.9	12545.4 – 55276.0
	14 - 42	3696.6 – 27601.7	16297.1 – 180594.7	8460.1 – 85493.5

The mean tissue residues (given in µg/kg fresh weight) at steady state are displayed in table A7_4_2-7.

Document IIIA Bioconcentration in aquatic organisms

SECTION A7.4.2
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		Characterisation of the radioactivity in fish sampled during the biotransformation phase showed that between 74 % and 96 % of the total radioactive residue (TRR) in edibles and viscera could be identified. The major component detected in all fish samples was the active ingredient, transfluthrin. It accounted for ca. 94 % of the TRR in edibles and for 66 % – 82 % of the TRR in viscera. Total radioactive residues (TRR) measured in edibles were 0.030 µg/g (day 7) and 0.037 µg/g (day 14). In viscera, 0.165 µg/g (day 7) and 0.220 µg/g (day 14) were found.	
79.1.4	Bioconcentration factor (BCF)	A BCF calculation based on parent compound was not possible, because neither in fish nor in the water phase stable steady state metabolite concentrations were measurable. Therefore all BCF calculations are based on TRR only.	
		The steady-state-BCF_{TRR} (based on whole fish, wet weight) in the 65 ng/L test level is about 1704 and in the 198 ng/L test level about 1861.	X
		The steady-state-BCF_{TRR} normalised to 6% lipid content in fish is in the 65 ng/L test level about 1471 and in the 198 ng/L test level about 1607 (see table A7_4_2-9).	X
79.1.5	Uptake and depuration rate constants	Because of inconsistencies in radioactivity measurements during the uptake phase the uptake rate constant (Ku) could not be calculated.	
		Depuration rate constant = 0.182 – 0.227 $days^{-1}$ (for the 65.0 & 198 ng/L exposure groups, respectively). See table A7_4_2-8.	
		(The depuration rate constant (Kd) was determined using the OriginTM non-linear kinetic modeling computer programme).	
79.1.6	Depuration time	DT_{50} = 3.1 – 3.8 days (for the 198 & 65.0 ng/L exposure groups, respectively). See table A7_4_2-8.	
		(The DT50 was determined OriginTM non-linear kinetic modeling computer programme).	
79.1.7	Metabolites	In the water samples collected during the exposure phase not only Transfluthrin, but also its metabolite, Tetrafluorobenzyl alcohol was detected between 9.41 % and 33.4 %. Since Tetrafluorobenzyl alcohol was not present at the beginning (day 0) of the exposure phase but appeared soon after introduction of fish (measured at day 2) to 9.41% and increased to 33.4% on day 28 its appearance is obviously due to metabolic degradation in fish.	
		In the water samples collected during the biotransformation phase Tetrafluorobenzyl alcohol was detected between 15.72 % and 20.83 %. The metabolite Tetrafluorobenzyl alcohol was also detected in edible fish parts between 1.83% and 2.18%. This metabolite was also found in profiles from viscera (1.07 % and 2.87 %) together with its oxidation product, Tetrafluorobenzoic acid (1.95 % and 4.62 %).	X

Document IIIA Bioconcentration in aquatic organisms

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79.1.8	Other Observations	Dissolved oxygen, pH-values and test temperature were measured once a week throughout the study in all aquaria. The dissolved oxygen concentrations ranged between 82 % and 104 % saturation (mean: 93-97 %). The pH values ranged from 7.0 to 7.2 with a mean value of 7.1 for all aquaria. The weekly measured water temperatures ranged between 21.5°C and 22.7°C (mean: 22.0°C - 22.2°C). Moreover the measured temperature inside the control aquarium remained between 21.0°C and 23.0°C (mean: 22.4). *Contents of TOC (total organic carbon) in each aquarium were measured once a week. Throughout the whole biological part of the study, all measured TOC values in the test vessels did not exceed the concentration of organic carbon originating from the test item and from the solubilising agent (nominal sum TOC is about 46.3 mg/L for all test levels including control) by more than 10 mg/L as expected by OECD guideline 305.*
79.2	**Estimation of bioconcentration**	As experimental data are available no estimates of BCF are required.

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80 APPLICANT'S SUMMARY AND CONCLUSION

80.1 Materials and methods

The bioconcentration and biotransformation of [methylene-^{14}C]-Transfluthrin was investigated in Bluegill sunfish. The study was conducted in accordance to the EPA Pesticide Assessment Guidelines, Subdivision E, §72-6, Subdivision N, §165-4, OPPTS 850.1730 (1996) and OECD Guideline 305.

In the first part of the study (bioconcentration) groups of 60 bluegill sunfish were exposed in glass aquaria (100 L) under flow-through conditions to nominal concentrations of 0 (DMF solvent control) 65 and 198 ng [^{14}C]- Transfluthrin/L for a period of 28 days (these levels were determined based on the results of previously conducted fish toxicity tests and on the detection limit in water). On day 28 of the exposure period the application of [^{14}C]- Transfluthrin was stopped and the depuration phase was initiated. The fish were exposed to flowing, uncontaminated dilution water for further 14 days. The test aquaria were maintained at a mean water temperature of 22.0-22.2°C.

The fish were observed initially and every 24 hours on working days for mortality and/or adverse behaviour. Fish were sampled during the exposure period on days 2, 3, 7, 10, 14, 21 and 28 and during the depuration period on days 29, 31 35, 38 and 42. On these days, four fish from each chamber were collected and processed (dissected) individually for *radioassay (LSC). Radioactivity in water samples was measured during the same intervals. On days 0, 28 and 42 of the study four additional fish were taken from each aquarium to determine the lipid content (using a modified method based on Bligh & Dyer (1959)).

*(*Analysis of Fish samples on days 2, 3, 7 and 10 showed inconsistencies therefore the method of fish sample preparation was changed for remaining fish to minimize inconsistencies based on the assumed volatility of the test item, which did not allow using the standard procedures for processing of fish samples).*

In the second part of the study (biotransformation) groups of 15 (30 in total) bluegill sunfish were exposed in glass aquaria (100 L) under flow-through conditions to a nominal concentration of 132 ng [^{14}C]-Transfluthrin/L for a period of 7 and 14 days. The test aquaria were maintained at a mean water temperature of 22.0-22.2°C.

The fish were observed initially and every 24 hours on working days for mortality and/or adverse behaviour. Fish were sampled on days 7 and 14; on each sampling day fifteen fish were collected and processed (dissected) individually for radioassay (LSC and combustion analysis). Water samples (3 x 10 ml) were taken from each aquarium during the same intervals and analysed.

Metabolite quantification was also carried out; for the determination of metabolites in water samples 500 ml were taken from the high concentration level of part 1 (198 ng/L) and from part 2 (132 ng/L). The samples were deep-frozen up to the analysis by HPLC. In addition stock

solutions (all concentrations) and water samples were analysed for content and stability in the beginning and the end of the exposure period (by HPLC).

Stock solutions of test material (in 2 L brown glass bottles) were prepared using dimethylformamide (DMF) as solvent. Stock solutions at concentrations of 0.65 mg/L, 1.98 mg/L and 1.32 mg/L were prepared to achieve test dose levels of 65 ng/L, 198 ng/L and 132 ng/L (nominal) respectively. 100 µl DMF/L dilution water (= 0.01 vol.-%) were used in this study as solvent carrier. Stock solutions and dilution water were supplied to the test aquaria at a rate of 2.5 mL/h and 25 L/hour respectively. The control aquarium also received an amount of dimethylformamide, which was equivalent to the exposure aquaria.

A dosing system was used to maintain mean water concentrations; a ProMinentR mikro g/5a dispenser (for dosing of stock solutions) and flow-meters (for water flow control) were used for the introduction of [14C]-Transfluthrin and diluent water in 2000 ml-mixing cells. The mixture was running continuously into the 100 L test aquaria. The diluter system was calibrated by volumetric measurements of dispenser aliquots and the flow-rate of flow meters.

Water quality parameters of dissolved oxygen; temperature and pH were measured initially and throughout the study in each aquarium once a week. In addition, the daily temperature-fluctuation was measured continuously in the control tank and recorded as hourly mean values. TOC was measured at the beginning of the test and then once a week.

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80.2 Results and discussion

During exposure fish exhibited normal behaviour. No mortalities were reported at any treatment level (including the controls) throughout the study.

The mean lipid content (day 0-28) for the fish used in the study was calculated to be 6.95 %.

The parent compound transfluthrin accounted for 67 % to 100 % of the radioactivity in the profiles of water samples. The metabolite Tetrafluorobenzyl alcohol was detected between 9.41 % and 33.4 %; its appearance is considered to be due to metabolic degradation in fish. The major component detected in all fish samples was the active ingredient, transfluthrin. It accounted for ca. 94 % of the TRR in edible tissues and for 66 % – 82 % of the TRR in viscera. The metabolite Tetrafluorobenzyl alcohol was detected in edible parts between 1.83% and 2.18%. This metabolite was also found in profiles from viscera (1.07 % and 2.87 %) together with its oxidation product, Tetrafluorobenzoic acid (1.95 % and 4.62 %).

Transfluthrin has been shown to accumulate in bluegill sunfish with a total residue bioconcentration factor of about 1704 to 1861 X for whole fish (sum of radiolabelled compounds, Transfluthrin parent, metabolites and mineralization products). When exposure ceases, the residues are depurated with a half-life of 3.1 – 3.8 days. After 14 days in uncontaminated water 86 % (nominal concentration of 65.0 ng/L) and 89 % (nominal concentration of 198 ng/L), respectively, of the mean plateau radioactivity were depurated from whole fish. By extrapolation it can be calculated that 95% of the mean plateau radioactivity would have been depurated from whole fish after 13 – 17 days. Due to inconsistencies in radioactivity measurements during the uptake phase the uptake rate constant (Ku) could not be calculated. However the depuration rate constant was calculated to be (whole fish) 0.182 –0.227 $days^{-1}$ (for the 65.0 & 198 ng/L exposure groups, respectively).

The average steady-state (days 14 - 28) bioconcentration factors were 612 X (edible parts) and 1704 X (whole fish) for 65.0 ng [^{14}C]-Transfluthrin/L and 640 X (edible parts) and 1861 X (whole fish) for 198 ng [^{14}C]-Transfluthrin/L. These values correspond to the calculated steady-state total residue levels of 40.4 µg/kg edible parts and 113 µg/kg whole fish for 65 ng [14C]- Transfluthrin/L and of 114 µg/kg edible parts and 332 µg/kg whole fish for 198 ng [14C]- Transfluthrin /L, respectively.

A BCF calculation based on parent compound was not possible, because neither in fish nor in the water phase stable steady state metabolite concentrations were measurable. Therefore all BCF calculations are based on TRR only. The steady-state-BCF_{TRR} (based on whole fish, wet weight) in the 65 ng/L test level is about 1704 and in the 198 ng/L test level about 1861. The steady-state-BCF_{TRR} normalised to 6% lipid content in fish is in the 65 ng/L test level about 1471 and in the 198 ng/L test level about 1607.

Water quality measurements were within acceptable limits.

80.3 Conclusion

Continuous exposure over a 28-day period of [methylene-^{14}C]-

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		Transfluthrin to bluegill sunfish resulted in steady-state-BCF_{TRR} (normalised to 6% lipid content in fish) values of 1471 and 1607 at 65 ng/L and 198 ng/L respectively.
80.3.1	Reliability	1
80.3.2	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02-03-2007
Materials and Methods	Applicant's version is adopted with the following comment: 3.1.1/3.1.2 Batch differs from those included in the batch analysis (Doc III A.2 confidential), but purity of test substance is adequate.

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Results and discussion

Applicant's version is adopted with the following additions/amendments:

4.1.3 At exposure concentration 198 ng/L (bioconcentration study), concentrations of transfluthrin in the water phase decreased with time from 100 % of TRR at t=0 to 90.6 % at t=2 and 66.6 % at t=28. Concentrations of TFB-OH increased concurrently from n,d, at t=0 to 9.4 % of TRR at t=2 and 33.4 % at t=28.
At 132 ng/L (biotransformation study), transfluthrin accounted for 79.2 % of TRR at t=7 and 84.3 % at t=14, corresponding values for TFB-OH were 20.8 and 15.7 % of TRR.
No explanation is given for the fact that in the biotransformation study at 132 ng/L concentrations of transfluthrin are stable, this in contrast to the bioconcentration experiment at 198 ng/L.

4.1.4 BCF-values are estimated on the basis of TRR, because parent and metabolite concentrations in water and fish were not stable during the BCF-study. Based on TRR a steady state was reached. However, in the biotransformation part, concentrations of transfluthrin in water and fish were relatively stable. The following data are taken from the Appendix with HPLC analyses (bold figures calculated by RMS):

day	concentration of transfluthrin in water	fish		
		edible	viscera	total
	ug/L	ug/g	ug/g	ug/g
7	0.085	0.028	0.135	**0.163**
14	0.092	0.035	0.145	**0.180**
mean	**0.089**			**0.172**

From this, a BCF of 1938 L/kg is calculated. This figure is in good agreement with the BCF's based on TRR (1704 and 1861 L/kg at 65 and 198 ng/L). Although the BCF of 1938 L/kg is less reliable because it is based on two time points only, the calculation indicates that the BCF based on TRR can be used as a reliable estimate of the BCF for transfluthrin.

The BCF is normalised to a lipid content of 6 %. It should be noted that a lipid fraction of 5 % is currently proposed within the framework of REACH[3]. Using this fraction, normalised BCF-values would be 1226 and 1339 L/kg at 65 and 198 ng/L, respectively. For the present assessment, however, normalisation is not applied, since lipid content (6.95%) was not outside the normal range.

4.1.6 The depuration time (DT_{90}) is 10.1-12.7 days

4.1.7 The conclusion that the presence of metabolite tetrafluorobenzyl alcohol is due to biotransformation in the fish and subsequent excretion of metabolites to the water is not necessarily true. The presence of metabolites in the water phase may also be due to degradation by bacteria in the water. This observation, however, does not influence the results.

The level of metabolites (%) in organisms accounting for > 10% of residues is for TFB-OH and TFB-COOH < 5%.

[3] DRAFT RIP 3.3-2 EWG 10 Aquatic Bioaccumulation

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Conclusion	Applicant's version is adopted. BCF-values of 1704 and 1861 L/kg are used for risk assessment.
Reliability	2 Instability of the test substance, BCF value based on TRR
Acceptability	acceptable
Remarks	

	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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Findings	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_4_2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Yes, DMF (dimethylformamide)
Concentration of vehicle	Approximately 100 µl/L dilution water (= 0.01 vol.%)
Vehicle control performed	Yes, the control aquarium also received an amount of dimethylformamide, which was equivalent to the exposure aquaria.
Other procedures	No

Table A7_4_2-2: Dilution water

Criteria	Details
Source	Reconstituted Water
Alkalinity	Not stated
Hardness	48 mg $CaCO_3$/L (40 - 60 mg $CaCO_3$/L)
PH	7.0 to 7.2
Oxygen content	82 % and 104 % saturation
Conductance	Not stated

Holding water different from dilution water	No

Table A7_4_2-3: Test organisms

Criteria	**Details**
Species/strain	Bluegill Sunfish (*Lepomis macrochirus)*
Source	[redacted]
Wild caught	No
Age/size	Part 1: The mean body wet weight of the fish (lot F 1/05 B) at the beginning of the test was 1.1 ± 0.25 g (Mean ± SD), the mean body length was 4.2 + 0.16 cm (Mean ± SD). Part 2: The mean body wet weight of lot F 2/04 at the beginning of the test was 18.2 ± 5.76 g (Mean + SD), the mean body length was 10.5 + 0.85 cm (Mean + SD).
Kind of food	Brutfutter Ecostart 17, BioMar, Denmark.
Amount of food/ Feeding of animals during test	During the acclimation and Part 1 of the, fish received 2 percent of mean body-weight of a standard fish-feed. Fish in Part 2 of the study received 1 percent of mean body-weight. The amount of feed was re-calculated once per week.
Feeding frequency	Daily
Pretreatment	All test fish were held in culture tanks on a 16-hour daylight photoperiod and observed for at least 14 days prior to testing.
Therapeutic or Prophylactic Treatments	Fish received a prophylactic treatment of Oxytetracyclin-Hydrochloride (4g/100L water) following arrival.

Table A7_4_2-4: Test system

Criteria	**Details**
Test type	Flow-through
Renewal of test solution	Not applicable
Volume of test vessels	100 litres
Volume/animal	Part 1: The initial loading was 0.11 - 0.66 g fish/L Part 2: initial loading was 0.91 g fish/L/day.
Number of animals/vessel	Part 1: 60 Part 2: 15
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	Not stated

Table A7_4_2-5: Test conditions

Criteria	Details
Test temperature	21.5 – 22.7°C (control aquarium – 21 -23 °C)
Dissolved oxygen	82 – 104% saturation
PH	7.0 – 7.2
Adjustment of pH	Not stated
Aeration of dilution water	Aerated reconstituted diluent water was used during the study, however the biotransformation test aquaria were specifically aerated during the study.
Intensity of irradiation	Not stated
Photoperiod	Assumed to be 16 hours light daily

Table A7_4_2-6: Lipid content (whole fish)

Conc. (ng/L)	Fish sample No.	Day 0		Day 28		Day 42	
		g/kg fresh weight	%	g/kg fresh weight	%	g/kg fresh weight	%
Control	1	66.7	6.67	70.2	7.02	89.1	8.91
Control	2	63.5	6.35	78.3	7.83	87.2	8.72
Control	3	64.2	6.42	0.5	7.05	91.7	9.17
Control	4	53.3	5.33	51.9	5.19	82.9	8.29
65	1	82.4	8.24	83.3	8.33	91.3	9.13
65	2	74.5	7.45	78.8	7.88	82.5	8.25
65	3	94.1	9.41	65.4	6.54	84.6	8.46
65	4	74.1	7.41	71.4	7.14	97.0	9.70
198	1	52.6	5.26	60.0	6.00	93.4	9.34
198	2	75.8	7.58	58.8	5.88	82.5	8.25
198	3	81.6	8.16	78.7	7.87	97.7	9.77
198	4	40.5	4.05	77.7	7.77	80.5	8.05
Mean		68.6	6.86	70.4	7.04	88.4	8.84
Overall mean		**6.95%**					

Table A7_4_2-7: Mean tissue residues (given in µg/kg fresh weight) at steady state

	Nominal test level of 65 ng [14C]- Transfluthrin/L	Nominal test level of 198 ng [14C]- Transfluthrin/L
Edible Parts:	40.4 µg/kg (based on TRR)	114 µg/kg (based on TRR)
Non Edible Parts:	233 µg/kg (based on TRR)	690 µg/kg (based on TRR)
Whole Fish:	113 µg/kg (based on TRR)	332 µg/kg (based on TRR)

Table A7_4_2-8: Steady-state, clearance rate constant (K_d) and the time for half clearance for edible parts, viscera and for whole fish (DT_{50})

Parameter (based on TRR)	Nominal test level of 65 ng [^{14}C]- Transfluthrin/L			Nominal test level of 198 ng [^{14}C]- Transfluthrin/L		
	Edible Parts	Viscera	Whole Fish	Edible Parts	Viscera	Whole Fish
Time to Reach 80% of	10.3	8.2	8.8	9.4	6.1	7.1

Steady-State (days)						
Time to Reach 95% of Steady-State (days)	19.2	15.3	16.5	17.6	11.4	13.2
t(1/2) for Clearance (days) (DT_{50})	4.4	3.5	3.8	4.1	2.6	3.1
Clearance Rate Constant (K_d) (1/day)	0.156 (± 0.03)	0.196 (± 0.03)	0.182 (± 0.03)	0.171 (± 0.03)	0.263 (± 0.07)	0.227 (± 0.05)

Table A7_4_2-9: BCF values

Calculated BCF values	**Nominal test level of 65 ng [^{14}C]- Transfluthrin/L**	**Nominal test level of 198 ng [^{14}C]- Transfluthrin/L**
$BCF_{TRR\ (whole\ fish,\ wet\ weight)}$	1704	1861
$BCF_{TRR\ (whole\ fish,\ normalised\ to\ 6\%\ lipid\ content)}$	1471	1607

Document IIIA **SECTION A7.4.3.1** **BPD Data Set IIIA /** **Annex Point XIII.2.1**	**Prolonged toxicity to an appropriate species of fish**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	The core effects data on fish, daphnia, algae and bacterial populations in sludge result in a $PNEC_{aquatic}$ for transfluthrin of 7.0 x 10^{-7} mg/L based upon the toxicity to rainbow trout (Doc IIA, Section 4.2). Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the aquatic environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for insect control in and around homes, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and entrance to the aquatic environment is very limited resulting in negligible exposure of aquatic organisms. The worst case contamination of surface water was identified as *via* washing of treated room surfaces following use of transfluthrin formulated as 'Raid Portable Electric'. The PEC surface water has been estimated as 3.3 x 10^{-8} mg/L with an associated worst case sediment PEC of 3.6 x 10^{-5} mg/kg (relevant Doc IIB, Section 3.3). In fact, from the relatively high log Kow (5.46) and the low water solubility (0.0575 mg/L) presence of transfluthrin in waste water (Doc IIB, Section 3.3) will be very limited. It is therefore considered that exposure of both surface water and sediment to transfluthrin will be negligible. From the core data set and the insignificant environmental concentrations an unacceptable risk to the aquatic environment following use of transfluthrin based household products is not shown. Moreover, as transfluthrin belongs to the chemistry of pyrethroids, its toxicity is likely to be rapidly developed, being fully expressed in acute studies. This is confirmed by the stable LC_{50} to rainbow trout at 48 and 96 hours of 0.7 µg/L each, showing no increase in toxicity with time. Hence, a prolonged toxicity study to an appropriate species of fish will not provide additional information of relevance for the risk assessment to the aquatic environment and as such, further testing is not justified.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

Document IIIA	Prolonged toxicity to an appropriate species of fish
SECTION A7.4.3.1 **BPD Data Set IIIA / Annex Point XIII.2.1**	
Date	02-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECaquatic and perform the risk assessment for surface water.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.4.3.2** **BPD Data Set IIIA / Annex Point XIII.2.2**	**Effects on reproduction and growth rate on an appropriate species of fish**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	The core effects data on fish, daphnia, algae and bacterial populations in sludge result in a $PNEC_{aquatic}$ for transfluthrin of 7.0 x 10^{-7} mg/L based upon the toxicity to rainbow trout (Doc IIA, Section 4.2). Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the aquatic environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for insect control in and around homes, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and entrance to the aquatic environment is very limited resulting in negligible exposure of aquatic organisms. The worst case contamination of surface water was identified as *via* washing of treated room surfaces following use of transfluthrin formulated as 'Raid Portable Electric'. The PEC surface water has been estimated as 3.3 x 10^{-8} mg/L with an associated worst case sediment PEC of 3.6 x 10^{-5} mg/kg (relevant Doc IIB, Section 3.3). In fact, from the relatively high log Kow (5.46) and the low water solubility (0.0575 mg/L) presence of transfluthrin in waste water (Doc IIB, Section 3.3) will be very limited. It is therefore considered that exposure of both surface water and sediment to transfluthrin will be negligible. From the core data set and the insignificant environmental concentrations an unacceptable risk to the aquatic environment following use of transfluthrin based household products is not shown. It needs to be considered, that transfluthrin belongs to the chemistry of pyrethroids. Hence, its toxicity is likely to be rapidly developed, being fully expressed in acute studies that result in mortality. This is confirmed by the stable LC_{50} to rainbow trout at 48 and 96 hours of 0.7 µg/L each, showing no increase in toxicity with time. As from the acute toxicity no risk to fish is deduced, it is highly unlikely that a study following effects on reproduction of fish after prolonged exposure would give any additional information that would be required to assess the risk to the aquatic environment. Moreover, transfluthrin is not persistent in the aquatic environment (DT_{50} in water phase ca. <2 days, see Doc. IIIA Section 7.1.2.2.2, Hellpointer, E. 1993) and therefore, long-term effects are unlikely. Overall, the risk to fish can be described by the current data set as minimal considering the intended uses as household products and therefore, further testing of fish for effects on reproduction and growth rate is not justified.	

Document IIIA **SECTION A7.4.3.2** **BPD Data Set IIIA / Annex Point XIII.2.2**	**Effects on reproduction and growth rate on an appropriate species of fish**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECaquatic and perform the risk assessment for surface water.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.4.3.3.1** **BPD Data Set IIIA /** **Annex Point XIII.2.3**	**Bioaccumulation in an appropriate species of fish**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	The proposed uses of transfluthrin in the EU are for insect control in and around homes, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and entrance to the aquatic environment is very limited resulting in negligible exposure of aquatic organisms. The worst case contamination of surface water results from the use of transfluthrin formulated as 'Raid Portable Electric'. Worst case estimations (relevant Doc IIB, Section 3.3) from the amateur indoor use of transfluthrin in a heated vaporiser (Raid Portable Electric), with subsequent deposition and transfer of residues from room surfaces to wastewater, results in negligible concentrations in surface water (<3.3 x 10^{-8} mg/l). The bioconcentration factor of transfluthrin as examined under flow-through conditions using Bluegill sunfish (*Lepomis macrochirus*) was 1471 – 1607, but significant metabolism into more polar metabolites occurred in the fish tissue. Hence, transfluthrin is not persistent in the fish and will be eliminated if exposure is interrupted (estimated clearance time for 50% depuration 3.8 days) (see Doc IIIA, Section 7.4.2). Based upon the very low concentrations in surface water resulting from use of household products a risk for secondary poisoning is not indicated. Following the Technical Guidance Document on Risk Assessment in Support of 98/8/EC, biomagnification in the food chain is also not indicated based upon a BCF < 2000. This is given by a biomagnification factor of 1. Therefore the intrinsic properties of transfluthrin are effectively covered by a) the available data on bioconcentration in fish b) the effects data on aquatic organisms, c) potential predators (bird, mammals), d) transfluthrin is not persistent in fish and e) the risk for secondary poisoning is low. Further data on bioaccumulation in the aquatic system are not therefore deemed necessary.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	02-03-2007	

Document IIIA	Bioaccumulation in an appropriate species of fish
SECTION A7.4.3.3.1 **BPD Data Set IIIA / Annex Point XIII.2.3**	
Evaluation of applicant's justification	The available information from the bioconcentration study with Bluegill sunfish is considered sufficient to address the risks of bioaccumulation.
Conclusion	No additional data needed.
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	

Document IIIA **SECTION A7.4.3.3.2** **BPD Data Set IIIA / Annex Point XIII.2.3**	**Bioaccumulation in an appropriate invertebrate species**
	JUSTIFICATION FOR NON-SUBMISSION OF DATA (Official use only)
Other existing data [ ] **Technically not feasible [ ]** **Scientifically unjustified [✓]** **Limited exposure [✓]** **Other justification [ ]**	
Detailed justification:	The core effects data on fish, daphnia, algae and bacterial populations in sludge result in a $PNEC_{aquatic}$ for transfluthrin of 7.0 x 10^{-7} mg/L based upon the toxicity to rainbow trout (Doc IIA, Section 4.2). Exposure of Bluegill sunfish (*Lepomis macrochirus*) to transfluthrin under flow-through conditions resulted in a BCF of 1471 - 1607 (see Doc IIIA, Section 7.4.2). Significant metabolism of the parent compound in fish tissue was observed and as a consequence, depuration was fast with a clearance half life of ca. 3.8 days. The proposed uses of transfluthrin in the EU are for insect control in and around homes, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, there is no direct release to the aquatic environment. The worst case contamination of surface water was identified as *via* washing of treated room surfaces following use of transfluthrin formulated as 'Raid Portable Electric'. The PEC surface water has been estimated as 3.3 x 10^{-8} mg/L with an associated worst case sediment PEC of 3.6 x 10^{-5} mg/kg (relevant Doc IIB, Section 3.3). From the available data no unacceptable risk to the aquatic environment is shown. The intrinsic properties of transfluthrin are well described by the experimentally derived bioconcentration factor in fish as well as the effects data on algae, fish, daphnia and bacterial populations in sewage sludge. As the outdoor exposure resulting from the use of household devices for insect control is extremely low, the risk to the aquatic environment is minimal. Given that there is also no direct release to surface water additional tests to evaluate the bioaccumulation in aquatic invertebrates are not justified.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02-03-2007
Evaluation of applicant's justification	The available information on bioaccumulation in fish is considered sufficient to address the risks of bioaccumulation.
Conclusion	Further information is not required.

Document IIIA	Bioaccumulation in an appropriate invertebrate species
SECTION A7.4.3.3.2 **BPD Data Set IIIA / Annex Point XIII.2.3**	
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	

Document IIIA **SECTION A7.4.3.4** **BPD Data Set IIIA / Annex Point XIII.2.4**	**Effects on reproduction and growth rate with an appropriate invertebrate species**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	The core effects data on fish, daphnia, algae and bacterial populations of sludge result in a $PNEC_{aquatic}$ for transfluthrin of 7.0×10^{-7} mg/L based upon the toxicity to rainbow trout (Doc IIA, Section 4.2). Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the aquatic environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for insect control in and around homes, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and entrance to the aquatic environment is very limited resulting in negligible exposure of aquatic organisms. The worst case contamination of surface water was identified as *via* washing of treated room surfaces following use of transfluthrin formulated as 'Raid Portable Electric'. The PEC surface water has been estimated as 3.3×10^{-8} mg/L with an associated worst case sediment PEC of 3.6×10^{-5} mg/kg (relevant Doc IIB, Section 3.3). In fact, from the relatively high log Kow (5.46) and the low water solubility (0.0575 mg/L) presence of transfluthrin in waste water (Doc IIB, Section 3.3) will be very limited. It is therefore considered that exposure of both surface water and sediment to transfluthrin will be negligible. Toxicity to aquatic invertebrates was within the range of toxicity to rainbow trout, with an EC_{50} of 0.0012 mg a.s./l. Hence, a special concern for aquatic invertebrates is not raised by the effects data from fish, daphnia and algae. From these properties and the very low or negligible environmental loading an unacceptable risk to the aquatic environment following use of transfluthrin based household products is not shown. This includes the consideration of the higher safety factor for transfer from acute to chronic risk. It needs to be considered, that transfluthrin belongs to the chemistry of pyrethroids. Hence, its toxicity is likely to be fully expressed in acute studies. The low acute toxicity to daphnia (as a sensitive species for aquatic invertebrates) provides strong support that a study following effects on reproduction of daphnia after prolonged exposure would not give any useful additional information on risk to the aquatic environment. Moreover, transfluthrin is not persistent in the aquatic environment (DT_{50} in water phase ca. <2 days, see Doc. IIIA Section 7.1.2.2.2, Hellpointer, E. 1993) and therefore, long-term effects are unlikely. Overall, the risk to aquatic invertebrates can be described by the current data set as minimal considering the intended uses as household products. Therefore, further testing for effects on reproduction and growth rate are not deemed necessary nor scientifically	

Document IIIA SECTION A7.4.3.4 BPD Data Set IIIA / Annex Point XIII.2.4	Effects on reproduction and growth rate with an appropriate invertebrate species
	justified.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECaquatic and perform the risk assessment for surface water.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.4.3.5** **BPD Data Set IIIA / Annex Point XIII.3.4**	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for small scale localised use, as domestic (amateur) insecticides, both indoors and outdoors e.g. patio use. Therefore it is considered that there will be negligible exposure to the outdoor aquatic and terrestrial compartments and low, localised exposure of the air compartment (see Doc's IIB, section 3.3). The worst case contamination of surface water results from the use of transfluthrin formulated as 'Raid Portable Electric'. Worst case estimations (relevant Doc IIB, section 3.3) from the use of transfluthrin in a vaporizer (Raid Portable Electric) results in negligible concentrations in surface water (<3.3 x 10^{-8} mg/L). Worst case contamination of soil *via* atmospheric deposition is from the use of one coil (Baygon mosquito coil); exposure is estimated to be 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). The respective aquatic and terrestrial PEC/PNEC ratios have been calculated to be significantly < 1 and therefore the risk to the aquatic and terrestrial environments are considered to be acceptable (relevant Doc IIC, Section 2). The worst case contamination of air results from the use of transfluthrin formulated as 'Raid Portable Electric'. Worst case estimations (Doc IIB, section 3.3) from the amateur indoor use of transfluthrin in a vaporizer (Raid Portable Electric) results in significantly low, localised concentrations in air (between 1.3 x 10^{-10} (100m from source) and 0.00735 mg/m^3 (indoor air concentration). A qualitative assessment based on the low toxicity of transfluthrin to birds and mammals and the low, localised exposure indicates that the risk to vertebrates (including 'companion animals' or pets) is minimal. Given that transfluthrin is a pyrethroid insecticide no residual toxic effects on plants are expected from any exposure route. Overall it is considered that the proposed uses pose no unacceptable risk to flora and fauna in the environment. The data set provided with the estimation on the environmental concentrations resulting from amateur use of household insecticides are considered sufficient to describe the risk profile of transfluthrin and its products. Hence, additional data will not give further information considered relevant for the proposed uses of transfluthrin in the EU. Additional tests are as such not scientifically justified.	

Document IIIA SECTION A7.4.3.5 BPD Data Set IIIA / Annex Point XIII.3.4	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-03-2007
Evaluation of applicant's justification	Information is available to derive PNECs for the aquatic and terrestrial compartment. Exposure of other specific non-target organisms is not considered relevant.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.4.3.5.1** **BPD Data Set IIIA / Annex Point XIII.3.4**	**Effects on sediment dwelling organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the aquatic environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for insect control in and around homes, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and entrance to the aquatic environment is very limited resulting in negligible exposure of aquatic organisms The freshwater $PNEC_{sed}$ is 7.6 x 10^{-4} mg/kg (wet wt) (Doc IIA, Section 4.2) (note that the $PNEC_{sed}$ includes a safety factor of 1000 versus the PNEC surface water by using the equilibrium partitioning and hence reflects an additional margin of safety). Due to the relatively high lipophilicity of transfluthrin (log Kow 5.46 and low water solubility (0.057 mg/l)) only limited amounts of compound are likely to reach the environment through wastewater (Doc IIB, section 3.3). However, worst case PECs (for Raid Portable Electric) in freshwater sediment were estimated (Doc IIB, Section 3.3), as follows: 2.1 x 10^{-8} mg/kg (single use) and 8.3 x 10^{-6} mg/kg (illustrative worst case) for discharge via a STP and 8.9 x 10^{-8} mg/kg (single use) and 3.6 x 10^{-5} mg/kg (illustrative worst case) for discharge direct to surface water. Comparison of these worst case exposure levels with the estimated $PNEC_{sed}$ value of 7.6 x 10^{-4} mg/kg (relevant Doc IIC, Section 2) demonstrate that the proposed uses of transfluthrin pose no risk to sediment dwelling organisms. The risk to sediment dwelling organisms using the equilibrium partitioning method had been shown to be acceptable; in addition there will be negligible exposure of sediment. Therefore the need to conduct studies on the effects to sediment dwelling organisms is considered to be scientifically unjustified.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	26-03-2007	

Document IIIA	Effects on sediment dwelling organisms
SECTION A7.4.3.5.1 **BPD Data Set IIIA / Annex Point XIII.3.4**	
Evaluation of applicant's justification	The initial risk assessment as performed by RMS points at a potential risk for sediment organisms after the indirect emission of transfluthrin via waste water (see Doc IIC, section 2.1.1). The initial risk assessment is based on data for the aquatic compartment. According to the TGD, the risks for sediment should be further addressed by conducting tests with benthic organisms using spiked sediment.
Conclusion	A test with benthic organisms using spiked sediment is considered necessary.
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	

Document IIIA	**Aquatic plant toxicity**	
SECTION A7.4.3.5.2 **BPD Data Set IIIA /** **Annex Point XIII.3.4**		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the aquatic environment will only arise from the use and disposal of transfluthrin products. The proposed uses of transfluthrin in the EU are for insect control closely associated with domestic areas, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and entrance to the aquatic environment is very limited resulting in negligible exposure of aquatic organisms. The worst case contamination of surface water was identified as *via* washing of treated room surfaces following use of transfluthrin formulated as 'Raid Portable Electric'. The PEC surface water has been estimated as 3.3 x 10^{-8} mg/L with an associated worst case sediment PEC of 3.6 x 10^{-5} mg/kg (relevant Doc IIB, Section 3.3). In fact, the relatively high log Kow (5.46) and low water solubility (0.0575 mg/L) mean that it is unlikely that transfluthrin will be present in wastewater (Doc IIB, Section 3.3). It is therefore considered that exposure of both surface water and sediment will be negligible. Toxicity of transfluthrin to aquatic algae is low, as expected from its insecticidal efficacy. The acute toxicity was determined with E_bC_{50} - and E_rC_{50} -values of >44 and >100 µg/L, respectively, indicating that toxic effects on algae are unlikely in the aquatic environment. Green algae, representative to some extent to plants, are the least sensitive species of the aquatic organisms tested and therefore, aquatic plants are not expected to be at risk from the proposed uses. Due to the negligible exposure of aquatic plants, the need to conduct studies on aquatic plant toxicity is considered to be scientifically unjustified.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	26-03-2007	

Document IIIA	Aquatic plant toxicity
SECTION A7.4.3.5.2 **BPD Data Set IIIA / Annex Point XIII.3.4**	
Evaluation of applicant's justification	Information is available to derive a PNECaquatic and perform the risk assessment for surface water. Since the product under consideration is an insecticide, information on aquatic plants in addition to algae is not considered necessary.
Conclusion	Further information is not required.
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	

Document IIIA SECTION A7.5.1.1 BPD Data Set IIA / Annex Point VII.7.4	Inhibition to microbiological activity (soil)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	A $PNEC_{soil(equil)}$ was estimated using the equilibrium partitioning method and was calculated as 6.2 x 10^{-4} mg/kg (Doc IIA, section 4.2). An active sludge respiration inhibition study (Doc IIIA, Section 7.4.1.4) showed that transfluthrin has low toxicity to aquatic microbial activity (EC_{50} > 10000 mg/l) therefore the estimated $PNEC_{soil(equil)}$ is considered to be extremely conservative. Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The proposed uses of transfluthrin in the EU are for insect control closely associated with domestic areas, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and direct exposure of soil is not anticipated. Worst case contamination of soil *via* atmospheric deposition is from the use of one coil (Baygon mosquito coil); exposure is estimated to be 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode after typical use of transfluthrin (8 hours) some degradation can be expected that results in further reduction of deposition (25% reduction in concentration). As a conclusion, soil exposure from use and disposal is considered to be negligible (see relevant Doc IIB, section 3.3.4). Based upon the low exposure, the low toxicity of transfluthrin to bacterial populations of sludge covering a broad range of different microbes, the risk for the terrestrial environment is minimal. Therefore, additional studies on the effects to soil non-target micro-organisms are not deemed necessary.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

Document IIIA	Inhibition to microbiological activity (soil)
SECTION A7.5.1.1 **BPD Data Set IIA / Annex Point VII.7.4**	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECsoil and perform the risk assessment for the terrestrial compartment. Since no risks are identified, the available information is considered sufficient.
Conclusion	Further information is not required.
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	

Document IIIA

Earthworm, acute toxicity test

SECTION A7.5.1.2
BPD Data Set IIIA / Annex Point XIII.3.2

			Official use only
		81 REFERENCE	
81.1	**Reference**	[redacted] (1991) Toxicity of NAK 4455 (tech.) to Earthworms, [redacted] [redacted] Report No. HBF/Rg 152, [BES Ref: MO-03-009355] Report date: November 22, 1991 Unpublished	
81.2	**Data protection**	Yes	
81.2.1	Data owner	Bayer CropScience	
81.2.2	Companies with letters of access		
81.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its inclusion on Annex I	
		82 GUIDELINES AND QUALITY ASSURANCE	
82.1	**Guideline study**	Yes OECD-Guideline No. 207 "OECD-Guideline for Testing Chemicals," "Earthworm, Acute Toxicity Tests", April 4, 1984	
82.2	**GLP**	Yes	
82.3	**Deviations**	No	
		83 METHOD	
83.1	**Test material**	NAK 4455 (transfluthrin technical)	
83.1.1	Lot/Batch number	250 987	X
83.1.2	Specification	As given in section 2	X
83.1.3	Purity	94.8%	
83.1.4	Composition of Product	N/A	
83.1.5	Further relevant properties	Description of test substance: brown clear melting Solubility in water: 0.057 mg/1	
83.1.6	Method of analysis	Not stated	
83.2	**Reference substance**	Yes, chloracetamide A.R, validation test performed separately in July of the same year	
83.2.1	Method of analysis for reference	Not stated	

Document IIIA **Earthworm, acute toxicity test**

SECTION A7.5.1.2
BPD Data Set IIIA / Annex Point XIII.3.2

	substance	
83.3	**Testing procedure**	
83.3.1	Preparation of the test substance	See table A7_5_1_2-1
83.3.2	Application of the test substance	2.81 g of the test substance was dissolved in 50 ml of acetone to obtain the stock solution. Test concentrations for the study were prepared by mixing equivalent parts of this stock solution into acetone. 5 ml of these solutions were then sprayed to each test container (with a chromatographic sprayer) onto the test substrate (consisting of 69% quartz sand, 10% peat, 20% kaolin clay and 1% calcium carbonate) while mixing thoroughly with a domestic mixer. At the same time, 100 ml of deionised water was mixed into the test substrate. The substrate was then aerated/mixed for some minutes to evaporate acetone.
83.3.3	Test organisms	See table A7_5_1_2-2
83.3.4	Test system	See table A7_5_1_2-3
83.3.5	Test conditions	See table A7_5_1_2-4
83.3.6	Test duration	14 days
83.3.7	Test parameter	Mortality and body weight of test animals.
83.3.8	Examination	Seven days after the start of the study, the number of surviving earthworms was counted by emptying the substrate out onto an inert surface and removing the earthworms by hand. The animals were then returned to the test container with the substrate. After 14 days, the weight and the number of surviving earthworms were determined. Earthworms which showed no reaction upon being prodded with a blunt probe were considered dead.
83.3.9	Monitoring of test substance concentration	Not required
83.3.10	Statistics	The LC_{50} was determined by Probit-Analysis according to the 'Maximum Likelihood' method. Weight alterations of the test organisms were statistically evaluated by the U-Test of Wilcoxon, Mann & Whitney (L. SACHS: Angewandte Statistik, Springer Verlag 1978; Probability level P = 0.05, two sided).
		84 RESULTS
84.1	**Filter paper test**	Not performed
84.1.1	Concentration	N/A
84.1.2	Number/ percentage of animals showing adverse effects	N/A

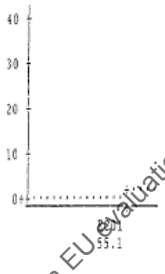
Document IIIA

Earthworm, acute toxicity test

SECTION A7.5.1.2

BPD Data Set IIIA / Annex Point XIII.3.2

84.1.3	Nature of adverse effects	N/A
84.2	**Soil test**	
84.2.1	Initial concentrations of test substance	10, 18, 32, 56, 100, 178, 316 and 562 mg/kg dry weight artificial soil
84.2.2	Effect data (Mortality)	See tables A7_5_1_2-5 and A7_5_1_2-6
84.2.3	Concentration / effect curve	



84.2.4	Other effects	Mean weight change in surviving worms:

Concentration (mg a.i./kg dry weight soil)	Weight change (%)
Control (solvent)	- 8 ± 5
10	+3 ± 7
18	+2 ± 4
32	-8 ± 3
56	-21 ± 5
100	-30 ± 6
178	-52 ± 7
316	-45 ± 1
562	-49 ± 0

40 worms per test concentration (n =4 test containers)

84.3 Results of controls

84.3.1	Mortality	No mortality occurred in the controls.
84.3.2	Number/ percentage of	None

	earthworms showing adverse effects		
84.3.3	Nature of adverse effects	N/A	
84.4	**Test with reference substance**	Performed	
84.4.1	Concentrations	10, 18, 24, 32 and 56 mg/kg	
84.4.2	Results	The 14 day LC_{50} was determined to be 32.6 mg/kg dry weight substrate (95% limits 30.4 - 35.8 mg/kg) (test performed 27th June 1991). The value is within the concentration range determined in international ring studies.	
		85 APPLICANT'S SUMMARY AND CONCLUSION	
85.1	**Materials and methods**	The study was conducted to OECD-Guideline No. 207 "OECD-Guideline for Testing Chemicals," "Earthworm, Acute Toxicity Tests", April 4, 1984. Earthworms were exposed to NAK 4455 (a.i. transfluthrin) for 14 days at nominal concentrations of 10, 18, 32, 56, 100, 178, 316 and 562 mg a.i./kg in an artificial soil consisting of sand, clay mineral and peat (10%). The test compound was thoroughly mixed into the artificial soil prior to the addition of the test organisms. After 7 and 14 days the number of surviving animals and their weight changes (day 14 only) during the test period were determined.	
85.2	**Results and discussion**	No control mortalities occurred during the test. No mortality was observed at concentrations of 10, 18 and 32 mg a.i./kg. 3, 5, 43, 85 and 98% earthworm mortality was observed at concentrations of 56, 100, 178, 316 and 562 mg a.i./kg respectively. Concentration related weight changes were also observed at 56 and 100 mg a.i./kg .	
85.2.1	NOEC	32 mg/kg dry weight soil based upon weight alterations)	
85.2.2	LC_{50}	14 day LC_{50} - 194 mg a.i./kg dry weight soil (95% confidence limits 172 - 219 mg/kg) (based on nominal test concentrations).	X
85.2.3	LOEC	56 mg/kg dry weight soil	
85.3	**Conclusion**	See validity criteria summarized in table A7_5_1_2-7.	
85.3.1	Other Conclusions	None	
85.3.2	Reliability	1	
85.3.3	Deficiencies	None	

Document IIIA

Earthworm, acute toxicity test

SECTION A7.5.1.2
BPD Data Set IIIA / Annex Point XIII.3.2

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02-03-2007
Materials and Methods	Applicant's version is adopted with the following comment: 3.1.1/3.1.2 Batch differs from those included in the batch analysis (Doc III A.2 confidential).
Results and discussion	Applicant's version is adopted with the following amendment: 5.2.2 LC50 is 194 mg/kg, based on nominal concentrations of the test substance. Purity is < 95 %, so correction is applied. Corrected for purity of 94.8 %, the LC50 is 184 mg as/kg dwt soil.
Conclusion	Applicant's version is adopted. The result LC50 184 mg/kg dwt soil (10 % OM) is used for risk assessment.
Reliability	1
Acceptability	acceptable
Remarks	
	COMMENTS FROM ... *(specify)*
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_5_1_2-1: Preparation of TS solution

Criteria	Details
Type and source of dilution water	no dilution in water, carrier pure acetone
Alkalinity / Salinity	-
Hardness	-
pH	-

Oxygen content	-
Conductance	-
Holding water different from dilution water	No
In case of the use of an organic solvent	
Dispersion	Yes, the test substance was weighed, added to acetone and stirred on a magnetic stirrer for one hour.
Vehicle	Yes, solvent - acetone
Concentration of vehicle	Not stated
Vehicle control performed	Yes, acetone control (acetone evaporated off prior to test start)
Other procedures	None

Table A7_5_1_2-2: Test organisms

Criteria	Details
Species/strain	*Eisenia foetida andrei*
Source of the initial stock	[redacted]
Culturing techniques	Worms were maintained at 22 ± 2°C, 70-90% relative humidity, 12:12 hour light/dark cycle. Culturing substrate consists of 70% (by weight) of natural soil, 25% peat, and 5% straw (dry weight). Worms were fed ground dried cattle manure at 14-intevals, at the same time the substrate is replenished with water. At approximately half-yearly intervals the animals are transferred to fresh substrate.
Age/weight	Weight of worms used in test at Day 0 ranged from 0.30 – 0.43 g (mean weight 0.331g).
Pre-treatment	The day prior to the study start, worms were removed from breeding substrate for adaptation and placed in test substrate (without test substance) and held under test conditions (20 ± 2°C, 70-90% relative humidity and constant light (400-800 lux)) until the start of the study.

Table A7_5_1_2-3: Test system

Criteria	Details
Artificial soil test substrate	The test substrate consists of 69% fine quartz sand (84% of the sand has a particle size of 0.06-0.2mm), 10% dried, finely ground peat (sphagnum peat, pH 2-4), 20% kaolin (kaolinite content of approx. 36%, pH approx. 7 and about 1% calcium carbonate (pure) to adjust to the pH value of 6 ± 0.5 (dry weight).
Size, volume and material of test container	1.5 L preserving jars
Amount of artificial soil (kg)/ container	0.5 kg dry weight per test vessel
Nominal levels of test concentrations	10, 18, 32, 56, 100, 178, 316 and 562 mg/kg artificial soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Not stated
Test performed in closed vessels due to significant volatility of test substrate	Yes, test vessels were covered with glass lids

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	20 ± 1°C
Moisture content Water content in % of the maximum water capacity	52.8 and 53.9
pH	Start of test: 5.97 / 5.94 End of test: 6.48 / 6.39
Adjustment of pH	Yes, about 1% calcium carbonate (pure) to adjust to the pH value to 6 ± 0.5 (dry weight).
Light intensity / photoperiod	Constant light (400-800 lux)
Relevant degradation products	None, not required

Table A7_5_1_2-5: Mortality data

Test Substance Concentration (nominal) [mg/kg artificial soil]	Mortality			
	Number		Percentage	
	7 d	14 d	7 d	14 d
Control	0	0	0	0
10	0	0	0	0
18	0	0	0	0
32	0	0	0	0
56	1	1	3	3
100	1	2	3	5
178	17	17	43	43
316	33	34	83	85
562	39	39	98	98

If it is not stated to the contrary the given values are means from n =4 test vessels, each with 10 worms.

Table A7_5_1_2-6: Effect data

	14 d [mg a.i./kg soil][1]	**95 % c l.**
NOEC	32	-
LC_{50}	194	172 - 219
LOEC	56	-

[1] effects data are based on nominal (n) concentrations

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD 207

	fulfilled	**Not fulfilled**
Mortality of control animals < 10%	**yes**	

Document IIIA	**Acute toxicity to plants**	
SECTION A7.5.1.3 **BPD Data Set IIIA / Annex Point XIII.3.4**		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	A $PNEC_{soil}$ was estimated using the equilibrium partitioning method and was calculated as 6.2 x 10^{-4} mg/kg (Doc IIA, section 4.2). In addition experimental data show that the acute toxicity of transfluthrin to earthworms is low (Doc IIIA, section 7.5.1.2); the $PNEC_{soil}$ (based on assessment factors) was calculated to be 0.07 mg/kg (Doc IIA, section 4.2). Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The proposed uses of transfluthrin in the EU are for insect control closely associated with domestic areas, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and direct exposure of soil is not anticipated. Worst case contamination of soil *via* atmospheric deposition is from the use of one coil (Baygon mosquito coil); exposure is estimated to be 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode after typical use of transfluthrin (8 hours) some degradation can be expected that results in further reduction of deposition (25% reduction in concentration). As a conclusion, soil exposure from use and disposal is considered to be negligible (see relevant Doc IIB, section 3.3.4). Moreover, transfluthrin is a pyrethroid that is non-toxic to algae and due to its insecticidal spectrum, not expected to be toxic to terrestrial plants. Based upon the low exposure and the low algal toxicity, the risk for terrestrial plants arising from use of transfluthrin in households is minimal. Therefore, additional studies on the effects to terrestrial plants are not required.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

Document IIIA	Acute toxicity to plants
SECTION A7.5.1.3 **BPD Data Set IIIA / Annex Point XIII.3.4**	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECsoil and perform the risk assessment for the terrestrial compartment. Since no risks are identified, the available information is considered sufficient.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.5.2.1** **BPD Data Set IIIA / Annex Point XIII.3.2**	**Reproduction study with other soil non-target macro-organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Acute earthworm toxicity data show that the active substance transfluthrin is of low toxicity to earthworms (14 day LC_{50} 194 mg/kg dry weight soil, corrected for OM (organic matter) content to 66 mg/kg). The $PNEC_{soil}$ based upon the maximum safety factor of 1000 was calculated to be 0.07 mg/kg (Doc IIA, section 4.2). Moreover, the NOEC was determined to be 32 mg/kg dw, hence the toxicity of the compound is well described by its acute effects, with sublethal effects not observed at concentrations 6 times lower than the LC_{50} for mortality. The PNEC appears therefore a very conservative approach. Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The proposed uses of transfluthrin in the EU are for insect control closely associated with domestic areas, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and in addition, direct contamination of soil is not anticipated as there is no use in relation to soil. Worst case contamination of soil *via* atmospheric deposition is from the use of one coil (Baygon mosquito coil); exposure is estimated to be 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode after typical use of transfluthrin (8 hours) some degradation can be expected that results in further reduction of deposition (25% reduction in concentration). As a conclusion, soil exposure from use and disposal is considered to be negligible (see relevant Doc IIB, section 3.3.4). Based upon the low acute toxicity of transfluthrin to earthworms including the high NOEC for sublethal effects, the extremely low deposition to soil, a risk to soil macro-organisms is not shown. As transfluthrin is exhibiting its toxicity-like other pyrethroids-on short term lethal effects, the risk to soil macro-organisms is sufficiently described by the available study and the corresponding PEC values. A reproduction study is therefore not scientifically justified.	

Document IIIA **SECTION A7.5.2.1** **BPD Data Set IIIA / Annex Point XIII.3.2**	**Reproduction study with other soil non-target macro-organisms**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECsoil and perform the risk assessment for the terrestrial compartment. Since no risks are identified, the available information is considered sufficient.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.5.2.2** **BPD Data Set IIIA / Annex Point XIII.3.2**	**Long-term test with terrestrial plants**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	A $PNEC_{soil(equil)}$ was estimated using the equilibrium partitioning method and was calculated to be 6.2 x 10^{-4} mg/kg (Doc IIA, section 4.2). Experimental data show that transfluthrin in not toxic to algae, which represent a primary producer and are related to the plant organism. Also, toxicity to earthworms is low (Doc IIIA, section 7.5.1.2); the $PNEC_{soil}$ (based on the most conservative assessment factor of 1000) was calculated to be 0.07 mg/kg (Doc IIA, section 4.2). Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The proposed uses of transfluthrin in the EU are for insect control closely associated with domestic areas, e.g. indoor/patio use of electric vaporizers, glowing mosquito coils on terraces and/or anti-moth discs. Therefore, release is on a small scale and direct exposure of soil is not anticipated. Worst case contamination of soil *via* atmospheric deposition is from the use of one coil (Baygon mosquito coil); exposure is estimated to be 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode after typical use of transfluthrin (8 hours) some degradation can be expected that results in further reduction of deposition (25% reduction in concentration). As a conclusion, soil exposure from use and disposal is considered to be negligible (see relevant Doc IIB, section 3.3.4). Moreover, transfluthrin is a pyrethroid that is non-toxic to algae and due to its insecticidal spectrum, not expected to be toxic to terrestrial plants. Based upon the low exposure and no evidence of toxicity to plant organisms as represented by algae, the risk for terrestrial plants arising from use of transfluthrin in households is minimal. Hence, a long-term test with terrestrial plants is not considered to result in any relevant information and as such not deemed necessary. This additional requirement for experimental data is not scientifically justified under the view of the existing data set for the proposed uses of transfluthrin in the EU.	

Document IIIA	Long-term test with terrestrial plants
SECTION A7.5.2.2 **BPD Data Set IIIA / Annex Point XIII.3.2**	
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECsoil and perform the risk assessment for the terrestrial compartment. Since no risks are identified, the available information is considered sufficient.
Conclusion	Further information is not required
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	

Document IIIA — Acute oral toxicity on birds

Bobwhite quail

SECTION A7.5.3.1.1/01

BPD Data Set IIIA / Annex Point XIII.1.1

			Official use only
		86 REFERENCE	
1.1	**Reference**	[redacted] (1987) Acute oral LD50 of NAK 4455 to Bobwhite quail, [redacted] [redacted] Report No.: VB-003, [BES Ref: MO-03-009681] Report date: November 16, 1987 Unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience	
1.2.2	Companies with letters of access		
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 inclusion on Annex I	
		87 GUIDELINES AND QUALITY ASSURANCE	
87.1	**Guideline study**	Yes EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms, § 71-1	
87.2	**GLP**	Yes	
87.3	**Deviations**	None	
		88 METHOD	
88.1	**Test material**	NAK 4455 (transfluthrin technical)	
88.1.1	Lot/Batch number	130187 (from 13th Jan. 1987)	X
88.1.2	Specification	As given in section 2	X
88.1.3	Purity	94.5%	
88.1.4	Composition of Product	N/A	
88.1.5	Further relevant properties	Appearance: dark brown liquid Density: 1.33 g/ml	
88.1.6	Method of analysis in the diet	No dietary test, acute single dosing in gelatine capsule by direct weighting of the test substance	
88.2	**Administration of**	See table A7_5_3_1_1(01)-1	

Document IIIA — Acute oral toxicity on birds

Bobwhite quail

SECTION A7.5.3.1.1/01

BPD Data Set IIIA / Annex Point XIII.1.1

	the test substance	
88.3	**Reference substance**	No
88.3.1	Method of analysis for reference substance	N/A
88.4	**Testing procedure**	
88.4.1	Test organisms	See table A7_5_3_1_1(01)-2
88.4.2	Test system	See table A7_5_3_1_1(01)-3
88.4.3	Test diet	Both food and water were provided *ad libitum* in acclimatisation and the test period except for a 15-hour pre-dosing fasting period. Diet (Batteriefutter LAB 50): Constituents: 17% crude protein, 5% crude fibre, 12% crude ash, 4% crude fat, 0.3% methionine, 3% Ca, 0.5% P, 0.12% Na. Additives per kg: 15000 i.u. Vitamin A, 1500 i.u. Vitamin D3, 15 mg vitamin E, 50 mg zinc bacitracin canthaxanthin BHT. Composition: 46.0% corn, 15.0% coarse soybean meal, 8.0% beans, 10.0% gluten of maize, 1.0% sugar beet molasses, 8.0% gluten of wheat, 6.0% calcium carbonate, 0.2% sodium chloride, 0.6% grieves cake, 2.2% soybean oil and 3.0% additive premix. No carrier substance was used for the test substance administration; the required amount of active ingredient was weighed directly into a gelatine capsule.
88.4.4	Test conditions	See table A7_5_3_1_1(01)-4
88.4.5	Duration of the test	Acclimation – approximately 2 weeks including fasting for at least 15 hours. Dosing on experimental start date followed by 14 days post-dosing observations.
88.4.6	Test parameter	Mortality, feed consumption at day 7-14, body weight, signs of toxicity and abnormal behaviour.
88.4.7	Examination / Observation	In the course of the post-treatment observation phase the birds were observed once per day. Body weights were recorded on Days 0, 7 and 14. Food consumption was measured between days 7-14 post application. All surviving birds were sacrificed at the end of the study and examined for gross pathology.
88.4.8	Statistics	The statistical evaluation of the data was not necessary as no symptoms of intoxication and no mortalities occurred at the highest dose tested (2000 mg a.i./kg).

Document IIIA — Acute oral toxicity on birds

Bobwhite quail

SECTION A7.5.3.1.1/01

BPD Data Set IIIA / Annex Point XIII.1.1

89 RESULTS

89.1	**Range finding test**	Not performed
89.1.1	Concentration	N/A
89.1.2	Number/ percentage of animals showing adverse effects	N/A
89.1.3	Nature of adverse effects	N/A
89.2	**Results test substance**	
89.2.1	Applied concentrations	0, 2000 mg a.i./kg bw
89.2.2	Effect data (Mortality)	See table A7_5_3_1_1(01)-5
89.2.3	Body weight (g)	

Dose (mg a.i./kg bw)	Sex/ bird No.	Day 0	Day 7	Day 14	change over 14 days[g]
Control	M/1	198	203	204	+6
	M/2	192	187	188	-4
	M/3	180	193	197	+17
	M/4	166	168	169	+3
	M/5	195	196	194	-1
	F/6	171	178	181	+10
	F/7	182	185	192	+10
	F/8	182	183	187	+5
	F/9	170	172	177	+7
	F/10	162	170	174	+12
2000	M/11	182	186	191	+9
	M/12	183	186	194	+11
	M/13	168	170	180	+12
	M/14	181	182	193	+12
	M/15	158	160	163	+5
	F/16	177	182	186	+9
	F/17	148	146	154	+6
	F/18	182	185	188	+6
	F/19	220	223	234	+14
	F/20	164	165	173	+9

Document IIIA — Acute oral toxicity on birds

Bobwhite quail

SECTION A7.5.3.1.1/01
BPD Data Set IIIA / Annex Point XIII.1.1

89.2.4 Feed consumption

Dose (mg a.i./kg bw)	Feed consumption (g)		Feed consumption (g/bird/day)
	Days 0-7	Days 7-14	Days 7- 14
2000	n.d.	1370	19.6
Control	n.d.	1770	25.3

n.d. – not determined

89.2.5 Concentration / response curve

Not applicable as no mortality reported in any of the treatment groups.

89.2.6 Other effects

For the duration of the test no behavioural disorders occurred in the treated or in the untreated control group, all birds behaved completely normal. Cannibalism was not observed. Food consumption in the treated groups was less than in the control group, however, this did not result in a reduction of body weight gain in comparison to the untreated group.

Gross pathological examination of the animals sacrificed at the end of the study showed no treatment related abnormalities. Genital organs of all animals were considerably reduced in size, which suggests that all animals were still impuberal at the time of the administration of the substance. Further, the testes of most of the males showed a marked blackening. As this atypical coloration occurred to the same extent in the animals from the control and test group, the findings are not considered to be test substance related. Birds from the same charge observed following this test did not show any impact on fertility.

89.3 Results of controls

89.3.1 Number/ percentage of animals showing adverse effects

No adverse effects observed.

89.3.2 Nature of adverse effects

All control birds were normal in appearance and behaviour throughout the test.

89.4 Test with reference substance

Not performed

89.4.1 Concentrations

N/A

89.4.2 Results

N/A

90 APPLICANT'S SUMMARY AND CONCLUSION

90.1 Materials and methods

The study was conducted in accordance with US EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms, § 71-1. Validity criteria were fulfilled and no deviations were noted. Dates of experimental work: 17 March - 31 March 1987.

17 week old Bobwhite quail (5 male and 5 female per test group) were

Document IIIA SECTION A7.5.3.1.1/01 BPD Data Set IIIA / Annex Point XIII.1.1	Acute oral toxicity on birds Bobwhite quail

dosed orally (via a gelatine capsule) with NAK 4455 (transfluthrin) at a nominal concentration of 2000 mg a.i./kg bw. An untreated control was also included in the study (birds received an empty gelatine capsule). Birds were observed for mortality and other signs of intoxication for 14 days post-treatment. Weight changes and food consumption were monitored. All surviving birds were scarified at test termination for gross-pathological examination.

Both food and water were provided *ad libitum* during the acclimatisation and test period except for a 15-hour pre-dosing fasting period.

Birds were maintained at 18 –20ºC, 20-40% relative humidity and an unspecified light:dark cycle.

90.2 Results and discussion

No mortality was observed in the controls or at the 2000 mg a.i./kg bw dose level.

Weight gains in the control and treated groups were comparable while the feed consumption in the treated group was markedly lower than in the untreated control group.

No behavioural abnormalities or symptoms of intoxication were observed in the treated or control groups throughout the study. At the end of the post-treatment observation period all animals were without treatment related pathological symptoms.

Gross pathological examination of the animals sacrificed at the end of the study revealed that the genital organs of all animals were considerably reduced in size, which suggests that all animals were still impuberal at the time of the administration of the substance. Further, the testes of most of the males showed a marked blackening. As this atypical coloration occurred to the same extent in the animals from the control and test group, the findings are not considered to be test substance related. Post study observation of incubated eggs from birds of the same charge as the test animals showed no impairment of fertility.

90.2.1 LD_{50} — >2000 mg a.i./kg bw

90.3 Conclusion — NAK 4455 (transfluthrin) is considered to be practically non-toxic (following acute oral administration) to Bobwhite quail. See also validity criteria summarized in table A7_5_3_1_1(01)-6.

90.3.1 Reliability — 1

90.3.2 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

Document IIIA — Acute oral toxicity on birds

Bobwhite quail

SECTION A7.5.3.1.1/01
BPD Data Set IIIA / Annex Point XIII.1.1

Date	02-03-2007
Materials and Methods	Applicant's version is adopted with the following amendment: 3.1.1/3.1.2 Batch differs from those included in the batch analysis (Doc III A 2 confidential).
Results and discussion	Applicant's version is adopted with the following amendment: LD50 in report is given as > 2000 mg/kg diet, whereas dose is expressed on the basis of kg bw. Applicant's summary is correct. 5.2.1 LD50 is > 2000 mg/kg bw, based on nominal concentrations of the test substance. Purity is < 95 %, so correction is applied. Corrected for purity of 94.5 %, the LD50 is > 1890 mg as/kg bw.
Conclusion	The result LD50 > 1890 mg/kg bw is used for risk assessment.
Reliability	1
Acceptability	acceptable
Remarks	

	COMMENTS FROM ... *(specify)*
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_5_3_1_1(01)-1:Method of administration of the test substance

Carrier / Vehicle	Details
Water	No, appropriate amount of the test substance was weighed directly into a gelatine capsule.
Organic carrier	No
Concentration of the carrier [% v/v]	N/A
Other vehicle	Gelatine capsule
Function of the carrier / vehicle	Facilitation of dosing and digestion

Table A7_5_3_1_1(01)-2:Test animals

Criteria	Details
Species/strain	Bobwhite quail (*Colinus virginianus*)
Source	Eggs of adults from [redacted] laid and hatched in the test facility. Reared as batch No.: V22/86.
Age (in weeks), sex and initial body weight (bw)	At test initiation aged 17 weeks:
Breeding population	All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. Eggs needed for the test were laid and incubated in the test facility. 55 (17.4%) out of 316 incubated eggs were not fertilized. 179 birds hatched on their own from the 261 fertilized eggs (68.6% of the fertilized eggs). Mortality: 56 birds (31.3%) died between hatch and acclimatisation.
Amount of food	Throughout acclimation (2 weeks) and testing, all test birds were fed *ad libitum*. During rearing birds were fed Kükenstarterfutter KST 60, and during testing birds were fed Batteriefutter LAB 50.
Age at time of first dosing	17 weeks
Health condition / medication	All birds appeared to be in good health at the initiation of the test. They received an antibiotic (zinc bacitracin) and a coccidiostatic (Amprolium-Ethopabat) substance prophylactically in the feed.

Sex	Initial body weight (g)	
	Control	2000 mg/kg bw
M	198	182
M	192	183
M	180	168
M	166	181
M	195	158
F	171	177
F	182	148
F	182	182
F	170	220
F	162	164

Table A7_5_3_1_1(01)-3:Test system

Criteria	**Details**
Test location	Test cages/pens in a heated hall
Holding pens Acclimatisation + post-treatment observation period: Test substance administration:	 70 x 70 x 70 cm (housing in groups) 23 x 17 x 13 cm (individual housing)
Number of animals	20 (5 males and 5 females per test group)
Number of animals per pen	5 birds per pen post-treatment: 1 bird per test pen on the day of test substance administration.
Number of animals per dose	10 (5 females and 5 males)
Pre-treatment / acclimation	Birds were acclimated to the test pens for 2 weeks prior to the test initiation. Batteriefutter LAB 50 diet and water provided *ad libitum* except for 15-hour pre-test fast.
Diet during test	Batteriefutter LAB 50 and water provided *ad libitum*.
Dosage levels (of test substance)	2000 mg a.i./kg bw (Nominal)
Replicate/dosage level	2 test pens per dosage level (1 male and 1 female)
Feed dosing method	The gelatine capsule was applied into the goiter of the birds with the fingers.
Dosing volume per application	The test substance was weighed into gelatine capsules at the 2000 mg a.i./kg bw dose level as follows:

Sex/animal No.	Animal Weight (g)	Amount of test substance (mg)
M/11	182	385
M/12	183	387
M/13	168	355
M/14	181	383
M/15	158	334
F/16	177	374
F/17	148	313
F/18	182	385
F/19	220	465
F/20	164	347

Criteria	**Details**
Frequency, duration and method of animal monitoring after dosing	On the day of dosing (day 0), all birds were observed for symptoms of intoxication continuously during the first hour of the test and hourly thereafter. During the post-treatment observation phase animals were observed once per day. A record was maintained of all mortality, signs of toxicity and abnormal behaviour.
Time and intervals of body weight determination	Body weights were measured individually at test initiation and on Days 7 and 14. Total feed consumption was determined on Days 7 to 14 for each dose group. Feed consumption/animal/day was determined by dividing the total amount consumed during the respective period by the total number of birds still living on the individual days.

Table A7_5_3_1_1(01)-4:Test conditions (housing)

Criteria	Details
Test temperature	18 –20ºC
Shielding of the animals	Not stated
Ventilation	Ventilation of the test room was through the doors and windows
Relative humidity	20 - 40%
Photoperiod and lighting	Daylight (time not defined)

Table A7_5_3_1_1(01)-5: Mortality data after test termination

Test substance dosage level (nominal) [mg a.i./kg bw]	Mortality after test termination (14 days)			
	[1]Total number per dose level		Percentage per dose level	
	Pen 1	Pen 2	Pen 1	Pen 2
Control	0	0	0	0
2000	0	0	0	0

[1] 5 animals per pen were exposed

Table A7_5_3_1_1(01)-6: Validity criteria for avian acute oral toxicity test according to US EPA guideline § 71-1

	Fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	

Document IIIA — Acute oral toxicity on birds

Canary bird

SECTION A7.5.3.1.1/02

BPD Data Set IIIA / Annex Point XIII.1.1

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91 REFERENCE

1.1	**Reference**	[redacted] (1987) Acute oral LD50 of NAK 4455 to the Canary bird (*Serinus canarius*), [redacted]. [redacted] Report No.: VK 315, [BES Ref: MO-04-009186] Report date: July 20, 1987 Unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience
1.2.2	Companies with letters of access	
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 inclusion on Annex I

92 GUIDELINES AND QUALITY ASSURANCE

92.1	**Guideline study**	Yes OECD Guideline No. 401 and US EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms, § 71-1
92.2	**GLP**	Yes
92.3	**Deviations**	Yes, these are detailed below, but are not considered to impact on the quality of the study. The Canary bird (*Serinus canarius*) was used as test species despite the fact that this bird species is not named explicitly in any guideline for the determination of the acute oral toxicity. Birds of one sex (female) only were used as the availability of male Canary birds is limited. The post-treatment observation of the birds was made on working days only as a routine service for weekends does not exist in the test facility. This deviation does not impair the value of the test results as no symptoms of intoxication occurred. Deviating from the EPA Guideline (§71-1) the feed consumption of the birds during the post-treatment observation period was not determined. This deviation was established in the study protocol prior to test initiation as the lack of toxic effects of the test product were known from earlier experiments. The development of the body weights of the birds indicates that no relevant differences in the feeding habits existed between the treated group and the untreated control group. Deviating from the OECD Guideline (No. 401) the highest tested dose used was 2000 mg/kg (Limit-Test Guideline: 5000 mg/kg). For the determination of the toxicity to birds this is common practice (see also

		EPA Guideline and BBA Guideline 1-2) as this upper limit is sufficient for the assessment of the risk to birds.	
		93 METHOD	
93.1	**Test material**	NAK 4455 (transfluthrin technical)	
93.1.1	Lot/Batch number	130187 (mixed batch from Jan 13, 1987)	X
93.1.2	Specification	As given in section 2	X
93.1.3	Purity	94.5%	
93.1.4	Composition of Product	N/A	
93.1.5	Further relevant properties	Appearance: dark brown liquid Density: 1.33 g/ml	
93.1.6	Method of analysis in the diet	no dietary study, direct dosing of liquid	
93.2	**Administration of the test substance**	Ca. 50 µl administered via tube, for details see table A7_5_3_1_1(02)-1	
93.3	**Reference substance**	No	
93.3.1	Method of analysis for reference substance	N/A	
93.4	**Testing procedure**		
93.4.1	Test organisms	Canary birds, See table A7_5_3_1_1(02)-2	
93.4.2	Test system	See table A7_5_3_1_1(02)-3	
93.4.3	Test diet	Both food and water were provided *ad libitum* in acclimatisation and the test period except for a 1-hour pre-dosing fasting period. Diet (Canary feed I Dacapo): Composition: 50% Canary seed, 6% oat kernels, 8% linseed, 15% turnip seed, natural, 5% turnip seed, red, 3% poppy seed, 4% hempseed, 5% pearl millet, 2% perilla seed, 2% fodder rape. The a.m. diet was treated with about 1% of Vitakalk® (vitamin and mineral supplement). In addition the birds were fed 1 - 2 leaves of commercial head lettuce on each workday. No carrier substance was used for the test substance administration; the required amount of active ingredient was dosed with a microliter syringe and administered directly by means of a stomach tube.	
93.4.4	Test conditions	See table A7_5_3_1_1(02)-4	

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Canary bird

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93.4.5	Duration of the test	Acclimation – approximately 2 weeks including fasting for 1 hour. Dosing on experimental start date followed by 14 days post-dosing observations.
93.4.6	Test parameter	Mortality, signs of toxicity and abnormal behaviour.
93.4.7	Examination / Observation	Birds were weighed on Days 0, 7 and 14. Time of occurrence of mortalities (if any) were noted. Symptoms of intoxication were noted (controls also observed in the same way). At the end of the post-treatment period all surviving birds were sacrificed and examined for gross pathology.
93.4.8	Statistics	The statistical evaluation of the data was not necessary as no symptoms of intoxication and no mortalities occurred at the highest dose tested (2000 mg a.i./kg).

94 RESULTS

94.1	**Range finding test**	Not performed
94.1.1	Concentration	N/A
94.1.2	Number/ percentage of animals showing adverse effects	N/A
94.1.3	Nature of adverse effects	N/A
94.2	**Results test substance**	
94.2.1	Applied concentrations	2000 mg a.i./kg bw
94.2.2	Effect data (Mortality)	No mortality
94.2.3	Body weight (g)	

Bird No.	Initial body weight (g)		Average body weight (g)			
			Day 7		Day 14	
	Control	2000 mg/kg	C	2000 mg/kg	C	2000 mg/kg
1	19.0	26.6	22.9	24.1	22.9	25.0
2	21.2	23.6				
3	23.0	21.2				
4	20.8	20.6				
5	20.0	20.4				
6	21.9	26.7				
7	23.8	24.7				
8	25.3	18.0				
9	25.7	22.2				
10	23.5	27.6				

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		C = Control
94.2.4	Feed consumption	Not determined, however the development of the body weights of the birds indicates that no relevant differences in the feeding habits existed between the treated group and the untreated control group.
94.2.5	Concentration / response curve	Not applicable as no deaths reported in any of the treatment groups.
94.2.6	Other effects	For the duration of the study no symptoms of intoxication occurred in the treated or in the untreated control group. Three treated animals showed temporary impulse to defaecate and irritation of the cloaca about 1/2 hour after test substance administration. The symptoms lasted for less than 1 hour. Gross pathological-anatomical examination at test termination showed no test substance related pathological findings. Two birds of the treated group had a changed liver (pale or stained clay-coloured, respectively). This finding is not attributed to the test substance as such alterations also occurred in untreated animals. Similarly, the described changes in the spleen and pancreas (shrunken, enlarged and anaemic) were not considered to be test substance related as alterations of these organs were also found in the control group.
94.3	**Results of controls**	
94.3.1	Number/ percentage of animals showing adverse effects	0% mortality
94.3.2	Nature of adverse effects	All control birds were normal in appearance and behaviour throughout the test.
94.4	**Test with reference substance**	Not performed
94.4.1	Concentrations	N/A
94.4.2	Results	N/A

95 APPLICANT'S SUMMARY AND CONCLUSION

95.1 Materials and methods

The study was conducted in accordance with OECD Guideline 401 and US EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms, § 71-1. Dates of experimental work: 04 May - 18 May 1987.

10 female canary birds 1 per test group were dosed orally (via stomach tube) with NAK 4455 (transfluthrin) at a nominal concentration of 2000 mg a.i./kg bw. An untreated control was also included in the study (birds received deionised water only). Birds were observed for mortality and other signs of intoxication for 14 days post treatment. Weight changes were monitored. All surviving birds were sacrificed at test termination for gross-pathological examination.

Both food and water were provided *ad libitum* during the acclimatisation and test period except for a 1-hour pre-dosing fasting

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Canary bird

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		period. Birds were maintained at 20 –25ºC, 40-70% relative humidity and a 12 hour light:dark cycle.
95.2	**Results and discussion**	No mortality was observed in the controls or at the 2000 mg a.i./kg bw dose level. For the duration of the study no symptoms of intoxication occurred in the treated or in the untreated control group. Three treated animals showed temporary impulse to defaecate and irritation of the cloaca about 1/2 hour after test substance administration. The symptoms lasted for less than 1 hour. Gross pathological-anatomical examination of the animals sacrificed at test termination showed no test substance related pathological findings. Two birds of the treated group had a changed liver (pale or stained clay-coloured, respectively). This finding is not attributed to the test substance as such alterations also occurred in untreated animals. Similarly, the described changes in the spleen and pancreas (shrunken, enlarged and anaemic) were not considered to be test substance related as alterations of these organs were also found in the control group.
95.2.1	LD_{50}	>2000 mg a.i./kg bw
95.3	**Conclusion**	NAK 4455 (transfluthrin) is considered to be practically non-toxic (following acute oral administration) to the Canary bird. See also validity criteria summarized in table A7_5_3_1_1(02)-6.
95.3.1	Reliability	1
95.3.2	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	02-03-2007
Materials and Methods	Applicant's version is adopted with the following amendment: 3.1.1/3.1.2 Batch differs from those included in the batch analysis (Doc III A.2 confidential).
Results and discussion	Applicant's version is adopted with the following amendment: LD50 in report is given as > 2000 mg/kg diet, whereas dose is expressed on the basis of kg bw. Applicant's summary is correct. 5.2.1 LD50 is > 2000 mg/kg bw, based on nominal concentrations of the test substance. Purity is < 95 %, so correction is applied. Corrected for purity of 94.5 %, the LD50 is > 1890 mg as/kg bw.
Conclusion	The result LD50 > 1890 mg/kg bw is used for risk assessment.

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Canary bird

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Reliability	1
Acceptability	acceptable
Remarks	

	COMMENTS FROM ... *(specify)*
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_5_3_1_1(02)-1:Method of administration of the test substance

Carrier / Vehicle	Details
Water	No, for the test substance application the active ingredient was dyed. For this purpose 4 g of test substance were treated/dissolved with 1 mg of Rhodamin B. Test cages were partly covered with moist filter paper in order to detect vomiting. The filter paper and dyestuff allowed the visual determination of vomiting of the smallest droplets. For the control group 4 g of deionised water was treated with 1 mg of Rhodamin B.
Organic carrier	No
Concentration of the carrier [% v/v]	N/A
Other vehicle	Rhodamin B
Function of the carrier / vehicle	To aid uptake efficiency and detect test substance regurgitation.

Table A7_5_3_1_1(02)-2:Test animals

Criteria	Details
Species/strain	Canary bird (*Serinus canarius*)
Source	[redacted]
Age (in weeks), sex and initial body weight (bw)	At test initiation aged approx. 1 year, sex - female:

Animal No.	Initial body weight (g)	
	Control	2000 mg/kg bw
1	19.0	26.6
2	21.2	23.6
3	23.0	21.2
4	20.8	20.6
5	20.0	20.4
6	21.9	26.7
7	23.8	24.7
8	25.3	18.0
9	25.7	22.2
10	23.5	27.6

Breeding population	Birds were from two hatches and only conditionally correspond phaenotypically to wild canary birds.
Amount of food	Throughout acclimation (2 weeks) and testing, all test birds were *ad libitum*. During acclimation and testing birds were fed Canary feed I Dacapo.
Age at time of first dosing	Approximately 1 year
Health condition / medication	All birds appeared to be in good health at test initiation. Birds were not treated for diseases before and during the test.

Table A7_5_3_1_1(02)-3:Test system

Criteria	**Details**
Test location	Test cages/pens
Holding pens	20 x 14 x 18 cm (individual housing)
Number of animals	20
Number of animals per pen	1 bird per pen
Number of animals per dose	10 (females)
Pre-treatment / acclimation	Birds were acclimated to the test pens for 2 weeks prior to the test initiation. Canary feed I Dacapo and water were provided *ad libitum* except for 1-hour pre-test fast.
Diet during test	Canary feed I Dacapo (a m. diet was treated with approx. 1% Vitakalk®, a vitamin and mineral supplement) and water provided *ad libitum*. In addition birds were fed 1-2 leaves of commercial head lettuce on each work day.
Dosage levels (of test substance)	Nominal 2000 mg a.i./kg bw
Replicate/dosage level	10 test pens per dosage level (1 female in each)
Feed dosing method	Test substance administration was by means of stomach tube. The administration was made with a microlitre syringe and a flexible polythylene hose (outer diameter 1.3 mm) into the gizzard.
Dosing volume per application	The test substance was weighed at the 2000 mg a.i./kg bw dose level as follows: Bird No. / Bird Weight (g) / Administered volume of test substance (µl) / Amount of test substance (mg) 1 / 26.6 / 42.3 / 56.3 2 / 23.6 / 37.6 / 50.0 3 / 21.2 / 33.7 / 44.8 4 / 20.6 / 32.8 / 43.6 5 / 20.4 / 32.5 / 43.2 6 / 26.7 / 42.5 / 56.5 7 / 24.7 / 39.3 / 52.3 8 / 18.0 / 28.6 / 38.0 9 / 22.2 / 35.3 / 46.9 10 / 27.6 / 43.9 / 58.4 Administered vol. in % of body weight = 0.16
Frequency, duration and method of animal monitoring after dosing	On the day of dosing (day 0), all birds were observed for symptoms of intoxication continuously during the first hour of the test and hourly thereafter. During the post-treatment observation phase birds were observed once per day except on weekend days. A record was maintained of all mortality, signs of toxicity and abnormal behaviour.
Time and intervals of body weight determination	Body weights were measured individually at test initiation and on Days 7 and 14.

Table A7_5_3_1_1(02)-4:Test conditions (housing)

Criteria	**Details**
Test temperature	20 –25ºC
Shielding of the animals	Not stated
Ventilation	8x air exchanges/hour
Relative humidity	40 - 70%
Photoperiod and lighting	12:12 hours light:dark, neonlight warm/white

Table A7_5_3_1_1(02)-5: Mortality data after test termination

Species: Canary Bird		
Dose (mg a.i./kg bw)	**dead**	**used**
2000	0	10
Control (untreated)	0	10
LD_{50} (50% mortality)	**> 2000 mg a.i./kg bw**	

Table A7_5_3_1_1(02)-6: Validity criteria for avian acute oral toxicity test according to OECD 401 and US EPA guideline § 71-1

	Fulfilled	**Not fulfilled**
Mortality of control animals <10%	**yes**	

Document IIIA SECTION A7.5.3.1.2 BPD Data Set IIIA / Annex Point XIII.1.2	Short-term toxicity on birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Although exposure of the terrestrial compartment is negligible as detailed below, an avian acute oral toxicity test is available. The data show that transfluthrin is not acutely toxic to birds (LD_{50} >2000 mg a.i./kg bw, see Doc IIIA Section 7.5.3.1.1). Potential routes of exposure for birds are usually direct ingestion of the product (in case of e.g. pellets) or indirect uptake of residues by intake of contaminated food, e.g. fish or earthworms as food items of the aquatic or terrestrial compartment, respectively. From the typical uses of transfluthrin, the electric vaporizer "Raid Portable Electric", "Baygon mosquito coil" or the anti-moth disc "Turbo 4 Seasons", no direct exposure of birds is anticipated. The devices are used in the presence of humans in and around houses, which counter-acts birds feeding at the time of use in the relevant area. Moreover, the product itself is not attractive to birds as it is neither of a typical form and size nor exposed on a terrain that would allow unintentional uptake by birds (as e.g. granules). As an example, the product packaging proposed for Raid Portable Electric is such that the active substance is contained inside a plastic container; therefore the structures are too large to be eaten by birds. Hence, an impact to birds from direct uptake of transfluthrin can be excluded. Alternatively to direct exposure, indirect uptake of feed contaminated with transfluthrin might in principle be possible as the active compound is of high lipophilicity and characterized by a BCF_{fish} of 1471 -1607. Hence, feeding on fish or on soil organisms is a principle route of exposure for birds but, as the use of transfluthrin based products result in almost negligible exposure of the outdoor environment (worst case concentration in the aquatic environment is 3.3 x 10^{-8} mg/L, and for soil 3.4 x 10^{-10} mg/kg), a risk to birds by secondary poisoning can be excluded. This is underlined by the expected scattered use of transfluthrin based products that prevents a repeated dietary exposure on a short or long-term basis. The risk to biomagnify in the food chain is low as the correlating BMF for a BCF < 2000 is 1 acc. to the Technical Guidance Document on Risk Assessment. As such, the risk for an upper end predator is not increased by accumulation of residues in the food chain. Due to the extremely limited potential for avian exposure and the low acute oral toxicity to birds the additional data requirement for a bird short-term dietary study is not justified.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

Document IIIA	Short-term toxicity on birds
SECTION A7.5.3.1.2 **BPD Data Set IIIA / Annex Point XIII.1.2**	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	For the proposed uses of transfluthrin, direct exposure of birds is not considered relevant. In accordance with TNsG on data requirements chapter 2.5 part B data are not required because the proposed insecticidal products are not used as baits, granulates or powder. Direct and long term exposure of birds is considered not relevant. On the other hand, since there is indirect emission to water and soil and the log Kow is > 3, there is a potential risk for secondary poisoning. However, a calculation on the basis of the predicted concentrations in fish and earthworms shows that in order to reach a PEC/PNEC ratio > 1, the LC_{50} should be < 5 – 49 mg/kg feed (see Doc IIC, 2.3.5). In view of the absence of acute effects up to doses of 1890 mg/kg bw, this is not expected. It is therefore considered justified, also in view of animal welfare, not to require further studies.
Conclusion	Further information is not required.
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	

Document IIIA **Section A7.5.3.1.3** **BPD Data Set IIIA / Annex Point XIII.1.3**	**Effects on reproduction of birds**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Although exposure of the terrestrial compartment is negligible as detailed below, an avian acute oral toxicity test is available. The data show that transfluthrin is not acutely toxic to birds (LD_{50} >2000 mg a.i./kg bw, see Doc IIIA Section 7.5.3.1.1). Potential routes of exposure for birds are usually direct ingestion of the product (in case of e.g. pellets) or indirect uptake of residues by intake of contaminated food, e.g. fish or earthworms as food items of the aquatic or terrestrial compartment, respectively. From the typical uses of transfluthrin, the electric vaporizer "Raid Portable Electric", "Baygon mosquito coil" or the anti-moth disc "Turbo 4 Seasons", no direct exposure of birds is anticipated. The devices are used in the presence of humans in and around houses, which counter-acts birds feeding at the time of use in the relevant area. Moreover, the product itself is not attractive to birds as it is neither of a typical form and size nor exposed on a terrain that would allow unintentional uptake by birds (as e.g. granules). As an example, the product packaging proposed for Raid Portable Electric is such that the active substance is contained inside a plastic container; therefore the structures are too large to be eaten by birds. Hence, an impact to birds from direct uptake of transfluthrin can be excluded. Alternatively to direct exposure, indirect uptake of feed contaminated with transfluthrin might in principle be possible as the active compound is of high lipophilicity and characterized by a BCF_{fish} of 1471 -1607. Hence, feeding on fish or on soil organisms is a principle route of exposure for birds but, as the use of transfluthrin based products result in almost negligible exposure of the outdoor environment (worst case concentration in the aquatic environment is 3.3×10^{-8} mg/L, and for soil 3.4×10^{-10} mg/kg), a risk to birds by secondary poisoning can be excluded. This is underlined by the expected scattered use of transfluthrin based products that prevents an exposure on a continuous basis (long-term). Repeated uptake of relevant residues of the active compound can be excluded and any adverse effects to bird populations are extremely unlikely. Moreover, the risk to biomagnify in the food chain is low as the correlating BMF for a BCF < 2000 is 1 acc. to the Technical Guidance Document on Risk Assessment. As such, the risk for an upper end predator is not increased by accumulation of residues in the food chain. From the extremely limited potential for avian exposure and the low acute oral toxicity of transfluthrin to birds the requirement for an avian reproduction study is not justified.	

Document IIIA **Section A7.5.3.1.3** **BPD Data Set IIIA / Annex Point XIII.1.3**	**Effects on reproduction of birds**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	In accordance with TNsG on data requirements chapter 2.5 part B data are not required because the proposed insecticidal products are not used as baits, granulates or powder. Direct and long term exposure of birds is considered not relevant. On the other hand, since there is indirect emission to water and soil and the log Kow is 5.46, there is a potential risk for secondary poisoning. However, a calculation on the basis of the predicted concentrations in fish and earthworms shows that in order to reach a PEC/PNEC ratio > 1 the NOEC should be exceptionally low (< 0.05 – 0.486 mg/kg feed; see Doc IIC, 2.3.5). It is therefore considered justified, also in view of animal welfare, not to require further studies.
Conclusion	Further information is not required.
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	

Document IIIA SECTION A7.5.4 BPD Data Set IIIA / Annex Point XIII.3.1	Effects on honeybees and other beneficial arthropods	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The proposed uses of transfluthrin in the EU are for small scale localised use, as domestic (amateur) insecticides, both indoors and outdoors e.g. patio use; no direct exposure of the terrestrial environment is anticipated. The worst case contamination of air results from the use of transfluthrin formulated as 'Raid Portable Electric'. The worst-case operator (non-professional) exposure assessment (see relevant Doc IIB, section 3.2) estimated the mean indoor event air concentration of transfluthrin during use of the product, Raid Portable Electric, to be 0.00735 mg/m^3. This is considered to be higher than the outdoor air concentration, as ventilation inside is restricted compared to the dilution expected outdoors (see Doc IIB, section 3.3.3). As a result exposure of the outdoor environment from the proposed indoor use of transfluthrin (as Raid Portable Electric) is anticipated to be negligible (see relevant Doc IIB, Section 3.3). Worst case local contamination of outdoor air assuming standard room ventilation rates has been estimated to be 2.6 x 10^{-10} mg/m^3 (100m from source). In addition, the estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone is 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode (8 hours for indoor use) some degradation of transfluthrin maybe expected (with up to 25% reduction in concentration). The worst case contamination of soil *via* atmospheric deposition results from the use of transfluthrin formulated as 'Baygon Mosquito coil', however this is equally insignificant. The estimated concentration in soil from the use of one coil is 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). As transfluthrin is an insecticide it is assumed that it has an intrinsic toxicity to honeybees and/or non-target arthropods, but due to the negligible outdoor concentrations the risk to honey bees and/or beneficial arthropods is considered minimal. Moreover, the predominant use of the indoor vaporizer and the mosquito coil is mostly during the evening and night, when bees are less active. Overall, the risk to bees and non-target arthropods resulting from domestic (amateur) uses of transfluthrin is minimal with only individual bees and/or beneficial arthropods being exposed in the immediate vicinity of treated areas. On a population level, no significant risk to	

Document IIIA SECTION A7.5.4 BPD Data Set IIIA / Annex Point XIII.3.1	Effects on honeybees and other beneficial arthropods
	honeybees and beneficial arthropods is anticipated. As a conclusion, a study on acute toxicity to bees or other arthropods is not deemed necessary as it will not provide any relevant information that changes the risk assessment based upon the minimal exposure from the proposed uses of transfluthrin in the EU.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	For the proposed uses of transfluthrin, exposure of bees is not considered likely. For Raid Portable Electric and Turbo 4 Seasons, there is no direct emission. The outdoor use of Baygon Mosquito Coil will most likely take place during evenings when abundance of actively foraging bees is not expected. Furthermore, the product will most likely be placed in the vicinity of the users (i.e. on terrace tables or verandas), where exposure is not likely.
Conclusion	Further information is not required.
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	

Document IIIA — Effects on beneficial arthropods other than bees (metabolite)

SECTION 7.5.4.1

BPD Data set IIIA/ Annex Point XIII.3.1

Official use only

		96 REFERENCE
96.1	**Reference**	[redacted] (2005); Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1). [redacted] [redacted] No.: P15HR [BES Ref. M-259607-01-1] Report date: 27 October 2005 Unpublished
96.2	**Data protection**	Yes
96.2.1	Data owner	Bayer CropScience
96.2.2	Companies with letter of access	
96.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I
		97 GUIDELINES AND QUALITY ASSURANCE
97.1	**Guideline study**	Yes Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.* 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).
97.2	**GLP**	Yes
97.3	**Deviations**	None
		98 METHOD
98.1	**Test material**	Cis and trans -3-(2,2-dichlorovinyl)2,2-dimethylcylopropane carboxylic acid (Beta-Cyfluthrin Permethric-acid) (1:1 mixture of the cis- and trans- isomer)
98.1.1	Lot/Batch number	a. (cis-isomer) 920622ELB03 b. (trans-isomer) 920622ELB04
98.1.2	Specification	Not relevant, metabolite testing
98.1.3	Purity	99.8% w/w
98.1.4	Composition of Product	1:1 mixture of the cis- and trans- isomer
98.1.5	Further relevant properties	Stability under correct storage conditions: June 02, 2010

Document IIIA — Effects on beneficial arthropods other than bees (metabolite)

SECTION 7.5.4.1

BPD Data set IIIA/ Annex Point XIII.3.1

98.1.6	Method of analysis	The test item was identified by MS and NMR.
98.2	**Toxic standard**	Yes, Dimethoate
98.2.1	Method of analysis for reference substance	N/A
98.3	**Test methods**	
98.3.1	Test organisms	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table B7_5_4_1-1
98.3.2	Test system	See table B7_5_4_1-2
98.3.3	Test conditions	See table B7_5_4_1-3
98.3.4	Test duration	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
98.3.5	Test parameter	Mortality and reproduction
98.3.6	Examination	14 days after test initiation mortality was assessed; Reproduction was examined on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
98.3.7	Monitoring of test substance concentration	No
98.3.8	Statistics	Mortality: A One-Way Analysis of Variance (ANOVA), followed by a Dunnett's t-test (1-sided, $p \leq 0.05$) was used to determine whether or not there were significant differences. The LC50 value was calculated by Probit analysis using Linear Max. Likelihood Regression. Reproduction: The Welch t-test for inhomogeneous variances (1-sided, $p \leq 0.05$) was used to determine significant differences The statistical software package ToxRat Professional 2.09 was used for these calculations.

99 RESULTS

99.1	**Soil test**	
99.1.1	Initial concentrations of test substance	10, 32, 100, 316 and 1000 mg/kg dry soil
99.1.2	Effects data Mortality/ Reproduction	Mortality: After 14 days of exposure, mortality ranged from 6.3-13.8% in the samples treated with up to 100 mg/kg soil (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed respectively (corrected mortality 24.7 and 93.3%). Reproduction: Statistical analysis (Welch t-test; 1-sided, $p \leq 0.05$) showed no significant difference concerning the cumulative number of juveniles per female over a total period of 7 days between the control

		and the concentrations of 100 and 316 mg test item/kg soil (dw). See table B7_5_4_1-4 and table B7_5_4_1-5.
99.2	**Results of controls**	
99.2.1	Mortality	In the control groups 7% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	Reproduction	The mean reproductive performance of the controls was 24.1 (no of juvenile/emale/7 days). Both control parameters are within acceptable guideline limits.
99.2.2	Number/ percentage of predator mites showing adverse effects	Not stated except reproduction and mortality see 4.2.2.
99.2.3	Nature of adverse effects	No other end points than mortality and reproduction success reported.
99.3	**Test with toxic standard**	Performed
99.3.1	Concentrations	5.0 mg/kg dry soil
99.3.2	Results	The toxic reference, dimethoate, caused 96.4% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.

100 APPLICANT'S SUMMARY AND CONCLUSION

100.1	**Materials and methods**	Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed with permethric-acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett et al. 1994). Validity criteria were fulfilled and no major deviations were noted. Permethric-acid was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content of 1.21 ± 0.27) at five nominal rates of 10, 32, 100, 316 and 1000 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation. Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of the two highest concentrations of the test item which caused less than 50% corrected mortality (i.e. 100 and 316 mg test item/kg soil (dw)). After 7 days in an untreated mating units, 20 females of each of the test item treatments and the water treatment were transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days

Document IIIA — Effects on beneficial arthropods other than bees (metabolite)

SECTION 7.5.4.1

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		later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days. Mortality and reproduction success in the treatment groups was statistically compared to the water control group.
100.2	**Results and discussion**	After 14 days of exposure, seven percent of adult mites died in the control. Mortality in the concentrations of 10, 32 and 100 mg test item/kg soil (dw) ranged from 6.3 – 13.8% mortality (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed, respectively (corrected mortality 24.7 and 93.3%). The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) showed a significant difference in the mortality after 14 days between the control and these concentrations. The LC50 value calculated by Probit analysis using Linear Max. Likelihood Regression was determined as 400.9 mg test item/kg soil (dw) (95% confidence limits could not be calculated due to mathematical reasons). Based upon the statistically significant different at 316 mg/kg soil (dw), the $NOEC_{Mortality}$ was determined to be 100 mg test item/kg soil (dw) and the $LOEC_{Mortality}$ was determined to be 316 mg test item/kg soil (dw). Reproduction in both the 100 and 316 mg/kg dry soil treatments were 23.7 and 26.4 juveniles per female over the 7-day reproduction period, with the control having produced 24.1 juveniles per female. The statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed no significant difference, thus the $NOEC_{Reproduction}$ was determined as >316 mg/kg soil.
100.2.1	LC_{50}	400.9 mg/kg dry soil
100.3	**Conclusion**	Permethric-acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of <100 mg/kg dry soil (NOEC) and theLC_{50} was 400.9 mg/kg dry soil. There were no adverse effects on reproduction at concentrations of >316 mg/kg dry soil.
100.3.1	Other Conclusions	Validity criteria were fulfilled
100.3.2	Reliability	1
100.3.3	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02-03-2007
Materials and Methods	Applicant's version is adopted.
Results and discussion	Applicant's version is adopted.

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Conclusion	Applicant's version is adopted. The result 14-days LC50 401 mg/kg dwt soil and 14-days NOEC 100 mg/kg dwt soil are considered reliable. However, the test was not performed with the active substance, but with a metabolite of cyfluthrin. The relevance for the present assessment is not clear, it is supposed that the notifier submitted this study to address the potential effects of permethric acid, which is one of the metabolites assumed to be formed in soil..
Reliability	1
Acceptability	acceptable
Remarks	Although in itself reliable, the result is not carried forward to the risk assessment, because it does not refer to transfluthrin. The proposed outdoor use of Baygon Mosquito Coil will most likely take place during evenings when abundance of active non-target arthropods is not expected. Furthermore, the product will most likely be placed in the vicinity of the users (i.e. on terrace tables or verandas), where exposure of leaf and soil dwelling non-target arthropods is not expected. Further information is therefore not required.
	COMMENTS FROM ... *(specify)*
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 B7_5_4_1-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae)
Source of the initial stock	[redacted]
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table B7_5_4_1-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0,01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 36.6
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameter. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 10, 32, 100, 316 and 1000 mg/kg dry soil
Number of replicates/concentration	4 (5 for water control)
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table B7_5_4_1-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table B7_5_4_1-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	7%		24.1
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
10	5.9%	P>0.05	Not assessed
32	-0.8%	P>0.05	Not assessed
100	7.3	P>0.05	1.9%
316	24.7	P<0.05*	-9.3%
1000	93.3	P<0.05*	Not assessed

* Statistically significantly different from deionised water control.

Table B7_5_4_1-5: Effect data

	28 d [mg/kg soil dry weight]
LC_{50}	400.9

Table B7_5_4_1-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	**Not fulfilled**
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)	**Yes**	

Document IIIA **SECTION A7.5.5** **BPD Data Set IIA / Annex Point VII.7.5**	**Bioconcentration, terrestrial**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the terrestrial environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The proposed uses of transfluthrin in the EU are for small scale localised use as domestic (amateur) insecticides both indoors and outdoors e.g. patio use; no direct exposure/contamination of the outdoor environment is anticipated (see Doc IIB, section 3.3). Mammalian studies have shown that there is rapid elimination of transfluthrin, with no indication of retention in any organ or tissues suggesting that there is a low potential for accumulation (Doc IIIA, Section 6). The fish bioconcentration factor (BCF) for transfluthrin was shown to be 1471-1607 (see Doc IIIA, Section 7.4.2). Being below 2000 the default biomagnification factor (BMF) as suggested by the Technical Guidance Document on Risk Assessment is 1 and as such, an accumulation in the food chain in unlikely. Exposure of the outdoor environment from the proposed uses of transfluthrin is negligible (see relevant Doc IIB's, Section 3.3). Worst case local contamination of outdoor air (from use of Raid Portable Electric) assuming standard room ventilation rates has been estimated to be 2.6 x 10^{-10} mg/m^3 (100m from source). Worst case contamination of soil *via* atmospheric deposition from use of one coil (Baygon mosquito coil) is estimated to be 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). The estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone is 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode (8 hours) some degradation of transfluthrin maybe expected (with up to 25% reduction in concentration). Moreover, as shown by aquatic metabolism studies (Doc. IIIA Section 7.1.2.2.2, Hellpointer, E. 1993), it is likely, that transfluthrin will degrade also in soil, limiting the time for uptake into soil organisms. By the combination of low deposition and degradation the accumulation level is assumed to be low. Hence, a risk for secondary poisoning for birds and mammals by feeding on soil organisms such as earthworms is minimal, additionally underlined by the low acute toxicity of transfluthrin to birds and mammals. Studies on bioconcentration in the terrestrial environment will not provide additional information that is relevant for the estimation of the risk to birds and mammals as the low release limits the risk for the terrestrial environment. Hence, the additional data requirement is not deemed necessary and considered without further contribution to determine the risk for the proposed uses of transfluthrin in the EU.	

Document IIIA **SECTION A7.5.5** **BPD Data Set IIA / Annex Point VII.7.5**	**Bioconcentration, terrestrial**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	For the proposed uses of transfluthrin, direct emission to soil is considered negligible. The potential risks for secondary poisoning resulting from indirect emissions can be addressed by using the calculation methods for bioconcentration in earthworms as given in the TGD.
Conclusion	Further information is not required.
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	

Document IIIA **SECTION A7.5.5.1** **BPD Data Set IIA / Annex Point VII.7.5**	**Bioconcentration, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	As shown in the Environmental Risk Assessment (see Doc IIC, Section 2.4), transfluthrin does not present a risk of secondary poisoning in the environment. Therefore, further studies on bioconcentration are not considered to be required.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	23-03-2007	
Evaluation of applicant's justification	For the proposed uses of transfluthrin, direct emission to soil is considered negligible. The available information is considered sufficient to address the risk of secondary poisoning.	
Conclusion	Further information is not required.	
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		

Document IIIA **SECTION A7.5.6** **BPD Data Set IIIA / Annex Point XIII.3**	**Effects on other terrestrial non-target organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [✓]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Manufacture and formulation of the active substance (a.s.) and representative products will be outside the EU therefore it is expected that exposure of the environment will only arise from the use and disposal of transfluthrin products. Disposal of product waste following use is not expected to contribute significantly to the environmental exposure (see Doc IIB's section 3.3). The worst case contamination of air results from the use of transfluthrin formulated as 'Raid Portable Electric'. The worst-case operator (non-professional) exposure assessment (see relevant Doc IIB, section 3.2) estimated the mean indoor event air concentration of transfluthrin during use of the product, Raid Portable Electric, to be 0.00735 mg/m^3. This is considered to be higher than the outdoor air concentration, as ventilation inside is restricted compared to the dilution expected outdoors. Worst case local contamination of outdoor air assuming standard room ventilation rates has been estimated to be 2.6 x 10^{-10} mg/m^3 (100m from source), which is considered to be an insignificant exposure concentration. In addition, the estimated atmospheric half-life of transfluthrin for gas-phase reactions with photochemically produced hydroxyl radicals is 19.4 hours and with ozone is 49 days (Document IIIA, section 7.3.1). Therefore during an emission episode after typical use of transfluthrin (8 hours) some degradation maybe expected (with up to 25% reduction in concentration). As a result exposure of the outdoor air from the proposed indoor use of transfluthrin (as Raid Portable Electric) is anticipated to be negligible (see relevant Doc IIB, Section 3.3). The worst case contamination of soil *via* atmospheric deposition results from the use of transfluthrin formulated as 'Baygon Mosquito coil', however this is equally insignificant. The estimated concentration in soil from the use of one coil is 6.8 x 10^{-11} mg/kg (multiple use = 3.4 x 10^{-10} mg/kg). As can be expected from domestic use of transfluthrin in household products, exposure of the outdoor environment is negligible. Hence, the risk for terrestrial non-target organisms is considered to be minimal. Consequently, further data will not provide any additional information relevant to assess the risk to terrestrial non-target organism posed from the proposed uses of transfluthrin in the EU. As such, testing of the toxicity to other terrestrial organisms is not deemed necessary.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

Document IIIA	Effects on other terrestrial non-target organisms
SECTION A7.5.6 **BPD Data Set IIIA / Annex Point XIII.3**	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	Information is available to derive a PNECsoil and to perform the risk assessment for the terrestrial compartment. Since no risks are identified, the available information is considered sufficient.
Conclusion	Further information is not required.
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	

Document IIIA	**Effects on mammals**	
SECTION A7.5.7 (7.5.7.1, 7.5.7.1.1, 7.5.7.1.2 & 7.5.7.1.3) **BPD Data Set IIIA / Annex Point XIII.3.4**		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [✓]	**Other justification [ ]**	
Detailed justification:	Data on the acute, short-term and reproductive toxicity of the active substance transfluthrin to mammals are provided (see Doc IIIA, Section 6). These data show that transfluthrin is of low acute toxicity to mammals. Mammals can be potentially exposed by direct ingestion of the product (in case of e.g. baits) or indirect uptake of residues by intake of contaminated food, e.g. fish or earthworms as food items of the aquatic or terrestrial compartment, respectively. From the typical uses of transfluthrin, the electric vaporizer "Raid Portable Electric", "Baygon mosquito coil" or the anti-moth disc "Turbo 4 Seasons", no direct exposure of mammals is anticipated. The devices are used in presence of humans in and around houses, which discourages feeding of wild mammals at the time of use in the relevant area. Moreover, the product itself is not attractive to mammals (e.g. mice) as it is used in a burning matrix (Baygon Mosquito coil), provided inside of a plastic container (Raid Portable Electric) or impregnated onto a cardboard disc (Turbo 4 Seasons). Hence, direct uptake of transfluthrin by wild mammals is highly unlikely. Alternatively to direct exposure, indirect uptake of feed contaminated with transfluthrin might in principle be possible as the active compound is of high lipophilicity and characterized by a BCF_{fish} of 1471 - 1607. Hence, feeding on fish or on soil organisms is a principle route of exposure for mammals but, as the use of transfluthrin based products results in almost negligible exposure of the outdoor environment (worst case concentration in the aquatic environment is 3.3×10^{-8} mg/L, and for soil 3.4×10^{-10} mg/kg), a risk to mammals by secondary poisoning can be excluded. This is underlined by the expected scattered use of transfluthrin based products that prevents an exposure on a continuous basis (long-term). Repeated uptake of relevant residues of the active compound can be excluded and any adverse effects to mammalian populations are extremely unlikely. Moreover, the risk to biomagnify in the food chain is low as the correlating BMF for a BCF < 2000 is 1 acc. to the Technical Guidance Document on Risk Assessment. As such, the risk for an upper end predator is not increased by accumulation of residues in the food chain. Due to negligible exposure of outdoor non-target terrestrial vertebrates and the availability of mammalian toxicity data any additional toxicity studies to terrestrial vertebrates are not justified and, for animal welfare reasons, should not be required. Mammalian toxicity data and indoor exposure levels were compared in the human operator exposure assessment (see Doc IIBs, Section 3.2) and	

Document IIIA SECTION A7.5.7 (7.5.7.1, 7.5.7.1.1, 7.5.7.1.2 & 7.5.7.1.3) BPD Data Set IIIA / Annex Point XIII.3.4	Effects on mammals
	showed no risks. It is therefore considered that there should be no risk to mammalian pets from the proposed uses.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23-03-2007
Evaluation of applicant's justification	For the proposed uses of transfluthrin, direct exposure of mammals is not considered relevant from the viewpoint of environmental risk assessment. Information for the assessment of indirect exposure can be obtained from the toxicological dossier.
Conclusion	Further information is not required.
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	