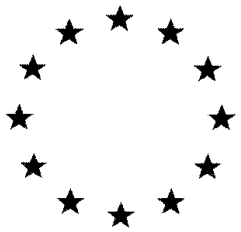
European Commission



TRANSFLUTHRIN

CAS number 118712-89-3

Document III-A
Section 2 Identity
Study Summaries
Active Substance

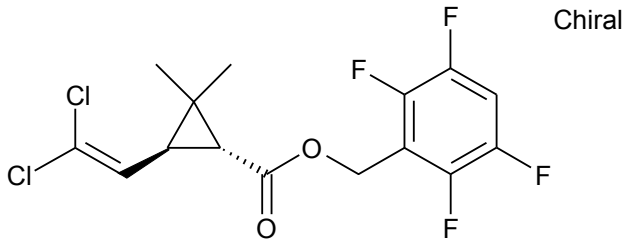
Rapporteur Member State: The Netherlands
August 2013

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

CONTENTS

DOC IIIA/ SECTION A2

Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common name (IIA2.1)**	Transfluthrin	
2.2	**Chemical name (IIA2.2)**	IUPAC: 2,3,5,6-tetrafluorobenzyl (1*R*,3*S*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or 2,3,5,6-tetrafluorobenzyl (1*R*)-*trans*-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate CA: (1*R*-*trans*)-(2,3,5,6-tetrafluorophenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate Other: Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, (2,3,5,6-tetrafluorophenyl) methyl ester, (1R, 3S)	
2.3	**Manufacturer´s development code number(s) (IIA2.3)**	NAK 4455 AE 0035474	
2.4	**CAS No and EC numbers (IIA2.4)**		
2.4.1	**CAS-No**	118712-89-3	X1
2.4.2	**EC-No**	EU Index No: 607-223-00-8 ELINCS No: 405-060-5	X1
2.4.3	**Other**	CIPAC No: 741	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**		
2.5.1	**Molecular formula**	$C_{15}H_{12}Cl_2F_4O_2$	
2.5.2	**Structural formula**		
2.5.3	**Molecular mass**	371.2 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	Please refer to IIIA Confidential data, section A2.6	

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Identity of Active Substance

2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	965 g/kg	96.5%
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	Please refer to IIIA Confidential data, section A2.8	
2.8.1	**Isomeric composition**	Please refer to IIIA Confidential data, section A2.8.1	
2.9	**The origin of the natural a.s. or the precursor(s) of the active substance (IIA2.9)**	Not relevant.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	January 2013
Materials and methods	X1 The EU index no. and ELINCS no. refer to the 1R,trans and 1S,trans configurations, which is not in agreement with the definition of transfluthrin, which is exclusively the 1R,trans isomer. The CAS registry no. does refer to the correct isomer.
Conclusion	Acceptable
Reliability	Not applicable.
Acceptability	Acceptable.
Remarks	None.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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	

DOC IIIA/ SECTION A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Official use only

Subsection

2.10.1 Human exposure towards active substance

2.10.1.1 Production

Production of active substance and formulated products

Transfluthrin and the representative products, Baygon Mosquito Coil, Raid Portable Electric and Turbo 4 Seasons are manufactured and formulated outside of the EU. Therefore in the EU there are no human exposures associated with production/formulation of either the active substance or the formulated products.

2.10.1.2/01 Intended use(s)

Baygon Mosquito Coil

1. Professional Users

The intended use for the formulated product is intended for the amateur, home use only market. There are no professional users.

2. Non-professional Users including the general public

The proposed use of the product is as a mosquito coil which is ignited and then allowed to completely burn out.

(i) via inhalational contact

Primary exposure (during application)

Primary exposure to transfluthrin may occur by inhalation uptake of respirable residues and oral uptake of non-respirable residues. Mean event exposures predicted using Consexpo Version 4.0 is 0.00515 mg/m^3.

Factoring in inhalation rates and bodyweights, the estimated inhalation and oral doses associated with use of a coil generated by ConsExpo 4.0 are for adults: 0.000341 mg/kg/d (acute inhalation), 0.000140 mg/kg/d (chronic inhalation), 0.0000419 mg/kg/d (acute non-respirable oral), and 0.0000172 mg/kg/d (chronic non-respirable oral). For children, the estimated inhalation and oral doses associated with use of a coil are: 0.000759 mg/kg/d (acute inhalation), 0.000312 mg/kg/d (chronic inhalation), 0.0000932 mg/kg/d (acute non-respirable oral), and 0.0000383 mg/kg/d (chronic non-respirable oral).

Secondary exposure (post-application)

The TNsG does not require an assessment of inhalation exposure post application. Measurements after the use of the mosquito coils containing transfluthrin are available. During the application period of about 7 hours, a mean concentration of transfluthrin of approx. 3 µg/m^3 air was detected. This airborne concentration reduced quickly to non detectable levels (<0.2 µg/m^3) within 2 hours after the end of application.

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(ii) via skin contact	Primary exposure (during application) Direct dermal contact with the active substance in the formulated product will be negligible. The active substance is contained within a high carbon content inert matrix. Due to the relatively high log Pow, transfluthrin will preferentially adsorb to carbon in the coil matrix. Considering the very low active substance content (0.03%) and its dilution within the coil matrix, the potential direct dermal contact with transfluthrin will be negligible. Therefore an assessment of primary dermal exposure is not considered necessary. Secondary exposure (post-application) Following application, volatilized residues may condense out of the air and deposit on surfaces. Residues on surfaces present the opportunity for exposure via direct dermal contact with the residues and subsequent oral contact with residues transferred to the hands. For adults, the estimated post-application dermal doses associated with use of a coil generated by ConsExpo 4.0 are: 4.98×10^{-6} mg/kg/d (acute) and 2.05×10^{-6} mg/kg/d (chronic). For children, the estimated post-application dermal doses associated with use of a coil are: 3.73×10^{-5} mg/kg/d (acute) and 1.53×10^{-5} mg/kg/d (chronic). For children, oral uptake is estimated assuming that it corresponds to 10% of the skin exposure. Estimated post-application oral doses for children are estimated to be: 3.73×10^{-5} mg/kg/d (acute) and 1.53×10^{-5} mg/kg/d (chronic).
(iii) via drinking water	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in surface water. Therefore contamination of drinking water will not occur.
(iv) via food	The mean event indoor air concentration was higher from the use of the Raid Portable Electric than from Baygon Mosquito Coil (no deposition on to surfaces is assumed for Turbo 4 Seasons in accordance with the guidance provided within the TNsG) and therefore subsequent worst case calculations are presented for Raid Portable Electric only (see 2.10.1.2/02 below).
(v) indirect via environment	The proposed use is for indoor and outdoor use (i.e. patio use). Environmental exposure will be negligible (see documents IIIA, 7.2.1, 7.1.2 and 7.3.2).

2.10.1.2/02 Intended use(s) **Raid Portable Electric**

1. Professional Users	The intended use for the formulated product is intended for the amateur, home use only market. There are no professional users.
2. Non-professional Users including the general public	The proposed use of the product is as a ready to use electric vapouriser for the domestic control of mosquitoes.
(i) via inhalational contact	Primary exposure (during application) Primary exposure to transfluthrin may occur by inhalation uptake of respirable residues and oral uptake of non-respirable residues. The mean event transfluthrin concentration in air predicted by ConsExpo 4.0 was 0.00735 mg/m^3.

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

	Factoring in inhalation rates and bodyweights, for adults, the estimated inhalation and oral doses associated with use of Raid Portable Electric are : 0.000484 mg/kg/d (acute inhalation), 0.000199 mg/kg/d (chronic inhalation), 0.0000603 mg/kg/d (acute non-respirable oral), and 0.0000248 mg/kg/d (chronic non-respirable oral). For children, the estimated inhalation and oral doses associated with use of Raid Portable Electric are: 0.00108 mg/kg/d (acute inhalation), 0.000445 mg/kg/d (chronic inhalation), 0.000135 mg/kg/d (acute non-respirable oral), and 0.0000554 mg/kg/d (chronic non-respirable oral). <u>Secondary exposure (post-application)</u> The TNsG does not require an assessment of inhalation exposure post application.
(ii) via skin contact	<u>Primary exposure (during application)</u> When used in accordance with the label instructions, direct contact with the formulated product will not occur as the refill containing the transfluthrin is handled via its plastic support and inserted in the slot between the grid and the fan. Therefore, primary dermal exposure is not expected. <u>Secondary exposure (post-application)</u> Following application, volatilized residues may condense out of the air and deposit on surfaces. Residues on surfaces present the opportunity for exposure via direct dermal contact with the residues and subsequent oral contact with residues transferred to the hands. For adults, the estimated post-application dermal doses associated with use of Raid Portable Electric generated by ConsExpo 4.0 are: 6.98×10^{-6} mg/kg/d (acute) and 2.87×10^{-6} mg/kg/d (chronic). For children, the estimated post-application dermal doses associated with use of Raid Portable Electric are: 5.22×10^{-5} mg/kg/d (acute) and 2.15×10^{-5} mg/kg/d (chronic). For children, oral uptake is estimated assuming that it corresponds to 10% of the skin (i.e., external dermal) exposure. Thus, estimated post-application oral doses for children are estimated to be: 5.22×10^{-5} mg/kg/d (acute) and 2.15×10^{-5} mg/kg/d (chronic).
(iii) via drinking water	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in surface water. Therefore contamination of drinking water will not occur.
(iv) via food	The proposed indoor use of transfluthrin (as Raid Portable Electric) with subsequent deposition and transference of residues from room surfaces to foodstuffs (sandwich of 150 cm^2 surface area), results in negligible potential residue levels in food which do not pose a risk to consumers (see document IIIA 6.15). As an illustrative worst case, if it assumed that no cleaning of the surface takes place at all during the 150 days duration of product use and that a sandwich placed on the surface on day 150 receives 149 days worth of 100% dislodged residues from this surface and direct deposition of the active substance onto its upper surface over 1 day.

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

	The intakes would be 3.9 x 10^{-5} mg/kg bw/day (10 kg toddler) and 6.4 x 10^{-6} mg/kg bw/day (60 kg adult).
(v) indirect via environment	The proposed use is for indoor use. Environmental exposure will be negligible (see documents IIIA, 7.2.1, 7.1.2 and 7.3.2).
2.10.1.2/03 Intended use(s)	Turbo 4 Seasons
1. Professional Users	The intended use for the formulated product is intended for the amateur, home use only market. There are no professional users.
2. Non-professional Users including the general public	The proposed use of the product is as a ready to use moth proofer to be used in closets.
(i) via inhalational contact	<u>Primary exposure (during application)</u> Primary exposure to transfluthrin may occur by inhalation uptake of respirable residues and oral uptake of non respirable residues. The mean event transfluthrin concentration in air through use of Turbo 4 Seasons predicted by ConsExpo 4.0 was 0.0154 mg/m3 Factoring in inhalation rates and bodyweights, for adults, the estimated inhalation and oral doses associated with use of Turbo 4 Seasons are 2.85×10^{-5} mg/kg/d (adults) and 5.77×10^{-5} mg/kg/d (children). <u>Secondary exposure (post-application)</u> The TNsG does not require an assessment of inhalation exposure post application.
(ii) via skin contact	Not applicable. According to the TNsG, the only exposure scenario of interest for strips or cassettes placed in closed spaces is inhalation exposure associated with use of the product. Consequently, there is <u>no</u> post-application human exposure.
(iii) via drinking water	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in the environment. Therefore contamination of drinking water will not occur.
(iv) via food	Not applicable. According to the TNsG, the only exposure scenario of interest for strips or cassettes placed in closed spaces is inhalation exposure associated with use of the product. Consequently, there is <u>no</u> post-application human exposure (i.e. from dislodgeable condensed residues).
(v) indirect via environment	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in the environment (see PECS in 2.10.2 below).
2.10.2 Environmental exposure towards active substance	
2.10.2.1 Production	<u>Production of active substance and formulated products</u> Transfluthrin and the representative products, Baygon Mosquito Coil, Raid Portable Electric and Turbo 4 Seasons are manufactured and

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

	formulated outside of the EU. Therefore in the EU there are no human exposures associated with production/formulation of either the active substance or the formulated products.
2.10.2.2/01 Intended use(s)	Baygon Mosquito Coil
Affected compartment(s):	The proposed *indoor* use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in soil, surface water and air (see PECs below). The proposed *outdoor* use of transfluthrin, with subsequent deposition directly to soil and surface water results in negligible concentrations in soil, surface water and air (see PECs below).
water	The proposed *indoor* use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in surface water. The proposed *outdoor* use of transfluthrin, with subsequent deposition directly to surface water results in negligible concentrations in surface water.
sediment	Predicted distribution to sludge (based on fate in STP, Appendix II, TGD, refined by EUSES, is 74.6% (compared to 23.2% in the water phase). Concentrations in sediment, resulting from negligible levels in surface water, will also be negligible.
air	The proposed indoor use of transfluthrin, with subsequent ventilation to outside results in negligible concentrations in air. The proposed *outdoor* use of transfluthrin with subsequent dilution in air results in negligible concentrations in air.
soil	The proposed *indoor* use of transfluthrin, with subsequent ventilation to outside, followed by atmospheric deposition of residues to soil results in negligible concentrations in soil. The proposed *outdoor* use of transfluthrin, with subsequent deposition directly to soil results in negligible concentrations in soil.
Predicted concentration in the affected compartment(s)	An estimation of the expected concentrations of a.s. in the affected compartments, using the relevant algorithms in the TGD, are detailed in document IIB-1, section 3.3.5 and summarised below.
water	5.9×10^{-11} mg/l (realistic worst case) 1.2×10^{-8} mg/l (illustrative worst case)
sediment	6.4×10^{-8} mg/kg (realistic worst case) 1.3×10^{-5} mg/kg (illustrative worst case)
air	$\geq 9.17 \times 10^{-11}$ (100m from source)
soil	6.8×10^{-11} mg/kg (realistic worst case) 3.4×10^{-10} mg/kg (illustrative worst case)
2.10.2.2/02 Intended use(s)	Raid Portable Electric

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Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Affected compartment(s):	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in soil, surface water and air (see PECs below).
water	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in surface water.
sediment	Predicted distribution to sludge (based on fate in STP, Appendix II, TGD, refined by EUSES, is 74.6% (compared to 23.2% in the water phase). Concentrations in sediment, resulting from negligible levels in surface water, will also be negligible..
air	The proposed indoor use of transfluthrin, with subsequent ventilation to outside results in negligible concentrations in air.
soil	The proposed indoor use of transfluthrin, with subsequent ventilation to outside, followed by atmospheric deposition of residues to soil results in negligible concentrations in soil.
Predicted concentration in the affected compartment(s)	An estimation of the expected concentrations of a.s. in the affected compartments, using the relevant algorithms in the TGD, are detailed in document IIB-2, section 3.3.5 and summarised below.
water	8.2×10^{-11} mg/l (realistic worst case) 3.3×10^{-8} mg/l (illustrative worst case)
sediment	8.9×10^{-8} mg/kg (realistic worst case) 3.6×10^{-5} mg/kg (illustrative worst case)
air	1.3×10^{-10} ($Clocal_{air}$, as defined in TGD, 100m from source) 2.6×10^{-10} mg/m^3 ($Clocal_{air}$, as defined in TGD, 100m from source)
soil	8.5×10^{-12} mg/kg (realistic worst case) 1.7×10^{-11} mg/kg (illustrative worst case)

2.10.2.2/02 Intended use(s)

Turbo 4 Seasons

Affected compartment(s):	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in soil, surface water and air (see PECs below).
water	The proposed indoor use of transfluthrin, with subsequent deposition and transference of residues from room surfaces to wastewater, results in negligible concentrations in surface water.
sediment	Predicted distribution to sludge (based on fate in STP, Appendix II, TGD, refined by EUSES, is 74.6% (compared to 23.2% in the water phase). Concentrations in sediment, resulting from negligible levels in surface water, will also be negligible..
air	The proposed indoor use of transfluthrin, with subsequent ventilation

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	to outside results in negligible concentrations in air.	
soil	The proposed indoor use of transfluthrin, with subsequent ventilation to outside, followed by atmospheric deposition of residues to soil results in negligible concentrations in soil.	
Predicted concentration in the affected compartment(s)	An estimation of the expected concentrations of a.s. in the affected compartments, using the relevant algorithms in the TGD, are detailed in document IIB-2, section 3.3.5 and summarised below.	
water	No exposure	
sediment	No exposure	
air	7.7×10^{-11} mg/m^3 (realistic worst case) 1.54×10^{-10} mg/m^3 (illustrative worst case)	$Clocal_{air}$, as defined in TGD, 100m from source:
soil	5.02×10^{-12} mg/kg (realistic worst case) 1.0×10^{-11} mg/kg (illustrative worst case)	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-09-2007*
Materials and methods	*2.10.1 Human exposure towards active substance.* Please refer to Doc IIB. *2.10.2 Environmental exposure towards active substance.* Please refer to Doc IIB.
Conclusion	Please refer to Doc IIB.
Reliability	n.a.
Acceptability	Please refer to Doc IIB.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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 A2.101.2.-01: Summary of predicted exposures through use of transfluthrin based products.

Raid Portable Electric				
	Acute/Seasonal Exposure (mg/kg/d)		Chronic Exposure (mg/kg/d)	
	Adult	Child	Adult	Child
Application: Inhalation	0.000484	0.00108	0.000199	0.000445
Application: Oral	0.0000603	0.0000135	0.0000248	0.0000554
Post-Application: Dermal	0.00000698	0.0000522	0.00000287	0.0000215
Post-Application: Oral	n.a.	0.0000522	n.a.	0.0000215
Integrated Exposure	0.000551	0.00132	0.000227	0.000543
Turbo 4 Seasons				
	Acute/Seasonal Exposure (mg/kg/d)		Chronic Exposure (mg/kg/d)	
	Adult	Child	Adult	Child
Application: Inhalation	0.00002.85	0.0000577	0.00002.85	0.0000577
Integrated Exposure	0.00002.85	0.0000577	0.00002.85	0.0000577
Baygon Coil				
	Acute/Seasonal Exposure (mg/kg/d)		Chronic Exposure (mg/kg/d)	
	Adult	Child	Adult	Child
Application: Inhalation	0.000341	0.000759	0.000140	0.000312
Application: Oral	0.0000419	0.0000932	0.0000172	0.0000383
Post-Application: Dermal	0.00000498	0.0000373	0.00000205	0.0000153
Post-Application: Oral	n.a.	0.0000373	n.a.	0.0000153
Integrated Exposure	0.000388	0.000926	0.000159	0.000380

DOC IIIA/ SECTION 2.10/01

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

Official use only

1 REFERENCE

1.1	**Reference**	Riegner, K., (1996) Study of the degradation and evaporation behaviour of transfluthrin in/on representative indoor surfaces. BAYER AG, Crop Protection Development, Institute of Metabolism Research and Residue Analysis, D-51368 Leverkusen – Bayerwerk. Report number: MR-691/96. [BES Ref: MO-04-012339]. Dates of experimental work: Not stated. Unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.

2 GUIDELINES

2.1	**Guideline study**	No
2.2	**GLP**	No
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Test Material**	Radiolabelled transfluthrin {[^{14}C]NAK 4455} with a radiochemical purity of 99.5%. The specific activity was 3.9 MBq/mg. [^{14}C]NAK 4455 was applied using a blank formulation with an aqueous base that is used in similar form in spray cans. However, this experiment did not use the propane and butane (propellant gases and solubilizers) otherwise used in the formulation, consequently [^{14}C]NAK 4455 had not completely dissolved in the application formula used.
3.2	**Test system**	The following surface materials were used:

Material	Description
Carpet	Velour carpet with Hessian backing. Exposed pieces 1 x 1 cm, 5 pieces per sample.
PVC	Untreated PVC floor covering. Exposed pieces 1 x 1 cm, 5 pieces per sample.
Wall paper	Pre-pasted coarse fibre wall paper. Exposed pieces 1 x 1 cm, 5 pieces per sample.
Wood	Chips of untreated pine.
Varnish	EISODUR® coloured varnish, silk-matt, topcoat with an alkyl resin base. The varnish was applied to glass. After drying, a strip of 1 x 5 cm was scraped off per sample.
Glass	Microscope slide.

DOC IIIA/ SECTION 2.10/01

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

3.3 Exposure and monitoring

The samples were exposed under room conditions in conical flasks in the laboratory. The conical flasks were fitted with air-permeable traps which allowed volatile compounds such as $^{14}CO_2$ and/or organic volatile compounds to be collected. The duration of exposure was 0, 10, 21 and 90 days.

3.4 Analytical method

The amount of radioactivity on the material samples and the amount of organic volatile compounds in the ethyl extracts and the amount of $^{14}CO_2$ in the cocktails were determined by liquid scintillation measurement (LS).

To determine the content of active substance, the extracts of the material samples were investigated by thin-layer chromatography. The "start zone activity" observed during the analysis with the first TLC method was chromatographed using a second thin-layer.

4 RESULTS AND DISCUSSION

Slight decomposition of the active substance of an average of 8% after 90 days could be found only in/on wallpaper, wood, varnish and glass. The reduction in the active substance content on surfaces was affected much more by evaporation, and this was determined semi-quantitatively.

About 3 weeks after application, the amount of recoverable active substance on wallpaper, wood, varnish and glass had fallen on average to 50 % of the starting amount. This process took place rather more slowly with wallpaper and wood and rather faster with varnish and glass; a finding which can be ascribed to the different evaporation behaviour. Only unchanged active substance evaporated and virtually no evaporation from carpet or PVC could be measured.

One problem was the inhomogenous distribution of the active substance in the application solution. However, as the study was aimed at recognition of possible decomposition of transfluthrin and not at the quantitation of evaporation this issue was acceptable.

DOC IIIA/ SECTION 2.10/01

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

5 APPLICANT'S SUMMARY AND CONCLUSION

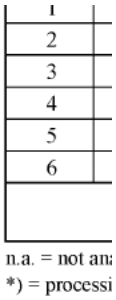
5.1	**Materials and methods**	Transfluthrin {[^{14}C]NAK 4455} was applied to representative indoor surfaces such as carpet, PVC, wallpaper, wood, varnish and glass at an average treatment amount of 3.4 mg/m^2. The degradation behaviour of [^{14}C]NAK 4455 under laboratory conditions was investigated over 90 days.
5.2	**Conclusion**	The active substance evaporated much more quickly wallpaper, wood, varnish and glass than it is broken down by chemical conversion. By contrast, in carpet and PVC only very slight decomposition could be found but very little evaporation. Here the adsorption / absorption effects appear to dominate.
5.2.1	Reliability	2
5.2.2	Deficiencies	Not applicable.

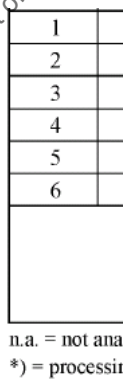
DOC IIIA/ SECTION 2.10/01

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	6-06-2007
Materials and methods	Applicant's version is acceptable.





Conclusion	Applicant's version is adopted.
Reliability	1
Acceptability	Acceptable.
Remarks	-
	COMMENTS FROM ...

DOC IIIA/ SECTION 2.10/01

Information relating to the exposure of the biocidal product

BPD Data set IIB/ Annex Point II2.10

Date	*Give date of comments submitted*
Results and discussion	*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*
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 2.10 (01)-01: Recovery in/on the material samples

No.	Material	Recovery (% of applied radioactivity)			
		Day 0*	Day 10	Day 21	Day 90
1	Carpet	100.3	100.6	NA	108.8
2	PVC	96.1	100.3	NA	109.2
3	Wallpaper	56.7	70.1	60.1	25.2
4	Wood	99.1	50.8	62.7	37.1
5	Varnish	89.2	28.2	38.2	61.7
6	Glass	88.8	33.8	50.8	38.4
Mean (Materials 3 – 6)		83	64	53	41

NA Not analysed

* Processing after about 2 hours

DOC IIIA/ SECTION 2.10/02

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

			Official use only
		6 REFERENCE	
6.1	**Reference**	Konig, T., (1996) Experiment to draw up balance sheets for the residue of transfluthrin (NAK 4455) after its use indoors. BAYER AG, Pesticides Development, Institute of Metabolism Research and Residue Analysis, D-51368 Leverkusen – Bayerwerk. Report number: MR-569/96. [BES Ref MO-03-01512]. Dates of experimental work: Not stated. Unpublished	
6.2	**Data protection**	Yes	
6.2.1	Data owner	Bayer CropScience	
6.2.2			
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 entry into Annex I.	
7		**GUIDELINES**	
7.1	**Guideline study**	No	
7.2	**GLP**	No	
7.3	**Deviations**	Not applicable	
		8 MATERIALS AND METHODS	
8.1	**Test Material**	Baygon® Master (membrane vapourizer), 37.5% by weight transfluthrin.	
8.2	**Test system**	The measurements were made in an experiment room approximately 17 m^2 in size with a volume of 52.4 m^3. The room was furnished only with a cabinet and two laboratory tables. The floor was covered with PVC and the walls, ceiling and floors were lined with paper tissues. The room was entered only once during the experiment for the purpose of sampling the air. The windows remained closed throughout the period of the experiment. The door was sealed with adhesive tape in order to prevent any air exchange as far as possible.	
8.3	**Exposure and monitoring**	The transfluthrin content in the room air was determined throughout the 24 hour application period. The quantity applied was determined by a differential weighing of the Baygon® Master refills.	
8.4	**Analytical method**	The air, paper tissue samples and rinsings from the Genius evaporator were analysed using gas chromatography with an electron capture	X

detection (ECD) system according to an unpublished in-house method.

9 RESULTS AND DISCUSSION

The results of the measurements on the room show that a concentration of approximately 4 µg/m^3 was reached after approximately 1 hour. Approximately 6 hours after the beginning of the application, the transfluthrin concentration was between 6 and 8 µg/l and remained so until the end of the experiment (the evaporation oven was switched off after 24 hours).

Analysis of the paper tissue showed that considerable minor quantities of active agent, averaging around 150 µg/m^2, were found on the floor, on the ceiling, and on the two walls adjacent to the wall on which the Genius evaporator was installed. The mean value on the wall facing the application wall was about 250 µg/m^2.

7.1 mg of transfluthrin was recovered from the Genius evaporator oven.

The quantity of transfluthrin consumed during the experiment was determined with a differential weighing of the refill before and after the experiment. The consumption of the formulation over the 24-hour period of the experiment was approx. 117 mg. An analysis of the transfluthrin content in the formulation after the application gave a value of 38.5%. This approximately corresponded to the content of 37.5% stated in the specification. A total applied quantity of 45.0 mg of transfluthrin was calculated from the stated quantities.

A total of 26 mg of transfluthrin was recovered from the investigated compartments: room air, paper tissues and Genius evaporator. If this quantity is compared with the total applied quantity of 45 mg a recovery of 57.8% is obtained.

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Information relating to the exposure of the biocidal product

10 APPLICANT'S SUMMARY AND CONCLUSION

10.1	**Materials and methods**	To determine the residues of transfluthrin indoors after its application by means of an evaporation oven, a Baygon® Master evaporator was operated in a closed room for 24 hours. Throughout the period of the application, air samples were taken and the quantity of transfluthrin adsorbed on to walls, floor and ceiling was determined by means of paper tissues with which the room had previously been lined.
10.2	**Conclusion**	The results of the analyses showed that the largest quantities of active agent transfluthrin (> 10 000 µg/m^2) were found on the wall immediately above the evaporation oven (chimney effect). The other wall surfaces displayed a markedly lower burden (approximately 100 - 200 µg/m^2). The concentrations in the room air throughout the period of the experiment were approximately 6 - 8 µg/m^3. In total, approximately 60% of the evaporated quantity could be recovered.
10.2.1	Reliability	2
10.2.2	Deficiencies	Not applicable.

DOC IIIA/ SECTION 2.10/02

Information relating to the exposure of the biocidal product

BPD Data set IIB/ Annex Point II2.10

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	6-6-2007
Materials and methods	*3.4 Analytical method:* Samples were analysed using an unpublished in-house method (00277). However, no study report on this method or its validation is included in the Dossier. Only in Doc IIA of the applicant, concise information is presented. Since the information from this study is not used in the risk assessment, no additional information is required.
Conclusion	Acceptable
Reliability	2
Acceptability	Acceptable, data were not used.
Remarks	None.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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 2.10 (02)-01: Total quantitiy of transfluthrin recovered

	Total quantity of transfluthrin (mg)
Room air (7.5 µg/m^3 at end of application)	0.4
Floor, ceiling (150 µg/m^2)	5.1
Wall A (150 µg/m^2)	2.3
Wall B (250 µg/m^2)	2.8
Wall C (150 µg/m^2)	2.3
Wall D (application)	6.0
Genius evaporator after application	7.1
Total	26.0

Table 2.10 (02)-02: Results of air measurements (µg/m^3)

Sampling time	Enrichment volume (L)	Mean value (µg/m^3)
Before application	120	<0.1
0 – 0.5 h	30	<0.1
0.5 – 1 h	30	0.5
1 – 2 h	60	4.2
2 – 3 h	60	3.9
3 – 4 h	60	4.3
4 – 6 h	120	4.7
6 – 8 h	120	6.8
8 – 10 h	120	7.4
10 – 12 h	120	7.8
14 – 16 h	120	6.1
18 – 20 h	120	6.6
22 – 24 h	120	7.5

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Information relating to the exposure of the biocidal product

BPD Data set IIB/ Annex Point II2.10

			Official use only
		11 REFERENCE	
11.1	**Reference**	Konig, T., (1994) Provisional Results on the desorption behaviour of NAK 4455 BAYER AG, Pesticides Development, Institute for Product Information and Residuum Analysis, Monheim. Report number: RA 060/94. [BES Ref MO-03-01156]. Unpublished	
11.2	**Data protection**	Yes	
11.2.1	Data owner	Bayer CropScience	
11.2.2			
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 entry into Annex I.	
12		**GUIDELINES**	
12.1	**Guideline study**	No	
12.2	**GLP**	No	
12.3	**Deviations**	Not applicable	
		13 MATERIALS AND METHODS	
13.1	**Test Material**	Aerosol can (specification: 0.05% NAK4455, 69.95% isopropanol, 30.00% propane/butane (15:85), ball valve 1 x 020 Buna SH65.040 ST.	
13.2	**Test system**	The experiment was carried out in the $1m^3$ glass chambers. Two plates of different materials (each 15 x 15 cm = 225 cm^2) were placed in each of the glass chambers. The materials used were: glass, ceramic, wood, PVC, carpet, paper.	
13.3	**Exposure and monitoring**	Prior to being placed in the glass chambers the two plates were sprayed with NAK 4455. Spraying height: approx. 20 cm, spraying speed: approx. 50 cm/sec. The chamber was kept closed throughout the experiment (no air exchange) and air samples were taken at intervals of one day in each case. The first sampling took place 24 hours after placing the plates in the chamber, the last sampling after one week	
13.4	**Analytical method**		X

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Information relating to the exposure of the biocidal product

14 RESULTS AND DISCUSSION

15 APPLICANT'S SUMMARY AND CONCLUSION

15.1 Materials and methods

Two plates of different materials previously sprayed with NAK 4455 (each 15 x 15 cm = 225 cm^2) were placed in each of 1 m^3 glass chambers. The chamber was then kept closed throughout the experiment (no air exchange) and air samples were taken at intervals of one day in each case. The first sampling took place 24 hours after the placing of the plates in the chamber, the last sampling after one week. The following materials were employed: glass, ceramic, wood, PVC, carpet, paper.

15.2 Conclusion

With the exception of carpet, there was a correlation between the quantity of NAK 4455 introduced into the chamber and the observed concentration in the room air, though the quantities measured in the room air make up only a small fraction of the introduced quantities.

Differences in the behaviour of carpet and paper and glass, ceramic, wood and PVC were observed. For glass, ceramic, wood and PVC the concentration in air was constantly reduced. An increase of the concentration in the room air could be observed for carpet and paper during the first three to four days after exposure. After a week, the concentrations were still at the initial level. This indicates a strongly delayed release of the quantity of active agent from both carpet and paper.

15.2.1 Reliability 2

15.2.2 Deficiencies Not applicable.

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Information relating to the exposure of the biocidal product

BPD Data set IIB/ Annex Point II2.10

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	6-6-2007
Materials and methods	*3.4 Analytical method:* No information is given (neither in the summary or in the study report). The submitted report (1994) discusses the provisional results and is very concise.
Conclusion	Study report is too concise to evaluate. Since the information from this study is not used in the risk assessment, no additional information is required.
Reliability	2
Acceptability	Acceptable.
Remarks	None.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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	

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BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

			Official use only
		16 REFERENCE	
16.1	**Reference**	Konig, T., (1993) Establishment of room air concentration and user exposure when NAK 4455 is applied in spray cans. BAYER AG,.Pesticides Development, Institute for Product Information and Residuum Analysis, Bayerwerk. Report Number:. RA 349/93. [BES Ref MO-03-010192]. Dates of experimental work: Not stated. Unpublished	
16.2	**Data protection**	Yes	
16.2.1	Data owner	Bayer CropScience	
16.2.2			
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 entry into Annex I	
17		**GUIDELINES**	
17.1	**Guideline study**	No	
17.2	**GLP**	No	
17.3	**Deviations**	Not applicable	
		18 MATERIALS AND METHODS	
18.1	**Test Material**	Aluminium spray cans (Lasercap version) filled with batch FL 1646/4169 (transfluthrin content 0.04%).	
18.2	**Test system**	The measurements were made in two experiment rooms approximately 14 m^2 in size with a volume of 42.86 m^3. The room was furnished only with a cupboard, table and two padded chairs. The floor was covered with PVC. The room was entered only for the purpose of taking samples during the test and the windows remained closed throughout the period of the experiment.	
18.3	**Exposure and monitoring**	Transfluthrin was sprayed into each room for about 8 seconds following the manufacturer's application instructions for the control of flying, insects (2 sec./10 m^3**).** During spraying and at suitable time intervals after the treatment, air samples were taken and analysed for transfluthrin. The quantity sprayed was determined by a differential weighing of the spray cans. Samples were taken of the air at two points in each of the rooms using pumps.	
18.4	**Analytical method**	The air samples were analysed using gas chromatography with an	X

electron capture detection (ECD) system according to an unpublished in-house method.

19 RESULTS AND DISCUSSION

In both test rooms similar distributions of the room air concentrations were noted.

The starting concentrations for both rooms were in the range of 136 to 148 µg/m^3 but in one room one pump varied considerably from the other figures (85 µg/m^3**),** which may be attributable to a fault during the first measurement.

There was a distinct decrease in concentrations for all four pumps for all other measurements. The concentrations had already fallen to approx. 10% of the starting concentration in the second half hour after application. The room air concentration of transfluthrin in both rooms was in the range of the detectable limit of 0.1 µg/m^3 24 hours after application.

20 APPLICANT'S SUMMARY AND CONCLUSION

20.1 Materials and methods

Transfluthrin (0.04%) was sprayed into two experiment rooms approximately 14 m^2 in size with a volume of 42.86 m^3. The room was furnished only with a cupboard, table and two padded chairs. The floor was covered with PVC.

The room was entered only for the purpose of taking samples during the test and the windows remained closed throughout the period of the experiment.

20.2 Conclusion

The measured room air concentration was of the order of 130 to 150 µg/m^3 (spray length about 8 seconds = 6 to 7 mg NAK 4455/test room) immediately after application, but had fallen after only half an hour to approx. 10% of the starting concentration. The concentrations were in the range of the detectable limit of 0.1 µg/m^3 24 hours after application.

20.2.1 Reliability 2

20.2.2 Deficiencies Not applicable.

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BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	6-6-2007
Materials and methods	*3.4 Analytical method:* Samples were analysed using an unpublished in-house method (00277). However, no study report on this method or its validation is included in the Dossier. Only in Doc IIA of the applicant, concise information is presented. The applicant is requested to submit a study report on this method and on its validation.
Conclusion	Acceptable. Since the information from this study is not used in the risk assessment, no additional information is required.
Reliability	2
Acceptability	Acceptable.
Remarks	None.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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 2.10 (04)-01: Room air measurement

Time	Pump 1 Test room 1 (µg/m³)	Pump 2 Test room 1 (µg/m³)	Pump 1 Test room 2 (µg/m³)	Pump 2 Test room 2 (µg/m³)
Before application	0	0	0	0
0 – 10 min	140	134	148	85
10 – 20 min	36	34	50	41
20 – 30 min	20	24	26	21
30 min – 1 h	9	11	18	13
1 – 2 h	3.1	3	5.8	5
2 – 3 h	1.3	1.7	2.1	2.4

3 – 4 h	0.9	1.5	0.9	0.9
7 – 8 h	0.4	0.5	0.4	0.3
23 – 24 h	<0.1	<1.0	0.13	0.11

DOC IIIA /SECTION 2.10/05

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

			Official use only
		21 REFERENCE	
21.1	**Reference**	Konig, T., (1993) Determination of room air concentration of NAK 4455 when mosquito coils containing NAK 4455 are used. BAYER AG, Crop Protection Research, Institute for Product Information and Residue Analysis, Monheim. Report Number: RA 150/93. [BES Ref MO-03-010197]. Dates of experimental work: Not stated. Unpublished	
21.2	**Data protection**	Yes	
21.2.1	Data owner	Bayer CropScience	
21.2.2			
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 entry into Annex I.	
22		**GUIDELINES**	
22.1	**Guideline study**	No	
22.2	**GLP**	No	
22.3	**Deviations**	Not applicable	
		23 MATERIALS AND METHODS	
23.1	**Test Material**	Mosquito coil.	
23.2	**Test system**	The measurements were made in two experiment rooms approximately 14 m^2 in size with a volume of 42.86 m^3. The room was partly furnished with a cupboard, desk, side table and two upholstered chairs. The floor was covered with PVC. The room was entered only for the purpose of taking samples during the test. One window remained open and the rooms were kept at a temperature of 20 ^oC throughout the period of the experiment.	X
23.3	**Exposure and monitoring**	A mosquito coil was placed approx 30 cm from the floor, ignited, then allowed to completely burn out. The application lasted 7 hours. Samples were taken of the air at two points in each of the rooms using pumps.	
23.4	**Analytical method**	The air samples were analysed using gas chromatography with an electron capture detection (ECD) system according to an unpublished in-house method.	X

DOC IIIA /SECTION 2.10/05

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

24 RESULTS AND DISCUSSION

Transfluthrin room air concentration ranged between 1.6 and 3.7 µg/m^3 during application. Just two hours after the end of application, the concentration fell below the detectable limit of 0.2 ug/m^3.

The recovery rates revealed by analysis were between 78 and 100%.

25 APPLICANT'S SUMMARY AND CONCLUSION

25.1 Materials and methods

A mosquito coil was placed approx 30 cm from the floor, ignited, then allowed to completely burn out. The application lasted 7 hours. Samples were taken of the air at two points in each of the rooms using pumps. The measurements were made in two experiment rooms approximately 14 m^2 in size with a volume of 42.86 m^3. The room was partly furnished with a cupboard, desk, side table and two upholstered chairs. The floor was covered with PVC. The room was entered only for the purpose of taking samples during the test. One window remained open and the rooms were kept at a temperature of 20 ºC throughout the period of the experiment.

25.2 Conclusion

Transfluthrin room air concentration ranged between 1.6 and 3.7 µg/m^3 during application. Just two hours after the end of application, the concentration fell below the detectable limit of 0.2 ug/m^3.

25.2.1 Reliability 2

25.2.2 Deficiencies Not applicable.

DOC IIIA /SECTION 2.10/05

BPD Data set IIB/ Annex Point II2.10

Information relating to the exposure of the biocidal product

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	6-6-2007
Materials and methods	*3.2 Test system:* During the test one window of each room was left open. In other, similar tests provided by the applicant, the windows were closed during the whole experiment. This appears to be contradictory *3.4 Analytical method:* Samples were analysed using an unpublished in-house method (00277). However, no study report on this method or its validation is included in the Dossier. Only in Doc IIA of the applicant, concise information is presented.
Conclusion	Acceptable, despite the lack of information on the Method of Analysis. ConsExpo calculations by the RMS using default values and the dimensions of the room in this study yielded similar air concentrations as were measured by the authors of this study. These experimentally determined concentrations were therefore only used for "validating"purposes.
Reliability	2
Acceptability	Acceptable.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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 2.10 (05)-01: Room air measurement

Application period	**Transfluthrin (µg/m³) Test room 1**	**Transfluthrin (µg/m³) Test room 2**
Before application	<0.2	<0.2
0 - 1 h after start of application	1.9	1.6
1 -2 h after start of application	2.5	2.0
2 - 3 h after start of application	2.4	2.6
3 – 4 h after start of application	1.7	1.6
4 – 6 h after start of application	3.7	3.1
6 – 7 h after start of application	2.2	1.7
0 – 1 h after end of application	0.3	0.4
1 – 2 h after end of application	<0.2	*
17 – 18 h after end of application	<0.2	<0.2

***** Pump failure so no samples recorded