European Commission

Pyriproxyfen

CAS number 95737-68-1

Document III-A

Section 1 & 2 : Applicant & Identity
Study Summaries
Active Substance

Rapporteur Member State: The Netherlands

January 2012

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

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Please refer to "Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8 EC Concerning the Placing of Biocidal Products on the Market (Appendix 7.1 and 7.2)" for a list of the Standard Terms and Abbreviations used in this document.

Section A1

Annex Point IIA1

1. Applicant

1.1 Applicant

Sumitomo Chemical (UK) PLC

Horatio House
75-85 Fulham Palace Road
London
W6 8JA
United Kingdom

[redacted]

Telephone: +44 (0)208 600 7713

[redacted]

[redacted]

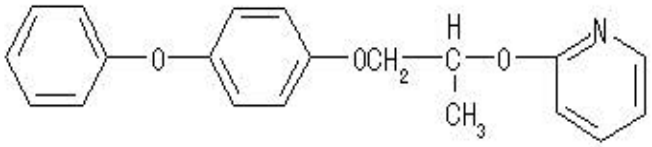
1.2 Manufacturer of Active Substance (if different)

Sumitomo Chemical Co. Ltd.

[redacted]

Section A2 **2. Identity of Active Substance**

Subsection (Annex Point)		**Official use only**
2.1 Common name (IIA2.1)	Pyriproxyfen	
2.2 Chemical name (IIA2.2)	IUPAC: 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether CA: 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	X1
2.3 Manufacturer´s development code number(s) (IIA2.3)	[redacted]	
2.4 CAS No and EC numbers (IIA2.4)	Non-entry field	
2.4.1 CAS-No	95737-68-1	
2.4.2 EC-No	429-800-1 (ELINCS)	
2.4.3 Other	715 (CIPAC)	

2.5 Molecular and structural formula, molecular mass (IIA2.5)	Non-entry field	
2.5.1 Molecular formula	$C_{20}H_{19}NO_3$	
2.5.2 Structural formula		
2.5.3 Molecular mass	321.37	
2.6 Method of manufacture of the active substance (IIA2.1)	Refer to confidential information presented in the Confidential Appendix	
2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)	Refer to confidential information presented in the Confidential Appendix	x2
2.8 Identity of impurities and additives, as appropriate (IIA2.8)	Refer to confidential information presented in the Confidential Appendix	

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)	Not relevant, as the active substance is not naturally occurring
2.10	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
2.10.1 Human exposure towards active substance	Not relevant as active substance as manufactured is not produced in the EU
2.10.1.1 Production	
i) Description of process	Not relevant as active substance as manufactured is not produced in the EU
ii) Workplace description	Not relevant as active substance as manufactured is not produced in the EU
iii) Inhalation exposure	Not relevant as active substance as manufactured is not produced in the EU
iv) Dermal exposure	Not relevant as active substance as manufactured is not produced in the EU
2.10.1.2 Intended use(s)	
1. Professional Users	
i) Description of application process	For detailed description of intended uses refer to IIIB, Section 5
ii) Workplace description	For detailed description of intended uses refer to IIIB, Section 5
iii) Inhalation exposure	For evaluation of primary (direct) exposure refer to IIB, Section 8.2
iv) Dermal exposure	For evaluation of primary (direct) exposure refer to IIB, Section 8.2
2. Non-professional Users including the general public	[redacted]
(i) via inhalational contact	For evaluation of primary (direct) exposure refer to IIB, Section 8.2
(ii) via skin contact	For evaluation of primary (direct) exposure refer to IIB, Section 8.2
(iii) via drinking water	For evaluation of secondary (indirect) exposure refer to IIB, Section 8.2
(iv) via food	For evaluation of secondary (indirect) exposure refer to IIB, Section 8.2

(v) indirect via environment	For evaluation of secondary (indirect) exposure refer to IIB, Section 8.2

2.10.2 Environmental exposure towards active substance

2.10.2.1 Production

(i) Releases into water	Not relevant as active substance as manufactured is not produced in the EU
(ii) Releases into air	Not relevant as active substance as manufactured is not produced in the EU
(iii) Waste disposal	Not relevant as active substance as manufactured is not produced in the EU

2.10.2.2 Intended use(s)

Affected compartment(s):	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Water	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Sediment	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Air	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Soil	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Predicted concentration in the affected compartment(s)	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Water	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Sediment	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Air	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3
Soil	For evaluation of exposure to environmental compartments refer to IIB, Section 8.3

[redacted]

European Commission

Pyriproxyfen

CAS number 95737-68-1

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Section 3 Phys-Chem
Study Summaries
Active Substance

Rapporteur Member State: The Netherlands

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

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Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)	-	-	-	-	-	-	-	
3.1.1 Melting point	OECD 102 equivalent to EEC A.1 - Heated metal block with capillary tube	[redacted]	Melting point: 48.0-50.0°C	-	[redacted]	[redacted]	[redacted]	
3.1.2 Boiling point	OECD 103 equivalent to EEC A.2 - Differential thermal analysis	[redacted]	Boiling point: 318°C	-	[redacted]	[redacted]	[redacted]	
3.1.3 Bulk density/ relative density	Gas comparison pyknometer method - equivalent to EEC A.3 OECD 109	[redacted]	Density: 1.26 g/cm^3 at 23°C	-	[redacted]	[redacted]	[redacted]	[redacted]
	Gas comparison pyknometer method - equivalent to EEC A.3 OECD 109	[redacted]	Relative density 1.143	-	[redacted]	[redacted]	[redacted]	[redacted]
3.2 Vapour pressure (IIA3.2)	OECD104 equivalent to EEC A.4 - Gas saturation method	[redacted]	Vapour pressure: <1.33 x 10^{-5} Pa (<1.0 x 10^{-7} mmHg) at 22.81°C	-	[redacted]	[redacted]	[redacted]	[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		[redacted]					[redacted]	
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	Calculation	-	Henry's law constant (calculated): <1.17 x 10^{-2} Pa m^3 mol^{-1} (<1.16 x 10^{-7} atm mol^{-1} m^3) at 22-25°C	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
3.3 Appearance (IIA3.3)	-	-	-	-	-	-	-	
3.3.1 Physical state	Physical state: In-house method (Visual inspection)*	[redacted]	Granular solid at 25°C	-	[redacted]	[redacted]	[redacted]	
	Physical state: In-house method (Visual inspection)*	[redacted]	Solid at 20°C	-.	[redacted]	[redacted]	[redacted]	
3.3.2 Colour	Colour: ASTM D1535-80*	[redacted]	Colour: White (Munsell colour: N9.5/90.0%R)	-	[redacted]	[redacted]	[redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.3.3 Odour	Colour: ASTM D1535-68*	[redacted]	Colour: Pale yellowish white (Munsell colour: 5Y(9/2))	-	[redacted]	[redacted]	[redacted]	
	ASTM D1292-86*		Odourless	-	[redacted]	[redacted]	[redacted]	
	General Notices of the Pharmacopoeia of Japan, 11th edition*		Faint characteristic odour	-	[redacted]	[redacted]	[redacted]	
3.4 Absorption spectra (IIA3.4)	-	-	-	-	-	-	-	
UV/VIS	In-house method*	[redacted]	**UV/VIS** (Ethanol solution) **UV/VIS absorption characteristics** λ_{max} = 271.6 nm $\varepsilon = 6.91 \times 10^3$ **Optical purity** Not applicable because pyriproxyfen is achiral	There is no absorption of pyriproxyfen in the visible region. Therefore, no visible spectrum was determined	[redacted]	[redacted]	[redacted]	[redacted]
IR	IR (KBr)		Data generated were consistent with the					

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			chemical structure					
NMR	NMR (^{1}H-NMR: 270 MHz)		Data generated were consistent with the chemical structure					
MS	MS (Electron impact ionisation)		Data generated were consistent with the chemical structure					
	IR (KBr), NMR (^{1}H-NMR: 300 MHz proton spectrum), MS (direct infusion, positive ion electrospray)	[redacted]	Data generated using IR, NMR and MS were consistent with the chemical structure	-	[redacted]	[redacted]	[redacted]	[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5)	EPA CG-1500[*1]	[redacted]	**In the neutral range** In distilled water: 0.367mg/l at 25°C **In the acidic range (pH 4 to 6) and in the alkaline range (pH 8 to 10)** Not required as pyriproxyfen is not capable of forming ions because of its extremely low solubility in water.	[redacted]	[redacted]	[redacted]	[redacted]	
	EEC A6, OECD 105	[redacted]	Mean water solubility at 20 ± 0.5°C pH 5: 0.058 mg/L pH 7: 0.101 mg/L pH 9: 0.119 mg/L [redacted]	-	[redacted]	[redacted]	[redacted]	[redacted]
3.6 Dissociation constant (-)	OECD 112 (Titration method or conductometric method or spectrophotometric method)	-	**Dissociation constant** Dissociation constant of pyriproxyfen could not be obtained because the solubility of pyriproxyfen in water was extremely low. [redacted] **d**	-	[redacted]	[redacted]	[redacted]	[redacted]
3.7 Solubility in organic	CIPAC MT181*	[redacted]	*n*-Heptane: 25 - 29 g/L at 20°C	-	[redacted]	[redacted]	[redacted]	[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
solvents, including the effect of temperature on solubility (IIIA3.1)		[redacted]	1,2-Dichloroethane: >1000 g/L at 20°C Methanol: 25 - 29 g/L at 20°C Acetone: >1000 g/L at 20°C *p*-Xylene: >1000 g/L at 20°C Ethyl acetate: >1000 g/L at 20°C				[redacted]	
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	-	-	-	Not required as the active substance as manufactured does not contain an organic solvent	-	-	-	[redacted]
3.9 Partition coefficient n-octanol/water (IIA3.6)	OECD 107 equivalent to EEC A.8 – Shake flask method	[redacted]	**n-octanol/ water partition co-efficient** log Pow = 5.37 at 25°C (pH 5.60-5.65) **Effect of pH (4 to 10) on the n-octanol/ water partition co-efficient** Not required as pyriproxyfen is not capable of forming ions because of its extremely low solubility in water.	[redacted]	[redacted]	[redacted]	[redacted]	
	EEC A8, OECD 117	[redacted]	Mean Log P_{ow} pH 5: 4.85 pH 7: 4.86 pH 9: 4.87	-	[redacted]	[redacted]	[redacted]	[redacted]

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
		[redacted]	Results demonstrate that n-octanol/ water partition co-efficient is not affected by pH.					
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	-	-	-	Refer to IIIB, 3.7 Pyriproxyfen is stable in the product when stored for 6 months at 40°C and 3 months at 60°C.	-	-	-	[redacted]
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	EEC A.10	[redacted]	Flammability: Not highly flammable	-	[redacted]	[redacted]	[redacted]	
	EEC A.12	[redacted]	Flammability (contact with water): No flammable gasses evolved	-	[redacted]	[redacted]	[redacted]	
	EEC A.15 (The melting point of the active substance is below 50°C)	[redacted]	Auto-flammability: No auto-ignition observed below 400°C, with sample volumes up to 1 mL, at an atmospheric pressure of 97.5 kPa.	-	[redacted]	[redacted]	[redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.12 Flash-point (IIA3.9)	-	-	-	Not required as the melting point of pyriproxyfen is not below 40°C.	-	-	-	
3.13 Surface tension (IIA3.10)	-	-	-	Not required as the solubility of the active substance in water is below 1mg/L.	-	-	-	
3.14 Viscosity (-)	-	-	-	Not required as the active substance is not a liquid	-	-	-	
3.15 Explosive properties (IIA3.11)	Theoretical assessment - Structural considerations and DSC testing	[redacted]	Pyriproxyfen is considered not to be potentially explosive based on the chemical structure and associated thermodynamic properties.	The experimental procedure described in EEC A.14 was not attempted because the assessment concluded that there was no strong evidence of explosive properties	[redacted]	[redacted]	[redacted]	
3.16 Oxidizing properties (IIA3.12)	Theoretical assessment - Structural considerations, oxygen balance and DSC testing	[redacted]	Pyriproxyfen is considered not to be potentially oxidising based on the chemical structure, oxygen balance and associated thermodynamic properties.	The experimental procedure described in EEC A.17 was not attempted because the assessment concluded that there was no strong evidence of oxidising properties	[redacted]	[redacted]	[redacted]	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.17 Reactivity towards container material (IIA3.13)	-	-	-	No evidence of reactivity towards containers.	-	-	-	

* No test guideline is specified

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]

[redacted]

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]		

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]		

[redacted]	[redacted]	
[redacted]	[redacted]	
[redacted]	[redacted]	

European Commission

Pyriproxyfen

CAS number 95737-68-1

Document III-A

Section 4 Analytical Methods
Study Summaries
Active Substance

Rapporteur Member State: The Netherlands

January 2012

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

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4.1 Analytical methods for the determination of pure active substances and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)

4.1.1 Methods for the determination of pure active substance in the active substance as manufactured

Section A4.1.1/01,02
Annex Point IIA 4.1.1

Methods for the determination of pure active substance in the active substance as manufactured

		Official use only
	1 Reference	
1.1 Reference	**Original validation report** [redacted] (2000) [redacted] **Addendum report** [redacted] (2002) [redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.	
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 Guidance and Quality Assurance	
2.1 Guideline study	No (methods used comparable to SANCO/3030/99 rev.4)	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 Materials and Methods	
3.1 Preliminary treatment		
3.1.1 Enrichment	A known weight of the technical material is dissolved in internal standard solution (ca. 0.067 % w/v p-benzyldiphenyl methanol solution)	
3.1.2 Cleanup	Not relevant	
3.2 Detection		
3.2.1 Separation method	Pyriproxyfen is separated by high performance liquid chromatography using a LiChrosorb RP-18 column at room temperature and a mobile phase of acetonitrile/water	
3.2.2 Detector	Pyriproxyfen is detected using an ultra violet absorption	

	photometer (HPLC-UV) at a wavelength of 254 nm
3.2.3 Standard(s)	Pyriproxyfen standards in p-benzyldiphenyl methanol (internal)
3.2.4 Interfering substance(s)	Internal standard, solvent, impurities
3.3 Linearity	
3.3.1 Calibration range	Concentrations of pyriproxyfen in internal standard solution (ca. 0.067 % w/v p-benzyldiphenyl methanol solution) were prepared by accurately weighing 40, 45, 50, 55 and 60 mg pyriproxyfen and dissolving in 10 mL of internal standard solution equivalent to 4.0, 4.5, 5.0, 5.5 and 6.0 mg/mL (corresponding to 80, 90, 100, 110 and 120% of the nominal concentration in the method i.e. 5.0 mg/mL). Internal standard was added equivalent to 0.67 mg/mL
3.3.2 Number of measurements	5 solutions at different concentration were prepared
3.3.3 Linearity	Results showed the response of the HPLC-UV to be linear when the peak area ratio of pyriproxyfen/internal standard was plotted against the concentration of the pyriproxyfen standard. Using the method of least squares the correlation coefficient was calculated to be 0.99996 (slope 0.01781, Y intercept 0.01289) The equation for the calibration line is as follows: y = 0.01781 x + 0.01289 y: peak area ratio of pyriproxyfen to the internal standard x: concentration of pyriproxyfen (%)
3.4 Specifity: interfering substances	A solution containing 5.0 mg/mL pyriproxyfen standard, 0.67 mg/mL internal standard and 10 µg/mL of each of impurities #2 and #6 (equivalent to 0.2% nominal concentration), 20 µg/mL of impurity #3 (equivalent to 0.4% nominal concentration), 100 µg/mL of impurity #4 (equivalent to 2.0% nominal concentration) and 25µg/mL of impurity #5 (equivalent to 0.5% nominal concentration) were analysed according to the analytical method. An example chromatogram presented in the report shows good specificity with no interference from solvent and complete resolution between neighbouring peaks The identity of the peak assigned as pyriproxyfen was confirmed ([redacted]2002[redacted] using HPLC-MS positive electrospray ionisation (ESI +ve) and showing that the mass spectrum of the peak identified in pyriproxyfen technical was identical to that of the pyriproxyfen standard
3.5 Recovery rates at different levels	Not performed. Accuracy of the method was evaluated from linearity, precision and specificity.
3.5.1 Relative standard deviation	Not performed. Accuracy of the method was evaluated from linearity, precision and specificity
3.6 Limit of determination	Not performed. The lowest calibration standard analysed as part of the test for linearity was 4.0 mg/mL although it is expected that the LOQ of the method could be lowered if necessary
3.7 Precision	
3.7.1 Repeatability	For precision, the content of pyriproxyfen in the technical material ([redacted]) was determined at 80%, 100% and 120% of the sample amount specified in the analytical method. Each

	level was determined in triplicate and the repeatability of the method evaluated The mean value and the standard deviation of the factors, which are quotients of the amount of pyriproxyfen related to the peak area ratios were used to calculate the RSD of 0.38%. The results are presented in Table A4.1.1-01
3.7.2 Independent laboratory validation	Not performed

4 Applicant's Summary and conclusion

4.1 Materials and methods	**Method –** Dissolving in internal standard in methanol. Quantification by HPLC-UV at 254 nm **Specificity** – Good resolution of the active substance from the internal standard and other impurities. No interference observed. Peak identity confirmed by HPLC-MS **Linearity** - Across the range of 80 –120% of the nominal concentration expected, the response of the HPLC-UV was found to be linear when the peak area ratio of pyriproxyfen/internal standard was plotted against the concentration of pyriproxyfen. Correlation coefficient was calculated to be 0.99996 **Accuracy –** Was based on linearity, precision and specificity of the method **Precision** – 0.38% RSD, no outliers removed
4.2 Conclusion	The analytical methods have been validated in terms of specificity, linearity, accuracy and precision and are therefore considered suitable for the determination of pyriproxyfen in the technical material. There are no existing CIPAC methods for pyriproxyfen.
4.2.1 Reliability	[redacted]
4.2.2 Deficiencies	[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]

Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	Comments from ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]		[redacted]
[redacted]	[redacted]		[redacted]
[redacted]	[redacted]		[redacted]

4.1.2 Methods for the determination of significant and/or relevant impurities and additives (eg. stabilisers) in the active substance as manufactured

There are no additives in the active substance as manufactured. Please refer to the Confidential Appendix for methods for the determination of significant and/or relevant impurities in the active substance as manufactured

4.2 Analytical methods in all relevant environmental media including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following

The studies carried out for the methods for the determination of residues are summarised below:

Matrix	Method	Limit of quantification	Reference
Soil	GC-NPD	0.01 mg/kg	[redacted] 2002a [redacted]
Drinking water	GC-NPD	0.1 µg/L	[redacted] 2002 [redacted]
Surface water	GC-NPD	0.01 µg/L	[redacted] (2001 [redacted]
Air	GC-NPD	0.04 µg/m^3	[redacted] (2001 [redacted]

NPD=Nitrogen phosphorus detector, MSD=Mass selective detector

Based on the validation results achieved it is considered that the methods indicated in the following text are acceptable for post registration surveillance for pyriproxyfen in accordance with EU guidance document SANCO/825/00

4.2.1 Residues in soil

Section A4.2.1/01 Residues in soil

Annex Point IIA 4.2.1

Official use only

1 Reference

1.1 Reference

[redacted] 2002 [redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

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 Guidance and Quality Assurance

2.1 Guideline study

Yes, EU Guidance document SANCO/825/00 rev.6

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3 Materials and Methods

3.1 Preliminary treatment

3.1.1 Enrichment

Pyriproxyfen is extracted from soil samples by shaking with acetone. Water was added beforehand in an amount that takes full account of the natural water content of the samples so that during extraction the acetone/water ratio remains constant at 2/1 (v/v)

3.1.2 Cleanup

Following extraction, an aliquot of the filtrate is taken into separating funnel and sodium chloride and cyclohexane/ethyl

	acetate=1/1 (v/v) is added. After repeated mixing excess water was separated. The evaporation residue of the organic phase is then applied to gel chromatography on polystylene gel Bio-Beads S-X3 and eluted with a mixture of cyclohexane/ethyl acetate=1/1 (v/v). The residue purified by gel chromatography is applied to silica gel with mixtures of hexane/toluene and toluene/acetone for clean-up. The fraction containing pyriproxyfen is then concentrated prior to analysis
3.2 Detection	
3.2.1 Separation method	Primary separation is by gas chromatography using a capillary column, DB-17 (18 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 m x 0.25 mm) Confirmatory separation is by gas chromatography using a capillary column, DB-17 (20 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 - 2 m x 0.32 mm)
3.2.2 Detector	Primary detection is by gas chromatography with a nitrogen phosphorous detector (GC-NPD) Confirmation detection is by gas chromatography with mass spectrometry (GC-MS, EI, positive) using ion m/z 226 for quantification and ions m/z 186, 136 and 96 as qualifier ions
3.2.3 Standard(s)	Pyriproxyfen standards in toluene (external)
3.2.4 Interfering substance(s)	Soil co-extractive material
3.3 Linearity	
3.3.1Calibration range	Concentrations of pyriproxyfen in toluene were prepared at 0.01, 0.02, 0.05, 0.1, 0.2, 0.5 and 1.0 µg/mL
3.3.2 Number of measurements	7 solutions at different concentration were prepared
3.3.3 Linearity	The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1 µg/ml was shown to be linear although correlation was performed using a least squares fit of a non-linear function. The correlation coefficient was 0.9995 using GC-NPD and 0.9996 using GC-MS.
3.4 Specifity: interfering substances	Specificity was measured by the analysis of control samples and confirmation of peak identity and recovery by GC-MS The method was shown to be specific with no interference being observed in control samples (<30% LOQ 0.01 mg/kg). The confirmatory method was adequately shown as the determination was performed using gas chromatography with a mass selective detector (MSD, quantification ion 226 and confirmation ions 96, 136 and 186)
3.5 Recovery rates at different levels	Validation of the method was performed by analysing control and fortified samples of soil (Speyer 2.3, Germany, sandy loam). Control soil was fortified with pyriproxyfen at 0.01and 0.10 mg/kg and then subjected to the analytical method. [redacted] The recovery values from soil at individual fortification levels

	ranged from 104.1 to 107.2% (mean 105.0%, n = 5) at 0.01 mg/kg and 92.3 to 110.7% (mean 102.6%, n = 5) at 0.1 mg/kg. The overall mean recovery was 103.8% (n = 10) Recovery confirmation using GC-MS ranged from 105.9 to 109.5% (mean 107.3%, n = 3) at 0.01 mg/kg and 102.4% (n = 1) at 0.1 mg/kg The maximum time between starting the extraction and measurement was 9 days (16 days for GC-MS). Extracts were stored in a refrigerator before GC measurement. Results indicate there is no impact due to this storage period
3.5.1 Relative standard deviation	The relative standard deviation at individual fortification levels was 1.2% (n = 5) at 0.01 mg/kg and 7.5% (n = 5) at 0.1 mg/kg. The overall relative standard deviation was 5.2% (n = 10) RSD confirmation using GC-MS was 1.8% (n = 3) at 0.01 mg/kg
3.6 Limit of determination	The LOQ was determined successfully at 0.01 mg/kg. An LOD was approximately 0.004 mg/kg estimated from the lowest calibration standard (0.01 µg/mL)
3.7 Precision	
3.7.1 Repeatability	Refer to 3.5.1
3.7.2 Independent laboratory validation	[redacted]

4 Applicant's Summary and conclusion

4.1 Materials and methods	**Method –** Extraction with acetone, clean up by liquid-liquid partition, GPC, followed by silica gel purification. Quantification by GC-NPD. Confirmation by GC-MS **Specificity** - No interference being observed in control samples (<30% LOQ 0.01 mg/kg). Peak identity and recovery confirmed by GC-MS **Linearity** - The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1.0 µg/mL was linear although correlation was performed using a least squares fit of a non-linear function. The correlation coefficient (r^2) was typically >0.9995 **Accuracy** - Overall mean recovery was 104%, n = 10 **Precision** - Overall RSD was 5.2%, n = 10 **Limit of quantification** - LOQ 0.01 mg/kg
4.2 Conclusion	The analytical method has been validated in terms of specificity, linearity, accuracy and precision and are therefore considered suitable for the determination of pyriproxyfen in soil The limit of quantification for the analytical method for residues of pyriproxyfen in soil is lower than the concentration of concern in exposure to non-target soil organisms. The results of the ecotoxicological studies of non-target soil organisms are as follows: Earthworm: LC50 >1000 mg/kg soil, NOEC 1000 mg/kg soil Soil non-target micro-organisms: NOEC 14 mg/kg soil Therefore, the method is suitable for the determination of

pyriproxyfen in soil for monitoring purposes

4.2.1 Reliability [redacted]

4.2.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Evaluation by Rapporteur Member State	
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Materials and Methods	
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Conclusion	
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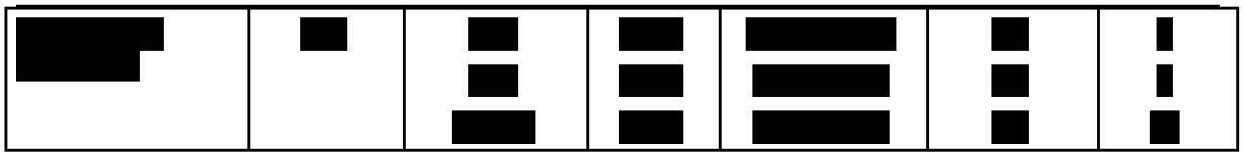
[redacted]



4.2.2 Residues in water (including drinking water and surface water)

Section A4.2.2/01 **Annex Point IIA 4.2.2**	**Residues in water (including drinking water and surface water)**	**Official use only**
	1 Reference	
1.1 Reference	[redacted] 2002 [redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.	
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 Guidance and Quality Assurance	
2.1 Guideline study	Yes, EU Guidance document SANCO/825/00 rev.6	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 Materials and Methods	
3.1 Preliminary treatment		
3.1.1 Enrichment	The water sample is passed through a solid phase extraction (SPE) C18 column under negative pressure. The SPE C18 column is then washed with 10 ml distilled water and dried by suction of air through the column for approximately 10 minutes. Pyriproxyfen is then eluted with 20 ml acetone. The eluate is evaporated to dryness and dissolved in toluene to an appropriate volume	
3.1.2 Cleanup	Not relevant	
3.2 Detection		
3.2.1 Separation method	Primary separation is by gas chromatography using a capillary column, DB-17 (18 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 m x 0.25 mm) Confirmatory separation is by gas chromatography using a capillary column, DB-17 (20 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 - 2 m x 0.32 mm)	

3.2.2 Detector	Primary detection is by gas chromatography with a nitrogen phosphorous detector (GC-NPD) Confirmation detection is by gas chromatography with mass spectrometry (GC-MS, EI, positive) using ion m/z 226 for quantification and ions m/z 186, 136 and 96 as qualifier ions
3.2.3 Standard(s)	Pyriproxyfen standards in toluene (external)
3.2.4 Interfering substance(s)	Drinking water co-extractive material
3.3 Linearity	
3.3.1Calibration range	Concentrations of pyriproxyfen in toluene were prepared at 0.01, 0.02, 0.05, 0.1, 0.2, 0.5 and 1.0 µg/mL
3.3.2 Number of measurements	7 solutions at different concentration were prepared
3.3.3 Linearity	The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1 µg/ml was shown to be linear although correlation was performed using a least squares fit of a non-linear function. The correlation coefficient was 0.9983 using GC-NPD and 0.9994 using GC-MS
3.4 Specifity: interfering substances	Specificity was measured by the analysis of control samples and confirmation of peak identity and recovery by GC-MS The method was shown to be specific with no interference being observed in control samples (<30% LOQ 0.1 µg/L). The confirmatory method was adequately shown as the determination was performed using gas chromatography with a mass selective detector (MSD, quantification ion 226 and confirmation ions 96, 136 and 186)
3.5 Recovery rates at different levels	Validation of the method was performed by analysing control and fortified samples of drinking water (regular laboratory tap water). Control water was fortified with pyriproxyfen at 0.1and 1.0 µg/L and then subjected to the analytical method. [redacted] The recovery values from water at individual fortification levels ranged from 97.4 to 111.0% (mean 104.2%, n = 5) at 0.1 µg/L and 74.8 to 83.5% (mean 78.9%, n = 5) at 1.0 µg/L. The overall mean recovery was 91.6% (n = 10) Recovery confirmation using GC-MS ranged from 91.8 to 94.2% (mean 92.6%, n = 3) at 0.1 µg/L and 83.7% (n = 1) at 1.0 µg/L The maximum time between starting the extraction and measurement was 7 days (15 days for GC-MS). Extracts were stored in a refrigerator before GC measurement. Results indicate there is no impact due to this storage period
3.5.1 Relative standard deviation	The relative standard deviation at individual fortification levels was 5.4% (n = 5) at 0.1 µg/L and 4.3% (n = 5) at 1.0 µg/L. The overall relative standard deviation was 15.3% (n = 10). RSD confirmation using GC-MS was 1.5% (n = 3) at 0.1 µg/L
3.6 Limit of determination	The LOQ was determined successfully at 0.1 µg/L. An LOD was approximately 0.02 µg/L estimated from the lowest calibration

	standard (0.01 µg/mL)
3.7 Precision	
3.7.1 Repeatability	Refer to 3.5.1
3.7.2 Independent laboratory validation	Not performed

4 Applicant's Summary and conclusion

4.1 Materials and methods	**Method –** Extraction with SPE C18 column. Quantification by GC-NPD. Confirmation by GC-MS. **Specificity** - No interference being observed in control samples (<30% LOQ 0.1 µg/L). Peak identity and recovery confirmed by GC-MS **Linearity** - The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1.0 µg/mL was linear although correlation was performed using a least squares fit of a non-linear function. The correlation coefficient (r^2) was typically >0.998 **Accuracy** - Overall mean recovery was 91.6%, n = 10 **Precision** - Overall RSD was 15.3%, n = 10 **Limit of quantification** - LOQ 0.1 µg/L
4.2 Conclusion	The analytical method has been validated in terms of specificity, linearity, accuracy and precision and has been successfully validated down to the EU limit of 0.1 µg/L. Therefore, the method is considered appropriate for post registration surveillance for pyriproxyfen in drinking water
4.2.1 Reliability	[redacted]
4.2.2 Deficiencies	[redacted]

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
[redacted]	[redacted]

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[redacted]	[redacted]

Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	
			[redacted]	[redacted]		
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A4.2.2/02
Annex Point IIA 4.2.2

Residues in water (including drinking water and surface water)

Official use only

1 Reference

1.1 Reference

[redacted]2001[redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

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 Guidance and Quality Assurance

2.1 Guideline study

Yes, EU Guidance document SANCO/825/00 rev.6

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3 Materials and Methods

3.1 Preliminary treatment

3.1.1 Enrichment

The water sample is passed through a solid phase extraction (SPE) C18 column under negative pressure. The SPE C18 column is then washed with 10 ml distilled water and dried by suction of air through the column for approximately 10 minutes. Pyriproxyfen is then eluted with 10 ml hexane. The eluate is evaporated to dryness and dissolved in toluene to an appropriate volume

3.1.2 Cleanup

Not relevant

3.2 Detection

3.2.1 Separation method

Primary separation is by gas chromatography using a capillary column, DB-17 (20 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 m x 0.25 mm)

Confirmatory separation is by gas chromatography using a capillary column, DB-17 (20 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 - 2 m x 0.32 mm)

3.2.2 Detector

Primary detection is by gas chromatography with a nitrogen phosphorous detector (GC-NPD)

Confirmation detection is by gas chromatography with mass spectrometry (GC-MS, EI, positive) using ion m/z 226 for quantification and ions m/z 186, 136 and 96 as qualifier ion

3.2.3 Standard(s)

Pyriproxyfen standards in toluene (external)

3.2.4 Interfering substance(s)	Surface water co-extractive material
3.3 Linearity	
3.3.1Calibration range	Concentrations of pyriproxyfen in toluene were prepared at 0.01, 0.02, 0.05, 0.1, 0.2 and 0.5 µg/mL
3.3.2 Number of measurements	6 solutions at different concentration were prepared
3.3.3 Linearity	The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 0.5 µg/ml was shown to be linear although correlation was performed using a least squares fit of a non-linear function for GC-MS. The correlation coefficient was 0.9999 using GC-NPD and 0.991 using GC-MS
3.4 Specifity: interfering substances	Specificity was measured by the analysis of control samples and confirmation of peak identity and recovery by GC-MS The method was shown to be specific with no interference being observed in control samples (<30% LOQ 0.01 µg/L). The confirmatory method was adequately shown as the determination was performed using gas chromatography with a mass selective detector (MSD, quantification ion 226 and confirmation ions 96, 136 and 186)
3.5 Recovery rates at different levels	Validation of the method was performed by analysing control and fortified samples of surface water (water from River Kleine Wiese, Germany). Control water was fortified with pyriproxyfen at 0.01and 0.10 µg/L and then subjected to the analytical method. The results are presented in Table A4.2.2-02 The recovery values from water at individual fortification levels ranged from 106.8 to 108.5% (mean 107.7%, n = 5) at 0.01 µg/L and 89.0 to 106.0% (mean 97.5%, n = 5) at 0.10 µg/L. The overall mean recovery was 102.6% (n = 10). Recovery confirmation using GC-MS was 100.7% (n = 1) at 0.10 µg/L. The maximum time between starting the extraction and measurement was 1 day (11 days for GC-MS). Extracts were stored in a freezer before GC measurement. Results indicate there is no impact due to this storage period
3.5.1 Relative standard deviation	The relative standard deviation at individual fortification levels was 0.6% (n = 5) at 0.01 µg/L and 7.1% (n = 5) at 0.10 µg/L. The overall relative standard deviation was 7.0% (n = 10)
3.6 Limit of determination	The LOQ was determined successfully at 0.1 µg/L. An LOD was approximately 0.005 µg/L estimated from the lowest calibration standard (0.01 µg/mL)
3.7 Precision	
3.7.1 Repeatability	Refer to 3.5.1
3.7.2 Independent laboratory validation	[redacted]

4 Applicant's Summary and conclusion

4.1 Materials and methods	**Method –** Extraction with SPE C18 column. Quantification by

GC-NPD. Confirmation by GC-MS

Specificity - No interference being observed in control samples (<30% LOQ 0.01 µg/L). Peak identity and recovery confirmed by GC-MS

Linearity - The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1.0 µg/mL was linear although correlation was performed using a least squares fit of a non-linear function for GC-MS. The correlation coefficient (r^2) was typically 0.9999 for GC-NPD and 0.991 for GC-MS.

Accuracy - Overall mean recovery was 102.6%, n = 10

Precision - Overall RSD was 7.0%, n = 10

Limit of quantification - LOQ 0.01 µg/L

4.2 Conclusion

The analytical method has been validated in terms of specificity, linearity, accuracy and precision and the limit of quantification for the method for the residues of pyriproxyfen in surface water is lower than the concentration of concern for exposure to the most sensitive species in aquatic non-target organisms (Daphnia magna NOEC (21 days) 0.015 µg/L). Therefore, the method is suitable for the determination of pyriproxyfen in surface water for monitoring purposes

4.2.1 Reliability

[redacted]

4.2.2 Deficiencies

[redacted]

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Evaluation by Rapporteur Member State
[redacted]

Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]		[redacted]	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.2.3 Residues in air

Section A4.2.3/01 Residues in air

Annex Point IIA 4.2.3

Official use only

1 Reference

1.1 Reference

[redacted]2001[redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Co., Ltd.

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 Guidance and Quality Assurance

2.1 Guideline study

Yes, EU Guidance document SANCO/825/00 rev.6 and BBA 'Richtlinien fur die Prufung von Pflanzenschutzmitteln im Zulassungsverfahren Teil I (1-2) Seite B/8, 2.5, 2. Auflage, November 1990 auf erstmalige/erneute Zulassung eines Pflanzenschutzmittels

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3 Materials and Methods

3.1 Preliminary treatment

3.1.1 Enrichment

Tenax adsorption tubes were placed in the air suction apparatus. The flow rate was adjusted to 1 L/min for each sample resulting in a sampling volume of about 360 L after a sampling period of 6 h. Pyriproxyfen was extracted from tenax adsorption tubes with 10 ml of toluene. The extract was filtrated through 0.45 µm filter prior to analysis

3.1.2 Cleanup

Not relevant

3.2 Detection

3.2.1 Separation method

Primary separation is by gas chromatography using a capillary column, DB-17 (20 m x 0.18 mm x 0.3 µm film) in conjunction with a pre-column of deactivated fused silica (1 m x 0.25 mm)

Confirmatory separation is by gas chromatography using a capillary column, DB-17 (20 m x 0.18 mm x 0.3 µm film)

3.2.2 Detector

Primary detection is by gas chromatography with a nitrogen phosphorous detector (GC-NPD)

Confirmation detection is by gas chromatography with mass spectrometry (GC-MS, EI, positive) using ion m/z 226 for quantification and ions m/z 186, 136 and 96 as qualifier ions.

3.2.3 Standard(s)	Pyriproxyfen standards in toluene (external)
3.2.4 Interfering substance(s)	Absorbent material and co-extractives from air
3.3 Linearity	
3.3.1Calibration range	Concentrations of pyriproxyfen in toluene were prepared at 0.01, 0.02, 0.05, 0.1, 0.2, 0.5 and 1.0 µg/mL
3.3.2 Number of measurements	7 solutions at different concentration were prepared
3.3.3 Linearity	The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1.0 µg/ml was shown to be linear although correlation was performed using a least squares fit of a non-linear function for GC-MS. The correlation coefficient typically in the range 0.995 to 0.999 using GC-NPD and 0.997 using GC-MS
3.4 Specifity: interfering substances	Specificity was measured by the analysis of control samples and confirmation of peak identity and recovery by GC-MS. The method was shown to be specific with no interference being observed in control samples (<30 % LOQ 1 µg/m^3). The confirmatory method was adequately shown as the determination was performed using gas chromatography with a mass selective detector (MSD, quantification ion 226 and confirmation ions 96, 136 and 186)
3.5 Recovery rates at different levels	Validation of the method was performed by fortifying traps containing Tenax absorbent and drawing air through the traps at 1 L/min for 6 hours (total 360 L) to simulate sampling conditions. Two different air sampling conditions were used. One set of traps sampled air at 20°C and relative humidity 30% whilst a second set of traps sampled air at 35°C and relative humidity >80%. For each set of sampling conditions, control traps were fortified in quintuplet with pyriproxyfen to simulate air concentrations of 1 and 10 µg/m^3. Secondary traps were attached to the main traps fortified at the higher concentration and were analysed to check for breakthrough of pyriproxyfen from the main trap Results showed good accuracy for both sets of samples. No breakthrough was observed from the main trap. [redacted] The recovery values from Tenax adsorption tubes at individual fortification levels ranged from: 88.8 to 94.4% (mean 91.3%, n = 5) at 1.0 µg/m^3 and 95.4 to 107.0% (mean 101.1%, n = 5) at 10 µg/m^3 for air at 20°C, 30% RH (overall mean 96.2%, n = 10) 107.2 to 109.0% (mean 108%, n = 5) at 1.0 µg/m^3 and 107.1 to 108.7% (mean 108.0%, n = 5) at 10 µg/m^3 for air at 35°C, 80% RH (overall mean 108.0%, n = 10). Recovery confirmation using GC-MS was 104.1% (n = 1) at 1.0 µg/m^3 The maximum time between starting the extraction and measurement was 7 days (14 days for GC-MS). Extracts were stored in a freezer before GC measurement. Results indicate there is no impact due to this storage period

3.5.1 Relative standard deviation	Results showed good repeatability for both sets of samples. The RSD values for Tenax adsorption tubes at individual fortification levels ranged from: 2.8 to 4.9% for air at 20°C, 30% RH (overall RSD 6.6%, n = 10) and 0.6 to 0.7% for air at 35°C, 80% RH (overall RSD 0.6%, n = 10)
3.6 Limit of determination	The LOQ was determined successfully at 1 µg/m^3. An LOD was approximately 0.3 µg/m^3 estimated from the lowest calibration standard (0.01 µg/mL)
3.7 Precision	
3.7.1 Repeatability	Refer to 3.5.1
3.7.2 Independent laboratory validation	[redacted]

4 Applicant's Summary and conclusion

4.1 Materials and methods	**Method –** Extraction of Tenax absorbent with toluene. Quantification by GC-NPD. Confirmation by GC-MS **Specificity** – No interference observed in control samples (<30% LOQ 1 µg/m^3). Confirmation of peak identity and recovery by GC-MS **Linearity** - The response of the GC-NPD and GC-MS to pyriproxyfen over the range 0.01 to 1.0 µg/ml was shown to be linear although correlation was performed using a least squares fit of a non-linear function. The correlation coefficient (r^2) was typically > 0.995 **Accuracy** - Overall mean recovery was 96.2% for air sampled at 20°C, RH 30% and 108% for air sampled at 35°C, RH >80% **Precision** – Overall RSD was 6.6% for air sampled at 20°C, RH 30% and 0.6% for air sampled at 35°C, RH >80% **Limit of quantification** - LOQ 1 µg/m^3 **Breakthrough** - No breakthrough of pyriproxyfen from the main traps
4.2 Conclusion	The analytical method has been validated in terms of specificity, linearity, accuracy and precision and the limit of quantification for the analytical method for residues of pyriproxyfen in air is 1 µg/m^3 which is sufficiently below the concentration C defined in the SANCO/825/00 rev.6, taking into account relevant health based limit values and relevant exposure levels. Therefore, the method is suitable for the determination of pyriproxyfen in air for monitoring purposes
4.2.1 Reliability	[redacted]
4.2.2 Deficiencies	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
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Materials and Methods	
Results and discussion	
Conclusion	
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[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.2.4 Residues in body fluids and tissues

No methods are required since pyriproxyfen is not classified as toxic or highly toxic

4.3 Residues in/on food or feedstuffs and other products where relevant

No methods are required since the product is not intended for use on food or feedstuffs

European Commission

Pyriproxyfen

CAS number 95737-68-1

Document III-A
Study Summaries
Active Substance
Efficacy

Rapporteur Member State: The Netherlands

January 2012

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