COMPETENT AUTHORITY REPORT

FENPROPIMORPH (PT 8)

Document IIIA

Active Substance

Section 1: Applicant
Section 2: Identity
Section 3: Physical & Chemical Properties

Rapporteur Member State: Spain
December 2006

Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Name:	Dr. Wolman GmbH (BASF Group)
Address:	Dr. Wolman-Str.31-33, D-76547 Sinzheim, Germany
Telephone:	(49) 7221-800-0
Fax number:	(49) 7221-800210
E-mail address:	Wendelin hettler@wolman.de Réne.Schwartz@wolman.de

1.2 Manufacturer of Active Substance (if different)

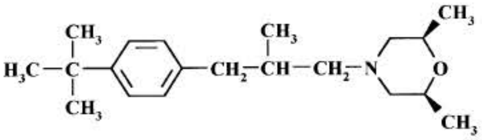
Name:	BASF Aktiengesellschaft Crop Protection
Address:	D-67114 Limburgerhof, Germany
Telephone:	(49) 621-60-0
Fax number:	(49) 621-60-79519
E-mail address:	
Location of manufacturing plant:	D-67114 Limburgerhof

1.3 Manufacturer of Product(s) (if different)

1) Wolsin FL 35

Name:	Dr. Wolman GmbH (BASF Group)
Address:	Dr. Wolman-Str.31-33, D-76547 Sinzheim, Germany
Telephone:	(49) 7221-800-0
Fax number:	(49) 7221-800210
E-mail address:	Wendelin hettler@wolman.de Réne.Schwartz@wolman.de

Section A2 Identity of Active Substance

Subsection **(Annex Point)**			**Official use only**
2.1	**Common name (IIA2.1)**	Fenpropimorph	
2.2	**Chemical name (IIA2.2)**	(+/-)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine	
2.3	**Manufacturer's development code number(s) (IIA2.3)**	BAS 421 F Corbel LAB 108406 Reg. No. 108406 CGA 101031	
2.4	**CAS No and EC numbers (IIA2.4)**	**Non-entry field**	
2.4.1	**CAS-No**	67564-91-4	
	Isomer 1	See confidential appendix (Substance 1)	
	Isomer 2	See confidential appendix (Substance 2)	
	Isomer 3	See confidential appendix (Substance 3)	
2.4.2	**EC-No**	266-719-9	
	Isomer 1	See confidential appendix (Substance 1)	
	Isomer 2	See confidential appendix (Substance 2)	
	Isomer 3	See confidential appendix (Substance 3)	
2.4.3	**Other**	CIPAC No.: 427	
2.5	**Molecular and structural formula, molecular mass (IIA2.5)**	**Non-entry field**	
2.5.1	**Molecular formula**	$C_{20}H_{33}NO$	
2.5.2	**Structural formula**	 The structural formulas of the isomers are presented in the confidential appendix.	
2.5.3	**Molecular mass**	303.5 g/mol	
2.6	**Method of manufacture of the active substance (IIA2.1)**	This confidential information is provided in Doc. III-A – Study summaries – Active substance – Appendix 2 – Confidential data and information	

Section A2 Identity of Active Substance

2.7	**Specification of the purity of the active substance, as appropriate (IIA2.7)**	g/kg g/l v/v % w/w % This confidential information is provided in Doc. III-A – Study summaries – Active substance – Appendix 2 – Confidential data and information
2.8	**Identity of impurities and additives, as appropriate (IIA2.8)**	See separate standard format
2.8.1	**Isomeric composition**	Fenpropimorph is a racemate; both enantiomers are similarly active. Therefore, there are no inactive isomers of Fenpropimorph. Geometrical and positional isomers are classified as impurities (see confidential appendix).
2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	This confidential information is provided in Doc. III-A – Effects assessment for the active substance – Appendix 2 – Confidential data and information

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable.
Conclusion	Applicant's version is adopted
Reliability	1
Acceptability	acceptable
Remarks	No further remarks

Section A2.10 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

Annex Point IIA2.10

Subsection		Official use only
2.10.1 Human exposure towards active substance		
2.10.1.1 Production		
i.) Description of process	This confidential information is provided in Doc. III-A – Effects assessment for the active substance – Appendix 2 – Confidential data and information	
ii.) Workplace description	The manufacturing process takes place in a closed system. The process is automated to the greatest possible extent. Exposure is minimised by using adequate engineering controls. Workers are expected to wear personal protective equipment according to the risk classification and the safety recommendations given in the safety data sheet. Respiratory protection: breathing protection if gases/vapours are formed. Gas filter EN141 Type A for gases/vapours of organic compounds Hand protection: suitable chemical resistant safety gloves (EN374) also with prolonged, direct contact (chloroprene rubber, polyvinylchloride and other) Eye protection: tightly fitting safety goggles (EN166) Body protection: apron, protecting boots, chemical-protection suit (EN465)	
iii.) Inhalation exposure	Fenpropimorph is manufactured since many years. The personnel who are handling Fenpropimorph in manufacturing are surveyed by regular medical examinations. Medical surveillance is a means of indirect measurement of exposure. No poisoning incidents are known to us. No observations regarding health effects after exposure of general population are known to us.	
iv.) Dermal exposure	Fenpropimorph is manufactured since many years. The personnel who are handling Fenpropimorph in manufacturing are surveyed by regular medical examinations. Medical surveillance is a means of indirect measurement of exposure. No poisoning incidents are known to us. A few cases of skin irritation were observed.	
2.10.1.2 Intended use(s)		
1. Professional Users		
i) Description of application process	Fenpropimorph is used for the manufacturing of wood preservatives. The manufacturing process for wood preservatives is a simple mixing process of the active substance with the formulation additives on an industrial scale.	

Section A2.10 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

Annex Point IIA2.10

ii) Workplace description	The manufacturing process of wood preservatives is a discontinuous batch process. In a stirring reactor, the ingredients are gradually added and stirred until complete dissolution forming the end use formulation. The end-formulation is then filled in suitable containers. The system can be considered as a closed system. The process is automated to the greatest possible extent. Exposure is minimised by using adequate engineering controls. Workers are expected to wear personal protective equipment so that health risk can be excluded.
iii) Inhalation exposure	Fenpropimorph containing wood preservatives are manufactured since many years. During this time, no cases of poisoning were observed.
iv) Dermal exposure	Fenpropimorph containing wood preservatives are manufactured since many years. During this time, no cases of poisoning were observed.
2. Non-professional users including the general public	Neither the active ingredient Fenpropimorph nor the formulated end use wood preservatives are intended to be used by non-professional users.
(i) via inhalational contact	—
(ii) via skin contact	—
(iii) via drinking water	—
(iv) via food	—
(v) indirect via environment	—
2.10.2 Environmental exposure towards active substance	
2.10.2.1 Production	Fenpropimorph is manufactured in a dedicated plant with spill containment installation, air treatment, and closed equipments. The complete installation adheres to the legal provisions (rules, directives, laws) regarding the prevention of pollution of ground and surface water as well as air and soil.
(i) Releases into water	
(ii) Releases into air	
(iii) Waste disposal	
2.10.2.2 Intended use(s)	
Affected compartment(s):	The production plant (mixing tank) is located in a hall on an impervious structurally sound floor and the formulated end-product (the wood preservative) is stored in appropriate containers under roof so that releases into soil and water are excluded. Due to the low vapour pressure of the used actives, the emission to air is negligible.
water	release excluded

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**
sediment	release excluded
air	negligible
soil	release excluded
Predicted concentration in the affected compartment(s)	—
water	release excluded
sediment	release excluded
air	negligible
soil	release excluded

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	August 2005
Materials and methods	The applicant's version is acceptable
Conclusion	The applicant's version is adopted
Reliability	
Acceptability	Acceptable
Remarks	

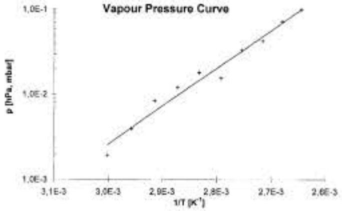
Section A3 Physical and Chemical Properties of Active Substance

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								
3.1.1 Melting point Melting pt. 1	OECD **Guideline** 102 "Melting Point / Melting Range" Determination of the melting point / melting range and the thermal conversions by capillary and liquid bath: The test substance was filled into a capillary tube and put into the melting point apparatus and heated up to c. 280°C Determination of the melting point / melting range and the thermal conversions by DSC: a) DSC curve was recorded from 25°C to –60°C with a cooling rate of 5 K/min, holding at –60°C for 30 min. and then heating up to 25 °C with a heating rate of 5 K/min. b) To check the thermal conversions from 25 °C up to 360 °C the heating rate was set to 5 K/min	Pure a.i. (purity 99.6%)	Value: -47 - -41 °C Decomposition: no Sublimation: no Determination of the melting point / melting range and the thermal conversions by capillary and liquid bath: Up to c. 280°C no visual effect was observed Determination of the melting point / melting range and the thermal conversions by DSC: a) The DSC plot showed no effects during the cooling down to – 60 °C and holding at this temperature for 30 minutes. An endothermic melting peak from – 47 °C up to – 41 °C was detected by heating up to 25 °C. b) At c. 310 °C an exothermic effect is observed which is interpreted as decomposition There is no endothermic effect other than related to the melting range. Therefore, sublimation or boiling of the test substance can be excluded.		Y	1	A 3.1.1 [redacted] (1999) Determination of the melting point and the appearance of Fenpropimorph [redacted] BASF DocID #1999/11214, unpublished	**X1**

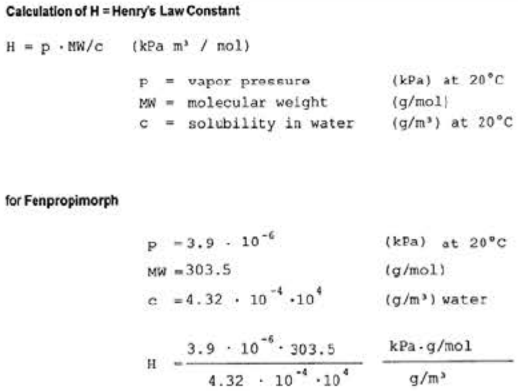
Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1.2 Boiling point Boiling pt. 1	OECD Guideline 102 "Melting Point / Melting Range" Thermal conversions were determined by DSC (See 3.1.1)	pure a.i. (purity 99.6%)	There is no endothermic effect other than related to the melting range. Therefore, sublimation or boiling of the test substance can be excluded (See 3.1.1)		Y	1	A 3.1.2 [redacted] (1999) Determination of the melting point and the appearance of Fenpropimorph [redacted] BASF DocID #1999/11214, unpublished	
3.1.3 Bulk density/relative density Bulk/rel. density 1	The density was determined with an oscillating densitometer DMA 55 according to the European communities method 84/449/EEC No. A3. A mechanical oscillator constructed in the form of an U-tube is vibrated at a specific frequency that depends on the mass of the oscillator. Introducing a sample changes the resonance frequency of the oscillator. Test temperature: 20°C The instrument was calibrated a the same day with pure water of known density at 20°C.	pure a.i. (purity 99.2%), liquid	0.934 at 20 °C	Two measurements were performed: 1. value: 0.93362 g/cm³; 2. value: 0.93362 g/cm³. Because the two values showed no difference, a third measurement was not required. The result was reported as mean value to be 0.934 g/cm³.	Y	1	A 3.1.3 [redacted] (1994) Physical and chemical properties report for Fenpropimorph (108 406) [redacted] BASF DocID #1994/10395 unpublished	

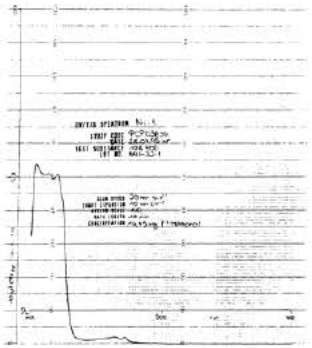
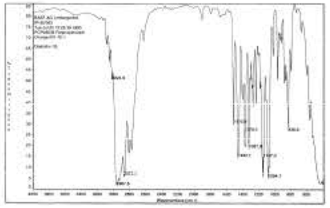
Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.1.4 Vapour pressure (IIA3.2)								
Vapour pressure 1	Internal method: CF/P 006 "Vapour pressure" Principle of method applied: determination of evaporation rate Volatility (g/m^2xh): 3.3×10^{-7} at 20°C 6.3×10^{-7} at 25°C Vapour pressure (hPa; mbar): 3.5×10^{-5} at 20°C 6.5×10^{-5} at 25°C	pure a.i. (purity 99.2%)	0.000035 hPa at 20 °C	No decomposition	Y	1	A 3.2/01 [redacted] (1994) Physical and chemical properties report for Fenpropimorph [redacted] BASF DocID #1994/10395, unpublished	**X2**
Vapour pressure 2	The method is based on the determination of accelerated evaporation rates for the test item at elevated temperatures and ambient pressure using thermogravimetry. The evaporation rates VT result from exposing the selected compound to a slowly flowing inert gas atmosphere, and monitoring the weight loss at defined isothermal temperatures T over appropriate periods of time. The evaporation rate is calculated from the weight loss per area and time of a sample coated glass plate. The vapour pressures p_T are calculated from the VT values by using the linear relationship between the logarithm of the evaporation rate. If necessary, an extrapolation to temperatures of 20 and 25°C can be made by regression analysis of log p_T vs. 1/T	pure a.i. (purity 98.9 %)	The vapour pressure at 20 °C of the pure active ingredient Fenpropimorph was determined to be 3.9E-5 mbar. The vapour pressure at 25 °C of the pure active ingredient Fenpropimorph was determined to be 7.0 E-5 mbar. 		Y	1	A 3.2/02 [redacted] (2004) Vapour pressure Fenpropimorph, BASF AG, [redacted] BASF DocID 2004/1016297, unpublished	**X3**
3.2 Henry´s Law Constant (Pt. I-A3.2)			The resulting Henry constant of the active substance is H = 2.656•10-4 kPa m^3/mol.		Y	1	A 3.2.1 [redacted]	

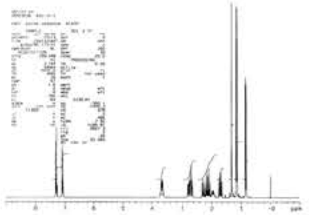
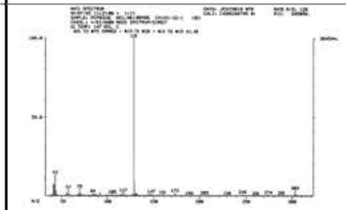
Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	**Method**	**Purity/ Specifi-cation**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Relia-bility**	**Reference**	**Official use only**
Henry´s Law Constant 1	The Henry constant can be calculated according to equation: $H = p \cdot MW/c$ (kPa m³/mol). p: vapour pressure ($3.5 \cdot 10^{-6}$ kPa at 20 °C) MW: molecular weight (303.5 g/mol) c: water solubility ($4.0 \cdot 10^{-4} \cdot 10^{4}$ g/m³ at 20 °C)						(1999) Henry's law constant for Fenpropimorph [redacted] BASF DocID #1999/10845, unpublished	
Henry´s Law Constant 2	 **Calculation of H = Henry's Law Constant** $H = p \cdot MW/c$ (kPa m³ / mol) p = vapor pressure (kPa) at 20°C MW = molecular weight (g/mol) c = solubility in water (g/m³) at 20°C **for Fenpropimorph** $p = 3.9 \cdot 10^{-6}$ (kPa) at 20°C $MW = 303.5$ (g/mol) $c = 4.32 \cdot 10^{-4} \cdot 10^{4}$ (g/m³) water $H = \frac{3.9 \cdot 10^{-6} \cdot 303.5}{4.32 \cdot 10^{-4} \cdot 10^{4}} \frac{kPa \cdot g/mol}{g/m^3}$		$H = 2.74 \times 10^{-4}$ (kPa m³/mol)		N	1	A 3.2.1/02 [redacted] 2004, Henry's law constant for Fenpropimorph, [redacted] BASF DocID 2004/1031205, unpublished	
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Liquid							**X4**
3.3.2 Colour	Colourless							
3.3.3 Odour	Faint aromatic							
3.4 Absorption spectra (IIA3.4)								
3.4.1 UV/VIS	Preparation of test solution: 14.45 mg of the test substance were weighed	99.6 %	UV molar extinction	The structure of	Y	1	A 3.4	

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
	into a 100 ml volumetric flask, dissolved in methanol using sonication and made to volume with methanol. An additional diluted solution was prepared by taking 10 ml aliquot and filling up to the mark in a 100 ml volumetric flask Measurements: first a blank spectrum (methanol in both cells) was recorded. Then a spectrum of the diluted test solution was measured in the range of 200 – 400 nm.		coefficient [l x mol-1 x cm-1]: 203 nm: 1.1 x 10000 219 nm: 1.1 x 10000 242 nm: 2.1 x 100 264 nm: 4.2 x 100 270 nm: 3.2 x 100 272 nm: 4.2 x 100 290 nm: baseline 	Fenpropimorph is confirmed by all spectra, UV, IR, NMR and MS.			[redacted] 1995, Spectra of Fenpropimorph Reg. No. 108 406 (PAI) [redacted] BASF DocID 96/10288, unpublished	
3.4.2 IR	Instrument: Nicolet Magna 550 sample preparation: Neat Sample-ID: PCP03636 Fenpropimorph Charge 691-32-1	99.6 %			Y	1	A 3.4 [redacted] 1995, Spectra of Fenpropimorph Reg. No. 108 406 (PAI). [redacted] BASF DocID 96/10288, unpublished	

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
3.4.3 NMR	Instrument: Varian U300 (300 MHz) Solvent/Reference:$CDCl_3$ / TMS Experiment: ^1H Sample-ID: PCP03636 Fenpropimorph Charge 691-32-1	99.6 %			Y	1	A 3.4 [redacted] 1995, Spectra of Fenpropimorph Reg. No. 108 406 (PAI), [redacted] BASF DocID 96/10288, unpublished	
3.4.4 MS	Instrument: Finnigan 4600 Inlet: Direct Ionisation: Electron Impact (EI)	99.6 %					A 3.4 [redacted] 1995, Spectra of Fenpropimorph Reg. No. 108 406 (PAI) [redacted] BASF DocID 96/10288, unpublished	
3.5 Solubility in water (IIA3.5) **3.5.1 Water solubility 1**	MT 157 CIPAC	standard purity	Solubility of Fenpropimorph at 20°C and pH 4.4 is 7.3 g/l Solubility of Fenpropimorphhydrochlorid at 20°C is 8.2 g/l		Y	1	A 3.5/01 [redacted] (1988) Solubility of fenpropimorphhydrochlorid in water [redacted]	**X5**

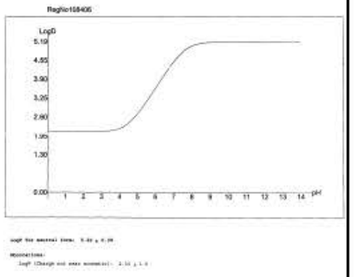
Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specifi-cation	Results	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.5.2 Water solubility 2	OECD Guideline 105 (12.5.81) and CIPAC 3053 / M	Pure a.i. (99.2%)	4.32 mg/l at 20 °C 3.53 mg/l at 20 °C pH: 9 - 11 pK: at 25 °C slightly soluble (0.1-100 mg/L) stable: yes Deg. Product: not measured	The solubility of purified Fenpropimorph at 20°C in the neutral range (purified water) is 4.3 mg/l, in the alkaline range at pH 9-11) 3.5 mg/l and in the acid range (pH 4.4) 7.3g/l.	Y	1	[redacted] BASF DocID #1988/10222 unpublished A 3.5/03 [redacted] (1988) Water solubility of fenpropimorph in neutral range and at pH 9-11 BASF AG, [redacted] BASF DocID #1988/11302 unpublished	
3.6 Dissociation constant (-)	OECD Guideline 112	Pure a.i. (purity 99.4%)	Acid-base constant: 7.02	The pKb value for Fenpropimorph at 20°C is 7.02 (pKa = 6.98 for Fenpropimorph hydrochloride).	Y	1	A 3.6 [redacted] (1988) Determination of the pKb value of fenpropimorph in water [redacted] BASF DocID #1988/11671, unpublished	
3.7 Solubility in organic solvents, including the effect of temperature on solubility	US-EPA Subdivision D, No. 63-8	99.2 %	725.35 - 816.7 other at 20 °C Acetone: 760.35 g/100ml Ethylacetate: 777.95 g/100ml Toluene: 764.60 g/100ml	Solubility has been determined by solution of a defined amount of substance	Y	1	A 3.7 [redacted]. (1992) Determination of	

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
(IIIA3.1)			Dichlormethane: 774.20 g/100ml n-Heptane: 725.35 g/100ml Acetonitrile: 772.70 g/100ml Methanol: 789.15 g/100ml Iso-Propanol: 816.70 g/100ml Octanol: 770.50 g/100ml Olive oil: 778.90 g/100ml	in a defined amount of solvent. From these data results the reported solubility. Dilution of the preparation has been shown that there is no miscibility gap. From this one can conclude that Fenpropimorph is miscible unlimited with the tested solvents. For this reason the assessed concentration has been reported as minimum value. The reported concentrations (ca. 7-8kg/L) exceed the upper limits of solubility specifications nowadays accepted by responsible authorities (250 g/L). No temperature dependence has to be assumed by these high solubilities and unlimited miscibilities respectively.			the solubility of Fenpropimorph in organic solvents at 20°C [redacted] BASF DocID #1992/11596, unpublished	

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
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)				The active substance as manufactured does not include an organic solvent				**X6**
3.9 Partition coefficient n-octanol/water (IIA3.6)								
3.9.1 log Pow 1	Directive 84/449/EEC, A.8 "Partition coefficient"	pure a.i. (purity 99.5%)	Log P_{OW} 2.6 - 4.4 at 22 °C	The log P_{OW} values of the test substance in different buffer solutions were found to be 2.6 at pH 5 and 4.1 at pH 7 and 4.4 at pH 9. In purified water the log Pow is 3.6	N	1	A 3.9 [redacted] (1986) Determination of the n-octanol water partition coefficient of fenpropimorph [redacted] BASF DocID #1986/10156 unpublished	
3.9.2 log Pow 2	EEC Method A.8. Appendix 1 The aqueous phase of Fenpropimorph dispersion of 2.0 % w/w in water was found to have a surface tension of 48.1 mN/m. According to EEC Method A.5.3.2 (interpretation of results) "substances showing a surface tension lower than 60 mN/m .... should be regarded as being surface-active materials". EEC method A.8. Appendix 1 presents options for the calculation of log P_{OW} values. They are recommended in A.8.3 (Reporting): "when the		PH dependent log P_{OW} curve of FPM: 		N	1	A 3.9/02 [redacted] (2004), Calculation of the pKa value of Fenpropimorph-hydrochloride and of pH dependent log P_{OW} values for Fenpropimorph	

Section A3 Physical and Chemical Properties of Active Substance

<table>
<tr><th>Subsection
(Annex Point)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Remarks/ Justification</th><th>GLP (Y/N)</th><th>Reliability</th><th>Reference</th><th>Official use only</th></tr>
<tr><td></td><td>methods are not applicable (e.g. surface active material), a calculated value .... should be provided”.
The section Calculation Methods of EEC method A.8. Appendix 1 mentions explicitly the computer software CLOGP-3. Since 1997 – the year of publication of the Testing Methods – the calculation programs have become more sophisticated and the increment tables for larger substructures have been improved. The advanced computer software ”ACD/LogP program” includes a module for calculating the pKa. Its application to Fenpropimorph-hydrochloride resulted in: pKa 7.6.
Using this value the log P_{OW} for Fenpropimorph was calculated for the range pH 0.00 - pH 14.00.</td><td></td><td>pH 5: log $P_{OW} = 2.72$
pH 7: log $P_{OW} = 4.50$
pH 9: log $P_{OW} = 5.18$</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)</td><td></td><td></td><td></td><td>Decomposition is observed at approx. 310 °C. Sublimation does not apply to a liquid.
Reference is also made to § 3.1.2 and the corresponding literature.</td><td></td><td></td><td></td><td>X7</td></tr>
<tr><td>3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)</td><td>Directive 84/449/EEC, A.15 "Auto-flammability of volatile liquids or gases"
Auto-flammability behaviour of gases and vapours is determined using the apparatus described in DIN 51794.
The tests were performed at an atmospheric pressure of 993 – 1002 mbar</td><td></td><td><table>
<tr><th>Test</th><th>lowest temperature (C)</th><th>quantity of sample (ml)</th><th>Ignition lag (s)</th></tr>
<tr><td>Preliminary test</td><td>265</td><td>1.00</td><td>8</td></tr>
<tr><td>Main test</td><td>270</td><td>0.28</td><td>17</td></tr>
<tr><td>1. repetition</td><td>270</td><td>0.28</td><td>6</td></tr>
</table>An auto-ignition temperature</td><td></td><td>Y</td><td>1</td><td>A 3.11
[redacted] (1999)
Evaluation of safety characteristics according to 92/69/EEC
[redacted]</td><td></td></tr>
</table>

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**
			of 265°C results from these data				[redacted] BASF DocID #1999/11009, unpublished	
3.12 Flash-point (IIA3.9)								
3.12.1 Flash-point 1	CIPAC Method MT 12 (Pensky / Martens-method): the test item is placed in a test vessel, which is progressively heated until the vapour reaches a sufficiently high concentration in air to produce a flammable mixture, which can be ignited.	Technical concentration (purity: 93.03 %)	157 °C	After a search run, 2 additional measurements were performed with the results: 1. value: 156.3 °C and 2. value: 157.3 °C. the result was reported as mean value to be 157 °C.	Y	1	A 3.12 [redacted] (1994) Physical and chemical properties report for Fenpropimorph [redacted] BASF DocID #1994/10392 unpublished	
3.12.2 Flash point 2								
3.13 Surface tension (IIA3.10)								
3.13.1 Surface tension 1	DIN 53914 EEC method A5.1.6.3 Ring method of Lecomte and Noüy: Surface tension is a phenomenon caused by intermolecular forces of attraction. The force necessary to break the film is measured with a platinum ring, which is attached to a torsion balance. The ring is pulled up from the liquid using a force that is known due to the calibration	Technical concentration (purity: 93.03 %)	Conc.: 0.5 vol% Surface tension 49.0 mN/m at 20 °C Conc.: 2.0 vol% Surface tension 48.9 mN/m at 20 °C		Y	1	A 3.13/01 [redacted]. (1994) Physical and chemical properties report for Fenpropimorph [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**
	of the instrument. Surface tension is measured in force per unit area; e.g. mN/m. The force measured to pull the ring from the liquid increases to a maximum, and then reduces before the film breaks. The maximum force is used to calculate absolute surface tension. The measured value must be adjusted by a correction factor, which accounts for the use of the ring and the density of the test substance. Instrument: Processor Tensiometer K12, Krüss Test Condition(s): Test Temperature: 20°C Test Concentration: 0.5% and 2.0% v/v Dilution medium: pure water The instrument was calibrated at the same day with Ethanol DAB 7 at 20°C with a known surface tension of 22.5 ± 0.5 mN/m. The correction of the data was done by the instrument automatically according to Harkins & Jordan using parameters reported on the print-out of the instrument.						[redacted] BASF DocID #1994/10392, unpublished	
3.13.2 Surface tension 2								
3.14 Viscosity (-)	Viscosity was measured by rotational viscometer (OECD guideline 114) Test temperature: 20°C Instrument: Contraves-Rheomat 115 Principle of method (see A 3.14 App.1 for detailed description): It is possible to determine the rheological properties of ideally viscous and non-ideally viscous products with a rotational viscometer using flow curves. The viscosities can be	Technical concentration (purity: 93.03 %)	The viscosity of the test sample is 229 - mPa s The test sample showed newtonian behaviour All measurements and the flow curves are documented in the raw data (see appendix A 3.14 App.2)		Y	1	A 3.14 [redacted]. (1994) Physical and chemical properties report for Fenpropimorph (technical active ingredient) [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
	calculated from the flow curves. In rotational viscometers, the liquid product is situated between two rotation-symmetrical and coaxially arranged surfaces, one of which rotates at a constant angular speed in terms of time. For this purpose, a torque must act on each lateral face.						[redacted] BASF DocID #1994/10392 unpublished A 3.14 App.1 Method No. CF-P 008, BASF DocID 92/10721 A 3.14 App.2 Raw data of report 1994/10392	
3.15 Explosive properties (IIA3.11)	92/69/EEC A 14 Performing of the test is not necessary because the missing of certain, reactive groups in the structural formula reveals that the substance will not disintegrate fast under development of gases and generation of heat (that means the substance does not represent an explosion hazard)			The excerpt from the UN Manual (see A 3.11 App. 1) presents on page 398 (Table A6.1) the chemical groups causing explosive properties. The substance Fenpropimorph does not contain any of the chemical groups listed in Table A6.1 indicating explosive properties.	Y	1	A 3.11 [redacted]. (1999) Evaluation of safety characteristics according to 92/69/EEC [redacted] BASF DocID #1999/11009, unpublished A 3.11 App. 1 Recommendations on the transport of dangerous goods – Manual of tests and criteria, BASF DocID #1999/1009036, published	**X8**

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specifi-cation	Results	Remarks/ Justification	GLP (Y/N)	Relia-bility	Reference	Official use only
3.16 Oxidizing properties (IIA3.12)	92/69/EEC A 17 Test EEC A.17 was not conducted because Fenpropimorph has no oxidizing potential, which is evident from the structural formulae.			Page 401 of the UN Manual (see A 3.11 App. 1) presents criteria for oxidizing properties for organic compounds in chapter 6.1.1: "For organic compounds, the classification procedure for oxidizing substances of Division 5.1 need not be applied if: (a) The compound does not contain oxygen, fluorine or chlorine; or (b) The compound contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen." For Fenpropimorph criterion (b) applies because the one oxygen atom is chemically bonded only to carbon.	Y	1	A 3.11 [redacted] (1999) Evaluation of safety characteristics according to 92/69/EEC [redacted] BASF DocID #1999/11009, unpublished A 3.11 App. 1 Recommendations on the transport of dangerous goods – Manual of tests and criteria, BASF DocID #1999/1009036, published	**X9**
3.17 Reactivity towards container material	Fenpropimorph and Fenpropimorph containing wood preservatives are used for many years. No incompatibility with the used HDPE (High Density Polyethylene) containers could be observed during this time.							**X10**

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**
(IIA3.13)								

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	August 2005
Comment	
Evaluation of data submitted under section A3	**3.1.1. Melting point** Materials and Method : The applicant's version is acceptable. Results: The applicant's version is adopted Reliability: 1 Acceptability: Acceptable Remarks: **X1**: The DSC plot has been attached as A.3.1.1 App. 1 **3.1.2. Boiling point** Materials and Method : The applicant's version is acceptable. Results: The applicant's version is adopted Reliability: 1 Acceptability: Acceptable **3.1.3. Relative density/bulk density** *- Relative density* Materials and Method : The applicant's version is acceptable. Results: The applicant's version is adopted Reliability: 1 Acceptability: Acceptable **3.2. Vapour pressure** *Vapour pressure 1* Materials and Method : (**X2**) The applicant applied an internal method for the determination of the vapour pressure by calculating the evaporation rate. The test report did not include a description of the method and all the experimental data. A new test has been provided by the applicant (Vapour pressure 2) Results: The results are acceptable as the vapour pressure obtained with this method is similar to that obtained using EEC A4 method. Reliability: 2 Acceptability: Acceptable *Vapour pressure 2* Materials and Method : (**X3**) The applicant has included this new study to determine the vapour pressure following one of the methods listed in EEC A.4 Results: The applicant's version is adopted Reliability: 1 Acceptability: Acceptable **3.2.1. Henry's Law Constant** Materials and Method : The applicant's version is acceptable. Results: The applicant's version is adopted Reliability: 1 Acceptability: Acceptable **3.3. Appearance** Materials and Method : The applicant's version is acceptable. (**X4**) However, the applicant has not indicated the test report where the appearance was determined. Ref. A.3.2 gives the information of the appearance of the active substance Results: The applicant's version is adopted Reliability: 1 Acceptability: Acceptable **3.4. Absorption spectra, and mass spectrum** Materials and Method : The applicant's version is acceptable. Results: The applicant's version is adopted Reliability: 1

Acceptability: Acceptable

3.5. Water solubility

Water solubility 1

Materials and Method : The applicant's version is acceptable. **X5**: The method used was the flask method
Results: The applicant's version is adopted.
Reliability: 1
Acceptability: Acceptable

Water solubility 2

Materials and Method : The applicant's version is acceptable. The water solubility of fenpropimorph was studied in the neutral and basic ranges with the column elution method.
Results: The applicant's version is adopted.
Reliability: 1
Acceptability: Acceptable

3.6. Dissociation constant

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.7. Solubility in organic solvents

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.8. Stability in organic solvents used in b.p.

X6: The non submission of data is justified by the applicant as the active substance does not include an organic solvent. Moreover, the biocidal product is not formulated with an organic solvent.

3.9 Partition coefficient

Log Pow 1

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

Log Pow 2

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.10 Thermal stability

Materials and Method : **X7**: The applicant has not performed an specific test for this parameter.
Results: The applicant's version is acceptable
Reliability: 2
Acceptability: Acceptable

3.11. Flammability including autoflammability

Materials and Method : The auto-ignition temperature was determined. The applicant's version is acceptable
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.12. Flash point

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.13 Surface tension

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.14. Viscosity

Materials and Method : The applicant's version is acceptable.
Results: The applicant's version is adopted
Reliability: 1
Acceptability: Acceptable

3.15. Explosive properties

X8: The applicant justifies the non performance of the test to study the explosive properties as fenpropimorph lacks of certain reactive groups in the structural formula it will not decompose fast under development of gases and generation of heat.
The applicant's version is adopted.

3.16. Oxidizing properties

X9: The applicant justifies the non performance of the test to study the oxidizing properties applying the UN Recommendations on the Transport of dangerous Goods – Manual of Tests and Criteria.
The applicant's version is adopted.

3.17. Reactivity towards the container

X10: The applicant has not presented any experimental data for the reactivity towards container material. The applicant indicates that no incompatibility with the used HDPE containers has been observed in the many years of use of this active substance.
The applicant's version is adopted.

COMPETENT AUTHORITY REPORT

FENPROPIMORPH (PT 8)

Document IIIA

Active Substance

Section 4: Analytical Methods for Detection and Identification

Rapporteur Member State: Spain
December 2006

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure substance**

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.1 [redacted] (1992) Analytical method CP No. 149/1: Determination of Fenpropimorph in techn. Fenpropimorph by capillary GC [redacted] BASF DocID #1992/11989, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA / authorisation	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Fenpropimorph is dissolved in propan-2-ol.	
3.1.2	Cleanup	Centrifugation in case the solution shows a slight precipitate	
3.2	**Detection**		
3.2.1	Separation method	Capillary GC	
3.2.2	Detector	Flame ionisation detection	
3.2.3	Standard(s)	Internal calibration with Eicosane	
3.2.4	Interfering substance(s)	No interferences due to other components in the active substance as manufactured could be detected in GC analysis. The result was confirmed by mass spectra of the AI peak.	
3.3	**Linearity**		
3.3.1	Calibration range		
3.3.2	Number of measurements		
3.3.3	Linearity	Linearity was proven for the relevant range. Inter-laboratory evaluation has resulted in the approved CIPAC method 427/TC/M3	
3.4	**Specificity: interfering substances**	The specificity of the active substance method was confirmed by comparison of the mean retention time (in GC analysis) of the reference substance Fenpropimorph PAI with the mean retention time of the peak of the test substance. No interferences due to other components in the active substance as manufactured could be detected in GC analysis. The result was	

Section A4 (4.1) Analytical Methods for Detection and Identification

Annex Point IIA4.1 **For pure substance**

confirmed by mass spectra of the AI peak.

3.5 Recovery rates at different levels

The accuracy of the procedure is assessed by the analysis of 5 samples. The samples were taken from Fenpropimorph TC, batch N 93. The recoveries found in the samples by replicate content determination are in a range of 91.62 – 92.04 5 (mean value of 91.76 %)

3.5.1 Relative standard deviation

0.18 %

3.6 Limit of determination

3.7 Precision

3.7.1 Repeatability

Precision

A representative batch of technical Fenpropimorph (N 93, CP 11193), produced in January 1991 at BASF Aktiengesellschaft, Ludwigshafen / FRG, was analysed using the method under consideration. The results are compiled in the table below:

Sample number CP 11179			
Weight [mg/50 ml]	Injection 1 [%]	Injection 2 [%]	Mean [%]
22.24	91.69	91.70	91.70
22.49	91.69	91.70	91.69
23.76	91.38	91.71	91.77
22.38	92.00	92.08	92.04
23.05	91.64	91.60	91.62
Total average:			91.76 %
Coefficient of variation:			0.18 %

Accuracy:

The identity of the sample with Fenpropimorph could be confirmed by comparison of the retention times of the active ingredient peak in the sample with those of the reference substance. The mean of the retention times of the Fenpropimorph peaks in the 20 injected solutions was 14.67 min. All values were between 14.65 and 14.73 min.

3.7.2 Independent laboratory validation

Yes, Inter-laboratory evaluation has resulted in the approved CIPAC method 427/TC/M3 (given in appendix 1 of reference A 4.1).

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Principle of the analytical method:

The active ingredient content is determined by gas chromatography on a capillary column coated with DB 17 and then quantified using an external standard. Eicosane is used as internal standard. The samples are injected using cold-on-column injection. X

The CIPAC method 427/TC/M3 using Eicosane as internal standard is essentially the same as described above

Section A4 (4.1) **Annex Point IIA4.1**	**Analytical Methods for Detection and Identification** **For pure substance**

4.2 Conclusion	The analytical method CP No. 149/1is suitable for the determination of Fenpropimorph in techn. Fenpropimorph by capillary GC. This is confirmed by the international accepted CIPAC method 427/TC/M3	
4.2.1 Reliability	1	
4.2.2 Deficiencies	No	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable
Conclusion	The applicant's version is adopted
Reliability	1
Acceptability	acceptable
Remarks	**X**: There is a mistake in subsection 4.1. The quantification of the active substance is performed using an internal standard not an external standard. The applicant has included as appendixes of reference A 4.1 the CIPAC method 427/TC/M3 together with the GC/MS chromatogram and the MS spectra of fenpropimorph.

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *soil*

Official use only

1 REFERENCE

1.1	**Reference**	A 4.2/01 [redacted] (2000) Validation of analytical method 468: determination of BAS 421 F and BF 421-2 in standard soil 2.2 + 2.3 [redacted] BASF DocID #2000/1004090, unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF AG
1.2.2	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/IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes EPA Guideline OPPTS 850.7100, April 1996 Directive 91/414/EWG
2.2	**GLP**	Yes
2.3	**Deviations**	No

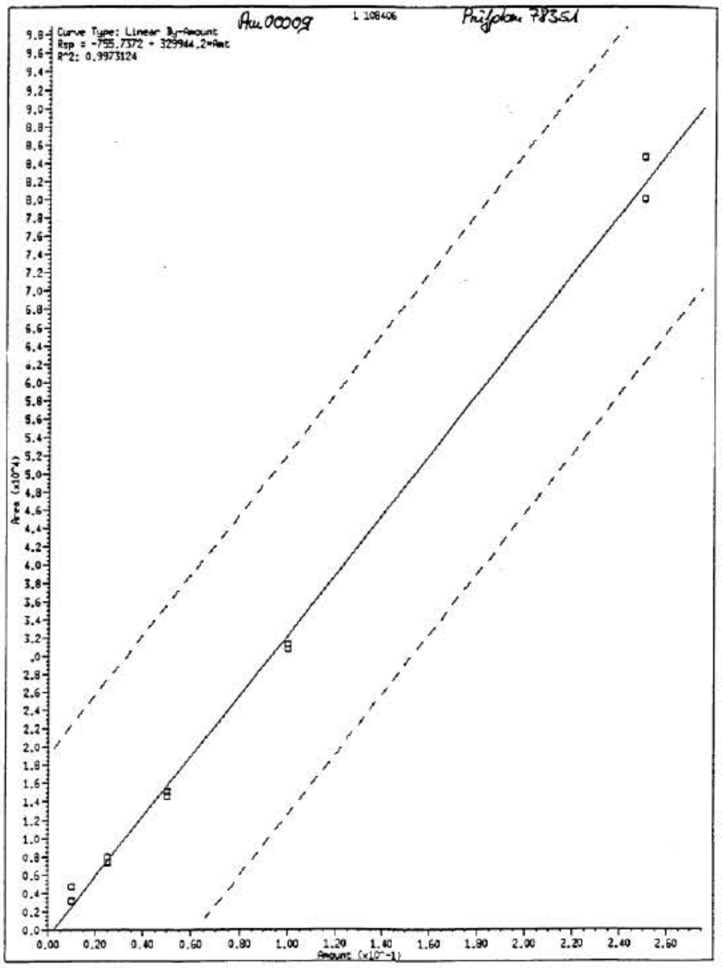
3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Enrichment of the active ingredients is achieved by solid phase extraction on a C_{18} SPE column
3.1.2	Cleanup	After the elution with dichloromethane/methanol, the extract is divided into two aliquots. A methylation step with diazomethane for the metabolite BF 421-2 (Fenpropimorph-acid) follows for one aliquot. Adding some drops of concentrated formic acid destructs remaining diazomethane. The reaction mixture and the other aliquot are evaporated to dryness and the final chromatographic analysis of Fenpropimorph and BF 421-2 (as methyl ester) is performed by capillary gas chromatography with MS detection.
3.2	**Detection**	
3.2.1	Separation method	Capillary Gas-chromatography with MS detection
3.2.2	Detector	MS
3.2.3	Standard(s)	BAS 421 F (Fenpropimorph, test substance was also used as reference substance) and BF 421-2 BF 421-2 = Methyl-2-methyl-2-[4-[2-methyl-3-(2,6-dimethyl-morpholine-4-yl) propyl] phenyl] propionic acid Empirical formula: $C_{20}H_{31}NO_3$ For GC/MS the Methyl Ester of BF 421-2 is used as reference substance BF 421-2-Me = Methyl-2-methyl-2-[4-[2-methyl-3-(2,6-dimethyl-morpholine-4-yl)propyl]phenyl]propionate Empirical formula: $C_{21}H_{33}NO_3$

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *soil*

3.2.4	Interfering substance(s)	None known
3.3	**Linearity**	
3.3.1	Calibration range	0.005 – 0.25 each for BAS 421 F (Fenpropimorph) and BF 421-2 (Methyl-2-methyl-2-[4-[2-methyl-3-(2,6-dimethylmorpholine-4-yl) propyl] phenyl] propionic acid*)*
3.3.2	Number of measurements	Duplicate measurements
3.3.3	Linearity	The calibration curve is linear in the range between 0.005 – 0.25 $R^2 = 0.9973124$



3.4	**Specifity: interfering substances**	Interfering substances are not mentioned in the report; the method is specific for Fenpropimorph and BAS 421-2.
3.5	**Recovery rates at different levels**	The overall recovery n=29 for Fenpropimorph in two types of soil was 90.1% with a coefficient of variation of 13.8% The overall recovery n=30 for Fenpropimorph acid in two types of soil was 99.0 % with a coefficient of variation of 13.3%

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *soil*

Recoveries of Fenpropimorph (BAS 421-F) in BBA standard soil 2.2:

Date of analysis: 1) 06-JUN-2000 2) 31-MAY-2000 3) 09-JUN-2000
Queuefile name: 1) AM00009 2) AM00010 3) AM00010b

Analyte added (mg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control1)	0.00	0.00				
0.011)	0.5	11.725	75,4			
0.011)	0.5	11.675	75,1			
0.011)	0.5	11.332	72,9			
0.013)	0.5	10.478	106.2			
0.013)	0.5	10.224	96.4	**85.2**	**15.1**	**17.8**
0.11)	5.0	57.570	92,6			
0.11)	5.0	54.642	87.9			
0.12)	5.0	57.906	93.1			
0.12)	5.0	48.238	77.6			
0.12)	5.0	48.874	78.6	**86.0**	**7.5**	**8.7**
control2)	0.00	0.00				
1.01)	50.0	114.471	110.4			
1.01)	50.0	108.605	104.8			
1.02)	50.0	101.356	97.8			
1.02)	50.0	108.102	104.3			
1.02)	50.0	125.442	121.0	**107.7**	**8.7**	**8.1**

Recoveries of Fenpropimorph acid (BF 421-2) determined as ME-ester in BBA standard soil 2.2:

Date of analysis: 1) 06-JUN-2000 2) 31-MAY-2000
Queuefile name: 1) AM00009a 2) AM000010a

Analyte added (mg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control1)	0.00	0.00				
0.011)	0.5	14.235	87.9			
0.011)	0.5	13.446	83.0			
0.011)	0.5	14.022	86.6			
0.012)	0.5	14.113	87.1			
0.012)	0.5	13.481	83.2	**85.6**	**2.3**	**2.7**
0.11)	5.0	60.912	94.0			
0.11)	5.0	57.053	88.1			
0.12)	5.0	62.518	96.5			
0.12)	5.0	59.785	92.3			
0.12)	5.0	60.530	93.4	**92.9**	**3.1**	**3.3**
control2)	0.00	0.00				
1.01)	50.0	99.078	91.8			
1.01)	50.0	91.790	85.0			
1.02)	50.0	102.926	95.3			
1.02)	50.0	117.450	108.8			
1.02)	50.0	96.353	89.2	**94.0**	**9.1**	**9.7**

Recoveries of Fenpropimorph (BAS 421-F) in BBA standard soil 2.3:

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *soil*

Date of analysis: 1) 05-JUN-2000 2) 07-JUN-2000
Queuefile name: 1) AM00011 2) AM00012

Analyte added (mg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control 1)	0.00	0.00				
0.01 1)	0.5	28.766	78.2			
0.01 1)	0.5	30.250	82.2			
0.01 1)	0.5	27.649	75.1			
0.01 2)	0.5	16.257	44.2			
0.01 2)	0.5	26.151	71.1	76.7	4.7	6.1
0.1 1)	5.0	58.500	79.5			
0.1 1)	5.0	61.981	84.2			
0.1 2)	5.0	64.877	88.2			
0.1 2)	5.0	65.100	88.5			
0.1 2)	5.0	67.949	92.3	86.5	4.9	5.6
control 2)	0.00	0.00				
1.0 1)	50.0	114.519	93.4			
1.0 1)	50.0	116.764	95.2			
1.0 2)	50.0	120.105	97.9			
1.0 2)	50.0	121.374	99.0			
1.0 2)	50.0	115.912	94.5	96.0	2.4	2.5

Recoveries of Fenpropimorph acid (BF 421-2) determined as ME-ester in BBA standard soil 2.3:

Date of analysis: 1) 05-JUN-2000 2) 07-JUN-2000
Queuefile name: 1) AM00011a 2) AM00012a

Analyte added (µg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control 1)	0.00	0.00				
0.01 1)	0.5	38.780	101.2			
0.01 1)	0.5	47.949	125.1			
0.01 1)	0.5	31.683	82.7			
0.01 2)	0.5	44.288	115.5			
0.01 2)	0.5	37.226	97.1	104.3	16.5	15.8
0.1 1)	5.0	69.871	91.1			
0.1 1)	5.0	66.815	87.2			
0.1 2)	5.0	84.351	110.0			
0.1 2)	5.0	89.360	116.6			
0.1 2)	5.0	86.883	113.3	103.6	13.5	13.0
control 2)	0.00	0.00				
1.0 1)	50.0	152.009	119.0			
1.0 1)	50.0	154.855	121.2			
1.0 2)	50.0	151.301	118.4			
1.0 2)	50.0	134.807	105.5			
1.0 2)	50.0	131.087	102.6	113.3	8.6	7.6

3.5.1 Relative standard deviation — See above

Section A4 (4.2) **Annex Point IIA4.2**	**Analytical Methods for Detection and Identification** *soil*
3.6 Limit of determination	Limit of quantitation: 0.01 mg/kg in soil Limit of detection: 5 pg/µl, which is the lowest standard injected into GC/MS.
3.7 Precision	
3.7.1 Repeatability	Recoveries are comparable high and consistent
3.7.2 Independent laboratory validation	Not performed
	4 APPLICANT'S SUMMARY AND CONCLUSION
4.1 Materials and methods	Guidelines: EPA Guideline, OPPTS 850.7100, and Directive 91/414/EEC: A 50 g soil sample is extracted twice with methanol/H_2O 80/20 each for one hour. After centrifugation, the extract is decanted into a round bottom flask. Methanol is evaporated using a vacuum rotation evaporator. The remaining water phase is made up to 100 g with H_2O and is adjusted to pH 4 with formic acid. Enrichment of the active substance is achieved by solid phase extraction on a C18 SPE column. After the elution with dichloromethan/methanol, the extract is divided into two aliquots. A methylation step with diazomethane for the metabolite BF 421-2 (Fenpropimorph-acid) follows for one aliquot. Adding some drops of concentrated formic acid destructs remaining diazomethane. The reaction mixture and the other aliquot are evaporated to dryness and the final chromatographic analysis of Fenpropimorph and BF 421-2 (as methyl ester) is performed by capillary gas chromatography with MS detection.
4.2 Results	Fenpropimorph and BF 421-2 (Fenpropimorph-acid) can be analysed down to the limit of determination of 0.01 mg/kg.
4.3 Conclusion	Based on soil metabolism results a parent and a metabolite soil method was developed proposed for monitoring purposes and to analyse field samples. The residues of Fenpropimorph and BF 421-2 in soil are covered by BASF method No. 468. This method fulfils the EU requirements concerning specificity (no/low interferences at the LOQ), repeatability (recoveries comparably high and consistent), limit of quantification (i.e. LOQ = 0.01 mg/kg for each analyte) and recovery (average values between 70 and 110% with an RSD <20%). MS-technique is used for final measurements. Overall it is concluded, that the described methodology is well suitable to correctly describe the residue situation of Fenpropimorph and BF 421-2 residues in soil.
4.3.1 Reliability	1
4.3.2 Deficiencies	No

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *soil*

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable however; the mass spectrometric detection should have been performed with at least two ions, one target ion and a qualifier ion.
Conclusion	The applicant's version is adopted
Reliability	2. The determination with mass spectrometry should have been performed with at least two ions.
Acceptability	acceptable
Remarks	No further remarks

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/02 [redacted] (1992) Sampling of air and determination of residues of parent compounds by gas chromatography [redacted] BASF DocID #1992/11729, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	Yes The study was performed in compliance with "Procedures and Principles of GLP in Switzerland", issued by the Department of the Interior, Bern, 1986; equivalent to "OECD Principles of Good Laboratory Practice", Paris.	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	A defined volume of air is sucked through a sorbent tube using an air sampler pump. The different layers of the tube are separated and Fenpropimorph is extracted with methanol using an ultrasonic bath.	
3.1.2	Cleanup	The methanol is evaporated and the residue is re-dissolved in hexane and Fenpropimorph is determined by gas chromatography using a PN detector	
3.2	**Detection**		
3.2.1	Separation method	Gas chromatography	
3.2.2	Detector	PN detector	
3.2.3	Standard(s)	Fenpropimorph	
3.2.4	Interfering substance(s)	Chromatographic interferences, which hindered the quantitation of Fenpropimorph, have not been encountered during the development of the present method.	
3.3	**Linearity**		
3.3.1	Calibration range	0.04 – 0.8 ng Fenpropimorph	
3.3.2	Number of measurements	3 measurements for 0.8 ng Fenpropimorph, 2 measurements for 0.04, 0.08 and 0.6 ng Fenpropimorph	
3.3.3	Linearity	The calibration curve is linear between 0.04 and 0.08 ng Fenpropimorph (the calibration curve is presented in A4_2_2b)	

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

3.4 Specifity: interfering substances

Chromatographic interferences, which hindered the quantitation of Fenpropimorph, have not been encountered during the development of the present method.

3.5 Recovery rates at different levels

Spiking level [µg/m³]	Sampling location	% Fenpropimorph found
1	Indoor	115
1	outdoor	119
2	Indoor	91
2	outdoor	91
10	Indoor	70
10	outdoor	64

Average recoveries: 79 %, s_{abs} = 14 %, n = 4

Acceptable recovery range: 59 – 99 %

The results of the recoveries at fortification level 1 µg/m³ were not taken into account, as the results at this level have a lower precision.

Further recovery values may be added and the range of acceptable recoveries may be updated accordingly.

3.5.1 Relative standard deviation

s_{abs} = 14 %, n = 4

3.6 Limit of determination

The ultimate limit of determination of this method was not determined. The lower practical level of Fenpropimorph in air quantified by this method is 1 µg/m³.

3.7 Precision

3.7.1 Repeatability

Results were comparable high and consistent

3.7.2 Independent laboratory validation

Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

A defined volume of air is sucked through a sorbent tube using an air sampler pump. The different layers of the tube are separated and Fenpropimorph is extracted with methanol using an ultrasonic bath. The methanol is evaporated and the residue is re-dissolved in hexane and Fenpropimorph is determined by gas chromatography using a PN detector.

4.2 Results

The method allows the quantitative determination of residues of the fungicide Fenpropimorph in air (gas, coarse dust and aerosols).

The lower practical level of quantitation by this method is 1 µg/m³ Fenpropimorph in air under the actual conditions during sampling.

4.3 Conclusion

The method was validated by analysis of fortified samples and evaluation of recoveries.

4.3.1 Reliability

1

4.3.2 Deficiencies

No

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version may be considered acceptable. However, only one replicate for each sampling location and spiking level have been carried out. Nevertheless, there is a validation of this method (Reference A 4.2/03) where at least three replicates have been done for each fortification level.
Conclusion	The applicant's version is adopted
Reliability	2 The recovery assays should have been carried out with at least three samples for each fortification level.
Acceptability	acceptable
Remarks	

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

Official use only

1 REFERENCE

1.1	**Reference**	A 4.2/03 [redacted] (1995) Report of special study 124/95. Validation of method REM 167.02 in air. Validation by analysis of fortified specimens and determination of recoveries, [redacted] BASF DocID #1995/10920, unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF AG
1.2.2	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/IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No
2.2	**GLP**	Yes The study was performed in compliance with “Procedures and Principles of GLP in Switzerland”, issued by the Department of the Interior, Bern, 1986; equivalent to “OECD Principles of Good Laboratory Practice”, Paris.
2.3	**Deviations**	No

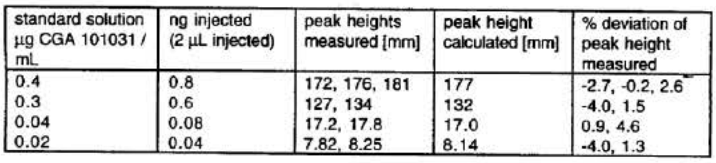
3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	A defined volume of air is sucked through a sorbent tube using an air sampler pump. The different layers of the tube are separated and Fenpropimorph is extracted with methanol using an ultrasonic bath.
3.1.2	Cleanup	The methanol is evaporated and the residue is re-dissolved in hexane and Fenpropimorph is determined by gas chromatography using a PN detector
3.2	**Detection**	
3.2.1	Separation method	Gas chromatography
3.2.2	Detector	PN detector
3.2.3	Standard(s)	Fenpropimorph
3.2.4	Interfering substance(s)	Chromatographic interferences, which hindered the quantitation of Fenpropimorph, have not been encountered during the development of the present method.
3.3	**Linearity**	
3.3.1	Calibration range	0.04 – 0.8 ng Fenpropimorph

Section A4 (4.2) Analytical Methods for Detection and Identification

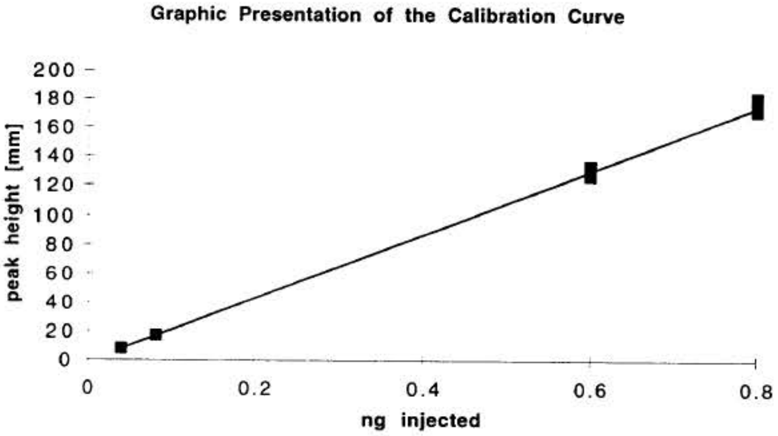
Annex Point IIA4.2 *air*

Example of a calibration curve:



standard solution µg CGA 101031 / mL	ng injected (2 µL injected)	peak heights measured [mm]	peak height calculated [mm]	% deviation of peak height measured
0.4	0.8	172, 176, 181	177	-2.7, -0.2, 2.6
0.3	0.6	127, 134	132	-4.0, 1.5
0.04	0.08	17.2, 17.8	17.0	0.9, 4.6
0.02	0.04	7.82, 8.25	8.14	-4.0, 1.3

Calibration curve: ng = (peak height [mm]- A) / B
Calculation according to General Calculation Method REM 119.06:
A: -0.7343, B: 221.9, s: 3.0% (s = square root of the variance of all relative deviations of the measured response to the corresponding calculated value of the response function).


Graphic Presentation of the Calibration Curve

3.3.2 Number of measurements — 3 measurements for 0.8 ng Fenpropimorph, 2 measurements for 0.04, 0.08 and 0.6 ng Fenpropimorph

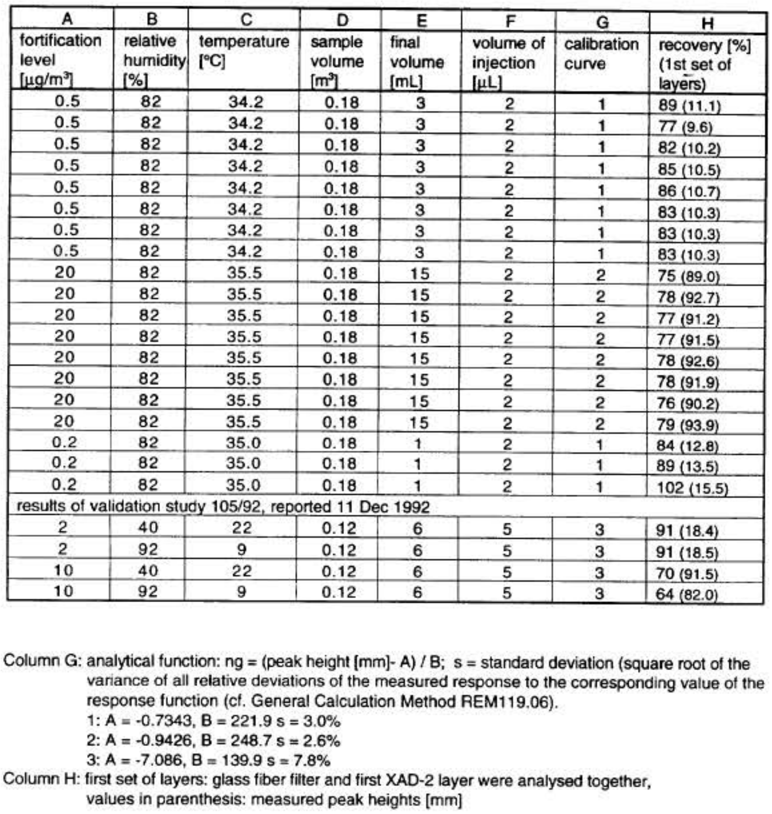
3.3.3 Linearity — The calibration curve is linear between 0.04 and 0.08 ng Fenpropimorph X1

3.4 Specifity: interfering substances — Chromatographic interferences, which hindered the quantitation of Fenpropimorph, have not been encountered during the development of the present method.

3.5 Recovery rates at different levels — Recoveries of fortified air sampling tubes (in percent of nominal value)

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*



A	B	C	D	E	F	G	H
fortification level [µg/m³]	relative humidity [%]	temperature [°C]	sample volume [m³]	final volume [mL]	volume of injection [µL]	calibration curve	recovery [%] (1st set of layers)
0.5	82	34.2	0.18	3	2	1	89 (11.1)
0.5	82	34.2	0.18	3	2	1	77 (9.6)
0.5	82	34.2	0.18	3	2	1	82 (10.2)
0.5	82	34.2	0.18	3	2	1	85 (10.5)
0.5	82	34.2	0.18	3	2	1	86 (10.7)
0.5	82	34.2	0.18	3	2	1	83 (10.3)
0.5	82	34.2	0.18	3	2	1	83 (10.3)
0.5	82	34.2	0.18	3	2	1	83 (10.3)
20	82	35.5	0.18	15	2	2	75 (89.0)
20	82	35.5	0.18	15	2	2	78 (92.7)
20	82	35.5	0.18	15	2	2	77 (91.2)
20	82	35.5	0.18	15	2	2	77 (91.5)
20	82	35.5	0.18	15	2	2	78 (92.6)
20	82	35.5	0.18	15	2	2	78 (91.9)
20	82	35.5	0.18	15	2	2	76 (90.2)
20	82	35.5	0.18	15	2	2	79 (93.9)
0.2	82	35.0	0.18	1	2	1	84 (12.8)
0.2	82	35.0	0.18	1	2	1	89 (13.5)
0.2	82	35.0	0.18	1	2	1	102 (15.5)
results of validation study 105/92, reported 11 Dec 1992							
2	40	22	0.12	6	5	3	91 (18.4)
2	92	9	0.12	6	5	3	91 (18.5)
10	40	22	0.12	6	5	3	70 (91.5)
10	92	9	0.12	6	5	3	64 (82.0)

Column G: analytical function: ng = (peak height [mm]- A) / B; s = standard deviation (square root of the variance of all relative deviations of the measured response to the corresponding value of the response function (cf. General Calculation Method REM119.06).
1: A = -0.7343, B = 221.9 s = 3.0%
2: A = -0.9426, B = 248.7 s = 2.6%
3: A = -7.086, B = 139.9 s = 7.8%
Column H: first set of layers: glass fiber filter and first XAD-2 layer were analysed together, values in parenthesis: measured peak heights [mm]

<u>Climatic conditions: ~ 35 °C, 82 % rel. humidity</u>

Average recovery (fortification level 0.5 µg/m³): 84 %, s_{rel} = 4 %, n=8

Average recovery (fortification level 20 µg/m³): 77 %, s_{rel} = 2 %, n=8

Average recovery (fortification level 0.2 µg/m³): 92 %, s_{rel} = 10 %, n=3

<u>Climatic conditions: 9 – 22 °C, 40 - 92 % rel. humidity</u>

Average recovery (cf. Report on special study 105/92): 79 %, s_{rel} = 18 %, n=4

<u>Overall average recovery:</u> 82 %, s_{rel} = 10 %, n= 23

3.5.1 Relative standard deviation — See above

3.6 Limit of determination — The limit of quantitation (LOQ) was set to 0.5 µg Fenpropimorph/m³ air. The final volume for injection into the gas chromatograph was 3 ml. In order to check a lower limit of quantitation 3 recovery tests at a LOQ of 2 µg/m³ (final volume 1 ml) were also performed. **X2**

3.7 Precision

3.7.1 Repeatability — Results were comparable high and consistent

3.7.2 Independent laboratory validation — Not performed

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

The experimental procedure (air sampling, cleanup and quantitation) is fully described in Method REM 167.02, issued December 11, 1992 (see Ref. A 4.2/02)

Principle of the method:

A defined volume of air is sucked through a sorbent tube using an air sampler pump. The different layers of the tube are separated and Fenpropimorph is extracted with methanol using an ultrasonic bath.

The methanol is evaporated and the residue is re-dissolved in hexane and Fenpropimorph is determined by gas chromatography using a PN detector

4.2 Results

Climatic conditions: ~ 35°C, 82 % rel. humidity
Average recovery (fortification level 0.5 $\mu g/m^3$): 84 %, s_{rel}=4 %, n=8
Average recovery (fortification level 20 $\mu g/m^3$): 77 %, s_{rel}=2 %, n=8
Average recovery (fortification level 0.2 $\mu g/m^3$): 92 %, s_{rel}=10 %, n=3

Climatic conditions: 9 – 22°C, 40 – 92 % rel. Humidity
Average recovery (cf. Report on Special Study 105/92): 79 %, s_{rel} = 18%, n = 4

Overall average recovery: 82 %, s_{rel} = 10 %, n = 23

Maximum capacity tested: 3.6 µg Fenpropimorph (recovery test 20 $\mu g/m^3$), no break through onto the second set of layers was observed (< 0.5 $\mu g/m^3$, < 0.09 µg/tube, < 2.5 %)

4.3 Conclusion

The method was validated by analysis of fortified samples and evaluation of recoveries.

4.3.1 Reliability 1

4.3.2 Deficiencies No

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable.
Conclusion	The applicant's version is adopted
Reliability	1
Acceptability	acceptable
Remarks	**X1**: There is a mistake in subsection 3.3.3; the calibration curve is linear between 0.04 and *0.8 ng* fenpropimorph. **X2**: There is a mistake in subsection 3.6. A lower limit of quantitation at 0.2 $\mu g/m^3$ was assayed not at 2 $\mu g/m^3$.

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/04 [redacted] (2000) To Ciba Geigy method REM 167.02. Confirmatory method for determination of BAS 421 F residues in air using GC/MS, [redacted] [redacted] BASF DocID #2000/1004091, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	Not mentioned	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	A defined volume of air is sucked through a sorbent tube using an air sampler pump. The different layers of the tube are separated and Fenpropimorph is extracted with methanol using an ultrasonic bath.	
3.1.2	Cleanup	The methanol is evaporated and the residue is re-dissolved in acetone and Fenpropimorph is determined by gas chromatography using a PN detector	
3.2	**Detection**		
3.2.1	Separation method	Gas chromatography	
3.2.2	Detector	MS detection	
3.2.3	Standard(s)	Internal (Dodemorph)	
3.2.4	Interfering substance(s)	No	
3.3	**Linearity**		
3.3.1	Calibration range	0.02 to 0.25 ng	
3.3.2	Number of measurements		
3.3.3	Linearity		

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

3.4 Specifity: interfering substances Residues of BAS 421 F (Fenpropimorph) are determined as active ingredient itself

3.5 Recovery rates at different levels

3.5.1 Relative standard deviation

3.6 Limit of determination

3.7 Precision

3.7.1 Repeatability

3.7.2 Independent laboratory validation Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

The collection procedure and the analytical steps are described in Method REM 167.02 CIBA-GEIGY (see A 4.2-02a, Ref. A 4.2/02)

The confirmatory technique is described in BASF method 454/0, page 16 (G. Ziegler, Validation of analytical method 454, Determination of BAS 421 F (Fenpropimorph) in tap and surface water, BASF Reg. Doc. #: 1999/11100, see A 4.2/05):

Type of method:	GC method for BAS 421 F with internal standardisation
Test systems:	tap water and surface water
Analyte fortified:	BAS 421 F
Analyte detected:	BAS 421 F
Extraction:	liquid/liquid with DCM
Determined as:	BAS 421 F
Method of determination:	GC with ^{63}Ni-FID
Confirmatory technique:	GC/MS can be used as confirmatory method

X

The extracts are dissolved in acetone instead of n-hexane.

The calibration standards in a range of 0.02 to 0.25 ng should also be prepared in acetone.

4.2 Results GC/MS can be used as confirmatory method

4.3 Conclusion For the investigation of air sample extracts, it is possible to use GC/MS as confirmatory method for the determination of BAS 421 F (Fenpropimorph) residues

4.3.1 Reliability 1

4.3.2 Deficiencies No

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *air*

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant states that fenpropimorph residues in air may be confirmed using a GC/MS developed for the confirmation of residues in water samples (Ref A 4.2/05). The sampling of air will be performed following the procedure described in Ref A 4.2/02. This method may be acceptable however the applicant does not provide any experimental data just the description of it.
Conclusion	The applicant's version is adopted with objections.
Reliability	2. The applicant has not provided results for this method
Acceptability	acceptable
Remarks	**X**: There is an editorial mistake; the correct method of determination is GC with N-FID

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/05 [redacted] (1999) Validation of analytical method No. 454. Determination of BAS 421 F (Fenpropimorph) in tap and surface water [redacted] BASF DocID #1999/11100, unpublished A 4.2/06 Ziegler, G. (1999) Report amendment No. 1 to final report: Validation of analytical method No. 454. Determination of BAS 421 F (Fenpropimorph) in tap and surface water BASF AG, Agrarzentrum Limburgerhof, Germany BASF DocID #1999/11298, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes EPA Guideline OPPTS 860.1340, August 1996, EU Guideline 8064/VI/97-rev4 15.12.98, Appendix 1 to § 19a Section 1 ChemG of 25th July 1994	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Enrichment of the active ingredient from a 500 g water sample is achieved by extraction with DCM. The DCM extract is evaporated to dryness.	
3.1.2	Cleanup	After a clean-up step with silica gel SPE column, the final chromatography analysis of BAS 421 F is determined by capillary gas chromatography with ^{63}Ni-FID using an internal standard	**X1**
3.2	**Detection**		
3.2.1	Separation method	Capillary gas chromatography with 63Ni-FID	**X1**
3.2.2	Detector	MS detection	
3.2.3	Standard(s)	Internal standard (Dodemorph)	
3.2.4	Interfering substance(s)	No	
3.3	**Linearity**		

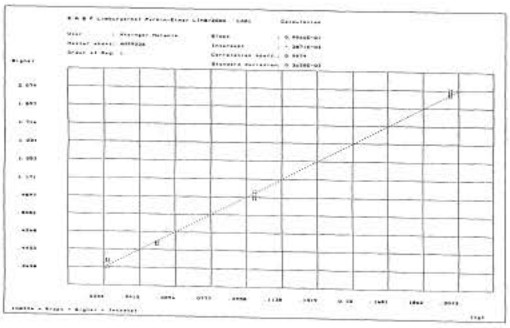
Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

3.3.1 Calibration range

0.025 µg/ml to 0.2 µg/ml

Calibration curve:



3.3.2 Number of measurements

2

3.3.3 Linearity

The calibration curve is linear between 0.025 µg/ml and 0.2 µg/ml

Correlation coefficient: 0.9974

3.4 Specifity: interfering substances

Method No. 454 allows the determination of BAS 421 F as active ingredient itself. If there are interfering peaks GC/MS analytic can be used for confirmation

3.5 Recovery rates at different levels

Table1: Recoveries of BAS 421 F in tap water

Water weigh in g	Fortification of BAS 421 F µg	ppb	Final volume ml	Injection Volume µl	Analyte found** ng	Recovery Indiv %	Mean	Standard Deviation	Coefficient of variation %
500	0.0	0.0	0.5	1	0	0	0	-	-
500	0.025	0.05	0.5	1	0.054	107.0			
500	0.025	0.05	0.5	1	0.053	106.1			
500	0.025	0.05	0.5	1	0.059	118.7	108.6	6.5	6.0
500	0.025	0.05	0.5	1	0.055	110.0			
500	0.025	0.05	0.5	1	0.051	101.1			
500	0.0	0.0	2.5	1	0	0	-	-	-
500	0.25	0.5	2.5	1	0.094	93.9			
500	0.25	0.5	2.5	1	0.097	97.0			
500	0.25	0.5	2.5	1	0.136	136.5***	97.8	3.7	3.8
500	0.25	0.5	2.5	1	0.097	97.4			
500	0.25	0.5	2.5	1	0.103	102.8			

* Start of laboratory analysis

** Recalculated from % recovery

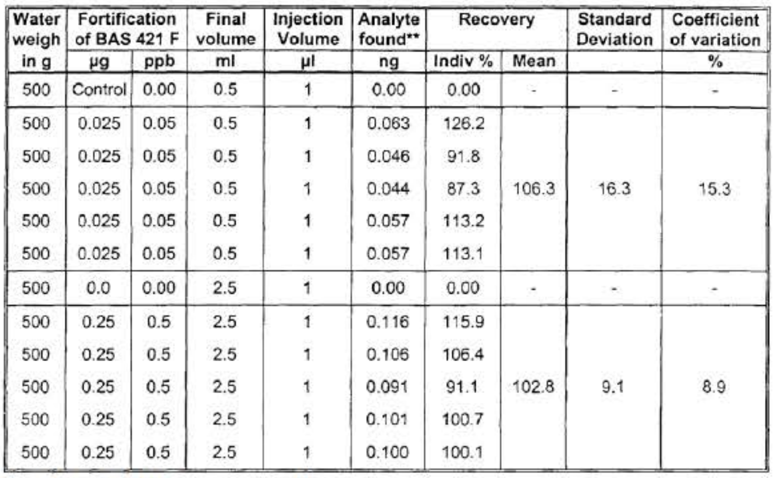
*** Outlier according to "Grubbs Ausreißertest"

The resulting average recovery (n=9) for series 1 (tap water) is 103.8 % with a coefficient of variation of 7.4 %.

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

Table2: Recoveries of BAS 421 F in surface water



Water weigh in g	Fortification of BAS 421 F		Final volume	Injection Volume	Analyte found**	Recovery		Standard Deviation	Coefficient of variation
	µg	ppb	ml	µl	ng	Indiv %	Mean		%
500	Control	0.00	0.5	1	0.00	0.00	-	-	-
500	0.025	0.05	0.5	1	0.063	126.2	106.3	16.3	15.3
500	0.025	0.05	0.5	1	0.046	91.8			
500	0.025	0.05	0.5	1	0.044	87.3			
500	0.025	0.05	0.5	1	0.057	113.2			
500	0.025	0.05	0.5	1	0.057	113.1			
500	0.0	0.00	2.5	1	0.00	0.00	-	-	-
500	0.25	0.5	2.5	1	0.116	115.9	102.8	9.1	8.9
500	0.25	0.5	2.5	1	0.106	106.4			
500	0.25	0.5	2.5	1	0.091	91.1			
500	0.25	0.5	2.5	1	0.101	100.7			
500	0.25	0.5	2.5	1	0.100	100.1			

* Start of laboratory analysis

** Recalculated from % recovery

The resulting average recovery (n=10) for series 2 (surface water) is 104.6 % with a coefficient of variation of 12.0 %

3.5.1 Relative standard deviation — See above

3.6 Limit of determination

For water, the limit of quantification of this method is 0.05 µg/kg (ppb) for BAS 421 F. The limit of detection is 25 pg/µl, which is the lowest standard injected into GC. Concerning surface water, this limit of quantitation is far below the LC_{50} and NOEC values of all relevant non-target organisms.

3.7 Precision

3.7.1 Repeatability

Sample matrix	Test substance	Fortification level [mg/kg]	Average recovery [%]	RSD [%]	No. of analyses
Tap water	Fenpropimorph	0.05 0.5	108.6 97.8	6.0 3.8	5 5
Surface water	Fenpropimorph	0.05 0.5	106.3 102.8	15.3 8.9	5 5

X2

3.7.2 Independent laboratory validation — Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Guidelines:

EPA Guideline OPPTS 860.1340, August 1996, EU Guideline 8064/VI/97-rev4 15.12.98, Appendix 1 to § 19a Section 1 ChemG of 25th July 1994

BASF Method 454 was developed as a GC residue method for the analysis of BAS 421 F (Fenpropimorph)

Enrichment of the active ingredient from a 500 g water sample is

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

achieved by extraction with DCM. The DCM extract is evaporated to dryness. After a clean-up step with silica gel SPE column, the final chromatography analysis of BAS 421 F is determined by capillary gas chromatography with ^{63}Ni-FID using an internal standard.

X1

GC/MS can be used as confirmatory method.

4.2 Results

The method has a limit of quantitation of 0.05 µg/kg in water.

In the in-house validation study performed with two types of water (tap and surface water) at fortification levels of 0,05 µg/kg and 0.5 µg/kg, the overall recoveries found for all concentrations tested are listed in the following table:

Matrix	Replicates	Mean recovery %	Coefficient of variation
Tap water Surface water	9* 10*	103.8 104.6	7.4 12.0
Tap and surface water	19	104.2	9.9

* recovery of 136.5 % from table 1 is not taken into account (outlier according to "Grubbs Ausreißertest)

The overall recovery n = 19 (1 outlier according to "Grubbs Ausreißertest") for the two types of water was 104.2 % with a coefficient of variation of 9.9 %

4.3 Conclusion

The validation results confirm that method 454 is well suited for the determination of BAS 421 F residues in tap water and surface water samples.

4.3.1 Reliability 1

4.3.2 Deficiencies No

Section A4 (4.2)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.2	*water*

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable
Conclusion	The applicant's version is adopted
Reliability	1
Acceptability	acceptable
Remarks	**X1**: As indicated in report amendment (Ref A 4.2/06), the correct detection method is N-FID not ^{63}Ni-FID. **X2**: There is a mistake in the fortification level units; the correct unit is µg/kg.

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

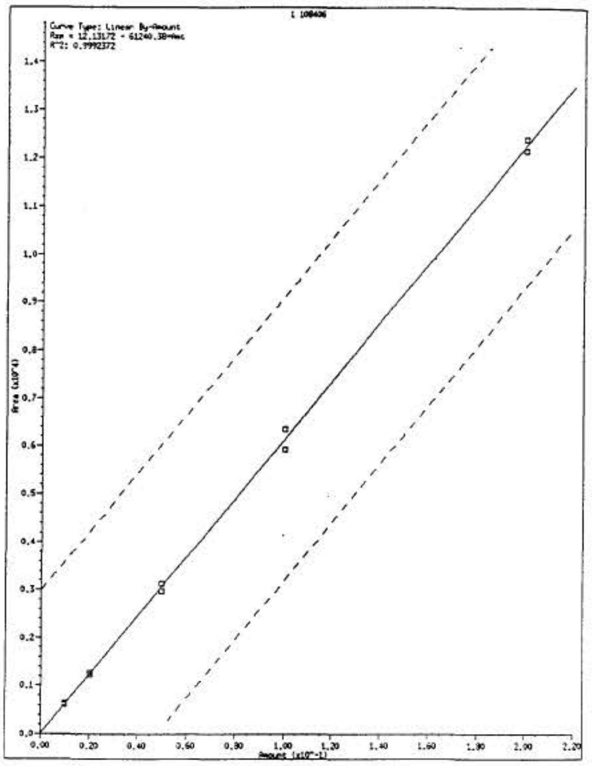
			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/07 [redacted] (2000) Validation of analytical method No. 465. Determination of BAS 421 F (Fenpropimorph) and BF 421-2 (Fenpropimorph acid) in tap and surface water [redacted] BASF DocID #2000/1004086, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, EPA Guideline, OPPTS 850.7100, April 1996, Directive 91/414/EEC, appendix 1 t $ 19a, section 1, Chemikaliengesetz of 25 July 1994 (Official bulletin/Federal Republic of Germany, I 1994, P. 1703)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	A 500 g water sample aliquot is adjusted with formic acid (conc.) to pH 4. Enrichment of the active ingredient is achieved by solid phase extraction on a C16 SPE column. After the elution with Dichloromethan/Methanol a methylation step with diazomethane follows.	**X1**
3.1.2	Cleanup	Remaining Diazomethane is destructed by adding some drops of concentrated formic acid. The reaction mixture is evaporated to dryness and the final chromatography analysis of BAS 421 F and BF 421-2 (as methylester) is determined by capillary gas chromatography with MS detection.	
3.2	**Detection**		
3.2.1	Separation method	Capillary gas chromatography with ^{63}Ni-FID	**X2**
3.2.2	Detector	MS detection	
3.2.3	Standard(s)	The test substance BAS 421 F (Fenpropimorph) was also used as reference substance. For GC/MS the Methyl ester of BF 421-2 is used as reference substance.	
3.2.4	Interfering substance(s)	No	
3.3	**Linearity**		
3.3.1	Calibration range	0.01 – 0.2 µg/ml	
3.3.2	Number of measurements	2	

Section A4 (4.2) Analytical Methods for Detection and Identification

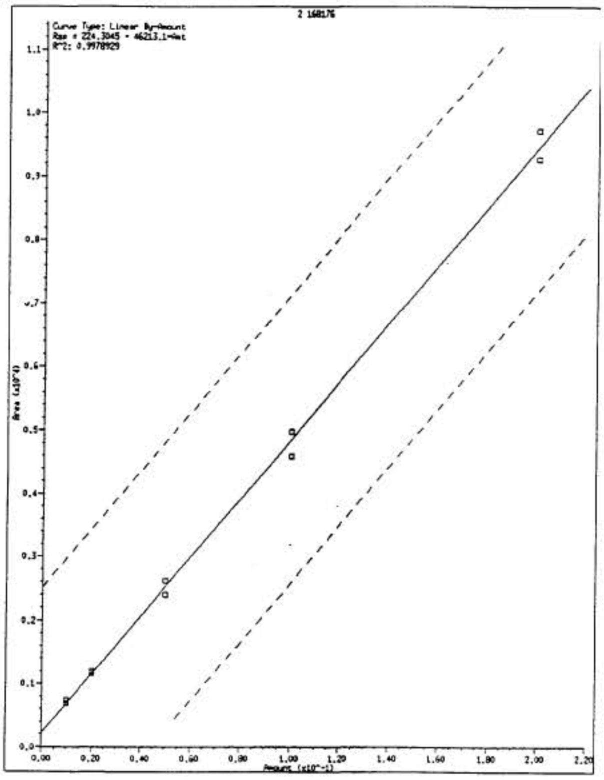
Annex Point IIA4.2 *water*

3.3.3 Linearity

Calibration curve of BAS 421 F (Fenpropimorph): $R^2 = 0.9992372$



Calibration curve of BF 421-2 (as methyl-ester): R^2 0.9978929



The calibration curves are linear between 0.01 – 0.2 µg/ml.

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

3.4 Specifity: interfering substances

No significant interferences (> 30% of LOQ) were observed indicating adequate specifity.

Residues of BAS 421 F and BF 421-2 are determined as active ingredient itself.

The method allows the specific determination of BAS 421 F (Fenpropimorph) and the metabolite BF 421-2 (Fenpropimorph acid) in water with the required limit of determination.

3.5 Recovery rates at different levels

Recoveries of Fenpropimorph (BAS 421 F) in tap water:

Analyte added (µg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control1)	0.00	0.0011				
0.051)	0.025	0.0267	102.2			
0.051)	0.025	0.0271	103.8			
0.051)	0.025	0.0252	96.3			
0.052)	0.025	0.0253	101.2			
0.052)	0.025	0.0259	103.4	101.4	3.0	3.0
0.51)	0.25	0.2444	97.3			
0.51)	0.25	0.2390	95.1			
0.52)	0.25	0.2606	104.2			
0.52)	0.25	0.2590	103.6			
0.52)	0.25	0.2512	100.5	100.1	3.9	3.9
control2)	0.00	0.00				
5.01)	2.5	2.5438	101.7			
5.01)	2.5	2.4500	97.9			
5.02)	2.5	2.3344	93.4			
5.02)	2.5	2.3331	93.3			
5.02)	2.5	2.3396	93.6	96.0	3.7	3.9

Recoveries of Fenpropimorph-acid (BF 421-2) determined as ME-ester in tap water:

Analyte added (µg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control1)	0.00	0.0021				
0.051)	0.025	0.0255	97.7			
0.051)	0.025	0.0267	102.6			
0.051)	0.025	0.0255	97.7			
0.052)	0.025	0.0248	95.2			
0.052)	0.025	0.02565	101.8	99.0	3.1	3.1
0.51)	0.25	0.2559	101.9			
0.51)	0.25	0.2575	102.6			
0.52)	0.25	0.2605	104.2			
0.52)	0.25	0.2675	107.0			
0.52)	0.25	0.2671	106.8	104.5	2.3	2.2
control2)	0.00	0.00				
5.01)	2.5	2.6328	105.3.			
5.01)	2.5	2.5824	103.3			
5.02)	2.5	2.4084	96.3			
5.02)	2.5	2.3992	96.0			
5.02)	2.5	2.4337	97.4	99.7	4.3	4.3

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

Recoveries of Fenpropimorph (BAS 421 F) in surface water:

Analyte added (µg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control$^{1)}$	0.00	0.0003				
0.05$^{1)}$	0.025	0.0251	99.4			
0.05$^{1)}$	0.025	0.0256	101.2			
0.05$^{1)}$	0.025	0.0246	97.4			
0.05$^{2)}$	0.025	0.0235	94.2			
0.05$^{2)}$	0.025	0.0246	98.4	98.1	2.6	2.7
0.5$^{1)}$	0.25	0.2427	97.0			
0.5$^{1)}$	0.25	0.2478	99.0			
0.5$^{2)}$	0.25	0.2393	95.7			
0.5$^{2)}$	0.25	0.2497	99.9			
0.5$^{2)}$	0.25	0.2408	96.3	97.6	1.8	1.8
control$^{2)}$	0.00	0.00				
5.0$^{1)}$	2.5	2.3454	93.8			
5.0$^{1)}$	2.5	2.3300	193.2			
5.0$^{2)}$	2.5	2.3379	93.5			
5.0$^{2)}$	2.5	2.3900	95.6			
5.0$^{2)}$	2.5	2.4072	96.3	94.5	1.4	1.5

Recoveries of Fenpropimorph-acid (BF 421-2) determined as ME-ester in surface water:

Analyte added (µg/kg)	Analyte added (µg)	Analyte found (µg)	Recovery (%)	Mean recovery (%)	Standard deviation +/-	Coefficient of variation (%)
Control$^{1)}$	0.00	0.00				
0.05$^{1)}$	0.025	0.0228	87.4			
0.05$^{1)}$	0.025	0.0235	90.2			
0.05$^{1)}$	0.025	0.0238	91.4			
0.05$^{2)}$	0.025	0.0219	84.0			
0.05$^{2)}$	0.025	0.0248	95.4	89.7	4.3	4.8
0.5$^{1)}$	0.25	0.2438	97.5			
0.5$^{1)}$	0.25	0.2526	101.0			
0.5$^{2)}$	0.25	0.2465	98.6			
0.5$^{2)}$	0.25	0.2622	104.9			
0.5$^{2)}$	0.25	0.2452	98.1	100.0	3.0	3.0
control$^{2)}$	0.00	0.00				
5.0$^{1)}$	2.5	2.4469	97.9			
5.0$^{1)}$	2.5	2.4228	96.9			
5.0$^{2)}$	2.5	2.6274	105.1			
5.0$^{2)}$	2.5	2.5523	102.1			
5.0$^{2)}$	2.5	2.5951	103.8	101.2	3.6	3.6

3.5.1 Relative standard deviation

See section 3.5 and 4.2

3.6 Limit of determination

The limit of quantification of this method is 0.05 µg/kg (ppb) for BAS 421 F and BF 421-1. The limit of detection is 10 pg/µl, which is the lowest standard injected into GC/MS. Concerning surface water, this limit of quantitation is far below the LC_{50} and NOEC values of all relevant non-target organisms.

3.7 Precision

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

3.7.1 Repeatability

Sample matrix	Test substance	Fortification level	Average recovery	RSD [%]	No. of analyses
Tap water	Fenpropimorph	0.05 0.5 5.0	101.4 100.1 96.0	3.0 3.9 3.9	5 5 5
	BF 421-2	0.05 0.5 5.0	99.0 104.5 99.7	3.1 2.2 4.3	5 5 5
Surface water	Fenpropimorph	0.05 0.5 5.0	98.2 97.6 94.5	2.7 1.8 1.5	5 5 5
	BF 421-2	0.05 0.5 5.0	89.7 100.0 101.2	4.8 3.0 3.6	5 5 5

3.7.2 Independent laboratory validation

Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Guidelines:

EPA Guideline, OPPTS 850.7100, April 1996, Directive 91/414/EEC

A 500 g water sample aliquot is adjusted with formic acid (conc.) to pH 4. Enrichment of the active ingredient is achieved by solid phase extraction on a C16 SPE column. After the elution with Dichloromethane / Methanol a methylation step with diazomethane follows.

X1

Remaining Diazomethane is destructed by adding some drops of concentrated formic acid. The reaction mixture is evaporated to dryness and the final chromatography analysis of BAS 421 F and BF 421-2 (as methylester) is determined by capillary gas chromatography with MS detection.

4.2 Results

Summary of the recoveries of method 465 at fortification levels of 0.05, 0.5 and 5.0 µg/kg:

Matrix	Replicates	Substance	Mean recovery (%)	SD (rel)
Tap / surface water	30	BAS 421 F	97.9	3.5
Tap / surface water	30	BF 421-2	99.0	5.7

4.3 Conclusion

The recovery rates confirm that method 465 is suitable to determine residues of BAS 421 F and BF 421-2 in tap water and surface water.

4.3.1 Reliability

1

4.3.2 Deficiencies

No

Section A4 (4.2) Analytical Methods for Detection and Identification

Annex Point IIA4.2 *water*

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable however; the mass spectrometric detection should have been performed with at least two m/z, not only with one ion.
Conclusion	The applicant's version is adopted
Reliability	2, since the MS detection was carried out with only one m/z.
Acceptability	acceptable
Remarks	**X1**: There is an editorial mistake, the SPE column is C18 not C16. **X2**: In subsection 3.2.1 it is indicated that the separation method is capillary gas chromatography with 63Ni-FID, when it is gas chromatography with *mass spectrometric detection.*

Section A4 (4.2)	**Analytical Methods for Detection and Identification**
Annex Point IIA4.2	**Water**

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/09 [redacted] 2005, Validation of analytical method 465/2 for determination of BAS 421 F (Fenpropimorph) and BF 421-2 (Fenpropimorph acid) in water using LC/MS-MS, [redacted] BASF DocID 2005/1013249, June 13, 2005, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, Guideline: residue analytical methods for post-registration control purposes (BBA, July 21, 1998) Guidance document for residue analytical methods SANCO/825/00 rev. 7 (17/03/2004)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**	Non-entry field	
3.1.1	Enrichment	The analytes in a 100 ml aliquot of the water sample are enriched on a C_{18} SPE column.	
3.1.2	Cleanup	Performed by elution of the SPE column with a mixture of dichloromethane / methanol 9+1 (v/v). The extracts are evaporated to dryness and dissolved in water/methanol 1*1 (v/v). An aliquot of the final volume is measured by LC-MS/MS	
3.2	**Detection**	Non-entry field	
3.2.1	Separation method	LC/MS-MS	
3.2.2	Detector	LC/MS-MS	
3.2.3	Standard(s)	Internal	**X1**
3.2.4	Interfering substance(s)	The method is specific to BAS 421 F and BF 421-2. The tested untreated water samples showed no interfering peaks at the retention times of BAS 421 F and BF 421-2. For these compounds corrected and uncorrected recovery values are identical.	
3.3	**Linearity**	Non-entry field	
3.3.1	Calibration range	0.25 – 5 ng/ml	
3.3.2	Number of measurements		
3.3.3	Linearity	All coefficients of correlation were in arrange of 0.9986 and 0.9999	
3.4	**Specifity: interfering substances**	The method is specific to BAS 421 F and BF 421-2.	

Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 **Water**

3.5 Recovery rates at different levels

The mean recoveries for fenpropimorph at LOQ in two types of water were in the range of 67.3 – 69.5 % and can be accepted due to an acceptable repeatability (mean 68.4 %, 11.9 5 RSD, n=20, mass transition 304->147). The mean recovery at LOQ for BF 421-2 (mass transition 334->107) was 85.8 % (13.5 % RSD, n=15).

X2

Summary of recoveries (corrected data)

Substance	Matrix	Replicates	Mean recovery* [%]	%RSD [%]
BAS 421 F	Tap water	10	69.5	12.9
(304 -> 147)	Surface water	10	67.3	11.3
BAS 421 F	Tap water	10	69.2	13.4
(304 -> 132)	Surface water	10	67.6	12.0
BF 421-2	Tap water	15	82.8	9.0
(334-> 91)	Surface water	10	92.5	4.4
BF 421-2	Tap water	15	83.0	9.6
(334 -> 107)	Surface water	10	95.1	7.1

*): corrected recovery

3.5.1 Relative standard deviation

See above

3.6 Limit of determination

The limit of detection for BAS 421 F and BF 421-2 is 0.0125 ng. It is here defined as the absolute amount of analyte injected into the LC-MS/MS instrument using the lowest standard of the calibration curve.
The limit of quantitation is 0.05 µg/L for water.

3.7 Precision

Non-entry field

3.7.1 Repeatability

3.7.2 Independent laboratory validation

In-house validation study

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Guideline: residue analytical methods for post-registration control purposes (BBA, July 21, 1998)
Guidance document for residue analytical methods SANCO/825/00 rev. 7 (17/03/2004)
BAS 421 F and its metabolite BF 421-2 were determined in fortified water samples of two different types (tap water, surface water). BASF analytical method 465/2 was validated for these matrices. The tested fortification levels were 0.05 and 0.5 µg/L.
Water samples were spiked with fenpropimorph and its metabolite BF 421-2 according to method 465/2 at the limit of quantitation (LOQ) and 10 x LOQ. Fortified sample recoveries are expressed in absolute figures as well as in percentage (%). The recovery data are corrected for interferences from matrix compounds of the appropriate unfortified sample.

4.2 Conclusion

Although in both matrices the recovery rates for fenpropimorph at LOQ are minor under the required limit of 70 % standard deviation and %RSD are in an acceptable range. So method 465/2 can be considered valid for the determination of fenpropimorph and its metabolite BF 421-2 in water with a validated limit of quantitation (LOQ) of 0.05 µg/L.
For quantitation and confirmation of fenpropimorph BASF method 465

Section A4 (4.2) **Annex Point IIA4.2**	**Analytical Methods for Detection and Identification** **Water**

(BASF Doc ID 2000/1004086) based on GC/MS detection can also be used.

4.2.1 Reliability 1

4.2.2 Deficiencies No

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2006
Materials and methods	X1: The standard is not internal but external X2: The mean recovery represents the mean of the recoveries obtained for both of the levels assayed.
Conclusion	The recovery rates achieved are rather low at LOQ level, however the %RSD are in an acceptable range
Reliability	1
Acceptability	acceptable
Remarks	No further remarks

Section A4 (4.2)	**Analytical Methods for Detection and Identification**	
Annex Point IIA4.2	**Soil**	

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.2/10 [redacted]., 2005, Validation of analytical method 576 for determination of BAS 421 F (Fenpropimorph) and BF 421-2 (Fenpropimorph acid) in soil using LC/MS-MS, [redacted] BASF DocID 2005/1013248, June 16, 2005, unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, Guidance document on residue analytical methods SANCO/825/00 rev. 7 (17/03/2004)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**	Non-entry field	
3.1.1	Enrichment	Twice extraction with methanol/water	
3.1.2	Cleanup	Centrifugation	
3.2	**Detection**	Non-entry field	
3.2.1	Separation method	LC/MS-MS	
3.2.2	Detector	LC/MS-MS	
3.2.3	Standard(s)	Internal	**X**
3.2.4	Interfering substance(s)	The tested untreated soil samples showed no interfering peaks at the retention time of BAS 421 F and BF 421-2. All blank values were < 20% LOQ.	
3.3	**Linearity**	Non-entry field	
3.3.1	Calibration range	A typical curve could cover a range from 0.25 to 5 ng/ml.	
3.3.2	Number of measurements		
3.3.3	Linearity	All coefficients of correlation were in a range of 0.9993 and 1.0000.	
3.4	**Specifity: interfering substances**	The method is specific to BAS 421 F and BF 421-2.	

Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 **Soil**

3.5 Recovery rates at different levels

Substance	Matrix	Replicates	Mean recovery* [%]	%RSD [%]
BAS 421 F	Soil 2.2	15	70.3	3.4
(304 -> 147)	Soil 5 M	15	77.9	4.8
BAS 421 F	Soil 2.2	15	71.2	2.7
(304 -> 132)	Soil 5 M	15	76.7	4.0
BF 421-2	Soil 2.2	15	91.3	4.2
(334-> 91)	Soil 5 M	10	98.2	3.0
BF 421-2	Soil 2.2	15	94.8	3.0
(334 -> 107)	Soil 5 M	10	98.8	3.9

*): corrected recovery

3.5.1 Relative standard deviation

See above

3.6 Limit of determination

The limit of detection for BAS 421 F and BF 421-2 is 0.0125 ng. It is here defined as the absolute amount of analyte injected into the LC-MS/MS instrument using the lowest standard of the calibration curve.
The limit of quantitation is 0.01 mg/kg soil.

3.7 Precision

Non-entry field

3.7.1 Repeatability

3.7.2 Independent laboratory validation

In-house validation method

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Guidelines covered: Guidance document on residue analytical methods SANCO/825/00 rev. 7 (17/03/2004).
An aliquot of the soil sample is first extracted with methanol/water by shaking on a mechanical shaker. The suspension is centrifuged and the extract is decanted. This extraction procedure is repeated twice with methanol/water each including shaking and centrifugation. The extracts are combined and adjusted to a volume of 50 ml. An aliquot of the final volume is measured using LC-MS/MS.
The described method allows the specific determination of Fenpropimorph and its metabolite BF 421-2 with the required limit of quantitation in soil.
The recovery trials were carried out with two types of soil: silty sand and loamy sand.
The spiking levels were 0.01 and 0.1 mg/kg. The fortified samples were analysed in 5 replicates. In addition at least one untreated control sample has been analysed per analytical sample set.

4.2 Conclusion

With one exception (BAS 421 F, 0.01 mg/kg fortification in soil 2.2 = LOQ) all mean recovery values are in the range 70 – 110 % as required by the EU guideline. The recoveries for Fenpropimorph at LOQ in loamy sand were in the range of 65 – 72 % and can be accepted due to the good repeatability (mean: 69.4 %, 3.1 % RSD, n=10). For each fortification level the % RSD values are < 20%.
Based on the results obtained the method is considered valid for the determination of BAS 421 F and BF 421-2 in soil with a validated limit of quantitation (LOQ) of 0.01 mg/kg.

Section A4 (4.2) **Annex Point IIA4.2**	**Analytical Methods for Detection and Identification** **Soil**

4.2.1	Reliability	1
4.2.2	Deficiencies	No

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2006
Materials and methods	The applicant's version is acceptable
Conclusion	The applicant's version is adopted
Reliability	1
Acceptability	Acceptable
Remarks	X: The standard is external not internal

Section A4 (4.2) **Annex Point IIA4.2**	**Analytical Methods for Detection and Identification** **Air**	
	1 REFERENCE	**Official use only**
1.1 Reference	A 4.2/11 [redacted] 2005, Validation of analytical method 577: Determination of Fenpropimorph (BAS 421 F) in air by HPLC/MS-MS, [redacted] BASF DocID 2005/1013247, June 16, 2005, unpublished	
1.2 Data protection	Yes	
1.2.1 Data owner	BASF AG	
1.2.2 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/IA	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes, SANCO 825/00/rev.7 (17/03/04) "Guidance document on residue analytical methods" SANCO 3029/99/rev.4; 11/07/00 "Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of directive 91/414" Anforderungen an Analysenmethoden zur Bestimmung von Pflanzenschutzmitteln im Rahmen des Zulassungsverfahrens (Nachrichtenbl. Deutsch. Pflanzenschutzd. 52, 2000, Seite 292)	
2.2 GLP	Yes	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Preliminary treatment	Non-entry field	
3.1.1 Enrichment	Enrichment of Fenpropimorph from air samples is achieved by adsorption on an acidified glass fibre filter	
3.1.2 Cleanup	Extraction with methanol/water	
3.2 Detection		
3.2.1 Separation method	LC/MS-MS on a C_{18} column	
3.2.2 Detector	LC/MS-MS on a C_{18} column	
3.2.3 Standard(s)	Internal	**X**
3.2.4 Interfering substance(s)	Under the described conditions the method is highly specific for the determination of BAS 421 F.	
3.3 Linearity	Non-entry field	
3.3.1 Calibration range	0.52 – 10.400 ng/ml	
3.3.2 Number of measurements		
3.3.3 Linearity	Calibration curves for BAS 421 F showed correlation coefficients in the following ranges: 0.99950 – 0.99996 for BAS 421 F (mass transition 304 -> 132) and 0.99939 – 0.99981 for BAS 421 F (mass transition 304 -> 147)	

Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 **Air**

3.4 Specifity: interfering substances

Under the described conditions the method is highly specific for the determination of BAS 421 F.

3.5 Recovery rates at different levels

Summary of the recoveries of method 577 (blank corrected data)

Substance	Fortification level	Replicates	Minimum recovery %	Maximum recovery %	Mean recovery %	Standard Deviation	Relative Standard Deviation %
BAS 421 F (304 -> 132)	0.1 C	6	77.1	92.4	85.3	5.4	6.4
BAS 421 F (304 -> 132)	10 C	6	83.9	100.1	95.6	6.0	6.3
BAS 421 F (304 -> 147)	0.1 C	6	80.1	97.8	88.8	6.3	7.1
BAS 421 F (304 -> 147)	10 C	6	82.2	103.0	95.9	7.2	7.5

3.5.1 Relative standard deviation

See above

3.6 Limit of determination

The limit of detection was not determined. The limit of quantitation was defined by the lowest fortification level successfully tested. i.e. 52 ng of the analyte for air.

3.7 Precision

Non-entry field

3.7.1 Repeatability

Repeatability is given.

3.7.2 Independent laboratory validation

In-house validation method

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Guidelines covered:

SANCO 825/00/rev.7 (17/03/04)
"Guidance document on residue analytical methods"

SANCO 3029/99/rev.4; 11/07/00
"Guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of directive 91/414"
Anforderungen an Analysenmethoden zur Bestimmung von Pflanzenschutzmitteln im Rahmen des Zulassungsverfahrens (Nachrichtenbl. Deutsch. Pflanzenschutzd. 52, 2000, Seite 292)
BAS 421 F collected on glass fibre filters is extracted with methanol/water and determined by HPLC / MS-MS. Although HPLC / MS-MS is highly specific, two monitored mass transitions of the analyte are validated in this study.

4.2 Conclusion

The method is validated down to 0.093 ng/L air and up to 9.7 ng/L air for BAS 421 F. No unacceptable blank values and breakthrough values were observed. Untreated air samples had no peaks of interference or peaks of interferences were < 30 % of the lowest fortification level. The results of the fortification experiments show that the recoveries were adequate. Statistical evaluations for BAS 421 F (mass transition 304 -> 132) showed recoveries ranging from 77.1 % to 100.1 % (RSD = 8.4 %, n = 12, corrected data). Recoveries ranging from 80.1 % to 103.0 % (RSD = 8.1 %, n=12, corrected data) could be found for BAS 421 F (mass transition 304->147).
The mean recovery for BAS 421 F (mass transition 304 -> 132) was 90.5 % (n=12, RSD=8.4 %, SD=7.6) for the corrected data.

Section A4 (4.2) **Annex Point IIA4.2**	**Analytical Methods for Detection and Identification** **Air**

The mean recovery for BAS 421 F (mass transition 304->147) was 92.4 % (n=12, RSD=8.1%, SD=7.4) for the corrected data.
Based on the results obtained the method is considered valid for the determination of BAS 421 F in air with a validated limit of quantitation (LOQ) of 52 ng BAS 421 F (lowest fortification level) and a validated limit of determination of 0.093 ng per litre air.

4.2.1 Reliability 1

4.2.2 Deficiencies No

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2006
Materials and methods	The applicant's version is acceptable
Conclusion	The applicant's version is adopted
Reliability	1
Acceptability	Acceptable
Remarks	X: The standard is external not internal

Section A4 (4.3) **Annex Point IIIA –IV.1**	**Analytical Methods for Detection and Identification** *Determination of metabolite in animal tissues, egg and milk*

			Official use only
		1 REFERENCE	
1.1	**Reference**	A 4.3 [redacted] (1995) Fenpropimorph (GCA 101031). Determination of metabolite CGA 294975 by high performance liquid chromatography (HPLC). Animal tissues, egg and milk [redacted] BASF DocID #1995/11081, unpublished	**X1**
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF AG	
1.2.2	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/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No specific guideline was followed. The validation method was tested with recovery experiments according to European Uniform Principles (Annex VI of EU Directive 91/414)	
2.2	**GLP**	Yes (validation study)	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Animal tissues: the specimen is extracted with methanol/aqueous buffer pH 9 (4 vol. + 1 vol.) by maceration. An aliquot of the extract is diluted with water and buffer pH 9 and partitioned with hexane. Milk: the specimen is extracted with acetonitrile/buffer pH 9 (90 vol. + 5 vol.). After filtration the acetonitrile is evaporated and the residue re-dissolved in methanol. After dilution with water and buffer pH 9, the mixture is purified by partitioning with hexane. Egg: the specimen is extracted with acetonitrile/buffer pH 9 (5 vol. + 1 vol.) by maceration. An aliquot of the extract is evaporated and the residue re-dissolved in methanol. After dilution with water and buffer pH 9, the mixture is purified by partitioning with hexane.	
3.1.2	Cleanup	Animal tissues, milk, egg: the analyte remaining in the aqueous phase is cleaned up on a C-18 bonded silica gel column. After passing the aqueous phase through a C-18 bonded silica gel cartridge the preparation is finalised by the following steps: - Washing with 2.5 ml of buffer pH 9 (diluted 1:10 with water) - Elution of CGA 294975 with 4 ml of buffer pH 9 (diluted 1:10 with water)/methanol (4 vol. + 6 vol.) - Evaporation to aqueous residue of less than 1.6 ml - Adjustment of the volume to 2 ml with phosphoric acid 1 % - Final determination using HPLC	
3.2	**Detection**		

Section A4 (4.3) Analytical Methods for Detection and Identification

Annex Point IIIA –IV.1 *Determination of metabolite in animal tissues, egg and milk*

3.2.1	Separation method	HPLC
3.2.2	Detector	UV-detector
3.2.3	Standard(s)	CGA 294975 (Fenpropimorph metabolite), reference substance for recovery tests and standardization
3.2.4	Interfering substance(s)	None known so far

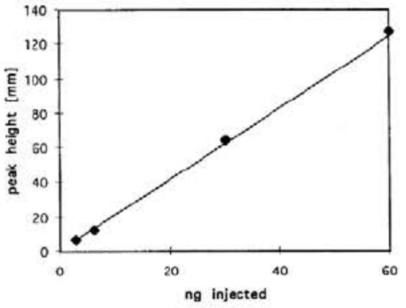
3.3 Linearity

3.3.1	Calibration range	3 – 60 ng
3.3.2	Number of measurements	2 per injected amount of CGA 294975
3.3.3	Linearity	Linear between 0.01 and 0.2 µg/ml (i.e. 3 – 60 ng) standard solution

Representative calibration curve:

standard solution µg CGA 294975 / mL	ng injected (300 µL injected)	peak heights measured [mm]	peak height calculated [mm]	% deviation of peak height measured
0.2	60	127, 128	127	-0.1, 0.6
0.1	30	64.5, 64.0	63.8	1.1, 0.4
0.02	6	13.0, 12.6	13.0	-0.3, -3.3
0.01	3	7.0, 6.5	6.7	4.5, -2.9

Calibration curve: ng = (peak height - A) / B
Calculation according to General Calculation Method REM 119.06: A: 0.3560, B: 2.114, s: 2.4 %
Quality criterion for standard curve: standard deviation s (s = square root of the variance of all relative deviations of the measured response to the corresponding calculated value of the response function), calculated according to REM 119.06 [cf. reference 5.1 given in method REM 167.03]). Maximum acceptable value for s: 10%.



3.4 Specifity: interfering substances None known so far

3.5 Recovery rates at different levels

Substrate	Fortification level (mg/kg)	Average recoveries (%)	S_{abs}	S_{rel}	N
Meat	0.01	105	5.6	5.4	8
Laboratory 1	0.10	97	2.3	2.3	8
Meat					
Laboratory 2	0.01	—	—		
Milk	2 µg/L	100	5.8	5.7	8
Laboratory 1	20 µg/L	86	4.9	5.7	8
Milk					
Laboratory 2	2 µg/L	—	—		
Liver	0.01	97	9.1	9.4	6
Laboratory 1	0.10				
Kidney	0.01	94	3.8	4.1	6
Laboratory 1	0.10				

Section A4 (4.3) Analytical Methods for Detection and Identification

Annex Point IIIA –IV.1 *Determination of metabolite in animal tissues, egg and milk*

Egg Laboratory 1	0.01 0.10	74	5.3	7.2	6

Overall recovery table

Substrate	N	Minimum	Maximum	Rel. difference	Average recovery (%)	S_{rel} (%)
Meat	19	83	116	33	99	7.7
Milk	19	62	107	45	88	16
Liver	6	81	106	25	97	9.4
Kidney	6	89	98	9	94	4.1
Egg	6	66	80	14	74	7.2

3.5.1 Relative standard deviation — See above

3.6 Limit of determination

Limit of detection was not established.

Limit of quantitation: 0.01 mg/kg (animal tissues, egg), 2 µg/L (milk)

3.7 Precision

3.7.1 Repeatability

Repeatability (one laboratory): the difference between minimum and maximum individual recovery value (fortification level = 0.01 mg/kg for meat and 2 µg/L for milk) was 19 % and 13 % for meat and milk, respectively (N = 8 values)

3.7.2 Independent laboratory validation

Not performed

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

Method REM 167.03 was tested with recovery experiments according to European Uniform Principles (Annex VI of EU Directive 91/414).

4.2 Results

All mean recoveries of the individual substrates as well as the overall mean recovery are within the range of 70 – 110 %.

All relative standard deviations are < 20 %.

The repeatability and the reproducibility were tested using meat and milk.

- Repeatability (one laboratory): the difference between minimum and maximum individual recovery value (fortification level = 0.01 mg/kg for meat and 2 µg/L for milk) was 19 % and 13 % for meat and milk, respectively (N = 8 values)
- Reproducibility (two laboratories): the difference between minimum and maximum individual recovery value (fortification level 0.01 mg/kg for meat and 2 µg/l for milk) was 33 % and 45 % for meat and milk, respectively (N = 11)

4.3 Conclusion

The method was proved to be successful.

4.3.1 Reliability — 1

4.3.2 Deficiencies — No

Section A4 (4.3)	**Analytical Methods for Detection and Identification**
Annex Point IIIA –IV.1	*Determination of metabolite in animal tissues, egg and milk*

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The method presented is for the determination of fenpropimorph acid, the main metabolite of fenpropimorph. The RMS has requested an analytical method for the determination of fenpropimorph in animal tissue that will be provided by the applicant. The method for the determination of fenpropimorph metabolite is acceptable
Conclusion	The applicant's version is adopted.
Reliability	1
Acceptability	acceptable
Remarks	**X1**: New information has been provided by the applicant and the reference number for this test study has changed from A.4.3 to A. 4.2/08

Section A4 (4.3) Analytical Methods for Detection and Identification

Annex Point IIIA-IV.1 **for food/feedstuffs**

Official use only

1 REFERENCE

1.1 Reference

[redacted] 1999, Validation of DFG method S 19 for the determination of Dimethenamid, Epoxiconazole, Fenpropimorph, Kresoxim-methyl, Metazachlor and Vinclozolin in various plant materials, [redacted] BASF Reg. Doc. 99/11462. (Ref. A 4.3/01)

X1

DFG method S 19 has been accepted 1998 by CEN as a multi-residue method for the gas chromatographic determination of pesticide residues in low-fat foodstuffs in the European norms DIN EN 12393-1, DIN EN 12393-2, DIN EN 12393-3.

Modified S 19 has been published 1999 as official method L-00.00-34: "Modulare Multimethode zur Bestimmung von Pflanzenschutzmittelrückständen in Lebensmittel" (modular multi residue method for the determination of pesticide residues in foodstuffs; adjusted revised form of DFG method S 19).

1.2 Data protection Yes

1.2.1 Data owner BASF AG

1.2.2 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/IA

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study No specific guideline was followed.

2.2 GLP Yes

2.3 Deviations No

3 MATERIALS AND METHODS

3.1 Preliminary treatment

3.1.1 Enrichment

<u>Treatment of samples before analysis:</u>

Tomato and lemon were homogenized thoroughly using a mincer. Wheat (grain) and rapeseed were homogenized thoroughly using a Moulinette® grinder. The homogenized samples were weighed into the extraction vessels and stored deep frozen subsequently until start of analysis.

<u>Analysis of samples:</u>

The control (untreated) samples were analysed in duplicate and fortified samples were analysed in quintuplet for each fortification level.

The samples of tomato, lemon, and grain were analysed for Fenpropimorph using DFG method S 19 with modified extraction. The weight of samples per analysis was 50 g.

Prior to extraction with acetone sodium hydrogen carbonate was added to the lemon samples to receive a slightly alkaline medium to avoid the loss of recovery for Fenpropimorph when extracting the lemon samples at their natural pH values.

3.1.2 Cleanup

The extraction of Fenpropimorph from tomato, lemon, and grain was performed according to DFG method S19 (gel permeation chromatography on Bio Beads S-X3 polystyrene gel).

Section A4 (4.3) Analytical Methods for Detection and Identification for food/feedstuffs

Annex Point IIIA-IV.1

The extraction of Fenpropimorph from rapeseed was performed according to DFG Cleanup method 5 (gel permeation chromatography on Bio Beads S-X3 polystyrene gel using a mixture of ethyl acetate/cyclohexane 1:1 as eluant and an automated gel permeation chromatography) followed by clean up procedures according to DFG method S19 (clean-up by gel-chromatography and mini-silica gel-column chromatography).

3.2 Detection

3.2.1 Separation method: Gas-chromatography

3.2.2 Detector: Gas-chromatography with mass selective detection (MSD)

3.2.3 Standard(s): External standard Fenpropimorph

3.2.4 Interfering substance(s): No significant interferences from the sample matrix were detected at the retention times corresponding to the test substances in the control samples except for Fenpropimorph in rapeseed.

3.3 Linearity

3.3.1 Calibration range: The reference substance Fenpropimorph (analytical grade) was used for preparing the external standard solutions. A one-point external standard calibration was carried out using peak height in integrator units (IU) from injections of sample extracts with known fortification levels versus standard solutions with concentrations of ca. 0.045 and 0.45 µg/ml.

3.3.2 Number of measurements: Fortified samples were analysed in quintuplet for each fortification level. Control samples were analysed in duplicate.

3.3.3 Linearity

3.4 Specifity: interfering substances: No significant interferences from the sample matrix were detected at the retention times corresponding to the test substances in the control samples except for Fenpropimorph in rapeseed.

3.5 Recovery rates at different levels: The following recoveries were obtained using GC/MSD:

Matrix	Fortification level (mg/kg)	Mean recovery (%)	Standard deviation (%)	Coefficient of variation (%)
Tomato	0.01	99	14.0	14
	0.1	101	9.3	9.2
Lemon	0.01	-	-	-
	0.1	-	-	-
Lemon	0.01	84	3.5	4.2
	0.1	80	6.0	7.5
Wheat grain	0.01	95	8.7	9.2
	0.1	89	7.8	8.8
Rapeseed	0.02	80	8.5	11
	0.2	93	14.0	15

Mean recoveries were within the range of 70 – 110 %.

The average percent recoveries (n=10 each matrix) were for:

Matrix	Mean (%)	Coefficient of variation (%)
Tomato	100	11
Lemon	82*	6.1*

Section A4 (4.3) Analytical Methods for Detection and Identification

Annex Point IIIA-IV.1 **for food/feedstuffs**

Wheat grain	92	9.1
Rapeseed	87	15

*After adding $NaHCO_3$ prior to extraction

3.5.1 Relative standard deviation — See above

3.6 Limit of determination — The limit of quantitation was 0.01 mg/kg in tomato, lemon, and wheat (grain) and 0.02 mg/kg in rapeseed.

3.7 Precision

3.7.1 Repeatability — The precision of the applied methods is within an acceptable range, because the coefficient of variation was for all matrices and all fortification levels below 20 %.

3.7.2 Independent laboratory validation — —

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

DFG method S 19 (with modified extraction)

DFG method S 19 (with DFG Clean-up Method 5) for rapeseed

DFG method S 19 has been accepted 1998 by CEN as a multi-residue method for the gas chromatographic determination of pesticide residues in low-fat foodstuffs in the European norms DIN EN 12393-1, DIN EN 12393-2, DIN EN 12393-3.

Modified S 19 has been published 1999 as official method L-00.00-34: “Modulare Multimethode zur Bestimmung von Pflanzenschutzmittelrückständen in Lebensmittel” (modular multi residue method for the determination of pesticide residues in foodstuffs; adjusted revised form of DFG method S 19).

4.2 Conclusion

The accuracy was considered to be acceptable since the mean recoveries were within the range of 70 – 110 %. All the results obtained using this method were within this range.

The precision of the applied methods is also within an acceptable range, because the coefficient of variation was for all matrices and all fortification levels below 20 %.

No significant interferences from the sample matrix were detected at the retention times corresponding to the test substances in the control samples except for Fenpropimorph in rapeseed.

The multi-residue method according to DFG method S 19 is therefore applicable for the determination of Fenpropimorph in tomato and wheat (grain). Moreover, DFG method S 19 permits the determination of residues of Fenpropimorph in lemon after adding sodium hydrogen carbonate to the sample prior to extraction and in the tested matrix of rapeseed (as a representative of commodities with high fat content).

4.2.1 Reliability — 1

4.2.2 Deficiencies — No

Section A4 (4.3) Analytical Methods for Detection and Identification

Annex Point IIIA-IV.1 **for food/feedstuffs**

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	July 2005
Materials and methods	The applicant's version is acceptable.
Conclusion	The applicant's version is adopted.
Reliability	1
Acceptability	acceptable
Remarks	**X1**: The RMS asked for an analytical method for the determination of fenpropimorph in food of plant origin that has been provided by the applicant (Ref A 4.3/01)

COMPETENT AUTHORITY REPORT

FENPROPIMORPH (PT 8)

Document IIIA
Active Substance

Section 5: Effectiveness against target organisms and intended uses

Rapporteur Member State: Spain
December 2006

Section A5 EFFECTIVENESS AGAINST TARGET ORGANISMS AND INTENDED USES

Subsection **(Annex Point)**			**Official use only**
5.1	**Function (IIA5.1)**	Fenpropimorph is used in the wood preservation area as a fungicide.	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Blue stain and wood discolouring fungi. Wood destroying fungi (brown rot and white rot).	**X1**
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Temporary, preventive protection of freshly sawn timber in areas with temperate or tropical climate. Preventive protection of wood for interior and exterior use (without permanent soil/water contact, but which may occasionally be subject to precipitation), e.g. roofing, wooden construction, windows …	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	Fenpropimorph belongs to the morpholine group of fungicides and is a systemic fungicide. Fenpropimorph controls mycelial growth and sporulation.	
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	Fenpropimorph is use for the formulation of wood preservative concentrates at concentrations between 1,5 and 6,0 %. Treatment solutions are prepared before use, diluting the concentrates in water. The concentration of the treatment solutions range from 1 – 10 % depending upon the timber species, the application method, the required retention or degree of hazard.	
	PT1		
	PTn		
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	Fenpropimorph inhibits different steps in the ergosterol biosynthetic pathway. The inhibition of sterol biosynthesis ultimately leads to fungal cell death.	
5.4.2	**Time delay**	Immediately after treatment and fixation/drying, the wood is protected against fungal attack.	
5.5	**Field of use envisaged (IIA5.5)** MG01: Disinfectants, general biocidal products	Protection of wood against blue-stain, wood discolouring fungi and wood-destroying fungi.	

	MG02: Preservatives	Product type PT08: Wood preservatives	
	MG03: Pest control MG04: Other biocidal products Further specification		
5.6	**User (IIA5.6)**	Industrial and professional users only. Fenpropimorph is not intended to be used by the general public.	**X2**
	Industrial		
	Professional		
	General public		
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**		
5.7.1	**Development of resistance**	Fenpropimorph is used in agriculture and horticulture for many years. Concerning the development of resistance in this field of use it can be said that some pathogens have shown a drift towards lower sensitivity but in most cases the situation is stabilising. No cases with total field resistance have been reported for this group of fungicides. In the wood preservation area, Fenpropimorph is always used in combination with other actives so that a resistance development seems to be extremely unlikely.	
5.7.2	**Management strategies**	Not necessary	
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	10 – 15 tonnes per year	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September 2005
Materials and methods	The applicant’s version is considered acceptable.
Conclusion	
Reliability	2
Acceptability	acceptable
Remarks	**X1**: It has to be demonstrated the efficacy for these uses, because the efficacy of the biocidal product has only been demonstrated against basidiomycetes. **X2** (Field 5.6): Fenpropimorph is not intended to be used by professionals, according to DOC IIB. Therefore this field has to be corrected to indicate: Industrial: Industrial users only Professional: Not intended General Public: Not intended