COMPETENT AUTHORITY REPORT

THIAMETHOXAM (PT 8)

Document IIIA
Active Substance

Rapporteur Member State: Spain
July 2007

INDEX

Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Syngenta European Center
GU2 7YH Guildford
United Kingdom

Contact person

[redacted]

1.2 **Manufacturer of Active Substance** (if different)

Syngenta Crop Protection AG
CH - 4002 Basle
Switzerland

Location of plant

[redacted]

Syngenta Crop Protection AG.

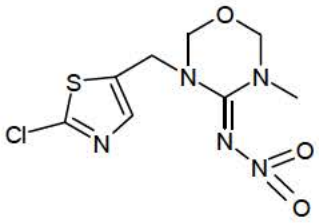
Contact point :

[redacted]

1.3 Manufacturer of Product(s) (if different)

1) Product 1

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	**Common name**	*thiamethoxam*	
2.2	**Chemical name**	***IUPAC nomenclature*** *:3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine* ***CA nomenclature*** *:3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine*	
2.3	**Manufacturer´s development code number(s)**	*CGA 293343*	
2.4	**CAS No and EC numbers**		
2.4.1	**CAS-No**	*153719-23-4*	
2.4.2	**EC-No**	*428-650-4*	
2.4.3	**CIPAC-No**	*637*	
2.5	**Molecular and structural formula, molecular mass**		
2.5.1	**Molecular formula**	$C_8H_{10}ClN_5O_3S$	
2.5.2	**Structural formula**		
2.5.3	**Molecular mass**	*291.7*	
2.6	**Method of manufacture of the active substance (IIA2.1)**	***CONFIDENTIAL information*** *- data provided separately*	
2.7	**Specification of the purity of the active substance, as appropriate**	*min. 980 g / kg*	
2.8	**Identity of impurities and additives, as appropriate**	***CONFIDENTIAL information*** *- data provided separately*	
2.9	**The origin of the natural active substance or the precursor(s) of the active substance**	*Not applicable*	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2005
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

Subsection		Official use only
2.10.1	**Human exposure towards active substance**	X1
2.10.1.1	**Production**	
	i) Description of process	
	ii) Workplace description	
	iii) Inhalation exposure	
	iv) Dermal exposure	
2.10.1.2	**Intended use(s)**	
	1. Professional Users	
	i) Description of application process	
	ii) Workplace description	
	iii) Inhalation exposure	
	iv) Dermal exposure	
	2. Non-professional Users including the general public	
	(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**	

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

active substance

2.10.2.1 Production

(i) Releases into water

(ii) Releases into air

(iii) Waste disposal

2.10.2.2 Intended use(s)

Affected compartment(s):

water

sediment

air

soil

Predicted concentration in the affected compartment(s)

water

sediment

air

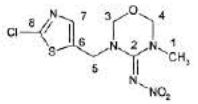
soil

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Comments	[redacted]

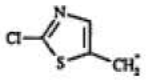
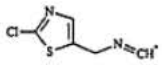
Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density								
3.1.1 Melting point	EEC A.1 OECD No.102	99.7 %	139.1°C	Capillary method	Y	1	Das, 1995a	
3.1.2 Boiling point	EEC A.2 OECD No.103	99.3 %	Thermal decomposition starts at about 147 °C (i.e. before the boiling point is reached)	Differential scanning calorimetry	Y	1	Das, 1997	
3.1.3 Bulk density/ relative density								
Density	EEC A.3	99.7 %	$1.57 \cdot 10^3$ kg / m³, therefore , relative density: 1.57	Air comparison pycnometer method	Y	1	Füldner, 1995	
3.2 Vapour pressure	EEC A.4 OECD No. 104	99.7 %	temperature: 25 °C $6.6 \cdot 10^{-9}$ Pa (extrapolated)	Gas saturation method	Y	1	Geoffroy, 1995	
3.2.1 Henry´s Law Constant			calculated: $4.7 \cdot 10^{-10}$ Pa · m³ / mol at 25°C	water solubility at 25 °C : 4100 g/m³ vapour pressure at 25 °C: $6.6 \cdot 10^{-9}$ Pa			Burkhard, 1996	
3.3 Appearance								
3.3.1 Physical state	visual test	pure a.i. (99.7 %)	fine crystalline powder		Y	1	Das, 1995b	
		technical grade a.i (98.2 %)	fine powder		Y	1	Das, 1998	
3.3.2 Colour	visual test	pure a.i. (99.7 %)	slightly cream		Y	1	Das, 1995b	
		technical grade a.i (98.2 %)	off-white		Y	1	Das, 1998	
3.3.3 Odour	organoleptic test	pure a.i. (99.7 %)	odourless		Y	1	Das, 1995b	
		technical grade a.i (98.2 %)	odourless		Y	1	Das, 1998	
3.4 Absorption spectra								

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
UV/VIS	SOP 201/2	99.7 %	For the absorption maxima at 255 nm the molar extinction coefficient was determined to be 16800 l / mol · cm in neutral solution. No absorption maximum between 290 nm and 750 nm was observed. Only slightly variations on extinction coefficients were observed at different pH.	Concentration and solvent: 2.2 mg in 100 ml methanol Quartz cell : 10 mm pathlength Reference solvent methanol	Y	1	Birk, 1995	
IR	SOP 202/2	99.7 %	Characteristic bands: 1598 cm^{-1} (NO2 stretch assym. And C=N- stretch sym.) 1265 cm^{-1} (NO2 stretch)	Sample preparation : KBr pellet (1 mg test substance in 300 mg KBr)	Y	1	Birk, 1995	
NMR	^{1}H-RMN: SOP 214/1	99.7 %	7.54 (s, 1H); 5.02 (s, 2H); 4.94 (s, 2H); 4.74 (s, 2H); 2.82 (s, 3H)	Operating temperature : room temperature Solvent :Acetone d6 Nucleus :^{1}H (300 MHz) I.S.: Acetone d6	Y	1	Birk, 1995	
	^{13}C-RMN:	99.3 %	 Shift (ppm) Assignment 35 1 44 5 80 3, 4	Operating temp : 293 K Solvent : CDCl3 Nucleus :^{13}C (75 MHz) I.S.:TMS	Y	1	Birk, 1998	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			134 6 141 7 154 8 157 2					
MS	SOP 204/2	99.7 %	m / z 291 M+ (not detected) 247 M+ - CH_2OCH_2 245 M+ - NO_2 215 m/z 245 – CH_2O 209 m/z 245 – HCl 179 m/z 209 – CH_2O  159  132	Type of analyzer : quadrupole Ionization mode : electron impact Detection : scan mode Ionizing energy : 70 eV	Y	1	Birk, 1995	
3.5 Solubility in water Water solubility	*including effects of pH (5-9)* EEC A.6 OECD No. 105	99.7 %	result: 4100 mg/l temperature: 25 °C	Flask method	Y	1	Stulz, 1995a	
3.6 Dissociation constant (-)	OECD 112	99.7 %	The test substance has no dissociation within the range pH 2 to pH 12		Y	1	Stulz, 1995b	
3.7 Solubility in organic solvents, including the effect of temperature on	SOP 209/5	98.2 %	temperature: 25 °C n-hexane: < 1 mg/l toluene: 680 mg/l dichloromethane: 110 g/l		Y	1	Stulz, 1998	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
solubility			methanol: 13 g/l n-octanol: 620 mg/l acetone: 48 g/l ethyl acetate: 7 g/l					
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products								**X1**
3.9 Partition coefficient n-octanol/water log Pow	*including effects of pH (5-9)* EEC A.8 OECD No. 107	99.7 %	result: -0.13 temperature: 25 °C pH: 6.84	Shake-flask method	Y	1	Stulz, 1995c	
3.10 Thermal stability, identity of relevant breakdown products	OECD No. 113	98.2 %	The sample shows neither without nor with air any peak between room temperature and melting point of the substance, resp. 150 °C.		Y	1	Angly, 1998a	
3.11 Flammability, including auto-flammability and identity of combustion products	EEC A.10 (Flammability of solids) EEC A.16 (Relative self-ignition temperature for solids)	98.2 % 98.2 %	The substance is not considered highly flammable No self-ignition was observed		Y Y	1 1	Angly, 1998b Angly, 1998c	
3.12 Flash-point	Not required as the test substance is a solid with a melting point > 40 °C					1		

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.13 Surface tension	OECD No.115	98.2 %	result: 71.7 mN/m temperature: 20 °C	Wilhelmy plate method	Y	1	Hörmann, 1998	
3.14 Viscosity	Not required as the test substance is a solid							
3.15 Explosive properties	EEC A.14	98.2 %	The substance is not considered an explosive, as concluded from test results on: Thermal sensitivity: effect of a flame Mechanical sensitivity: shock and friction		Y	1	Angly, 1998d	
3.16 Oxidizing properties	EEC A.17	98.2 %	The substance is not considered an oxidizing substance		Y	1	Angly, 1998e	
3.17 Reactivity towards container material								**X2**

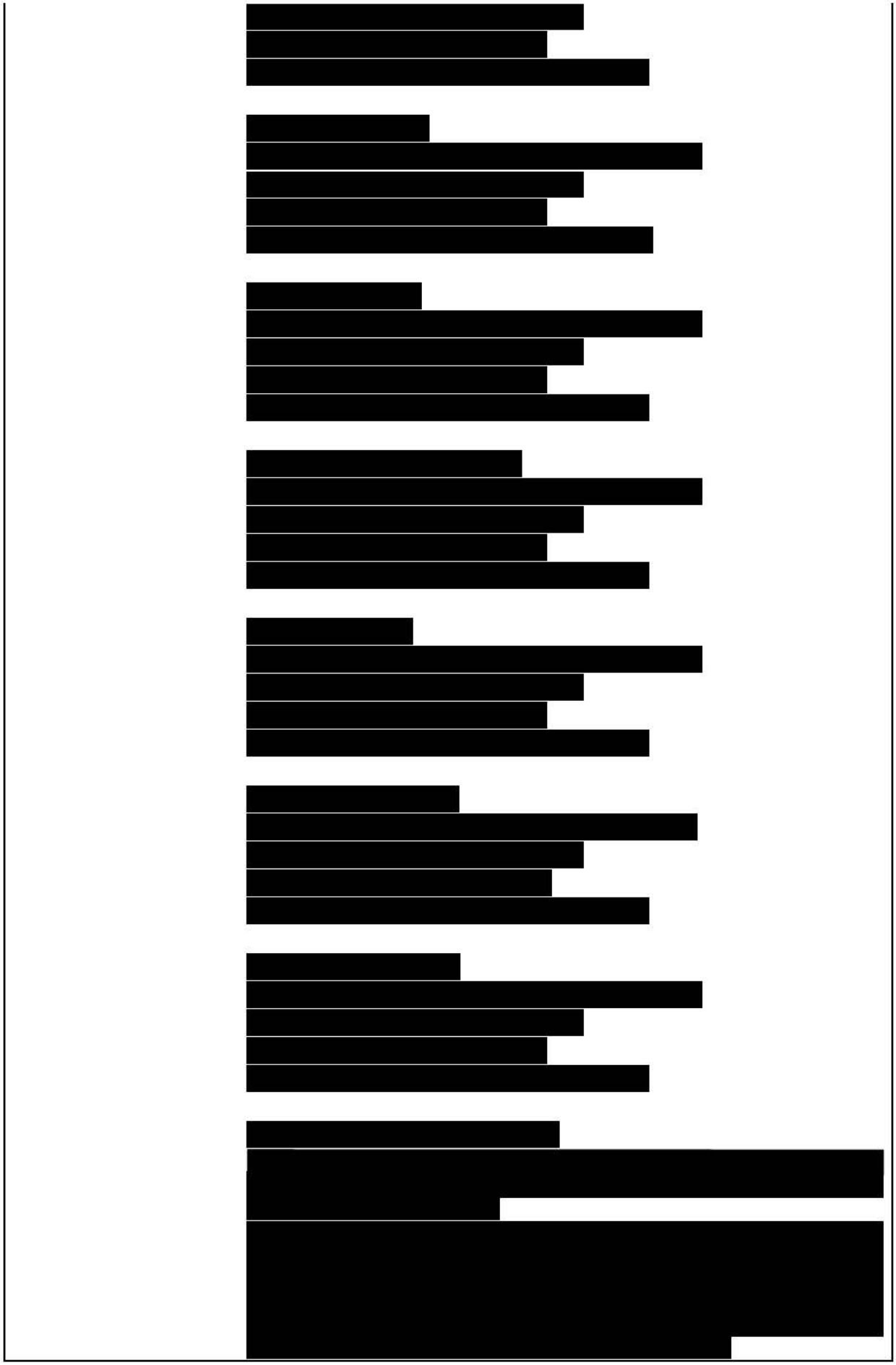
Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date May 2005

Comment

Evaluation of data submitted under section A3



Section A4.1	Analytical Methods for Detection and Identification Active substance

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Comments	[redacted]

Official use only

1 REFERENCE

1.1 Reference

Dull, B (2003a)
Determination of content by HPLC
SA-1/1, 21.02.2003
not GLP, not published
Syngenta File N° CGA293343/1694

Dull, B (2003b)
Validation of analytical method SA-1/1
110033, 24.03.2003
GLP, not published
Syngenta File N° CGA293343/1709

1.2 Data protection Yes/

1.2.1 Data owner Syngenta Crop Protection AG

1.2.2 Companies with letter of access

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

2.2 GLP Yes

2.3 Deviations None

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	**Enrichment**	The technical material is dissolved in 0.1% aqueous phosphoric acid/ acetonitrile (8+2)
3.1.2	**Cleanup**	No purification steps are necessary
3.2	**Detection**	
3.2.1	**Separation method**	HPLC chromatography on a Nucleodur C18 column using 0.1 % phosphoric acid in water / acetonitrile / methanol (80 / 5 / 15) as eluent with a linear gradient program
3.2.2	**Detector**	UV detector, 254 nm
3.2.3	**Standard(s)**	External standard.
3.2.4	**Interfering substance(s)**	There are no substances which would interfere with the detection of the analyte
3.3	**Linearity**	
3.3.1	**Calibration range**	50-150% of weight of active substance
3.3.2	**Number of measurements**	5 data points
3.3.3	**Linearity**	$r^2 = 0.9996$
3.4	**Specifity: interfering substances**	The HPLC method is able to separate the active substance thiamethoxam from its by-products and the solvent
3.5	**Recovery rates at different levels**	98.0 – 100.4 % Mean: 99.5%
3.5.1	**Relative standard deviation**	1.3 %
3.6	**Limit of determination**	
3.7	**Precision**	
3.7.1	**Repeatability**	Relative standard deviation : 0.21% Mean value of repeatability stuy: 99.26 %
3.7.2	**Independent laboratory validation**	

98/8 Doc IIIA section No.	**4.2 / 01 &02**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil**
91/414 Annex Point addressed	**II 4.2.2 / 01 & 03 & 05**	**Analytical methods for determination of residues – residues in soil**

Title of the Study	**Determination of CGA 293343 and CGA 322704 by HPLC, plant material, soil (including validation)**
Dossier Reference:	4.2.2 (4.2.1/05), 4.2.2 (4.2.1/03, validation)
Method Numbers: Author: Novartis file number:	REM 179.03 P. Mair (analytical method), C. Giannone (validation) 293343 – 206, 293343 – 514 (validation)
Name and address of the testing facility:	Ciba-Geigy Ltd, Basel, Switzerland
Test Substance:	CGA 293343
Date of Issue:	May 5, 1998, July 21, 1998 (validation)
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Reliability indicator	1

Findings

Method: For quantification of thiamethoxam and CGA 322704 in soil (25 g, dry matter content), samples are extracted by shaking with water / methanol (10 ml, 1 + 1; vol. + vol.) for 1h at 260 r.p m. An aliquot of the filtered extract is concentrated to 7 ml and diluted with water and passed through a phenyl solid-phase cartridge. The analyte is eluted from the phenyl cartridge with water / methanol (1+ 1; vol. + vol.). The volume of the eluate is reduced to 1.5 ml by evaporating under 3 ml reduced pressure. After diluting the concentrated eluate with water to 2.5 ml, this solution is injected into a HPLC two column switching system with UV-detector (Column 1: 125 mm x 2 mm Nucleosil C18 5 µm and Column 2: 125 mm x 2 mm Nucleosil 100 Phenyl 7µm, 255 nm or 270 nm for CGA 293343 and for CGA 322704 respectively. Mobile phase 1: water/methanol (85:15) and Mobile phase 2: water/acetonitrile (8:2).

Specificity: No interference was detected during method validation. A confirmatory method using HPLC/MS/MS is proposed.

Linearity: calibration curve is provided as part of method validation.

Accuracy: The accuracy of the method is established based on the findings for specificity, recovery and linearity. Recovery > 70 %. LOQ = 0.002 ppm. See Table 1.

Repeatability: cv % < 20 %. See Table 1.

Table 1

Validation of Rem 179.03						
Reference analyte	**matrix**	**Fortification level [mg/kg]**	**Recovery rate [%]**		**cv [%]**	**n**
			mean	**range**		
thiamethoxam	soil	0.002	99	95 - 106	6	3
		0.02	77	64 - 94	20	3
CGA 322704	soil	0.002	101	94 - 106	6	3
		0.02	78	66 - 95	19	3

Conclusions: LOQ of 0.002 mg a.i. / kg soil

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	**4.2 / 03 & 04**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (b) Air**
91/414 Annex Point addressed	**II 4.2.4 / 01 & 02**	**Analytical methods for determination of residues – residues in air**

Title of the Study	**Determination of CGA 293343 by high performance liquid chromatography (including validation)**
Dossier Reference:	4.2.4/01, 4.2.4/02 (validation)
Method number: Author: Novartis File No.:	REM 179.04 R.Tribolet (analytical method), R. Tribolet (validation) 293343 – 343, 293343 – 344 (validation)
Name and address of the testing facility:	Novartis Crop Protection AG, Basel, Switzerland
Test substance:	CGA 293343
Date of issue:	October 20, 1997, October 20, 1997 (validation)
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Reliability indicator	1

Findings

Method: Thiamethoxam is sorbed from air in XAD-2 sorbent tubes. Air sampled for 6h at a flow rate of 0.5 L/min. The different layers of an air sampling tube are separated and thiamethoxam is extracted with methanol (2 x 5 ml) using an ultra sonic bath (2 x 5 min). The methanol is evaporated and the residue is dissolved in 5 ml methanol / water (3 + 7; vol. + vol.). Quantitation of thiamethoxam is done by HPLC using UV detection (Column Spherisorb PC 18, 5 µm, UV 255 nm. Mobile phase: methanol water (3 +7; vol + vol).

Specificity: No interferences were observed.

Linearity: : The accuracy of the method is established based on the findings for specificity, recovery and linearity. Validation curve provided as part of the method calibration.

Accuracy: Mean recovery 90 % at LOQ.

Repeatability: cv % = 3 at LOQ.

Reference (analyte)	matrix	Fortification level [µg/m^3]	Recovery rate [%]		cv [%]	n
			mean	range		
(thiamethoxam)	air	0.5	90	84 - 93	3	8
		20	87	83 - 89	2	8

Reproducibility: not tested since there is not clean-up step within the method.

Conclusions: LOQ = 0.5 **µg/m^3**

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	**4.2 / 05 & 06 & 07**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water**
91/414 Annex Point addressed	**II 4.2.3 / 01 & 02 & 03**	**Analytical methods for determination of residues – residues in water**

Title of the Study	**Determination of CGA 293343 and CGA 322704 by HPLC, potable water (including validation)**
Dossier Reference:	4.2.3/01, 4.2.3/02 (validation), 4.2.3/03 (validation surface water)
Method Number: Author: Novartis file No.:	REM 179.05 P. Mair (analytical method), P. Mair (validation), P. Mair (validation surface water) 293343 – 389, 293343 – 390 (validation), 293343 – 697 (validation suface water)
Name and address of the testing facility:	Novartis Crop Protection AG, Basel, Switzerland
Test substance:	CGA 293343
Date of issue:	December 2, 1997 (analytical method) December 16, 1997 (validation) September 11, 1998 (validation surface water)
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Reliability indicator	1

Method: Samples of potable water (200 ml) are extracted by solid phase extraction on a Lichrolut EN solid-phase extraction cartridge. The disk is washed with water/ methanol (3 ml; 1 + 1; vol. + vol.). The analytes are eluted with acetonitrile-methanol (5 ml; 2 + 8; vol. + vol.). The volume of the eluate is reduced to less than 0.5 ml by evaporating under reduced pressure. The concentrated eluate is diluted with water (2 ml).

For surface water samples an additional cleanup step using a phenyl cartridge is necessary. The surface water 20 ml is passed through the cartridge and the eluate is discarded. The cartridge is mounted on top of the EN cartridge. The analytes are eluted with 3 ml of water / methanol (1 + 1; vol. + vol.) from the phenyl onto the EN cartridge. The eluate and the phenyl cartridge are discarded. Further cleanup is done as described above for the potable water samples excluding the wash step for the EN cartridge. Final quantitation of thiamethoxam and CGA 322704 is performed by HPLC using UV detection. (Column 125 mm x 2 mm Nucleosil C18-5µm. Mobile phase: water-acetonitrile (85 + 15; vol + vol) at 0.25 ml/min. In case of problems, it is possible to use the 2 system approach.

Specificity: No interferences are detected. Two confirmatory HPLC/MS/MS methods are provided.

Linearity: Validation curve provided as part of the method calibration.

Accuracy: The accuracy of the method is established based on the findings for specificity, recovery and linearity. Recovery > 90 %.

Repeatability: cv % < 20 %.

Reference (analyte)	matrix	Fortification level [µg/L]	Recovery rate [%]		cv [%]	n
			mean	Range		
Mair, 1997b (IIA, 4.2.3/02)						
(thiamethoxam)	water	0.05	102	71 - 113	14	11*
		0.50	87	79 - 92	5	8
(CGA 322704)	water	0.05	94	86 - 105	7	11*
		0.50	90	82 - 95	5	8
Mair, 1998 (IIA, 4.2.3/03)						
(thiamethoxam)	surface water (River Rhein)	0.5	109	100 - 114	5	8
		5.0	95	87 - 105	7	8
(CGA 322704)	surface water (River Rhein)	0.5	95	85 - 102	7	8
		5.0	96	90 - 103	5	8
(thiamethoxam)	surface water (River Birs)	0.5	84	78 - 92	8	8
(CGA 322704)	surface water (River Birs)	0.5	90	87 - 99	6	8

Conclusions: LOQ (drinking water) = 0.05 µg/L; LOQ (surface water) = 0.5 µg/L

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

* including results of independent lab validation

98/8 Doc IIIA section No.	**4.2 / 08 & 09**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (d) Animal and human body fluids and tissues**
91/414 Annex Point addressed	**II 4.2.1 / 01 & 02**	**Analytical methods for determination of residues – residues in and/or on plants, plant products, foodstuffs (of plant and animal origin), feeding stuffs**

Title of the Study	**Analytical method for the determination of residues of CGA 293343 and the metabolite CGA 322704 in animal and crop substrates by high performance liquid chromatography with detection by UV and mass spectrometry, including validation data (including independent laboratory validation)**
Dossier Reference:	4.2.1/01 , 4.2.1 /02
Method Numbers: Author: Novartis file number:	AG-675 [redacted] 293343 – 820, 293343 – 847 (validation)
Name and address of the testing facility:	[redacted]
Test Substance:	CGA 293343
Date of Issue:	September 18, 1998, November 11, 1998 (validation)
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles [ ]
Reliability indicator	1

Findings

Method: Ten-gram samples are extracted twice by homogenisation in acetonitrile / water (8 + 2, vol. + vol.). Liquid samples such as milk and eggs, are extracted by shaking for 20 minutes in acetonitrile / water (8 + 2, vol. + vol.). The total extract volume is 200 mL.

A 100 mL aliquot is measured (for milk the entire 200 mL is analysed). A liquid-liquid partition using toluene and hexane is performed prior to evaporation. The reduced, aqueous sample is first purified by reverse-phase solid-phase extraction (SPE) by loading onto a phenyl cartridge. After elution from the phenyl SPE cartridge with methanol / water (1 + 1; vol. + vol.), the sample is evaporated to aqueous and the compounds are partitioned into ethyl acetate. The ethyl acetate fraction is evaporated and the sample is further purified by normal phase SPE using both an amino cartridge and an alumina cartridge. After elution from the alumina column, the samples are evaporated and reconstituted in mobile phase for determination by normal phase HPLC/UV. The normal phase column is a Waters Spherisorb S5 NH_2 (250 mm x 4.6 mm I.D.), with a mobile phase of hexane:ethyl acetate: isopropanol:methanol (11 + 3 + 1 + 1; vol. + vol. + vol. + vol.).

Specificity: The method is specific and confirmation is possible by evaporating the final fraction, reconstituting the sample in CH_3CN :water and analysing using HPLC/MS or HPLC/MS/MS. No interferences were detected during the validation study, however in residue trials minor interferences were detected in broccoli and cabbage. Reanalysis with HPLC/MS solved the problem.

Linearity: Calibration plots gave a correlation coefficient > 0.99 (number calibration points = 6).

Accuracy: The accuracy of the method is established based on the findings for specificity, recovery and linearity.

Repeatability: See table below

Reference (analyte)	Matrix	Fortification level [mg/kg]	Recovery rate [%]		cv [%]	n
(thiamethoxam)	fat (cow, omental)	0.01	--	80 / 86	--	2
		0.2	--	83	--	1
		2.0	--	86 /79	--	2
(CGA 322704)	fat (cow, omental)	0.01	--	85 /87	--	2
		0.2	--	87	--	1
		2.0	--	90 / 85	--	2
(thiamethoxam)	kidney (cow)	0.01	--	88 / 91	--	2
		0.1	--	83	--	1
		1.0	--	83	--	1
(CGA 322704)	kidney (cow)	0.01	--	90 / 94	--	2
		0.1	--	87	--	1
		0.5	--	90 / 85	--	1
(thiamethoxam)	liver (cow)	0.01	--	85 / 84	--	2
		0.1	--	86	--	1
		0.5	--	90 / 85	--	2
(CGA 322704)	liver (cow)	0.01	--	92 / 91	--	2
		0.1	--	88	--	1
		0.5	--	90 / 86	--	2
(thiamethoxam)	meat (goat muscle)	0.01	--	86 / 86	--	2
		1.0	--	88	--	1
(CGA 322704)	meat (goat muscle)	0.01	--	88 / 88	--	2
		1.0	--	89	--	1
(thiamethoxam)	Milk (goat)	0.005	--	113 / 104	--	2
		0.5	--	88	--	1
(CGA 322704)	Milk (goat)	0.005	--	96 / 96	--	2
		0.5	--	90	--	1
(thiamethoxam)	Eggs	0.01	--	92	--	1
		0.2	--	81	--	1
		2.0	--	83 / 84	--	2
(CGA 322704)	Eggs	0.01	--	95	--	1
		0.2	--	85	--	1
		2.0	--	88 / 89	--	2
(thiamethoxam)	fat (poultry)	0.01	--	98 / 85	--	2
		0.1	--	90	--	1
		1.0	--	83 / 86	--	2
(CGA 322704)	fat (poultry)	0.01	--	93 / 94	--	2
		0.1	--	94	--	1
		1.0	--	89 / 93	--	2

Reference (analyte)	Matrix	Fortification level [mg/kg]	Recovery rate [%]		cv [%]	n
(thiamethoxam)	milk	0.005	98	71 - 122	12	22
		0.05	91	83 - 96	84- 97	5
		0.1	93	90 - 98	4	7
		0.2	89	80 - 93	6	5
		0.5	88	83 - 91	4	5

Reference (analyte)	Matrix	Fortification level [mg/kg]	Recovery rate [%]		cv [%]	n
(CGA 322704)	milk	0.005	96	72 -113	11	22
		0.05	92	84 - 97	6	5
		0.1	96	90 - 102	5	7
		0.2	92	83 - 95	5	5
		0.5	92	90 - 94	2	5
(thiamethoxam)	kidney (cow)	0.01	102	84 - 113	14	4
		0.1	--	91	--	1
		0.2	--	81	--	1
(CGA 322704)	kidney (cow)	0.01	96	84 - 106	15	4
		0.1	--	88	--	1
		0.2	--	84	--	1
(thiamethoxam)	liver (cow)	0.01	78	73 - 87	11	3
		0.05	--	78	--	1
		0.1	--	87	--	1
		0.5	--	77	--	1
(CGA 322704)	liver (cow)	0.01	80	72 - 94	15	3
		0.05	--	71	--	1
		0.1	--	89	--	1
		0.5	--	80	--	1
(thiamethoxam)	omental fat /	0.01	--	77 / 85	--	1/1

Reference (analyte)	Matrix	Fortification level [mg/kg]	Recovery rate [%]		cv [%]	n
	perinal fat(cow)	0.1	--	88 / --	--	1/0
		0.2	--	-- / 86	--	0/1
(CGA 322704)	omental fat / perinal fat(cow)	0.01	--	84 / 95	--	1/1
		0.1	--	90 / --	--	1/0
		0.2	--	--/ 90	--	0/1
(thiamethoxam)	round muscle	0.01	81	77 - 84	4	3
		0.05	--	96	--	1
		0.1	--	87	--	1
		0.5	--	79	--	1
(CGA 322704)	round muscle	0.01	84	77 - 92	9	3
		0.05	--	95	--	1
		0.1	--	90	--	1
		0.5	--	83	--	1
(thiamethoxam)	tenderloin muscle	0.01	76	69 - 93	16	3
		0.05	--	86	--	1
		0.1	--	82	--	1
		0.2	--	89	--	1
(CGA 322704)	tenderloin muscle	0.01	75	67 - 96	19	3
		0.05	--	86	--	1
		0.1	--	84	--	1
		0.2	--	91	--	1
(thiamethoxam + CGA 322704)	beef liver	0.01	--	100 / 110	--	1/1
		0.1	--	87 / 88	--	1/1
	eggs	0.01	--	90 / 90	--	1/1
		0.1	--	100 / 82	--	1/1
	milk	0.005	--	100 / 100	--	1/1
		0.02	--	100 / 100	--	1/1

Note: at least one blank sample for each matrice and set of fortifications was performed.

Reproducibility of the method has been demonstrated for liver and milk by independent laboratory validation.

Conclusions: LOQ = 0.01 ppm for most matrices except for milk (LOQ = 0.005 ppm). This method allows the determination of thiamethoxam and its major metabolite CGA-322704. Also validation for the analysis of poultry metabolite CGA-265307 are included. Independent laboratory validation include whole milk.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

5.1. Function

Thiamethoxam is an insecticide.

5.2 Organism(s) to be controlled and products, organisms or objects to be protected

5.2.1. Organism(s) to be controlled

The efficacy data for thiamethoxam are summarized in Table 5.2.1 – 1. The studies have been summarized in Appendix 1 to this document.

Conclusion: Thiamethoxam is effective against wood pests as demonstrated for termites (*R. flavipis, R. hegani, R. santonensis)* and the house longhorn beetle (*H. bajulus)*. The toxic threshold for termites is between 0.13 and 0.32 % (m/m) and 0.25 and 0.4 % (m/m) without and with leaching, respectively. The threshold for the house longhorn beetle is 0.025 % (m/m) after leaching. The data show that leaching may has an influence on the efficacy.

5.2.2. Products, objects or organisms to be protected

Thiamethoxam based formulations are designed to protect industrial and engineered wood (e.g. OSB, plywood, mill wood).

5.3. Effects on target organisms, and likely concentration at which the active substance will be used

5.3.1. Effects on target organisms

Thiamethoxam is an insecticide with protective and curative properties. Thiamethoxam is active against many insect classes including those of wood pests.

5.3.2. Likely concentrations at which the active substance will be used

Thiamethoxam will be manufactured as a 10% concentrate that is diluted to 1% for dipping industrial uses and small scale dipping professional uses; 0.15% for double vacuum industrial uses; 0.005% for pressure impregnation industrial uses and 0.04 % for non-professional applications (brushing and spraying).

5.4. Mode of action (including time delay)

5.4.1. Mode of action

There is evidence that thiamethoxam interacts with the receptor protein of nicotinic acetyl choline receptors in the nerve cell membrane.

5.4.2. Time delay

Although death can be delayed for up to 24 hours, the intoxicated insect irreversibly stops feeding and is thus comparable to knock-down substances.

Table 5.2.1 – 1 Summary of efficacy data for thiamethoxam

Test Substance	Test organism	Test system	Test results	Reference
Thiameth-oxam tech.	Termites: *Reticulitermes flavipis* *Reticulitermes hegani*	Laboratory tests with treated filter paper or wood blocks. 8 concentrations: 0.005 – 10.0 ppm 30 individuals and 3 replicates per treatment LC50 values calculated by POLO-	Filter paper test LC_{50}: 1.2 ppm; LC_{90}: 2.8 ppm (after 7 days) Wood block test LC_{50}0: 6.64 ppm; LC_{90}: 14.24 ppm (after 7 days)	Hu, 2001
Thiameth-oxam tech.	Termites: *Reticulitermes santonensis*	EN 117, pine sapwood treated by dipping; test substance dissolved in acetone; 3 concentrations: 0.063 %, 0.025 %, 0.0063 % (m/m)	Toxic range: > 0.025 % < 0.063 % (m/m) equivalent to > 0.13 < 0.32 kg ? m^{-3}	Rudolph & Pantos, 2001
Thiameth-oxam tech.	Termites: *Reticulitermes santonensis*	EN 117 + EN 84, pine sapwood treated by dipping; test substance dissolved in acetone concentrations: 0.025 %, 0.04 %, 0.063 %, 0.1 % and 0.25 % (m/m) Drying period 26 days. Aging and leaching for approx. 12 months	Toxic range after leaching: >0.25 < 0.40 (m/m) equivalent to > 1.3 < 1.9 kg ? m^{-3}	Hertel & Santos, 2002
Thiameth-oxam tech.	House longhorn beetle: *Hylotrupes bajulus (L.)*	EN 46 + EN 84, pine sapwood treated by dipping; test substance dissolved in acetone concentrations: 0.1 %, 0.25 %, 0.4 %, 0.63 % and 1.00 % (m/m) Aging and leaching for approx. 12 months	Threshold value after leaching: 0.025 % (m/m) (120 g ? m^{-3})	Hertel & Teuber, 2002

5.5. Field of use envisaged

Wood preservative use (PT 8)

5.6. User: industrial, professional, general public (non-professional)

Thiamethoxam containing products are used:

- for industrial wood preservation; the application techniques are double-vacuum process, pressure impregnation and dipping.
- for indoor (*in situ*) remedial wood preservation by professionals. These are mainly small scale dipping, spraying, brushing and injection techniques.
- for do-it-yourself *in situ* treatment of wood (non-professional); the application techniques are brushing and spraying, indoor.

5.7. Information on the occurrence or possible occurrence of the development of resistance and appropriate management

5.7.1. Development of resistance

Only a small portion of wood is treated with Thiamethoxam based products. Pests such as H. bajulus can find refuge in the forest and thus the selection pressure is low. Moreover, these wood insects have a life cycle of up to 5 years. Hence, the development of resistance to thiamethoxam is unlikely.

The probability of resistance in social insects like termites is very small because of the long development cycle and the wide range of chemicals with different mode of actions on the market.

5.7.2. Management strategies

In areas where the presence of tolerance strains is confirmed, alternate control methods are recommended (e.g. alternation or combination with other insecticides having a different mode of action).

5.8. Likely tonnage to be placed on the market per year

[redacted]

Section A5.3.1 / 01 Annex Point/III-A5.3.1	Effects on Target Organisms	
	1 REFERENCE	Official use only
1.1 Reference	X.P. Hu (2001), Initial tests on toxicity and residual effectiveness of [redacted] and [redacted], Department of Entomology, Auburn University, Auburn, AL, USA, November 28, 2001.	
1.2 Data protection	Yes	
1.2.1 Data owner	Janssen Pharmaceutica, N.V., Plant and Material Protection Division, Beerse, Belgium	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No	
2.2 GLP *(only where required)*	No	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Target pest	*Reticulitermes flavipes and Reticulitermes. hegani.*	
3.3 Test Method		
3.3.1 Procedure	Response and toxicity test: Termites were exposed in the laboratory to filter paper or wood blocks treated with dilutions of test substances at 0.005, 0.05, 0.1, 0.5, 1.0, 5.0, 10.0 ppm. Termite mortality was observed at intervals of 1, 2, 7, 10, 15, 20, 25 days. Killing speed: Wood blocks were treated with 0.5x, 1x, 5x and 10x LC50.	
	4 RESULTS	
	See below.	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The response, toxicity and killing time was evaluated for [redacted] (Thiamethoxam) in filter paper and wood block laboratory assays. The filter papers and wood blocks were treated at concentrations of 0.005, 0.05, 0.1, 0.5, 1.0, 5.0, 10.0 ppm.	
5.2 Results and discussion	No feeding deterrence occurred in termites exposed to concentrations up to 10 ppm. At day 7 the LC50 value was 1.17 and 6.64 ppm in the filter paper and wood block test, respectively. The values were lower at all alter observation intervals (see Table 1). The killing speed test indicated that 4 days might be the minimum feeding period to kill about 50 % termites at 5x and 10x LC50. After 10 days the mortality went up to	

Section A5.3.1 / 01 Annex Point/III-A5.3.1	Effects on Target Organisms	
	100% at those concentrations.	

Table 1 Toxicity test with [redacted]

Day	LC50 (LC90) [ppm]			
	7	10	15	20
Filter Paper	1.17 (2.83)	0.86 (1.57)	0.59 (0.77)	0.52 (0.57)
Wood Block	6.64 (14.24)	2.81 (7.27)	0.89 (3.83)	-

Table2 Killing Speed of [redacted]

LC50	% Mortality			
	1	2 Day	4 Day	10 Day
0.5	0	0	0	82
1x	0	0	5	93
5x	0	0	40	100
10x	0	2	42	100

5.3 Conclusion	[redacted] (Thiamethoxam) has no deterrent effects. Lethal concentrations (LC50) to termites are 1.17 and 6.64 ppm in the filter paper and wood block test. At that concentration 93% of termites died within 10 days.	
5.3.1 Reliability	1	
5.3.2 Deficiencies	No	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and Methods	[redacted]
Results and discussion	[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A5.3.1 / 02 Annex Point/III-A5.3.1	Effects on Target Organisms	
	1 REFERENCE	Official use only
1.1 Reference	D. Rudolph and S. Pantos (2000), 5th Test report under development agreement "Termiticide", Bundeanstalt für Materialforschung und -prüfung, Berlin, Germany, August 2, 2000.	
1.2 Data protection	Yes	
1.2.1 Data owner	Janssen Pharmaceutica, N.V., Plant and Material Protection Division, Beerse, Belgium	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	EN 117, 1990	
2.2 GLP *(only where required)*	No	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Target pest	*Reticulitermes santonensis*	
3.3 Test Method		
3.3.1 Procedure	Wooden blocks (Pinus sylvestris L.) were treated at concentration of 0.063%, 0.025%, and 0.0063% (m/m) by dipping. The test substance was dissolved in acetone. Termites were exposed for 8 weeks	
	4 RESULTS	
	See below.	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	Tests were conducted according to EN 117. Wooden blocks were treated with [redacted] (thiamethoxam) in acetone at 0.063, 0.025, 0.0063% (m/m).	
5.2 Results and discussion	The data are summarized in Table 1.	

Table 1 **Determination of efficacy threshold of [redacted] against Reticulitermes santonensis according to EN 117**

Concentration	Sample	Retention			Survivors				
		Solvent	Test substance	Mean	worker		cohorts	Nymphs	Rating
		per sample	per sample	value					
%	Number	g	kg/m3	kg/m3	n	%	n	n	
0,063	1	9,54	0,32	0,32	1	0	0	0	0
	2	9,77	0,33		85	34	2	1	1
	3	9,57	0,32		92	37	0	1	0
	4	9,54	0,32		8	3	0	1	0
	5	9,94	0,33		110	44	1	3	1
0,025	6	9.91	0,13	0,13	93	37	0	7	2
	7	9,60	0,13		53	21	2	0	0
	8	9,63	0,13		79	32	1	0	0
	9	9,91	0,13		99	40	2	0	0
	10	9,41	0,13		41	16	1	1	2
0,0063	11	8,78	0,030	0,029	0	o		0	2
	12	8,43	0,028		121	48	1	0	2
	13	8,86	0,030		0	0		0	2
	14	8,69	0,029		24	10	1	1	2
	15	8,73	0,029		100	40	1	0	2
acetone treated	16	8,70	0	0	184	74	2	2	4
	17	8,89	0		199	80	2	0	4
	18	8,43	0		197	79	2	1	4
	19	8,26	0		194	78	2	2	4
	20	8,43	0		193	77	2	2	4
untreated control	21	-	-	-	193	77	2	1	4
	22				169	68	2	0	4
	23	-	-		166	66	1	0	4
	24	-	-		162	65	1	0	4
	25	-	-		166	66	2	0	4

Ratings: 0 = no attack, 1 = traces of nibling, 2 = light attack, 3 = moderate attack, 4 = severe attack

5.3 Conclusion	[redacted] (Thiamethoxam) shows efficacy against termites in the rage of 0.13 and 0.32 kg/m3 after 8 weeks.	
5.3.1 Reliability	1	
5.3.2 Deficiencies	No	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and Methods	[redacted]
	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A5.3.1 / 03 Annex Point/III-A5.3.1	Effects on Target Organisms	
	1 REFERENCE	Official use only
1.1 Reference	H. Hertel and S. Pantos (2002), Summarizing report of investigations according to DIN EN 117 and DIN EN 84 under the development contract "Termiticides"., Bundesanstalt für Materialforschung und -prüfung, Berlin, Germany, January 11, 2002.	
1.2 Data protection	Yes	
1.2.1 Data owner	Janssen Pharmaceutica, N.V., Plant and Material Protection Division, Beerse, Belgium	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	EN 117 & EN84	
2.2 GLP *(only where required)*	No	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Lot/Batch number	[redacted] (thiamethoxam)	
3.1.2 Target pest	*Reticulitermes santonensis*	
3.3 Test Method		
3.3.1 Procedure	Pine sapwood (Pinus sylvestris L.) was treated at concentration of 0.10 %, 0.25 %, 0.4 %, 0.63 % and 1.00 % (m/m) by dipping. The test substance was dissolved in acetone.	
	4 RESULTS	
	See below.	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	Tests were conducted according to EN 117. Wooden blocks were treated with [redacted] (thiamethoxam) in acetone at 0.063, 0.025, 0.0063% (m/m).	
5.2 Results and discussion	The data are summaried in Table 1.	

Table 1 Determination of toxic values [redacted]" against Reticulitermes santonensis in accordance with EN 117 after leaching in accordance with DIN EN 84

Concentration	Sample	Retention			Survivors				Rating
		Solution	Test substance		Workers		Soldiers	Nymphs	
		per wood block	per wood block	Mean value					
%	number	g	kgm-3	kgm-3	n	%	n	N	
1,00	36A	8,34	4,45	4,51	0	0	0	0	0
	37A	8,48	4,52		92	37	0	0	0
	38A	8,26	4,41		117	47	2	0	0
	39A	8,33	4,44		20	8	1	0	0
	40A	8,84	4,71		74	30	2	1	0
0,63	31A	8,01	2,69	2,73	6	2	0	0	0
	32A	8,13	2,73		0	0	0	0	0
	33A	7,85	2,64		34	17	1	1	0
	34A	8,07	2,71		0	0	0	0	0
	35A	8,62	2,90		0	0	0	0	0
0,40	26A	9,21	1,96	1,90	45	18	1	1	0
	27A	9,14	1,95		55	22	0	1	1
	28A	9,16	1,95		58	23	1	2	0
	29A	9,15	1,95		39	16	1	0	0
	30A	7,82	1,67		0	0	0	0	I
0,25	30b	9,67	1,29	1,29	0	0	0	0	0
	30c	9,67	1,29		0	0	0	0	2
	31a	9,65	1,29		52	21	1	0	2
	31b	9,65	1,29		0	0	0	0	2
	31c	9,65	1,29		0	0	0	0	0
0,10	3578	8,09	0,43	0,44	0	0	0	0	2
	8387	6,83	0,36		0	0	0	0	1
	4842	9,18	0,49		0	0	0	0	2
	4837	8,70	0,46		0	0	0	0	2
	4615	8,66	0,46		0	0	0	0	0
Acetone Treatment	41A	8,11	-	-	0	0	0	0	3
	42A	8,19	-		0	0	0	0	4
	43A	8,15	-		45	18	2	1	3
	44A	8,17	-		39	16	0	2	3
	45A	8,55	-		110	44	1	J	3
Untreated control	21A	-	-	-	170	68	2	0	4
	22A	-	-		187	75	1	0	4
	23A	-	-		167	67	1	0	4
	24A	-	-		156	62	1	0	4
	25A	-	-		0	0	0	0	4

Rating: 0 = no attack; 1 = traces of gnawing; 2 = slight attack; 3 = moderate attack; 4 = severe attack

5.3 Conclusion	After leaching, the toxic concentrations of [redacted] (Thiamethoxam) against termites were in the range of 1.29 and 1.90 kg/m3 equivalent to 0.25 and 0.40 % (m/m).	
5.3.1 Reliability	1	
5.3.2 Deficiencies	No	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A5.3.1 / 04 Annex Point/III-A5.3.1	Effects on Target Organisms	
	1 REFERENCE	Official use only
1.1 Reference	H. Hertel and C. Teuber (2002), Test Report: Determination of preventive action of the formulation [redacted] against recently hatched larvae of the haouse longhorn beetle Hylotrupes bajulus L. after leaching., Bundesanstalt für Materialforschung und -prüfung, Berlin, Germany, March 15, 2002.	
1.2 Data protection	Yes	
1.2.1 Data owner	Janssen Pharmaceutica, N.V., Plant and Material Protection Division, Beerse, Belgium	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	EN 84 (1997)	
2.2 GLP *(only where required)*	No	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material		
3.1.1 Lot/Batch number	[redacted] (thiamethoxam)	
3.1.2 Target pest	*Hylotrupes bajulus (L.)*	
3.3 Test Method		
3.3.1 Procedure	Pine sapwood (Pinus sylvestris L.) was treated at concentration of 0.25 %, 0.1 %, 0.063 % o.004 % and 0.025 % (m/m) by dipping. The test substance was dissolved in acetone. Evaluation occurred after 4 weeks.	
	4 RESULTS	
	See below.	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	Test were conducted according to EN 84. Wooden blocks were treated with [redacted] (thiamethoxam) in acetone at 0.25 %, 0.1 %, 0.063 % 0.04 % and 0.025 % (m/m).	
5.2 Results and discussion	The data are summaried in Table 1.	

Table 1 Efficacy of [redacted] against freshly hatched larvae of the house longhorn beetle after leaching

		Number of recovered larvae			
		Mortality after		Survivors after	
Concentration (%) mass	Test period weeks	No boring activity	boring activity	No boring activity	Not recovered
0 25	4	7	3	0	.
		9[1]	1	0	-
		10[1]	0	0	-
		8[1]	1	0	1
		7[1]	3	0	-
		9[1]	1	0	-
0 1	4	7[1]	3	0	-
		9[1]	1	0	.
		9[1]	1	0	-
		9[1]	1	0	-
		9[1]	1	0	-
		6[1]	4	0	-
0.063	4	7[1]	3	0	-
		9[1]	1	0	-
		7[1]	3	0	-
		8[1]	2	0	.
		10[1]	0	0	-
		41	5	0	1
0.04	4	5	5	0	-
		6[1]	4	0	-
		8	2	0	-
		10	0	0	-
		8[1]	2	0	-
		6	1	0	3
0.025	4	6	3	0	1
		5	5	0	-
		7	3	0	-
		4[1]	6	0	-
		7	3	0	-
		9[1]	1	0	-
Solvent control after leaching	4	0	2	7	1
		0	1	9	-
		0	0	9	1
Untreated control	4	0	2	8	-
		0	1	9	-
		0	0	10	-

[1] Some larvae had started gnawing, but were not able to bore into the wood

5.3 Conclusion	The toxic threshold of preventive protection of [redacted] (thiamethoxam) after leaching was below 0.025 % (m/m) at an application of 120 g/m3.	
5.3.1 Reliability	1	
5.3.2 Deficiencies	No	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	