Nominal	Measured End			
controls	0	0		
10	9.6	0	24 h	> 100
18	17.3	0	**48 h**	**> 100**
32	35.5	0		
58	56.0	0		
100	97.2	10	**NOEC: 100 mg/L**	

[a] calculated based on nominal concentrations

Observations: After 48 hours of exposure, no immobilisation or behavioural changes of daphnids had occurred at any of the test concentrations, nor in the controls.

Conclusion: The acute 48-hour EC_{50} for *Daphnia magna* when exposed to CGA 322704 (metabolite of thiamethoxam) under static conditions was determined to be > 100 mg/L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	30/11/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.2 / 06	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4	Acute toxicity to invertebrates

1.	Annex point(s)	**II A, 8.2.4** **Acute Toxicity to Aquatic Invertebrates**
2.	Location in Dossier	Section 6
3.	Authors / Year	Maetzler, P. (1998a)
	Title	22 ACUTE TOXICITY OF CGA 355190 TO *DAPHNIA MAGNA* (IMMOBILISATION TEST)
	Report No. / Date	G 54114, 982589 / 30.10.1998
	Novartis File N°	Novartis Study # 355190-3
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Services AG, Scientific Services, Ecotox Center, CH-4002 Basle, Switzerland
5.	Dates of work	August 18, 1998 through August 20, 1998
6.	Test substance	Company Code: CGA 355190, Batch number: [redacted]
7.	Test method	OECD Guideline No.: 202, Paris 1984 and 92/69/EEC, C.2. 1992.
8.	Deviations	none
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) OECD Principles of Good Laboratory, May 1981. 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: CGA 355190, Batch No. [redacted] The acute toxicity of CGA 355190 to *Daphnia magna* was determined in a 48-hour static test. The test was performed as a limit test with one test substance concentration (100 mg/L) and a blank control. For each concentration 20 *Daphnia* divided into two groups of 10 animals were used. Each 250 ml test vessel contained 60-100 mL test solution or the blank control. The temperature during exposure was between 19 and 20°C. During exposure water concentrations were always close to nominal values and were in the range of 99.5 at test initiation to 103.5% of nominals at the end of exposure in all samples. Results were therefore expressed in nominal values.

Findings:

Acute toxicity of CGA 355190 (metabolite of thiamethoxam) to Daphnia magna

Concentration [mg/L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50}[a] [mg/L] (95 % conf. interval)
Nominal	Mean measured			
controls	< 0.40	0	24 h	> 100
100	101.5	0	**48 h**	**> 100**
			NOEC: 100 mg/L	

[a] calculated based on nominal concentrations

Observations: After 48 hours of exposure, no immobilisation or behavioural changes of daphnids had occurred at any of the test concentrations, nor in the controls.

Conclusion: The acute 48-hour EC_{50} for *Daphnia magna* when exposed to CGA 355190 (metabolite of thiamethoxam) under static conditions was determined to be > 100 mg/L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	30/11/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.2 / 07	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4	Acute toxicity to invertebrates

1.	Annex point(s)	**II A, 8.2.4** **Acute Toxicity to Aquatic Invertebrates**
2.	Location in Dossier	Section 6
3.	Authors / Year	Seyfried, B. (1998b)
	Title	23 ACUTE TOXICITY OF NOA 407475 (METABOLITE OF CGA 293343) TO *DAPHNIA MAGNA* IN A 48-HOUR IMMOBILISATION TEST
	Report No. / Date	688803 / 22.09.1998
	Novartis File N°	Novartis Study # 407475-11
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	RCC Ltd, Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland
5.	Dates of work	July 06, 1998 through August 26, 1998
6.	Test substance	Company Code: NOA 407475, Batch number: [redacted]
7.	Test method	OECD Guideline No.: 202, Paris 1984 and 92/69/EEC, C.2. 1992.
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) OECD Principles of Good Laboratory, May 1981. 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: NOA 407475, Batch No. [redacted] %. The acute toxicity of NOA 407475 to *Daphnia magna* was determined in a 48-hour static test. Five test concentration were employed with nominal values of 4.6, 10, 22, 46 and 100 mg/L. For each concentration 20 *Daphnia* divided into two groups of 10 animals were used. Each 100 mL test vessel contained 50 mL test solution or the blank control. Two test series with the same test concentrations but with different initial pH-values were performed. In the first series using freshly prepared, non-equilibrated test media, the initial pH-values ranged from 8.1 to 9.5 and were positively correlated with increasing concentration of NOA 407475 in the test media. In the second test series equilibrated test media with initial pH-values in the range of 8.2 to 8.4 were used. The temperature during exposure was 20°C ± 2. During exposure water concentrations were measured in the range from 86 to 109% of the nominal values. Results were therefore expressed in nominal values.

Findings:

Acute toxicity of NOA 407475 (metabolite of thiamethoxam) to Daphnia magna

Concentration [mg/L]		Immobilisation after 48 h [%]		Exposure period [hours]	EC_{50}* pH not equilibrated [mg /L]	EC_{50} [a] pH equilibrated [mg/L]
Nominal	Mean measured	pH not equilibrated	pH equlibrated			
controls	-	0	0			
4.6	-	0	0	24 h	> 100	> 100
10	9.08	0	0	**48 h**	**91.5**	**82.9**
22	19.4	0	15			
46	39.6	0	25			
100	87.5	5	55	**48-h EC_0 and NOEC: 10 mg /L**		

[a] calculated based on nominal concentrations

Observations: After 48 hours of exposure, immobilisation of daphnids occurred at concentrations of 22 and 46 mg/L for the not-equilibrated and the equilibrated test media, respectively. The slightly different 48h EC_{50} values found for the two test series can be explained by the usual biological variations in acute toxicity tests with *Daphnia*. They are unlikely to be due to the different pH-values at the start of the tests.

Conclusion: The acute 48-hour EC_{50} for *Daphnia magna* when exposed to NOA 407475 (metabolite of thiamethoxam) under static conditions was determined to be 91.5 mg/L (pH not equilibrated) and 82.9 mg/L (pH equilibrated).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]

Conclusion	[redacted] s.
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 section No.	Doc IIIA	7.4.1.2 / 08	Acute toxicity to invertebrates
91/414 Point addressed	Annex	II 8.2.4	Acute toxicity to invertebrates

1.	Annex point(s)	**II A, 8.2.4 Acute Toxicity to Aquatic Invertebrates**
2.	Location in Dossier	Section 6
3.	Authors (Year)	Wallace, S.J. (2002b)
	Title	24 NOA 459602 (Thiamethoxam metabolite): Acute toxicity to *daphnia magna*
	Report No. / Date	BL7244/B/ 19.04.2002
	Syngenta File N°	459602/0017
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Brixham Environmental Laboratory, Brixham, Devon, England
5.	Dates of work	11th December 2001 through to 13th December 2001
6.	Test substance	Company Code: NOA 459602., Batch number: [redacted]
7.	Test method	OECD - Guideline No.: 202, Part I, Paris 1984
8.	Deviations	None
9.	GLP	The study was conducted to conform with the UK Principles of Good Laboratory Practice (United Kingdom) GLP Regulations 1999) These principles are in accordance with the OECD Principles of Good Laboratory Practice, revised 1997 (ENV/MC/CHEM(98)17). These international standards are acceptable to the United States Environmental Protection Agency and this study, therefore satisfies the requirements of 40 CFR Part 160 and 40 CFR Part 792.

Test System: NOA 459602 (metabolite of thiamethoxam), Batch No.: [redacted]. Test species: waterflea, *Daphnia magna* Straus; age: first instars less than 24 hours; source: in-house culture (Brixham Environmental Laboratory, England). Number of daphnids: for the test item test concentration and the water control four replicates each with 5 daphnids were used. Test vessels: 250 mL glass beakers containing 200 mL test medium (reconstituted water, Elendt's M4). The test media were not exchanged and not aerated during the test. Nor were the daphnia fed during the test. All test vessels were placed under controlled environmental conditions at 21 ± 1 °C and a lighting regime of 16 hours light and 8 hours dark per day.
The test concentration (nominal: 120 mg NOA 459602/L) was evaluated in this test. For the test concentration a single stock solution was prepared without using a solvent. In addition to the test item treatment a blank control with dilution water only was included. Test duration: 48 hours. The number of dead or immobilised organisms was counted at 24 and 48 hours. Dissolved oxygen and pH were measured at the start and end of the test. Total hardness of the water was determined at test start. Samples of the test media were taken from the excess of the freshly prepared test solutions and from the test vessels after 48 hours for the analytical determination (HPLC) of the test concentrations.

Findings: Results are given on basis of nominal concentrations since concentrations did not vary being 100% of nominal at test start and 100 % of nominal at test end. The water temperature was 19.9-20.5 °C during the test period. The dissolved oxygen content ranged between 94.8% and 97.0% of saturation and pH values ranged from 7.97 to 8.14. The total hardness at test start was 220.3 mg $CaCO_3$/L.

Acute toxicity of NOA 459602 (metabolite of thiamethoxam) to Daphnia magna

Concentration [mg NOA 459602 / L]			Immobilisation after 48 h [%]	Exposure period [hours]	LC_{50} [a] (95 % conf. interval) [mg NOA 459602 / L]
Nominal	Start	End	-		
Control	<0.75	<0.75	0		
120	120	120	0	**48 h**	**> 120 (n.a.)**
				NOEC: 120 mg NOA 459602 / L	

[a] based on nominal concentrations; n.a. = not applicable

Observations: No immobilisation or abnormal behaviour was observed in either treatment during the test period.

Conclusion: The acute 48-hour LC_{50} for *Daphnia magna* exposed to NOA 459602 (metabolite of thiamethoxam) under static conditions was determined to be > 120 mg /L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.2 / 09	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4	Acute toxicity to invertebrates

1.	**Annex point(s)**	**II A, 8.2.4** **Acute Toxicity to Aquatic Invertebrates**
2.	**Location in Dossier**	Section 6
3.	**Authors (Year)**	Knauer, K. (2000a)
	Title	25 Acute Toxicity Test of CGA 293343 tech.to the ephemeroptera *Cloen* sp. under static conditions
	Report No. / Date	2002613 / 10.07.2000
	Syngenta File N°	293343/1228
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	**Testing facility**	Syngenta Crop Protection AG, Basel Switzerland
5.	**Dates of work**	1st June 2000 through 9th June, 2000
6.	**Test substance**	ISO common name thiamethoxam. Company Code: CGA 293343 tech.; Batch number: [redacted]
7.	**Test method**	OECD-Guideline No.: 202, Paris 1984 EEC-C.2, December 29, 1992 U.S. EPA-FIFRA Guideline Number 72-2, December 24, 1989 U.S. EPA OPPTS Test Guideline OPPTS 850.1010, April, 1996
8.	**Deviations**	None
9.	**GLP**	GLP with the exception of range finding test, the study was conducted in compliance with the Siss Ordinance relating to Good Laboratory Practice, adopted 2nd February, 2000 (RS 813.016.5). This ordinance is based upon the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted 26th November, 1997 by decision of the OECD Council [C (97) 186/Final]. These procedures are based on the OECD Principles of Good Laboratory Practice adopted 12th May, 1981 by the decision of the OECD Council [C (81) 30 (Final)] concerning Mutual Acceptance of Data in the Assessment of Chemicals, as ammended by the Council Decision-Recommendation of 2 October, 1989 concerning Compliance with Principles of Good Laboratory Practice Council [C (89) 87 (Final)].

Test System: Thiamethoxam technical, Batch No. [redacted] %. The acute toxicity of thiamethoxam (technical) to the aquatic insect Ephemeroptera *Cloeon* Sp. has been determined at six different test concentrations and a blank control at a temperature of 19 °C. The test organism, *Cloeon* Sp. was collected from a natural assemblage from the Novartis Crop Protection field aquatic ecosystem at Stein, Aargau, Switzerland, then transferred, together with the natural pond water, to an aquarium housed in the Novartis laboratories. The single species required for testing was accordingly separated. *Cloeon* Sp. were acclimatised for at least a period of 20-h. No feed was provided during the 48-h test period. A range-finding test was performed at six concentrations (0.001, 0.01, 0.1, 1, 10 and 100 mg/L nominal) prior to embarking upon the definitive study phase. Based on results from the range-finder, the definitive test was conducted at 0 (Control), 0.0031, 0.0063, 0.013, 0.025, 0.050 and 0.100 mg thiamethoxam/L. Analysis of fortified test solutions at 0-hr and 48-hrs indicated that measured exposure concentrations were, respectively, in the range 93-104% and 86-100% of the nominal concentrations. Four replicates per test concentration containing 5 organisms per replicate were prepared in 250 mL glass test vessels containing 200 mL of test solution (CGA 293343 tech. dissolved in pond water). Test vessels containing *Cloeon* Sp. were incubated in a climatic chamber for a period of 48-hours and subjected to a 16 hour light / 8 hour dark light regime, employing a 30 minute transition period. Average light intensity, during periods of illumination, was in the order of 20 $\mu E/m^2 sec$. Water quality measurements included pH (range 8.2-8.5), temperature (constant at 19 °C) and oxygen content (87-96% of saturation) monitoring. Immobilisation or other behavioural changes were recorded after 24- and 48-hours.

Findings: No immobilisation was observed in the control (blank pond water medium) during the course of the 48-hour exposure period, with no unexpected phenomena being observed. The test was thus deemed valid. The results are presented below.

Acute toxicity of thiamethoxam (tech.) to Ephemeroptera Cloeon

Concentration [µg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [µg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.5 / < 0.5	0	24 h	19
3.1	3.05 / 3.11	0		
6.3	6.55 / 6.32	0	**48 h**	**14**
13	11.9 / 11.2	50		
25	25.0 / 24.2	90		
50	48.6 / 47.8	100	**NOEC^: 6.3 µg a.i./L**	
100	92.5 / 91.1	100		

[a] calculated based on nominal concentrations

^ Highest concentration with no immobilisation or behavioural changes

Conclusion: The acute 48-hour EC_{50} for the Ephemeroptera *Cloeon* Sp. when exposed to thiamethoxam under static conditions was determined to be 14 µg a.i./L. The 48-hour NOEC was determined to be 6.3 µg a.i./L based on no evidence of immobilisation or behavioural changes.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2/12/2004
Materials and Methods	[redacted] r.
Results and discussion	[redacted] l
Conclusion	[redacted] e
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.4.1.2 / 10	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4	Acute toxicity to invertebrates

1.	Annex point(s)	**II A, 8.2.4 Acute Toxicity to Aquatic Invertebrates**
2.	Location in Dossier	Section 6
3.	Authors (Year)	Mank, M.A. and Krueger, H.O. (1998)
	Title	26 CGA 293343 Technical: A 48-hour static acute toxicity test with the midge (*Chironomus riparius*).
	Report No. / Date	819-98 / 15.10.1998
	Syngenta File N°	293343/0890
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Wildlife International Ltd., Maryland, USA
5.	Dates of work	29th September 1998 through 1st October 1998
6.	Test substance	ISO common name thiamethoxam; Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	US-EPA, 1982, FIFRA Subdivision E, EPA 540/9-82-024. US-EPA, 1985, FIFRA Subdivision E, EPA 540/9-85-005. ASTM Standard Method E729-96a, 1994.
8.	Deviations	None
9.	GLP	The study was conducted in compliance with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989; OECD Principles of Good Laboratory Practice, OCDE/GD (92) 32, Environment Monograph No. 45, Paris 1992; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Bureau, 10 August 1984.

Test System: Thiamethoxam technical; Batch No.: [redacted]
Test organism: *Chironomus riparius* were obtained from a commercial supplier. Midges were cultured in water. Midge egg casings and newly hatched midges were held for six days (22 °C, pH 8.3-8.7, dissolved oxygen 8.4-8.6 mg/L) prior to collection for testing. Organisms used for the test were two days old and appeared to be in the 2nd instar development stage. *Chironomus riparius* were exposed to a geometric series of five test concentrations and a negative (dilution water - filtered well water decsribed as "moderately-hard") Control. Two replicate test chambers (2 L test beakers containing 1 L of test solution, equivalent to a depth of 7.9 cm) were prepared for each treatment level, and 10 midges indiscriminately introduced into each test chamber. Nominal test concentrations were 0, 6.3, 13, 25, 50 and 100 µg a.i./L. Mean measured concentrations of between 100 and 105% of nominal were determined as the average of duplicate sample analyses taken at 0-hr and 48-hr. Test chambers were placed in a water bath and incubated at a constant temperature of 22 ± 1 °C during the course of the experiment. A photoperiod of 16 hours light (approximately 501 Lux) and 8 hours of darkness, applying a 30 minute transition period were used. Measured physical parameters included: water temperature, pH, dissolved O_2, hardness, alkalinity and specific conductance. Observations were made periodically (after 1-, 24- and 48-hours) to determine the number of mortalities and immobility of test organisms, and the number of individuals exhibiting clinical signs of toxicity or abnormal behaviour were registered.

Findings: Results from both the biological- and analytical-phase of the study are presented below.

Acute toxicity of thiamethoxam (tech.) to Chironomus riparius

Concentration [µg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [µg a.i./L] (95 % conf. interval)
Nominal	Mean Measured Beginning / End			
control	< LOQ / < LOQ	0	**24 h**	**61**
6.3	6.88 / 6.40	0		
13	13.3 / 12.4	0	**48 h**	**35**
25	26.8 / 25.2	10		
50	53.0 / 51.2	95		
100	105 / 102	100	**NOEC: 13 µg a.i./L**	

[a] EC_{50} calculations based on mean measured thiamethoxam concentrations

Midges in the negative Control, 6.6 and 13 µg a.i./L treatment levels all appeared normal and healthy throughout the test. After an exposure period of 48-hr, mortality in the 26, 52 and 104 µg a.i./L treatment groups represented 10, 95 and 100 %, respectively.

Conclusion: The 48-hr EC_{50} and NOEC value for *Chironomus riparius* exposed to thiamethoxam fortified in the water-phase were determined to be 35 µg a.i./L and 13 µg a.i./L, respectively.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.3 / 01 Growth inhibition test on algae
91/414 Annex Point addressed	II 8.2.6 / 01 Effects on algal growth

1.	Annex point(s)	**II A, 8.2.6 Effects on Algal Growth**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grade, R. (1996a)
	Title	27 GROWTH INHIBITION TEST OF CGA 293343 TECH. TO GREEN ALGAE (SELENASTRUM CAPRICORNUTUM) IN A STATIC SYSTEM
	Report No. / Date	95G005 / 12.01.1996
	Novartis File N°	Novartis Study # CGA 293343-35
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Ecotoxicology Department, CH-4002 Basle Switzerland
5.	Dates of work	October 10, 1995 through October 25, 1995
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	OECD - Guideline No. 201, Paris 1984, Guideline 92/69/EEC: C3. U.S. EPA Pesticide Assessment Guidelines, Subdivision J, Section No. 122-2 and 123-2 (1989).
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) OECD Principles of Good Laboratory, May 1981. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical; Batch No. [redacted] After a preculture period of three days, *Selenastrum capricornutum* (initial cell density 9700 cells/mL) was exposed to nominal test concentrations of 0.8, 1.6, 3.2, 6.4, 12.8, 25.6, 50 and 100 mg test substances/L for 72 hours. The measured test substance concentrations were 0.82, 1.59, 3.19, 6.12, 13.08, 26.75, 51.25, 100.45 at the start of the study and 0.66, 0.93, 1.92, 4.5, 9.91, 20.56, 45.24, 81.78 mg test substance/L at the end of exposure, respectively. The toxicity values are based on measured concentrations at the end of the study.

Findings:

Acute toxicity of thiamethoxam to green algae

Concentration [mg a.i./L]	Cell densities after 72 hours	Inhibition [a] (growth rates)	72-h E_bC_{50} [b] (95% conf. interval)	72-h E_rC_{50} [b] (95% conf. interval)

Nominal	Measured End	[cells x 10^4/mL]	[%]	[mg a.i./L]	[mg a.i./L]
control	0	111.9	0.0		
0.8	0.66	126.7	0.0		
1.6	0.93	120.3	0.0	**> 81.8**	**> 81.8**
3.2	1.92	143.3	0.0	none	none
6.4	4.5	105.0	1.5		
12.8	9.91	106.5	1.0		
25.6	20.56	106.5	1.1		
50	45.24	91.5	5.8	**NOE_rC: 81.8 mg a.i./L**	
100	81.78	109.8	0.3		

[a] a negative inhibition indicates stimulation
[b] calculated based on measured end concentrations

Conclusion: The 72-hour E_rC_{50} and E_bC_{50} for *Selenastrum capricornutum* when exposed to thiamethoxam were determined to be > 81.8 mg a.i./L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	3/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.3 / 02	Growth inhibition test on algae
91/414 Annex Point addressed	II 8.2.6 / 03	Effects on algal growth

1.	Annex point(s)	**II A, 8.2.6** **Effects on Algal Growth**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grade, R. (1998a)
	Title	**28 GROWTH INHIBITION TEST OF CGA 293343 TECH. TO GREEN ALGAE (SELENASTRUM CAPRICORNUTUM) UNDER STATIC CONDITIONS**
	Report No. / Date	972549 / 16.06.1998
	Novartis File N°	Novartis Study # CGA 293343-580
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Ecotoxicology Department, CH-4002 Basle Switzerland
5.	Dates of work	April 21, 1997 through April 25, 1997
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	OECD - Guideline No. 201, Paris 1984 static system guideline 92/69/EEC: C3. U.S. EPA Pesticide Assessment Guidelines, Subdivision J, Section No. 122-2 and 123-2 (1982). EPA ecological test guidelines, OPPTS 850.54000, Public Draft, April 1996. Deviation of pH > 1.5 units
8.	Deviations	none
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) OECD Principles of Good Laboratory, May 1981. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical; Batch No. [redacted] After a preculture period of three days, *Selenastrum capricornutum* (Also known as *Pseudokirch. subcapitata SAG 61.81*) (initial cell density 10100 cells/mL) was exposed to nominal test concentrations of 10, 18, 32, 58 and 100 mg thiamethoxam/L for 96 hours. The measured test substance concentrations were 10.1, 18.0, 32.8, 58.0 and 101.9 at the start of the study and 6.8, 16.3, 29.7, 52.1 and 91.7 mg thiamethoxam/L at the end of exposure, respectively. The measured test concentrations of thiamethoxam were within 100 ± 20% of the nominal values. The toxicity values are, therefore, based on nominal concentrations.

Findings:

Acute toxicity of thiamethoxam to green algae

Concentration [mg a.i./L]		Cell densities after 96 hours	Inhibition [a] (growth rates)	96-h E_bC_{50} [b] (95% conf. interval)	96-h E_rC_{50} [b] (95% conf. interval)
Nominal	Measured End	[cells x 10^4/mL]	[%]	[mg a.i./L]	[mg a.i./L]
control	0	1081	-		
10	6.8	1193	0.0	> 100 none	> 100 none
18	16.3	1376	0.0		
32	29.7	1261	0.0		
58	52.1	1165	0.0		
100	91.7	1112	0.0	NOE$_r$C: 100 mg a.i./L	

[a] a negative inhibition indicates stimulation

[b] calculated based on nominal concentrations

Conclusion: The 96-hour E_rC_{50} and E_bC_{50} for *Selenastrum capricornutum* when exposed to thiamethoxam were determined to be > 100 mg a.i./L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.3 / 03 Growth inhibition test on algae
91/414 Annex Point addressed	II 8.2.6 / 02 Effects on algal growth

1.	Annex point(s)	**II A, 8.2.6 Effects on Algal Growth**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grade, R. (1997)
	Title	**29 GROWTH INHIBITION TEST OF CGA 322704 (METABOLITE OF CGA 293343) TO GREEN ALGAE (SELENASTRUM CAPRICORNUTUM) UNDER STATIC CONDITIONS**
	Report No. / Date	962529 / 09.01.1997
	Novartis File N°	Novartis Study # CGA 322704-7
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Ecotoxicology Department, CH-4002 Basle Switzerland
5.	Dates of work	November 12, 1996 through November 22, 1996
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted]
7.	Test method	OECD - Guideline No. 201, Paris 1984, Gu ideline 92/69/EEC: C3. U.S. EPA Pesticide Assessment Guidelines, Subdivision J, Section No. 122-2 and 123-2 (1989).
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) OECD Principles of Good Laboratory, May 1981. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: CGA 322704, Batch No. [redacted] The influence of CGA 322704 on the growth of the green algal species *Selenastrum capricornutum* was investigated in a 72-hour static test. After a preculture period of three days, *Selenastrum capricornutum* (initial cell density 10200 cells/mL) was exposed to nominal test concentrations of 6.25, 12.5, 25, 50 and 100 mg CGA 322704/L for 72 hours. The measured test substance concentrations were 5.7, 11.0, 22.5, 44.0, 94.5 and 5.5, 10.1, 20.9, 45.5, and 91.2 mg CGA 322704/L at the start and the end of exposure, respectively. At all times measured start and measured end concentrations were close to nominal values, therefore, the toxicity values are based on nominal concentrations.

Findings:

Acute toxicity of CGA 322704 (metabolite of thiamethoxam) to green algae

Concentration [mg /L]	Cell densities [a] after 72 hours	Inhibition [b] (growth rates)	72-h E_bC_{50} [c] (95 % conf. interval	72-h E_rC_{50} [c] (95 % conf. interval)

Nominal	Measured End	[mean emission]	[%]	[mg/L]	[mg/L]
control	0	788.3	-		
6.25	5.5	776.3	0.1		
12.5	10.1	766.3	0.3	**> 100**	**> 100**
25	20.9	731.7	1.2	(107-1078)	(216-37500)
50	45.5	679.7	2.6		
100	91.2	497.7	8.5	**NOE_rC: 50 mg/L**	

[a] mean emission: initial cell density (10200 cells/mL) = 3.88
[b] a negative inhibition indicates stimulation
[c] calculated based on nominal concentrations

Conclusion: The 72-hour E_rC_{50} and E_bC_{50} for *Selenastrum capricornutum* when exposed to CGA 322704 (metabolite of thiamethoxam) were determined to be > 100 mg /L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.3 / 04	Growth inhibition test on algae
91/414 Annex Point addressed	II 8.2.6 / 04	Effects on algal growth

1.	Annex point(s)	**II A, 8.2.6** **Effects on Algal Growth**
2.	Location in Dossier	Section 6
3.	Authors / Year	Maetzler, P. (1998b)
	Title	**30 TOXICITY OF CGA 355190 TO GREEN ALGAE (GROWTH INHIBITION TEST)**
	Report No. / Date	G54117, 982590 / 30.10.1998
	Novartis File N°	Novartis Study # 355190-4
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Services AG, Sientific Services, Ecotox Center, CH-4002 Basle Switzerland
5.	Dates of work	September 08, 1998 through September 11, 1998
6.	Test substance	Company Code: CGA 355190, Batch number: [redacted]
7.	Test method	OECD - Guideline No. 201, Paris 1984, Gu ideline 92/69/EEC: C3.
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) OECD Principles of Good Laboratory, May 1981. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: CGA 355190, Batch No. [redacted] The influence of CGA 355190 on the growth of the green algal species *Pseudokirchneriella subcapitata* alias *Scenedesmus subspicatus* was investigated in a 72-hour static test. After a preculture period of three days, *the green algae* (initial cell density 10,000 cells/mL) were exposed to nominal test concentrations of 4.3, 9.4, 21, 45 and 100 mg CGA 355190/L for 72 hours. The measured test substance concentrations were in the range of 98.8 - 100.5% of nominal values during the test. At all times measured start and measured end concentrations were close to nominal values, therefore, the toxicity values are based on nominal concentrations.

Findings:

Acute toxicity of CGA 355190 (metabolite of thiamethoxam) to green algae

Concentration [mg/L]		Cell densities [a] after 72 hours	Inhibition [b] (growth rates)	72-h E_bC_{50} [c] (95 % conf. interval	72-h E_rC_{50} [c] (95 % conf. interval)
Nominal	Measured End	[biomass]	[%]	[mg/L]	[mg/L]
control	0	712.44	-		

4.3	n.d.	728.78	-0.7		
9.4	n.d.	695.44	0.6	**> 100**	**> 100**
21.0	n.d.	699.44	0.5	(-)	(-)
45.0	43.9	730.56	-0.7	NOE$_r$C: 100 mg/L	
100	99.0	621.78	3.1		

[a] particle number x 1000
[b] a negative inhibition indicates stimulation
[c] calculated based on nominal concentrations

Conclusion: The 72-hour E_rC_{50} and E_bC_{50} for *Selenastrum capricornutum* when exposed to CGA 355190 (metabolite of thiamethoxam) were determined to be > 100 mg /L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.4.1.3 / 05 Growth inhibition test on algae
91/414 Annex Point addressed	II 8.2.6 / 04 Effects on algal growth

1.	Annex point(s)	**II A, 8.2.6 Effects on Algal Growth**
2.	Location in Dossier	Section 6
3.	Authors / Year	Seyfried, B. (1998c)
	Title	**31 TOXICITY OF NOA 407475 (METABOLITE OF CGA 293343) TO *SENEDESMUS SUBSPICATUS* IN A 72-HOUR ALGAL GROWTH INHIBITION TEST**
	Report No. / Date	688825 / 14.08.1998
	Novartis File N°	Novartis Study # 407475-9
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	RCC Ltd., Environmental Chemistry & Pharmanalytics Division, Itingen, Switzerland
5.	Dates of work	July 03, 1998 through July 22, 1998
6.	Test substance	Company Code: NOA 407475, Batch number: [redacted]
7.	Test method	OECD - Guideline No. 201, Paris 1984, Gu ideline 92/69/EEC: C3.
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) OECD Principles of Good Laboratory, May 1981. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: NOA 407474, Batch No. [redacted] %. The influence of NOA 407475 on the growth of the green algal species *Scenedesmus subspicatus* was investigated in a 72-hour static test. After a preculture period of three days, *Scenedesmus subspicatus* (initial cell density 10,000 cells/mL) was exposed to nominal test concentrations of 1.0, 2.2, 4.6, 10.0, 22.0 and 46.0 mg/L. Additionally, a control was tested in parallel. The mean analytically determined concentrations of NOA 407475 in the analyzed test media ranged from 86 to 101% of the nominal values during the test period of 72 hours. At all times measured start and measured end concentrations were close to nominal values, therefore, the toxicity values are based on nominal concentrations.

Findings:

Acute toxicity of NOA 407475 (metabolite of thiamethoxam) to green algae

Concentration [mg/L]	Cell densities [a] after 72 hours	Inhibition [b] (growth rates)	72-h E_bC_{50} [c] (95 % conf. interval	72-h E_rC_{50} [c] (95 % conf. interval)

Nominal	Mean Measured	[cells x 10^4/mL]	[%]	[mg/L]	[mg/L]
control	-	91.6	0.0		
1.0	-	97.0	-1.7		
2.2	-	90.5	0.0	**14.0**	**33.8**
4.6	4.6	87.6	0.6	(6.9-20.3)	(20.5-125.4)
10.0	9.1	41.2	17.3		
22.0	19.0	19.7	33.7	**NOE_rC and NOE_bC: 4.6 mg /L**	
46.0	40	6.1	60.0		

[a] initial cell density (10'000 cells/mL)
[b] a negative inhibition indicates stimulation
[c] calculated based on nominal concentrations

Conclusion: The 72-hour E_rC_{50} and E_bC_{50} for *Selenastrum subspicatus* when exposed to NOA 407475 (metabolite of thiamethoxam) were determined to be 33.8 mg /L and 14.0 mg /L, respectively.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]e.
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.4.1.3 / 06	Growth inhibition test on algae
91/414 Annex Point addressed	II 8.2.6	Effects on algal growth

1.	Annex point(s)	**II A, 8.2.6**	**Effects on Algal Growth**
2.	Location in Dossier	Section 6	
3.	Authors (Year)	Wallace, S.J. (2002c)	
	Title	32 NOA 459602 (Thiamethoxam metabolite): Acute toxicity to the green algae (*Selenastrum capricornutum*)	
	Report No. / Date	BL7245/B/ 25.04.2002	
	Syngenta File N°	Syngenta Study # 459602-0018	
	Source / Owner	Unpublished / Syngenta Crop Protection AG	
4.	Testing facility	Brixham Environmental Laboratory, Brixham, Devon, England	
5.	Dates of work	10th December 2001 through to 14th December 2001	
6.	Test substance	Company Code: NOA 459602., Batch number: [redacted]	
7.	Test method	US Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Ecological Effects Test Guideline OPPTS 850.5400 Algal Toxicity, Tiers I and II "Public Draft". April 1996	
8.	Deviations	None	
9.	GLP	The study was conducted to conform with the UK Principles of Good Laboratory Practice (United Kingdom) GLP Regulations 1999) These principles are in accordance with the OECD Principles of Good Laboratory Practice, revised 1997 (ENV/MC/CHEM(98)17). These international standards are acceptable to the United States Environmental Protection Agency and this study, therefore satisfies the requirements of 40 CFR Part 160 and 40 CFR Part 792.	

Test System: NOA 459602 (metabolite of thiamethoxam), Batch No. [redacted]. Freshwater green algae, *Selenastrum capricornutum* (strain: ATCC 22662; from an exponentially growing 3 day-old pre-culture; source: in-house culture) were exposed to five concentrations of the test item under static conditions for a period of 96 hours. The following nominal test item concentrations were tested: 7.5, 15, 30, 60 and 120 mg NOA 459602 per litre. A single stock solution (the highest test concentration) was prepared by mixing an appropriate amount of the test item directly into the sterile culture medium without additional solvent. Dilution of aliquots of this stock solution with sterile culture medium yielded the lower concentrations. A blank control with test medium only was included. The starting concentration of algal cells was approximately 1.01 x 10^4 cells/mL. Three replicate test chambers were maintained for the test item treatment groups and six replicates for the control group. The test flasks comprised 250 ml conical glass flasks each containing 100 mL of the appropriate test solution/algal suspension. The flasks were randomly positioned within a laboratory shaker and continuously shaken at 100 rpm under continuous illumination.

Samples from each replicate of the test groups were collected at approximately 24-hour intervals for the determination of the algal cell density by means of a cell counter. The temperature of the incubator was measured daily. The pH was recorded at 0 h and 96 h. Test item concentrations were measured (HPLC) on samples taken from the excess test solutions at test start and from the flask at the end of the test.

Findings: Results are given on basis of nominal concentrations since concentrations varied between 100 to 113% of nominal at test start and 107 to 113% of nominal at test end. During the test period, temperature was maintained at 23.9-24.0 °C and the light intensity measured once during the study was 4040 lux (49.1 µE/m^2·sec, in terms of quantum response). The pH ranged from 7.41 to 7.47 at test start, and 9.28 to 9.93 at test termination (increase in pH due to the massive growth of algae in control and test item groups).

Acute toxicity of NOA 459602 (metabolite of thiamethoxam) to green algae

Concentration [mg NOA 459602 / L]			Cell density after 96 hours	Inhibition (AUC) - 96 h	96-h E_rC_{50} [a] (95% confid. limit)	96-h E_bC_{50} [a] (95% confid. limit)
Nominal	Measured Day 0	Day 4	[cells x 10^4/mL]	[%]	[mg NOA 459602 / L]	[mg NOA 459602 / L]
Control	<0.75	<0.75	388	-	> 120 (n.a.)	> 120 (n.a.)
7.5	8.0	8.2	390	1		
15	17	17	378	2		
30	31	33	369	6	NOE$_r$C: 60 mg NOA 459602/ L	NOE$_b$C: 60 mg NOA 459602/ L
60	61	64	348	10		
120	120	130	314	17*		

[a] based on nominal concentrations
n.a. = not applicable
* significant difference (P=0.05) from the culture medium

Observations: The density of the cells in the control group increased by factor 388 during the course of the test (exponential growth), demonstrating the validity of the test system. In the test item treatment after 96 hours a dose-responsive inhibition was observed. However, at all test item concentrations tested the percentage inhibition compared to the controls was < 50% and only in the highest test item concentration was this inhibition > 10% and statistically significant.

Conclusion: The acute E_bC_{50} (96 h) for green algae exposed to NOA 459602 (metabolite of thiamethoxam) was determined to be > 120 mg /L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

Remarks

98/8 Doc IIIA section No.	7.4.1.4 / 01	Inhibition of microbiological activity
91/414 Annex Point addressed	II 8.7 / 01	Effects on biological methods for sewage treatment

1.	Annex point(s)	II A, 8.7 **Effects on biological methods for sewage treatment**
2.	Location in Dossier	Section 6,
3.	Authors (year)	Grade, R. (1996b)
	Title	Report on the test for activated sludge respiration inhibition of CGA 293343 tech.
	Report No., Date Novartis File N°(Desire) Owner	95G002, 8 January 1996 293343/34 Novartis Crop Protection AG
4.	Testing facility	Ciba-Geigy Ltd. Ecotoxicology Department CH-4002 Basle Switzerland
5.	Dates of work	Study Initiation: 4 September 1995 Experimental Start: 20 September 1995 Experimental Termination: 20 September 1995 Study Completion: 4 September 1995
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	OECD- Guideline No.: 209 (Paris 1984) A settled sludge was used instead of a centrifuged sludge. The test substance was directly applied to the test medium and not as a stock solution.
8.	Deviations	none
9.	GLP	Yes , with the exception of the deviations to the protocol, the study was performed in compliance with Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, March 1986 (Verfahren und Grundsätze der Guten Laborpraxis (GLP) in der Schweiz, März 1986), issued by the Swiss Federal Department of the Interior and the Intercantonal Office for the Control of Medicaments, Switzerland. These procedures are based on the OECD Principles of Good Laboratory Practice, adopted May, 1981 by the decision of the OECD Council [C (81) 30 (Final)] concerning mutual acceptance of data in the assessment of chemicals.

Test System: CGA 293343 technical; Batch No.: [redacted] Activated sludge from the Reinach Sewage Treatment Plant in Switzerland was fed a standard amount of synthetic sewage. The pH of the sludge before use was 8.4. After settlement, 1.72 g sludge/L inoculate were treated with five test doses of thiamethoxam ranging from 1.0 to 100.0 mg a.i./L, two treatment blanks and three doses of a toxic standard (3,5-dichlorphenol) ranging from 3.2 to 32.0 mg a.i./L. Nominal concentrations were used. Oxygen consumption of bacteria was measured for three hours.

Findings:

Effects of thiamethoxam on activated sludge respiration

Nominal conc. [mg a.i./L]	Consumption rate [mg O_2/l/h]	Inhibition [a] [%]	EC_{50} [mg a.i./L]
1.0	69.2	1	
3.2	64.9	7	

10.0	72.7	-4	
32.0	50.0	28	
100.0	77.8	-11	> 100
Blank 1	70.6	-1	
Blank 2	69.2	1	
toxic standard 3.2	64.9	7	
10.	53.3	24	
32.0	15.6	78	2.19

[a] negative inhibition indicates stimulation

Conclusion: The 3-hour EC_{20}, EC_{50} and EC_{80} values were estimated to be >100 mg/L. No dose response relationship between the test substance doses and the Oxygen consumption rates were found, implying that CGA 293343 did not have an inhibitory effect on activated sludge respiration.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17/03/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.3.1 / 01	Prolonged toxicity to an appropriate species of fish
91/414 Annex Point addressed	II 8.2.2.1 / 01	Chronic toxicity test on juvenile fish

1.	Annex point(s)	**II A, 8.2.2.1** **Chronic Toxicity Test on Juvenile Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**33 PROLONGED TOXICITY TEST OF CGA 293343 TECH. TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) IN THE FLOW-THROUGH SYSTEM**
	Report No. / Date	95R003/ 30.07.1997
	Novartis File N°	Novartis Study # 293343-296
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	February 5, 1997 through March 25, 1997
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	OECD Guideline No.: 204, Fish- Prolonged Toxicity Test, 04/04/1984
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) OECD Principles of Good Laboratory, May 1981. 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical; Batch No.: [redacted] %. In a prolonged exposure test, effects of thiamethoxam on the growth and behaviour of juvenile Rainbow trout *(Oncorhynchus mykiss)* were investigated under flow-through conditions. The criteria for effects were mortality, weight gain, increase in length, food conversion index and other non-lethal effects on behaviour. Survival and growth were monitored during a period of 28 days of exposure. The study was performed with one tank per concentration and control containing ten fish each. Fish were individually marked and had a mean body weight of 1.8 g and a mean length of 57 mm at the beginning of the test. Five concentrations between 10 and 100 mg a.i./L were tested. The test substance appeared homogeneously distributed in the test vessels at all test times and test concentrations. The actual mean concentrations of thiamethoxam were 9.4, 19, 34, 60, and 109 mg a.i./L. corresponding to 95-109% of the nominal concentrations. Results are based on nominal concentrations.

Findings:

Prolonged toxicity of thiamethoxam to Rainbow trout

Concentration [mg a.i./L]		Mortality	Food conversion Index	Mean length of juveniles (28d)	Mean wet weight of juveniles (28d)
Nominal	Mean measured	[%]		[mm]	[mg]
Control	0	0	112.3	74.0	4.2
10	9.5	0	143.3	72.3	3.8
18	19	0	116.4	74.0	4.0
32	34	0	113.5	73.2	3.8
58	60	0	115.7	70.9	3.6
100	109	0	137.0	72.7	3.8

Observations: After 28 d exposure, no sublethal effects such as growth parameters (rate of weight gain, change in length and food conversion), feeding activity, change in swimming behaviour or respiratory function, pigmentation, loss of equilibrium as well as a reaction to external stimuli were observed at any concentration.

Conclusion: The NOEC (28 days) with regard to lethal and sublethal effects of thiamethoxam on Rainbow trout was 100 mg a.i./L. The LOEC was > 100 mg a.i./L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A 7.4.3.(01) Annex Point IIIA XIII.3		Effects on aquatic organisms – further studies	
		34 REFERENCE	**Official use only**
34.1	**Reference**	Ashwell, J., Dark, R. Emburey, S. (2003) Thiamethoxam 25 WG (A9584C) Outdoor Microcosm Study to Assess Effects on Aquatic Organisms. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Unpublished Report no. RJ3379B (Syngenta File no. CGA293343/1851). Study dates. 15th April – 19th September 2002.	
34.2	**Data protection**	Yes.	
34.2.1	Data owner	Syngenta Crop Protection.	
34.2.2	Companies with letter of access	[redacted]	
34.2.3	Criteria for data protection	[redacted]	
		35 GUIDELINES AND QUALITY ASSURANCE	
35.1	**Guideline study**	CLASSIC (Community Level Aquatic System Studies – Interpretation Criteria)(2002). Proceedings from the 1999 CLASSIC workshop. Society of Environmental Toxicology and Chemistry (SETAC), Florida and SETAC-Europe Brussels. HARAP (1999). Guidance document on higher-tier aquatic risk assessment for pesticides. Society of Environmental Toxicology and Chemistry-Europe, Brussels 179pp.	
35.2	**GLP**	Yes.	
35.3	**Deviations**	No.	
		36 MATERIALS AND METHODS	
36.1	**Test material**	ACTARA' 25 WG (A-9584).	
36.1.1	Lot/Batch number	[redacted]	
36.1.2	Purity	[redacted] (w/w) thiamethoxam.	
36.2	**Reference substance**	Not used.	
36.3	**Testing procedure**	An outdoor pond microcosm study was conducted to investigate the effects of A-9584 C on communities of freshwater organisms. The test systems were rectangular varied depth microcosms containing approximately 1300 L of water over 10 cm sediment, stocked with macrophytes and invertebrates. Communities were allowed to establish in the microcosms for a period of 12 weeks before chemical application. The replicated study design consisted of five A-9584 C treatments at 100, 30, 10, 3 and 1 µg ai/L, and an untreated control. A single application of A-9584 C was made to the microcosms on 18th June 2002. Application was made by direct addition and thorough mixing to rapidly distribute the formulation throughout the water column - taking the toxicological approach favoured by HARAP (Guidance document on Higher Tier Aquatic Risk Assessment for Pesticides, 1999) and CLASSIC (Community-Level Aquatic System Studies-Interpretation Criteria, 2002). Physico-chemical properties of the water and	

Section A 7.4.3.(01) Annex Point IIIA XIII.3		Effects on aquatic organisms – further studies	
		phytoplankton, zooplankton and macroinvertebrate communities were studied for up to 93 days after application. Multivariate analysis (Principal Response Curves method) was used to identify any treatment-related changes in community composition. Analysis of variance was also used to look at population level differences for selected taxa; those not analysed were considered to be either too variable in occurrence or not abundant enough to permit meaningful conclusions to be drawn.	
		37 RESULTS	
37.1	**Range finding test**	Not performed.	
37.2	**Results test substance**		
37.2.1	Initial concentration of test substance	Initial concentrations of thiamethoxam in the microcosms were measured at between 81 and 130 % of nominal (mean 99 %), and so it was considered that the appropriate treatment levels had been achieved at dosing.	
37.2.2	Effect data	No long-term ecologically adverse effects (on physicochemical parameters or communities of phytoplankton, zooplankton and macroinvertebrates) were observed at any of the treatment levels (up to and including 100 µg ai/L). An effect on Chironomidae was observed at 100 µg ai/L; however, this was an isolated event seen only in the emergence trap samples on day 15, and was not observed at any subsequent sampling points. The rapid dissipation of thiamethoxam in the microcosms as compared to laboratory-based tests is the likely explanation for effects seen in laboratory tests not being observed in this study.	
		38 APPLICANT'S SUMMARY AND CONCLUSION	
38.1	**Materials and methods**	As above.	
38.2	**Results and discussion**	Initial concentrations of thiamethoxam in the microcosms were measured at between 81 and 130 % of nominal (mean 99 %), and so it was considered that the appropriate treatment levels had been achieved at dosing. Thiamethoxam concentrations then declined rapidly following application with treatment means ranging from 34 % to 60 % of applied after 3 days. Concentrations were at or below 0.6 µg/L in all microcosms after 21 days. Results are reported in relation to nominal application concentrations of thiamethoxam.	
38.2.1	NOEC	30 µg ai/L.	
38.3	**Conclusion**	The No Observed Ecologically Adverse Effect Concentration (NOEAEC) of A-9584 C in an outdoor pond microcosm study was 100 µg ai/L, and 30 µg ai/L was determined to be the overall $NOEC_{community}$	
38.3.1	Reliability	1	
38.3.2	Deficiencies	No	

Section A 7.4.3.(01) **Annex Point IIIA XIII.3**	**Effects on aquatic organisms – further studies**	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	7-03-06	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks	[redacted]	

98/8 Doc IIIA section No.	7.4.3.2 / 01	*Effects on reproduction and growth rate on an appropriate species of fish*
91/414 Annex Point addressed	II 8.2.2.2 / 01	Fish early life stage toxicity test

1.	Annex point(s)	**II A, 8.2.2.2 Fish early life stage toxicity test**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	39 CGA-293343: AN EARLY LIFE-STAGE TOXICITY TEST WITH THE RAINBOW TROUT (ONCORHYNCHUS MYKISS)
	Report No. / Date	322-96, 108A-188 / 14.02.1997
	Novartis File N°	Novartis Study # 293343-205
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	September 13, 1996 through December 12, 1996
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	U.S. EPA Pesticide Assessment Guidelines, Subdivision E, Section No. 72-4(a) (1982), ASTM Standard E 1241-88 (1988) Standard Guide for conducting Early Life-Stage Toxicity Tests with Fish, and US EPA Standard Evaluation Procedure , Fish Early Stage Test.
8.	Deviations	none
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989; OECD, ISBN 92-84-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984..

Test System: Thiamethoxam technical; Batch No.: [redacted]
In a sub-chronic test, effects of thiamethoxam on early life stages of Rainbow trout *(Oncorhynchus mykiss)* were investigated under flow-through conditions. The criteria for effects were hatching success of embryos, time to hatch, time for larvae to swim-up and growth and survival of juveniles during a study period of 88 days. Fish embryos were exposed to a geometric series of five concentrations and a negative control. Four replicate test chambers were maintained in each treatment and control group, with each test chamber containing two incubation cups. The test was initiated with the distribution of newly-fertilised eggs to the incubation cups. Each cup contained 15 embryos resulting in a total of 30 embryos per replicate and 120 embryos per concentration group. The total exposure period was 88 days which included a 28-day hatching period and a 60-day post-hatch period. Insoluble material was not observed and the substance appeared in solution in all test vessels and at all times and concentrations. The mean measured concentrations of thiamethoxam based on weekly measurements were, 1.3, 2.5, 5.1, 10 and 20 mg test substance/L in the treated groups. The following calculations and values are based on mean measured concentrations.

Findings:

Toxicity of thiamethoxam to the early life stages of Rainbow trout

Concentration [mg a.i./L]		Percent hatch	Percent survival 18 d post hatch	Mean length of juveniles 60 d post hatch	Mean wet weight of juveniles 60-d post hatch
Nominal	Mean measured	[%]	[%]	[mm]	[mg]
control	0	77	98	50.5	0.277
1.3	1.3	73	99	51.3	0.28
2.5	2.5	74	99	51.1	0.277
5.0	5.1	75	100	50.9	0.277
10	10	76	100	51.3	0.283
20	20	73	100	51.7	0.29

Observations: There were no apparent treatment-related effects on time to hatch, hatching success, time to reach swim-up stage of development, larvae survival, fry survival or growth of Rainbow trout exposed to thiamethoxam.

Conclusion: The NOEC was 20 mg a.i./L, the highest concentration tested, while the LOEC were estimated to be greater than 20 mg a.i./L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.4.3.4 / 01	Effects on reproduction and growth rate with an appropriate invertebrate species
91/414 Annex Point addressed	II 8.2.5 / 01	Chronic toxicity to aquatic invertebrates

1.	Annex point(s)	**II A, 8.2.5 Chronic Toxicity to Aquatic Invertebrates**
2.	Location in Dossier	Section 6
3.	Authors / Year	Neumann, C. (1997b)
	Title	40 *DAPHNIA MAGNA* REPRODUCTION TEST: EFFECTS OF CGA 293343 ON THE REPRODUCTION OF THE CLADOCERAN *DAPHNIA MAGNA* STRAUS IN A SEMI-STATIC LABORATORY TEST
	Report No. / Date	95G004 / 24.09.1997
	Novartis File N°	Novartis Study # 293343-323
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection, Inc. Ecological Toxicology Laboratory, CH-4002, Basle, Switzerland.
5.	Dates of work	September 25, 1996 through February 26, 1997.
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., [redacted]
7.	Test method	OECD Guideline No.: 202, Paris 1984 (revised draft of OECD Guideline 202 Part II, January 1996), FIFRA Guideline No.72-4, December 24, 1989.
8.	Deviations	none
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) OECD Principles of Good Laboratory, May 1981. 4) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical; [redacted] Test organism: *Daphnia magna*; Age: ≤ 24 hours old; Daphnids were exposed to a geometric series of five concentrations of the test substance and a water control under semi-static conditions with renewal of the test solution three times a week. Ten replicate test chambers were maintained in each treatment and the control group. Nominal test concentrations were: 6.0, 12.5, 25.0, 50.0 and 100 mg/L. Measured contents of thiamethoxam in all test concentrations were greater than or equal to 90% of the nominal values throughout the exposure period with two exceptions of 89.6 and 81.6% of nominal for 12.5 mg/L on days 5 and 19 of exposure. Measured end concentrations were 6.5, 12.5, 24.9, 50.2, and 100.3 100 mg/L. The results were reported based on nominal values. Biological observations on adult survival, immobilisation and changes in behaviour or appearance were recorded daily. With the onset of brood production, young survival and immobilisation were also recorded daily.

Findings:

Reproductive toxicity of thiamethoxam to Daphnia magna

Concentration [mg a.i./L]		Adult mortality	Mean Time to first brood	Immobilisation of young daphnids	Mean Young/ female	Mean Adult Length
Nominal	Measured end	21 d [number]	[days]	21 d [%]	[number]	21 d [mm]
Control	0	0	9.0	0	122.2	4466
6	6.5	1	9.6	0	105.9	4312
12.5	12.5	1	8.9	0	117.3	4177
25	24.9	0	9.2	0	119.7	4432
50	50.2	1	9.0	0.8	125.4	4406
100	100.3	1	9.1	0	101.9	4282

Observations: Parental viability as well as the reproductive output of the cladoceran *Daphnia magna* strauss were not affected by the treatment with thiamethoxam up to nominal concentrations of 100 mg/L. Nor were clinical signs of toxicity or any other sublethal effects observed among the parent and the off-spring generation.

Conclusion: The No-observed-effect concentration was determined to be 100 mg/L (NOEC reproduction 21d). The lowest-observed-effect concentration (LOEC reproduction 21d) for the number of young produced per parent animal was not found within the test concentration range and was estimated to be greater than 100 mg/L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.3.5.1 / 01	Effects on sediment dwelling organism
91/414 Annex Point addressed	II 8.2.7 / 01	Effects on sediment dwelling organisms

1.	Annex point(s)	**II A, 8.2.7** **Effects on sediment dwelling organisms**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grade, R. (1998b)
	Title	**41 TOXICITY TEST OF CGA 293343 TECH. ON SEDIMENT-DWELLING *CHIRONOMUS RIPARIUS* (SYN. *CHIRONOMUS THUMMI*) UNDER STATIC CONDITIONS**
	Report No. / Date\	972552 / 02.10.1998
	Novartis File N°	Novartis Study # 293343-720
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection, Inc., Ecotoxicology Laboratories, CH-4002, Basle, Switzerland
5.	Dates of work	February 24, 1998 through May 5, 1998
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	BBA Guideline Proposal, 1995, Effects of Plant Protection Products on Sediment-Dwelling Larvae of Chironomus riparius in a water-Sediment System. OECD Guideline for Testing of Chemicals, Proposal for toxicity Test with Chironomidae, November 1997.
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) OECD Principles of Good Laboratory, May 1981. 4) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical; Batch No.: [redacted]%;. Test organism: *Chironomus riparius* larvae *(syn. Chironomjus thummi)*; Age: 2-3 days old 1st instar larvae. Two exposure scenarios were included in a water-sediment test system. In scenario A, thiamethoxam was applied to the water phase simulating a spray drift event. In scenario B, which was intended to simulate a run-off event, the compound was added to the sediment. The tests were performed in 1-L glass beakers containing approximately 1.6 cm sediment and a water column of 8 cm height at the beginning and of about 6 cm height at the end of the study. A constant temperature of 20 ± 2°C was maintained during the test with a photoperiod of 16 hours light and 8 hours dark.

Exposure Scenario A: A range of concentrations of thiamethoxam (1.25, 2.5, 5, 10, 20 and 50 µg/L) was applied below the surface to the water column of sediment-water systems using a pipette. The test was carried out under static conditions. Twenty-four hours before addition of the test substance 20 1st instar larvae of *Chironumus riparius* were introduced in the test vessels.

Measured test concentrations in the water phase were below the limit of detection for the first four concentrations and ranged between 9 and 33 µg a.i./L for the three highest concentrations at 1 to 3 hours after application of the substance. At the end of the study (day 30) measured concentrations had decreased below the limit of detection at all test concentrations. None of the metabolites could be identified. Results are based on nominal concentrations in the water phase.

Exposure Scenario B: Thiamethoxam treated sand was mixed with aged artificial sediment at a range of concentration (12.5, 25, 50, 100, 200 and 400 µg/kg sediment dry weight). The spiked sediment and water were added to the test vessels 21 hours prior to the introduction of *Chironomus* larvae and the start of the test.

Actual measured test concentrations in the water phase were below the limit of detection at test day 0 after addition of the larvae, except for the two highest dose levels (measured concentrations 6 and 11 µg/L in water). At the end of the study corresponding values were still below the limit of detection and were 11 and 13 µg/L for the two highest dose levels. In the sediment, measured concentrations ranged from being below the limit of detection to 160 µg/ kg sediment for the highest dose level (400 µg/kg sediment nominal) at test day 0. For this dose level, measured concentrations were 86, 76 and 0% of nominal values at day 0, 7 and 30, respectively. Traces of CGA 355190 were detected in these samples at day 30. No other metabolites could be identified in the remaining samples from any concentration level. Results were based on nominal concentrations in the sediment.

The biological assessment was based on impacts on full maturation of the larvae to adult midges. Main parameters examined were the rate and time of emergence and the total number of emerging male and female midges.

Findings:

Scenario A: Application to the Water Phase

Table 7.4.3.5.1/01-1 Chronic toxicity of thiamethoxam to Chironomus riparius following application to the water phase

Concentration [µg a.i./L]		Emergence Rate	Development Rate	30-d $E_{EM}C_{50}$ [a]	30-d $E_{DE}C_{50}$ [a]
Nominal	Measured Start (day 0)	[Mean midge emerged]	[Mean develoment rate]	[mg a.i./L]	[mg a.i./L]
0	-	1.28	0.087		
1.25	< LOQ	1.23	0.076	**0.0114**	**> 0.010**
2.5	< LOQ	1.26	0.073		
5.0	< LOQ	1.25	0.075		
10.0	9.0	1.22	0.075		
20.0	16.0	0.0	-	**NOEC = 0.010 mg a.i./L**	
40.0	33.0	0.0	-		

LOQ: limit of quantification
[a] $E_{EM}C_{50}$: Endpoint Emergence rate / $E_{DE}C_{50}$: Endpoint Development rate

Scenario B: Application to the Sediment

Table 7.4.3.5.1/01-2 Chronic toxicity of thiamethoxam to Chironomus riparius following application to the sediment

Concentration [µg a.i./kg dry weight]		Emergence Rate	Development Rate	30-d $E_{EM}C_{50}$ [a]	30-d $E_{DE}C_{50}$ [a]
Nominal	Measured Start (in sediment)	[Mean midge emerged]	[Mean develoment rate]	[mg a.i./kg sediment]	[mg a.i./kg sediment]
0	-	1.29	0.070		
12.5	< LOQ	1.31	0.066	**0.11**	**> 0.10**
25.0	< LOQ	1.06	0.068		
50.0	< LOQ	1.13	0.071		
100	< LOQ	1.08	0.071		
200	< LOQ	0.0	-	**NOEC = 0.10 mg a.i./kg sediment**	
400	160	0.0	-		

LOQ: limit of quantification
[a] $E_{EM}C_{50}$: Endpoint Emergence rate / $E_{DE}C_{50}$: Endpoint Development rate

Observations: Emergence in the controls was greater than 80% and the mean development time for the larvae in exposure scenario A and B was not longer than 23 days.

Conclusion: Exposure of *Chironomus riparius* to thiamethoxam, which was incorporated in the sediment simulating a run-off event, resulted in EC_{50} values of 0.11 mg a.i./kg for the emergence rate of larvae to adult midges and of > 0.10 mg a.i./kg sediment dry weight for the development rate of larvae. The NOEC was 0.10 mg a.i./kg sediment for both parameters.

If thiamethoxam is applied to the water phase the EC_{50} values for emergence and development rate in *Chironomus riparius* were 0.0114 and > 0.010 mg a.i./L water. The NOEC was 0.010 mg a.i./L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
	[redacted]
	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.4.3.5.1 / 02	Effects on sediment dwelling organism
91/414 Annex Point addressed	II 8.2.7 / 02	Effects on sediment dwelling organisms

1.	Annex point(s)	**II A, 8.2.7**	**Effects on sediment dwelling organisms**
2.	Location in Dossier	Section 6	
3.	Authors (Year)	Grade, R. (1999)	
	Title	Toxicity test of CGA 322704 (Metabolite of CGA 293343) on sediment-dwelling chironomus riparius (syn. *Chironomus thummi*) under static conditions.	
	Report No. / Date\	982581 / 09.02.1999	
	Syngenta File N°	322704/021	
	Source / Owner	Unpublished / Syngenta Crop Protection AG	
4.	Testing facility	Novartis Crop Protection, Inc., Ecotoxicology Laboratories, CH-4002, Basle, Switzerland	
5.	Dates of work	19th August 1998 through to 16th October, 1998	
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted]	
7.	Test method	BBA Guideline Proposal, 1995, Effects of Plant Protection Products on Sediment-Dwelling Larvae of Chironomus riparius in a water-Sediment System. OECD Guideline for Testing of Chemicals, Proposal for toxicity Test with Chironomidae, May 1998.	
8.	Deviations	None	
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. OECD Principles of Good Laboratory, May 1981.	

Test System: CGA 322704 (metabolite of thiamethoxam); Batch No.: [redacted] Test organism: *Chironomus riparius* larvae *(syn. Chironomus thummi)*; Age: 2-3 days old 1st instar larvae. The scenario in which the compound is added to the sediment and which is intended to simulate a run-off event was selected as a most probable exposure scenario for metabolites. The test was performed in 1-L glass beakers containing approximately 1.6 cm sediment and a water column of 8 cm height at the beginning and of about 6 cm height at the end of the study. A constant temperature of 20 ± 2°C was maintained during the test with a photoperiod of 16 hours light and 8 hours dark.

Exposure Scenario: CGA 322704 treated sand was mixed with aged artificial sediment at a range of concentrations (3.8, 7.5, 15, 30, 60 and 120 µg/kg sediment dry weight). The test concentrations were selected based on the results of a range finding study. The spiked sediment and water were added to the test vessels about 48 hours prior to the introduction of *Chironomus* larvae and the start of the test.

Findings: Actual measured concentrations of CGA 322704 in the water phase at test day 0 after addition of the larvae were below the limit of detection in the two lowest test concentrations and 0.3, 0.8, 0.14 and 0.78 µg/L in the remaining groups. At the end of the study (test day 28) corresponding values were below the limit of detection for the two lowest doses and 0.3, 0.9, 4.4 and 6.5 µg/L for four higher dose levels. The sediment concentrations were measured in samples from the two highest administration rates i.e. 60 and 120 µg/kg sediment dry weight equivalent to 48 and 96 µg/kg sediment wet weight. At day 0, 7 and 28 the measured

test substance concentrations in the sediment including interstitial water were 22, 18 and 18 µg/kg and 43, 39 and 18 µg/kg, respectively.

There were no indications on different sensitivities of sexes, therefore male and female results were pooled for statistical analysis. The biological assessment was based on impacts on full maturation of the larvae to adult midges. Main parameters examined were the rate and time of emergence and the total number of emerging male and female midges.

Emergence in the control samples was greater than 80% and the mean development time for the larvae was not longer than 23 days.

Findings:

Table 7.4.3.5.1/02-1 Chronic toxicity of CGA 322704 (metabolite of thiamethoxam) to Chironomus riparius following application to the sediment

Concentration CGA 322704		Emergence Rate	Development Rate	28-d $E_{EM}C_{50}$ [a]	28-d $E_{DE}C_{50}$ [a]
Nominal [µg/kg dry weight sediment]	Measured Start (sum sediment and water) [% nominal]	[Mean midge emerged]	[Mean of development rate per vessel]	[mg/kg sediment]	[mg/kg sediment]
0	-	0.88	0.057		
3.8	n.m.	0.90	0.060	**0.025**	**0.0529**
7.5	n.m.	0.92	0.060		
15	n.m.	0.90	0.069		
30	n.m.	0.12	0.037		
60	62	0.00	-	**NOEC = 0.015 mg/kg sediment**	
120	82	0.00	-		

n.m. = not measured

[a] $E_{EM}C_{50}$: Endpoint Emergence rate / $E_{DE}C_{50}$: Endpoint Development rate

Conclusion: Exposure of *Chironomus riparius* to CGA 322704 (metabolite of thiamethoxam) which was incorporated in the sediment simulating a run-off event, resulted in EC_{50} values of 0.025 mg/kg for the emergence rate of larvae to adult midges and of 0.0529 mg/kg sediment dry weight for the development rate of larvae. The NOEC was 0.015 mg CGA 322704/kg sediment for both parameters.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]

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

98/8 Doc IIIA section No.	7.4.3.5.1 / 03	Effects on sediment dwelling organism
91/414 Annex Point addressed	II 8.2.7 / 03	Effects on sediment dwelling organisms

1.	Annex point(s)	**II A, 8.2.7** **Effects on sediment dwelling organisms**
2.	Location in Dossier	Section 6
3.	Authors (Year)	Grade, R. (2000)
	Title	Toxicity Test of NOA 407475 (Metabolite of CGA 293343) on Sediment-Dwelling Chironomus riparius (syn. *Chironomus thummi*) under Static Conditions
	Report No. / Date\	982580 /July 12, 2000
	Syngenta File N°	407475/ 14
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Novartis Crop Protection, Inc., Ecotoxicology Laboratories, CH-4002, Basle, Switzerland
5.	Dates of work	20th January, 1999 through to 28th May, 1999
6.	Test substance	Company Code: NOA 407475, Batch number: [redacted]
7.	Test method	BBA Guideline Proposal, 1995, Effects of Plant Protection Products on Sediment-Dwelling Larvae of Chironomus riparius in a water-Sediment System. OECD Guideline for Testing of Chemicals, Proposal for toxicity Test with Chironomidae, May 1998.
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. OECD Principles of Good Laboratory, May 1981.

Test System: NOA 407475 (metabolite of thiamethoxam); Batch No.: [redacted] Test organism: *Chironomus riparius* larvae *(syn. Chironomus thummi)*; Age: 2-3 days old 1st instar larvae. The scenario in which the compound is added to the sediment and which is intended to simulate a run-off event was selected as a most probable exposure scenario for metabolites. The test was performed in 1-L glass beakers containing approximately 1.6 cm sediment and a water column of 8 cm height at the beginning and of about 6 cm height at the end of the study. A constant temperature of 20 ± 2°C was maintained during the test with a photoperiod of 16 hours light and 8 hours dark.

Exposure Scenario: NOA 407475 treated sand was mixed with aged artificial sediment at a range of concentrations (32, 63, 125, 250, 500 and 1000 µg/kg sediment dry weight). The test concentrations were selected based on the results of a range finding study. The spiked sediment and water were added to the test vessels about 48 hours prior to the introduction of *Chironomus* larvae and the start of the test.

Findings: Actual measured concentrations of NOA 407475 in the water phase were <LOD (limit of detection, 0.005 mg/L).at test day 0, 2, 7, 14 and 28 at the highest test concentration of 1.0 mg/kg sediment dry weight. Test substance concentrations in the sediment were analysed from specimens with the highest administration rate, i.e. 1000 µg/kg. The interstitial water was separated from the sediment specimens by centrifugation. The remaining sediment was extracted by stirring with a mixture of acetonitrile/water (75/25, V/V). At day –2, 0, 7 and 28

the measured test substance concentrations in the sediment (incl. interstitial water) were 91, 100, 100 and 100 µg/test vessel at a nominal concentration of 120 µg/test vessel. Total recovery from test system was 76, 83, 83 and 83 % of the nominal concentration at day –2, 0, 7 and 28.

There were no indications on different sensitivities of sexes at all test concentrations, therefore male and female results were pooled for statistical analysis. The biological assessment was based on impacts on full maturation of the larvae to adult midge. Main parameters examined were the rate and time of emergence and the total number of emerging male and female midges.

Emergence in the control samples was greater than 80% and the mean development time for the larvae was not longer than 23 days.

Table 7.4.3.5.1/03-1 Chronic toxicity of NOA 407475 (metabolite of thiamethoxam) to Chironomus riparius following application to the sediment

Concentration NOA 407475		Emergence Rate	Development Rate	28-d $E_{EM}C_{50}$ [a]	28-d $E_{DE}C_{50}$ [a]
Nominal [µg/kg dry weight sediment]	Measured Start (sum sediment and water) [% nominal]	[Mean midge emerged]	[Mean of development rate per vessel]	[mg/kg sediment]	[mg/kg sediment]
0	-	0.97	0.050		
32	n.m.	0.97	0.051	> 1.0	> 1.0
63	n.m.	0.98	0.054		
125	n.m.	0.95	0.052		
250	n.m.	0.95	0.048		
500	n.m	0.97	0.046	NOEC = 1.0 mg/kg sediment	
1000	83	0.85	0.058		

n.m. = not measured

[a] $E_{EM}C_{50}$: Endpoint Emergence rate / $E_{DE}C_{50}$: Endpoint Development rate

Conclusion: Exposure of *Chironomus riparius* to NOA 407475 (metabolite of thiamethoxam) which was incorporated in the sediment, resulted in EC_{50} values of >1.0 mg /kg for the emergence rate of larvae to adult midges and for the development rate of larvae. The NOEC was 1.0 mg /kg sediment for both parameters, the highest concentration tested.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 section No.	Doc IIIA	7.4.3.5.1 / 04	Effects on sediment dwelling organism
91/414 Point addressed	Annex	II 8.2.7 / 04	Effects on sediment dwelling organisms

1.	Annex point(s)	**II A, 8.2.7**	**Effects on sediment dwelling organisms**
2.	Location in Dossier	Section 6	
3.	Authors (Year)	Grade, R. (2002)	
	Title	Toxicity test of NOA 459602 (Metabolite of CGA 293343) on sediment-dwelling *Chironomus riparius (syn. Chironomus thummi)* under static conditions.	
	Report No. / Date\	2012671 / 04.06.2002	
	Syngenta File N°	459602/0009	
	Source / Owner	Unpublished / Syngenta Crop Protection AG	
4.	Testing facility	Syngenta Crop Protection AG. CH-4002, Basel, Switzerland	
5.	Dates of work	14th February 2002 through to 11th April 2002	
6.	Test substance	Company Code: NOA 459602, Batch number: [redacted]	
7.	Test method	Effects of Plant Protection Products on the Development of Sediment Dwelling Larvae of *Chironomus riparius* in a Water-Sediment System (BBA Guideline Proposal 1995) OECD Guideline for Testing of Chemicals, Proposal for a new Guideline 219, Sediment-water Chironomid toxicity test using spiked water, February 2001.	
8.	Deviations	None	
9.	GLP	With the exception of the range finding test, characterisation of sediment and development of analytical method, this study was performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice, adopted February 2nd, 2000 (RS 813.016.5). This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C (97) 186 (Final)].	

Test System: NOA 459602 (metabolite of thiamethoxam); Batch No.: [redacted] Test organism: *Chironomus riparius* larvae *(syn. Chironomus thummi)*; Age: 2-3 days old 1st instar larvae. The scenario in which the compound is added to the water and which is intended to simulate a spray-drift event was selected as a most probable exposure scenario for this metabolite. The test was performed in 1-L glass beakers containing approximately 1.6 cm sediment and a water column of approximtely 8 cm height at the beginning. Three replicates were set up to study emergence, whilst an additional replicate was included to determine larval survival and growth by day 10. A constant temperature of 21.0 – 21.7°C was maintained during the test with a photoperiod of 16 hours light and 8 hours dark and a light intensity of approximately 1000 lux. The conductivity was 790 and 785 µS/cm and the water hardness corresponded to 282 and 280 mg $CaCO_3$/L (two bottles).

Exposure Scenario: NOA 459602 stock solutions were added to the water column and the upper water layer was gently mixed without disrurbing the aged artificial sediment to give a range of concentrations (3.13, 6.25, 12.5, 50 and 100 mg/L). The test concentrations were selected based on the results of a range finding study. The water column was treated one day after the introduction of *Chironomus* larvae (20 larvae per test vessel).

Findings: Actual measured concentrations of NOA 459602 were 3.3, 7.1, 13.7, 53.3 and 106.9 mg/L, corresponding to 105.4, 113.6, 109.6, 106.6 and 106.9 % of nominal concentrations at the beginning of the test. At the end of the study (day 24) measured concentrations of NOA 459602 in the water phase were 2.7, 4.5, 10.9, 40.2 and 82.0 mg/L, corresponding to 86.3, 72.0, 87.2, 80.4 and 82.0 % of nominal concentrations at the beginning of the test. NOA 459602 concentrations in the sediment and the interstitial water was measured only for the highest test concentration and the lower one and the control. The amount in the sediment increased from 0.84 to 8.6 and 7.8 % of total nominal concentration of 50 mg/L at day 0, 7 and 24, respectively. For nominal concentration of 100 mg/L the amount in the sediment increased from 1.0 to 7.7 and 7.9 of total on these respective sampling days.

Oxygen content ranged from 5.1 to 6.8 mg/L just after application of the test item to test vessels. At test termination the oxygen content was within a range of 8.0 to 9.8 mg/L. The pH increased from 7.1 to 7.4 just after application to values ranging from 8.6 to 9.2 at test termination.

There were no indications of different sensitivities of sexes at all test concentrations, therefore male and female results were pooled for statistical analysis. The biological assessment was based on impacts on full maturation of the larvae to adult midge. Main parameters examined were the rate and time of emergence and the total number of emerging male and female midges. Growth measurements of the larvae via the estimation of the weight was carried out. After 10 days of exposure 17, 18, 20, 16, 20 and 19 larvae were found at blank and at test concentrations of 3.13, 6.25, 12.5, 50 and 100 mg/L. The corresponding average dry weight of the test groups were 1.43, 1.49, 1.38, 1.48, 1.25 and 1.39 mg/larvae.

Emergence in the control samples was greater than 80% and the mean development time for the larvae was not longer than 23 days.

Table 7.4.3.5.1/04-1 Chronic toxicity of NOA 459602 (metabolite of thiamethoxam) to Chironomus riparius following application to the water phase

Concentration NOA 459602		Emergence Rate	Development Rate	24-d $E_{EM}C_{50}$ [a]	24-d $E_{DE}C_{50}$ [a]
Nominal in water phase [mg/L]	Measured in water phase at a start [% nominal]	[Mean midge emerged/ introduced larvae]	[Mean of development rate per vessel]	[mg/L]	[mg/L]
0	-	0.98	0.072		
3.13	105.4	0.90	0.074	56.0	n.d.
6.25	113.6	0.93	0.072		
12.5	109.6	0.88	0.068		
50	106.6	0.90	0.075		
100	106.9	0.0	-	NOEC = 50 mg/L	

n.d. = not determined

[a] $E_{EM}C_{50}$: Endpoint Emergence rate / $E_{DE}C_{50}$: Endpoint Development rate

Conclusion: Exposure of *Chironomus riparius* to NOA 459602 (metabolite of thiamethoxam) which was incorporated in the water phase, resulted in EC_{50} values of 56.0 mg/L for the emergence rate of larvae to adult midges. No EC_{50} value for the development rate of larvae could be calculated. The NOEC for emergence rate and development rate were 50 mg /L for both parameters.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A 7.4.3.5.1 Annex Point IIIA XIII.3.4		Effects on sediment dwelling organisms	
		42 REFERENCE	Official use only
42.1	**Reference**	Smyth, D.V., Brown, R.J., Maynard, S.J., (2004); CGA 322704 (Thiamethoxam metabolite): Toxicity to the sediment dweller *Chironomus riparius* using spiked water. Brixham Environmental Laboratory, Brixham, Devon, England, Report No.: BL7987/B (Syngenta Project No. 2033605), 2 December 2004 (unpublished).	
42.2	**Data protection**	Yes.	
42.2.1	Data owner	Syngenta Crop Protection	
42.2.2	Companies with letter of access	None.	
42.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.	
		43 GUIDELINES AND QUALITY ASSURANCE	
43.1	**Guideline study**	Proposal for a new OECD Guideline 219: "Sediment-Water Chironomid Toxicity Test Using Spiked Water" (February 2001).	
43.2	**GLP**	Yes (certified laboratory).	
43.3	**Deviations**	None.	
		44 METHOD	
44.1	**Test material**	CGA 322704 (metabolite of CGA 293343)	
44.1.1	Lot/Batch number	[redacted]	
44.1.2	Purity	[redacted]	
44.1.3	Further relevant properties	Not applicable	x
44.2	**Preparation of TS solution for poorly soluble or volatile test substances**	A primary stock solution was prepared by direct addition to ASTM 'hard' water (prepared at half strength). Secondary stock solutions were prepared by using either aliquots of the primary stock or a higher concentration secondary stock solutions to dilution water	
44.3	**Reference substance**	Not used in this study.	x
44.4	**Testing procedure**		
44.4.1	Dilution water and sediment	See Table A 7.4.3.5.1-1	
44.4.2	Test organisms	See Table A 7.4.3.5.1-2	
44.4.3	Test system	See Table A 7.4.3.5.1-3	
44.4.4	Test conditions	See Table A 7.4.3.5.1-4	
44.4.5	Duration of the test	28 days.	
44.4.6	Test parameter	Emerged midges, development rate.	

Section A 7.4.3.5.1 Annex Point IIIA XIII.3.4		Effects on sediment dwelling organisms	
44.4.7	Examination / Sampling	Sex, time and number of emerged adults were observed daily during period of emergence.	
44.4.8	Monitoring of TS concentration	Yes. 0, 7, 28 days.	
44.4.9	Statistics	Normality analysis (Shapiro and Wilks, 1965), homogeneity of variance (Snedecor and Cochran, 1980), parametric analysis (Hayslett and Murphy, 1976), Mann Whitney U-test (Zar, 1999), probit analysis (Stephan, 1977).	
		45 RESULTS	
45.1	**Range finding test**	Not mentioned.	
45.2	**Results test substance**		
45.2.1	Initial concentrations of test substance	0.073, 0.22, 0.67, 2.0, 6.0 and 18 µg/L (nominal initial). See Table A 7.4.3.5.1-5.	
45.2.2	Effect data	See Table A 7.4.3.5.1-6,7,8.	
45.3	**Results of controls**	See Table A 7.4.3.5.1-5,6,7,8	
45.4	**Test with reference substance**	Not performed in this study.	x
		46 APPLICANT'S SUMMARY AND CONCLUSION	
46.1	**Materials and methods**	The influence of CGA 322704 (thiamethoxam metabolite) on development and emergence of larvae of *Chironomus riparius* in a water-sediment system was investigated according to the new OECD Guideline 219: "Sediment-Water Chironomid Toxicity Test Using Spiked Water" (February 2001). Larvae of *Chironomus riparius* (1st instars < 48 hours old, 4 beakers per test concentration and control with 20 animals each) were exposed for 28 days in a static test system to concentrations of 0.073, 0.22, 0.67, 2.0, 6.0 and 18 µg/L (nominal initial) in a water-sediment system (spiked water).	
46.2	**Results and discussion**	The validity criteria of the study were met, see table A7.4.3.5.1-9 The analytical results for the test concentrations of 0.22, 0.67, 2.0, 6.0 and 18 µg/L were 0.21, 0.69, 2.1, 4.9, and 15 µg/L, corresponding to 95, 103, 105, 82 and 83% of nominal concentrations on day 0. See table A 7.4.3.5.1-00. The results of the study are based on the nominal exposure concentrations. No emergence occurred at test concentrations of 6.0 and 18 µg /L. Total numbers of emerged midges were significantly lower in the 2.0 µg/L treatment. The EC_{50} based on the number of emerged midges after 28 days was calculated to be 1.2 µg/L (95% confidence intervals of 0.96 to 1.5	

Section A 7.4.3.5.1 Annex Point IIIA XIII.3.4	Effects on sediment dwelling organisms	
	µg/L). The nominal test concentrations of 0.67 µg/L and below were assessed as having no effect on chironomid emergence (P=0.05) based on the criteria time to first emergence, mean emergence time, number emerged after 28 days and the sex ratio of adults.	
46.2.1 NOEC	Time to first emergence – 2.0 µg/L Mean emergence time - 2.0 µg/L Number emerged after 28 days – 0.67 µg/L Sex ratio of adults – 0.67 µg/L	
46.3 Conclusion	The overall no-observed effect concentration (NOEC) for the study was 0.67 µg/L	
46.3.1 Reliability	1	
46.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11/4/2006	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		

Table A 7.4.3.5.1-1: Dilution water and sediment

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A 7.4.3.5.1-2: Test organisms

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A 7.4.3.5.1-3 Test system

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

[redacted]	[redacted]

Table A 7.4.3.5.1-4: Test conditions

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A 7.4.3.5.1-5: Analysis of CGA 322704 (thiamethoxam metabolite) in overlying water

Initial nominal concentration (µg/L)	Measured CGA 322704 concentrations (µg/L)		
	Day 0	Day 7	Day 28

[a] mean of triplicate analysis

Table A 7.4.3.5.1-6: Influence on the emergence and development of *Chironomus riparius* after 28 days (based on nominal initial concentrations of CGA322704)

Initial nominal concentration (µg/L)	Emergence of inserted larvae			Development (pooled sex)
	Time to first emergence (d)	Mean emergence time (d)	Mean total (%)	Mean rate (1/d)

- no emergence

Table A 7.4.3.5.1-7: Sex ratio of emerged adults

Initial nominal concentration (µg/L)	% males				
	Replicate A	Replicate B	Replicate C	Replicate D	Mean
[redacted]					

NR – replicate value not reported and excluded from statistical determination, error in number of midges added
* - significantly different to the control (P=0.05)
- no emergence

Table A 7.4.3.5.1-8: Influence on the emergence and development after 28 days (based on nominal initial concentrations)

Parameter	EC_{50} (µg/L)	95% confidence interval	No-observed effect concentration (P=0.05) (µg/L)
[redacted]			

Table A 7.4.3.5.1-9: Validity criteria for invertebrate reproduction test according to OECD Guideline 219

Criterion	fulfilled	Not fullfilled
[redacted]		

98/8 section No.	Doc IIIA	7.4.3.5.2 / 01	Aquatic plant toxicity
91/414 Point addressed	Annex	II 8.2.8 / 01	Aquatic plants

1.	Annex point(s)	**II A, 8.2.8 Aquatic Plants**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grade, R. (1998c)
	Title	**47 ACUTE TOXICITY TEST OF CGA-293343 TECH. TO THE DUCKWEED *LEMNA GIBBA* G3 UNDER SEMI-STATIC CONDITIONS**
	Report No. / Date\	972561 / 16.06.1998
	Novartis File N°	Novartis Study # 293343-595
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Ecotoxicology Department, CH-4002 Basle Switzerland
5.	Dates of work	October 17, 1997 through November 24, 1997
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted] Purity: [redacted]
7.	Test method	ASTM Guideline E1415-91, Lemna gibba. US-EPA FIFRA Guideline Number 122-2 and 123-2 OECD Guideline (Draft proposal, July 1996) OPPTS Guideline, 850.4400, Lemna gibba. EPA ecological test guidelines, Public Draft, April 1996.
8.	Deviations	None
9.	GLP	The study was conducted to conform with Good Laboratory Practice Standards as published by: 1) Good Laboratory Practice in Switzerland, Procedures and Principles, March 1986. 1) OECD Principles of Good Laboratory, May 1981. 1) U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160, 17 August 1989 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical; Batch No. [redacted] %. Fronds of *Lemna gibba* (strain G3) were exposed for 7 days to CGA 299343 in a static test system with renewal of the test solution after 3 days. Six concentrations ranging from nominal 3.13 to 100 mg/L were employed with three replicates per treatment level and the controls. The test was initiated by placing asceptically five plants with 2-5 fronds into each test vessel. At intervals of 3 days and at test termination fronds were counted and biological observations were made. The results are based on mean measured concentrations and are reported as the 7-day NOE_rC and E_rC_{50} values (the concentrations of test substance that reduced frond number and growth rate by 50% as compared to the control).

Findings:

Acute toxicity of thiamethoxam to aquatic higher plants

Frond production, relative to control, based upon frond number (growth rate) and frond dry weight (biomass) on Day 7						
Concentration [mg a.i./L]		Mean Frond Number	Mean Frond dry weight (biomass)	Reduction in growth rate [a]	Exposure period	EC_{50} (95 % conf. interval)
Nominal	Mean Measured	[mean indiv. counts]	[mg dry weight]	[%]	[days]	[mg a.i./L]
Control	-	181	29.6	0.00		
3.13	2.9	169	25.1	4.51		
6.25	5.7	184	29.3	0.04	7-day	> 90.2
12.5	11.4	172	25.9	4.14		
25	22.0	177	26.0	2.45		
50	43.9	185	31.5	0.91		
100	90.2	177	27.1	2.65	NOEC: 90.2 mg a.i./L	

[a] promotion of lemna growth with regard to control

Conclusion: The 7-day E_rC_{50} value for frond density was determined to be > 90.2 mg a.i./L, based on mean measured concentrations, and > 100 mg a.i./L based on nominal values. The EC_{50}, expressed as the reduction in frond biomass (dry weight), was also > 90.2 mg a.i./L. The NOEC for effects on frond density and biomass was found to be 90.2 mg a.i./L, the highest concentration tested.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 section No.	Doc IIIA	7.5.1.1 / 01	Inhibition of microbiological activity
91/414 Point addressed	Annex II	8.5 / 01	Effects on soil non-target micro-organisms

1.	Annex point(s)	**II A, 8.5 Effects on soil non-target micro-organisms**
2.	Location in Dossier	Section 6,
3.	Authors (year)	Bader, U. (1998):
	Title	The effect of CGA 293343 tech. on soil respiration and nitrification
	Report No., Date Novartis File N°(Desire) Owner	972515, 24 April, 1998 293343/532 Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG Basel Switzerland
5.	Dates of work	Study Initiation: 2 July 1997 Experimental Start: 14 January 1998 Experimental Termination: 27 February 1998 Study Completion: 24 April, 1998
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted] Purity: [redacted]
7.	Test method	BBA Guidelines, Part VI, 1-1 (2. edition) March 1990. OECD Guidelines for Testing of Chemicals (Draft June 1996), Soil Microorganisms, Carbon and Nitrogen Mineralisation. SETAC-Europe, Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides (March 1995). Deviations: Measuring of ammonium, nitrite and nitrate concentrations in soil was performed after amending the soil with powered Lucerne, the respiration rate was measured in soil not amended with Lucerne meal.
8.	Deviations	none
9.	GLP	Yes , Good Laboratory Practice (GLP) in Switzerland, Procedures and principles, March 1986, issued by the Federal department of the Interior and the Intercantonal Office for the Control of Medicaments, Switzerland. These are based on the OECD Principles of Good Laboratory Practice , adopted 12 May, 1981 by the decision of the OECD Council [C (81) 30 (Final)] concerning Mutual Acceptance of Data in the Assessment of Chemicals, the Recommendation of the Council of 26 July, 1983 concerning the Mutual Recognition of Compliance with Good Laboratory Practice [C (83) 95 (Final)], and the Council Decision-Recommendation of 2 October, 1989 concerning Compliance with Principles of Good Laboratory Practice Council [C (89) 87 (Final)]. With the exception of the determination of soil properties by Agrolab AG, CH-6030 Ebikon.

Test System: Thiamethoxam tech.; Batch No.: [redacted]%. The possible effects of thiamethoxam on soil micro-organisms were determined by measuring the rate of short-term respiration and nitrogen conversions (nitrogen mineralisation and nitrification) in soil treated with nominal test concentrations of 0.27 and 2.67 mg thiamethoxam/kg dry soil (10 times the lower test concentration).

The microbial biomass of the loamy sand, (0.99 % organic carbon and 71.86 % sand, pH 7.5), was measured prior to applying the test substance by substrate-induced respiration. The biomass was calculated from the constant initial respiration rate. It was determined to be 67 mg C per 100 g dry soil and confirm adequate microbial activity of the soil. Based on these results 1000

mg glucose per 100 g soil dry weight was added to the soil samples and the initial short-term respiration rates were measured over a period of approximately 24 hours. Soil respiration was measured over a period of 28 days. Nitrogen conversion was determined by measuring the content of NH_4-N and NO_3-N (NO_3 and NO_2-N) in soil amended with lucerne meal as a nitrogen source. Ammonium-N nitrite-N and nitrate-N were determined after 0-3 hours, 14 days and 28 days after application. The test method was calibrated with the reference substance Dinoseb.

Findings:

Rates of short-term respiration measured during the constant initial phase of respiration (% deviation of treated samples from the control)

Samples	Control	0.27 mg CGA 293343/kg dry soil		2.7 mg CGA 293343/kg dry soil		Dinoseb	
	[mg CO2/h]	[mg CO_2/h]	%	[mg CO_2/h]	%	[mg CO_2/h]	%
0-3 hours	1.858	1.882	1.3	1.845	-0.7	1.669	-10.2
day 14	2.067	2.000	-3.2	1.971	-4.6	1.396	-32.5
day 28	1.633	1.587	-2.8	1.524	-6.7	0.960	-41.2

After 0, 14 and 28 days of exposure no significant test substance induced effects on soil short term respiration rates were observed.

NO_3-N, NH_4-N and total-N concentrations in thiamethoxam- and dinoseb treated soil: Average concentrations in mg/100g soil dry weight at the lower and higher test item concentrations

Samples	Incubation								
	0-3 hours			14 Days			28 Days		
	NO_3-N	NH_4-N	Total-N	NO_3-N	NH_4-N	Total-N	NO_3-N	NH_4-N	Total-N
	[mg/100g soil dry weight]								
Control	4.70	0.93	5.7	6.50	1.30	7.8	8.15	0.55	8.7
0.27 mg CGA 293343/kg [a]	4.57	0.90	5.6	6.33	0.93	7.3	8.23	0.40	8.6
2.7 mg CGA 293343/kg [a]	4.47	0.97	5.5	6.07	0.87	6.9	7.97	0.43	8.4
Dinoseb	4.040	0.87	5.4	8.13	0.50	8.6	10.03	0.37	10.4

[a] kg dry weight of soil

NO_3-N, NH_4-N and total-N concentrations in thiamethoxam- and dinoseb treated soil: % deviation of treated samples from the control at the lower and higher test item concentrations

Samples	Incubation Day		
	0-3 hours	14 Days	28 Days
	[Total N, % deviation from control]		
Control	-	-	-
0.27 mg CGA 293343/kg [a]	-1.8	-6.4	-1.1
2.7 mg CGA 293343/kg [a]	-3.5	-11.5	-3.4
Dinoseb	-5.3	10.3	19.5

[a] kg dry weight of soil

In the loamy sand total-N concentrations over the whole incubation period, i.e. after 0, 14 and 28 days exposure to thiamethoxam, deviated by less than 12 % from the control at 0.27 mg thiamethoxam and 2.7 mg thiamethoxam/kg dry weight soil.

Conclusion: Thiamethoxam had no significant effects on soil short-term respiration rates or on nitrogen conversion up to a dose rate of 2.67 mg/kg dry soil. At test termination, 28 days after the treatment with thiamethoxam, short-term respiration and nitrogen conversion in soil differed by less than 12% from the control at all treatment rates. Thiamethoxam at the concentrations tested, therefore had, no adverse effects on organic matter turnover and hence on soil fertility according to the classification scheme given by Malkomes 1990[28].

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	29/12/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]d
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

[28]Malkomes, H.P. 1990/03: Richtlinien für die amtliche Prüfung von Pflanzenschutzmitteln Teil VII-1. 2. Auflage, Auswirkungen auf die Aktivität der Bodenmikroflora.

98/8 Doc IIIA section No.	7.5.1.1 / 02	Inhibition of microbiological activity
91/414 Annex Point addressed	II 8.5 / 01	Effects on soil non-target micro-organisms

1.	Annex point(s)	**II A, 8.5** **Effects on soil non-target micro-organisms**
2.	Location in Dossier	Section 6,
3.	Authors (Year)	Bader, U. (1999):
	Title	The effect of CGA 322704 + CGA 355190 (two Metabolites of CGA 293343) on soil respiration and nitrification
	Report No., Date	992668 / 11.11.1999
	Syngenta File N°	322704/0023
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Basel, Switzerland
5.	Dates of work	19th May 1999 through to 16th August 1999
6.	Test substance	Company Code: CGA 322704., Batch number: [redacted], Purity: [redacted]% Company Code: CGA 355190., Batch number: [redacted], Purity: [redacted]
7.	Test method	OECD Guidelines for Testing of Chemicals (revised draft January 1999), Proposal for a new Guideline 216, Soil Micro-organisms, Nitrogen Transformation test and Proposal for a new Guideline 217, Soil Micro-organisms, Carbon Transformation Test.
8.	Deviations	None
9.	GLP	Good Laboratory Practice (GLP) in Switzerland, Procedures and principles, March 1986, issued by the Federal department of the Interior and the Intercantonal Office for the Control of Medicaments, Switzerland. These are based on the OECD Principles of Good Laboratory Practice , adopted 12 May, 1981 by the decision of the OECD Council [C (81) 30 (Final)] concerning Mutual Acceptance of Data in the Assessment of Chemicals, the Recommendation of the Council of 26 July, 1983 concerning the Mutual Recognition of Compliance with Good Laboratory Practice [C (83) 95 (Final)], and the Council Decision-Recommendation of 2 October, 1989 concerning Compliance with Principles of Good Laboratory Practice Council [C (89) 87 (Final)]. With the exception of the determination of soil properties by Agrolab AG, CH-6030 Ebikon.

Test System: The possible effects of two metabolites of thiamethoxam, CGA 322704 and CGA 355190, on soil micro-organisms were determined by measuring the rate of short-term respiration and nitrogen conversions (nitrogen mineralisation and nitrification) in soil treated with nominal test concentrations of 0.1 and 0.5 mg of both CGA 322704 and of CGA 355190 /kg dry soil.

The microbial biomass of the loamy sand (1.78-1.86% OC, 56.4-64.2% sand) was measured prior to applying the test substance by substrate-induced respiration. The biomass was calculated from the constant initial respiration rate. It was determined to be 27.2 mg C per 100 g dry soil used for the respiration test and 23.5 mg in the soil used for the nitrogen transformation test. This confirms adequate microbial activity of the soil.

Based on these results 400 mg glucose per 100 g soil dry weight were added to the soil samples and the initial short-term respiration rates were measured over a period of approximately 24 hours. Soil respiration samples were taken after incubation periods of 1-3 hours, 7, 14 and 28 days at 20 ± 1° C in the dark.

Nitrogen conversion was determined by measuring the content of ammonium nitrogen (NH_4-N) and nitrate and nitrite nitrogen (NO_3- and NO_2-N) in soil amended with lucerne meal as a

nitrogen source. Ammonium-N, nitrite-N and nitrate-N were determined after 1-3 hours, 7 days, 14 days and 28 days after application. The test method was calibrated with the reference substance Dinoseb.

Findings:

Rates of short-term respiration measured during the constant initial phase of respiration (% deviation of CGA 322704 + CGA 355190 treated samples from the control)

Samples	Control	0.1 mg/kg dry soil		0.5 mg/kg dry soil		Dinoseb	
	[mg CO2/h]	[mg CO_2/h]	%	[mg CO_2/h]	%	[mg CO_2/h]	%
1-3 hours	11.57	10.86	-6.1	9.63	-16.8	10.21	-11.8
day 7	11.49	11.04	-3.9	10.35	-9.9	8.33	-27.5
day 14	9.35	9.82	5.0	9.37	0.2	6.29	-32.7
day 28	10.55	9.86	-6.5	9.47	-10.2	5.72	-45.8

After 0, 7, 14 and 28 days of exposure no significant test item induced effects on soil short term respiration rates were observed for both application rates.

NO_3-N, NH_4-N, NO_2-N and total-N concentrations in CGA 322704 + CGA 355190 - and in dinoseb treated soil: average concentrations in mg/kg soil dry weight at the lower and higher test item concentrations

Samples		Control	0.1 mg/kg dry soil	0.5 mg/kg dry soil	Dinoseb
1- 3 hours	NO_3-N	17.7	17.8	17.8	17.8
	NH_4-N	7.5	10.0	10.0	9.0
	NO_2-N	0.3	0.2	0.5	0.8
	Total-N	**25.5**	**28.0**	**28.3**	**27.6**
7 days	NO_3-N	27.1	19.4	16.4	37.3
	NH_4-N	4.8	4.7	4.7	5.0
	NO_2-N	0.2	0.2	0.2	0.7
	Total-N	**32.1**	**24.3**	**21.3**	**43.0**
14 days	NO_3-N	40.2	35.5	31.5	62.5
	NH_4-N	3.0	3.7	3.3	3.3
	NO_2-N	0.2	0.2	0.2	0.2
	Total-N	**43.4**	**39.4**	**35.0**	**66.0**
28 days	NO_3-N	55.6	51.1	50.5	80.1
	NH_4-N	1.5	1.7	2.0	1.3
	NO_2-N	0.2	0.2	0.2	0.2
	Total-N	**57.3**	**53.0**	**52.7**	**81.6**

Total N = sum of NO_3^-, NO_2^- and NH_4^+

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]

[redacted]

Conclusion

Reliability

Acceptability

Remarks

98/8 Doc IIIA section No.	7.5.1.2 / 01	Acute toxicity to earthworm and other non-target macro-organism
91/414 Annex Point addressed	II 8.4.1 / 01	Effects on earthworms: Acute toxicity

1.	Annex point(s)	**II A, 8.4.1 Effects on earthworms: Acute toxicity**
2.	Location in Dossier	Section 6,
3.	Authors (year)	Candolfi, M.P. (1995)
	Title	CGA 293343 tech: 14-day acute toxicity test with the earthworm (*Eisenia foetida*).
	Report No., Date Novartis File N°(Desire) Owner	95-065-1008, 28 November, 1995 293343/23 Novartis Crop Protection AG
4.	Testing facility	Springborn Laboratories AG Horn Switzerland
5.	Dates of work	Study Initiation: 4 September 1995 Experimental Start: 25 September 1995 Experimental Termination: 10 October 1995 Study Completion: 28 November, 1995
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted] Purity: [redacted]
7.	Test method	OECD-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test
8.	Deviations	none
9.	GLP	Yes , Performed in compliance with all the pertinent OECD and Swiss Good Laboratory Practice Standards (OECD, 1992; Eidg. Dept. des Innern, 1988) with the following exception: routine soil contaminant screening analysis for pesticides, PCBs and metals were conducted using standard U.S. EPA procedures by Lancaster Laboratories, Lancaster, PA.

Test System: Thiamethoxam tech.; Batch No.: [redacted]%. Test organism: earthworm (*Eisenia foetida foetida*); Age: mature adults with clitellum (> 2 months old); weight range of earthworms 300 to 600 mg; Source: Gier-Angel, Neuenhof, Switzerland. Earthworms were dosed by uniformly mixing the test substance into an artificial soil substrate which was then dispensed into each test vessel. The moisture content of the soil was 34 to 35% and the pH was 5.5 to 5.6. The study was a limit test with one test substance concentration of 1000 mg a.i./kg soil dry weight and one deionized water control (artificial soil substrate). Experimental design: 40 earthworms with 4 replicates per treatment (each replicate with 10 earthworms). Test duration: 14 days. Assessments on mortality and abnormal behaviour were made at 7 and 14 days after treatment. The worms were weighed at the beginning and end of the test.

Findings:

Acute toxicity of thiamethoxam to earthworms

Concentration [mg a.i./kg soil]	Mortality [%]		Mean Burrowing time [minutes]		Mean live weight [mg]		Mean change in live weight [%]	Exposure period [days]	LC_{50} (95 % conf. interval) [mg a.i./kg soil]
	7 d	14 d	0 d	7 d	0 d	14 d	0 - 14 d		
Control	0.0	0.0	4.5	4.0	349.3	361.2	3.4	**14**	**>1000 (none)**
1000	5.0	7.5	4.3	8.3	342.3	278.5	-18.6	14-d NOEC: <1000 mg a.i./kg soil	

Observations: A significant higher burrowing time of earthworms in the test item group (8.3 minutes) was noted compared to earthworms from the control group (4 minutes). Earthworms exposed to the control soil remained stable in weight over the 14 day exposure period, while, earthworms exposed to thiamethoxam lost weight (- 18.6%).

Conclusion: The 14-day LC_{50} for earthworms exposed to thiamethoxam was determined to be > 1000 mg a.i./kg dry weight soil and the overall NOEC was determined to be < 1000 mg a.i./kg dry weight soil (the only concentration tested).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]

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

98/8 Doc IIIA section No.	7.5.1.2 / 02 Acute toxicity to earthworm and other non-target macro-organism
91/414 Annex Point addressed	II 8.4.1 / 02 Effects on earthworms: Acute toxicity

1.	Annex point(s)	**II A, 8.4.1 Effects on earthworms: Acute toxicity**
2.	Location in Dossier	Section 6,
3.	Authors (Year)	Bryan, R.L. (1999a)
	Title	NOA 407475: An acute toxicity study with the Earthworm in an artificial soil substrate.
	Report No. / Date	108-417 / 09.12.1999
	Syngenta File N°	407475/0013
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Wildlife International, Ltd., 8598 Commerce Drive, Easton, Maryland 21601
5.	Dates of work	14th October 1999 through to 28th October 1999
6.	Test substance	Company Code: NOA 407475, Batch number: [redacted], Purity: [redacted]
7.	Test method	OECD-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test
8.	Deviations	Verification of the test concentrations, stability and homogeneity in the soil were not determined.
9.	GLP	Performed in compliance with all the pertinent Good Laboratory Practice Standards U.S. Environmental Protection Agency 40 CFR Parts 160 and 792, 17 August 1989, OECD and Japan MAFF) with the following exception : The stability of the test substance under storage conditions at the site was not conducted in accordance with GLP.

Test System: The acute effects of NOA 407475, metabolite of thiamethoxam; batch No. [redacted] on earthworms was tested.. Earthworms (*Eisenia foetida foetida*); of mature age with an average individual body weight 310 to 360 mg; Source: Willingham Worm Farm, Butler Georgia. Earthworms were dosed by uniformly mixing the test substance into an artificial soil substrate which was then dispensed into each test vessel. The moisture content of the soil was 33% approximately and the pH at preparation on day 0 was between 7.8 to 8.1. The worms were exposed to five test concentrations of 62.5, 125, 250, 500 and 1000 mg NOA 407475/kg of dry soil. Four replicate test chambers were maintained in each treatment and control group, with 10 worms in each chamber. Assessments on mortality and abnormal behaviour were made at 7 and 14 days after treatment. The worms were weighed at the beginning and end of the test and were not fed during testing. A reference toxicity test was conducted with chloroacetamide.

Findings: Acute toxicity of NOA 407475 (metabolite of thiamethoxam) to earthworms

Concentration of NOA 407475	Mortality [%]		Mean live weight [mg]		Mean change in live weight [%]	Exposure period	LC_{50} (95 % conf. interval)
[mg /kg soil]	7 d	14 d	0 d	14 d	0 - 14 d	[days]	[mg /kg soil]
Control	0.0	0.0	360	210	-41.7		
62.5	0.0	0.0	320	220	-31.3		
125	0.0	0.0	310	200	-35.5	**14**	**>1000 (none)**
250	0.0	0.0	310	190	-38.7		

500	0.0	0.0	320	180	-43.8	
1000	0.0	0.0	310	180	-41.9	14-d NOEC: 125 mg /kg soil

Observations: There was no apparent aversion to the soil in any of the treatment groups. All worms had burrowed into the soil within 75 minutes. Bodyweight change during the test was not statistically significant ($p>0.05$) at any concentration tested in comparison to the control group. There was some thinning and reduced reaction to external stimuli observed in the 250, 500 and 1000 mg/kg treatment group at test termination. There were no mortalities in any treatment group.

Conclusion: The 14-day LC_{50} for earthworms exposed to NOA 407405 (metabolite of thiamethoxam) was determined to be > 1000 mg /kg dry weight soil and the overall NOEC was determined to be 125 mg /kg dry weight soil based on thinning and reduced reaction observed in the three highest treatment groups.

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.1.2 / 03 Acute toxicity to earthworm and other non-target macro-organism
91/414 Annex Point addressed	II 8.4.1 / 03 Effects on earthworms: Acute toxicity

1.	**Annex point(s)**	**II A, 8.4.1 Effects on earthworms: Acute toxicity**
2.	**Location in Dossier**	Section 6,
3.	**Authors (Year)**	Bryan, R.L. (1999b)
	Title	CGA 355190: An acute toxicity study with the Earthworm in an artificial soil substrate.
	Report No. / Date	108-425 / 09.12.1999
	Syngenta File N°	355190/0006
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	**Testing facility**	Wildlife International, Ltd., 8598 Commerce Drive, Easton, Maryland 21601
5.	**Dates of work**	21st October 1999 through to 5th November 1999
6.	**Test substance**	Company Code: CGA 355190, Batch number: [redacted]
7.	**Test method**	OECD-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test
8.	**Deviations**	Verification of the test concentrations, stability and homogeneity in the soil were not determined.
9.	**GLP**	Performed in compliance with all the pertinent Good Laboratory Practice Standards U.S. Environmental Protection Agency 40 CFR Parts 160 and 792, 17 August 1989, OECD and Japan MAFF) with the following exception : The stability of the test substance under storage conditions at the site was not conducted in accordance with GLP.

Test System: CGA 355190, metabolite of thiamethoxam; batch No. [redacted] was used a s test substance. Test organism: earthworm (*Eisenia fetida*); Age: mature adults average individual body weight of earthworms was 300 to 320 mg; Source: Willingham Worm Farm, Butler Georgia, U.S.A. Earthworms were dosed by uniformly mixing the test substance into an artificial soil substrate which was then dispensed into each test vessel. The moisture content of the soil was 33% approximately and the pH at preparation on day 0 was between 7.6 to 7.7. The worms were exposed to five test concentrations of 62.5, 125, 250, 500 and 1000 mg CGA 355190/kg of dry soil. Four replicate test chambers were maintained in each treatment and control group, with 10 worms in each chamber. Assessments on mortality and abnormal behaviour were made at 7 and 14 days after treatment. The worms were weighed at the beginning and end of the test and were not fed during testing. A reference toxicity test was conducted with chloroacetamide. The test units were maintained at 20-22°C under continuous light of 458-772 lux.

Findings: Acute toxicity of CGA 355190 (metabolite of thiamethoxam) to earthworms

Concentration of CGA 355190	Mortality [%]		Mean live weight [mg]		Mean change in live weight [%]	Exposure period	LC_{50} (95 % conf. interval)
[mg /kg soil]	7 d	14 d	0 d	14 d	0 - 14 d	[days]	[mg /kg soil]
Control	0.0	0.0	320	230	-28.1		
62.5	0.0	0.0	320	220	-31.3		
125	0.0	0.0	310	210	-32.3	**14**	**753 (500-1000)**
250	2.5	2.5	320	210	-34.4		
500	0.0	0.0	310	180	-41.9		
1000	77.5	92.5	300	200	-33.3	14-d NOEC: 250 mg /kg soil	

Observations: There was no apparent aversion to the soil in any of the treatment groups on day 0, with all worms having burrowed into the soil within 75 minutes. On day 7 all worms having burrowed into the soil within 30 minutes, with the exception of of the highest test item concentration, in which aversion was noted. With one worm not having buried within 105 minutes. During the test the change in bodyweight was statistically significant ($p>0.05$) at the 500 mg/kg concentration tested in the comparison to the control group. No significant bodyweight differences were observed in the highest test item treatment and the control. However the statistical results for this treatment should be interpreted with caution due to the low numbers of surviving worms in this treatment. There was some thinning observed in the 500 and 1000 mg/kg treatment group at test termination. One worm from the 250 mg/kg treatment group was not found and presumed dead on day 7. However, the mortality was considered incidental.

Conclusion: The 14-day LC_{50} for earthworms exposed to CGA 355190 (metabolite of thiamethoxam) was determined to be 753 mg /kg dry weight soil and the overall NOEC was determined to be 250 mg /kg dry weight soil based on thinning and reduced reaction observed in the two highest treatment groups and mortality observed in the highest treatment group.

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	LC_{50}: 753 mg ai/kg dry soil(with a confidence interval of 500-1000 mg ai/kg dry [redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.1.2 / 04 Acute toxicity to earthworm and other non-target macro-organism
91/414 Annex Point addressed	II 8.4.1 / 04 Effects on earthworms: Acute toxicity

1.	Annex point(s)	**II A, 8.4.1 Effects on earthworms: Acute toxicity**
2.	Location in Dossier	Section 6,
3.	Authors (Year)	Pfeifle, V. (2000)
	Title	Acute Toxicity of CGA 355190 to the Earthworm *Eisenia fetida*.
	Report No. / Date	2002506 / 16.10.2000
	Syngenta File N°	355190/0007
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Solvias AG, Basel, Switzerland
5.	Dates of work	14th September 2000 through to 29th September 2000
6.	Test substance	Company Code: CGA 355190, Batch number: [redacted]
7.	Test method	OECD-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test Commission Directive 87/302/EEC, Official Journal of the European Communities L133, Part C, pp 95-98.
8.	Deviations	None
9.	GLP	Performed in compliance with the Swiss Ordinance relating to Good Laboratory Practice, adopted February 2nd, 2000 [RS 813.016.5]. This Ordinance is based on the OECD Principles of Good Laboratory Practice, as revised in 1997 and adopted November 26th, 1997 by decision of the OECD Council [C(97)186/Final]. These procedures are based on the OECD Principles of Good Laboratory Practice, adopted May 12, 1981 by Decision of the OECD Council [C (81) 30 (Final)] concerning Mutual Acceptance of Data in the Assessment of Chemicals, as amended by the Council Decision-Recommendation of 2nd October 1989 concerning Compliance with Principles of Good Laboratory Practice [C (89) 87 (Final)].

Test System: CGA 355190, metabolite of thiamethoxam; batch No. [redacted] was the test item. Test organism: earthworm (*Eisenia fetida*); Age: approximately 9 month old mature adults average replicate body weight of earthworms was 330 to 384 mg; Source: From cultures at the testing facility, orginally obtained from SARL; Moulin, Litz, France. The test units consisted of 1.5 L glass jars filled with 700 g moist soil, equivalent to 500 g dry weight (soil specifications according to OECD 207). The test item was uniformly mixed into an artificial soil substrate which was then dispensed into each test unit. The moisture content of the soil was 37.3-37.8% and the pH at preparation on day 0 was 5.8 to 6.1. The worms were exposed to five test concentrations of 95, 171, 309, 556 and 1000 mg CGA 355190/kg of dry soil, by placing them on the soil surface. Four replicate test units were maintained in each treatment and control group, with 10 worms in each unit. Assessments on the mortality and behaviour/condition were made at 7 and 14 days after treatment, at which times the soil was removed from the test units and sorted through for the worms. Following the assessment on day 7 the soil was returned to the test units and the surviving worms replaced on the soil surface. The worms were weighed at the beginning and end of the test and were not fed during testing. In addition burrowing times were noted on days 0 and 7. The results from a reference toxicity test with chloroacetamide were also reported. The test units were maintained in continuous light (mean 448 lux) at a temperature of 18.5-21.0°C

Findings:

Acute toxicity of CGA 355190 (metabolite of thiamethoxam) to earthworms

Concentration of CGA 355190	Mortality [%]		Mean live weight [mg]		Mean change in live weight [%]	Exposure period	LC_{50} (95 % conf. interval)
[mg /kg soil]	7 d	14 d	0 d	14 d	0 - 14 d	[days]	[mg /kg soil]
Control	0.0	0.0	350	332	-5		
95	0.0	0.0	345	308	-11		
171	0.0	0.0	352	309	-12	**14**	**> 1000 (none)**
309	0.0	0.0	339	280	-18		
556	0.0	0.0	345	263	-24		
1000	0.0	5.0	348	225	-35	14-d NOEC: 171 mg /kg soil	

Observations: In the control and all test item treatments up to and including 556 mg CGA 355190/kg dry weight soil all worms had burrowed beneath the soil surface within 15 minutes at test start and on day 7. At the highest concentration tested (1000 mg/kg dry weight soil) all worms had buried beneath the soil surface within 15 minutes of the test start. However, on day 7 worms had still not buried within 2 hours of placing them on the soil surface. No sublethal effects, such as abnormal behaviour, flaccidity or other symptoms were observed in the control and the test item concentrations of 95, 171 and 309 mg/kg dry weight soil. At 556 mg CGA 355190/kg dry weight soil no sublethal effects were noted at day 7. However, after 14 days of exposure light flaccidity and open wounds were noted. At 1000 mg CGA 355190/kg dry weight soil moderate flaccidity was noted at day 7, with open wounds and severe flaccidity being recorded by test end. A dose-dependant reduction in bodyweight was observed during the test with such reductions being statistically significantly greater than in the control, in the test item concentrations of 171 mg/kg dry weight soil and higher. Despite the statistically significant difference of the decrease in body weight in the 171 mg/kg dry weight soil treatment group, the effect can be regarded as lying within the normal biological variation of the historical control in this test system, and is therefore considered not to be biologically relevant.

Conclusion: The 14-day LC_{50} for earthworms exposed to CGA 355190 (metabolite of thiamethoxam) was determined to be > 1000 mg /kg dry weight soil and the overall NOEC was determined to be 171 mg /kg dry weight soil based on biologically relevant bodyweight reductions in the three highest treatment groups.

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.5.1.2 / 05	Acute toxicity to earthworm and other non-target macro-organism
91/414 Annex Point addressed	II 8.4.1 / 05	Effects on earthworms: Acute toxicity

1.	Annex point(s)	**II A, 8.4.1** **Effects on earthworms: Acute toxicity**
2.	Location in Dossier	Section 6,
3.	Authors (Year)	Porch, J.R (2000)
	Title	CGA 322704: An acute toxicity study with the Earthworm in an artificial soil substrate.
	Report No. / Date	108-418A 28.03.2000
	Syngenta File N°	322704/0026
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Wildlife International, Ltd., 8598 Commerce Drive, Easton, Maryland 21601
5.	Dates of work	11th January 2000 through to 26th January 2000
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted]
7.	Test method	OECD-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test
8.	Deviations	Verification of the test concentrations, stability and homogeneity in the soil were not determined.
9.	GLP	Performed in compliance with all the pertinent Good Laboratory Practice Standards U.S. Environmental Protection Agency 40 CFR Parts 160 and 792, 17 August 1989, OECD and Japan MAFF) with the following exception : The stability of the test substance under storage conditions at the site was not conducted in accordance with GLP.

Test System: CGA 322704, metabolite of thiamethoxam; batch No. [redacted] was used a s test substance. Test organism: earthworm (*Eisenia foetida foetida*); Age: mature adults average individual body weight of earthworms was 400 to 440 mg; Source: Worm Man's Worm Farm, Monroe Twp., NJ. Earthworms were dosed by uniformly mixing the test substance into an artificial soil substrate which was then dispensed into each test vessel. The moisture content of the soil was approximately 31% of the dry weight of the soil and the pH at preparation on day 0 was between 6.7 to 6.9. The worms were exposed to six test concentrations of 1.25, 2.50, 5.00, 10.0, 20.0 and 40.0 mg CGA 322704/kg of dry soil. The test concentrations were selected based upon the results of a range finding study. Four replicate test chambers were maintained in each treatment and control group, with 10 worms in each chamber. Assessments on mortality and signs of toxicity were made at 7 and 14 days after treatment. The worms were weighed at the beginning and end of the test and were not fed during testing. A reference toxicity test was conducted with chloroacetamide.

Findings:

Acute toxicity of CGA 322704 (metabolite of thiamethoxam) to earthworms

Concentration of CGA 322704	Mortality [%]		Mean live weight [mg]		Mean change in live weight [%]	Exposure period	LC_{50} (95 % conf. interval)
[mg /kg soil]	7 d	14 d	0 d	14 d	0 - 14 d	[days]	[mg /kg soil]
Control	0.0	0.0	430	370	-14.0		
1.25	0.0	0.0	420	330	-21.4		
2.50	0.0	0.0	430	340	-20.9	**14**	**5.93 (5.31-6.65)**
5.00	5.0	30.0	400	310	-22.5		
10.0	47.5	95.0	410	350	-14.6		
20.0	97.5	100.0	430	-	-		
40.0	100.0	100.0	440	-	-	14-d NOEC: 2.50 mg /kg soil	

Observations: As was observed in the control group, a slight loss in average individual body weights from day 0 to day 14 is typical, since the worms were not fed during the test. There was no apparent aversion to the soil in any of the treatment groups on day 0. All worms had burrowed into the soil within one hour on Day 0. There was apparent aversion to the soil on day 7. Two worms had not burrowed in the 5.00 mg/kg group after two hours. In the 10.0 mg/kg group eight worms had not burrowed and an additional worm had partially burrowed. All worms in the two lowest treatment groups were normal in appearance and behaviour on day 14. In the 5.00 mg/kg group signs of toxicity such as necrosis, thinner in size and demonstrating reduced reaction to mechanical stimuli were observed on during the test.

Conclusion: The 14-day LC_{50} for earthworms exposed to CGA 322704 (metabolite of thiamethoxam) was determined to be 5.93 mg /kg dry weight soil and the overall NOEC was determined to be 2.50 mg /kg dry weight soil based on, signs of necrotic appearance, thinning and reduced reaction observed in the four highest treatment groups.

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	13/01/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.5.1.2 / 06 Acute toxicity to earthworm and other non-target macro-organism
91/414 Annex Point addressed	II 8.4.1 / 06 Effects on earthworms: Acute toxicity

1.	**Annex point(s)**	**II A, 8.4.1** **Effects on earthworms: Acute toxicity**
2.	**Location in Dossier**	Section 6,
3.	**Authors (Year)**	Gillham, A. (2002)
	Title	Acute toxicity (LC_{50}) of the metabolite NOA 459602 to the Earthworm (*Eisenia fetida*) in an artificial soil test.
	Report No., Date	JW2401 / 28.02.2002
	Syngenta File N°	459602/0004
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	**Testing facility**	Central Science Laboratory, Sand Hutton, York, England.
5.	**Dates of work**	12th December 2001 through to 22nd January 2002
6.	**Test substance**	Company Code: NOA 459602; batch No. [redacted]
7.	**Test method**	OECD-Guideline No. 207, 1984, Earthworm, Acute Toxicity Test. Directive 87/302/EEC, Part C.
8.	**Deviations**	None
9.	**GLP**	Performed in compliance with United Kingdom Good Laboratory Practice Statutory Instrument No. 3106 December 1999. These regulations are in accordance with the OECD Principles of Good Laboratory Practice 1997 [ENV/MC/CHEM(98)17] and re believed to be consistent with the EPA (FIFRA regulations.

Test System: NOA 459602, metabolite of thiamethoxam; batch No. [redacted] Test organism: earthworm (*Eisenia fetida*); Age: mature adults at least 2 months old with clitellum, average individual body weight of earthworms was 300 to 600 mg. Earthworms were dosed by uniformly mixing the test item into an artificial soil substrate which was then dispensed into each test vessel. The moisture content of the soil was approximately 35% of the soil dry weight and the pH at preparation on day 0 was 6 ± 0.5. The worms were exposed to two test concentrations of 100 and 1000 mg NOA 459602/kg of dry soil. Four replicate test chambers were maintained in each treatment and control group, with 10 worms in each chamber. Assessments on mortality and signs of toxicity were made at 7 and 14 days after treatment. The worms were weighed at the beginning and end of the test and were not fed during testing. A reference toxicity test was conducted with chloroacetamide at a single concentration of 50 mg/kg dry soil. The test vessels were maintained at 20.0 to 21.3°C and in continuous light of bewteen 430-525 lux.

Findings:

Acute toxicity of NOA 459602 (metabolite of thiamethoxam) to earthworms

Concentration of NOA 459602	Mortality [%]		Mean live weight [mg]		Mean change in live weight [%]	Exposure period	LC_{50} (95 % conf. interval)
[mg /kg soil]	7 d	14 d	0 d	14 d	0 - 14 d	[days]	[mg /kg soil]
Control	0.0	0.0	407	384	- 6		
100	0.0	0.0	411	396	- 4	**14**	**> 1000 (n.a.)**
1000	0.0	0.0	413	398	- 4	14-d NOEC: 1000 mg /kg soil	
Chloroacetamide 50 mg /kg soil	-	100	415	n.a.	n.a.		

n.a. - not applicable

Observations: As was observed in the control group, a slight loss in average individual body weights from day 0 to day 14 is typical, since the worms were not fed during the test. There were no mortalities or abnormal signs of behaviour (such as worms remaining on the soil surface) in the control and eirther of the two test item treatments. All worms died within 14 days of exposure to chloroacetamide at 50 mg/kg dry soil.

Conclusion: The 14-day LC_{50} for earthworms exposed to NOA 459602 (metabolite of thiamethoxam) was determined to be > 1000 mg /kg dry weight soil and the overall NOEC was determined to be 1000 mg /kg dry weight (the highest concentration tested).

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
[redacted]	

Section A7.5.1.2 (applicant) Earthworm, reproduction toxicity test (applicant)

Section A7.5.2.1_01 Annex Point IIIA XIII 3.2 Reproduction study with other soil non-target macro-organisms

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		48 REFERENCE
48.1	**Reference**	Bätscher, R. (2000): Effects of CGA 322704 (metabolite of CGA 293343) on survival, growth, and reproduction of the earthworm *Eisenia fetida* RCC Ltd., Report No.: 773976 (Syngenta Project No. 2002615), 9 October 2000 (unpublished).
48.2	**Data protection**	Yes.
48.2.1	Data owner	Syngenta Crop Protection
48.2.2	Companies with letter of access	[redacted]
48.2.3	Criteria for data protection	[redacted]
		49 GUIDELINES AND QUALITY ASSURANCE
49.1	**Guideline study**	ISO 11268-2: 1998 (E) BBA Guideline Part VI, 2-2, 1994
49.2	**GLP**	Yes.
49.3	**Deviations**	None.
		50 METHOD
50.1	**Test material**	CGA 322704 (metabolite of CGA 293343)
50.1.1	Lot/Batch number	[redacted]
50.1.2	Specification	As given in section 2
50.1.3	Purity	[redacted]
50.2	**Reference substance**	Benomyl WS50% was applied in a similar, separate study at 10 mg formulation/kg dry soil (equivalent to 5 mg a.s./kg dry soil).
50.3	**Testing procedure**	
50.3.1	Preparation of the test substance	The test substance was dissolved in purified water to provide a stock solution of 15 mg/L. This was diluted tenfold to provide the 0.3 mg/kg application solution, further dilutions were sued to prepare the 0.18 and 0.06 mg/kg application solutions (see table A7_5_1_2-1)
50.3.2	Application of the test substance	Each test replicate was prepared individually by the addition of 100 Ml of the appropriate application solution to the individual test vessel containing 500 g soil (dry weight).
50.3.3	Test organisms	See table A7_5_1_2-2
50.3.4	Test system	See table A7_5_1_2-3
50.3.5	Test conditions	See table A7_5_1_2-4
50.3.6	Test duration	8 weeks, adults were present for the first weeks, the second four week

		was without adults
50.3.7	Test parameter	Mean weight, mortality and reproduction, qualitative assessment of food consumption
50.3.8	Examination	See tables A7_5_1_2-5 – 7 for details of examinations
50.3.9	Monitoring of test substance concentration	No
50.3.10	Statistics	Williams-test, one sided smaller

51 RESULTS

51.1	**Filter paper test**	Not performed
51.1.1	Concentration	Not applicable
51.1.2	Number/ percentage of animals showing adverse effects	Not applicable
51.1.3	Nature of adverse effects	Not applicable
51.2	**Soil test**	
51.2.1	Initial concentrations of test substance	0.06, 0.18 and 0.3 mg/kg dry soil
51.2.2	Effect data (mortality, weight and reproduction)	The mortality data is presented in table A7_5_1_2-5; Body weight data is presented in table A7_5_1_2-6; Reproduction data is presented in table A7_5_1_2-7
51.2.3	Concentration / effect curve	Not applicable
51.2.4	Other effects	Not applicable
51.3	**Results of controls**	
51.3.1	Mortality	Control mortality was 5% (2 dead worms from 40).
51.3.2	Number/ percentage of earthworms showing adverse effects	No worms showed any adverse effects
51.3.3	Nature of adverse effects	Not applicable
51.4	**Test with reference substance**	Performed (as a separate study)

Section A7.5.1.2 (applicant) Earthworm, reproduction toxicity test (applicant)

Section A7.5.2.1_01
Annex Point IIIA XIII 3.2

Reproduction study with other soil non-target macro-organisms

51.4.1	Concentrations	5 mg a.s./kg dry soil
51.4.2	Results	Survival rate was not significantly affected, however a significant reduction in mean body weight was observed. The reproduction rate of *Eisenia fetida* was almost completely inhibited (0.1% of the control value).

52 APPLICANT'S SUMMARY AND CONCLUSION

52.1	**Materials and methods**	ISO 11268-2: 1998 (E) BBA Guideline Part VI, 2-2, 1994 No deviations
52.2	**Results and discussion**	The control group mortality was 5% after 28 days exposure. Mortality in the 0.06, 0.18 and 0.3 mg/kg treatments was 0, 2.5 and 0% respectively. Therefore CGA 322704 had no effect on the survival rate of adult *E. fetida* up to a rate of 0.3 mg/kg dry soil. There was a temporary reduction in food consumption in the 0.18 and 0.3 mg/kg treatments on day 7 only. The mean body weight of the control earthworms increased by 25% during the exposure period. The increases in body weight in the CGA 322704 treatments were slightly lower compared to the control, 12, 19 and 19% in the 0.06, 0.18 and 0.3 mg/kg treatments respectively. However, this slight reduction was not statistically significant. In the control the mean number of juveniles produced per surviving adult was 17.4. The mean number of juveniles produced per surviving adult was 17.9, 7.3 and 10.4 in the 0.06, 0.18 and 0.3 mg/kg treatments respectively. The reproduction rate was 103% of the control for the 0.06 mg/kg treatment, 42 and 60% for the 0.18 and 0.3 mg/kg treatments respectively. Reproduction was significantly reduced at the 0.18 and 0.3 mg/kg treatments (α = 0.05)
52.2.1	NOEC	The highest concentration of CGA 322704 tested without toxic effects on survival, body weight and reproduction of *Eisenia fetida* was 0.06 mg/kg dry soil.
52.3	**Conclusion**	The highest concentration of CGA 322704 tested without toxic effects on survival, body weight and reproduction of *Eisenia fetida* was 0.06 mg/kg dry soil. The validity criteria of the study were met, see table A7_5_1_2-8.
52.3.1	Other Conclusions	None
52.3.2	Reliability	1
52.3.3	Deficiencies	No

Section A7.5.1.2 (applicant) Earthworm, reproduction toxicity test (applicant)

Section A7.5.2.1_01 Annex Point IIIA XIII 3.2 Reproduction study with other soil non-target macro-organisms

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	21/03/2006
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Table A7_5_1_2-1: Preparation of TS solution

Criteria	Details
Type and source of dilution water	Purified water
In case of the use of an organic solvent	
Dispersion	No

Table A7_5_1_1-2: Test organisms

Criteria	Details
Species/strain	*Eisenia fetida*
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]