Findings: Overall recoveries comprising adsorption and desorption steps ranged from 95.6 ± 6.0% to 100.7 ± 8.8 % for the four concentrations used. The stability of CGA 322704 during the process was confirmed by HPLC. The 1/n values obtained indicate that a nonlinear relationship exists between concentrations in solution and adsorption. The Freundlich adsorption coefficient K_F varied between 1.06 mL/g for the sand and 8.00 mL/g for the sandy clay loam. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 70.5 to 382.5 mL/g with an average K_{OC} value of 173.5 mL/g. The desorption K_{OC} values were higher than the adsorption K_{OC} values with an average of 387.7 mL/g. This indicates that adsorption was not fully reversible. The data are presented in Table 2.

Table 2 Adsorption and desorption constants of CGA 322704 in various soils (Concha 1998b)

Soil texture	Adsorption (mL/g)			1. Desorption (mL/g)		
	K_F	K_{OC}	1/n	K_F	K_{OC}	1/n
Carman Sandy loam	1.53	382.5	0.7708	4.01	1002.5	0.7958
Niagara Clay	1.48	70.5	0.8104	3.31	157.6	0.7641
Lakeland Sand	1.06	176.7	0.8170	2.52	420.0	0.8708
Rignold Sandy Loam	8.00	205.1	0.7719	12.14	311.3	0.7457
Honeywood Loam	2.04	113.3	0.8178	3.93	218.3	0.8150
Niagara Silt loam	1.49	93.1	0.7625	3.46	216.3	0.8726
Average	**2.60**	**173.5**	**0.7917**	**4.90**	**387.7**	**0.8107**

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Date	28/02/05
Materials and Methods	[redacted]

[redacted]

[redacted]

Reference Substance	Reference No.	Purity	Receipt Date	Reassay Date
CGA-322704	DAH-XXIV-18	>99.9%	8/21/97	5/99
NOA-404617	DAH-XXIV-27	99.9%	8/21/97	6/99

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

98/8 Doc IIIA section No.	7.2.3.1 / 07	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2	Adsorption and desorption

1.	Annex point(s)	**II A, 7.1.2 Adsorption and Desorption**
2.	Location in Dossier	Section 5
3.	Authors (year)	Hein, W., Dorn, R. (2001c)
	Title	Adsorption /Desorption of [Thiazol-2-^{14}C]-CGA 322704 on Birkenheide Soil
	Report No., Date Syngenta File N° Owner	NOV19, 12 September, 2001 322704/0034 Syngenta Crop Protection AG
4.	Testing facility	Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau, 67435 Neustadt an der Weinstrasse, Germany
5.	Dates of work	Experimental Start: November 15, 2000 Experimental termination: July 2, 2001
6.	Test substance	CGA 322704 (metabolite of thiamethoxam) Company Code: (thiazol-4-^{14}C) CGA 322704, Batch: [redacted] specific radioactivity: 2.08 MBq/mg, radiochemical purity: [redacted]%
7.	Test method	OECD Guideline for Testing of Chemicals, No 106 "Adsorption/Desorption", Jan. 21, 2000
8.	Deviations	Supplemental study.
9.	GLP	yes (Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau (SLFA), Breitenweg 71, D-67435 Neustadt/Weinst)

Test system: Adsorption and desorption of [Thiazol-2-^{14}C]-CGA 322704 were measured using a batch equilibrium procedure to determine the Kd and the K_{OC} values ^{14}C-labelled CGA 322704. For the test one soil characterised in Table 1 was used. Analytical grade ^{14}C labelled CGA 322704 with a specific radioactivity of 2.08 MBq/mg and a radiochemical purity of [redacted]% was prepared in aqueous 0.01 M $CaCl_2$ solution at 5 concentrations between 0.01 and 5.00 mg/litre. The solutions were added to soil and allowed to equilibrate in the dark while shaking in a controlled temperature incubator at 20°C for 48 hours. After equilibration the phases were separated by centrifugation and thiamethoxam concentrations determined by liquid scintillation counting (LSC) of the aqueous phases and by difference for the soil phases. The soil phases were next desorbed twice with 0.01 M $CaCl_2$ solution for 24 hours and concentrations determined by combustion of the soil and by LSC of the aqueous phases following centrifugation. All data were evaluated using the Freundlich equation and values for Kd (sorption constant), K_{OC} (sorption coefficient) and n were determined.

Table 1 Parameters of the soil used for adsorption/desorption (Hein, Dorn 2001c)

		Soil
Name		Birkenheide
Origin		Rhineland Palatinate, Germany
Batch No.		10/2000
Classification		Weak loamy sand
Particle size:	clay (%)	6.0
	silt (%)	22.4
	sand (%)	71.6
PH ($CaCl_2$)		6.0
PH (KCl)		6.3
$CaCO_3$ (%)		<0.1
Organic carbon (%)		0.90
CEC (meq/ 100g soil)		8

Findings: The Freundlich adsorption coefficient K_F was 0.70 mL/g. CGA 322704 is a compound with a low sorption capacity to most soils. The adsorption constants corrected for the organic carbon content (K_{OC}) was 77 mL/g. The data are presented in Table 2. The first desorption of CGA 322704 from the soil was nearly equal to adsorption as shown by the similar desorption coefficient (0.83 mL/g) calculated after the first desorption step. The value after the second step was higher thus demonstrating that adsorption was not fully reversible.

The ^{14}C material balance ranged between 93.7 and 101.0 % recovery for the soil tested. Analysis of the extracts after the adsorption step showed that > 99% of the radioactivity consisted of parent compound.

Table 2 Adsorption and desorption constants of thiamethoxam in soil Birkenheide (Hein, Dorn 2001c)

Soil texture	Adsorption (mL/g)			1st Desorption (mL/g)			2nd Desorption (mL/g)		
	K_F	K_{OC}	N	K_F	K_{OC}	N	K_F	K_{OC}	N
Birkenheide Weak loamy sand	0.70	77	0.8462	0.83	92	0.8500	0.9866	110	0.8486

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Date	28/02/05
Materials and Methods	[redacted]

[redacted]

Results and discussion

[redacted]

Table 06: Percent adsorption/desorption of ^{14}C-labelled CGA 322704 on soil after various equilibration times

Equilibration time	6 h[1)]	24 h[1)]	48 h[1)]	72 h[1)]
Adsorption	31.0 %	32.5 %	36.2 %	36.1 %
Desorption	72.9 %	72.6 %	72.7 %	--

[1)] Mean was calculated from duplicate specimens

[redacted]

Conclusion [redacted] e.

Reliability [redacted]

Acceptability [redacted]

Remarks

98/8 Doc IIIA section No.	7.2.3.1 / 08	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2 / 06	Adsorption and desorption

1.	**Annex point(s)**	**II A, 7.1.2** **Adsorption and Desorption of relevant metabolites**
2.	**Location in Dossier**	Section 5
3.	**Authors (year)**	R. Phaff (1997b)
	Title	Adsorption / Desorption of CGA 322704 in Various Soil Types
	Report No., Date **Syngenta File N°(Desire)** **Owner**	96RP06, April 23, 1997 322704/10 Syngenta Crop Protection AG
4.	**Testing facility**	Novartis Crop Protection AG Product Safety/Ecochemistry 4002 Basel, Switzerland
5.	**Dates of work**	Study Initiation: September 5, 1996 Study Completion: April 23, 1997
6.	**Test substance**	Company code CGA 322704 Company Code: ^{14}C-CGA 293343, Batch [redacted] specific radioactivity: 2.04 MBq/mg radiochemical purity: [redacted]
7.	**Test method**	The study was conducted in compliance with: European Community Commission Directive 95/36/EC of 22 July, 1995, amending Council Directive 91/414/EEC, Annex II, Point 7.1.2. and with: OECD Guideline for Testing of Chemicals, 'Adsorption / Desorption', 106, adopted: 12 May 1981
8.	**Deviations**	none
9.	**GLP**	This 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 Federal Department of the Interior and the Intercantonal Office for the Control of Medicaments, Switzerland. These procedures are based on OECD Principles of GLP adopted on 12 May 1981 by Decision of the OECD Council concerning Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30 (Final)]. Exception: Soil characterization was performed by AgroLab AG, Ebikon / Root, Switzerland.

Test system: Adsorption and desorption of thiazolyl-^{14}C labelled CGA 322704 was measured using the same soils and the same test system as for the adsorption/desorption study with the as thiamethoxam *(Keller 1996)*. The specific activity of the test material was 2.04 MBq/mg with a radiochemical purity of [redacted]%. The five test solutions ranged from 0.10 to 2.00 mg/ litre. Each experiment was performed in duplicate.

Findings: The Freundlich adsorption coefficient K_F varied between 1.46 mL/g for the loam and 14.60 mL/g for the humic soil. The metabolite CGA 322704 is a compound with a low sorption capacity to most soils. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 62 to 74 mL/g with an average K_{OC} value of 70 mL/g. The data are presented in Table 1.

Table 1: Adsorption and desorption constants of CGA 322704 in various soils (Phaff 1997b)

Soil texture	Adsorption (mL/g)			1st Desorption (mL/g)			2nd Desorption (mL/g)		
	K_F	K_{OC}	1/n	K_F	K_{OC}	1/n	K_F	K_{OC}	1/n
Gartenacker loam	1.47	74	0.8381	1.17	59	0.7919	1.03	52	0.7275
Vetroz silt loam	2.94	63	0.7581	2.71	58	0.7242	2.44	52	0.6580
Illarsaz humic silt loam	14.49	74	0.8896	16.10	81	0.8820	18.77	95	0.8809

Desorption of CGA 322704 from the soils was nearly equal to adsorption as shown by the similar desorption coefficients (1.14 to 16.27 mL/g) calculated after the first desorption step. The values after the second step were in the same order of magnitude. The slopes 1/n for the adsorption and desorption isotherms were on average 0.7945 $\pm$ 0.0833 indicating that the Freundlich isotherms would not strongly follow the Nernst distribution law. The ^{14}C material balance ranged between 94.4 and 100.3 % recovery for the three soils tested. Analysis of the extracts after the adsorption step showed that the radioactivity consisted entirely of CGA 322704.

	Evaluation by Competent Authorities
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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/02/05
Materials and Methods	Adsorption and desorption of thiazolyl-^{14}C labelled CGA 322704 (Chemical [redacted] P.
Results and discussion	[redacted]

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

98/8 Doc IIIA section No.	7.2.3.1 / 09	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2	Adsorption and desorption

1.	Annex point(s)	**II A, 7.1.2 Adsorption and Desorption**
2.	Location in Dossier	Section 5
3.	Authors (year)	Scott, M. (1998)
	Title	Soil Adsorption and Desorption of Oxadiazinyl-^{14}C-CGA 353042 by the Batch Equilibrium Method
	Report No., Date Syngenta File N° Owner	629-98, November 24, 1998 353042/0002 Syngenta Crop Protection AG
4.	Testing facility	Novartis Crop Protection Inc, Greensboro, USA
5.	Dates of work	Experimental Start: September 15, 1998 Experimental termination: November 9, 1998
6.	Test substance	CGA 353042 (metabolite of thiamethoxam) Company Code: (oxadiazinyl-2-^{14}C) CGA 353042, Batch: [redacted], specific radioactivity: 1.71 MBq/mg, radiochemical purity: [redacted]%
7.	Test method	Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate: 40 CFR 158, Subdivision N, Series 163-1, US Environmental Protection Agency, October 18, 1982. Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada, Section 6.2, B, 1 "Mobility, Adsorption/Desorption Measurements".
8.	Deviations	none
9.	GLP	yes

Test system: A study was performed to measure adsorption and desorption of CGA 353042 by the batch equilibrium method. Aqueous test solutions of oxadiazinyl-^{14}C labeled CGA 353042 (Batch [redacted] specific radioactivity 46.3 µCi/mg) in 0.01M calcium chloride were used at four concentrations 0.1, 0.5, 1.0 and 2.5 µg/mL. The study was conducted at 25°C by shaking 7.0 g soil and 17.5 mL test solution (1.25 g soil and 35 mL test solution for the Canadian/Rignold sandy loam) for 23 hours. After centrifugation and decanting the supernatants, desorption was done as above with fresh calcium chloride solution. The characteristics of the six soils used is shown in Table 1.

Table 1 Characteristics of soils used for adsorption/desorption (Scott 1998)

Series	Hanford	Niagara	Lakeland	Rignold	Honeywood	Nassau
Origin	Sanger, California, USA	Livingston New York, USA	Andersonville Georgia, USA	Carman, Manitoba, CDN	Plattsville, Ontario, CDN	Livingston New York, USA
Batch No.	635W-003	635W-005	635W-006	635W-007	635W-008	635W-011
Classification	Sandy loam	Clay	Sand	Sandy loam	Loam	Silt loam
Particle size: sand (%)	60	18	90	62	40	29
Silt (%)	32	40	8	28	48	56
Clay (%)	8	42	2	10	12	15
pH	8.0	7.5	5.8	6.4	5.7	7.1
WHC (%) at 33 kPa	9.9	29.5	4.7	21.7	20.3	21.9
Organic matter (%)	0.7	3.5	1.0	6.6	3.0	2.7
Organic carbon (%)	0.4	2.0	0.6	3.8	1.7	1.5
CEC (meq/ 100g soil)	7.7	17.2	3.9	22.8	10.7	9.4

Findings: Overall recoveries comprising adsorption and desorption steps ranged from 89.3 % to 96.9 % for the four concentrations used. The stability of CGA 353042 during the process was confirmed by HPLC. The 1/n values obtained indicate that a nonlinear relationship exists between concentrations in solution and adsorption. The Freundlich adsorption coefficient K_F varied between 1.92 mL/g for the sand and 27.94 mL/g for the Rignold sandy loam. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 198 to 1425 mL/g with an average K_{OC} value of 530.64 mL/g. The desorption K_{OC} values were higher than the adsorption K_{OC} values with an average of 387.7 mL/g. This indicates that adsorption was not fully reversible. The data are presented in Table 2.

Table 2 Adsorption and desorption constants of CGA 353042 in soils (Scott 1998)

Soil texture	Adsorption (mL/g)			1. Desorption (mL/g)		
	K_F	K_{OC}	1/n	K_F	K_{OC}	1/n
Carman Sandy loam	5.70	1425.00	0.8777	7.39	1847.50	0.8329
Niagara Clay	5.10	255.00	0.8838	7.77	388.50	0.9046
Lakeland Sand	1.92	320.00	0.8911	3.22	536.67	0.8951
Rignold Sandy Loam	27.94	735.26	0.8126	33.12	871.58	0.8332
Honeywood Loam	4.26	250.59	0.9084	6.75	397.06	0.9138
Niagara Silt loam	2.97	198.00	0.8427	4.44	296.00	0.8697
Average	**7.98**	**530.64**	**0.8694**	**10.45**	**722.89**	**0.8749**

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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/02/05
Materials and Methods	[redacted]
	Comments:
	[redacted]

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

98/8 Doc IIIA section No.	7.2.3.1 / 10	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2 / 02	Adsorption and desorption

1.	Annex point(s)	**II A, 7.1.2 Adsorption and Desorption of metabolites**
2.	Location in Dossier	Section 5
3.	Authors (year)	M. Concha, T. Hathcock.(1998)
	Title Report No., Date Syngenta File N°(Desire) Owner	Soil adsorption / desorption of 14C-CGA 355190 by the batch equilibrium method Final Report No. 411-97, 30.11.1998 Syngenta File N° 355190-5 Syngenta Crop Protection AG
4.	Testing facility	PTRL West, Inc. 4123-B Lakeside Drive Richmond, CA 94806, USA
5.	Dates of work	Study Initiation: September 2, 1998 Experimental Completion: November 11, 1998 Study Completion: November 30, 1998
6.	Test substance	Company code CGA 355190 Company Code: ^{14}C-thiazolyl - CGA 355190, Batch [redacted] Specific radioactivity: 1.92 MBq/mg Radiochemical purity: [redacted]
7.	Test method	The study was conducted in compliance with: Environmental Fate Data Requirement, 40 CFR 158, Subdivision N, Series 163-1, Leaching and Adsorption/Desorption Studies and with: Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada, section 6.2, B, 1 "Mobility, Adsorption/Desorption Measurements"
8.	Deviations	none
9.	GLP	Yes , EPA Good Laboratory Practice Standards (40 CFR Part 160) Exception: Clay mineralogy conducted at North Dakota University was nor carried out according to GLP...

Test system: A study to measure adsorption and desorption of the soil metabolite CGA 355190 using a batch equilibrium was performed in USA using the same soils as for metabolite NOA 407475. Aqueous test solutions of thiazolyl-^{14}C labeled CGA 355190 in 0.01M calcium chloride were used at four concentrations ranging from 0.1 to 5.3 mg/liter. The study was conducted at 25°C by shaking 7.0g soil and 12 mL test solution for 24 hours. After centrifugation and decanting the supernatants, desorption was done as above with fresh calcium chloride solution.

Findings: Overall recoveries comprising adsorption and desorption steps ranged from 96.8 % to 99.3 % for the four concentrations used. The stability of CGA 355190 during the process was confirmed by TLC. The 1/n values obtained (average of 0.8190) indicate that a nonlinear relationship exists between concentrations in solution and adsorption. The Freundlich adsorption coefficient K_F varied between 0.63 mL/g for the sand and 4.1 mL/g for the Canadian sandy loam. CGA 355190 is a compound with a slight to moderate sorption capacity to most soils. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 37.6 to 187.5 mL/g with an average K_{OC} value of 91.5 mL/g. The desorption K_{OC} values were higher

than the adsorption K_{OC} values with an average of 316.8 mL/g. This indicates that once adsorbed to soil, metabolite CGA 355190 is less likely to be removed into the aqueous phase. The data are presented in Table 1.

Table 1: Soil adsorption and desorption constants of metabolite CGA 355190 in various soils (Concha & Hathcock 1998a)

Soil texture	clay [%]	silt [%]	sand [%]	CEC meq	pH	OC [%]	Adsorption [mL/g] K_F	Adsorption [mL/g] K_{OC}	Adsorption [mL/g] 1/n	1st Desorption [mL/g] K_F	1st Desorption [mL/g] K_{OC}	1st Desorption [mL/g] 1/n
California sandy loam	8	32	60	77.7	8.0	0.4	0.75	187.5	0.8112	3.41	852.5	0.9887
Clay	42	40	18	17.2	7.5	2.0	0.79	37.6	0.8441	2.99	142.4	0.9935
Sand	2	8	90	3.9	5.8	0.6	0.63	105.0	0.8285	2.33	388.3	0.9955
Canadian sandy loam	10	28	62	22.8	6.4	3.8	4.11	105.4	0.8073	7.76	199.0	0.9970
Canadian loam	12	48	40	10.7	5.7	1.7	1.11	61.7	0.8178	3.10	172.2	0.9990
Silt loam	15	56	29	9.4	7.1	1.5	0.83	51.9	0.8048	2.34	146.3	0.9987
Average							**1.37**	**91.5**	**0.8190**	**3.66**	**316.8**	**0.9954**

CEC = cation exchange capacity (meq/100g soil)

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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/02/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]

Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.2.3.1 / 11	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2	Adsorption and desorption

1.	Annex point(s)	**II A, 7.1.2 Adsorption and Desorption**
2.	Location in Dossier	Section 5
3.	Authors (year)	Concha, M. & Hathcock. (1998b)
	Title	Soil Adsorption/Desorption of [Thiazole-2-^{14}C-NOA 404617 by the Batch Equilibrium Method
	Report No., Date Syngenta File N° Owner	Proj.No 721-97, November 30, 1998 404617/0001 Syngenta Crop Protection AG
4.	Testing facility	PTRL West Inc., Richmond, USA
5.	Dates of work	Experimental Start: September 28, 1998 Experimental termination: November 24, 1998
6.	Test substance	NOA 404617 (metabolite of thiamethoxam) Company Code: (Thiazolyl-2-^{14}C) NOA 404617, Batch: [redacted] specific radioactivity: 1.55 MBq/mg, radiochemical purity: [redacted]
7.	Test method	Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate: 40 CFR 158, Subdivision N, Series 163-1, US Environmental Protection Agency, October 18, 1982. Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada, Section 6.2, B, 1 "Mobility, Adsorption/Desorption Measurements".
8.	Deviations	none
9.	GLP	yes

Test system: A study was performed to measure adsorption and desorption of NOA 404617 by the batch equilibrium method. Aqueous test solutions of thiazole-^{14}C labelled NOA 404617 (Batch [redacted] specific radioactivity 41.8 µCi/mg) in 0.01M calcium chloride were used at four concentrations 0.11, 1.10, 2.62 and 4.94 µg/mL. The study was conducted at 25°C by shaking 7.0 g soil and 12 mL test solution for 24 hours. After centrifugation and decanting the supernatants, desorption was done as above with fresh calcium chloride solution for the 0.11, 1.10 and 2.62 µg/mL samples. Three consecutive desorptions were performed for the 4.94 µg/mL samples. The characteristics of the six soils used are shown in Table 1.

Table 1 Characteristics of soils used for adsorption/desorption (Concha & Hathcock 1998b)

Series	Hanford	Niagara	Lakeland	Rignold	Honeywood	Nassau
Origin	Sanger, California, USA	Livingston New York, USA	Andersonville Georgia, USA	Carman, Manitoba, CDN	Plattsville, Ontario, CDN	Livingston New York, USA
Batch No.	635W-3	635W-5A	635W-6	635W-7A	635W-8A	635W-11
Classification	Sandy loam	Clay	Sand	Sandy loam	Loam	Silt loam
Particle size: sand (%)	60	18	90	62	40	29
Silt (%)	32	40	8	28	48	56
Clay (%)	8	42	2	10	12	15
PH	8.0	7.5	5.8	6.4	5.7	7.1
WHC (%) at 33 kPa	9.9	29.5	4.7	21.7	20.3	21.9

Organic matter (%)	0.7	3.5	1.0	6.6	3.0	2.7
Organic carbon (%)	0.4	2.0	0.6	3.8	1.7	1.5
CEC (meq/ 100g soil)	7.7	17.2	3.9	22.8	10.7	9.4

Findings: Overall mass balance for all soils and all doses ranged from 97.7 ± 1.5 % to 101.8 ± 1.1 %. The stability of NOA 404617 during the process was confirmed by HPLC. The 1/n values obtained indicate that a nonlinear relationship exists between concentrations in solution and adsorption. The Freundlich adsorption coefficient K_F varied between 0.24 mL/g for the clay and 1.4 mL/g for the Rignold sandy loam. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 11.4 to 53.3 mL/g with an average K_{OC} value of 35.4 mL/g. The desorption K_{OC} values were higher than the adsorption K_{OC} values with an average of 192 mL/g. This indicates that adsorption was not fully reversible. The data are presented in Table 2.

Table 2 Adsorption and desorption constants of NOA 404617 in various soils (Concha & Hathcock 1998b)

Soil texture	Adsorption (mL/g)			1. Desorption (mL/g)		
	K_F	K_{OC}	1/n	K_F	K_{OC}	1/n
Carman Sandy loam	0.29	72.5	0.7856	2.12	530.0	0.9404
Niagara Clay	0.24	11.4	0.8119	2.10	100.0	0.8282
Lakeland Sand	0.32	53.3	0.7702	1.49	248.3	0.8989
Rignold Sandy Loam	1.40	35.9	0.8147	3.12	80.0	0.7517
Honeywood Loam	0.41	22.8	0.7690	1.74	96.7	0.8475
Niagara Silt loam	0.26	16.3	0.7289	1.55	96.0	0.8135
Average	**0.49**	**35.4**	**0.7801**	**2.02**	**192.0**	**0.8467**

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	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/02/05
Materials and Methods	[redacted]
Results and discussion	[redacted]

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

98/8 Doc IIIA section No.	7.2.3.1 / 12	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2 / 05	Adsorption and desorption

1.	Annex point(s)	**II A, 7.1.2**	**Adsorption and Desorption of metabolites**
2.	Location in Dossier	Section 5	
3.	Authors (year)	J.Peters (1998)	
	Title	Soil adsorption and desorption of Thiazolyl-2-14C-NOA 407475 by the batch equilibrium method	
	Report No., Date	Final report No. 420-98, 19.11.1998	
	Syngenta File N°(Desire)	Syngenta File N° 407475-12	
	Owner	Syngenta Crop Protection AG	
4.	Testing facility	Novartis Crop Protection Inc Environmental Safety Department Greensboro, NC 27419, USA	
5.	Dates of work	Study Initiation: August 6, 1998 Experimental Completion: November 10, 1998 Study Completion: November 19, 1998	
6.	Test substance	Company code NOA 407475 Company Code: ^{14}C-thiazolyl - NOA 407475, Batch [redacted]-2 Specific radioactivity: 1.38 MBq/mg Radiochemical purity [redacted]	
7.	Test method	The study was conducted in compliance with: Environmental Fate Data Requirement, 40 CFR 158, Subdivision N, Series 163-1, Leaching and Adsorption/Desorption Studies and with: Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada, section 6.2, B, 1 "Mobility, Adsorption/Desorption Measurements"	
8.	Deviations	none	
9.	GLP	Yes , EPA Good Laboratory Practice Standards (40 CFR Part 160) Exception: Clay mineralogy conducted at North Dakota University was nor carried out according to GLP...	

Test system: A study to measure adsorption and desorption of the anaerobic soil and aquatic sediment metabolite NOA 407475 using a batch equilibrium was performed in USA using the same soils as for metabolite CGA 355190. Aqueous test solutions of thiazolyl-^{14}C labeled NOA 407475 in 0.01M calcium chloride were used at four concentrations ranging from 0.1 to 2.5 mg/liter. The study was conducted at 25°C by shaking 7.0g soil and 35 mL test solution for 24 hours. After centrifugation and decanting the supernatants, desorption was done as above with fresh calcium chloride solution.

Findings: Overall recoveries comprising adsorption and desorption steps ranged from 90.3 % to 99.6 % for the four concentrations used. The stability of NOA 407475 during the process was confirmed by TLC. The 1/n values obtained (average of 0.8261) indicate that a nonlinear relationship exists between concentrations in solution and adsorption. The Freundlich adsorption coefficient K_F varied between 2.8 mL/g for the sand and 44.5 mL/g for the Canadian sandy loam. NOA 407475 is a compound with a strong to very strong sorption capacity to most soils. The adsorption constants corrected for the organic carbon content (K_{OC}) ranged from 433

to 1550 mL/g with an average K_{OC} value of 761.2 mL/g. The desorption K_{OC} values were higher than the adsorption K_{OC} values with an average of 1014.7 mL/g. This indicates that once adsorbed to soil, metabolite NOA 407475 is unlikely to be removed into the aqueous phase. The data are presented in Table 1.

Table 1: Soil adsorption and desorption constants of metabolite NOA 407475 in various soils (Peters 1998)

	clay	silt	sand	CEC	pH	OC	Adsorption [mL/g]			1st Desorption [mL/g]		
Soil texture	[%]	[%]	[%]	meq		[%]	K_F	K_{OC}	1/n	K_F	K_{OC}	1/n
California sandy loam	8	32	60	77.7	8.0	0.4	6.2	1550.0	0.8084	8.7	2175.0	0.7931
Clay	42	40	18	17.2	7.5	2.0	10.1	505.0	0.8525	12.5	625.0	0.8578
Sand	2	8	90	3.9	5.8	0.6	2.8	466.7	0.8180	5.4	900.0	0.8659
Canadian sandy loam	10	28	62	22.8	6.4	3.8	44.5	1171.1	0.8306	47.4	1247.4	0.8482
Canadian loam	12	48	40	10.7	5.7	1.7	7.5	441.2	0.8416	10.1	594.1	0.8505
Silt loam	15	56	29	9.4	7.1	1.5	6.5	433.3	0.8053	8.2	546.7	0.8144
Average							**12.9**	**761.2**	**0.8261**	**15.4**	**1014.7**	**0.8383**

CEC = cation exchange capacity (meq/100g soil)

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/02/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]

Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.2.3.1 / 13	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2	Adsorption and desorption

1.	**Annex point(s)**	**II A, 7.1.2 Adsorption and Desorption**
2.	**Location in Dossier**	Section 5
3.	**Authors (year)**	Nicollier, G. (2002)
	Title	Adsorption / Desorption of [Thiazol-2-^{14}C]NOA 459602 in Various Soils and Time Dependent Sorption
	Report No., Date	01GN08, July 03, 2002
	Syngenta File N°	459602/0015
	Owner	Syngenta Crop Protection AG
4.	**Testing facility**	Syngenta Crop Protection AG, Basel, Switzerland
5.	**Dates of work**	Study initiation: November 22, 2001 Experimental Start: November 29, 2001 Experimental termination: April 15, 2002 Study termination: July 3, 2002
6.	**Test substance**	NOA 459602 (metabolite of thiamethoxam) Company Code: (Thiazolyl-2-^{14}C) NOA 49602, Batch: [redacted] 1, specific radioactivity: 0.899 MBq/mg, radiochemical purity: [redacted]
7.	**Test method**	European Community Commission Directives 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC: Annex II: 7.1.2, Adsorption and Desorption. "OECD No. 106, Adsorption / Desorption", adopted January 21, 2000.
8.	**Deviations**	none
9.	**GLP**	yes

Test system: The adsorption and desorption of the test substance NOA 459602, i.e. 5-(5-methyl-4-nitroimino-[1,3,5]oxadiazinan-3-ylmethyl)-thiazole-2-sulfonic acid, was studied in three soil types by the batch equilibrium method. In addition the effect of ageing on the desorption of NOA 459602 from soil was investigated. For both tests three soils characterised in table 1 were used.

Batch equilibrium pre-test: Analytical grade ^{14}C labelled CGA 459602 with a specific radioactivity of 0.899 MBq/mg and a radiochemical purity of 99.1 % was prepared in aqueous 0.01 M $CaCl_2$ solution at a concentration of ca. 0.5 mg/Litre. The solution was added to soil and allowed to equilibrate in the dark while shaking in a controlled temperature incubator at 20°C for 2, 6 24 and 48 hours. After equilibration the phases were separated by centrifugation and the radioactivity determined by liquid scintillation counting (LSC) of the aqueous phases. At the end of the adsorption and desorption step, the supernatents were submitted to HPLC analysis to check the stability of the test substance during the test.

Time Dependent Sorption: In this test desorption of [Thiazol-2-^{14}C] NOA 459602 was measured in soil samples aged at 20 ° C at 40 % MWC from the soil degradation study (Reischmann 2002).

Duplicate samples were harvested on day 34 and 71 after application. Desorption was determined by suspending the soil samples in 0.01 M $CaCl_2$-solution for 24 hours (soil: solution ratio 1:1). The soils were subsequently extracted with acetonitrile water (4:1;v,v). The desorption solutions and soil extracts were assayed and analysed by HPLC. The non-extractable radioactivity was determined after combustion of the soil residue.

Table 1: Parameters of soils used

	Adsorption/desorption (Pre-test)			Time Dependent Sorption		
Soil	Borstel	Gartenacker	Pappelacker	Borstel	Gartenacker	Pappelacker
No.	1	2	3	1	2	3
Origin	Germany	Switzerland	Switzerland	Germany	Switzerland	Switzerland

Batch-No.	5/00	3/01	7/98	5/00b	06/01	06/01
Classification (USDA)	Sandy Loam	Loam /silt Loam	Loamy Sand	Sandy Loam	Loam /silt Loam	Loamy Sand
pH (KCl)	5.14	7.3	7.5	5.6	7.2	7.3
$CaCO_3$ [%]	< 0.3	7.0	9.8	< 0.3	6.4	7.4
Organic carbon [%]	1.0	2.2	1.1	1.00	2.12	1.2
CEC [meq / 100 g soil]	7.2	14.6	5.9	8.2	14.2	7.4
Particle size:						
Clay [%]	7.3	10.4	3.1	6.6	10.5	6.4
Silt [%]	17.9	53.7	21.9	15.9	49.3	22.9
Sand [%]	74.9	35.9	75.0	77.5	40.2	70.7

Findings: Pre-test: Data showed that the adsorption equilibrium was reached after approximately 6 hours of shaking. After 24 hours the maximum adsorption was 0.7 % in Gartenacker soil (at an initial test substance concentration of 0.5 µg/ml and for a soil-to-solution ratio of 10 g soil and 10 ml 0.01 M $CaCl_2$). No adsorption on the surface of the test vessels was found in the control samples (-1.1 % after 24 hours).

After 24 hours of desorption no desorbed radioactivity was found due to the very low amounts of NOA 459602 adsorbed to the soils. In the pre-test the test substance was stable in the supernatants during the adsorption and desorption steps.

Based on the pre-test results – approximately 100% of applied radioactivity was determined in the aqueous phase of the soil/water systems after 24 or 48 hours of adsorption and therefore no adsorption of the test compound to soil occurred - the adsorption coefficients (K_d) as well as the coefficient related to the soil organic carbon (K_{OC}) could not be calculated.

Time Dependent Sorption (Aged Kd): Throughout the course of the study, the material balance for each soil type ranged from an average of 91.6% to 108.1% of applied radioactivity. Volatiles in form of $^{14}CO_2$ accounted for 6.9%, 22.4% and 27.0% of the applied radioactivity for Borstel, Gartenacker and Pappelacker soils at day 71, respectively. The Kd and Koc values for the time dependent sorption are summarised in Table 2:

Table 2: Desorption constants of NOA 459602 in three soils

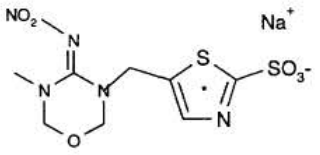
Soil	Incubation Time [Days]	pH (KCl)	Organic Carbon Content (%)	Desorption K_d (ml/g)	Koc (ml/g)	Kom (ml/g)
Borstel	34	5.6	1.0	0.19	18.6	10.8
(sandy loam)	71			0.18	17.6	10.2
Gartenacker	34	7.2	2.1	0.45	22.1	12.8
(sandy silt loam)	71			0.72	33.8	19.6
Pappelacker	34	7.3	1.2	0.35	29.5	17.1
(Loamy sand)	71			0.63	52.3	30.3
Mean				**0.42**	**29.0**	**16.8**

The sorption of the test compound in the three soils increased considerably by the ageing period of 34 days. Prolongation of the incubation time to 71 days increased further the sorption in Gartenacker and Pappelacker soil.

The mean sorption K_{oc}-value was 29.0 (ml/g) and the mean sorption coefficient normalised to the organic matter content (K_{om}) was calculated to be 16.8 (ml/g).

In conclusion, NOA 459602 was found to be weakly adsorbed depending on the pH value of the soil. Furthermore, it was found that the leaching potential is affected not

only by the physical and chemical properties of the test substance and soil but also by the residence time in the soil.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/02/05
Materials and Methods	[redacted]  [redacted]
Results and discussion	[redacted]

[redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks

98/8 Doc IIIA section No.	7.2.3.1 / 14	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.2	Adsorption and desorption

1.	Annex point(s)	**II A, 7.1.2 Adsorption and Desorption**
2.	Location in Dossier	Section 5
3.	Authors (year)	Hein, W., (2001)
	Title	Time Dependent Sorption of [Thiazol-2-^{14}C]-CGA 322704 in Birkenheide Soil
	Report No., Date Syngenta File N° Owner	Proj.No NOV21, September 12, 2001 322704/0036 Syngenta Crop Protection AG
4.	Testing facility	Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau, 67435 Neustadt an der Weinstrasse, Germany
5.	Dates of work	Experimental Start: November 29, 2000 Experimental termination: May 14, 2001
6.	Test substance	CGA 322704 (metabolite of thiamethoxam) Company Code: (thiazol-4-^{14}C) CGA 322704, Batch: [redacted], specific radioactivity: 2.08 MBq/mg, radiochemical purity: [redacted]%
7.	Test method	OECD Guideline for Testing of Chemicals, No 106 "Adsorption/Desorption", Jan. 21, 2000
8.	Deviations	Supplemental study.
9.	GLP	yes (Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau (SLFA), Breitenweg 71, D-67435 Neustadt/Weinst)

Test system: The study was carried out in order to investigate the effect of ageing on the desorption of CGA 322704 from soil. For the test one soil type characterised in Table 1 was used. [^{14}C]-CGA 322704 was applied on soil with an application rate of about 82.2 µg/kg dry soil equivalent corresponding to 36 % of 200 g/ha maximum field rate of parent thiamethoxam, assuming an even distribution of the active ingredient in the top 5 cm soil layer and a soil bulk density of 1.5 g/cm^3. The incubation conditions were: aerobic; dark; 40% max. water holding capacity; and temperature 20 ± 2°C. Duplicate samples were taken immediately after application (0 days), then at 1, 2, 4, 7, 14, 21, 30, 45 and 91 days after treatment. In order to determine the amount of CGA 322704 desorbed after the respective incubation period, the soil samples were extracted with 0.01 M $CaCl_2$-solution for 24 hours. After equilibration the phases were separated by centrifugation and concentrations of CGA 322704 determined by liquid scintillation counting (LSC) of the aqueous phase. The data were evaluated using the Freundlich equation and values for K_d (sorption constant) were determined. All soil samples were submitted to exhaustive extraction, the extracts were concentrated and analysed by HPLC and the results verified by TLC. The concentration in the soil was determined by combustion.

Table 1 Characteristics of the soil used for adsorption/desorption (Hein 2001)

		Soil
Name		Birkenheide
Origin		Rhineland Palatinate, Germany
Batch No.		10/2000
Classification		Weak loamy sand
Particle size:	clay (%)	6.0
	silt (%)	22.4
	sand (%)	71.6
PH ($CaCl_2$)		6.0
PH (KCl)		6.3
$CaCO_3$ (%)		<0.1
Organic carbon (%)		0.90
CEC (meq/ 100g soil)		8

Findings: The calculated K_d-values nearly tripled over the incubation period. On Day 0 the K_d-value for CGA 322704 was determined to be 1.00 mL/g. At the end of the incubation period on Day 91 the K_d-value was determined to be 2.77 mL/g. This corresponds to a factor of about 2.8. The data are presented in Table 2.

Table 2 Desorption constants of CGA 322704 in soil Birkenheide (Hein, 2001)

Sampling date	K_d (mL/g)	K_{OC} (mL/g)*
0	1.00	111.1
1	1.11	123.3
2	1.01	112.2
4	1.09	121.1
7	1.26	140.0
14	1.59	176.7
21	1.79	198.9
30	1.92	213.3
45	2.28	253.3
91	2.77	307.8

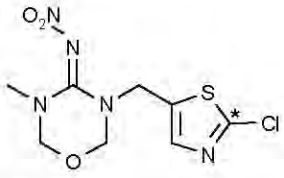
* derived by formular $K_{oc} = \frac{K_d * 100}{\% \text{ org C}}$

The increase between Day 45 and Day 91 was at lower rates than between Day 0 and Day 45. This may indicate that the distribution coefficient approaches a plateau value.

The ^{14}C material balance ranged between 90.7% and 95.7% recovery for the soil tested. Analysis of the extracts after the desorption step showed that >99.0% of the radioactivity consisted of CGA 322704.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/11/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.2.3.2 / 01	Mobility in at least three soil types and where relevant mobility of metabolites and degradation products
91/414 Annex Point addressed	II 7.1.3.1 / 01	Column leaching studies

1.2	Title	Leaching Model Study with CGA 293343 in four Soils under Laboratory Conditions
1.3	Report and/or project N° Syngenta File N°(Desire)	95DA02 293343/49
1.4	Lab. Report N°	95DA02
1.5	Cross reference to original study / report	7.1.3.1 /01
1.6	Authors	Report: Adam, D. Summary: Adam, D.
1.7	Date of report	April 10, 1996
1.8	Published / owner	Unpublished/Syngenta Crop Protection AG, Basel, Switzerland
2.1	Testing facility	Novartis Crop Protection AG Product Safety / Ecochemistry 4002 Basel, Switzerland
2.2	Dates of experimental work	September 13, 1995 until February 7, 1996
3.	Objectives	Determination of the leaching behaviour of CGA 293343 in four different soils under laboratory conditions. Results were compared to an internal reference herbicide (Monuron)
4.1	Test substance	ISO common name: Trade name: Batch: [redacted] ^{14}C-labelled test substance: Yes [x] No [ ] Specific activity of [.^{14}C.]: 2.12 Mbq/mg (= 57.82 µCi/mg) Radiochemical purity of the test substance: [redacted] (w/w) Structural formula: (* position of label)  Formulation used for study: Yes [x] No [ ] Type of formulation (if used): WG 25 Co-solvent for application (if used): acetonitrile
4.2	Specification	See 4.1
4.3	Storage stability	The chemical is stable when stored at about -20°C in the dark
4.4	Stability in vehicle	The test substance was found to be stable in the vehicle when analysed by TLC before and after application
4.5	Homogeneity in vehicle	The test substance was prepared as a homogeneous solution in acetonitrile
4.6	Validity	Not applicable
4.7	Vehicle / solvent	Acetonitrile Lichrosolv® (Merck Darmstadt, Germany)
4.8	Physical form	radiolabelled CGA 293343 was supplied as a solution in benzene

5.1	Test method	The study was conducted in compliance with the: Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, Society of Environmental Toxicology and Chemistry, SETAC Europe 1995 and under consideration of: Richtlinie für die amtliche Prüfung von Pflanzenschutzmitteln; Teil IV, 4-2: "Versickerungsverhalten von Pflanzenschutzmitteln", Biologische Bundesanstalt für Land- und Forstwirtschaft, Bundesrepublik Deutschland, Dezember 1986. Dutch Registration Guidelines, March 3, 1988; Section G. 1.2b, Leaching through soil columns
5.2	Justification	The study was designed to meet international registration requirements for assessing the mobility of pesticides in soil.
5.3	Copy of method	Available on request
6	Choice of method	not applicable
7	Deviations	none

8.1	Certified laboratory	Yes
8.2	Certifying authority	Federal Department of Home Affairs, Switzerland
8.3	GLP	GLP Switzerland based on OECD
8.4	Justification	not applicable
9.1	GEP	Not applicable
9.2	Type of facility (official or officially recognised)	Not applicable
9.3	Justification	Not applicable

10 Test system

System		1	2	3	4
Origin of soil:		Col-lombey CH	Speyer 2.1 FRG	Garten-acker CH	Vetroz CH
Batch-No:		9/92	136	10/93	3/75
Analysis date:		April 1994	April 1994	Nov-ember 1993	April 1994
Classification (USDA):		Loamy sand	Sand	Loam	Silt loam
Particle size distribution:	% silt	15.40	6.10	48.00	58.50
	% sand	79.40	88.70	40.10	18.20
	% clay	5.20	5.20	11.90	23.30
Organic matter content:	(%)	not given in report			
Organic carbon content:	(%)	2.00	0.30	2.00	4.70
Total nitrogen:	(%)	0.26	0.05	0.33	0.43
pH:	(KCl)	7.60	6.80	7.10	7.20
CaCO3:	(%)	7.50	0.10	7.40	56.00
Cation exchange capacity:	(mmol/z/ 100g soil)	14.50	3.90	12.70	28.10
Bulk density (air dried and sieved (2 mm) soil)	(g/ml)	1.29	1.63	1.05	0.99
Maximum water holding capacity (MWC; pF<0.3):	(ml H_2O/ 100g dry soil)	not determined			
Field capacity (FC; pF=2.5):	(ml H_2O/ 100g dry soil)	not determined			

Column length	30 cm

Column inner diameter	4 cm
Soil prewetted	yes
Soil layers analysed	yes
Rain, total amount	200 mm
Rain period	constant head method, 1 -5 days depending on soil type
Rain quality	dist. Water [ ] CaCl2 [x] (conc = 0.01M)
Method of flooding	from bottom to top
Duplicate analysis	Yes [x] (leachates) No [ ]

Test conditions	
Treatment rate:	25.59µg per column corresponding to 0.205 kg/ha
Temperature [°C]:	20 ± 1°C
Methods used for analysis:	HPLC/TLC
Methods used for the identification of degradates:	HPLC/TLC

11 Statistics

The penetration depth of the parent molecule CGA 293343 is compared with Monuron by calculating the relative mobility factors (RMF):

$$RMF = \frac{\text{leaching distance of CGA 293343}}{\text{leaching distance of Monuron}}$$

12 References (published) none

13 Unpublished data none

Findings: The penetration depth of thiamethoxam into the soil profile was greater than 28 cm in all investigated soils except in the silt loam (penetration depth 20 cm).

In the leachates of the sandy soil (Speyer 2.1) and the loam (Gartenacker) major amounts of radioactivity were found i.e. 59.2 % (duplicate 64.1 %) for the sand and 11.0 % (duplicate: 8.2 %) for the loam. The amount of radioactivity recovered in the leachate of the loamy sand (Collombey) and the silt loam (Vetroz) was 2.4 %. Beside parent thiamethoxam no metabolites were detected in the leachates or in the soil columns, demonstrating the stability of the test substance during the leaching procedure.

The mobility of the test substance was found to be 1.19 times higher as compared to the reference substance monuron. Based on the results of this test thiamethoxam was classified to be moderately mobile in soil (mobility class III).

Table 1: Column leaching of ^{14}C- thiamethoxam after an artificial rainfall of 200 mm (Adam 1996b)

Test results					
Origin of soil:		Gartenacker	Vetroz	Collombey	Speyer 2.1
Soil texture		loam	silt loam	loamy sand	sand
Soil 0 - 10 cm	%*	35.1	46.1	15.6	8.0
Soil 10 - 20 cm	%*	38.8	50.3	63.7	6.7
Soil 20 - 30 cm	%*	17.3	1.2	19.8	16.2
Soil Total	%*	91.2	97.6	99.1	30.9
Leachate	%*	11.0	2.4	1.6	59.2
Total recovery	%*	102.2	100.0	100.7	90.02

* Percent of radioactivity applied to the column.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/11/2004
Materials and Methods	[redacted]

Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No. 7.3.1 / 01	Phototransformation in air (estimation method), including identification of breakdown products
91/414 Annex II Point addressed 7.2.2 / 01	Rate and route of degradation in air

1.2	Title	Volatilization of ^{14}C-Thiazolring-Labelled CGA 293343 from Soil Surface under controlled Laboratory Conditions
1.3	Report and/or project N° Syngenta File N°(Desire)	96DA03 293343/104
1.4	Lab. Report N°	96DA03
1.5	Cross reference to original study / report	7.2.2 /01
1.6	Authors	Report: Adam, D Summary: Adam, D
1.7	Date of report	August 15, 1996
1.8	Published / owner	Owned by Syngenta Crop Protection AG, not published
2.1	Testing facility	Novartis Crop Protection AG Product Safety / Ecochemistry 4002 Basel, Switzerland
2.2	Dates of experimental work	Exper. Start: April 17, 1996 Exper. Termination: June 6, 1996
3.	Objectives	The objectives of this study were to evaluate and quantify the importance of the volatilization process for CGA 293343 under laboratory conditions. For this purpose, the surface of soil samples was treated with the ^{14}C-labelled test substance in a model system and the amount of CGA 293343 lost through volatilization was measured at an air flow of 1 m / s.
4.1	Test substance	ISO common name: thiamethoxam Trade name: Batch: [redacted] ^{14}C-labelled test substance: Yes [x] Specific activity of [.....]: 2.25 MBq/mg (=60.82 µCi/mg) Radiochemical purity of the test substance: [redacted] (w/w) Structural formula: (position of label *) Formulation used for study: Yes [x] No [ ] Type of formulation (if used): WG25 Co-solvent for application (if used):
4.2	Specification	See 4.1
4.3	Storage stability	The chemical is stable when stored at about -20°C in the dark
4.4	Stability in vehicle	The test substance was found to be stable in the vehicle when analysed by HPLC before and after application
4.5	Homogeneity in vehicle	The test substance was prepared as a homogeneous solution in water
4.6	Validity	Not applicable
4.7	Vehicle / solvent	Not applicable
4.8	Physical form	Suspension in water
5.1	Test method	Richtlinien für die Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren, Teil IV, 6-1: "Prüfung des Verflüchtigungsverhaltens und des Verbleibs von Pflanzenschutzmitteln in der Luft; Modellkammerversuch (2.3.3.2)". Biologische Bundesanstalt für Land- und Forstwirtschaft Bundesrepublik Deutschland, Juli 1990.
5.2	Justification	National Guideline to fulfil national requirements
5.3	Copy of method	Available on request

6	**Choice of method**	Not applicable
7	**Deviations**	None
8.1	**Certified laboratory**	Yes
8.2	**Certifying authority**	Federal Department of Interior, Switzerland
8.3	**GLP**	GLP Switzerland based on OECD
8.4	**Justification**	not applicable
9.1	**GEP**	Not applicable
9.2	**Type of facility (official or officially recognised)**	Not applicable
9.3	**Justification**	Not applicable

10 **Test system**

System		Standard soil 2.1
Origin of soil:		Speyer;FRG
Batch-No:		89(Bo 2.1)
Classification (USDA):		Sand
Particle size distribution:	% clay	4.1
	% silt	7.6
	% sand	88.3
Organic carbon content:	(%)	0.60
pH (KCl):		8.2
$CaCO_3$:	(%)	not given in the report
Cation exchange capacity:	(meq/100g soil)	6.0
Maximum water holding capacity (MWC; pF<0.3):	(ml H_2O/100g dry soil)	23.49
Apparatus	See Attachment 1	
Soil moisture (%-MWC)	60	
Soil samples analysed	5	
Sampling times (hours)	0, 1, 3, 6 and 24	
Duplicate analysis	Yes [ ] No [x]	
Test conditions		
Treatment rate (kg a.i./ha):	0.190	
Temperature [°C]:	20	
Methods used for analysis:	HPLC, TLC and Liquid scintillation counting	
Air humidity	35 % r.h.	
Air flow rate (m/s)	1 (= 2040 ml/min or 21176.5 air exchanges/hr.)	

11	**Statistics**	Not applicable
12	**References (published)**	Not applicable
13	**Unpublished data**	Not applicable

Findings: thiamethoxam is practically non volatile from soil surfaces at an air flow rate of 1 m/s. Under the test conditions described, a non significant loss of ≤ 2.2% of applied dose could be detected by the indirect volatilisation method.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/11/2004

Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No. 7.3.1 / 02	Phototransformation in air (estimation method), including identification of breakdown products
91/414 Annex II Point addressed 7.2.2 / 02	Route and rate of degradation in air

1.2	Title	Atmospheric oxidation of CGA 293343 by hydroxyl radicals; rate estimation.
1.3	Report and/or project N° Syngenta File N°(Desire)	Report no. 95A958023SM, 293343/477.
1.4	Lab. Report N°	Project no. 98SM10.
1.5	Location in Dossier	Section 5, 7.2.2/02
1.6	Authors	E. Stamm.
1.7	Date of report	24. March 1998.
1.8	Published / owner	Unpublished/Syngenta Crop Protection
2.1	Testing facility	Novartis Crop Protection, Product Safety / Ecology, Chemodynamics PP 2.544, CH-4022 Basel, Switzerland.
2.2	Dates of experimental work	Not applicable (modeling study).
3.	Objectives	Estimation of the half-life of CGA 293343 in the atmoshere by hydroxyl radical oxidation, using mathematical modeling.
4.1	Test substance	CGA 293343.
4.2	Specification	Not applicable.
4.3	Storage stability	Not applicable.
4.4	Stability in vehicle	Not applicable.
4.5	Homogeneity in vehicle	Not applicable.
4.6	Validity	Not applicable.
4.7	Vehicle / solvent	Not applicable.
4.8	Physical form	Not applicable.
5.1	Test method	Not applicable.
5.2	Justification	Not applicable.
5.3	Copy of method	A description of method is included in study report.
6	Choice of method	Not applicable.
7	Deviations	Not applicable.
8.1	Certified laboratory	Not applicable.
8.2	Certifying authority	Not applicable.
8.3	GLP	Not applicable.
8.4	Justification	Not applicable
9.1	GEP	Not applicable.
9.2	Type of facility (official or officially recognised)	Not applicable.
9.3	Justification	Not applicable.
10	Test system	Computer programme: Atmospheric oxidation program V 1.75 (Syracuse Research Corporation, Syracuse, New York 13210). Based on: Method of Atkinson (1988).
11	Statistics	Not applicable.
12	References (published)	Atkinson, R. (1988): Environ. Toxicol. Chem., 7, 435.
13	Unpublished data	No unpublished data cited in this summary.

Test system: To further understand the fate of thiamethoxam in air, the rate constant for the reaction with OH-radicals was estimated according to the increment procedure described by Atkinson[27], which allows an estimation of the degradation of a compound by OH-radicals in the atmosphere by using structure-reactivity relations.

Findings: The dominating degradation processes for thiamethoxam are abstraction of hydrogen by hydroxyl radicals and reaction with N, S and -OH fragments of the molecule. With an estimated rate constant of $54.1214 \cdot 10^{-12}$ cm^3 x molecule-s^{-1} (minimum) and an average concentration of OH-radicals of $1.5 \cdot 10^6$ cm^{-3} in the atmosphere, the atmospheric oxidation of thiamethoxam by hydroxyl radicals revealed an estimated half-life (Atkinson method) between 0.5 and 2.5 hours.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/11/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	
Acceptability	[redacted]
Remarks	

[27] For an overview see: R. Atkinson: a) Estimation of gas-phase hydroxyl radical rate constants for organic chemicals, Environment. Toxic. Chem. 7 (1988) 435, b) Kinetics and mechanisms of the gas-phase reactions of the hydroxyl radical with organic compounds under atmospheric conditions, Chem. Rev. 85 (1986), 69, c) A structure-activity relationship for the estimation of rate constants for the gase phase reaction of OH radicals with organic compounds, J.Chem. Kin. 19 (1987) 799

98/8 Doc IIIA section No.	7.4.1.1 / 01	Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1 / 03	Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted] (1996)
	Title	10 ACUTE TOXICITY TEST OF CGA 293343 TECH. TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) IN THE FLOW-THROUGH SYSTEM
	Report No. / Date	95R002 / 30.01.1996
	Novartis File N°	Novartis Study # 293343-36
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	September 15, 1995 until December 6, 1995
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	OECD Guideline No.: 203; U.S. EPA FIFRA Pesticide Assessment Guidelines, Subdivision E, Section No. 72-1; 92/69/EEC C.1.
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] %. Juvenile Rainbow trout, *Oncorhynchus mykiss*, (mean body length 53 mm; mean body weight 135 g) were exposed to one concentration of the test substance (nominally 100 mg/L) under flow-through conditions for 96 hours. Seven fish randomly selected were employed in the treatment group and the water control group with one test chamber each. The compound appeared to be homogeneously distributed in the test vessels at all observation times and concentrations, however, at the start of the test the formation of small clumps clogging the valve of the pump lead to the high variation of the test substance concentration measured during the first 24 hours of the study. Measured concentrations of thiamethoxam determined daily ranged from 39 to 243% of nominal during the first 24 hours and from 108 to 125 % during the following 72 hours of the test. Taking into account the irregular dosing at the start of the test, the compound seemed to be stable in the test solution over the period of the study under flow-through conditions. Results are based on the mean measured concentration of 125 mg a.i./L.

Findings:

Acute toxicity of thiamethoxam to Rainbow trout

Concentration [mg a.i./L]		Mortality after 96 h [%]	Exposure period [hours]	LC_{50}[a] [mg a.i./L] (95 % conf. interval)
Nominal	Mean measured			
control	0	0	24 h	> 125
100	125	0	**96 h**	> 125
			NOEC: 125 mg a.i./L	

[a] calculated based on measured concentrations

Observations: No sublethal effects, such as a change in pigmentation, loss of equilibrium, change in the swimming behaviour or in the respiratory function were observed at any time of the study.

Conclusion: The acute 96-hour LC_{50} for Rainbow trout exposed under flow-through conditions was determined to be > 125 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	09/02/2005
Materials and Methods	[redacted]

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

98/8 Doc IIIA section No.	7.4.1.1 / 02	Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1 / 05	Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	11 ACUTE TOXICITY TEST OF CGA 293343 TECH. TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) UNDER FLOW-THROUGH CONDITIONS
	Report No. / Date	972548 / 26.11.1997
	Novartis File N°	Novartis Study # 293343-388
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	June 10, 1997 through June 14, 1997
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	OECD Guideline No.: 203; U.S. EPA FIFRA Pesticide Assessment Guidelines, Subdivision E, Section No. 72-1; 92/69/EEC C.1. (Total Length: mean 54 mm, (range 49-62 mm) based on 20 fish, one fish out of 20 was exceeding the OECD range of 40-60 mm)
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] Juvenile Rainbow trout, *Oncorhynchus mykiss*, (mean body length 54 mm; mean body weight 139 g) were exposed to one concentration of the test substance (nominally 100 mg/L) under flow-through conditions for 96 hours. Thirty fish randomly selected were employed in the treatment group (3 replicates of 10 fish) and 20 fish in the water control group (2 replicates of 10) with 10 fish per test chamber. The compound was homogeneously distributed in the test vessels at all observation times and concentrations. No precipitation was observed in the stock solution or the testing solutions throughout the duration of the test. Measured concentrations of thiamethoxam determined daily ranged from 89-120% of nominal concentrations over the period of the test. The mean measured concentration was 107 mg ai/l. Results are based on nominal values.

Findings:

Acute toxicity of thiamethoxam to Rainbow trout

Concentration [mg a.i./L]		Mortality after 96 h [%]	Exposure period [hours]	LC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Mean measured			
control	0	0	24 h	> 100
100	107	0	**96-h**	> 100
			NOEC: 100 mg a.i./L	

[a] calculated based on nominal concentrations

Observations: No sublethal effects, such as a change in pigmentation, loss of equilibrium, change in the swimming behaviour or in the respiratory function were observed at any time of the study.

Conclusion: The acute 96-hour LC_{50} for Rainbow trout exposed under flow-through conditions was 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	09/03/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.1 / 03	Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1 / 02	Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**12** CGA-293343 A 96-HOUR FLOW-THROUGH ACUTE TOXICITY TEST WITH THE BLUEGILL, ***LEPOMIS MACROCHIRUS***
	Report No. / Date	108A-189 / 14.10.1996
	Novartis File N°	Novartis Study # 293343-145
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	September 5, 1996 through September 9, 1996
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted] Purity: [redacted]
7.	Test method	U.S. EPA FIFRA Pesticide Assessment Guidelines, Subdivision E, Section No.72-1 (1982), and ASTM Standard E 729-88a.
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] Bluegill sunfish (*Lepomis macrochirus*) (mean body length 22 mm; mean body weight 0.28 g) were exposed to five concentrations of the test substance (nominal test concentrations of 16, 26, 43, 72 and 120 mg a.i./L) under flow-through conditions for a period of 96 hours. Two groups of ten fish randomly selected were employed per concentration and the water control. After incorporating the test substance into the diluter system, test solutions appeared clear and colourless. Measured test concentrations of thiamethoxam ranged from 81-96% of the nominal values during the period of exposure. The mean measured concentrations were 14, 24, 40, 64 and 114 mg test substance/l. The following values are based on mean measured concentrations.

Findings:

Acute toxicity of thiamethoxam to Bluegill sunfish

Concentration [mg a.i./L]		Mortality after 96 h [%]	Exposure period [hours]	LC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Mean measured			
control	0	0	24 h	> 114
16	14	0	48 h	> 114
26	24	0	72 h	> 114
43	40	0	96 h	> 114
72	64	0	NOEC: 114 mg a.i./L	
120	114	0		

[a] calculated based on measured concentrations

Observations: No mortalities were observed and fish appeared normal throughout the test with no overt signs of toxicity or any other sublethal effects.

Conclusion: The acute 96-hour LC_{50} for Bluegill sunfish exposed to thiamethoxam under flow-through conditions was determined to be >114 mg a.i./L.

Evaluation by Competent Authorities	
	7.4.1.1./03 Drottar and Swigert 1996 108A-189
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09/02/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 section No.	Doc IIIA	7.4.1.1 / 04	Acute toxicity to fish
91/414 Point addressed	Annex II	8.2.1 / 06	Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	13 ACUTE TOXICITY TEST OF CGA 322704 (METABOLITE OF CGA 293343) TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) IN THE STATIC SYSTEM
	Report No. / Date	962527 / 21.01.1997
	Novartis File N°	Novartis Study # 322704-9
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	August 19, 1996 through November 5, 1996
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted]
7.	Test method	OECD Guideline No.: 203; 92/69/EEC C.1. U.S. EPA FIFRA Pesticide Assessment Guidelines, Subdivision E, Section No. 72-1; (Deviation from FIFRA -Guideline: Number of replicates of test organisms, Continuous monitoring of temperature and equilibration time)
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 322704, Batch No. [redacted] The test was performed as a limit test. Juvenile Rainbow trout, *Oncorhynchus mykiss*, (mean body length 53 mm; mean body weight 13 g) were exposed to one concentration of the test substance (nominally 100 mg/L) under static test conditions for 96 hours. Seven fish per test concentration, and control were added to each aquarium. Measured concentrations of CGA 322704 determined at the beginning and the end of the test ranged from 72% to 102% of nominal values. Based on the dissolved fraction in the samples the measured concentrations were 70% and 100% of the nominal values, respectively. However, a precipitate was observed at 100 mg ai/l from the start of the test until 24h of exposure which lead to a 70% recovery in the dissolved fraction at the beginning of exposure. After 24 hours this precipitate was completely dissolved resulting in 100% recovery at the end of the exposure period. Therefore, the following values are based on nominal concentrations.

Findings:

Acute toxicity of CGA 322704 (metabolite of thiamethoxam) to Rainbow trout

Concentration of CGA 322704 [mg /L]		Mortality after 96 h [%]	Exposure period [hours]	LC_{50} [a] [mg/L] (95 % conf. interval)
Nominal	Mean measured			
control	0	0		
100	87	0	**96 h**	> 100
			NOEC: 100 mg/L	

[a] based on nominal values

Observations: No sublethal effects, such as a change in pigmentation, loss of equilibrium, change in the swimming behaviour or in the respiratory function were observed at any time of the study.

Conclusion: The acute 96-hour LC_{50} for Rainbow trout exposed to CGA 322704 (metabolite of thiamethoxam) under static conditions was determined to be >100 mg /L.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09/03/05
Materials and Methods	[redacted]
Results and discussion	[redacted] ed.
Conclusion	[redacted] l
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.1 / 05	Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1 / 02	Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	14 ACUTE TOXICITY OF CGA 355190 (METABOLITE OF CGA 293343) FOR RAINBOW TROUT (DETERMINATION OF THE LC-VALUES)
	Report No. / Date	G 54104, 982588 / 29.10.1998
	Novartis File N°	Novartis Study # 355190-2
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	September 7, 1998 through September 30, 1998
6.	Test substance	Company Code: CGA 355190, Batch number: [redacted]
7.	Test method	OECD Guideline No.: 203; 92/69/EEC C.1.
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 test was performed as a limit test. Juvenile Rainbow trout, *Oncorhynchus mykiss*, (mean body length 42 mm; mean body weight 0.68 g) were exposed to one concentration of the test substance (nominally 100 mg/L) under static test conditions for 96 hours. Seven fish per test concentration and control were added to each aquarium. Measured concentrations of CGA 355190 determined at the beginning and the end of the test ranged from 95.1% to 96.9% of nominal values. Therefore, the following values are based on nominal concentrations.

Findings:

Acute toxicity of CGA 355190 (metabolite of thiamethoxam) to Rainbow trout

Concentration of CGA 355190 [mg /L]		Mortality after 96 h [%]	Exposure period [hours]	LC_{50} [mg/L] (95 % conf. interval) [a]
Nominal	Mean measured			
control	< 0.4	0		
100	95.8	0	**96 h**	> 100
			NOEC: 100 mg/L	

[a] based on nominal values

Observations: No sublethal effects, such as a change in pigmentation, loss of equilibrium, change in the swimming behaviour and in the respiratory function were observed at any time of the study.

Conclusion: The acute 96-hour LC_{50} for Rainbow trout exposed to CGA 355190 (metabolite of thiamethoxam) under static conditions was determined to be >100 mg /L.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10/03/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.1 / 06	Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1 / 07	Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**15 ACUTE TOXICITY OF NOA 407475 (METABOLITE OF CGA 293343) TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*) IN A 96-HOUR STATIC TEST**
	Report No. / Date	688781 / 14.08.1998
	Novartis File N°	Novartis Study # 407475-10
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	July 06, 1998 through July 22, 1998
6.	Test substance	Company Code: NOA 407475, Batch number: [redacted]
7.	Test method	OECD Guideline No.: 203; 92/69/EEC C.1.
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 test was performed as a Limit test. Juvenile Rainbow trout, *Oncorhynchus mykiss*, (mean body length 46 ± 0.2 mm; mean body weight 1.00 ± 0.2 g) were exposed to one concentration of the test substance (nominally 100 mg/L) under static test conditions for 96 hours. Seven fish per test concentration, and control were added to each aquarium. Measured concentrations of NOA 407574 determined at the beginning and the end of the test were 87 % of nominal values. Therefore, the following values are based on nominal concentrations.

Findings:

Acute toxicity of NOA 407475 (metabolite of thiamethoxam) to Rainbow trout

Concentration of NOA 407475 [mg /L]		Mortality after 96 h [%]	Exposure period [hours]	LC_{50} [a] [mg/L] (95 % conf. interval)
Nominal	Mean measured			
control	< 0.4	0		
100	87.0	0	**96 h**	> 100
			NOEC: 100 mg/L	

[a] based on nominal values

Observations: No sublethal effects, such as a change in pigmentation, loss of equilibrium, change in the swimming behaviour or in the respiratory function were observed at any time of the study.

Conclusion: The acute 96-hour LC_{50} for Rainbow trout exposed to NOA 407475 (metabolite of thiamethoxam) under static conditions was determined to be >100 mg /L.

Evaluation by Competent Authorities	
	7.4.1.1/06 Seyfried, 1998a 688781
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10/03/05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.1 / 7 Acute toxicity to fish
91/414 Annex Point addressed	II 8.2.1 Acute toxicity to fish

1.	Annex point(s)	**II A, 8.2.1** **Acute Toxicity to Fish**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	16 NOA 459602 (THIAMETHOXAM METABOLITE): ACUTE TOXICITY TEST TO RAINBOW TROUT (*ONCORHYNCHUS MYKISS*).
	Report No. / Date	01-0416/B / 14.08.1998
	Novartis File N°	459602/0016
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	July 06, 1998 through July 22, 1998
6.	Test substance	Company Code: NOA 459602, Batch number: [redacted]
7.	Test method	OECD - Guideline No.: 203, Paris 1992; 92/69/EEC C.1.
8.	Deviations	None
9.	GLP	Yes (certified laboratory)

Test System: NOA 459602 (metabolite of thiamethoxam), Batch No.: [redacted] Rainbow trout, *Oncorhynchus mykiss*, (source: [redacted] control fish at test end: mean body length 57 mm (range 55 to 59 mm); mean body weight 2.43 g (range 1.36 to 3.71 g) were exposed to a single concentration of the test item under static conditions for a period of 96 hours. The test concentration (nominal: 120 mg NOA 459602 per litre) was evaluated. For the test concentration a single stock solution was prepared without using a solvent. In addition to the test item treatment a blank water control was tested. One group of 10 fish randomly selected were maintained in the treatment and control groups. The test was performed in 40 L-glass aquaria containing 25 L of test solution. Loading rate was approximately 0.97 g fish/L (test end in control).

Mortalities and symptoms of toxicity were recorded after 3, 24, 48, 72 and 96 hours. Temperature, dissolved oxygen and pH were measured daily in each test chamber. Total hardness of the water was determined periodically at the laboratory. Samples of test media from the test item and control aquaria were taken before test start and after 96 hours for the analytical determination (HPLC) of the test concentrations.

Findings: Results are given on basis of nominal concentrations. Concentrations varied between 100% of nominal at test start and 108% of nominal at test end. The overall mean concentration was 108% of nominal. The water temperature was in the range of 14.9 to 15.3 °C and a lighting regime of 16 hours light and 8 hours dark per day was employed. The dissolved oxygen content varied between 97 and 102 % of saturation, pH was 7.39 – 7.76, at test start the total hardness was 45.0 mg $CaCO_3$/L and the conductivity was 209 µS/cm.

Table 1 Acute toxicity of NOA 459602 (metabolite of thiamethoxam) to rainbow trout

	Mortality	Exposure	LC_{50} [a]

Concentration [mg NOA 459602 / L]			after 96 h [%]	period [hours]	(95 % conf. interval) [mg NOA 459602 / L]
Nominal	Start	End	-		
Control	<0.75	<0.75	0		
120	120	130	0	**96 h**	**> 120 (n.a.)**
				NOEC: 120 mg NOA 459602 / L	

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

Observations: No mortalities or sublethal effects were observed at any time of the study.

Conclusion: The acute 96-hour LC_{50} for Rainbow trout exposed to NOA 459602 (metabolite of thiamethoxam) under static conditions was determined to be > 120 mg /L.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 10/03/05

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks

98/8 Doc IIIA section No.	7.4.1.2 / 01	Acute toxicity to invertebrates
91/414 Annex Point addressed	II 8.2.4 / 04	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	Neumann, C. (1996)
	Title	**17 ACUTE TOXICITY TEST OF CGA 293343 TO THE CLADOCERAN *DAPHNIA MAGNA* STRAUS UNDER STATIC CONDITIONS**
	Report No. / Date	95G003 / 25.04.1996
	Novartis File N°	Novartis Study # 293343-43
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection, Inc. Ecotoxicology Laboratories, CH-4002 Basle Switzerland
5.	Dates of work	September 5, 1995 through September 7, 1995
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number [redacted]
7.	Test method	OECD Guideline No.: 202, Paris 1984 and FIFRA Guideline No.: 72-2, 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. 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: Thiamethoxam technical, Batch No. [redacted] The acute toxicity of thiamethoxam to *Daphnia magna* has been determined with five concentrations of test substance and a blank control at a temperature of 20 ±2 °C. Daphnids were exposed to the test concentrations under static conditions. For each concentration and the control, four replicates were set up. Each replicate consisted of 5 daphnids in 100 mL test medium (M4 medium). The daphnids were observed for immobilisation and behavioural changes after 24 h and 48 h of exposure. Nominal concentrations of thiamethoxam were 10, 18, 32, 58 and 100 mg/L. Concentrations measured at the test initiation were 9.92, 19.46, 35.85, 62.23, and 109.5 mg/L. At test termination measured concentrations were 11.15, 18.34, 37.05, 58.78 and 102.1 mg/L. Since the test substance was stable under the experimental conditions and constant exposure maintained throughout the static exposure, results are based on nominal concentrations.

Findings:

Acute toxicity of thiamethoxam to Dapnia magna

Concentration [mg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured End			
controls	0	0	24 h	> 100
10	11.15	0		
18	18.34	0	**48 h**	**> 100**
32	37.05	0		
58	58.78	5		
100	102.1	15	**NOEC: 32 mg a.i./L**	

[a] calculated based on nominal concentrations

Observations: A low percentage of immobilisation was recorded only at the highest concentrations of 58 and 100 mg a.i./L No further effects on daphnids were observed.

Conclusion: The acute 48-hour EC_{50} of *Daphnia magna* exposed to thiamethoxam under static conditions was 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	23/11/04
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 / 02	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. (2000b)
	Title	18 Acute toxicity test of CGA 293343 tech. to *Gammarus* Sp. under static conditions
	Report No. / Date	2002614 / 10.07.2000
	Syngenta File N°	293343-1229
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Syngenta Crop Protection AG, Basel Switzerland
5.	Dates of work	9th June 2000 through 17th 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 freshwater crustacean *Gammarus* Sp. has been determined at six different test concentrations and a blank control at a temperature of 20 ± 2 °C. The test organism, *Gammarus* Sp. was collected from the River Kastelbach, Kaltbrunnental, Switzerland, then transferred, together with the natural river water, to an aquarium housed in the Novartis laboratories. The single species required for testing was accordingly separated. *Gammarus* Sp. was 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 four concentrations (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), 1.6, 3.1, 6.3, 13, 25 and 50 mg thiamethoxam/L. Analysis of fortified test solutions at 0-hr and 48-hrs indicated that measured exposure concentrations were, respectively, in the range 93-99% and 92-96% 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 river water). Test vessels containing *Gammarus* 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 the order of 24 $\mu E/m^2sec$. Water quality measurements included pH (range 8.3-8.5), temperature (constant at 21 °C) and oxygen content (range 65-101 % 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 Gammarus

Concentration [mg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.01 / < 0.01	0	24 h	15
1.6	1.57 / 1.56	40		
3.1	3.07 / 2.94	50	**48 h**	**2.8**
6.3	6.13 / 5.85	60		
13	12.1 / 12.5	95		
25	24.0 / 23.1	95	**NOEC^: < 1.6 mg a.i./L**	
50	47.4 / 46.7	100		

[a] calculated based on nominal concentrations

^ Highest concentration with no immobilisation or behavioural changes

Conclusion: The acute 48-hour EC_{50} for the *Gammarus* Sp. when exposed to thiamethoxam under static conditions was determined to be 2.8 mg a.i./L. The 48-hour NOEC was determined to be less than 1.6 mg a.i./L, the lowest concentration level 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	24/11/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]

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

98/8 Doc IIIA section No.	7.4.1.2 / 03	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. (2000c)
	Title	19 Acute toxicity test (24h) of CGA 293343 tech. to three invertebrate species *Daphnia pulex* Leydig, *Thamnocephalus platyurus*, and *Brachionus calyciflorus* under static conditions.
	Report No. / Date	2002612 / 21.07.2000
	Syngenta File N°	293343/1274
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Syngenta Crop Protection AG, Basel Switzerland
5.	Dates of work	6th June 2000 through 15th 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 three individual invertebrate species (*Daphnia pulex* Leydig, *Thamnocephalus platyurus* both of which are freshwater crustaceans, and *Brachionus calyciflorus*, a freshwater rotifer species) has been determined under static conditions at six different test concentrations, plus a blank control, at a temperature of between 21 and 24 °C. A 24-hour exposure period was employed for the definitive test in view of the rapid metabolic characteristics of the test species. Additional prolongation could potentially result in starvation. *Daphnia pulex* and *Thamnocephalus platyurus* (both genus *Daphnia*) and *Brachionus calyciflorus* (genus *Brachionus*) were obtained from a reliable commercial supplier. The test animals were derived from cysts and ephippia hatched in the laboratory according to the given standard operating procedure. The acclimation period lasted for at least 2 hours, not exceeding 48 hours, and for *Brachionus* not in excess of 32 hours. The hatched organisms were maintained in a "moderately hard" reconstituted water (in-line with the formula recommended by the US EPA) and adjusted to pH 8.5. Stock solutions of thiamethoxam were prepared in "moderately hard" reconstituted water medium. A range-finding test was performed at three concentrations (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), 3.1, 6.3, 12.5, 25, 50 and 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 97-116% and 96-113% of the nominal concentrations for the test conducted with *Daphnia pulex*, and, 95-118% and 95-117% of nominal over the same exposure period for both *Thamnocephalus* and *Brachionus*. A total of 20, 30 and 30 organisms, respectively for *Daphnia pulex* Leydig, *Brachionus calcyciflorus* and *Thamnocephalus platyurus*, for each test concentration and the control, constituting, respectively, four, three and six replicates at each test concentration and control were performed. Multiwell plates were adopted as test vessels for the test. The following volumes were correspondingly used: *Daphnia pulex*, 5 mL; *Thamnocephalus platyurus*, 1 mL; *Brachionus calyciflorus*, 0.3 mL. Test vessels were incubated in a climatic chamber regulated at 21 to 24 °C. The test was performed in the dark. Water quality measurements included the following parameters: pH (range 8.0-8.3), temperature (21-22 °C for *Daphnia pulex* test, 23-24 °C for the two remaining species), oxygen content (93-101 % of saturation), hardness (82-84 mg $CaCO_3$/L), and conductivity (301-318 µS/cm). Immobilisation or other behavioural changes were recorded after 24-hours.

Findings: No immobilisation was observed in the control (blank culture medium) during the course of the 24-hour exposure period, with no unexpected phenomena being observed. The test was thus deemed valid. The results of the acute tests performed with *Daphnia pulex*, *Thamnocephalus platyurus* and *Brachionus calcyiflorus* are presented below.

Acute toxicity of thiamethoxam (tech.) to Daphnia pulex

Concentration [mg a.i./L]		Immobilisation after 24 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.01 / < 0.01	0		
3.1	3.12 / 3.08	0		
6.3	7.28 / 7.05	10		
12.5	12.6 / 12.8	15	**24 h**	**> 100**
25	24.9 / 24.2	25		
50	48.7 / 47.9	10		
100	97.6 / 98.3	20	**NOEC^: 6.3 mg a.i./L**	

[a] calculated based on nominal concentrations

^ Highest concentration with ≤ 10% immobilisation or behavioural changes (NB - up to 10% immobilisation is considered acceptable in the control to fulfill test validity criteria)

Acute toxicity of thiamethoxam (tech.) to Thamnocephalus platyurus

Concentration [mg a.i./L]		Immobilisation after 24 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.01 / < 0.01	0		
3.1	3.13 / 3.13	3.3		
6.3	7.38 / 7.34	3.3		
12.5	12.5 / 12.2	3.3	**24 h**	**> 100**
25	23.8 / 24.5	0		
50	48.3 / 47.4	3.3		
100	101.3 / 98.5	3.3	**NOEC^: 100 mg a.i./L**	

[a] calculated based on nominal concentrations

^ Highest concentration with ≤ 10% immobilisation or behavioural changes (NB - up to 10% immobilisation is considered acceptable in the control to fulfill test validity criteria)

Acute toxicity of thiamethoxam (tech.) to Brachionus calyciflorus

Concentration [mg a.i./L]		Immobilisation after 24 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.01 / < 0.01	0		
3.1	3.13 / 3.13	0		
6.3	7.38 / 7.34	0		
12.5	12.5 / 12.2	0	**24 h**	**> 100**
25	23.8 / 24.5	0		
50	48.3 / 47.4	6.7		
100	101.3 / 98.5	0	**NOEC^: 100 mg a.i./L**	

[a] calculated based on nominal concentrations

^ Highest concentration with ≤ 10% immobilisation or behavioural changes (NB - up to 10% immobilisation is considered acceptable in the control to fulfill test validity criteria)

Observations: The EC_{50} was not attained for any of the three species tested, and thus is cited as > 100 mg a.i./L, where 100 mg a.i./L represents the highest test concentration studied. With reference to the accepted validity criteria set for Control samples, which permits up to a maximum of 10 % immobilisation over the period of the test and applying this principle to the various test concentrations studied, an NOEC of 6.3 mg a.i./L, 100 mg a.i./L and 100 mg a.i./L was established for *Daphnia pulex*, *Thamnocephalus platyurus* and *Brachionus calyciflorus*, respectively.

Conclusion: The acute 24-hour EC_{50} for *Daphnia pulex*, *Thamnocephalus platyurus* and *Brachionus calyciflorus* when exposed tro thiamethoxam under static conditions was 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	26/11/2004
Materials and Methods	[redacted]
	[redacted] rt).
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.4.1.2 / 04	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. (2000d)
	Title	20 Acute toxicity test of CGA 293343 tech. to individual invertebrate species and molluscs from a natural pond assemblage under static conditions.
	Report No. / Date	2002642 / 21.07.2000
	Syngenta File N°	293343/1273
	Source / Owner	Unpublished / Syngenta Crop Protection AG
4.	Testing facility	Syngenta Crop Protection AG, Basel Switzerland
5.	Dates of work	20th June 2000 through 5th July, 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 several invertebrate and mollusc species, notably *Chaoborus* Sp., a freshwater aquatic species, and Ostracoda, a freshwater crustacean, from the former group and *Lymnea stagnalis* and *Radix peregra* from the mollusc group of organisms. The test organisms were collected from a natural assemblage from the Novartis Crop Protection field aquatic ecosystem at Stein, Aargau, Switzerland, and transferred, together with the natural pond water, to an aquarium housed in the Novartis laboratories. The single species required for testing were accordingly separated and acclimatised for at least a period of 20-h. No feed was provided during the 48-h test period. Several range-finding tests were performed at various concentrations for the various species (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 tests, the definitive tests were conducted at the following nominal concentrations: *Chaoborus* Sp. Control (0), 1.6, 3.1, 6.3, 13, 25 and 50 mg thiamethoxam/L; Ostracoda Control (0), 0.016, 0.031, 0.063, 0.125, 0.25 and 0.50 mg thiamethoxam/L; *Lymnea stagnalis* and *Radix peregra* Control (0), 100 mg thiamethoxam/L, only. Analysis of fortified test solutions at 0-hr and 48-hrs indicated that measured exposure concentrations were in the range 82-102 % of the nominal concentrations for all test systems. Stock solutions and corresponding dilutions were performed in pond water. Four replicates per test concentration containing 5 organisms per replicate were prepared. Exposure of *Chaoborus* Sp. was performed in 250 mL glass test vessels containing 200 mL of test solution (thiamethoxam tech. dissolved

in pond water). Petri dishes (60 mL) containing 40 mL of test solution were employed for the exposure of Ostracoda and both mollusc species. Test vessels containing the various species were incubated in a climatic chamber at 20 ± 2 °C 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 the order of 21 µE/m^2sec during the *Chaoborus* Sp. and mollusc exposure tests, and 16 µE/m^2sec during the test with Ostracoda. Water quality measurements included pH (range for all tests 7.4-9.2), temperature (constant at 20 °C), oxygen content (range for all tests 86-167% of saturation), water hardness and conductivity (334 mg $CaCO_3$/L and 202 µS/cm, respectively). 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 on the following Tables.

Acute toxicity of thiamethoxam (tech.) to Chaoborus Sp.

Concentration [mg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.05 / < 0.05	0	24 h	6.9
1.6	1.51 / 1.43	0		
3.1	3.06 / 2.97	5	**48 h**	**5.5**
6.3	5.99 / 6.14	80		
13	13.3 / 12.7	90		
25	24.4 / 23.0	100	**NOEC^: 3.1 mg a.i./L**	
50	46.1 / 45.0	100		

[a] calculated based on nominal concentrations

^ Highest concentration with no immobilisation or behavioural changes

Acute toxicity of thiamethoxam (tech.) to Ostracoda

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	< 2 / < 2	0	24 h	240
16	13.1 / 13.2	0		
31	25.3 / 26.4	0	**48 h**	**180**
63	54.9 / 54.9	0		
125	113 / 112	30		
250	236 / 233	65	**NOEC^: 63 µg a.i./L**	
500	466 / 466	100		

[a] calculated based on nominal concentrations

^ Highest concentration with no immobilisation or behavioural changes

Acute toxicity of thiamethoxam (tech.) to Lymnea stagnalis

Concentration [mg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.05 / < 0.05	0	24 h	> 100
100	94.8 / 98.8	0	**48 h**	**> 100**
			NOEC^: 100 mg a.i./L	

[a] calculated based on nominal concentrations

^ Highest concentration with no immobilisation or behavioural changes

Acute toxicity of thiamethoxam (tech.) to Radix peregra

Concentration [mg a.i./L]		Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [mg a.i./L] (95 % conf. interval)
Nominal	Measured Beginning / End			
control	< 0.05 / < 0.05	5	24 h	> 100
100	93.9 / 92.7	10	**48 h**	**> 100**
			NOEC^: 100 mg a.i./L	

[a] calculated based on nominal concentrations

^ Highest concentration with ≤ 10% immobilisation or behavioural changes (NB - up to 10% immobilisation is considered acceptable in the control to fulfill test validity criteria)

Conclusion: The 48-hour EC_{50} for the invertebrates *Chaoborus* Sp., Ostracoda when exposed to thiamethoxam under static conditions was 5.5 mg a.i./L and 0.18 mg a.i./L, respectively. The 48-hour EC_{50} was not attained for either of the two mollusc species tested, and thus is cited as > 100 mg a.i./L, where 100 mg a.i./L represents the highest test concentration studied. The NOEC was determined to be 3.1 mg a.i./L, 0.063 mg a.i./L for *Chaoborus* Sp. and Ostracoda, respectively, and 100 mg a.i./L for both *Lymnea stagnalis* and *Radix peregra*.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/11/2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]ble.
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 section No.	Doc IIIA	7.4.1.2 / 05	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	Neumann, C. (1997a)
	Title	21 ACUTE TOXICITY TEST OF CGA 322704 (METABOLITE OF CGA 293343) TO THE CLADOCERAN *DAPHNIA MAGNA* STRAUS UNDER STATIC CONDITIONS
	Report No. / Date	962528 / 31.01.1997
	Novartis File N°	Novartis Study # 322704-8
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection, Inc. Ecotoxicology Laboratories, CH-4002 Basle Switzerland
5.	Dates of work	August 27, 1996 through October 31, 1996
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted]
7.	Test method	OECD Guideline No.: 202, Paris 1984 and FIFRA Guideline No.: 72-2, 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. 1) Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984.

Test System: CGA 3322704, Batch No. [redacted] The acute toxicity of CGA 322704 to *Daphnia magna* was determined in a 48-hour static test with five test substance concentrations and a blank control. At initiation, 120 daphnids were randomly selected and equally distributed among four replicates of each treatment and the control (5 animals/replicate). Each 150 mL test vessel contained 100 mL test solution or the blank control. The temperature during exposure was 20 ± 2°C. Five concentrations were employed of nominal 10, 18, 32, 58 and 100 mg/L. During exposure water concentrations were always close to nominal values both at test initiation as well as at the end of the end of exposure and were > 95% of nominals in all samples. Results were therefore expressed in nominal values.

Findings:

Acute toxicity of CGA 322704 (metabolite of thiamethoxam) to Daphnia magna

Concentration [mg/L]	Immobilisation after 48 h [%]	Exposure period [hours]	EC_{50} [a] [mg/L] (95 % conf. interval)