Table A7_5_1_1-3: Test system

Criteria	Details
Artificial soil test substrate	Sphagnum moss peat – 10% Kaolinite clay – 20% Sand – 69% Calcium carbonate ($CaCO_3$) - 0.3% Food (dried horse manure) – 1% Moisture content was adjusted to approximately 33% using purified water.
Size, volume and material of test container	Glass dishes with a diameter of 14 cm and a height of 7 cm. Test vessels were covered by transparent lids. Lids had a fine mesh (mesh size 0.5 mm) to allow air exchange.
Amount of artificial soil (kg)/ container	500 g dry weight (soil depth of 5 – 6 cm.
Nominal levels of test concentrations	0.06, 0.18 and 0.3 mg/kg dry soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Room lighting
Feeding	5 g of air dried horse manure was added to the test vessels when they were prepared. After the addition of the earthworms 2.5 g of food was added to each vessel, thereafter approximately 2 – 4 g was added to the adults weekly. The offspring were fed only once at the start of the 4 week period.
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	Room temperature was in the range 19 to 22°C. Temporarily the temperature was between 22 and 23 °C due to technical problems. However, the results demonstrate that this did not affect the outcome of the study.
Moisture content	Soil moisture content was 33% at the start of the study and 35 – 37% at the termination of the study (8 weeks).
pH	pH was in the range 6.2 – 6.4 at the test start and pH was 6.2 in all treatments at the end of the study (8 weeks)
Adjustment of pH	No
Light intensity / photoperiod	Photoperiod was 16 hours light, 8 hours dark Light intensity was approximately 620 – 730 lux.

Table A7_5_1_2-5: Mortality data

Test Substance Concentration (nominal) [mg/kg artificial soil]	Vessel number	No. of earthworms exposed	Number of surviving earthworms	Total number of dead earthworms after 4 weeks exposure	% mortality after 4 weeks
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table A7_5_1_2-6: Mean body weights of earthworms at the start and end of the four week exposure period

Test Substance Concentration (nominal) [mg/kg artificial soil]	Vessel number	Day 0		Day 28		Difference	
		No of earthworms	Mean weight (mg)	No of earthworms	Mean weight (mg)	(mg)	(%)

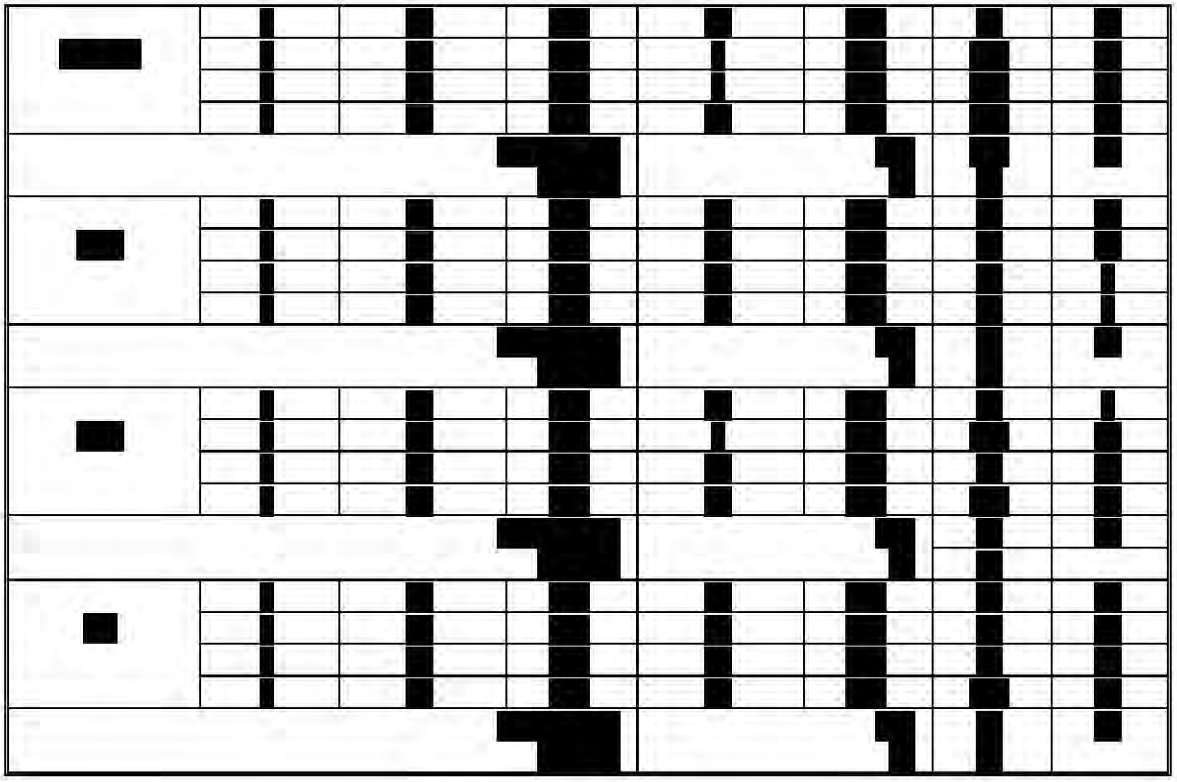

Table A7_5_1_2-7: Reproduction

Test Substance Concentration (nominal) [mg/kg artificial soil]	Vessel number	Juvenile worms		Reproduction rate			
		No. per vessel	Mean ± SD	Per surviving adult	Mean ± SD	CV (%)	% of control

* - significantly different to the control (Williams Test, one sided smaller, $\alpha = 0.05$)

Table A7_5_1_2-8: Validity criteria for earthworm reproduction study

Criterion	Fulfilled	Not fulfilled
Reproduction: at least 30 juveniles per test vessel in the control, coefficient of variance ≤30%	**yes**	-

Section A7.4.3.5/01 (applicant)

A. 7.5.2.1_02
Annex Point IIIA XIII 2.4

Effects on any other specific, non-target organisms (flora or fauna) believed to be at risk – Earthworm field study (applicant)

Reproduction study with other soil non-target macro-organisms

Official use only

53 REFERENCE

53.1	**Reference**	Pease, G. & Webster, D. (2004) CGA322704 (A metabolite of CGA293343 (thiamethoxam)): A field study to investigate the forced effect and recovery of earthworm populations following application to a bare field site in Denmark Ecotox Ltd. Tavistock, Devon, England, Report No.: ER-04-KCB 196 (Syngenta Project No. 2033604), 4 November 2004 (unpublished).
53.2	**Data protection**	Yes.
53.2.1	Data owner	Syngenta Crop Protection
53.2.2	Companies with letter of access	[redacted]
53.2.3	Criteria for data protection	[redacted]

54 GUIDELINES AND QUALITY ASSURANCE

54.1	**Guideline study**	BBA Part V1-2-3 (1994) and ISO 11268-3 (1999)
54.2	**GLP**	Yes, except for weather data
54.3	**Deviations**	None.

55 METHOD

55.1	**Test material**	CGA 322704 (metabolite of CGA 293343)
55.1.1	Lot/Batch number	[redacted]
55.1.2	Specification	As given in section 2
55.1.3	Purity	[redacted]
55.2	**Reference substance**	Carbendazim applied at a rate of 4000 g a.s./ha.
55.3	**Testing procedure**	
55.3.1	Pre-treatment assessment	On 30 May 2003 a pre-study earthworm sample was conducted to determine whether the site yielded sufficient numbers of earthworms per m^2 (BBA 1994 and ISO 11268-3 1999 guidelines) and included appropriate representative species. Earthworm species representative of the major functional groups were present on the site at the time of the pre-treatment sampling, including *Apporectodea longa*, and *Aporrectodea caliginosa*, epilobous juveniles were the dominant groups in terms of numbers and biomass. Adults of other species, such as *Lumbricus terrestris* and *Allolobophora chlorotica*, were also present. There were fewer occurrences of epigeic species such as *Lumbricus festivus* and *L. castaneus*.
55.3.2	Test location and	Study site - The study site was a bare earth field site in Denmark, which

	design	had been undisturbed and untreated since 2000. The site was approximately 141 x 56 m, approximately 0.75 hectare. A randomised block design of five treatments and four replicates was used. Each replicate was approximately 12 x 12 m (with an inner sampling area of 10 x 10 m) with an approximately 5 m dividing strip of grass between plots. The treatments were as follows: Control (water) 37.5 g CGA 322704/ha 75 g CGA 322704/ha 150 g CGA 322704/ha Reference substance, carbendazim 4000 g a.s./ha
55.3.3	Soil characterisation	Following analysis the soil on the site was classified as a loamy sand. The mean pH was 5.7, the mean cation exchange capacity (meq/100g) was 7.9, mean organic matter content was 1.8% w/w and the mean water holding capacity was 11.0% w/w. The mean soil components content was sand 815, silt 95 and clay 10%.
55.3.4	Test organisms	Field population of earthworms
55.3.5	Application of the test substance	The application was made to the site on 16 June 2003. All treatments were applied using a tractor mounted Hardi LX MB boom and nozzle sprayer with a 12 m boom and 50 cm nozzle spacing. The nozzles were Hardi ISO LD 03 110 flat fan low drift type. Water was applied to the control plots first, followed by the CGA 322704 treatments from low to high rate. The carbendazim treatment was applied last. The application volume was equivalent to 1000 L/ha. The percentage of applied volume of spray in relation to the percentage of actual volume per plot ranged from a minimum of 97.9% (in the control treatment) to a maximum of 101.7% (in the 150g/ha treatment).
55.3.6	Test conditions	Irrigation - A permanent Bording Mobil M5 irrigation system at the study site was used both before and after treatment application. Between 4 June 2003 and 15 June 2003 (pre-treatment), approximately 50 mm irrigation was applied to the site. A combination of 22 mm rainfall and irrigation at the site was recorded for the 3-day period following application. In the 5 day period, 8 to 13 July 2003 leading up to the first post-treatment sampling occasion approximately 34 mm irrigation was applied to the site. An electronic data monitoring system was installed approximately 50 m from the site, it was programmed to record minimum and maximum air and soil temperatures and daily rainfall. Soil moisture was recorded on each sampling occasion.
55.3.7	Test duration	386 days
55.3.8	Test parameter	Earthworm abundance and biomass
55.3.9	Sampling	Earthworm sampling - Sampling took place within a central 10 m x 10 m area of each plot (12 m x 12 m), using four 0.25 m^2 quadrats in each plot, combined to give a sample of 1m^2. Earthworms were sampled using a digging (to a depth of approximately 30 cm) and hand-sorting method on all occasions. For a period of seven days immediately after application, surface searches were carried out daily and earthworms

collected from the same four 1 m^2 areas per plot were identified and counted in the test and reference item treatments.

55.3.10 Monitoring of test substance concentration

Yes. Analysis was performed by high performance liquid chromatography with triple quadrople mass spectrometry detection (LC-MS/MS).

55.3.11 Statistics

For both abundance and biomass, totals per plot were calculated before analysis was performed. One of the assumptions of the analysis was that the variances in earthworm abundance/biomass between plots in different treatment groups are equal. This assumption was appropriate for earthworm biomass but not for earthworm abundance, where treatment groups with larger mean counts tend to have larger variances and *vice versa*. Before analysis, therefore, both pre- and post treatment abundance data were transformed onto a $\log_{10}$ (abundance + 1) scale. This transformation is commonly used to correct for the specific form of heterogeneity of variance observed in abundance data (Sokal and Rohlf, 1981). An analysis of variance, appropriate to a randomised complete block design, was performed on the transformed pre-treatment abundance data and untransformed pre-treatment biomass data. In each case, the pooled estimate of residual error variance obtained was used to compare each treatment to a control using a two-sided Dunnett's t-test (Hsu, 1996) at a significant level $p<0.05$.

An analysis of covariance, appropriate to a randomised block design, was performed on the transformed post-treatment abundance data, using the transformed pre-treatment abundance data as a covariate, and on the untransformed post-treatment biomass data, using the untransformed pre-treatment biomass data as covariate. These analyses were followed by significance tests (F-tests) at the significance level $p < 0.05$ to determine whether the pre-treatment abundance/biomass data influenced the post-treatment abundance/biomass data. If the covariate was found to be significant, an analysis of covariance was selected whereas, if the covariate was not found to be significant, an analysis of variance was selected. For both abundance and biomass data, the pooled estimate of residual error obtained from the selected form of analysis was sued to compare each treatment to the control using a two-sided Dunnett's test (Hsu, 1996) at the 5% significance level.

56 RESULTS

56.1 Field study

56.1.1 Measured concentrations of test substance

CGA 322704 residues in the plots applied with the lowest test rate ranged from 18.5 to 27.6 g /ha.

CGA 322704 residues in the plots applied with the medium test rate ranged from 31.1to 82.9 g /ha.

CGA 322704 residues in the plots applied with the highest test rate ranged from 68.0 to 114.3 g /ha.

There was no contamination of the control plots.

56.1.2 Meteorological data

The meteorological data is presented in table A7_4_3_4-1.

Section A7.4.3.5/01 (applicant) Effects on any other specific, non-target organisms (flora or fauna) believed to be at risk – Earthworm field study (applicant)

A. 7.5.2.1_02
Annex Point IIIA XIII 2.4

Reproduction study with other soil non-target macro-organisms

56.1.3	Effect data (biomass and abundance)	Total mean number of earthworms collected on each sampling occasion following application of CGA322704 in the field is presented in table A7_4_3_4-2. Total mean weight (g) of earthworms collected on each sampling occasion following application of CGA322704 in the field is presented in table A7_4_3_4-3.
56.2	**Test with reference substance**	
56.2.1	Concentrations	4000 g a.s./ha
56.2.2	Results	There were significant differences between the reference item, carbendazim, applied at 4000 g ai/ha for total numbers and biomass of earthworms when compared with controls approximately one, four and nine months after treatment. These data confirm the validity of the study. There were no significant differences between the reference item treatment and the controls for any taxa on the final sampling occasion approximately one year after application.

57 APPLICANT'S SUMMARY AND CONCLUSION

57.1	**Materials and methods**	BBA Part V1-2-3 (1994) and ISO 11268-3 (1999). No deviations
57.2	**Results and discussion**	Results of the post-treatment surface searches showed that ≤ 1 % of the pre-treatment sample population died on the surface during the first week after application in the test and reference item treatments. A significant reduction in abundance for 'epilobous juveniles' and 'total juveniles' was observed at the lowest test item application rate of 37.5 g/ha approximately one month after application. Biomass for 'other epilobous juveniles' was also significantly different when compared to control at approximately one month after application. There were no significant differences in either abundance or biomass in any other groups or on any subsequent sampling occasion. There were no significant reductions in total earthworm abundance on any post-treatment sampling occasion in the 75 g /ha treatment. Biomass was significantly lower in this treatment for 'total earthworms' on one post-treatment sampling occasion only, approximately three months after application. There were no subsequent effects on abundance or biomass for any taxon. Abundance of *A. caliginosa* was lower in the 150 g/ha treatment than in the controls on one occasion only, but biomass was significantly lower in this treatment for three taxa; *A. caliginosa* on one occasion only approximately nine months after application; 'other epilobous juveniles' at one and three months after application; 'total earthworms' at approximately three months after application. There were no effects of this treatment on either abundance or biomass on the final sampling occasion approximately one year after application. On the final sampling occasion, approximately one year after application, there were no significant differences between the controls and the test material, CGA 322704 applied at 37.5, 75 or 150 g /ha in

Section A7.4.3.5/01 (applicant) Effects on any other specific, non-target organisms (flora or fauna) believed to be at risk – Earthworm field study (applicant)

A. 7.5.2.1_02
Annex Point IIIA XIII 2.4

Reproduction study with other soil non-target macro-organisms

		either abundance or biomass of earthworms.
57.3	**Conclusion**	CGA322704, when applied at three rates of 37.5, 75 and 150 g CGA 322704/ ha showed no adverse effects on earthworm populations for either ecological groups or individual species in samples collected one year after application of the treatments. Equivalent to a thiamethoxam maximum rate of approximately 200 g thiamethoxam/ha.
57.3.1	Other Conclusions	None
57.3.2	Reliability	1
57.3.3	Deficiencies	No

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

Table A7_4_3_4-1: Monthly rainfall, mean soil moisutre potential and minimum and maximum air and soil temperatures during the study period

Date	Rainfall (mm)	Minimum air temperature (°C)	Maximum air temperature (°C)	Minimum soil temperature (°C)	Maximum soil temperature (°C)	Mean soil moisture potential (hPa)
June 5 – 30 2005	100.7	8.2	27.9	12.5	20.3	Pre-treat (13 Jun to 02 Jul 03) 47.0
July 2003	64.4	10.3	34.6	14.7	23.1	1 MAA (07 Jul to 22 jul 03) 74.4
August 2003	64.6	4.8	34.6	12.3	23.6	*
September 2003	31.9	1.7	27.8	7.7	21.6	3 MAA (09 Sep to 22 Sep 03) 91.1
October 2003	36.2	-5.7	17.6	1.6	12.3	*
November 2003	56.3	-1.4	13.8	2.7	8.8	*
December 2003	51.8	-7.3	9.3	0.1	7.3	6 MAA (24 Nov to 10 Dec 03) 12.1
January 2004	88.7	-11.0	6.6	-0.6	2.8	*
February 2004	49.9	-5.8	11.1	-5.8	7.1	*
March 2004	47.0	-5.1	15.8	-5.1	15.8	9 MAA (09 Mar to 25 Mar 04) 17.6
April 2004	32.7	0.5	19.7	0.5	17.9	*
May 2004	30.2	2.6	26.3	8.4	16.7	*
June 2004	70.3	4.1	26.4	11.6	18.3	12 MAA (29 Jun to 09 Jul 04) 188.2
July 1- 9 2004	40.1	7.1	24.2	12.9	17.9	*
For the year	**Ttoal 764.8**	**Minimum -11.0**	**Maximum 34.6**	**Minimum -5.8**	**Maximum 23.6**	**Mean 71.7**

* - no soil potentiometer reading taken

MAA – months after application

Table A7_4_3_4-2: Total mean number of earthworms collected on each sampling occasion following application of CGA322704 in the field

Treatment	Application rate	Mean total number of earthworms collected / m^2					
		Pre-treatment	28DAT	92DAT	169DAT	274DAT	386DAT
[redacted]							

DAT – Days after treatment.
*Significantly different from the control in Dunnett's test, ($p<0.05$).

Table A7_5_1_1-3: Total mean weight (g) of earthworms collected on each sampling occasion following application of CGA322704 in the field

Treatment	Application rate	Mean total number of earthworms collected / m^2					
		Pre-treatment	28DAT	92DAT	169DAT	274DAT	386DAT
[redacted]							

DAT – Days after treatment.
*Significantly different from the control in Dunnett's test ($p<0.05$).

98/8 Doc IIIA section No.	7.5.3.1.1 / 01	Acute oral toxicity
91/414 Annex Point addressed	II 8.1.1 / 02	Effects on birds - Acute oral toxicity

1.	**Annex point(s)**	**II A, 8.1.1** **Effects on Birds - Acute Oral Toxicity**
2.	**Location in Dossier**	Section 6
3.	**Authors / Year**	[redacted]
	Title	**58 CGA 293343 ACUTE ORAL TOXICITY (LD50) TO THE BOBWHITE QUAIL**
	Report No. / Date	CBG 744, 960155 / 23.04.1996
	Novartis File N°	Novartis Study # 293343-46
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	**Testing facility**	[redacted]
5.	**Dates of work**	December 19, 1995 to January 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 Assessment Guidelines, Subdivision E, Section No. 71-1 (October 1982) and its revised draft (1988).
8.	**Deviations**	None noted
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 92-64-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984. Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health and Social Security, and Department of Health, 1989. EC Council directive, 87/18 EEC of 18 December 1986.

Test System: Thiamethoxam technical, Batch No. [redacted] %. Thiamethoxam, dispersed in 1% methylcellulose, was administered to individual Bobwhite quail, *Colinus virginianus* by oral intubation using a disposable syringe and a CH10 Nelaton plastic catheter. Sixty adult birds (30 males and 30 females), approximately 22 months old with a body weight range of 171-208 g at study initiation, were distributed by random draw into 6 groups of ten birds each (five males / five females), with five treatment groups and one control group. Treatment levels: 125, 250, 500, 1000 and 2000 mg/kg. The birds were examined for mortality, clinical signs, body weight gain and food consumption for a period of 14 days.

Findings:

Acute oral toxicity of thiamethoxam to the bobwhite quail

Dose [mg/kg bw]	Toxicological results [a]	LLD[3] [mg/kg bw]	LD_{50} [mg/kg bw]	NOEL [mg/kg bw]
Control	0 / 0 / 10	**1000**	**1552**	**125**
125	0 / 0 / 10			
250	0 / 0 / 10			
500	0 / 0 / 10			
1000	2 / 4 / 10			
2000	7 / 9 / 10			

[a] number of birds which died / number of birds with overt clinical signs / total number of birds exposed

Clinical signs: Clinical signs of toxicity were observed at 1000 and 200 mg/kg. These included subdued behaviour, unsteadiness and ruffled feathers. Some females at 2000 mg/kg did not show clinical signs of toxicity until several days after dosing. Markedly lower food consumption and large body weight losses occurred at 1000 and 2000 mg/kg. Slight effects on both parameters were noted at 250 and 500 mg/kg.

Gross necropsy: At necropsy, clinical findings were mainly in birds from the dose group 2000 mg/kg and were generally associated with body weight loss. Red/dark coloured intestines were also observed in a few birds.

Conclusion: The acute oral LD_{50} of bobwhite quail exposed to thiamethoxam was determined to be 1552 mg/kg bw.

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]able.
Conclusion	[redacted]
	[redacted]
	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 section No.	Doc IIIA	7.5.3.1.1 / 02	Acute oral toxicity
91/414 Point addressed	Annex	II 8.1.1 / 03	Effects on birds - Acute oral toxicity

1.	Annex point(s)	**II A, 8.1.1** **Effects on Birds - Acute Oral Toxicity**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**59 CGA 293343 ACUTE ORAL TOXICITY (LD50) TO THE MALLARD DUCK**
	Report No. / Date	CBG 745, 960013 / 23.04.1996
	Novartis File N°	Novartis Study # 293343-44
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	January 3, 1996 through January 17, 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. 71-1 (October 1982) and draft revised guideline 71-1 dated march 1988.
8.	Deviations	None noted
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 92-64-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984. Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health and Social Security, and Department of Health, 1989. EC Council directive, 87/18 EEC of 18 December 1986.

Test System: Thiamethoxam technical, Batch No. [redacted] Purity [redacted] %. Thiamethoxam, dispersed in 1% methylcellulose, was administered to individual Mallard ducks *(Anas platyrhynchos)* by oral intubation using a disposable syringe and a CH10 Nelaton plastic catheter. Sixty adult birds (30 males and 30 females), 21 weeks old with a body weight range of 925-1375 g at study initiation, were distributed by random draw into six groups of ten birds each (five males / five females), with five treatment groups and one control group. Treatment levels: 76, 137, 247, 444 and 800 mg/kg. The birds were examined for mortality, clinical signs, body weight gain and food consumption for a period of 14 days.

Findings:

Acute oral toxicity of thiamethoxam to the Mallard duck

Dose [mg/kg bw]	Toxicological results[a]	LLD[29] [mg/kg bw]	LD_{50} [mg/kg bw]	NOEL [mg/kg bw]
Control	0 / 0 / 10	444	576	>76
76	0 / 0 / 10			
137	0 / 0 / 10			
247	0 / 10 / 10			
444	4 / 10 / 10			
800	7 / 10 / 10			

[a] number of birds which died / number of birds with overt clinical signs / total number of birds exposed

Clinical signs: All treated birds vomited after dosing. Clinical signs of toxicity were observed at 247 mg/kg and above. These included subdued behaviour, unsteadiness and inability to stand. Body weight losses occurred at 444 and 800 mg/kg during the week following dosing. No food was consumed by birds from the highest treatment group of 800 mg/kg during days 1 to 3 after dosing. In all other treatment groups food consumption was generally low relative to controls.

Gross necropsy: At necropsy, abnormalities were found in a few birds at 800 and 444 mg/kg found dead after dosing. These findings were mainly in the gastrointestinal tract and included colouration of intestines and watery red fluid in the abdominal cavity.

Conclusion: The acute oral LD_{50} of the Mallard duck exposed to thiamethoxam was determined to be 576 mg/kg bw.

29 Lowest lethal dose

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 section No.	Doc IIIA	7.5.3.1.1 / 03	Acute oral toxicity
91/414 Point addressed	Annex	II 8.1.1 / 01	Effects on birds - Acute oral toxicity

1.	Annex point(s)	**II A, 8.1.1**	**Effects on Birds - Acute Oral Toxicity**
2.	Location in Dossier	Section 6	
3.	Authors / Year	[redacted]	
	Title	**60 ACUTE ORAL TOXICITY STUDY IN BOBWHITE QUAIL WITH CGA 322704**	
	Report No. / Date	Notox 242257, 982601 / 07.10.1998	
	Novartis File N°	Novartis Study # 322704-17	
	Source / Owner	Unpublished / Novartis Crop Protection AG	
4.	Testing facility	[redacted]	
5.	Dates of work	July 15, 1998 to August 12, 1998	
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted] Purity: [redacted]	
7.	Test method	U.S. EPA Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organisms, Series 71-Avian and Mammalian Testing, § 71-1, Avian single dose oral LD_{50} test, October 1982 and draft revised guideline, dated March 1988.	
8.	Deviations	None noted	
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 92-64-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984. Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health and Social Security, and Department of Health, 1989. EC Council directive, 87/18 EEC of 18 December 1986.	

Test System: CGA 322704 technical, Batch No. [redacted] Purity [redacted]%. CGA 322704 was administered by oral gavage, using corn oil as a vehicle, to five birds (Bobwhite quail, *Colinus virginianus)* of each sex at 192, 343, 617, 1111 or 2000 mg/kg body weight. A control group of five birds of each sex was dosed with vehicle (5 ml/kg body weight). Birds were observed at periodic intervals on the day of dosing and daily thereafter. Body weight was determined at day 1 (start of study), day 8, day 11 and/or day 12 (for some birds), day 15 and at death. Food consumption was measured from days 1-4, 4-8, 8-11 and 11-15. Macroscopic post-mortem examination was performed on the day of death or at termination (day 15).

Findings:

Acute toxicity of CGA 322704 (metabolite of thiamethoxam) to the Bobwhite quail

Dose [mg/kg bw]	Toxicological results [a]	LLD^{30} [mg/kg bw]	LD_{50} [mg/kg bw]	NOEL [mg/kg bw]
Control	0 / 0 / 10	**2000**	**> 2000**	**191**
192	0 / 0 / 10			
343	1 / 1 / 10			
617	0 / 1 / 10			
1111	0 / 10 / 10			
2000	2 / 10 / 10			

[a] number of birds which died / number of birds with overt clinical signs / total number of birds exposed

Clinical signs: Clinical signs of toxicity were observed from dose levels of 343 mg/kg bw onwards. These included hunched posture, lethargy, ventro-lateral recumbency, uncoordinated movement, abnormal gait, emaciation and ptosis which were seen in most birds from the two highest dose groups (1111 and 2000 mg/kg bw) between 3 hours and 12 days after dosing. Markedly lower food consumption and large body weight losses occurred at dose levels of 1111 and 2000 mg/kg bw. Slight effects on body weight gain were noted at 343 mg/kg but were not observed in birds receiving 617 mg/kg bw. The NOEL in this study was 191 mg/kg bw.

Gross necropsy: At necropsy, clinical findings were mainly in birds from the dose groups 617, 1111 and 2000 mg/kg and were in general enlarged red spleens, emaciation and dark red livers reduced in size.

Conclusion: The acute oral LD_{50} of the Bobwhite quail exposed to CGA 322704 (metabolite of thiamethoxam) was determined to be > 2000 mg/kg bw.

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/01/2005
Materials and Methods	[redacted]

[30] Lowest lethal dose

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

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

98/8 Doc IIIA section No.	7.5.3.1.2 / 01	Short term toxicity
91/414 Annex Point addressed	II 8.1.2 / 01	Effects on birds - Short-term dietary toxicity

1.	Annex point(s)	**II A, 8.1.2** **Effects on Birds - Short-Term Dietary Toxicity**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**61 CGA 293343 SUBACUTE DIETARY (LC50) TO THE BOBWHITE QUAIL**
	Report No. / Date	CBG 746, 960156 / 01.05.1996
	Novartis File N°	Novartis Study # 293343-47
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	December 21, 1995 through December 29, 1998
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. 71-2 (October 1982), and OECD Guideline 205 (4 April, 1984), and ASTM Standard E857-87 (1987).
8.	Deviations	None noted
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 92-64-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984. Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health and Social Security, and Department of Health, 1989. EC Council directive, 87/18 EEC of 18 December 1986.

Test System: Thiamethoxam technical, Batch No. [redacted] Purity [redacted]%. Thiamethoxam was incorporated into the basal diet and offered *ad libitum* to Bobwhite quail (*Colinus virginianus*). Ten birds per dose level, (7 days old, body weight range of 10.1- 10.3 g, unsexed), were assigned to the treatment groups by random draw. There were six treatment and two control groups. The birds received the appropriate dietary concentrations *ad libitum* for five consecutive days and were maintained on basal diet for an additional three-day observation period. Treatment levels: 163, 325, 650, 1300, 2600 and 5200 mg/kg feed. Mortalities, clinical observations, body weight gain and food consumption were recorded.

The mean measured concentrations of thiamethoxam in the diets fed during the study were within 10% of nominal values. Test diet formulations were homogeneously blended and stable for a period representing the maximum time from preparation to completion of dosing.

Findings:

Short-term dietary toxicity of thiamethoxam to the Bobwhite quail

Dose [mg/kg feed]	Toxicological results[a]	LLC[31] [mg/kg feed]	LC_{50} [mg/kg feed]	NOEC [mg/kg feed]
Control	0 / 0 / 20	**> 5200**	**> 5200**	**1300**
163	0 / 0 / 10			
325	0 / 0 / 10			
650	0 / 0 / 10			
1300	0 / 0 / 10			
2600	0 / 0 / 10			
5200	0 / 0 / 10			

[a] number of birds which died / number of birds with overt clinical signs / total number of birds exposed

Observations: There were no mortalities, overt symptoms of toxicity or behavioural abnormalities at any test substance concentration. Group mean body weight gain was reduced at 2600 and 5200 mg/kg feed relative to controls. Although food consumption was variable between the groups, there were no treatment-related trends apparent. Due to the reduction in body weight gain at 2600 and 5200 mg/kg feed, the no observed effect level was considered to be 1300 mg/kg feed. The short-term dietary LC_{50} of the Bobwhite quail was determined to be > 5200 mg/kg feed. From day 0 to day 5 the mean bodyweight of birds in the highest treatment group was 15.85 g/bird and the mean food consumption in this treatment during this period was 5.88 g food/bird/day. Therefore the LC_{50} can alternatively be expressed as > 1.929 g thiamethoxam/kg b.w./day taking into account the actual consumption and bodyweights recorded in this study.

Gross necropsy: No treatment related abnormalities were detected.

Conclusion: The short-term dietary LC_{50} of the Bobwhite quail exposed to thiamethoxam was determined to be > 5200 mg/kg feed, equivalent to an LD_{50} of or > 1.929 g thiamethoxam/kg b.w./day.

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/01/2005
Materials and Methods	[redacted].

31 Lowest lethal concentration

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

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

98/8 Doc IIIA section No.	7.5.3.1.2 / 02	Short term toxicity
91/414 Annex Point addressed	II 8.1.2 / 02	Effects on birds - Short-term dietary toxicity

1.	Annex point(s)	**II A, 8.1.2** **Effects on Birds - Short-Term Dietary Toxicity**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**62 CGA 293343 SUBACUTE DIETARY TOXICITY (LC50) TO THE MALLARD DUCK**
	Report No. / Date	CBG 747, 960199 / 23.04.1996
	Novartis File N°	Novartis Study # 293343-45
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	December 21, 1995 through December 29, 1995
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. 71-2 (October 1982), and OECD Guideline 205 (4 August 1984), and ASTM Standard E857-87 (1987).
8.	Deviations	None noted
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 92-64-12367-9, Paris 1982; and Japan MAFF, 59 NohSan, Notification No. 3850, Agricultural Production Burea, 10 August 1984. Good Laboratory Practice, The United Kingdom Compliance Programme, Department of Health and Social Security, and Department of Health, 1989. EC Council directive, 87/18 EEC of 18 December 1986.

Test System: Thiamethoxam technical, Batch No. [redacted], Purity [redacted] %. Thiamethoxam was incorporated into the basal diet and offered *ad libitum* to Mallard duck *(Anas platyrhynchos)*. Ten birds per dose level, (6 days old, body weight range of 83 - 84 g, unsexed), were assigned to the treatment groups by random draw. There were six treatment and two control groups. The birds received the appropriate dietary concentrations *ad libitum* for five consecutive days and were maintained on basal diet for an additional three-day observation period. Treatment levels: 163, 325, 650, 1300, 2600 and 5200 mg/kg feed. Mortalities, clinical observations, body weight gain and food consumption were recorded.

The mean measured concentrations of thiamethoxam in the diets fed during the study were within 10% of nominal values. Test diet formulations were homogeneously blended and stable for a period representing the maximum time from preparation to completion of dosing.

Findings:

Short-term dietary toxicity of thiamethoxam to the Mallard duck

Dose [mg/kg feed]	Toxicological results[a]	LLC[32] [mg/kg feed]	LC_{50} [mg/kg feed]	NOEC [mg/kg feed]
Control	0 / 0 / 20	**> 5200**	**> 5200**	**163**
163	0 / 0 / 10			
325	0 / 0 / 10			
650	0 / 0 / 10			
1300	0 / 0 / 10			
2600	0 / 0 / 10			
5200	0 / 0 / 10			

[a] number of birds which died / number of birds with overt clinical signs / total number of birds exposed

Observations: There were no mortalities, overt symptoms of toxicity or behavioural abnormalities at any test substance concentration. A treatment related reduction in group mean body weight gain was noted at 1300 mg/kg feed and above. A slight reduction was also noted at 325 and 650 mg/kg feed. In the post-treatment period a compensatory gain in body weight had occurred in these dose groups. There was also a reduction in feed consumption in the three highest dose groups during the treatment period which had improved by the end of the study. Due to the reduction in body weight gain and food consumption noted at 1300 mg/kg feed and above and the slight reduction in body weight gain at 325 and 650 mg/kg feed, the no observed effect level was considered to be 163 mg/kg feed. From day 0 to day 5 the mean bodyweight of birds in the highest treatment group was 150.5 g/bird and the mean food consumption in this treatment during this period was 34 g food/bird/day. Therefore the LC_{50} can alternatively be expressed as > 1.175 g thiamethoxam/kg b.w./day taking into account the actual consumption and bodyweights recorded in this study.

Gross necropsy: No abnormalities were detected.

Conclusion: The short-term dietary LC_{50} of the Mallard duck exposed to thiamethoxam was determined to be > 5200 mg/kg feed, equivalent to an LD_{50} of > 1.175 g thiamethoxam/kg b.w./day.

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17/01/2005
Materials and Methods	[redacted]e
Results and discussion	[redacted]

32 Lowest lethal concentration

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

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

98/8 Doc IIIA section No.	7.5.3.1.3 / 01	Effects on reproduction
91/414 Annex Point addressed	II 8.1.3 / 02	Effects on birds - Subchronic toxicity and reproduction

1.	Annex point(s)	**II A, 8.1.3 Effects on Birds - Subchronic Toxicity and Reproduction**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**63 THE REPRODUCTIVE TOXICITY TEST OF CGA-293343 TECHNICAL WITH THE NORTHERN BOBWHITE (*COLINUS VIRGINANUS*)**
	Report No. / Date	029518 / 09.07.1998
	Novartis File N°	Novartis Study # 293343-653
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	September 5, 1996 through March 28, 1997
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted] Purity: [redacted]%
7.	Test method	US EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms (EPA, 1982), and in ASTM Standard Practice for Conducting Avian Reproduction Test, DRAFT No. 9, 1983.
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.

Test System: Thiamethoxam technical, Batch [redacted] Purity [redacted] %. Test species: adult bobwhites (*Colinus virginianus*), approaching their first breeding season; age 18 weeks and 1 day; weight between 168.7-237.1 g for males and females; Source: [redacted]. One hundred and forty-four birds, including three dose groups and one control group were employed in the study. Each treatment and the control group consisted of 18 replicates, one male and one female per replicate. Birds were offered test diet containing 100, 300 and 900 mg thiamethoxam/ kg feed over a period of 23 weeks. After 13 weeks of treatment, first eggs were set for incubation and observed until 14 days post-hatch. Exposure of the parental generation continued for 10 weeks of egg production. Adults were observed daily for mortality, abnormal behaviour and signs of toxicity. Reproductive parameters such as the number of eggs laid, number of eggs cracked, egg shell thickness, embryonic viability and chick survival were assessed.

The mean measured concentrations of thiamethoxam in test diet formulations analysed during the study were 95.08 ± 13.3 for the 100 mg/kg feed level; 309.89 ± 28.4 for the 300 mg/kg feed level and 946.42 ± 129.8 for the 900 mg/kg feed dose level confirming the accuracy of preparation. Storage stability of the test substance under frozen and ambient storage conditions was also performed. No significant loss of thiamethoxam occurred over the storage periods.

Findings:

Reproductive toxicity of thiamethoxam to the Northen bobwhite

Reproductive parameters	Control	100 mg / kg feed	300 mg kg feed	900 mg / kg feed
Total eggs laid in each group	990	1139	918	876
Eggs laid / per hen	61.8	63.3	61.2	51.5
Eggs laid / per day per hen	0.87	0.89	0.86	0.73
Eggs cracked	9	10	9	8
Eggs cracked / eggs laid	0.009	0.009	0.010	0.009
Mean egg shell thickness (mm)	0.209	0.207	0.208	0.210
Eggs set	901	1040	835	786
Fertile eggs	815	986	787	706
Fertile eggs/ eggs set	0.90	0.95	0.94	0.90
Viable embryos	794	972	777	690
Viable embryos / fertile eggs	0.97	0.99	0.99	0.99
Hatchlings	755	933	745	650
Hatchlings / viable embryos	0.95	0.96	0.96	0.94
14-Day old survivors	429	501	497	412
14-Day old survivors / of hatchlings	0.57	0.54	0.67	0.63
Hatchlings / eggs set	0.84	0.90	0.89	0.83
14-Day old survivors / eggs set	0.48	0.48	0.60	0.52
14-Day old survivors/hen	26.8	27.8	33.13	24.2
Mean chick body weight at hatching (g)	6.22	6.39	6.21	6.16
Mean chick body weight at 14 days (g)	22.07	20.94	22.84	22.62
NOEL	**900 mg/kg feed**			

Observations: There were six mortalities in the adult quail population during the treatment period including birds from all dose groups and the control group. It was considered that these mortalities were not treatment related and all surviving birds were noted to be normal in appearance and behaviour with a few exceptions. No overt signs of treatment-related toxicity were observed in the study. Bodyweight and food consumption in the treatment groups were not significantly different from the control group. Post-mortem examination of adult birds revealed no treatment-related abnormalities and all findings are regarded as typical in a large group of birds maintained on an *ad libitum* feed. There were no significant differences on the reproductive parameters detected at any level of treatment when statistically compared against the control group.

Conclusion: The reproductive no-observed-effect concentration during this study was determined to be 900 mg/ kg feed (equivalent to 74.0 mg a.i./kg b.w./day).

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.3.1.3 / 02	Effects on reproduction
91/414 Annex Point addressed	II 8.1.3 / 01	Effects on birds - Subchronic toxicity and reproduction

1.	Annex point(s)	**II A, 8.1.3 Effects on Birds - Subchronic Toxicity and Reproduction**
2.	Location in Dossier	Section 6
3.	Authors / Year	[redacted]
	Title	**64 THE REPRODUCTIVE TOXICITY TEST OF CGA-293343 TECHNICAL WITH THE MALLARD DUCK (*ANAS PLATYRHYNCHOS*)**
	Report No.	029710 / 09.11.1998
	Novartis File N°	Novartis Study # 293343-889
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	[redacted]
5.	Dates of work	March 3, 1998 through September 8, 1998
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted] Purity: [redacted]
7.	Test method	US EPA Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms (EPA, 1982), and in ASTM Standard Practice for Conducting Avian Reproduction Test, DRAFT No. 9, 1983.
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.

Test System: CGA 293343 technical, Batch No. [redacted], Purity [redacted] %. Test species: adult Mallard Duck (*Anas platyrhynchos)*, approaching their first breeding season; age 25 weeks and 1 day; weight between 937.7 - 1022.6 g for males and females; Source [redacted] One hundred and twenty-eight birds, including three dose groups and one control group were employed in the study. Each treatment and the control group consisted of 16 replicates, one male and one female per replicate. Birds were offered test diet containing 100, 300 and 900 mg CGA 293343/ kg feed over a period of 189 days (27 weeks). After 11 weeks and 2 days of treatment, first eggs were set for incubation and observed until 14 days post-hatch. Exposure of the parental generation continued for 10 weeks of egg production. Adults were observed daily for mortality, abnormal behaviour and signs of toxicity. Reproductive parameters such as the number of eggs laid, number of eggs cracked, egg shell thickness, embryonic viability and chick survival were assessed.

The mean measured concentrations of CGA 293343 in test diet formulations analysed during the study were 101.82 ± 19.47 for the 100 mg/kg feed level; 307.14 ± 34.33 for the 300 mg/kg feed level and 908.75 ± 73.72 for the 900 mg/kg feed dose level confirming the accuracy of preparation. Storage stability of the test substance under frozen and ambient storage conditions was also performed. No significant loss of CGA 293343 occurred between the storage periods and feed mixing intervals; at the 100 and 900 mg/kg feed dose levels, a 10.5% and 6.7% decrease in concentrations were observed by day 21 when feed mix was again prepared.

Findings:

Reproductive toxicity of thiamethoxam to the Mallard duck

Reproductive parameters	Control	100 mg / kg feed	300 mg / kg feed	900 mg / kg feed
Number of Replicates (productive pairs)	16	14	12	16
Total eggs laid in each group	718	580	558	551
Eggs laid / per hen	44.88	41.43	46.50	34.44
Eggs laid / per day per hen	0.64	0.59	0.66	0.49
Eggs cracked	44	39	25	22
Eggs cracked / eggs laid	0.06	0.07	0.04	0.04
Mean egg shell thickness (mm)	0.353	0.357	0.361	0.353
Eggs set	616	492	480	479
Fertile eggs	567	453	457	427
Fertile eggs/ eggs set	0.92	0.92	0.95	0.89
Viable embryos	536	412	421	378
Viable embryos / fertile eggs	0.95	0.91	0.92	0.89
Hatchlings	458	334	361	324
Hatchlings / viable embryos	0.85	0.81	0.86	0.86
14-Day old survivors	420	320	345	306
14-Day old survivors / of hatchlings	0.92	0.96	0.96	0.94
Hatchlings / eggs set	0.74	0.68	0.75	0.68
14-Day old survivors / eggs set	0.68	0.65	0.72	0.64
14-Day old survivors/hen	26.25	22.86	28.75	19.13
Mean chick body weight at hatching (g)	36.4	35.7	35.3	35.2
Mean chick body weight at 14 days (g)	189.7	225.3	222.6	229.5
NOEL	**300 mg/kg feed**			

Observations: There was only one mortality in the adult mallard population (female, 100 mg/kg feed test group) during the treatment period including birds from all dose groups and the control group. The mortality was not treatment related and the majority of birds were noted to be normal in appearance and behaviour with a few exceptions. No overt signs of treatment-related toxicity were observed in the study. There were five females that did not lay eggs at any time during this study, one in the 100 mg/kg feed group and four in the 300 mg/kg feed group. All hens in the 900 mg/kg feed group laid eggs. Since there was no indication of a dose-response relationship, the occurrence of non-layers in the 100 and 300 mg/kg feed groups was considered not to be related to the test substance. Food consumption in the treatment groups was not significantly different from the control group. Post-mortem examination of adult birds revealed no treatment-related abnormalities and all findings are regarded as typical in a large group of birds maintained on *ad libitum* feed. There were no significant differences in the reproductive parameters detected at any level of treatment when statistically compared against the control group. Subtle yet statistically significant decreases in adult body weight were detected in males from the 900 ppm test groups as compared to the controls in the last two weighing intervals. At termination, the average adult male body weights for 0, 100, 300, and 900 mg/kg feed test groups were 1225.7, 1197.4, 1113.6, and 1109.3 grams, respectively.

Conclusion: The reproductive no-observed-effect concentration during this study was determined to be 300 mg/kg feed (equivalent to 34.9 mg a.i./kg b.w./day).

Section 7.5.3.1.1 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	19/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No.	7.5.4.1 / 01	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.1.1 / 01	Bees: Acute toxicity

1.	Annex point(s)	**II A, 8.3.1.1** **Bees: Acute Toxicity**
2.	Location in Dossier	Section 6
3.	Authors / Year	Kleiner, R. (1995)
	Title	**65 TESTING TOXICITY TO HONEYBEE -*APIS MELLIFERA* L. (LABORATORY) ACCORDING TO EPPO GUIDELINE NO. 170: CGA-293343**
	Report No. / Date	951048045 / 25.10.1995
	Novartis File N°	Novartis Study # 293343-18
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	BIOCHEM GmbH Karlsruhe, Labor Cunnersdorf, Am Wieseneck 7, D-04451, Cunnersdorf, Germany
5.	Dates of work	September 20, 1995 through September 27, 1995
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343 tech., Batch number: [redacted]
7.	Test method	EPPO Guideline No. 170
8.	Deviations	None
9.	GLP	Study was conducted according to the Principles of Good Laboratory Practice (GLP) Chemikaliengesetz, July 1994, Anhang 1).

Test System: Thiamethoxam technical, Batch number [redacted]; [redacted]% purity. Test species: *Apis mellifera* L. (Hymenoptera: Apidae); Source: beekeeper (Weimann) in Gottscheina, Germany.

Oral test: Bees were dosed by group feeding using a 50% sucrose solution. Nominal concentrations were used. The treatments were as follows: Six test doses of thiamethoxam (ranging from 0.002- 0.02 µg ai/bee), one control dose (50% sucrose-water solution) and six doses of a toxic standard (dimethoate 400 g/L EC, ranging from 0.20 to 0.40 µg ai/bee). Test duration: 48 hours. Experimental design: 3 replicates/treatment, 10 bees/ replicate. Biological observations on mortality and behaviour were made at 24 and 48 hours after application.

Contact test: Bees were dosed by topical application. Nominal concentrations were used. The test substance was dissolved in acetone. Bees received six test doses of thiamethoxam ranging from 0.005 to 0.05 µg ai/bee, one carrier control dose (acetone) and six doses of a toxic standard (dimethoate 400 g/L EC, ranging from 0.0313 to 1.0 µg ai/bee). Test duration: 48h. Experimental design: 3 replicates/ treatment, 10 bees/replicate. Biological observations on mortality and behaviour were made at 24 and 48 hours after application.

Findings:

Acute toxicity of CGA 293343 via oral exposure in the laboratory

Dose level [µg/bee]	Mortality following oral exposure [%]	Exposure period	LD_{50}

		24 h	48 h	[hours]	[µg/bee]
control	sucrose	0	0		
thiamethoxam	0.002	0	0		
	0.004	43	43	**24**	**0.005**
	0.008	83	83		
	0.12	87	87	**48**	**0.005**
	0.016	97	97		
	0.02	97	97		
Toxic standard	0.20	3	3		
	0.24	3	10	24	0.374
	0.28	13	23		
	0.32	40	50	48	0.335
	0.36	30	53		
	0.40	67	77		

Acute toxicity of CGA 293343 via contact exposure in the laboratory

Dose level [µg/bee]		Mortality following contact exposure [%]		Exposure period	LD_{50}
		24 h	48 h	[hours]	[µg/bee]
control	sucrose	0	0		
thiamethoxam	0.005	0	0		
	0.01	0	7	**24**	**0.027**
	0.02	17	23		
	0.03	67	70	**48**	**0.024**
	0.04	87	87		
	0.05	100	100		
Toxic standard	0.0313	0	0		
	0.0625	0	7		
	0.125	0	13	24	0.363
	0.25	7	30		
	0.5	90	90	48	0.260
	1.0	100	100		

Observations: Affected bees showed restlessness, irritation, uncontrollable motions and dorsal position before dying. Twenty-four hours and 48 hours after application the surviving bees exhibited no behavioural anomalies. In the reference treatment apathy, uncontrollable motions and dorsal position of affected bees could be observed before dying.

Conclusion: The acute 48-hour LD_{50} of *Apis mellifera* exposed to thiamethoxam via oral exposure in the laboratory was determined to be 0.005 µg/bee. The acute 48-hour LD_{50} of *Apis mellifera* exposed to thiamethoxam via contact exposure in the laboratory was determined to be 0.024 µg/bee.

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

	Evaluation by Competent Authorities
Date	20/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.5.4.1 / 02	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.1.1 / 02	Bees: Acute toxicity

1.	Annex point(s)	**II A, 8.3.1.1**	**Bees: Acute Toxicity**
2.	Location in Dossier	Section 6	
3.	Authors / Year	Nengel, S. (1997)	
	Title	**66 ASSESSMENT OF SIDE EFFECTS OF CGA 322704 TO THE HONEYBEE, *APIS MELLIFERA* L. IN THE LABORATORY**	
	Report No. / Date	97071/01-BLEU, 972512 / 14.07.1997	
	Novartis File N°	Novartis Study # 322704-11	
	Source / Owner	Unpublished / Novartis Crop Protection AG	
4.	Testing facility	GAB Biotechnology GmbH, Niefern, Germany	
5.	Dates of work	April 22, 1997 through April 24, 1997	
6.	Test substance	Company Code: CGA 322704, Batch number: [redacted], Purity: [redacted]%	
7.	Test method	EPPO Guideline No. 170	
8.	Deviations	None	
9.	GLP	Study was conducted according to the Principles of Good Laboratory Practice (GLP) Chemikaliengesetz, July 1994, Anhang 1). The OECD Principles of Good Laboratory Practice	

Test System: CGA 322704 technical, batch number [redacted] purity. Test species: *Apis mellifera* L. (Hymenoptera: Apidae); Source: beekeeper (B. Deger) in Baden-Würtemberg, Germany. Age: approximately 22- 32 days old.

Oral test: Bees were dosed by group feeding using a 50% sucrose solution. Nominal concentrations were used. Five test doses of the metabolite of thiamethoxam (ranging from 0.0016-0.0625 µg CGA 322704/bee), one control dose (50% sucrose-water solution) and four doses of a toxic standard 'Rogor' (dimethoate 400 g/L EC, ranging from 0.0675 to 0.15 µg a.i./bee) were tested. Test duration: 48 hours. For each treatment five replicate groups of 10 bees were tested.

Contact test: Bees were dosed by topical application. Nominal concentrations were used. The test item was dissolved in water in combination with a surface-tension-lowering substance ("Citowett" at 1 mL/L water). Bees received five test doses of the metabolite of thiamethoxam ranging from 0.0016 to 0.0625 µg CGA 322704/bee, one carrier control dose (water in combination with a surfactant-tension-lowering substance: 'Citowett' 1 mL/L) and four doses of a toxic standard (dimethoate 400 g/L EC, ranging from 0.08-0.20 µg ai/bee). Test duration: 48h. For each treatment, five replicate groups of 10 bees were tested. Foloowing both oral and contact exposure observations on mortality and behaviour were made at 24 and 48 hours after dosing.

Findings:

Acute toxicity of the metabolite CGA 322704 via oral exposure

Dose level [µg/bee]			Mortality oral [%] following exposure		Exposure period	LD_{50} (95 % conf. interval)
	nominal	actual intake	24 h	48 h	[hours]	[µg/bee]
control	sucrose	0	0	0		
CGA 322704	0.0016	0.0015	0	0		
	0.004	0.0044	0	4.0		
	0.01	0.0114	28.0	28.0	**48**	**0.0168**
	0.025	0.0222	64.0	66.0		(0.0139-0.0203)
	0.0625	0.0481	100	100		
Dimethoate	0.675	0.0791	0	4.0		
	0.084	0.0956	10.0	24.0	48	0.1263
	0.105	0.1208	36.0	42.0		(0.1181-0.1351)
	0.15	0.1647	66.0	80.0		

Acute toxicity of the metabolite CGA 322704 via contact exposure in the laboratory

Dose level [µg/bee]		Mortality contact [%] following exposure		Exposure period	LD_{50} (95 % conf. interval)
	nominal	24 h	48 h	[hours]	[µg/bee]
control	Carrier [a]	0	0		
CGA 322704	0.0016	0	0		
	0.004	4.0	4.0		
	0.01	4.0	10.0	48	**0.0275**
	0.025	32.0	38.0		(0.0226-0.0335)
	0.0625	88.0	88.0		
Dimethoate	0.08	0	0		
	0.12	4.0	4.0	48	0.1644
	0.16	28.0	42.0		(0.1573-0.1718)
	0.20	80.0	88.0		

[a] water in combination with a surfactant-tension-lowering substance: 'Citowett' 1 mL/L

Observations: In regard to the behaviour the treated bees did not differ from the controls at any time during the test. Results obtained for the toxic standard dimethoate where within the accepted range indicating the validity of this study.

Conclusion: The acute 48-hour LD_{50} of *Apis mellifera* exposed to CGA 322704 via oral exposure in the laboratory was determined to be 0.0168 µg/bee. The acute 48-hour LD_{50} of *Apis mellifera* exposed to thiamethoxam via contact exposure in the laboratory was determined to be 0.0275 µg/bee

	Evaluation by Competent Authorities
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	Evaluation by Competent Authorities
Date	20/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.5.4.1 / 03	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.1.1	

1.	Annex point(s)	**II A, 8.3.1.1 Non target arthropods**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grimm, C. (1998a)
	Title	Acute Toxicity Test of CGA 293343 FS 350 (A-9700 B) to the predatory ground beetle *Poecilus cupreus* L. (Coleoptera: Carabidae).
	Report No. / Date	983663, November 2, 1998
	Syngentra File N°	293343/0876
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Basel, Switzerland
5.	Dates of work	September 4, 1998 through September 21, 1998
6.	Test substance	Company Code: CGA 293343 tech., formulated product A9700 B, Batch number: [redacted]
7.	Test method	Heimbach, U. (1992): Laboratory method to test effects of pesticides on *Poecilus cupreus* (Coleoptera, Carabidae). IOBC/WPRS Bulletin 1992/XV/3:103-109..
8.	Deviations	The test item was applied as a seed dressing and not sprayed on the sand surface
9.	GLP	Yes – certified laboratory

Test System: CGA 293343 FS 350 (A-9700 B, formulation containing 358 g CGA 293343/L). Test species: *Poecilus cupreus* L. (Coleoptera, Carabidae); Age: 4-5 week old adult beetles; Source: BTL Bio-Test Labor GmbH, Birkenallee 19, D-18184, Sagerheide, Germany. Adult beetles, housed in plastic boxes (175 cm^2 surface area) filled with approximately 250 g quartz sand moistened to 70% of its maximum water holding capacity, were exposed by adding treated summer wheat seeds (*Triticum aestivum* var. Greina) to the test units (placed on the sand surface) nominally dressed with A-9700 B at a rate of 70 g a.i./100 kg seed. The sowing rate was equivalent to 200 kg wheat seeds/ha. The treatments were as follows: one test unit each containing 10 wheat seeds dressed with the test item, with a deionised water control and with a toxic standard (methyl-parathion WP 40) at a dressing rate equivalent to 160 g a.i./100 kg seeds, respectively. Experimental design: six beetles (three male and three female)/replicate, five replicates/treatment. Test duration: 14 days. At test initiation, and on test days 2, 4, 7 and 10 the beetles were fed one perforated fly pupae, *Calliphora spp.*, per surviving beetle. Biological observations on mortality and behaviour were recorded 2, 4 6 hours and at 1, 2, 4, 7, 10 and 14 days after treatment. In addition, food consumption (fly pupae) was recorded at 2, 4, 7, 10 and 14 days after treatment. At these times it was also recorded whether the beetles appeared to have been feeding on the treated seeds. The test units were maintained at a temperature of 17.0-20.0°C, a relative humidity range of 65-96% under a 16 hour light:8 hour dark regime with a light intensity of 900-1100 lux.

Findings:

Acute toxicity of CRUISER® 350 FS (A-9700 B) treated wheat seeds on P. cupreus adults under laboratory conditions

	Effects on Mortality and Food Consumption

Treatment	14- day mean mortality [%]	Average number of fly pupae consumed per evaluation interval [pupae/beetle]
Control	0	0.57
CRUISER® 350 FS 70 g ai/100 kg seeds	100	0.50
Toxic standard	100	n.a.

n.a. – not assessed

Observations: No abnormal behaviour of the beetles was observed in the control. The first signs of detrimental changes in behaviour of the beetles treated with the test item were observed 4 hours after exposure and 2 hours after exposure in the toxic standard treatment. After 4 days of exposure in the test item treatment and after 2 days of exposure in the toxic standard treatment all beetles were found dead. The mean food consumption per beetle per assessment interval was 0.57 pupae and 0.50 pupae in the control and test item treatment, respectively. However, it should be noted that due to the total mortality in the test item treatment by 4 days, the consumption value for this treatment is based only upon the feeding during first 2 days of exposure. No feeding consumption data were obtained for the toxic standard treatment as there were no surviving beetles at the first feeding evalution.

Conclusion: After 4 days of exposure to wheat seeds nominally dressed with 200 mL CRUISER® 350 FS (A-9700 B)/kg seed (equivalent to 70 g a.i./100 kg seed) and a sowing rate of 200 kg seeds/ha, 100 % mortality of *P. cupreus* adults occurred under laboratory conditions.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	25/01/2004
Materials and Methods	[redacted]

	Evaluation by Competent Authorities
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.5.4.1 / 04	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.1.1	

1.	Annex point(s)	**II A, 8.3.1.1 Non target arthropods**
2.	Location in Dossier	Section 6
3.	Authors / Year	Grimm, C. (1998b)
	Title	Acute toxicity of CGA 293343 FS 350 (A-9700 B) to the rove beetle *Aleochara bilineata* Gyll. (Coleoptera Staphylinidae)
	Report No. / Date	983664, November 3, 1998
	Syngentra File N°	293343/0877
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Basel, Switzerland
5.	Dates of work	September 4,1998through September 25, 1998
6.	Test substance	Company Code: CGA 293343 tech., formulated product A9700 B, Batch number: [redacted]
7.	Test method	Samsoe-Petersen, L. (1992): Laboratory method for testing side-effects of pesticides on the rove beetle *Aleochara bilineata*-adults. IOBC Bulletin 1992/XV/3: 82-88.
8.	Deviations	The test item was applied as a seed dressing and not sprayed on the sand surface
9.	GLP	Yes – certified laboratory

Test System: CGA 293343 FS 350 (A-9700 B, formulation containing 358 g CGA 293343/L). Test species: *Aleochara bilineata* gyllenhal (Coleoptera Staphylinidae); Age: 7 to 12-day old female beetles; Source: De Groene Vlieg, Nieuwe Tonge, Netherlands. Adult beetles, housed in plastic test units (surface area of 18.86 cm^2), containing a layer of quartz sand (36 g moist sand/test unit), were exposed by adding treated summer wheat seeds (*Triticum aestivum* var. Greina) to the test units (placed on the sand surface) nominally dressed with A-9700 B at a rate of 70 g a.i./100 kg seed. The sowing rate was equivalent to 200 kg wheat seeds/ha. The treatments were as follows: one test unit each containing 1 wheat seed dressed with the test item, with a deionised water control and with a toxic standard (methyl-parathion WP 40) at a dressing rate equivalent to 160 g a.i./100 kg seeds, respectively. Experimental design: ten replicates per treatment each with 1 *Aleochara bilineata* female. Test duration: 14 days (4 days of exposure, followed by a 10 day egg viability phase). Mortality, behaviour and food consumption (number of fly eggs of *Protophormia terraenovae*) of the beetles were recorded on test day 1, 2, 3 and 4. The number of *Aleochara bilineata* eggs laid until test day 4 were detemined following their separation from the sand substrate, and the number of hatched larvae were recorded over the following 10 days, whilst being maintained on moist filter paper in Petri dishes. The test units were maintained at a temperature of 17.0-21.0°C, a relative humidity range of 65-90% under a 16 hour light: 8 hour dark regime with a light intensity of 180-400 lux.

Findings:

Acute toxicity of CRUISER® 350 FS (A-9700 B) treated wheat seeds on A. bilineata females under laboratory conditions

Treatment	Effects on Mortality and Food Consumption		Effects on Reproduction	
	Cumulative Mortality on day 4 [%]	Average number of onion fly eggs consumed day 0-day 4 [eggs/beetle]	Average number of eggs laid during the 4 day exposure phase [eggs/beetle]	Hatching success of the eggs laid during the 4 day exposure phase [%]
Control	0	217.7	53.6	93.4
CRUISER® 350 FS 70 g a.i./100 kg seeds	90	46.0	0.0	n.a. [b]
Toxic standard	100	n.a. [a]	n.a. [b]	n.a. [b]

[a] n.a.: not applicable due to 100% mortality
[b] n.a.: not applicable as no eggs were laid

Observations: No abnormal behaviour of the beetles was observed in the control. Exposure of rove beetles to CRUISER® 350 FS treated wheat seeds had severe effects on the mortality, feeding rate and egg production. On days 1 and 3 of exposure the number of consumed onion fly eggs was significantly reduced in the test item treatment group compared to the control group. No eggs were produced in the CRUISER® 350 FS treatment group compared to 53.6 eggs per beetle in the control group, with 93.4% of them hatching. Since no eggs were laid following test item treatment, no hatching rate could therefore be determined.

Conclusion: After 4 days of exposure to wheat seeds nominally dressed with 200 mL CRUISER® 350 FS (A-9700 B)/kg seed (equivalent to 70 g a.i./100 kg seed) and a sowing rate of 200 kg seeds/ha, 90 % mortality of *A. bilineata* adults occurred under laboratory conditions. The food consumption during this period was reduced and no eggs were oviposited. Resulting in an R-value (based on reproduction) of 0.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/01/2004

	Evaluation by Competent Authorities
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 section No.	Doc IIIA	7.5.4.1 / 05	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Point addressed	Annex	II 8.3.1.1	

1.	Annex point(s)	**II A, 8.3.1.1 Non target arthropods**
2.	Location in Dossier	Section 6
3.	Authors / Year	Reber, B. (2000)
	Title	Acute Toxicity Test of CGA 293343 FS 350 (A 9700 B) to larvae of the predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae).
	Report No. / Date	2003631, November 7, 2000
	Syngentra File N°	293343/1336
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Basel, Switzerland
5.	Dates of work	September 26, 2000 through October 24, 2000
6.	Test substance	Company Code: CGA 293343 tech., formulated product A9700 B, Batch number: [redacted]
7.	Test method	Heimbach, U. (1998): Testing the effects of plant protection products on larvae of the carabid beetle *Poecilus cupreus* (Coleoptera, Carabidae) in the laboratory, method and results. IOBC/WPRS Vol. 21(6): 21-28.
8.	Deviations	The test item was applied as a seed dressing and not sprayed on the sand surface
9.	GLP	Yes – certified laboratory

Test System: CGA 293343 FS 350 (A 9700 B, formulation containing 358 g/L CGA 293343). Test species: *Poecilus cupreus* L. (Coleoptera, Carabidae); Age: 24-48 hour old larvae; Source: BioChem Agrar, D-04451, Cunnersdorf, Germany. Beetle larvae introduced into glass tubes (2.2 cm diameter, 7 cm high) containing 5 cm depth of LUFA 2.1 soil adjusted to 30% of its water holding capacity. Just prior to beetle introduction a single pea seed *Pisum sativum* and one half of a thawed pupae of *Calliphora* spp. (food) was placed on the soil surface. Each tube was covered by a lid with holes of 2mm diameter to allow ventillation. The pea seeds introduced for the test item treatment group had been dressed with 150 mL A-9700 B/100 kg seed (equivalent to 52.5 g a.i./100 kg seed). Those in the toxic standard treatment group had been dressed with 400 g Methylparathion WP 40 (containing 40% methylparathion)/100 kg seed. Seeds introduced into the control test units had been treated with deionised water. The sowing density in all treatment groups was equivalent to 7143 kg seeds/ha (resulting in an application rate of 3750 g a.i./ha). This application rate is approximately 60 times and 29 times the maximum application rates of thiamethoxam resulting for the proposed uses of CRUISER® 350 FS in cereals and peas, respectively. Experimental design: 1 larvae/replicate, 40 replicates/treatment. Test duration 14 days. Biological observations were made 3 times/week during which the mortality was determined. At these times the surviving larvae were fed with half of a thawed pupa of *Calliphora* spp. placed on the soil surface and the old food was removed. The test units were maintained in darkness at a temperature of 19.5-21.0°C and 68-82% relative humidity during the test.

Findings:

Effects of CRUISER® 350 FS (A-9700 B) treated pea seeds on larvae of P. cupreus under extended laboratory conditions

Treatment[a]	14- day mean mortality [%]
Control	7.5
CRUISER® 350 FS 52.5 g a.i./100 kg seeds	100
Toxic standard	100

[a] all treatments received pea seeds sown at a density equivalent to 7143 kg seeds/ha

Observations: After 5 days of exposure, all larvae in the test item treatment and in the toxic standard treatment were found dead on the soil surface.

Conclusion: After 5 days of exposure to pea seeds dressed with 150 mL CRUISER® 350 FS (A-9700 B)/kg seed (equivalent to 52.5 g a.i./100 kg seed) and a sowing rate of 7143 kg seeds/ha, 100 % mortality of *P. cupreus* larvae occurred under extended laboratory conditions. It should be noted that this exagerated sowing density of 7143 kg seeds/ha resulted in a a very unrealistic application rate of 3750 g a.i./ha. This application rate is approximately 60 times and 29 times the maximum application rates of thiamethoxam resulting for the proposed uses of CRUISER® 350 FS in cereals and peas, respectively

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/01/2005

	Evaluation by Competent Authorities
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.5.4.1 / 06 Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.1.1

1.	Annex point(s)	**II A, 8.3.1.1 Non target arthropods**
2.	Location in Dossier	Section 6
3.	Authors / Year	Candolfi, M.P., (1998a)
	Title	Acute Toxicity Test of CGA 293343 FS 350 (A 9700 B) to larvae of the predatory ground beetle Poecilus cupreus L. (Coleoptera: Carabidae).
	Report No. / Date	983772October 28, 1998
	Syngentra File N°	293343/0797
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	Testing facility	Novartis Crop Protection AG, Basel, Switzerland
5.	Dates of work	June 8, 1998through June 22, 1998
6.	Test substance	Company Code: CGA 293343 tech., formulated product A9567 B, Batch number: [redacted]
7.	Test method	BARRETT, K.L., GRANDY, N., HARRISON, E.G., HASSAN, S. AND OOMEN, P. (eds.) 1994: Guidance Document on Regulatory Testing Procedures for Pesticides with Non-Target Arthropods. From the ESCORT Workshop (European Standard Characteristics of Beneficial Regulatory Testing); Wageningen, Holland, 28 - 30 March, 1994. Dohmen *et al.*, (1998): Testing side effects of pesticides on carabid beetles. Draft Ring-Testing Guideline. A joint initiative of EPPO, BART, IOBC and COMET. Heimbach, U., Büchs, U. & Abel, Ch. (1992): A semi-field method close to field conditions to test effects of pesticides on *Poecilus cupreus* (Coleoptera, Carabidae). IOBC/WPRS Bulletin XV/3:159-165.
8.	Deviations	The test item was applied as a seed dressing and not sprayed on the sand surface
9.	GLP	Yes – certified laboratory

Test System: CRUISER® WS 70 (A-9567 B, formulation containing 70.1% CGA 293343). Test species: *Poecilus cupreus* L. (Coleoptera, Carabidae); Age: adult beetles (23 days after emerging from hibernation); Source: BTL, Sagerheide, Germany. Adult beetles, housed in exposure units (50 cm square metal frames, which enclosed an area of 0.25 m^2 and approximately 25 cm deep). The units were sunken 10-15 cm into the soil with approximately 10 cm protruding. The soil at the field site in Stein (Northern Switzerland) had the following characteristics; 58.29% sand, 17.33% clay and 24.38% silt, the organic carbon was 1.96% and pH was 7.14. A Summer wheat (cultivar Greina) seed density of 200 kg seeds/ha was used. The seeds were equally distributed in rows (distance between rows 7 cm and 2.5 cm distance between seeds in the row) at a depth of approximately 1-2 cm. The units were covered with a large mesh netting to avoid disturbance by birds or other large animals yet minimizing the influence of the microclimate.

Treatments were as follows: CRUISER® WS 70 (A-9567 B) 70 g a.i./100 kg seeds, equivalent to 140 g a.i./ha with a seed density of 200 kg wheat seeds/ha, a control (seeds treated with tap water) and a toxic standard (ME 605), which was applied on bran (which served as bait) at the following dosage based on 1 ha. 450 g formulated product + 24 L water + 50 kg bran. The bait was spread on to the soil after planting the seeds (the seeds having been treated only with tap water). Experimental design: ten beetles (five males and five females)/replicate, four

replicates/treatment. Test duration: 14 days. At test initiation, and on test days 2, 4, 7 and 10 the beetles were fed 10 fly pupae, *Calliphora spp.* fixed on cardboard (2 pieces of cardboard per replicate each with five pupae). Biological observations on mortality and behaviour were recorded at 1-3 hours after beetle introduction and thereafter at 1, 2, 4, 7, 10 and 14 days after test initiation. In addition, food consumption (fly pupae) was recorded on 2, 4, 7, 10 and 14 days after treatment.

Findings:

Effects of CRUISER® 70 WS (A-9567 B) treated wheat seeds on P. cupreus adults under semi-field conditions

Treatment	Effects on Mortality and Food Consumption	
	Mortality [%]	Average number of fly pupae consumed per beetle per day
Control	7.5	0.27
CRUISER® WS 70 70 g a.i./100 kg seeds	25.0	0.26
Toxic standard	82.5	0.28

Observations: Over the 14 days of exposure a significant effect on mortality was observed in the CRUISER® WS 70 (A-9567 B) treatment when compared to the control, however the corrected mortality was only 18.9%. At test termination sublethal effects on beetle behaviour could be observed in the CRUISER® WS 70 (A-9567 B) treatment; 33.3% of the surviving beetles exposed to the CRUISER® WS 70 (A-9567 B) showed co-ordination problems, whilst all surviving beetles of the control demonstrated normal behaviour. No overall effect on feeding rate (study average) was observed in the CRUISER® WS 70 (A-9567 B) treatment when compared to the control.

Conclusion: CRUISER® WS 70 (A-9567 B) applied at a rate of 70 g a.i./ 100 kg seeds (equivalent to 140 g a.i./ha with a seed density of 200 kg wheat seeds/ha) resulted in a corrected mortality of 18.9% after 14 days of exposure under semi-field conditions and 33.3% of the beetles demonstrated co-ordination problems.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	27/01/2005

	Evaluation by Competent Authorities
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 section No.	Doc IIIA	7.5.4.1 / 07	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Point addressed	Annex	II 8.3.1.1	

1.	**Annex point(s)**	**II A, 8.3.1.1 Non target arthropods**
2.	**Location in Dossier**	Section 6
3.	**Authors / Year**	Candolfi, M.P., (1998b)
	Title	Toxicity of CRUISER® WS 70 (A-9567 B) to *Aleochara bilineata* Gyll. (Coleoptera, Staphylinidae) under semi-field conditions.
	Report No. / Date	983771, November 17, 1998
	Syngentra File N°	293343/0842
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	**Testing facility**	Novartis Crop Protection AG, Basel, Switzerland
5.	**Dates of work**	June 26, 1998 through August 31, 1998
6.	**Test substance**	Company Code: CGA 293343 tech., formulated product A9567 B, Batch number: [redacted]
7.	**Test method**	BARRETT, K.L., GRANDY, N., HARRISON, E.G., HASSAN, S. AND OOMEN, P. (eds.) 1994: Guidance Document on Regulatory Testing Procedures for Pesticides with Non-Target Arthropods. From the ESCORT Workshop (European Standard Characteristics of Beneficial Regulatory Testing); Wageningen, Holland, 28 - 30 March, 1994. MORETH, L., NATON, E. (1992): Richtlinie zur Prüfung der Nebenwirkung von Pflanzenschutzmitteln auf *Aleochara bilineata* Gyll. (Col., Staphilinidae) (Halbfreilandprüfung). Bulletin IOBC/WPRS 1992/XV/3; 152-158 Naton, E. (1988): Richtlinie zur Prüfung der Nebenwirkung von Pflanzenschutzmitteln auf *Aleochara bilineata* Gyll. (Col., Staphilinidae) (erweiterter Laborversuch). Bulletin IOBC/WPRS 1988/XI/4; 119-126.
8.	**Deviations**	The test item was applied as a seed dressing and not sprayed on the sand surface
9.	**GLP**	Yes – certified laboratory

Test System: CRUISER® WS 70 (A-9567 B; formulation containing 70.1% Thiamethoxam). Test species: *Aleochara bilineata* Gyll. (Coleoptera: Staphylinidae); Age: 4 day old adults; Source: De Groene Vlieg, Nieuwe tonge, The Netherlands.

The reproductive performance (parasitism of onion fly *Delia antiqua* pupae) by adult *Aleochara bilineata* exposed to treated seeds (treated with CRUISER® WS 70) under semi-field conditions with rain protection by automatically closing, UV-permeable plastic roofing was assessed. The exposure units were plastic containers (57 cm x 37 cm, approximately 21 cm high) containing an approximately 11-12 cm layer of Speyer 2.1 soil. The moisture content of the soil was maintained at approximately 35-40% of the maximum water holding capacity. A seed (Summer wheat) density of 4.218 g seeds/unit was calculated based on 200 kg seeds/ha. The seeds were equally distributed in rows (distance between rows 7 cm) and planting approximately 1 cm deep. The units were covered with a fine mesh netting to avoid predation and test insect escape. On days 0, 1, 3, 6, 8, 10, 13, 17 and 20 the beetles were fed with thawed *Chironomus* sp. larvae. On days 6, 13 and 20, approximately 5000 *D. antiqua* pupae per replicate (unit) were added to the exposure units. The fly pupae being buried in 3 rows (1-3 cm deep). The second and third introductions of fly pupae were placed in new rows, each beside the previous rows. On day 27 after exposure, the rows were opened and all onion fly pupae were carefully removed and set up under laboratory conditions.

The units used to assess parasitism rate consisted of a plexiglass tube (diameter 24 cm, height 25 cm) sealed on the top with a netting and on the bottom with an aluminium plate. Inside the tube a sieve positioned on top of a glass dish (diameter 18.5 cm, height 9 cm) was used to hold the parasitised pupae. The emerging adult beetles fell through the sieve into the dish, where they were collected and counted to determine the number of offspring per replicate. The parasitised pupae remained in the units until all the adult *A. bilineata* emerged.

Treatments were as follows: CRUISER® WS 70 (A-9567 B) 70 g a.i./100 kg seeds, equivalent to 140 g a.i./ha with a seed density of 200 kg wheat seeds/ha, a tap water control and a toxic standard (Curaterr GR 5, at a rate of 1 g/m furrow). Experimental design: 200 beetles (100 males and 100 females)/replicate, four replicates per treatment. Test duration: Exposure time; 27 days under field conditions. Reproduction time; 35 days under laboratory conditions.

Findings:

Effects of CRUISER® 70 WS (A-9567 B) treated wheat seeds on A. bilineata fecundity under semi-field conditions

Treatment	Treatment rate	Emergence [total no. of beetles emerged from the fly pupae]	Percentage fly pupae parasitised by *A. bilineata*	Reduction in the reproduction level compared to control [%]
Control[a]	-	3184	21.2	-
CRUISER® WS 70 [a]	140 g a.i./ha	1064	7.1	66.6
Toxic standard [b]	1g / 5 m furrow	3	0.0	99.9

[a] seed treatment

[b] For each row of seeds planted, 0.57 g Curaterr GR 5 was spread in the soil near the seeds

Observations: The average number of *Aleochara bilineata* that emerged from the onion fly pupae was 3184 in the control, 1064 in the CRUISER® WS 70 (A-9567 B) treatment and 3 in the toxic standard treatment. The values for both the CRUISER® WS 70 (A-9567 B) treatment and the toxic standard treatment were statistically significantly lower than the value recorded in the control treatment. The average percentage parasitism was 21.2 % in the control, 7.1 % in the CRUISER® WS 70 (A-9567 B) treatment and < 0.1 % in the toxic standard treatment. The percentage reduction in parasitism compared to the control was 66.58% for the CRUISER® WS 70 (A-9567 B) treatment and 99.90% for the toxic standard treatment

Conclusion: CRUISER® WS 70 (A-9567 B) applied at a rate of 70 g a.i./ 100 kg seeds (equivalent to 140 g a.i./ha with a seed density of 200 kg wheat seeds/ha) resulted in a 66.6 % reduction of *A. bilineata* fecundity compared to the control under semi-field conditions.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/01/2005

	Evaluation by Competent Authorities
Materials and Methods	[redacted]
Results and discussion	[redacted]

	Evaluation by Competent Authorities
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 section No.	Doc IIIA	7.5.4.1 / 08	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Point addressed	Annex	II 8.3.1.1	

1.	**Annex point(s)**	**II A, 8.3.1.1 Non target arthropods**
2.	**Location in Dossier**	Section 6
3.	**Authors / Year**	Ruggle and Bolsinger., (1998)
	Title	Biological activity of metabolitesof Thiamthoxam CGA293343 on insects and mites.
	Report No. / Date	October 14, 1998
	Syngentra File N°	293343/0894
	Source / Owner	Unpublished / Novartis Crop Protection AG
4.	**Testing facility**	Novartis Crop Protection AG, Basel, Switzerland
5.	**Dates of work**	August 1, 1995 through July 21, 1998
6.	**Test substance**	Company Code: CGA 293343 tech., formulated product A9567 B, Batch number: [redacted]
7.	**Test method**	Internal screening method
8.	**Deviations**	n.a.
9.	**GLP**	No

Test System: the metabolites were tested for biological activity in standard laboratory screening assays as follows:

Spodoptera littoralis:
Contact/feeding activity: Cotton leaf discs on agar were sprayed with test solution and infested with L-1 larvae.
Systemic activity: Corn seedlings were directly treated in test solution. Six days after introduction, the leaves were cut and transferred into petri dishes with moist filter paper and infested with L-1 larvae.

Diabrotica balteata:
Treatment of corn seedlings in a petri dish and infestation with L-3 larvae

Heliothis virescens:
Fresh eggs (0-24 hours old) were placed on filter paper in a Petri dish. On top went artificial diet that was treated with the test solution.

Aphis craccivora:
The test solution was sprayed on pea seedlings that were infested with a mixed population.

Myzus persicae:
The test solution was sprayed on pea seedlings that were infested with a mixed population.

Nilaparvata lugens:
Rice seedlings were sprayed with test solution and infested with N-3 nymphs.

Tetranychus urticae:
Bean leaf discs on agar in a Petri dish were infested with mixed population.

Findings:

Mortality (%) of metabolites of CGA 293343 on insects and mite bioassays at 100 ppm.

Test Species	Test method	CGA 355190	NOA 404617	NOA 407475	CGA 322704
Aphis craccivora	contact	0	0	0	100
Myzus persicae	systemic	0	0	0	100
Spodoptera littoralis	feeling/contact	0	0	0	100
Spodoptera littoralis	sytemic	0	0	0	100
Heliothis virescens	egg hatch	0	0	0	100
	L-1 mortality	0	0	0	n.a.
	L-1 effect	0	0	0	n.a
Diabrotica balteata	feeding/contact	0	0	0	100
Nilaparvata lugens	N-3 mortality	0	0	0	0
	F-1 reduction	-	-	0	100
Tetranychus urticae	egg hatch	0	0	0	0
	larval mortality	0	0	0	0
	adult mortality	0	0	0	0

Conclusion: CGA355190, NOA 404617 and NOA 407475 show no biological activity in the bioassays while CGA 322704 is very active except of *Tetranychus urticae*.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	28/01/2005
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]ffects of thiamethoxam used as biocide within the wood preservative PT8 group.

Section A 7.5.1.2(01) (applicant) **Section 7.5.6** **Annex Point IIIA XIII.3.2**		Acute toxicity test on earthworms or other soil non-target organisms (applicant) **Effects on other terrestrial non-target organisms**	
		67 REFERENCE	Official use only
67.1	**Reference**	Bader, U. (2001): The effects of CGA 322704 (metabolite of thiamethoxam (CGA 293343)) on the decomposition of organic material in a field litterbag test. Syngenta Crop Protection AG, Basel, Switzerland, unpublished report No. 2002619.	
67.2	**Data protection**	Yes.	
67.2.1	Data owner	Syngenta Crop Protection.	
67.2.2	Companies with letter of access	[redacted]	
67.2.3	Criteria for data protection	[redacted]	
		68 GUIDELINES AND QUALITY ASSURANCE	
68.1	**Guideline study**	None available; but based upon the minutes of a meeting in February 2000 organised by the BBA Biologische Bundesanstalt für Land- und Forstwirtschaft Bundesrepublik Deutschland) on the requirement of data according to Council Directive 91/414/EEC, annnex III, point 10.6.2.	
68.2	**GLP**	Yes (certified laboratory), with the exception of the determination of soil properties and measurement of weather conditions.	
68.3	**Deviations**	None.	
		69 METHOD	
69.1	**Test material**	CGA 322704 (metabolite of thiamethoxam).	
69.1.1	Lot/Batch number	[redacted]	
69.1.2	Purity	[redacted]	
69.2	**Reference substance**	Benlate® WP 50 (benomyl).	
69.3	**Testing procedure**	Within the field 12 plots (each of 4 x 4 m) were marked in an area of approximately 25 x 25 m. With each plot 2-3 meters apart. There were three treatment groups tested (control, test item and reference item), with 4 plots randomly assigned to each treatment. In each plot 36-40 litterbags were randonly distributed, separated from one another by at least 44 cm and 50 cm from the plot margin. Each bag was 12 x 12 cm wide, made from synthetic netting with a mesh size of 6-8 mm, three sides of the bag were sown together. Into each bag was placed 2.95-5.02 g (dry weight) of the wheat straw, cut into 5-10 cm pieces. The individual weights of the bags were recorded before test start. The fourth side of the bags were then closed with steel clamps. With the litterbags placed on the meadow surface (mown 7 days before application) within their respective plots a single application was made to the litterbags on 14th June 2000 at volumes equivalent to 500 L/ha with a backpack sprayer, with measures taken to avoid drift to neighbouring plots. The test item CGA 322704 was applied at a concentration of 141.4 mg/L (equivalent to 70.7 g/ha). The reference item Benlate® WP 50 was applied at 4 kg a.i.(benomyl)/ha and the	

Section A 7.5.1.2(01) (applicant) **Section 7.5.6** **Annex Point IIIA XIII.3.2**	Acute toxicity test on earthworms or other soil non-target organisms (applicant) **Effects on other terrestrial non-target organisms**	
	control was treated with tap water. After the spray residues had dried (1 hour), the litterbags were buried approximately 5 cm deep amongst the roots of the meadow grass within the respective plots. In such a way that the bags lay horizontally amongst the roots of the meadow grass, covered by the grass. The bags were sampled, 0, 33, 92, 155 and 275 days after the application. On each sampling occasion, eight randomly selected bags were collected from each plot (32 bags/treatment/sampling time). The degradation of the straw was measured based on the determination of the ash free dry weight of the initial straw used and of the straw recovered at the sampling days.	
	70 RESULTS	
70.1 Soil test	See 5.2.	
70.2 Test with reference substance	See 5.2.	
	71 APPLICANT'S SUMMARY AND CONCLUSION	
71.1 Materials and methods	As above.	
71.2 Results and discussion	The results of all treatments showed similar variations of the determined degradation values (relative standard deviation = 9.8%, range 4.8-21.7% with only 2 values > 15%). The relative standard deviations over the 4 treated replicates of each group were 9.2%, 9.3% and 11.0% for the control, the reference item and the test item, respectively. The difference of decomposition of the reference item to the control was statistically highly significant (p=0.001) at day 33, day 155 and day 275. The difference of the test item to the control was statistically significant (p=0.05) at day 33 and day 275. On days 33 and 275 the deviation from the control in the CGA 322704 treated group was 8.5% and 4.3%, respectively. In line with current guidance, since the deviation at test end is less than 10%, no unacceptable effects on litter decomposition are noted for this treatment group. The comparisons of the percentage degradation (see table) show no relevant difference between the control and CGA 322704, but a slower degradation following the reference item treatment in the first 92 days of the test and a faster degradation in the following 183 days. The average degradation rates again show a similar course of degradation in the control and CGA 322704 treatment, but a lower degradation rate of the reference item during the period 0-33 days, an almost equal rate in the next period (33-92 days) and a much faster rate in the third observation interval (92-155 days). During the final period of the test (155-275 days) similar degradation rates were again observed.	
71.3 Conclusion	No relevant differences from the control in the degradation of organic material in the field were observed during the 275 day test period following the application of CGA 322704 (metabolite of thiamethoxam at 70.7 g/ha).	
71.3.1 Reliability	1.	
71.3.2 Deficiencies	None.	

Section A 7.5.1.2(01) (applicant) **Section 7.5.6** **Annex Point IIIA XIII.3.2**	Acute toxicity test on earthworms or other soil non-target organisms (applicant) **Effects on other terrestrial non-target organisms**	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	7-03-2006	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks	[redacted]	

Organic matter litter decomposition after treatment with CGA 322704 (metabolite of thiamethoxam)

	Degradation n days after application (%)							
Treatment	**Day 33**	**Deviation[a]** (%)	**Day 92**	**Deviation[a]** (%)	**Day 155**	**Deviation[a]** (%)	**Day 275**	**Deviation[a]** (%)
Control	48.5	-	73.8	-	78.7	-	85.6	-
CGA 322704	44.4	8.5*	74.2	-0.5	76.4	2.9	81.9	4.3*
Toxic reference	38.5	20.6*	69.8	5.4	88.7	-12.7*	90.9	-6.2*

[a] Deviation (%) = deviation of treatment relative to control

* statistically significantly different from the control at p=0.05

Negative values for effect indicate a faster decomposition compared to the control.

Section A 7.4.3.1(01) Annex Point IIIA XIII.3		Effects on aquatic organisms – further studies	
		72 REFERENCE	**Official use only**
72.1	**Reference**	Ashwell, J., Dark, R. Emburey, S. (2003) Thiamethoxam 25 WG (A9584C) Outdoor Microcosm Study to Assess Effects on Aquatic Organisms. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Unpublished Report no. RJ3379B (Syngenta File no. CGA293343/1851). Study dates. 15th April – 19th September 2002.	
72.2	**Data protection**	Yes.	
72.2.1	Data owner	Syngenta Crop Protection.	
72.2.2	Companies with letter of access	[redacted]	
72.2.3	Criteria for data protection	[redacted]	
		73 GUIDELINES AND QUALITY ASSURANCE	
73.1	**Guideline study**	CLASSIC (Community Level Aquatic System Studies – Interpretation Criteria)(2002). Proceedings from the 1999 CLASSIC workshop. Society of Environmental Toxicology and Chemistry (SETAC), Florida and SETAC-Europe Brussels. HARAP (1999). Guidance document on higher-tier aquatic risk assessment for pesticides. Society of Environmental Toxicology and Chemistry-Europe, Brussels 179pp.	
73.2	**GLP**	Yes.	
73.3	**Deviations**	No.	
		74 MATERIALS AND METHODS	
74.1	**Test material**	ACTARA' 25 WG (A-9584).	
74.1.1	Lot/Batch number	[redacted]	
74.1.2	Purity	[redacted] (w/w) thiamethoxam.	
74.2	**Reference substance**	Not used.	
74.3	**Testing procedure**	An outdoor pond microcosm study was conducted to investigate the effects of A-9584 C on communities of freshwater organisms. The test systems were rectangular varied depth microcosms containing approximately 1300 L of water over 10 cm sediment, stocked with macrophytes and invertebrates. Communities were allowed to establish in the microcosms for a period of 12 weeks before chemical application. The replicated study design consisted of five A-9584 C treatments at 100, 30, 10, 3 and 1 µg ai/L, and an untreated control. A single application of A-9584 C was made to the microcosms on 18th June 2002. Application was made by direct addition and thorough mixing to rapidly distribute the formulation throughout the water column - taking the toxicological approach favoured by HARAP (Guidance document on Higher Tier Aquatic Risk Assessment for Pesticides, 1999) and CLASSIC (Community-Level Aquatic System Studies-Interpretation Criteria, 2002). Physico-chemical properties of the water and phytoplankton, zooplankton and macroinvertebrate communities were studied for up to 93 days after application. Multivariate analysis (Principal Response Curves method) was used to identify any treatment-related changes in community composition.	**X1** **X2**

Section A 7.4.3.1(01) Annex Point IIIA XIII.3		Effects on aquatic organisms – further studies	
		Analysis of variance was also used to look at population level differences for selected taxa; those not analysed were considered to be either too variable in occurrence or not abundant enough to permit meaningful conclusions to be drawn.	
		75 RESULTS	
75.1	**Range finding test**	Not performed.	
75.2	**Results test substance**		
75.2.1	Initial concentration of test substance	Initial concentrations of thiamethoxam in the microcosms were measured at between 81 and 130 % of nominal (mean 99 %), and so it was considered that the appropriate treatment levels had been achieved at dosing.	**X3**
75.2.2	Effect data	No long-term ecologically adverse effects (on physicochemical parameters or communities of phytoplankton, zooplankton and macroinvertebrates) were observed at any of the treatment levels (up to and including 100 µg ai/L). An effect on Chironomidae was observed at 100 µg ai/L; however, this was an isolated event seen only in the emergence trap samples on day 15, and was not observed at any subsequent sampling points. The rapid dissipation of thiamethoxam in the microcosms as compared to laboratory-based tests is the likely explanation for effects seen in laboratory tests not being observed in this study.	
		76 APPLICANT'S SUMMARY AND CONCLUSION	
76.1	**Materials and methods**	As above.	
76.2	**Results and discussion**	Initial concentrations of thiamethoxam in the microcosms were measured at between 81 and 130 % of nominal (mean 99 %), and so it was considered that the appropriate treatment levels had been achieved at dosing. Thiamethoxam concentrations then declined rapidly following application with treatment means ranging from 34 % to 60 % of applied after 3 days. Concentrations were at or below 0.6 µg/L in all microcosms after 21 days. Results are reported in relation to nominal application concentrations of thiamethoxam.	
76.2.1	NOEC	30 µg ai/L.	
76.3	**Conclusion**	The No Observed Ecologically Adverse Effect Concentration (NOEAEC) of A-9584 C in an outdoor pond microcosm study was 100 µg ai/L, and 30 µg ai/L was determined to be the overall $NOEC_{community}$	**X3**
76.3.1	Reliability	1	
76.3.2	Deficiencies	No	

Section A 7.4.3.1(01) **Annex Point IIIA XIII.3**	**Effects on aquatic organisms – further studies**	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*13-03-2008*	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	
Remarks		

Section A8 Measures necessary to protect man, animals and the environment

~~7~~6.~~1~~8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

A Safety Data Sheet is enclosed in appendices of Document I.1

Hazard identification:	**Health hazards**	Harmful if swallowed.
	Environmental hazards	Slight

Handling and storage:

Store the product in closed original containers, protect from light and humidity and from temperatures below -10°C and above 35°C. Avoid leaving any product leftovers on or at the side of containers.

Store separate from food, feed and stimulants.

Transport information:

Use unbreakable containers, make sure they cannot fall, and label in accordance with regulations.

UN number: 3226

- **Classification Rail / Road RID / ADR:** Class 4.1 Cipher 36B Kemmler Index 40
  CEFIC No. 41G19 Label 4A
  Proper shipping name: self-reactive solid type D
  Additional information: (thiamethoxam)
- **Classification Sea IMDG-Code:** Class 4.1 Page 4168 Packing group II
  Label 4A marine pollutant no
  Proper shipping name: self-reactive solid type D
  Additional information: (thiamethoxam 95%)
- **Classification Air ICAO / IATA - DGR:** Class 4.1 Packing group II Label 4A
  Loading instructions for passenger aircraft : 429
  Max. quantity per packaging for passenger aircraft: 5 kg
  Loading instructions for cargo : 430
  Max. quantity per packaging for cargo aircraft : 10 kg
  Proper shipping name: self-reactive solid type D
  Additional information: (thiamethoxam)

Fire:

Extinguishing media: powder, foam, carbon dioxide or waterspray
(do not use direct jet of water)

~~7~~6.~~2~~8.2 In case of fire, nature of reaction products, combustion gases, etc.

Combustion gases: Thiamethoxam contains the elements carbon, hydrogen, chlorine, nitrogen, oxygen and sulfur. In the event of fire the formation of hydrogen cyanide, carbon monoxide, carbon dioxide, hydrochloric acid, phosgene, nitrogen oxides, sulfur

oxides and sulfuric acid must be anticipated. The combustion products are toxic, and irritant.

~~7.6.3.8.~~3 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non target organisms.

Effects of concern were not found for thiamethoxam used as ~~wood protection product~~ as insecticide on sewage organisms or relevant to the food chain were found during the assessment. Please refer to DocIIIA section 7.

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

9. CLASIFICATION AND LABELLING

9.1. Proposed classification

Classification	As in 30th ATP Draft Proposal	
Class of danger	**Xn:**	harmful
	N:	dangerous for the environment
R-phrases	**R22**:	Harmful if swallowed
	R50/53:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
S-phrases	**S46**:	If swallowed, seek medical advice immediately and show this container or label
	S60:	This material and its container must be disposed of as hazardous waste
	S61:	Avoid release to the environment. Refer to special instructions/Safety data sheets

Because of the high toxicity of the substance, setting specific lower concentration limits for the substance should be considered for both environmental effects when the substance is under discussion for inclusion on Annex VI of Regulation (EC) No 1272/2008.

Classification according to the Regulation (EC) No 1272/2008 of the European Parliament and of the Council and the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS"):

GHS Pictograms	 GHS07	 GHS09
Signal Word	Warning	Hazardous to the aquatic environment
Classification for human health	Hazard class and category: Hazard statement	Acute Tox. 4 H302: Harmful if swallowed
Classification for the Environment	Hazard class and category Hazard statement	Aquatic acute 1 Aquatic chronic 1 H400 H410
Response precautionary statements	P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell	

THIAMETHOXAM

Ref-List Doc. A
Section 5

Reference List of Submitted Documentation

The rest of the reference list is in the product PT8

References by Annex point

Thiamethoxam techn. = CGA 293343 A,
Owner: NAH = Novartis Animal Health Inc., Basel, Switzerland
SYN = Syngenta Crop Protection AG, Basel Switzerland

Section 5 reference list					
A5.10.1	Anonymous	2001	Susceptibility to thiamethoxam in Danish field populations of houseflies Musca domestica Ministry of Food, Agriculture and Fisheries, Denmark, report no. 01-2001, February 2001	Y	NAH
A5.10.2	Weeks, S	2003	Efficacy of residual deposits of thiamethoxam against the pharoah ant. Syngenta Crop Protection report no. 1P/01/014, 27 February, 2003 (unpublished).	Y	SYN
A5.10.3	Weeks, S., Cross, N	2002	Thiamethoxam: Intrinsic activity against German and American cockroaches. Syngenta Crop Protection report no. 1P/01/012, 22 October, 2002 (unpublished).	Y	NAH
A5.10.4	Moyses, E.W. & Gfeller, F.J	1998	Musca domestica: laboratory bioassay methodology for neonicotinoids Novartis Sanidad Health Report no. 583 unpublished	Y	NAH
A5.10.5	Moyses, E.W. & Gfeller, F.J	2002	Preliminary bioassays for insecticide resistance in a *Musca domestica* field strain French Novartis Sanidad Health Report no. IDL 684 unpublished	Y	NAH
A5.10.6	Anon.	2001	Control of Argentine ants with Actar 25 WG. La Cruz Test Center of Entomology, June, 2003 Not GLP, not published	Y	SYN

COMPETENT AUTHORITY REPORT

THIAMETHOXAM (PT 18)

Document III-A

Active Substance

Reference List

Section 7

Rapporteur Member State: Spain

June 2008

(1) Owner: SYN = Syngenta Crop Protection AG, Basel

Directive 98/8	Author(s)	Year	Title, Source, Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner (1)
A7.1.1.1.1/01	Clark, A.	1998c	Hydrolysis of 2-14C-thiazolyl CGA 293343 under laboratory conditions Ciba-Geigy Corp., Greensboro, United States ABR-96106, 17.09.1998 GLP, not published Syngenta File N° CGA293343/0753	Y	SCP
A7.1.1.1.1/02	Lowery, E.	1997	Hydrolysis of 14C-Guanidine-CGA 293343 under laboratory conditions Ciba-Geigy Corp., Greensboro, United States ABR-97013, 03.11.1997 GLP, not published Syngenta File N° CGA293343/0373	Y	SCP
A7.1.1.1.1/03	Ulbrich, R.	1999	Hydrolysis of 14C-labelled CGA 322704 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 98UL03, 19.02.1999 GLP, not published Syngenta File N° CGA322704/0020	Y	SCP
A7.1.1.1.2/01	Zetzsch, C.	1997	Quantum yield of the Photochemical degradation of CGA 293343 in aqueous solution ITA Frauenhofer-Inst., Hannover, Germany 11G97014, 12.09.1997 GLP, not published Syngenta File N° CGA293343/0469	Y	SCP
A7.1.1.1.2/02	Rüdel, H.	1998	Quantum yield of the photochemical degradation of CGA 322704 ITA Frauenhofer-Inst., Hannover, Germany NOV-001/7-21, 10.11.1998 GLP, not published Syngenta File N° CGA322704/0018	Y	SCP
A7.1.1.1.2/03	Schwartz, B.	1998b	Photodegradation of 14C-Thiazolyl-CGA 293343 in pH 5 buffered solution under artificial light Novartis Crop Protection Inc., Greensboro, United States ABR-98091, 27.10.1998 GLP, not published Syngenta File N° CGA293343/0798	Y	SCP
A7.1.1.1.2/04	Sparrow, K.	1997c	Final report: Photodegradation of 14C-[Guanidine]-CGA 293343 in pH 5 buffered solution under artificial light Ciba-Geigy Corp., Greensboro, United States ABR-97023, 27.10.1997 GLP, not published Syngenta File N° CGA293343/0375	Y	SCP
A7.1.1.2.1	Grade, R.	1996	Report on the test for ready biodegradability of CGA 293343 tech. in the carbondioxide evolution test Ciba-Geigy Ltd., Basel, Switzerland 95G001, 08.01.1996 GLP, not published Syngenta File N° CGA293343/0031	Y	SCP
A7.1.2.2.1/01	Adam, D.	1997	Paddy soil metabolism of 14C-Thiazolring labeled CGA 293343 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 95DA04, 15.12.1997 GLP, not published Syngenta File N° CGA293343/0452	Y	SCP
A7.1.2.2.1/02	Adam, D.	1998a	Paddy soil metabolism of 14C-Oxadiazinring labeled CGA 293343 under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 95DA05, 07.01.1998	Y	SCP

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			GLP, not published Syngenta File N° CGA293343/0402		
A7.1.2.2.2/01	Adam, D.	1998 b	Degradation and metabolism of 14C-oxadiazinring labeled CGA 293343 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 96DA02, 04.02.1998 GLP, not published Syngenta File N° CGA293343/0436	Y	SCP
A7.1.2.2.2/02	Adam, D.	1998 c	Degradation and metabolism of 14C-thiazolring labeled CGA 293343 in two aerobic aquatic systems under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland 96DA01, 09.01.1998 GLP, not published Syngenta File N° CGA293343/0401	Y	SCP
A7.2.2.1/01	Phaff, R.	1997 a	Rate of degradation of CGA 293343 in soil under various conditions Ciba-Geigy Ltd., Basel, Switzerland 95RP03, 23.05.1997 GLP, not published Syngenta File N° CGA293343/0098	Y	SCP
A7.2.2.1/02	Adam, D.	1996	Degradation of 14C-Thiazolring labelled CGA 293343 in various soils under laboratory conditions Ciba-Geigy Ltd., Basel, Switzerland 95DA03, 17.12.1996 GLP, not published Syngenta File N° CGA293343/0141	Y	SCP
A7.2.2.1/02a	Ellgehausen, H.	1998	Calculation of adsorption constants of soil metabolite CGA 322704 Novartis Crop Protection AG, Basel, Switzerland 98EH04, 06.10.1998 GLP, not published Syngenta File N° CGA322704/0015	Y	SCP
A7.2.2.1/03	Dixon, B.	1998	Aerobic soil metabolism of (14C-thiazole) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 505-95, 16.03.1998 GLP, not published Syngenta File N° CGA293343/0478	Y	SCP
A7.2.2.1/04	Schwartz, B.	1998	Final report: Aerobic soil metabolism of 14C-(guanidine) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 504-95, 03.03.1998 GLP, not published Syngenta File N° CGA293343/0453	Y	SCP
A7.2.2.1/05	Cruz, S.M.	1998	Metabolism of 14C-guanidine CGA 293343 in viable and sterile clay loam soil under aerobic conditions Novartis Crop Protection Inc., Greensboro, United States 148-97, 18.09.1998 GLP, not published Syngenta File N° CGA293343/0752	Y	SCP
A7.2.1/06	Adam, D.	1999 b	Degradation of 14C-Thiazole labelled CGA 322704 in Schwaderloch soil under aerobic conditions at 20°C Novartis Crop Protection AG, Basel, Switzerland 99DA06, 18.11.1999 GLP, not published Syngenta File N° CGA322704/0024	Y	SCP
A7.2.2.1/07	Reischmann, F.J.	2002	Rate of degradation of [Thiazole-2-14C] labelled NOA 459602 in three soils under aerobic laboratory conditions at 20 degred C	Y	SCP

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			Syngenta Crop Protection AG, Basel, Switzerland 01RF03, 09.09.2002 GLP, not published Syngenta File N° NOA459602/0020		
A7.2.2.2/01	Pointurier, R.	1998	Residue study with CGA 293343 in or on soil in south of France ADME - Bioanalyses, Aigues-Vives, France 9731003, 30.09.1998 GLP, not published Syngenta File N° CGA293343/0746	Y	SCP
A7.2.2.2/02	Smith, J.A.	1998	Determination of residues of CGA 293343 and the metabolite CGA 322704 in soil Novartis Agro GmbH, Frankfurt, Germany GB 66197, 29.09.1998 GLP, not published Syngenta File N° CGA293343/0750	Y	SCP
A7.2.2.4/01	Sparrow, K.	1997 a	Photodegradation of 14C-Thiazolyl-CGA 293343 on soil under artificial light Novartis Crop Protection Inc., Greensboro, United States ABR-97011, 07.07.1997 GLP, not published Syngenta File N° CGA293343/0374	Y	SCP
A7.2.2.4/02	Sparrow, K.	1997 b	Photodegradation of 14C-Guanidine-CGA 293343 on soil under artificial light Novartis Crop Protection Inc., Greensboro, United States ABR-97012, 07.07.1997 GLP, not published Syngenta File N° CGA293343/0376	Y	SCP
A7.2.2.4/03	Clark, A.	1998 a	Anaerobic aquatic metabolism of 14C-(thiazole) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 507-95, 13.03.1998 GLP, not published Syngenta File N° CGA293343/0468	Y	SCP
A7.2.2.4/04	Clark, A.	1998 b	Anaerobic aquatic metabolism of 14C-(guanidine) CGA 293343 Novartis Crop Protection Inc., Greensboro, United States 506-95, 12.03.1998 GLP, not published Syngenta File N° CGA293343/0467	Y	SCP
A7.2.3.1/01	Concha, M.	1998 a	Soil adsorption / desorption of 14C-guanidine-CGA 293343 by the batch equilibrium method 612W, 02.11.1998 GLP, not published Syngenta File N° CGA293343/0835	Y	SCP
A7.2.3.1/02	Keller, A.	1996	Adsorption / desorption of CGA 293343 in various soil types Ciba-Geigy Ltd., Basel, Switzerland 95AK03, 12.06.1996 GLP, not published Syngenta File N° CGA293343/0078	Y	SCP
A7.2.3.1/03	Peters, J.	2000	Time dependent sorpion of technical and of 2SC formulated (Thiazolyl-2-14C)-labeled CGA 293343 in two different soils Novartis Crop Protection Inc., Greensboro, United States 1200-99, 28.03.2000 GLP, not published Syngenta File N° CGA293343/1214	Y	SCP
A7.2.3.1/04	Peters, J.	2001	Time Dependent Sorption of (Thiazolyl-2- 14C)-Labelled CGA 293343 in Various Soils	Y	SCP

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			Syngenta Crop Protection, Inc., Greensboro, United States 200-00, 08.05.2001 GLP, not published Syngenta File N° CGA293343/1377		
A7.2.3.1/05	Hein, W. Dorn, R.	2001 a	Adsorption/Desorption of [Oxidiazin-4-]-CGA 293343 on Birkenheide Soil SLFA - Neustadt, Neustadt, Germany NOV18, 01.08.2001 GLP, not published Syngenta File N° CGA293343/1380	Y	SCP
A7.2.3.1/06	Concha, M.	1998	Adsorption / desorption of 14C-thiazole CGA 322704 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 419-96, 30.11.1998 GLP, not published Syngenta File N° CGA322704/0019	Y	SCP
A7.2.3.1/07	Hein, W. Dorn, R.	2001	Adsorption/Desorption of [Thiazol-2-14C]-CGA322704 on Birkenheide Soil SLFA - Neustadt, Neustadt, Germany NOV19, 12.09.2001 GLP, not published Syngenta File N° CGA322704/0034	Y	SCP
A7.2.3.1/08	Phaff, R.	1997	Adsorption / desorption of CGA 322704 in various soil types Novartis Crop Protection AG, Basel, Switzerland 96RP06, 23.04.1997 GLP, not published Syngenta File N° CGA322704/0010	Y	SCP
A7.2.3.1/09	Scott, M.	1998	Soil adsorption and desorption of Oxadiazinyl-14C-CGA 353042 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 629-98, 24.11.1998 GLP, not published Syngenta File N° CGA353042/0002	Y	SCP
A7.2.3.1/10	Concha, M. Hathcock, T.	1998	Soil adsorption / desorption of 14C-CGA 355190 by the batch equilibrium method 411-97, 30.11.1998 GLP, not published Syngenta File N° CGA355190/0005	Y	SCP
A7.2.3.1/11	Concha, M. Hathcock, T.	1998	Soil adsorption and desorption of (Thiazole-2-14C-NOA 404617 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 721-97, 30.11.1998 GLP, not published Syngenta File N° NOA404617/0001	Y	SCP
A7.2.3.1/12	Peters, J.	1998	Soil adsorption and desorption of Thiazolyl-2-14C-NOA 407475 by the batch equilibrium method Novartis Crop Protection Inc., Greensboro, United States 420-98, 19.11.1998 GLP, not published Syngenta File N° NOA407475/0012	Y	SCP
A7.2.3.1/13	Nicollier, G.	2000	Adsorption / Desorption of [Thiazol-2-^{14}C]NOA 459602 in Various Soils and Time Dependent Sorption Syngenta Crop Protection AG, Basel, Switzerland 01GN08, 3.7.2002 GLP, not published Syngenta File N° NOA459602/0015	Y	SCP
A7.2.3.1/14	Hein, W.	2001	Time Dependent Sorption of [Thiazol-2- 14C]-CGA322704 in Birkenheide Soil SLFA - Neustadt, Neustadt, Germany	Y	SCP

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			NOV21, 12.09.2001 GLP, not published Syngenta File N° CGA322704/0036		
A7.2.3.2	Adam, D.	1996	Leaching model study with CGA 293343 in four soils under laboratory conditions Ciba-Geigy Ltd., Basel, Switzerland 95DA02, 10.04.1996 GLP, not published Syngenta File N° CGA293343/0049	Y	SCP
A7.3.1/01	Adam, D.	1996	Volatilization of 14C-Thiazolring-Labelled CGA 293343 from soil surface under controlled laboratory conditions Ciba-Geigy Ltd., Basel, Switzerland 96DA03, 15.08.1996 GLP, not published Syngenta File N° CGA293343/0104	Y	SCP
A7.3.1/02	Stamm, E.	1998	Atmospheric oxidation of CGA 293343 by hydroxyl radicals Novartis Crop Protection AG, Basel, Switzerland 98SM10, 24.03.1998 not GLP, not published Syngenta File N° CGA293343/0477	Y	SCP
A7.4.1.1/01	[redacted]	1996	Acute toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) in the flow-through system [redacted] 95R002, 30.01.1996 GLP, not published Syngenta File N° CGA293343/0036	Y	SCP
A7.4.1.1/02	[redacted]	1997 a	Acute toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) under flow-through conditions [redacted] 972548, 26.11.1997 GLP, not published Syngenta File N° CGA293343/0388	Y	SCP
A7.4.1.1/03	[redacted]	1996	CGA 293343: A 96-hour flow-through acute toxicity test with the bluegill (Lepomis macrochirus) [redacted] 205-96, 14.10.1996 GLP, not published Syngenta File N° CGA293343/0145	Y	SCP
A7.4.1.1/04	[redacted]	1997 b	Acute toxicity test of CGA 322704 (Metabolite of CGA 293343) to rainbow trout (Oncorhynchus mykiss) in the static system [redacted] 962527, 21.01.1997 GLP, not published Syngenta File N° CGA322704/0009	Y	SCP
A7.4.1.1/05	[redacted]	1998	Acute toxicity of CGA 355190 (metabolite of CGA 293343) for Rainbow trout [redacted] G 541 04, 29.10.1998 GLP, not published Syngenta File N° CGA355190/0002	Y	SCP
A7.4.1.1/06	[redacted]	1998 a	Acute toxicity of NOA 407475 (metabolite of CGA 293343) to rainbow trout (Oncorhynchus mykiss) in a 96-hour static test [redacted] 688781, 14.08.1998 GLP, not published Syngenta File N° NOA407475/0010	Y	SCP
A7.4.1.1/07	[redacted]	2002	NOA459602 (Thiamethoxam metabolite): Acute toxicity to	Y	SCP

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		a	rainbow trout (Oncorhynchus mykiss) [redacted] BL7243/B, 17.04.2002 GLP, not published Syngenta File N° NOA459602/0016		
A7.4.1.2/01	Neumann, Ch.	1996	Acute toxicity test of CGA 293343 to the cladoceran daphnia magna straus under static conditions Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95G003, 25.04.1996 GLP, not published Syngenta File N° CGA293343/0043	Y	SCP
A7.4.1.2/02	Knauer, K.	2000 b	Acute toxicity test of CGA 293343 tech. to the Gammarus sp. under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002614, 10.07.2000 GLP, not published Syngenta File N° CGA293343/1229	Y	SCP
A7.4.1.2/03	Knauer, K.	2000 c	Acute toxicity test (24h) of CGA 293343 tech. to three invertebrate species Daphnia pulex leydig, Thamnocephalus platyurus, and Brachionus calyciflorus under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002612, 21.07.2000 GLP, not published Syngenta File N° CGA293343/1274	Y	SCP
A7.4.1.2/04	Knauer, K.	2000 d	Acute toxicity test of CGA 293343 tech. to individual invertebrate species and molluscs from a natural pond assemblage under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002642, 21.07.2000 GLP, not published Syngenta File N° CGA293343/1273	Y	SCP
A7.4.1.2/05	Neumann, Ch.	1997 a	Acute toxicity test of CGA 322704 (Metabolite of CGA 293343) to the cladoceran Daphnia magna strauss under static conditions Novartis Crop Protection AG, Basel, Switzerland 962528, 31.01.1997 GLP, not published Syngenta File N° CGA322704/0008	Y	SCP
A7.4.1.2/06	Maetzler, P.	1998	Acute toxicity of CGA 355190 to Daphnia magna (Immobilisation test) Novartis Services AG, Basel, Switzerland G 541 14, 30.10.1998 GLP, not published Syngenta File N° CGA355190/0003	Y	SCP
A7.4.1.2/07	Seyfried, B.	1998 b	Acute toxicity of NOA 407475 (metabolite of CGA 293343) to Daphnia magna in a 48-hour immobilization test RCC AG, Itingen, Switzerland 688803, 22.09.1998 GLP, not published Syngenta File N° NOA407475/0011	Y	SCP
A7.4.1.2/08	Wallace, SJ	2002 b	NOA459602 (Thiamethoxam metabolite): Acute toxicity to Daphnia magna Brixham Environmental Laboratory, Brixham, United Kingdom BL7244/B, 17.04.2002 GLP, not published Syngenta File N° NOA459602/0017	Y	SCP
A7.4.1.2/09	Knauer, K.	2000	Acute toxicity test of CGA 293343 tech. to the	Y	SCP

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		a	Ephemeroptera Cloeon sp. under static conditions Novartis Crop Protection AG, Basel, Switzerland 2002613, 10.07.2000 GLP, not published Syngenta File N° CGA293343/1228		
A7.4.1.2/10	Mank, M.A. Krueger, H.O.	1998	CGA 293343 technical: a 48-hour static acute toxicity test with the midge (Chironomus riparius) Wildlife International Ltd., Easton, MD, United States 819-98, 15.10.1998 GLP, not published Syngenta File N° CGA293343/0890	Y	SCP
A7.4.1.3/01	Grade, R.	1996 a	Growth inhibition test of CGA 293343 tech. to green algae (Selenastrum capricornutum) in a static system Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95G005, 12.01.1996 GLP, not published Syngenta File N° CGA293343/0035	Y	SCP
A7.4.1.3/02	Grade, R.	1998 a	Growth inhibition test of CGA 293343 tech. to green algae (Selenastrum capricornutum) under static conditions Novartis Crop Protection AG, Basel, Switzerland 972549, 16.06.1998 GLP, not published Syngenta File N° CGA293343/0580	Y	SCP
A7.4.1.3/03	Grade, R.	1997	Growth inhibition test of CGA 322704 (Metabolite of CGA 293343) to green algae (Selenastrum capricornutum) under static conditions Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 962529, 09.01.1997 GLP, not published Syngenta File N° CGA322704/0007	Y	SCP
A7.4.1.3/04	Maetzler, P.	1998 b	Toxicity of CGA 355190 to Green algae (Growth inhibition test) Novartis Services AG, Basel, Switzerland G 541 17, 30.10.1998 GLP, not published Syngenta File N° CGA355190/0004	Y	SCP
A7.4.1.3/05	Seyfried, B.	1998 c	Toxicity of NOA 407475 (metabolite of CGA 293343) to Scenedesmus subspicatus in a 72-hour algal growth inhibition test RCC AG, Itingen, Switzerland 688825, 14.08.1998 GLP, not published Syngenta File N° NOA407475/0009	Y	SCP
A7.4.1.3/06	Wallace, SJ	2002 c	NOA459602 (Thiamethoxam metabolite): Toxicity to the Green Alga Selenastrum capricornutum Brixham Environmental Laboratory, Brixham, United Kingdom BL7245/B, 17.04.2002 GLP, not published Syngenta File N° NOA459602/0018	Y	SCP
A7.4.1.4	Grade, R.	1996 b	Report on the test for activated sludge respiration inhibition of CGA 293343 tech. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland 95G002, 08.01.1996 GLP, not published Syngenta File N° CGA293343/0034	Y	SCP
A 7.4.3./01	Ashwell, J., Dark, R. Emburey, S.	2003	Thiamethoxam 25 WG (A9584C) Outdoor Microcosm Study to Assess Effects on Aquatic Organisms. Syngenta, Jealott's Hill International	Y	SCP

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			Research Centre, Bracknell, Berkshire, UK. Unpublished Report no. RJ3379B (Syngenta File no. CGA293343/1851). Study dates. 15th April – 19th September 2002.		
A7.4.3.1	[redacted]	1997 c	Prolonged toxicity test of CGA 293343 tech. to rainbow trout (Oncorhynchus mykiss) in the flow-through system [redacted] 95R003, 30.07.1997 GLP, not published Syngenta File N° CGA293343/0296	Y	SCP
A7.4.3.2	[redacted]	1997	CGA 293343: an early life-stage toxicity test with the rainbow trout (Oncorhynchus mykiss) [redacted] 322-96, 14.02.1997 GLP, not published Syngenta File N° CGA293343/0205	Y	SCP
A7.4.3.4	Neumann, Ch.	1997 b	Daphnia magna reproduction test: effects of CGA 293343 on the reproduction of the cladoceran Daphnia magna straus in a semi-static laboratory test Novartis Crop Protection AG, Basel, Switzerland 95G004, 24.09.1997 GLP, not published Syngenta File N° CGA293343/0323	Y	SCP
A7.4.3.5.1/01	Grade, R.	1998 b	Toxicity test of CGA 293343 tech. on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland 972552, 02.10.1998 GLP, not published Syngenta File N° CGA293343/0720	Y	SCP
A7.4.3.5.1/02	Grade, R.	1999	Toxicity test of CGA 322704 (Metabolite of CGA 293343) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland 982581, 09.02.1999 GLP, not published Syngenta File N° CGA322704/0021	Y	SCP
A7.4.3.5.1/03	Grade, R.	2000	Toxicity test of NOA 407475 (Metabolite of CGA 293343) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions Novartis Crop Protection AG, Basel, Switzerland 982580, 12.07.2000 GLP, not published Syngenta File N° NOA407475/0014	Y	SCP
A7.4.3.5.1/04	Grade, R	2002	Toxicity Test of NOA 459602 (Metabolite of Thiamethoxam) on Sediment-Dwelling Chironomus riparius (syn. Chironomus thummi) under Static Conditions Syngenta Crop Protection AG, Basel, Switzerland 2012671, 04.06.2002 GLP, not published Syngenta File N° NOA459602/0009	Y	SCP
A7.4.3.5.1/05	Smyth, D.V., Brown, R.J., Maynard, S.J.,	2004	CGA 322704 (Thiamethoxam metabolite): Toxicity to the sediment dweller *Chironomus riparius* using spiked water. Brixham Environmental Laboratory, Brixham, Devon, England, Report No.: BL7987/B (Syngenta Project No. 2033605), 2 December 2004 (unpublished).	Y	SCP
A7.4.3.5.2	Grade, R.	1998 c	Acute toxicity test of CGA 293343 tech. to the duckweed Lemna gibba G3 under semi-static conditions	Y	SCP