98/8 Doc IIIA section No.	7.1.1.2.1 / 01	Ready biodegradability
91/414 Annex Point addressed	II 7.2.1.3.1 / 01	Ready biodegradability

1.	Annex point(s)	**IIA, 7.2.1.3.1 Ready biodegradability**
2.	Location in Dossier	Section 5
3.	Authors (year) Title Report No., Date Syngenta File No(Desire) Owner	R.Grade (1996) Report on the test for ready biodegradability of CGA 293343 tech. in the carbondioxide evolution test Study No. 95G001, 8. January, 1996. 293343/31 Syngenta Crop Protection AG
4.	Testing facility	Ciba Geigy Ltd, Product Safety / Ecotoxicology, 4002 Basel, Switzerland
5.	Dates of work	September 20, 1995 to October 25, 1995
6.	Test substance	CGA 293343, [redacted]
7.	Test method	The study was be conducted in compliance with: OECD Guideline No.: 301/B (Paris 17/07/92) 92/69/EEC C.4-C.
8.	Deviations	Only one CO_2 scrubber was used.
9.	GLP	This study was performed in compliance with Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, March 1986 [Verfahren und Grundsaetze der Guten Laborpraxis (GLP) in der Schweiz, Maerz 1986] issued by the Federal Department of the Interior and the Intercantonal Office for the Control of Medicaments, Switzerland. These procedures are based on OECD Principles of GLP adopted on 12 May 1981 by Decision of the OECD Council concerning Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30 (Final)].

Test system: The test was performed with thiamethoxam technical grade of 98.6% purity. For the toxicity control, where the test substance and reference were applied together, the reference amount was 15.0 mg DOC/l and the test substance amount was 15.6 mg TOC/l. During exposure the evolved CO_2 was measured at 0, 3, 6, 8, 10, 13, 17, 21, 24, 28 and 29 days. The test system is described Table 1.

Table 1: Test system for carbon dioxide evolution study (Grade 1996)

pH:	8.0 (after collection)
Source:	Sewage treatment plant, CH-4153 Reinach, Switzerland.
Test concentration:	45.0 - 47.9 mg /l, corresponding to 14.8 - 15.8 mg TOC/l
Duration:	29 days
Temperature	22 ± 2°C, diffuse light
Test water:	Distilled water

Findings: The biodegradation of the test substance was 7% in 29 days, therefore the test substance was not readily biodegradable in this test. thiamethoxam did not inhibit the biodegradation of the reference substance (sodium benzoate). According to the 7th Amendment to Directive 67/548/EEC, i.e. Directive 92/32/EEC, the ecotoxicological classification for thiamethoxam is: "not readily biodegradable".

Evaluation by Competent Authorities	
	7.1.1.2.1/01
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	23/08/04
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]"
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

98/8 Doc IIIA section No.	7.1.2.1.2	*Anaerobic biodegradation*
91/414 Annex Point addressed	II 7.1.1.1.2 / 01	Supplementary soil degradation studies - anaerobic degradation

1.2	Title	Anaerobic Aquatic Metabolism of (^{14}C-thiazole) CGA 293343
1.3	Report and/or project N° Syngenta°(Desire)	ABR-96099 293343/468
1.4	Lab. Report N°	507-95
1.5	Location in Dossier	Section 5,
1.6	Authors	Adora Clark, Ph.D.
1.7	Date of report	March 13, 1998
1.8	Published / owner	Unpublished report, Syngenta Crop Protection AG
2.1	Testing facility	Novartis Crop Protection Inc Environmental Safety Department, Greensboro, NC 27419, USA PTRL West, Incorporated, Richmond, CA 94806, USA
2.2.	Dates of work	Study Initiation: 25 September, 1995 Experimental Start: 14 November, 1995 Experimental Termination: Study Completion: 13 March, 1998
3.	Objectives	Determine formation and decline of degradates from incubation of CGA-293343 under anaerobic aquatic conditions.
4.1	Test substance	ISO common name: thiamethoxam Trade name: Not applicable Batch: [redacted] ^{14}C-labeled test substance Yes [x] (^{14}C-thiazole) CGA 293343 Specific activity of [.....] 1.49 Mbq/mg Radiochemical purity of the test substance: [redacted] Structural formula: **labeled in thiazole ring** (*position of label)
4.2	Specification	See Section 4.1
4.3	Storage stability	Stable
4.4	Stability in vehicle	Stable
4.5	Homogeneity in vehicle	Available, but not reported
4.6	Validity	Available, but not reported
4.7	Vehicle / solvent	Acetonitrile
4.8	Physical form	Available, but not reported
5.1	Test method	This Anaerobic Aquatic Soil Metabolism study was designed to meet EPA Guidelines for degradation in aquatic sediment under anaerobic conditions (guideline 162-3).
5.2	Justification	Usually, field soils are used as aquatic sediments. Therefore, this design meets essentially European guidelines as required in: Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC: Annex I: 7.1.1.1.2. Supplementary Studies: Anaerobic Degradation

5.3	**Copy of method**	Test method available, but not reported
6	**Choice of method**	Available, but not reported
7	**Deviations**	The clay minerology was not conducted under GLP
8.1	**Certified laboratory**	Not applicable
8.2	**Certifying authority**	Not applicable
8.3	**GLP**	yes
8.4	**Justification**	This study was designed to meet EPA Guidelines for degradation in aquatic sediment under anaerobic conditions (guideline 162-3).
9.1	**GEP**	Not applicable
9.2	**Type of facility (official or officially recognised)**	Not applicable
9.3	**Justification**	Not applicable

10 Test system

Water characteristics	Origin	HPLC Grade water purchased from Fisher Scientific, Pittsburgh, PA.
	The water was sterile filtered and sparged with nitrogen overnight.	

Sediment characteristics	Origin	Novartis Crop Protection western research Station, Fresno County, California
	pH	7.3
	Redox potential (mV)	not reported
	Organic matter (%)	0.6
	Total nitrogen (%)	0.056
	Total phosphorus (%)	not reported
	Cation exchange capacity (meq/100 g sediment)	7.4
	Particle size distribution - % clay - % silt - % sand	 8 25 67
	Classification (USDA)	Sandy loam
soil/water slurry: Total Anaerobic Bacteria in (CFU/g dry sediment)	Experimental start: Day 90 Day 182 Day 365	0.22 0.10 0.20 0.51

Equilibrium of test system and treatment	
Incubation conditions	Equilibration under nitrogen
Weight of water (mL)	100
Weight of sediment (dry weight g)	50
Temperature	25.0 °C
Exclusion of light	Yes [x] No [ ]
Equilibrium time of test system	35 days
Treatment rate	0.1 µg/g
Sampling intervals	0, 7, 15, 21, 29, 43, 62, 90, 120, 180, 272, 365 days
Replicates	Yes [x] No [ ]

11	**Statistics**	kinetics
12	**References (published)**	None
13	**Unpublished data**	None

Test system: The route and rate of degradation of ^{14}C-thiamethoxam was investigated over 365 days at 2 concentrations: 0.1 mg/kg ('kinetic', chosen based on an application rate of 200g as/ha, 15 cm soil layer, bulk density 1.5) and 5.3 mg/kg ('bulk', 50 x exaggerated application rate) in a sandy loam soil flooded with water and equilibrated under nitrogen. The degradation products were characterised by TLC and HPLC co-chromatography with reference standards and identified by mass-spectroscopy. Further details of the soil characteristics are presented in Table 1 (same soil as used in aerobic experiment, microbial biomass measurements only relevant for aerobic incubation).

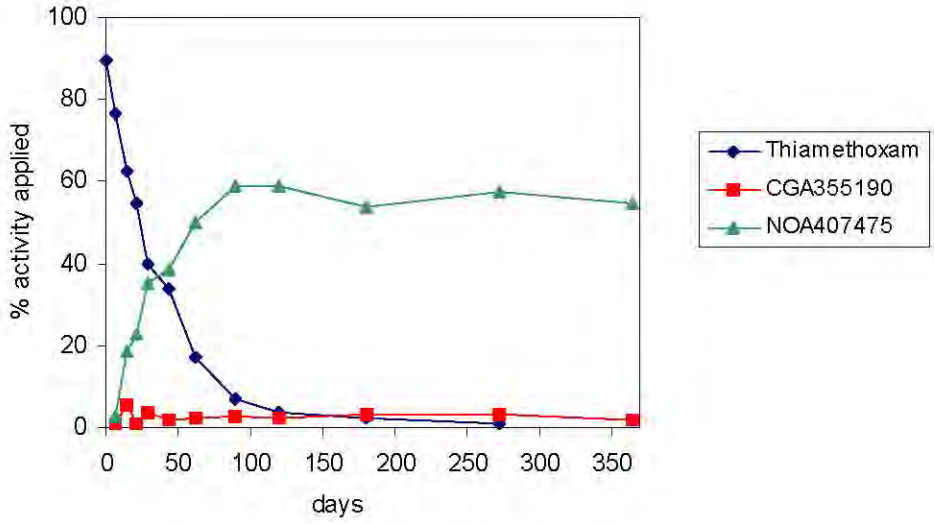
Findings: The mean total applied radioactivity recovered from the sample matrices (material balance) ranged from 90.7% to 98.8% for the kinetic samples and from 89.5% to 95.6% for the bulk samples. Thiazolyl-^{14}C labelled thiamethoxam was metabolised quite rapidly under anaerobic conditions to form the denitro compound NOA 407475 as a major metabolite with a plateau value of 58.8% to 58.9% from day 90 to day 120 and a decrease to 54.7% at day 365 (kinetic experiment). For the bulk experiment the peak was reached at day 180 with 57.6% with a decrease to 51.0% at day 365. The hydrolysis product CGA 355190 was also present peaking at 5.4% (kinetic, day 15) and at 18.1% (bulk, day 90) before its decline to 2.0% and 2.1%, respectively. All remaining components were below 2.8% (kinetic) and below 5.2% (bulk) of the dose. Some of the metabolites characterised by co-chromatography were CGA 322704, CGA 353968 and NOA 404617. Volatiles reached a maximum of 2.7% (kinetic) and 4.4% (bulk) of applied radioactivity and were identified as carbon dioxide. Non - extractables reached 19.5% (kinetic) and 13.0%(bulk).

Table 1: Distribution of radioactivity after application of ^{14}C-Thiazole-thiamethoxam in sandy loam soil, anaerobic conditions, as percent of applied dose (Clark, 1998a).

Incubation time [days]	Thiamethoxam [%]	CGA355190 [%]	NOA407475 [%]	Volatiles [%]	non extractables [%]
0	89.2	< LOD	< LOD	< LOD	0.5
7	76.2	1.0	3.1	0.5	4.0
15	62.4	5.5	18.4	0.3	3.1
21	54.9	1.9	22.9	0.3	5.6
29	39.6	3.9	35.4	1.1	5.3
43	34.6	1.8	42.3	0.1	6.0
62	17.0	2.1	50.2	0.2	15.8
90	7.1	3.1	58.9	0.7	18.0
120	3.9	2.5	58.9	1.0	17.2
180	2.6	3.4	53.9	2.7	18.9
272	0.9	3.3	57.3	2.5	19.5
365	< LOD	2.0	54.7	1.6	18.8

LOD: Level of detection

Figure 1: Formation and decline of major metabolites for ^{14}C- Thiazole -thiamethoxam in a sandy loam soil under anaerobic conditions (Clark, 1998a)



	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*24/09/2004*
Materials and Methods	[redacted]

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

[redacted]

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

98/8 Doc IIIA section No.	7.1.2.1.2	*Anaerobic biodegradation*
91/414 Annex II Point addressed	7.1.1.1.2	Supplementary soil degradation studies - anaerobic degradation

1.	Annex point(s)	**IIA, 7.2.1.1.2 degradation**	**Supplementary soil degradation studies - anaerobic**
2.	Location in Dossier	Section 5,	
3.	Authors (year) Title Report No., Date Syngenta File N° Owner	Clark, A.(1998b) Anaerobic Aquatic Metabolism of (^{14}C-Guanidine)-CGA 293343 ABR-96098, March 12, 1998 293343/0467 Syngenta Crop Protection AG	
4.	Testing facility	Novartis Crop Protection, Inc. Environmental Safety Department Greensboro, NC, USA	
5.	Dates of work	-	
6.	Test substance	ISO common name: Batch: ^{14}C-labelled test substance Specific activity of [^{14}C] Radiochemical purity of the test substance:	thiamethoxam company code: CGA 293343 [redacted] Guanidinyl-4-^{14}C label 1.57 Mbq/mg [redacted]
7.	Test method	Environmental fate data requirement 40 CFR 158, Subdivision N: Series 162-3, EPA, USA. Field soils were used as aquatic sediments. Therefore, this design meets essentially European guidelines as required in: Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC: Annex I: 7.1.1.1.2. Supplementary Studies: Anaerobic Degradation.	
8.	Deviations	No deviations have to be reported	
9.	GLP	yes (Novartis Crop Protection, Inc., Greensboro, NC, USA)	

Test system: This second anaerobic aquatic metabolism study was performed under the identical conditions as the first study (Clark 1998a) but using guanidine-^{14}C labelled thiamethoxam. The soil characteristics were the same as in the first study same soil as used in aerobic experiment, microbial biomass measurements only relevant for aerobic incubation).

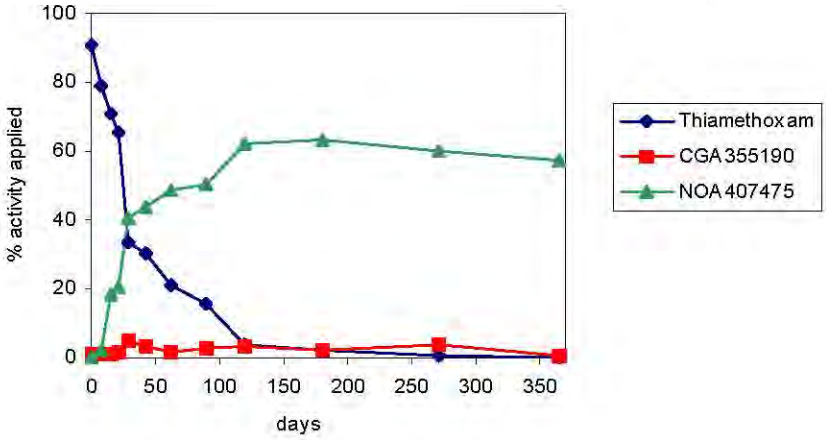
Findings: The mean total applied radioactivity recovered from the sample matrices (material balance) ranged from 98.7% to 107.3% for the kinetic samples and from 89.6% to 98.0% for the bulk samples. The distribution of radioactivity and the formation and decline of major metabolites is shown in Table 1 and Figure 1, respectively. Guanidine -^{14}C labelled thiamethoxam was metabolised quite rapidly under anaerobic conditions to form the denitro compound NOA 407475 as a major metabolite with a peak value of 62.3% at day 120 and a decrease to 57.5% at day 365 (kinetic experiment). For the bulk experiment the peak was reached at day 62 with 58.4% and a decrease to 45.3% at day 365. The hydrolysis product CGA 355190 was also present peaking with 4.8% (kinetic) and 15.2% (bulk) at day 62 before its decline to 0.6% and 2.1%, respectively. All remaining components were below 3.8% of the dose. Some of the metabolites characterised by co-chromatography were CGA 322704, CGA 353968 and NOA 404617. Volatiles reached a maximum of 7.1% (kinetic) and 6.7% (bulk) of applied radioactivity and were identified as carbon dioxide. Non - extractables reached 22.4% (kinetic) and 12.6%(bulk).

Table 1: Distribution of radioactivity after application of ^{14}C-Guanidine-thiamethoxam in sandy loam soil, anaerobic conditions, as percent of applied dose (Clark, 1998b).

Incubation time [days]	Thiamethoxam [%]	CGA355190 [%]	NOA407475 [%]	Volatiles [%]	Non extractables [%]
0	90.9	1.0	< LOD	< LOD	0.9
7	79.1	1.0	2.1	0.5	5.0
15	70.7	1.3	18.4	1.0	5.3
21	65.6	1.7	20.5	1.8	5.2
29	33.4	4.8	40.7	1.4	5.8
43	30.3	3.0	43.6	1.3	7.7
62	21.2	1.6	48.5	2.4	18.2
90	15.9	2.6	50.2	3.6	21.8
120	4.0	3.0	62.3	7.1	14.8
180	2.0	2.3	63.4	4.5	22.1
272	0.6	3.6	59.8	5.6	19.0
365	< LOD	0.6	57.5	5.3	22.4

LOD: Level of detectability

Figure 1: Formation and decline of major metabolites for ^{14}C- Guanidine - thiamethoxam in a sandy loam soil under anaerobic conditions (Clark, 1998b)



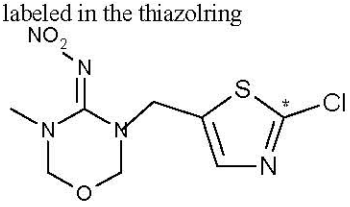
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	24/09/2004
Materials and Methods	[redacted]

Results and discussion

[redacted]

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

98/8 section No.	Doc IIIA	7.1.2.2.1 / 01	Aerobic aquatic degradation study
91/414 Point addressed	Annex	II 7.2.1.3.2	Water / sediment study

1.2	Title	Paddy Soil Metabolism of ^{14}C- Thiazolring Labeled CGA 293343 under Laboratory Conditions
1.3	Report and/or project N° Syngenta File N°(Desire)	96DA04 293343/452
1.4	Lab. Report N°	96DA04
1.5	Location in Dossier	Section 5
1.6	Authors	Report: Adam D. Summary: Adam D.
1.7	Date of report	December 15, 1997
1.8	Published / owner	Unpublished/Syngenta Crop Protection AG, Basel, Switzerland
2.1	Testing facility	Novartis Crop Protection AG
2.2	Dates of experimental work	September 26, 1996 until November 20, 1997
3.	Objectives	To provide information on the rate of dissipation and metabolism of ^{14}C-CGA 293343 and its degradation products in a model paddy system under aerobic conditions.
4.1	Test substance	CGA 293343
4.2	Specification	labeled in the thiazolring 
4.3	Storage stability	stable at - 20 °C
4.4	Stability in vehicle	the test substance was found to be stable when analysed by HPLC before and after treatment
4.5	Homogeneity in vehicle	the test substance was prepared as a homogeneous solution in acetone
4.6	Validity	not applicable
4.7	Vehicle / solvent	acetone (Merck Darmstadt, FRG)
4.8	Physical form	crystalline
5.1	Test method	Guidedance on toxicology study data for application of agricultural chemical registration, 59 Nohsan No. 4200, January 28, 1985, Ministry of Agriculture, Forestry and Fisheries.
5.2	Justification	The study was designed to meet Japaneserequirements to assess the metabolism of CGA 293343 in paddy soil.
5.3	Copy of method	available on request
6	Choice of method	not applicable
7	Deviations	none
8.1	Certified laboratory	yes
8.2	Certifying authority	Federal Department of Interior, Switzerland
8.3	GLP	GLP Switzerland based on OECD
88.4	Justification	not applicable
9.1	GEP	not applicable

9.2	Type of facility (official or officially recognised)	not applicable
9.3	Justification	not applicable
10	Test system	The metabolism of ^{14}C-thiazolring labeled CGA 293343 was investigated in a Japanese paddy soil (Ono Station, Hyogo, Japan see Table 1 for soil characteristics). The concentration of the test compound was 0.51 mg/kg dry soil, corresponding to 2.2 times the max. recommended single field application rate of 0.3 kg a.i./ha, assuming a homogeneous distribution of the test substance in the top 10 cm of the soil and a soil density of 1.3 g/ml. The incubation conditions were aerobic, dark, 25 ± 2 °C 363 days of incubation.

Sediment characteristics:			
source	Ono Station, Hyogo Japan		
sand [%]:	47.1	total nitrogen [%]:	0.18
silt [%]:	35.8	organic carbon [%]:	1.9
clay [%]:	17.1	CEC [mVal/100g]:	17.8
pH	5.0	Biomass [mg C/100g dry soil] at start at end	135.4 140.8

11	Statistics	DT 50 and DT 90 values were calculated using first order one and two compartment kinetics
12	References (published)	none
13	Unpublished data	No references to unpublished data were made in this summary

Findings: Over the course of the experiment an increasing proportion of radioactivity in the water phase was translocated into the sediment. Bound residues in the soil increased continuously reaching a level of 61.9% at the end of the study. Fractioning of the bound radioactivity after treatment with 0.5N NaOH at RT left 8.5% with fulvic acids and 0.6% with humic acids. The remaining radioactivity in soil could not be allocated. Carbon dioxide evolution was modest and amounted to 3.6% of applied radioactivity at day 363. The overall recovery of the system was 97.1±5.3%. Dissipation of the parent molecule from the water phase proceeded via adsorption to the soil matrix where the compound was reduced yielding the denitro metabolite NOA 407475 with a maximum of 37.1% at day 120 and a decrease to 26.9% at the end of the study. NOA 407475 was only extracted from the sediment by applying harsh extraction methods (acetonitrile/water 4/1 and acetonitrile/0.1N HCl 9/1 under reflux for two hours each). Metabolite CGA 355190 was sporadically observed in the soil at levels below the limit of quantification (0.85% of applied dose). No metabolite could be detected in the water phase at any time. The distribution of radioactivity at the various time intervals is shown in Table 1. Based on the concentrations in water and in sediment half-lives (DT_{50}) and DT_{90} values were determined by applying first order one and two compartment reaction kinetics (Table 2).

Table 1: Radioactivity distribution of thiazolyl-^{14}C thiamethoxam and metabolites in paddy soil system as percent of applied dose

Time days	Water Layer	Sediment Extractables		Non Extractable	CO_2	Recovery
	Thiamethoxam	thiamethoxam	NOA407475			
0	97.5	5.3	<LOD	0.6	-	104.5
3	51.8	48.3	<LOD	<LOD	0.06	101.1
8	37.7	59.6	0.6	1.1	0.27	99.6
16	27.3	69.7	1.0	1.6	0.24	99.8
42	10.5	58.8	16.9	9.4	0.42	96.0
58	6.2	36.3	29.9	20.5	2.65	95.6
120	1.6	20.0	37.1	35.1	0.99	95.6
182	0.6	7.2	28.6	45.2	3.11	85.6
363	<LOD	2.0	26.9	61.9	3.57	96.4

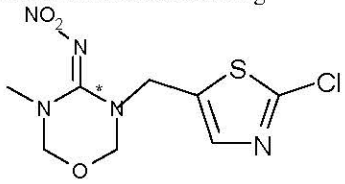
Table 2: Half-lives of thiazolyl-^{14}C thiamethoxam and NOA 407475 in paddy system

	Total System		Water		Sediment	
(days)	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}
thiamethoxam	51.6	162.3	3.3	43.7	46.6	154.8
NOA 407475	-	-	-	-	330	1097

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*23/8/04*
Materials and Methods	**Comments**: • [redacted]
Results and discussion	**Comments:** [redacted]
Conclusion	[redacted]

	[redacted]
Reliability	[redacted]
Acceptability	
Remarks	

98/8 Doc IIIA section No.	7.1.2.2.1 / 02	Aerobic aquatic degradation study
91/414 Annex Point addressed	II 7.2.1.3.2	Water / sediment study

1.2	Title	Paddy Soil Metabolism of ^{14}C- Oxadiazin ring Labeled CGA 293343 under Laboratory Conditions
1.3	Report and/or project N° Syngenta File N°(Desire)	96DA05 293343/402
1.4	Lab. Report N°	96DA05
1.5	Location in Dossier	Section 5
1.6	Authors	Report: Adam D. Summary: Adam D.
1.7	Date of report	January 7, 1998
1.8	Published / owner	Unpublished/Syngenta Crop Protection AG, Basel, Switzerland
2.1	Testing facility	Novartis Crop Protection AG
2.2	Dates of experimental work	September 26, 1996 until November 20, 1997
3.	Objectives	To provide information on the rate of dissipation and metabolism of ^{14}C-CGA 293343 and its degradation products in a model paddy system under aerobic conditions.
4.1	Test substance	CGA 293343
4.2	Specification	labeled in the oxadiazinring 
4.3	Storage stability	stable at - 20 °C
4.4	Stability in vehicle	the test substance was found to be stable when analysed by HPLC before and after treatment
4.5	Homogeneity in vehicle	the test substance was prepared as a homogeneous solution in acetone
4.6	Validity	not applicable
4.7	Vehicle / solvent	acetone (Merck Darmstadt, FRG)
4.8.	Physical form	crystalline
5.1	Test method	Guidance on toxicology study data for application of agricultural chemical registration, 59 Nohsan No. 4200, January 28, 1985, Ministry of Agriculture, Forestry and Fisheries.
5.2	Justification	The study was designed to meet Japanese requirements to assess the metabolism of CGA 293343 in paddy soil.
5.3	Copy of method	available on request
6	Choice of method	not applicable
7	Deviations	none
8.1	Certified laboratory	yes
8.2	Certifying authority	Federal Department of Interior, Switzerland
8.3	GLP	GLP Switzerland based on OECD
8.4	Justification	not applicable
9.1	GEP	not applicable

9.2	Type of facility (official or officially recognised)	not applicable
9.3	Justification	not applicable
10	Test system	The metabolism of ^{14}C-oxadiazinring labeled CGA 293343 was investigated in a Japanese paddy soil (Ono Station, Hyogo, Japan see Table 1 for soil characteristics). The concentration of the test compound was 0.52 mg/kg dry soil, corresponding to 2.2 times the max. recommended single field application rate of 0.3 kg a.i./ha, assuming a homogeneous distribution of the test substance in the top 10 cm of the soil and a soil density of 1.3 g/ml. The incubation conditions were aerobic, dark, 25 ± 2 °C 363 days of incubation.
11	Statistics	DT 50 and DT 90 values were calculated using first order one and two compartment kinetics
12	References (published)	none
13	Unpublished data	No references to unpublished data were made in this summary

Findings: Results of this study were nearly identical to the study performed with the ^{14}C-thiazolyl labeled test substance. They are summarized in Table 1 and in Table 2.

Table 1: Radioactivity distribution of guanidine -^{14}C thiamethoxam and metabolites in paddy soil system as percent of applied dose

Time days	Water Layer	Sediment Extractables		Non Extractable	CO_2	Recovery
	Thiamethoxam	thiamethoxam	NOA407475			
0	91.2	6.7	<LOD	1.1	-	100.5
3	52.5	47.5	1.0	0.9	0.04	101.9
8	33.8	60.0	1.8	1.8	0.09	97.9
16	26.3	65.5	4.7	3.0	0.27	99.7
42	11.6	56.4	18.3	13.3	0.87	100.4
58	6.7	40.9	30.8	20.4	1.00	99.7
120	1.8	16.6	39.1	40.3	1.21	99.0
182	0.4	10.5	39.0	43.6	1.28	94.8
363	<LOD	1.9	30.8	62.8	2.15	99.3

Table 2: Half-lives of guanidine -^{14}C thiamethoxam and NOA 407475 in paddy system

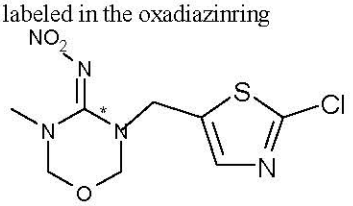
	Total System		Water		Sediment	
(days)	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}
thiamethoxam	51.8	170	3.4	47.1	39.2	130.2
NOA 407475	-	-	-	-	159	529

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*23/8/04*
Materials and Methods	**Comments**: [redacted]
Results and discussion	**Comments:** [redacted]

[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	
Remarks	

98/8 section No.	Doc IIIA	7.1.2.2.2 / 01	Water sediment degradation study
91/414 Point addressed	Annex II	7.2.1.3.2	Water / sediment study

1.2	Title	Degradation and Metabolism of ^{14}C-oxadiazinring Labeled CGA 293343 in two Aerobic Aquatic Systems under Laboratory Conditions
1.3	Report and/or project N° Syngenta File N°(Desire)	96DA02 293343/436
1.4	Lab. Report N°	96DA02.
1.5	Location in Dossier	Section 5
1.6	Authors	Report: Adam D. Summary: Adam D.
1.7	Date of report	February 4, 1998
1.8	Published / owner	Unpublished/Syngenta Crop Protection AG, Basel, Switzerland
2.1	Testing facility	Novartis Crop Protection AG
2.2	Dates of experimental work	August 20, 1996 until November 13, 1997
3.	Objectives	To provide information on the rate of dissipation and metabolism of ^{14}C-CGA 293343 and its degradation products in two equilibrated water/sediment systems under aerobic conditions.
4.1	Test substance	CGA 293343
4.2	Specification	labeled in the oxadiazinring 
4.3	Storage stability	stable at - 20 °C
4.4	Stability in vehicle	the test substance was found to be stable when analysed by HPLC before and after treatment
4.5	Homogeneity in vehicle	the test substance was prepared as a homogeneous solution in acetonitrile
4.6	Validity	not applicable
4.7	Vehicle / solvent	acetonitrile (Merck Darmstadt, FRG)
4.8	Physical form	crystalline
5.1	Test method	Commission Directive 95/36/EC of July 14, 1995 amending Council Directive 91/414/EEC: Annex II: 7.2.1.3.2. Water/Sediment Study; referencing Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, 8.2. Aerobic Aquatic Degradation, Society of Environmental Toxicology and Chemistry, SETAC Europe Richtlinie für die Prüfung von Pflanzenschutzmitteln, Teil IV, 5-1, Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment-System. Biologische Bundesanstalt für Land- und Forstwirtschaft Bundesrepublik Deutschland, Dezember 1990.
5.2	Justification	The study was designed to meet several requirements to assess the metabolism of CGA 293343 in water/sediment systems.
5.3	Copy of method	available on request
6	Choice of method	not applicable
7	Deviations	none
8.1	Certified laboratory	yes
8.2	Certifying authority	Federal Department of Interior, Switzerland

8.3	GLP	GLP Switzerland based on OECD
8.4	Justification	not applicable
9.1	GEP	not applicable
9.2	Type of facility (official or officially recognised)	not applicable
9.3	Justification	not applicable
10	Test system	The metabolism of ^{14}C-oxadiazinring labeled CGA 293343 was investigated in two equilibrated water sediment systems (see Tables 1 and 2 for water and sediment characteristics). The concentration of the test compound was 0.1 mg/kg with respect to the water phase, corresponding to 1.5 times the max. recommended single field application rate of 0.2 kg a.i./ha (assuming a homogeneous distribution of the test substance to a water depth of 30 cm). The incubation conditions were aerobic, dark, 20 ± 2 °C, 100 days of incubation.
11	Statistics	DT 50 and DT 90 values were calculated using first order one and two compartment kinetics
12	References (published)	none
13	Unpublished data	Adam, D., Paddy Soil Metabolism of ^{14}C-oxadiazinring Labeled CGA 293343 under Laboratory Conditions. Project report 96DA05 (1998) Syngenta Crop Protection AG, Environmental Safety / Ecochemistry, 4002 Basel, Switzerland

Findings: Results of the radioactivity distribution between water and sediment and formation and decline of the major metabolite NOA 407475, bound residues and carbon dioxide were very similar to the study performed with the thiazolyl-^{14}C labelled test compound. The distribution and nature of radioactivity for the incubation period in the river and pond water-sediment systems are shown in Table 1 and 2. The denitro metabolite NOA 407475 reached maximum concentrations of 40.9% at day 58 and of 47.4% at day 100 in the river and pond sediment, respectively. The metabolite CGA 355190 was observed in both water and sediment of the 2 systems at levels <5% of applied dose. Half-lives and DT_{90} values for thiamethoxam are presented in Table 7.2.1.3.2 - 7.

Table 1: Radioactivity distribution of guanidine-^{14}C thiamethoxam and metabolites in river aquatic system as percent of applied dose

Time days	Water Layer		Sediment Extractables			Non Extractable	CO_2	Recovery
	thiamethoxam	CGA 355190	thiamethoxam	CGA 355190	NOA407475			
0	88.7	<LOD	12.4	<LOD	<LOD	0.9	-	102.1
1	55.0	<LOD.	25.6	<LOD	2.3	10.0	0.03	92.9
3	57.3	<LOD	32.5	<LOD	<LOD	4.6	0.04	94.4
8	44.2	<LOD.	36.6	1.1	8.6	2.6	0.06	94.9
16	39.7	<LOD	32.1	2.5	15.9	4.7	0.88	95.8
42	24.7	<LOD	24.1	2.9	34.5	11.5	1.42	102.4
58	16.2	1.0	13.3	2.6	40.9	15.5	3.03	92.5
80	11.4	2.5	12.6	4.0	34.6	22.2	4.89	92.3
100	13.6	4.5	11.5	4.4	35.9	19.8	7.22	97.8

Table 2: Radioactivity distribution of guanidine-^{14}C thiamethoxam and metabolites in pond aquatic system as percent of applied dose

Time days	Water Layer		Sediment Extractables			Non Extractable	CO_2	Recovery
	thiamethoxam	CGA 355190	thiamethoxam	CGA 355190	NOA407475			
0	97.8	<LOD	3.7	<LOD	<LOD	0.6	-	102.1
1	80.6	<LOD	13.4	<LOD	<LOD	2.8	0.00	96.7
3	74.4	<LOD	20.1	<LOD	<LOD	2.5	0.03	97.0
9	54.6	2.3	24.2	1.3	2.3	7.8	0.00	93.7

16	*	*	*	*	*	*	*	*
42	21.3	3.6	15.7	3.7	31.6	10.4	2.74	88.9
58	10.6	3.0	15.2	2.7	34.8	14.4	3.12	85.4
80	7.5	1.4	10.6	3.3	40.2	20.2	7.18	90.4
100	6.4	<LOD	10.4	3.2	47.4	23.9	5.97	98.2

* Data for day 16 disregarded due to double application

Table 3: Half-lives of guanidine -^{14}C thiamethoxam in aquatic systems

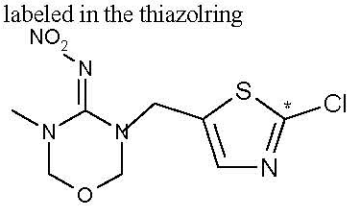
	Total System		Water		Sediment	
(days)	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}
River	35.3	615.6	5.8	89.2	11.5	>100
Pond	28.4	325.4	13.2	69.7	9.8	>100

As discussed for the aquatic study above (*Adam,1998a*), distribution coefficients k_d for any time can be estimated based on the relative distribution of thiamethoxam to water/sediment in Table 1 and Table 2 for Rhine river and pond aquatic systems, respectively. 55 µg ^{14}C-thiamethoxam were applied per flask. After 42 days of incubation the concentrations of ^{14}C-thiamethoxam in the sediments can be calculated to be about 65 µg/kg and 44 µg/kg in the river and pond and the concentration in water can be calculated to about 25 µg/litre and 21 µg/litre, respectively. Thus, the mean sediment/water distribution coefficient can be estimated to be k_d = 2.6 and 2.1 mL/g.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*23/8/04*
Materials and Methods	**Comments**:
	• [redacted]
Results and discussion	**Comments:**
	a) [redacted]

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

98/8 Doc IIIA section No.	7.1.2.2.2 / 02	Water sediment degradation study
91/414 Annex Point addressed	II 7.2.1.3.2	Water / sediment study

1.2	Title	Degradation and Metabolism of 14C-thiazolring Labeled CGA 293343 in two Aerobic Aquatic Systems under Laboratory Conditions
1.3	Report and/or project N° Syngenta File N°(Desire)	96DA01 293343/401
1.4	Lab. Report N°	96DA01
1.5	Location in Dossier	Section 5
1.6	Authors	Report: Adam D. Summary: Adam D.
1.7	Date of report	January 9, 1998
1.8	Published / owner	Unpublished/Syngenta Crop Protection AG, Basel, Switzerland
2.1	Testing facility	Novartis Crop Protection AG
2.2	Dates of experimental work	June 4, 1996 until November 13, 1997
3.	Objectives	To provide information on the rate of dissipation and metabolism of ^{14}C-CGA 293343 and its degradation products in two equilibrated water/sediment systems under aerobic conditions.
4.1	Test substance	CGA 293343
4.2	Specification	labeled in the thiazolring 
4.3	Storage stability	stable at - 20 °C
4.4	Stability in vehicle	the test substance was found to be stable when analysed by HPLC before and after treatment
4.5	Homogeneity in vehicle	the test substance was prepared as a homogeneous solution in acetonitrile
4.6	Validity	not applicable
4.7	Vehicle / solvent	acetonitrile (Merck Darmstadt, FRG)
4.8	Physical form	crystalline
5.1	Test method	Commission Directive 95/36/EC of July 14, 1995 amending Council Directive 91/414/EEC: Annex II: 7.2.1.3.2. Water/Sediment Study; referencing Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, 8.2. Aerobic Aquatic Degradation, Society of Environmental Toxicology and Chemistry, SETAC Europe Richtlinie für die Prüfung von Pflanzenschutzmitteln, Teil IV, 5-1, Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment-System. Biologische Bundesanstalt für Land- und Forstwirtschaft Bundesrepublik Deutschland, Dezember 1990.
5.2	Justification	The study was designed to meet several requirements to assess the metabolism of CGA 293343 in water/sediment systems.
5.3	Copy of method	available on request
6	Choice of method	not applicable
7	Deviations	none

8.1	**Certified laboratory**	yes
8.2	**Certifying authority**	Federal Department of Interior, Switzerland
8.3	**GLP**	GLP Switzerland based on OECD
8.4	**Justification**	not applicable
9.1	**GEP**	not applicable
9.2	**Type of facility (official or officially recognised)**	not applicable
9.3	**Justification**	not applicable
10	**Test system**	The metabolism of ^{14}C-thiazolring labeled CGA 293343 was investigated in two equilibrated water sediment systems (see Tables 1 and 2 for water and sediment characteristics). The concentration of the test compound was 0.1 mg/kg with respect to the water phase, corresponding to 1.5 times the max. recommended single field application rate of 0.2 kg a.i./ha (assuming a homogeneous distribution of the test substance to a water depth to 30 cm). The incubation conditions were aerobic, dark, 20 ± 2 °C, 100 days of incubation.

Water/sediment characteristics of river and pond systems

Sediment characteristics:	**River (Rhine)**	**Pond (Rheinfelden)**
sand [%]:	41.8	30.9
silt [%]:	48.4	41.3
clay [%]:	9.8	27.8
pH	7.5	-
total nitrogen [%]:	0.1	0.19
organic carbon [%]:	1.7	2.2
CEC [mVal/100g]:	10.9	17.8
Biomass [mg C/100g dry soil]:	78	119
Water characteristics		
pH	8.25	7.9
Oxygen content (mg/l)	0.1	0.9
TOC (mg/l)	2.5	5.6
total nitrogen (mg/l)	3.3	3.6

11	**Statistics**	DT 50 and DT 90 values were calculated using first order one and two compartment kinetics
12	**References (published)**	none
13	**Unpublished data**	Adam, D., Paddy Soil Metabolism of ^{14}C-Thiazolring Labeled CGA 293343 under Laboratory Conditions. Project report 96DA04 (1997) Syngenta Crop Protection AG, Environmental Safety / Ecochemistry, 4002 Basel, Switzerland

Findings: In both systems the radioactivity in the water phase decreased over the incubation period reaching 18% (river) and 6% (pond) of the applied radioactivity at day 100. In the sediment the amount of non extractable radioactivity increased continuously to a level of 13.8% (river) and 15.0% (pond). All volatile radioactivity was characterized as carbon dioxide. It reached 6.3% (river) and 9.3% (pond) at day 100, indicating some mineralisation. The distribution and nature of radioactivity for the incubation period in the river and pond water-sediment systems are shown in Table 1 and 2. Dissipation of the parent molecule from the water phase proceeded mainly via adsorption to the sediment matrix where the compound was reduced to the denitro metabolite NOA 407475. NOA 407475 could be extracted by a harsh extraction method using acetonitrile-water and acetonitrile-hydrochloric acid under reflux. It reached maximum concentrations of 37.0% at day 58 and decreased to 35.4% at day 100 in the river and of 47.4% at day 42 and of 45.5% at day 100 in the pond sediment, respectively. The other metabolite identified as CGA 355190 was observed in both water and sediment of the river system at levels below 5% beginning at day 42. In the pond system it was present beginning at day 8 at lower levels. Based on the concentrations of the parent molecule in water and sediment, half-lives (DT_{50}) and DT_{90} values were determined by applying first order one and two compartment reaction kinetics (Table 3).

Table 1: Radioactivity distribution of thiazolyl-^{14}C thiamethoxam and metabolites in river aquatic system as percent of applied dose

Time days	Water Layer		Sediment Extractables			Non Extractable	CO_2	Recovery
	thiamethoxam	CGA 355190	thiamethoxam	CGA 355190	NOA407475			
0	102.0	<LOD	1.5	<LOD	<LOD	0.3	-	103.8
1	81.5	<LOD.	13.5	<LOD	<LOD.	0.4	0.02	95.3
3	78.1	<LOD	23.4	<LOD	<LOD	2.0	0.09	103.6
8	63.6	<LOD.	27.2	<LOD.	<LOD	5.3	0.88	98.2
16	37.2	<LOD	33.6	<LOD	18.8	5.1	1.40	96.0
42	21.9	3.0	21.9	<LOD	33.0	7.5	1.07	94.1
58	22.9	1.5	13.6	4.1	37.0	5.8	1.56	94.0
80	16.2	3.5	12.7	4.0	30. 7	12.6	2.41	88.0
100	11.8	4.0	12.2	4.7	35.4	13.8	6.34	90.9

Table 2: Radioactivity distribution of thiazolyl-^{14}C thiamethoxam and metabolites in pond aquatic system as percent of applied dose

Time days	Water Layer		Sediment Extractables			Non Extractable	CO_2	Recovery
	thiamethoxam	CGA 355190	thiamethoxam	CGA 355190	NOA407475			
0	104.7	<LOD	2.4	<LOD	<LOD	0.7	-	107.8
1	85.2	<LOD	14.9	<LOD	<LOD	1.0	0.02	101.1
3	75.9	<LOD	21.2	<LOD	<LOD	3.5	0.07	100.6
8	53.7	2.2	22.3	1.2	15.1	4.4	0.05	99.9
16	33.6	1.1	31.2	<LOD	16.2	7.5	0.44	92.2
42	12.3	2.1	14.5	3.4	47.4	7.1	2.19	89.0
58	26.7	1.3	13.9	2.5	32.1	21.9	5.70	106.0
80	2.97	<LOD	9.8	2.6	46.3	25.3	3.17	88.7
100	6.2	<LOD	9.8	3.4	45. 5	15.0	9.28	89.0

Table 3: Half-lives of thiazolyl-^{14}C thiamethoxam in aquatic systems

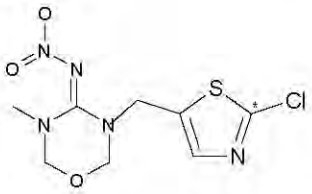
	Total System		Water		Sediment	
(days)	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}
River	36.3	317.4	11.0	132.3	12.6	41.9
Pond	25.7	130.9	8.4	76.9	15.6	51.9

Based on the relative distribution of thiamethoxam to water/sediment in Table 1 and Table 2 for Rhine river and pond aquatic systems, respectively, distribution coefficients k_d for any time can be estimated taking the dimensions of the systems into account. After decantation/centrifugation about 540 mL water phase represented the water layer. The mean dry weight of the sediments was 122 g per flask for the river and for the pond system corresponding to about 200 g wet sediments taken for extraction after decanting. 52 µg ^{14}C-thiamethoxam were applied per flask. After 16 days of incubation equilibrium was reached in both systems and about 34% of the applied radioactivity were found in both systems in the water phase as well as in the sediment. The concentrations of ^{14}C-thiamethoxam in the sediments can be calculated to be about 89 µg/kg and the concentration of ^{14}C-thiamethoxam in water can be calculated to about 33 µg/litre. Thus, a mean sediment/water distribution coefficient can be estimated to be k_d = 2.7 mL/g.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*23/8/04*
Materials and Methods	**Comments**: • [redacted]
Results and discussion	**Comments:** g) [redacted]
Conclusion	[redacted]

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

98/8 Doc IIIA section No.	7.2.2.1 / 01	The rate and route of degradation including identification of the process involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
91/414 Annex Point addressed	II 7.1.1.2.1 / 03	Rate of degradation in soil - laboratory studies

1.2	Title	RATE OF DEGRADATION OF CGA 293343 IN SOIL UNDER VARIOUS CONDITIONS
1.3	Report and/or project N° Syngenta File N°(Desire)	95RP03 293343/98
1.4	Lab. Report N°	95RP03
1.5	Cross reference to original study / report	
1.6	Authors	Report: Dr. R. Phaff Summary: Dr. R. Phaff
1.7	Date of report	May 23, 1997a
1.8	Published / owner	Owned by Syngenta Crop Protection AG, not published
2.1	Testing facility	Novartis Crop Protection AG Environmental Safety/Ecochemistry 4002 Basel, Switzerland
2.2	Dates of experimental work	May 15, 1995 until January 7, 1997
3.	Objectives	The objectives of the study were to determine the rates and routes of degradation of CGA 293 343 in soil incubated under various laboratory conditions..
4.1	Test substance	ISO common name: thiamethoxam Trade name: Batch: [redacted] ^{14}C-labelled test substance: Yes [x] No [ ] Specific activity of [.....]: 2.45 Mbq/mg (=66.22 µCi/mg) Radiochemical purity of the test substance: [redacted] Structural formula: (position of label)  Formulation used for study: Yes [ ] No [x] Type of formulation (if used): Co-solvent for application (if used): acetone
4.2	Specification	See 4.1
4.3	Storage stability	The chemical is stable when stored at about -20°C in the dark
4.4	Stability in vehicle	The test substance was found to be stable in the vehicle when analysed by TLC before and after application
4.5	Homogeneity in vehicle	The test substance was prepared as a homogeneous solution in acetonitrile
4.6	Validity	Not applicable
4.5	Vehicle / solvent	Acetone

4.7	**Physical form**	crystalline, slightly beige
5.1	**Test method**	Danish Law of the Ministry of the Environment, September 1, 1987. Dutch Registration Guideline, Section G.1: Behaviour in Soil; Ministry of Agriculture and Fisheries, Ministry of Public Health and Environmental Hygiene, Ministry of Social Affairs, January 1987. Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada; Section C: Biotransformation: 1: Soil-Degradation Pathways and Persistence, July 15, 1987
5.2	**Justification**	not applicable
5.3	**Copy of method**	available on request
6	**Choice of method**	not applicable
7	**Deviations**	none
8.1	**Certified laboratory**	yes
8.2	**Certifying authority**	Federal Department of Interior, Switzerland
8.3	**GLP**	GLP Switzerland based on OECD
8.4	**Justification**	not applicable
9.1	**GEP**	Not applicable
9.2	**Type of facility (official or officially recognised)**	Not applicable
9.3	**Justification**	Not applicable

10 Test system

Origin (textural class)	Gartenacker (silty loam soil)
Batch Nr.	4/95
Collecting Date:	April 18, 1995
Analysis Date:	June 12, 1995
pH (KCl)	7.15
Organic Carbon	2.50 %
Total Nitrogen	0.32 %
CEC[26]	14.90 mmol/z/100 g soil
Particle Size Distribution -Clay (<0.002 mm) -Silt (0.002 - 0.05 mm) -Loam (0.05 - 2 mm)	 11.10 % 55.00 % 33.90 %
Maximum Water Holding Capacity	69.87 g water / 100g dry soil
Field Capacity (1.8 pF)	49.17 g water / 100g dry soil
Microbial Biomass - Start - after 191 days	 79 mg C/100 g dry soil) 61 mg C/100 g dry soil) at 20°C 55 mg C/100 g dry soil) at 10°C

Test conditions		A	B	C	D
Incubation temperature(s)	(℃)	20±2	20±2	10±2	20±2
Humidity	(%FC)	60	40	60	60
Treatment rate:	(mg a.i./ kg soil)	0.9	0.9	0.9	0.1
Incubation time:	(days)	363	363	363	363
Number of samples taken for analysis:		20	20	20	20
Methods used for analysis	HPLC	-	-	-	-
	TLC	x	x	x	x
	GC	-	-	-	-
Methods for the identification of degradates		cochromatography, LC-MS			

11 Statistics The rate of disappearance of CGA 293343 was calculated by applying first order reaction kinetics

12 References (published) none

13 Unpublished data none

Findings: The metabolite formed with the highest concentration was the compound CGA 322704, N-(2-Chloro-thiazol-5-ylmethyl)-N'-methyl-N''-nitro-guanidine. Its structure was confirmed by mass spectral analysis. It reached its maximum concentration of 24%, 17% and 36 % for the experiments A, B and D on day 128, 189 and 90, respectively. Thereafter the

[26] Cation Exchange Capacity

concentration of the metabolite declined thus demonstrating its transient nature. In experiment C at a temperature of 10°C CGA 322704 reached a maximum of 29% at the end of the study. Details of the degradation patterns observed for incubation part A-D are summarised in Table 1.

Besides CGA 322704 only minor amounts of extractable degradation products were observed. The sum of unknown metabolites in the experiments A, B, C and D reached maximum levels of 8.1% at day 189, of 4.4% at day 128, of 3.7% at day 189 and of 8.5% at day 128, respectively with a subsequent decline. Identification of the 8.1% fractions (experiment A, day 189) by co-chromatography with reference compounds showed 3 components: CGA 355190 (4.9%), CGA 265307 (2.7%) and CGA 353968 (0.7%). The data indicate that the pattern of decline is the same under all conditions but that the rate of degradation of the as and the main metabolite CGA 322704 show some dependence on incubation temperature, as concentration and soil humidity.

The mineralisation of thiazolyl-^{14}C labelled thiamethoxam to carbon dioxide increased steadily with time in all experiments and reached a maximum of 44.2% at the low 0.11 mg/kg treatment rate. Bound residues also increased with time reaching a maximum of 19.5% after 363 days in study part B.

Table 1: Recovery and degradation pattern of soil degradation of ^{14}C-thiamethoxam under various conditions (Phaff 1997a)

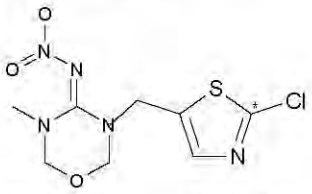
Days after application	Volatiles (CO_2) [%]*	Extractables [%]*	Extractables (Soxhlet) [%]*	CGA-293343 [%]*	CGA-322704 [%]*	Unknown [%]*	Non-extractables [%]*	Total [%]*
Part A: 20°C, 60% FC, 0.91 mg/kg								
0	n.d.	101.1	5.6	106.7	n.d.	n.d.	0.5	107.1
3	0.1	94.4	3.7	98.1	n.d.	n.d.	1.5	99.8
7	0.5	92.2	5.7	93.5	4.4	n.d.	1.4	99.8
14	1.5	89.1	5.6	89.0	5.7	n.d.	2.2	98.4
28	3.5	83.9	5.3	81.6	7.6	n.d.	3.4	96.0
58	7.0	75.1	5.3	58.9	18.4	3.1	5.5	93.0
90	9.9	64.2	5.4	45.3	20.3	4.1	7.6	87.1
128	15.2	53.5	6.4	31.1	23.5	5.4	9.8	84.9
189	21.7	40.6	5.4	15.5	22.4	8.1	12.6	80.2
363	32.1	20.8	4.0	4.2	17.0	3.6	16.2	73.0
Part B: 20°C, 40% FC, 0.91 mg/kg								
0	n.d.	100.6	4.9	105.6	n.d.	n.d.	0.4	106.0
3	n.d.	93.8	3.4	97.2	n.d.	n.d.	1.5	98.7
7	0.2	92.6	6.1	94.5	4.2	n.d.	1.4	100.3
14	0.6	91.0	6.0	95.4	1.5	n.d.	1.9	99.4
28	1.0	89.1	5.2	88.9	5.3	n.d.	2.8	98.0
58	2.7	82.1	6.3	77.2	9.2	2.0	4.2	95.2
90	5.4	75.2	6.0	65.4	11.6	4.1	6.1	92.5
128	8.9	65.6	6.0	53.7	13.4	4.4	8.1	88.5
189	13.1	56.1	5.8	40.9	16.7	4.3	11.0	86.0
363	23.5	27.3	4.3	17.6	10.9	3.0	19.5	74.6
Part C: 10°C, 60% FC, 0.91 mg/kg								
0	n.d.	101.4	2.7	106.0	n.d.	n.d.	n.d.	106.5
3	0.1	95.9	3.3	99.2	n.d.	n.d.	1.4	100.7
7	0.4	93.6	4.6	95.6	2.6	n.d.	1.2	99.7
14	0.8	92.6	5.0	96.4	1.2	n.d.	1.3	99.6
28	1.6	92.5	4.3	93.0	3.8	n.d.	1.8	100.2
58	3.2	89.2	4.5	83.0	10.8	n.d.	2.5	99.4
90	4.5	84.4	5.6	76.5	11.1	2.4	3.2	97.7
128	6.6	81.2	5.9	71.4	14.0	1.8	3.7	97.4
189	9.4	73.9	5.8	57.7	18.3	3.7	5.1	94.2
363	16.7	60.8	5.7	34.0	29.3	2.2	8.4	91.6
Part D: 20°C, 60% FC, 0.11 mg/kg								
0	n.d.	103.8	6.5	110.3	n.d.	n.d.	0.5	110.9
3	0.5	93.4	4.3	97.7	n.d.	n.d.	1.3	99.5
7	1.4	87.9	7.7	89.5	6.1	n.d.	1.8	98.8
14	3.5	85.6	5.4	80.8	9.4	n.d.	2.9	97.3
28	7.0	82.2	5.0	66.4	18.3	2.5	4.5	98.6
58	14.0	63.1	5.8	31.8	33.5	3.6	7.5	90.4
90	21.3	50.8	5.9	15.5	35.6	5.6	10.9	88.9
128	28.9	40.0	6.8	6.2	32.1	8.5	12.7	88.3
189	35.2	26.1	6.2	3.6	21.6	7.1	15.6	83.0
363	44.2	13.9	4.3	1.0	14.4	2.7	16.8	79.1

* Percent of applied radioactivity, average of duplicates. n.d. = not detected

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26/08/04

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

98/8 Doc IIIA section No. 7.2.2.1 / 02	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**
91/414 Annex II Point addressed 7.1.1.1.1	**Soil route of degradation: Aerobic degradation**

1.2	**Title**	DEGRADATION OF ^{14}C-THIAZOLRING LABELLED CGA 293343 IN VARIOUS SOILS UNDER LABORATORY CONDITIONS
1.3	**Report and/or project N° Syngenta File N°(Desire)**	95DA03 293343/141
1.4	**Lab. Report N°**	95DA03
1.5	**Location in dossier**	Section 5
1.6	**Authors**	Report: Adam, D. Summary: Adam, D.
1.7	**Date of report**	December 17, 1996
1.8	**Published / owner**	Unpublished/Syngenta Crop Protection AG, Basel, Switzerland
2.1	**Testing facility**	Novartis Crop Protection AG Product Safety / Ecochemistry 4002 Basel, Switzerland
2.2	**Dates of experimental work**	November 16, 1995 until November 21, 1996
3.	**Objectives**	The objectives of the study were to determine the rate of degradation in the different soils examined.
4.1	**Test substance**	ISO common name: thiamethoxam Trade name: Batch: [redacted] ^{14}C-labelled test substance: Yes [x] No [ ] Specific activity of [.....]: 2.12 Mbq/mg (=57.82 µCi/mg) / 2.25 Mbq/mg (= 61.37 µCi/mg) Radiochemical purity of the test substance: [redacted] Structural formula: (position of label)  Formulation used for study: Yes [ ] No [x] Type of formulation (if used): Co-solvent for application (if used): acetonitrile
4.2	**Specification**	See 4.1
4.3	**Storage stability**	The chemical is stable when stored at about -20°C in the dark
4.4	**Stability in vehicle**	The test substance was found to be stable in the vehicle when analysed by HPLC before and after application
4.5	**Homogeneity in vehicle**	The test substance was prepared as a homogeneous solution in acetonitrile
4.6	**Validity**	Not applicable
4.7	**Vehicle / solvent**	Acetonitrile Lichrosolv® (Merck Darmstadt, Germany)
4.8	**Physical form**	crystalline, slightly beige

5.1	Test method	Richtlinie für die amtliche Prüfung von Pflanzenschutzmitteln, Teil IV, 4-1: "Verbleib von Pflanzenschutzmitteln im Boden: Abbau, Umwandlung und Metabolismus." Biologische Bundesanstalt für Land und Forstwirtschaft, Bundesrepublik Deutschland, Dezember, 1986.
5.2	Justification	not applicable
5.3	Copy of method	available on request
6	Choice of method	not applicable
7	Deviations	none
8.1	Certified laboratory	yes
8.2	Certifying authority	Federal Department of Interior, Switzerland
8.3	GLP	GLP Switzerland based on OECD
8.4	Justification	not applicable
9.1	GEP	Not applicable
9.2	Type of facility (official or officially recognised)	Not applicable
9.3	Justification	Not applicable

10 Test system

System		1	2	3	4	5
Origin of soil:		Collombey (stored in the greenhouse)	Speyer 2.1 (stored in the greenhouse)	Weide (stored in the greenhouse)	Pappelacker (field fresh)	Weide (field fresh)
Batch-No:		6/95	89	6/95	PA_5/96	WE_5/96
Analysis date:		Nov. 6, 95	May 4,95	July 20, 95	June 5, 96	June 5, 96
Classification (USDA):		loamy sand	sand	sandy loam	loamy sand	sandy loam
Particle size distribution:	% silt	15.2	7.6	31.5	22.7	31.8
	% sand	78.6	88.3	62.3	74.4	63.8
	% clay	6.2	4.1	6.2	2.9	4.4
Organic matter content:	(%)	not given in report				
Organic carbon content:	(%)	1.7	0.6	1.3	1.1	1.3
Total nitrogen:	(%)	0.21	0.18	0.14	0.1	0.14
pH:		7.4	8.2	7.55	7.6	7.5
$CaCO_3$:	(%)	7.2	0.1	11	9.7	10.2
Cation exchange capacity:	(meq/ 100g soil)	14.3	6	14.5	6.5	8.2
Bulk density (air dried and sieved (2 mm) soil)	(g/ml)	not given in report				
Maximum water holding capacity (MWC; pF<0.3):	(ml H_2O/ 100g dry soil)	46.7	23.5	47.2	39.5	47.4
Field capacity (FC; pF=2.5):	(ml H_2O/ 100g dry soil)	36.2	18.8	36.3	29.3	36.6
Microbial biomass (mg/100 g dry soil):	At start: At end:	37.1 26.6	11.8 6.5	36.7 18.0	35.5 17.8	29.6 22.8
Soil conditions	Aerobic:	x	x	x	x	x
Soil moisture:	%- MWC:	40%	40%	40%	40%	40%

Test conditions		1	2	3	4	5
Incubation temperature(s)	(°C)	20±2	20±2	20±2	20±2	20±2
Treatment rate:	(mg a.i./ kg soil)	0.496	0.496	0.496	0.492	0.492
Incubation time:	(days)	181	181	181	121	121
Number of samples taken for analysis:		24	24	24	10	10
Methods used for analysis	HPLC	x	x	x	x	x
	TLC	x	x	x	x	x
	GC	-	-	-	-	-
Methods for the identification of degradates		cochromatography, LC-MS				

11 Statistics

The rate of disappearance of CGA 293343 was calculated by applying first order one- and two- compartment reaction kinetics

12 References (published)

none

13 Unpublished data

none

Findings: Details of the degradation pattern and the radioactivity balance are given in Table 1. The percentage of extractable radioactivity decreased in all soil types with time. The main extractable metabolite observed was CGA 322704 in all soils. It reached maximum amounts corresponding to between 4.6% of applied radioactivity in the Speyer 2.1 soil after 181 days and 18.9% in the Weide field soil after 121 days. CGA 322704 was identified by standard reference cochromatography and by mass spectroscopy. An additional metabolite identified was the hydrolysis product CGA 355190. It was observed in all soils except in the Speyer 2.1 soil, in amounts ≤2.4% of the applied dose. Unknown chromatographic fractions consisted of up to 5 individual compounds reaching in sum 6.5% of the applied dose as a maximum.

Bound residues reached a maximum concentration between 10.2% and 16.6% after 181 days in the greenhouse soils and of 7.6% and 9.6% after 121 days in the field soils. Volatile radioactivity was identified as carbon dioxide. It reached between 12.1% and 21.1% after 181 days in the greenhouse soils and between 12.1% and 14.2% after 121 days in the field soils.

The data show that the route and pattern of the thiamethoxam degradation is independent of the soil type.

Table 1: Distribution and recovery of radioactivity in percent of applied ^{14}C-thiamethoxam in various soils under laboratory conditions (Adam 1996a).

Days after applic.	Volatiles (CO_2) [%]	Extrac-tables [%]	Extract. Soxhlet [%]	CGA-293343 [%]	CGA-322704 [%]	CGA-355190 [%]	Un-known* [%]	Non-extrac-tables [%]	Total [%]
Collombey Soil stored in greenhouse									
0	n.d	99.0	n.d.	99.0	< 0.5	< 0.5	< 0.5	2.2	101.2
3	0.3	97.2	2.7	97.7	1.2	< 0.5	1.0	0.6	100.7
7	0.7	95.6	2.9	96.4	1.8	< 0.5	< 0.5	1.2	100.4
14	1.4	92.9	3.5	90.8	1.1	< 0.5	4.5	1.6	99.4
21	1.7	91.0	3.3	88.1	4.5	< 0.5	1.7	2.3	98.3
28	2.3	90.9	3.4	86.5	4.4	< 0.5	3.2	2.3	98.8
45	3.9	87.1	4.3	79.2	7.8	< 0.5	4.4	3.0	98.3
59	5.2	84.5	4.7	77.2	8.2	< 0.5	3.5	4.4	98.8
90	7.7	79.2	4.4	67.5	11.3	< 0.5	4.4	5.8	97.1
120	9.5	76.1	5.0	61.9	12.4	< 0.5	6.5	7.0	97.5
153	11.7	71.4	5.3	54.8	14.3	1.3	6.3	8.0	96.5
181	13.5	68.2	5.6	53.7	12.9	1.2	5.4	10.2	97.4
Speyer 2.1 Soil stored in greenhouse									
0	n.d.	101.2	n.d.	101.2	< 0.5	< 0.5	< 0.5	1.1	102.3
3	0.4	96.3	n.d.	95.2	0.3	< 0.5	0.8	3.7	100.4
7	0.8	96.5	2.6	96.7	0.6	< 0.5	1.7	2.9	102.8
14	1.3	89.1	4.1	87.1	3.2	< 0.5	2.9	4.2	98.7
21	1.9	90.3	4.4	89.0	1.4	< 0.5	4.3	4.9	101.6
28	2.6	87.2	5.5	87.8	1.7	< 0.5	3.2	5.2	100.4
45	3.9	84.1	7.0	83.6	2.3	< 0.5	5.1	5.8	100.8
59	5.0	78.9	6.2	77.9	2.5	< 0.5	4.6	9.0	99.0
90	7.1	76.3	5.6	73.6	3.0	< 0.5	5.2	11.6	100.6
120	9.0	72.1	8.5	70.7	3.9	< 0.5	6.0	11.9	101.4
153	10.8	69.0	6.9	66.6	4.2	< 0.5	5.2	14.1	100.9
181	12.1	63.7	7.4	61.1	4.6	< 0.5	5.4	16.6	99.8
Weide Soil stored in greenhouse									
0	n.d.	97.8	n.d.	97.6	0.3	< 0.5	< 0.5	2.5	100.4
3	0.5	94.9	2.6	95.8	1.3	< 0.5	0.3	0.7	98.6
7	0.6	95.5	3.3	97.1	1.2	< 0.5	0.5	1.3	100.7
14	1.7	90.3	4.1	88.0	3.2	< 0.5	3.3	1.8	97.9
21	2.8	90.0	3.4	86.9	4.2	< 0.5	2.3	2.9	99.1
28	3.2	86.2	4.2	82.3	5.2	< 0.5	2.9	3.0	96.6
45	5.8	84.0	5.1	77.4	7.2	< 0.5	4.5	3.9	98.8
59	7.9	79.6	5.2	71.2	9.2	< 0.5	4.5	5.9	98.6
90	12.0	72.5	5.3	59.4	12.3	< 0.5	6.1	7.5	97.3
120	15.3	68.8	6.0	55.8	13.0	< 0.5	6.0	8.8	99.0
153	18.6	63.5	5.6	47.5	14.6	0.8	6.2	10.0	97.8
181	21.1	63.8	5.6	47.0	15.1	1.2	6.1	12.5	102.9
Weide field soil									
0	n.d.	95.5	2.3	97.0	< 0.5	0.9	< 0.5	0.1	97.9
3	0.6	95.3	3.3	96.3	1.6	0.6	< 0.5	0.7	99.9
7	1.4	91.7	3.6	91.4	2.6	0.6	0.7	1.2	97.8
14	2.8	88.6	4.1	86.4	4.8	0.8	0.8	1.9	97.4
21	4.4	89.4	3.5	80.6	8.0	1.0	3.3	2.5	99.8
28	5.2	82.0	4.5	72.8	9.5	0.8	3.4	3.7	95.4
45	8.0	79.1	4.8	66.2	12.8	< 0.5	4.8	4. 9	96.8
62	10. 5	73.3	3.4	55.1	14.2	1.2	6.2	6.3	93.4
90	13.3	64.8	4.9	44.6	16.8	0.8	7.5	8.5	91.5
121	14.2	56.9	6.0	36.3	18.9	< 0.5	7.6	9. 6	86.6
Pappelacker field soil									
0	n.d.	96.6	2.0	97.3	< 0.5	1.4	< 0.5	0.1	98.7
3	0.4	96.2	2.9	96.8	1.0	1.2	< 0.5	0.8	100.2
7	1.0	90.3	4.1	91.5	1.6	1.3	< 0.5	1.2	96.6
14	2.2	87.8	4.3	87.5	3.0	1.6	< 0.5	1.6	95.9
21	3.4	89.2	3.6	86.6	5.1	< 0.5	1.0	2.4	98.4

Days after applic.	Volatiles (CO_2) [%]	Extrac-tables [%]	Extract. Soxhlet [%]	CGA-293343 [%]	CGA-322704 [%]	CGA-355190 [%]	Un-known* [%]	Non-extrac-tables [%]	Total [%]
28	4.4	81.7	6.0	78.7	5.8	2.4	0.8	3.9	96.0
45	6.6	79.6	5.5	73.4	8.3	1.0	2.4	4.1	95.7
62	8.6	77.9	3.8	68.0	10.1	1.3	2.3	5.1	95.3
90	10.9	69.3	6.7	60.8	11.8	1.0	2.4	7.7	94.6
121	12.1	63.3	7.8	54.7	12.9	< 0.5	3.6	7.6	90.8

*: Unknown chromatographic fractions (up to 5 compounds).

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*08/09/04*
Materials and Methods	**Comments**: [redacted]
Results and discussion	**Comments:** [redacted]
Conclusion	[redacted]

[redacted]

Reliability	[redacted]
Acceptability	[redacted]
Remarks	

98/8 Doc IIIA section No. 7.2.2.1 / 02a	The rate and route of fegradation including identification of the process involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
91/414 Annex Point addressed II 7.1.1.2.1 / 02	Rate of degradation in soil - laboratory studies

1.	Annex point(s)	**IIA,7.1.1.2.1 Rate of degradation in soil - laboratory studies**
2.	Location in Dossier	Section 5
3.	Authors (year) Title Report No., Date Source Owner Syngenta File No. (DESIRE)	Ellgehausen, H. (1998a) Calculation of the Degradation Kinetics of Metabolite CGA 322704 in Sandy Soil Collombey Report No 98EH04, October 9, 1998 Environmental safety/ Ecochemistry, Novartis Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland CGA 322704 /16
4.	Testing facility	Environmental safety/ Ecochemistry, Novartis Crop Protection AG, Basel, Switzerland
5.	Dates of work	September - October 9, 1998
6.	Test substance	not applicable
7.	Test method	The study was performed to generate supplemental data to satisfy the following guidelines: Commission Directive 95/36/EC amending Council Directive 91/414/EEC, Annex 1; fate and Behaviour in the Environment: 7.1 Fate and Behaviour in Soil, 7.1.1.2 rate of degradation laboratory studies, 1997.
8.	Deviations	none
9.	GLP	not applicable

Findings: The rate of disappearance of thiamethoxam was calculated by applying first order one - and two - compartment reaction kinetics. The values are presented in Table 1. The data indicate that degradation in soils taken directly from the field is somewhat faster as compared to soils stored before use. The comparably long half-life of 272 days in the Speyer 2.1 soil with low microbial activity indicates that thiamethoxam degradation is a microbially driven process.

The data in the Collombey sandy soil allowed the calculation of kinetics of the dissipation of the metabolite CGA 322704 by using the ModelMaker software (Version 3.0.2; SB Technology Ltd.). The DT_{50} obtained was 75 days with a corresponding DT_{90} of 250 days. In the other soils tested CGA 322704 did not reach an apparent peak concentration during the experimental period of 121 and 181 days, respectively.

Table 1: Results of degradation kinetics for thiamethoxam and amounts of bound residues and carbon dioxide in five different soil systems (Adam 1996a)

Soil	Incubation time	thiamethoxam	thiamethoxam	$^{14}CO_2$	Non extractable
	[days]	DT_{50} [days]	DT_{90} [days]	[% appl. act.]*	[% appl. act.]*
Collombey (greenhouse)	181	184	694	13.5	10.2
Speyer 2.1 (greenhouse)	181	272	1013	12.1	16.6
Weide (greenhouse)	181	143	475	21.1	12.5
Pappelacker (field)	121	164	911	12.1	7.6
Weide (field)	121	80	266	14.2	9.6

* at completion of study

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

98/8 Doc IIIA section No.	7.2.2.1 / 03	The rate and route of degradation including identification of the process involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
91/414 Annex Point addressed	II 7.1.1.1.1 / 02	Soil route of degradation: Aerobic degradation

1.	Annex point(s)	**II A, 7.1.1.1.1 Soil Route of Degradation: Aerobic degradation**
2.	Location in Dossier	Section 5,
3.	Authors (year)	B.Dixon (1998)
	Title	Aerobic Soil Metabolism of (^{14}C-thiazole) CGA 293343
Report No., Date		ABR-96059, March 16, 1998
Syngenta File N°(Desire)		293343/478
Owner		Syngenta Crop Protection AG
4.	Testing facility	Novartis Crop Protection Inc Environmental Safety Department Greensboro, NC 27419, USA and PTRL West, Incorporated Richmond, CA 94806, USA
5.	Dates of work	Study Initiation: 25 September, 1995 Experimental Start: 16 October, 1995 Experimental Termination: Study Completion: 16 March, 1998
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343, (^{14}C-thiazolyl)CGA 293343, Batch [redacted] specific radioactivity: 1.09 MBq/mg radiochemical purity: [redacted]
7.	Test method	US EPA Environmental Fate Data requirement, 40 CFR Section 158, Subdivision N, series 162-1.
8.	Deviations	none
9.	GLP	Yes , EPA Good Laboratory Practice Standards (40 CFR Part 160) with the exception of the soil characterization performed at Agvise Laboratories Inc.

Test system: In this study the degradation of ^{14}C-thiazol-labelled thiamethoxam was investigated in a Californian sandy loam soil for one year. The biological portion of the study was contracted at PTRL West, Inc., Richmond, California (study No. 573W). Soil was dosed at two concentrations, 0.09 mg/kg (kinetic viable test, corresponding to a field rate of 200 g/ha assuming a homogeneous distribution in the top 15 cm soil layer and a soil density of 1.5 g/cm^3) and 4.98 mg/kg (bulk viable test). Incubation was at 25°C and 75% field moisture capacity in the dark under aerobic conditions for 365 days. Soil samples were aerated and trapped for volatiles continuously. Duplicate samples were taken at regular intervals (12 for the 0.09 mg/kg and 8 for the 4.98 mg/kg incubations) to determine the metabolism occurring. Additional tests were performed under initially sterile conditions. Details of the soil characteristics are summarised in Table 1.

Table 1: Parameters of soil used for thiamethoxam metabolism (Dixon, 1998 and Schwartz, 1998a)

Location of collection		Novartis Crop Protection, Western Research Station, Sanger, California	
Date of collection (field/greenhouse)		September 6, 1995	
pH		7.3	
Organic matter (%)		0.6	
CEC (meq/100 g soil)		7.4	
Water holding capacity at 33 kPa (%)		10.9	
Classification (USDA)		sandy loam	
Particle size:	Clay (%)	8	
	Silt (%)	25	
	Sand (%)	67	
Microbial biomass (mg C/100 g soil):		**^{14}C-Thiazol study**	**^{14}C-Guanidine study**
day 0		17.5	17.5
4.5 months		29.0	20.0
12 months		19.0	23.5

Findings: For both the 0.09 and the 4.98 mg/kg incubations the amount of extractable radioactivity decreased steadily during the 365 days of incubation. Results for the dissipation of thiamethoxam and the formation and decline of metabolites , bound residues and carbon dioxide are shown in Table 2 and Figure 1 for the 0.09 mg/kg concentration (kinetic viable test). A quantitatively and qualitatively similar pattern was observed for the 4.98 mg/kg incubation (bulk viable test).

For the kinetic viable test the sum of the extracts 1 and 2 (acetonitrile and acetonitrile-ammonium chloride solution at room temperature) decreased from 99.7% on day 0 to 52.0% at day 365. Most of the extractable radioactivity in the extracts was identified as undegraded thiamethoxam. There were multiple minor components detected by two dimensional TLC. Some of these minor components were observed only intermittently during the 365 days. Components characterised by co-chromatography were CGA 322704 and CGA 355190 at concentrations below 5% of applied dose and CGA 309335 and CGA 353968 at concentrations below 1.5% of applied dose. With the exception of CGA 309335 all other components identified had also been observed in the soil metabolism study with the ^{14}C-guanidine-labelled material.

Aerobic volatile generation of carbon dioxide increased to an average of 11% at day 268 and to 7% at day 365 indicating mineralisation of the thiazol ring. The non-extractables reached a maximum of 28% at day 365. Harsh extraction under strong alkaline conditions (1M NaOH) had released up to 18% of applied radioactivity mostly in the fulvic acid fraction.

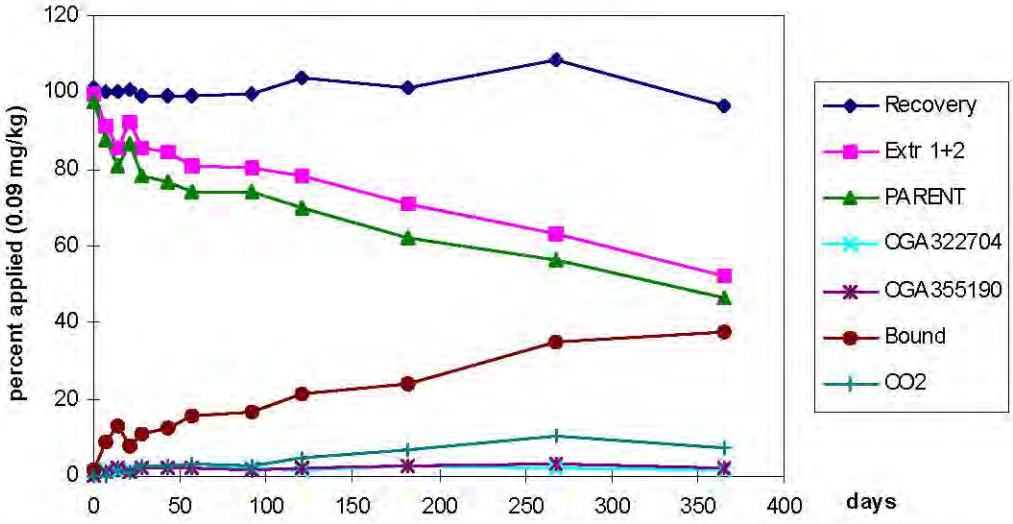
The initial degradation of thiamethoxam in the sterile soil was mainly due to hydrolytic degradation. CGA 355190 was one of the major degradates in the hydrolysis studies. This degradate accumulated under the initially sterile conditions whereas in the viable soil incubations it was also formed as an intermediate but was metabolized further.

Table 2: Distribution and recovery of radioactivity after application of ^{14}C-thiamethoxam in a Californian sandy loam, kinetic viable incubation (Dixon 1998).

Time after applic. [days]	Volatiles (CO_2) [%]	Extract. 1 + 2 [%]	CGA-293343 [%]	CGA-322704 [%]	CGA-355190 [%]	Harsh Extract [%]	Non-extrac-tables [%]	Total Recovery [%]
0	np	99.7	97.4	0.9	0.2	np	1.4	101.1
7	0.3	91.1	87.5	1.3	1.0	np	8. 7	100.0
14	1.7	85.4	81.1	1.1	2.1	np	13.3	100.4
21	1.0	92.1	86.6	1.6	1.0	np	7.7	100.8
28	2.6	85.6	78.1	1.9	2.2	7.3	3.9	99.4
43	2.4	84.5	76.5	1.9	2.2	np	12.3	99.2
57	3.1	80.7	73.9	2.1	2.3	np	15.6	99.4
92	2.6	80.4	73.9	1.9	1.8	9.3	7.6	99.9
121	4.8	78.0	69.9	1.7	2.3	np	15.2	98.0
182	6.7	70.7	61.9	2.4	2.5	11.5	9.6	98.2
268	10.7	62.9	56.2	2.1	3.0	17.7	17.4	108.6
365	7.1	52.0	46.2	1.5	2.3	9.2	28.1	96.6

np: not performed

Figure 1: Formation and decline of major metabolites for ^{14}C-Thiazol-thiamethoxam in a Californian sandy loam (Dixon 1998)



Bound = sum of non-extractable radioactivity and radioactivity in harsh extracts

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10/09/04
Materials and Methods	**Comments**: [redacted]
Results and discussion	[redacted]

[redacted]

Conclusion

[redacted]

[redacted]

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

Reliability indicator	[redacted]

98/8 Doc IIIA section No.	7.2.2.1 / 04	The rate and route of degradation including identification of the process involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
91/414 Annex Point addressed	II 7.1.1.1.1 / 03	Soil route of degradation: Aerobic degradation

1.	Annex point(s)	**II A, 7.1.1.1.1** **Soil Route of Degradation: Aerobic degradation**
2.	Location in Dossier	Section 5,
3.	Authors (year)	B.Schwartz, (1998a)
	Title	Final report: Aerobic Soil Metabolism of (^{14}C-guanidine) CGA 293343
Report No., Date		ABR-96084, March 3, 1998
Syngenta File N°(Desire)		293343/453
Owner		Syngenta Crop Protection AG
4.	Testing facility	Novartis Crop Protection Inc Environmental Safety Department Greensboro, NC 27419, USA and PTRL West, Incorporated Richmond, CA 94806, USA
5.	Dates of work	Study Initiation: 25 September, 1995 Experimental Start: October 3, 1995 Experimental Termination: Study Completion: 16 March, 1998
6.	Test substance	ISO common name thiamethoxam. Company Code: CGA 293343, (^{14}C-guanidine)CGA 293343 [redacted] specific radioactivity: 1.57 MBq/mg radiochemical purity: [redacted]
7.	Test method	US EPA Environmental Fate Data requirement, 40 CFR Section 158, Subdivision N, Series 162-1.
8.	Deviations	none
9.	GLP	Yes , EPA Good Laboratory Practice Standards (40 CFR Part 160) with the exception of the soil characterization performed at Agvise Laboratories Inc.

Test system: In this second aerobic soil metabolism study the degradation of thiamethoxam was investigated by using ^{14}C-guanidine-labelled material. As above the biological portion of the study was contracted at PTRL West Inc., Richmond, California (study No. 572W). The dosage levels were 0.09 mg/kg (kinetic viable test, corresponding to a field rate of 200 g/ha assuming a homogeneous distribution in the top 15 cm soil layer and a soil density of 1.5 g/cm^3) and 4.90 mg/kg (bulk viable test). Test soil, incubation conditions and soil sampling regimen were the same as for the study with the ^{14}C-thiazol-labelled material. Additional tests were performed under initially sterile conditions.

Findings: As with the ^{14}C-thiazol-labelled material the amount of extractable radioactivity decreased steadily during the 365 days incubation for both concentrations. Results for the dissipation of thiamethoxam and the formation and decline of metabolites, bound residues and carbon dioxide are shown in Table 1 and Figure 1 for the 0.09 mg/kg concentration (kinetic viable test). A quantitatively and qualitatively similar pattern was observed for the 4.98 mg/kg incubation (bulk viable test).
The sum of the extracts 1 and 2 (acetonitrile and acetonitrile-ammonium chloride solution at room temperature) decreased from 100% on day 0 to 53% at day 365. Most of the extractable radioactivity in the extracts was identified as undegraded thiamethoxam. There were up to 30 multiple minor components detected by two dimensional TLC. Some of these minor