

components were observed only intermittently during the 365 days and there was no evidence for accumulation of any degradate. Components characterised by co-chromatography and mass spectral analysis were CGA 322704, CGA 355190 and CGA 282149 at maximum concentrations below 6% of applied dose and CGA 353968 at concentrations below 1% of applied dose. With the exception of CGA 282149 all other components had also been observed in the soil metabolism study with the <sup>14</sup>C-thiazol-labelled material.

Again a significant mineralisation was observed with 10% of applied radioactivity released as carbon dioxide after 365 days. Unextractable radioactivity was also formed but did not follow an increasing pattern with incubation time.

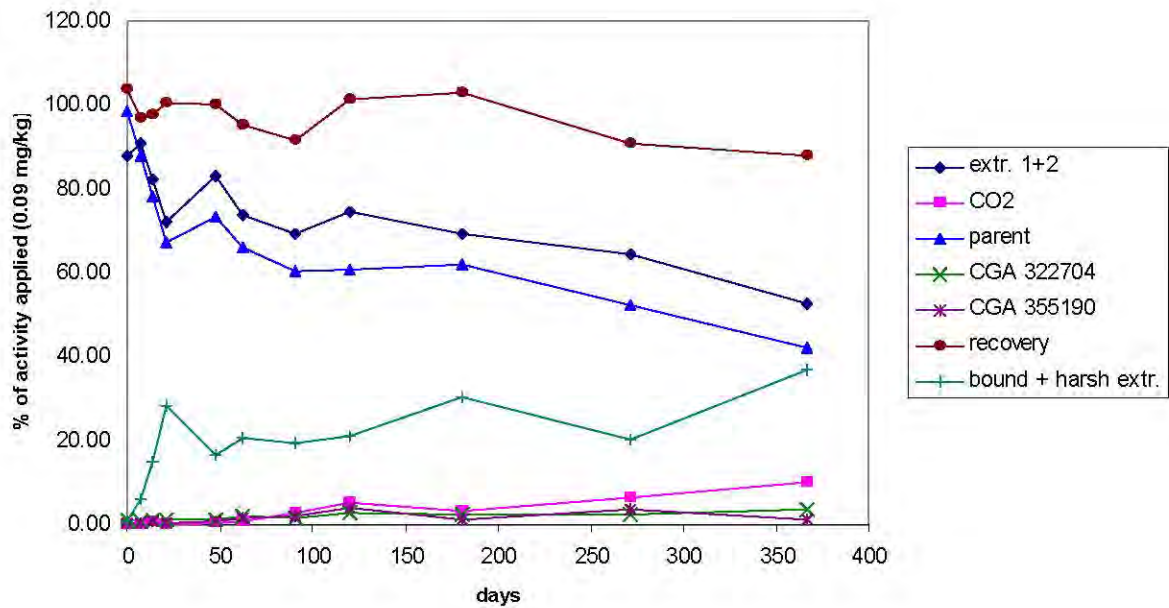
Under sterile conditions the degradation occurred slower with the similar pattern of degradates.

**Table 1: Distribution and recovery of radioactivity after application of <sup>14</sup>C-thiamethoxam in a Californian sandy loam, kinetic viable incubation (Schwartz 1998a).**

Time after applic [days]	Volatiles (CO <sub>2</sub> ) [%]	Extract. 1 + 2 [%]	CGA-293343 [%]	CGA-322704 [%]	CGA-355190 [%]	Harsh Extract [%]	Non-extractables [%]	Total Recovery [%]
0	np	102.9	98.6	1.4	0.5	np	0.7	103.7
7	0.1	90.7	87.8	1.0	0.5	np	6.3	97.1
14	0.7	82.2	78.3	1.3	0.7	np	15.0	97.9
21	0.1	72.0	67.3	1.4	0.6	np	28.4	100.5
48	0.4	83.0	73.2	1.4	0.7	np	16.6	100.0
62	0.9	73.7	66.1	2.1	1.6	np	20.6	95.2
91	2.9	69.4	60.5	1.7	2.1	11.6	8.0	91.8
120	5.3	74.7	60.8	2.9	3.9	np	21.2	101.2
181	3.1	69.5	62.2	2.4	1.4	15.4	14.9	102.9
272 / 274	6.5	64.3	52.3	2.3	3.6	13.1	7.1	91.0
365 / 367	10.2	52.8	42.2	3.8	1.4	12.1	24.9	87.8

np: not performed

Figure 1: Formation and decline of major metabolites for <sup>14</sup>C- Guanidine - thiamethoxam in a Californian sandy loam (Schwartz 1998a)



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

Evaluation by Competent Authorities	
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>	
<b>Date</b>	15/09/04
<b>Materials and Methods</b>	<b>Comments:</b> [Redacted]
<b>Results and discussion</b>	[Redacted]

	
	<ul style="list-style-type: none"><li></li><li></li><li></li></ul>
<b>Conclusion</b>	
<b>Reliability</b>	
<b>Acceptability</b>	
<b>Remarks</b>	

98/8	Doc	IIIA	7.2.2.1 / 05	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	II	7.1.1.1.1 / 01	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)** S.M. Cruz, (1998)  
**Title** Metabolism of <sup>14</sup>C-guanidine - CGA 293343 in Viable and Sterile Clay Loam Soil Under Aerobic Conditions  
**Report No., Date** ABR-98046, 18 September, 1998  
**Syngenta File N°(Desire)** 293343/752  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc  
Environmental Safety Department  
Greensboro, NC 27419, USA
5. **Dates of work** Study Initiation: 30 January, 1997  
Experimental Start: October 3, 1995  
Experimental Termination:  
Study Completion: 18 September, 1998
6. **Test substance** ISO common name thiamethoxam. Company Code: CGA 293343,  
(<sup>14</sup>C-guanidine)CGA 293343, Batch [REDACTED]  
specific radioactivity: 2.2 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 aerobic soil metabolism study the degradation of thiamethoxam was investigated by using a clay loam soil originating from Manitoba, Canada. Soil was dosed at a concentration of 0.1 mg/kg of <sup>14</sup>C-guanidine-thiamethoxam, corresponding to a field rate of 200 g/ha and uniform distribution in 15 cm soil with a density of 1.5 g/cm<sup>3</sup>. Incubation was at 25°C and 75% field moisture capacity in the dark. Soil samples were aerated and trapped for volatiles continuously. Duplicate samples were taken at regular intervals up to one year to determine material balance and the metabolism occurring. Soil samples were extracted consecutively with acetonitrile, acetonitrile/hydrochloric acid and sodium hydroxide/methanol under reflux. Extracts were submitted to HPLC and 2D-TLC for characterization of radioactivity. A parallel test series was performed for six months under initially sterile conditions. Details of the soil characteristics are summarised in Table 1.



**Table 1: Parameters of soil used for thiamethoxam metabolism (Cruz 1998)**

Location of collection	Portage la Prairie, Elm River Research Farm Manitoba, Canada	
Date of collection (field/greenhouse)	November 26, 1996	
pH	7.6	
Organic carbon (%)	2.5	
CEC (meq/100 g soil)	25.5	
Water holding capacity (%) at 33 kPa (field moisture capacity)	32.5	
Classification (USDA)	clay loam	
Particle size:	Clay (%)	37
	Silt (%)	21
	Sand (%)	42
Microbial biomass (mg C/100 g soil):		
day 0	10.3	
6 months	61.3	
12 months	64.8	

**Findings:** Results for the dissipation of thiamethoxam and the formation and decline of metabolites, bound residues and carbon dioxide in the Canadian clay loam soil are shown in Table 3 (viable test) and Table 2 (sterile test). Throughout the course of the study, the material balance ranged from 92.3% to 105.5% of the applied dose. In the viable test the sum of the extracts 1 and 2 (acetonitrile and acetonitrile-ammonium chloride solution pH 5, at room temperature) decreased continuously from 97.4% on day 0 to 46.4% after 12 months. The major metabolite formed with a maximum of 23.1% of applied dose after six months was the urea analogue CGA 355190. CGA 322704 which was the main metabolite in all other soil metabolism studies performed was observed at concentrations below 2% of applied dose at all time intervals in this study. CGA 353968, the further urea metabolite with the oxadiazinyl ring opened is a possible common degradate originating from CGA 355190 and CGA 322704; it reached a level of 3.8% after 12 months. CGA 282149 which is the product of the bridge cleavage between the two rings was detected with a maximum of 6.8% after six months. Aerobic volatile generation of carbon dioxide increased to 39.0% after one year indicating mineralisation of the guanidine moiety. The non-extractable radioactivity reached a maximum of 9.4% after three months and decreased to 6.9% after one year.

In the sterile clay loam soil the degradation to CGA 355190 and CGA 322704 occurred more slowly indicating that the metabolism of thiamethoxam depends on the microbial viability of the soil.

**Table 2: Distribution and recovery of radioactivity after application of <sup>14</sup>C-thiamethoxam in Canadian sterile soil (Cruz, 1998).**

Time after applic.	Volatiles (CO <sub>2</sub> ) [%]	Extractables [%]	CGA-293343 [%]	CGA-322704 [%]	CGA-282149 [%]	CGA-355190 [%]	CGA-353968 [%]	Non-extractables [%]	Total Recovery [%]
Day 0	-	97.2	96.4	0.5	< lod	0.5	< lod	4.5	104.7
Day 2	0.2	96.8	95.0	0.8	< lod	< lod	< lod	2.1	99.1
Day 7	0.2	96.6	96.1	0.2	< lod	0.3	< lod	4.7	101.6
Day 14	0	92.5	91.2	0.4	< lod	0.6	< lod	6.0	98.6
Day 30	0.2	92.9	90.9	0.6	0.2	1.0	< lod	7.9	100.9
Month 3	0.7	92.4	83.4	0.6	< lod	2.0	< lod	6.5	99.6
Month 6	2.1	89.1	80.9	1.4	< lod	5.5	< lod	14.4	105.5

lod = limit of determination

**Table 3: Distribution and recovery of radioactivity after application of <sup>14</sup>C-thiamethoxam in Canadian viable soil (Cruz, 1998).**

Time after applic.	Volatiles (CO <sub>2</sub> ) [%]	Extractables [%]	CGA-293343 [%]	CGA-322704 [%]	CGA-282149 [%]	CGA-355190 [%]	CGA-353968 [%]	Non-extractables [%]	Total Recovery [%]
Day 0	-	97.4	97.0	0.3	< lod	< lod	< lod	1.1	98.5
Day 2	0.2	97.1	96.0	0.9	< lod	< lod	< lod	2.3	99.5
Day 7	0.3	94.9	93.0	0.8	0.2	0.9	< lod	4.7	99.9
Day 14	0.4	97.6	95.8	1.1	< lod	0.9	< lod	6.4	104.3
Day 30	1.1	91.9	79.5	1.0	0.9	2.5	< lod	5.1	98.2
Month 3	9.0	78.8	46.9	2.0	3.7	15.4	1.6	9.4	97.3
Month 6	21.2	67.0	25.3	1.2	6.8	23.1	2.9	9.2	97.4
Month 9	25.6	62.8	24.6	1.3	5.3	20.0	3.1	7.4	95.8
Month 12	39.0	46.4	9.0	1.3	2.8	21.7	3.8	6.9	92.3

lod = limit of determination

Evaluation by Competent Authorities	
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>	
<b>Date</b>	16/09/04
<b>Materials and Methods</b>	<p><b>Comments:</b></p> <ul style="list-style-type: none"> <li>• [REDACTED]</li> <li>█ [REDACTED]</li> <li>█ [REDACTED]</li> <li>█ [REDACTED] P</li> </ul>
<b>Results and discussion</b>	<p><b>Comments:</b></p> <ul style="list-style-type: none"> <li>• [REDACTED]</li> <li>█ [REDACTED]</li> <li>█ [REDACTED]</li> </ul>

[Redacted text block]

**Conclusion**

[Redacted text block]

**Reliability**

[Redacted]

**Acceptability**

[Redacted]

**Remarks**

[Redacted text block]

98/8 section No.	Doc IIIA	7.2.2.1 06	/	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 Point addressed	Annex II	7.1.1.1.1		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)** Adam, D. (1999a)  
**Title** Degradation of <sup>14</sup>C-Thiazole Labelled CGA 322704 in Schwaderloch Soil under Aerobic Conditions at 20°C
- Report No., Date** 99DA06, November 18, 1999  
**Syngenta File N°(Desire)** 322704/0024  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc  
Environmental Safety Department  
Basel, Switzerland
5. **Dates of work** Study Initiation: April 27, 1999  
Experimental Start: May 4, 1999  
Experimental Termination: October 5, 1999  
Study Completion: November 18, 1999
6. **Test substance** Company Code: CGA 322704 (metabolite of thiamethoxam),  
(<sup>14</sup>C-thiazole) CGA 322704, [REDACTED]  
specific radioactivity: 2.02 MBq/mg  
radiochemical purity: [REDACTED]
7. **Test method** Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC:  
Annex II: Fate and Behaviour in the Environment; 7.1 Fate and Behaviour in soil, 7.1.1.2.  
Rate of Degradation
8. **Deviations** none
9. **GLP** yes (Novartis Crop Protection AG, 4002 Basel, Switzerland)

**Test system:** The degradation CGA 322704 (major metabolite of thiamethoxam) was evaluated in Schwaderloch sandy loam. Separate soil samples were treated with <sup>14</sup>C-thiazole labelled CGA 322704 at a concentration of 0.12 mg/kg dry soil.

The incubation was done at 20°C and 40 % of Maximum Water Holding Capacity in 300 mL Erlenmeyer flasks with 75 g soil/flask. Details of the sampling intervals and soil parameters are given in Table 1 and in Table 2.

Table 1: Soil characteristic of Schwaderloch soil

Soil	Schwaderloch
Origin	Schwaderloch, CH
Batch-No	April 99
Classification	sandy loam
pH	7.4
Organic carbon (%)	1.2
CaCO <sub>3</sub>	10.0
N total	0.02
Particle size:	
Clay (%)	11.6
Silt (%)	21.5
Sand (%)	67
Field capacity (FC; g/100 g soil)	30.9
Bulk density (g/cm <sup>3</sup> )	1.3
Max. water holding cap. (MWC; g/100 g soil)	44.8
Microbial biomass (mg C/100 dry soil) start	62.9
Microbial biomass (mg C/100 dry soil) end (120 days)	32.3

**Findings:** The overall recovery, comprising the soil extracts, non-extractable residues and volatile products ranged from 96.7 to 102.5 % of the applied radioactivity.

The extractable radioactivity decreased from 102.3 % at the beginning of the study to 69.5 % after 120 days of incubation. Correspondingly non-extractables increased from 0.1 % to 7.5 % of the applied dose at the end of the experiment. The mineralisation rate of CGA 322704 was 19.7 % after 120 days. Organic volatiles were found to be negligible ( $\leq 0.1$  % of the applied radioactivity). The degradation rate of CGA 322704 was calculated by assuming pseudo first-order reaction kinetics (one compartment model). CGA 322704 degraded with a DT50 of 178.2 days and a DT-90 of 592 days.

In Schwaderloch soil CGA 322704 was mainly mineralised to carbon dioxide and to a lesser extent bound to the soil. During the experiment only one compound was detected in amounts up to 5.8 % of the applied radioactivity. It was identified as CGA 265307 i.e. N-(2-chloro-thiazole-5-ylmethyl)-N'-nitro-guanidine by co-chromatography on HPLC and 2D-TLC.

Table 2 Distribution of radioactivity in Schwaderloch soil after application of <sup>14</sup>C-CGA 322704 (in % of radioactivity applied)

Incubation Day	Total Extractables	Non-extractables	CO <sub>2</sub>	CGA 322704	Unknown	CGA 265307	Recovery
0	102.3	0.1	n.a.	100.5	0.9	0.9	102.5
3	97.8	1.1	0.6	96.6	0.5	0.7	99.5
7	98.5	1.4	1.6	96.7	1.1	0.6	101.5
14	95.3	2.3	3.3	92.4	< LD	< LD	100.9
28	90.9	3.1	6.5	87.8	0.5	2.5	100.6
64	78.7	5.9	13.3	74.1	0.5	4.2	98.0
90	74.3	7.7	16.0	70.0	0.1	4.0	98.1
120	69.5	7.5	19.7	63.6	< LQ	5.8	96.7

< LD = lower than detection limit; < LQ = lower than limit of quantification; n.a. not applicable

**In conclusion,** CGA 322704 was degraded in Schwaderloch soil with a half-life of 178.2 days and a DT90 value of 591.9 days. The degradation pathway of CGA 322704 was the N-des-methylation to CGA 265307, the mineralisation to carbon dioxide accounting for up to 19.7 % and formation of bound residues (7.5 % at the end of the study).

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

<b>Date</b>	17/09/04
<b>Materials and Methods</b>	<b>Comments:</b> <ul style="list-style-type: none"><li>• [REDACTED]</li><li>█ [REDACTED]</li><li>█ [REDACTED]</li></ul>
<b>Results and discussion</b>	<b>Comments:</b> <ul style="list-style-type: none"><li>• [REDACTED]</li><li>█ [REDACTED]</li><li>• [REDACTED]</li></ul>
<b>Conclusion</b>	[REDACTED]
<b>Reliability</b>	█ [REDACTED]
<b>Acceptability</b>	[REDACTED]
<b>Remarks</b>	

98/8 section No.	Doc IIIA	7.2.2.1 07	/	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 Point addressed	Annex II	7.1.1.1.1		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)** Reischmann, F.-J.(2002)  
**Title** Rate of Degradation of [Thiazole-2-<sup>14</sup>C]-labelled NOA 459602 in Three Soils under Aerobic Laboratory Conditions at 20 °C
- Report No., Date** 01RF03, September 9, 2002  
**Syngenta File N°(Desire)** 459602/0020  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc  
Environmental Safety Department  
Basel, Switzerland
5. **Dates of work** Study Initiation: November 22, 2002  
Experimental Start: November 23, 2002  
Experimental Termination: August 7, 2002  
Study Completion: September 9, 2002
6. **Test substance** Company Code: CGA 459602 (metabolite of thiamethoxam), (<sup>14</sup>C-thiazole) CGA 459602, [REDACTED]  
specific radioactivity: 0.899 MBq/mg  
radiochemical purity: [REDACTED]
7. **Test method** Commission Directive 95/36/EC amending Council Directive 91/4/EEC, Annex I, Fate and Behaviour in the Environment; 7.1 Fate and behaviour in soil, 7.1.1.2 rate of degradation (1997).
8. **Deviations** none
9. **GLP** Yes (Syngenta Crop Protection AG, 4002 Basel, Switzerland)

**Test system:** In this study the degradation rate of <sup>14</sup>C-NOA 459602 (labeled in the thiazolring) in three different soil types was investigated. The study was performed with three soils: Borstel loamy sand, Gartenacker silt loam, and Pappelacker sandy loam (soil properties see Table 1) were treated with the test substance at a rate of 0.097 mg/kg soil. Aerobic samples were incubated in the dark over 121 days at a soil moisture content of 40 % of the maximum water holding capacity.



Table 1 Soil characteristics and test conditions

Soil		Borstel	Gartenacker	Pappelacker
Origin		D	CH	CH
Batch		5/00	10/01	10/01
Classification (USDA)		loamy sand	silt loam	sandy loam
pH (KCl)	(-log(H))	--	7.32	7.51
pH (CaCl <sub>2</sub> )	(-log(H))	5.6		
CaCO <sub>3</sub>	(%)	0	7.80	9.80
Organic carbon	(%)	1.68*	1.99	1.10
N <sub>total</sub>	(%)	0.11	0.20	0.10
CEC	(meq / 100 g soil)	8.2	12.61	6.48
Particle size: Clay	(%)	6.6	9.58	6.33
Silt	(%)	15.9	51.78	22.36
Sand	(%)	77.5	38.65	71.31
Bulk density	(g / ml; disturbed)	1.39	1.12	1.26
Maximum water holding capacity (MWC)	(g water / 100 g dry soil)	20.0	64.43	44.45
Field capacity at 1/3 bar	(g water / 100 g dry soil)	--	44.38	28.63
Microbial biomass at study start	(mg C / 100 g soil)	15.31	37.47	29.98
at study end		14.80	38.14	26.17

\* Organic matter content (OM): 2.9 %; organic carbon content (OC) = OM / 1.724  
 $\Rightarrow 2.9 / 1.724 = 1.68 \% \text{ OC}$ .

The main objective of the study was the determination of the disappearance time for 50 % (= DT<sub>50</sub>) and 90 % (= DT<sub>90</sub>) of the test substance. All samples were submitted to exhaustive extraction, the extracts were concentrated and analysed by HPLC and the results verified by TLC. A total radioactivity balance and the <sup>14</sup>C-distribution were established for each sample.

**Findings:** The overall recovery comprising the soil extracts, non-extractable residues and volatile products was between 89.9 % and 96.3 % of total applied radioactivity (all values in the report are given in % of the applied dose and are the average of two replicates).

In Borstel soil, the extractable radioactivity declined from 94.9 % at the beginning of the study to 72.4 % at day 121. The non-extractable radioactivity increased steadily to 7.3 % at the end of the study.

Carbon dioxide increased as the study progressed and amounted to 14.2 % at day 121.

Negligible amounts (< 0.1 %) of organic volatiles were generated.

The test substance, NOA 459602, decreased from 94.6 % (day 0) to 58.4 % at the end of the study.

Besides the test substance the metabolite SYN 501406, i.e. sodium; 5-(N'-methyl-N''-nitroguanidinomethyl)-thiazole-2-sulfonate, was found. It reached 7.8 %, its highest concentration, at day 90. After 121 days of incubation SYN 501406 accounted for 7.4 %.

Furthermore, two metabolites, SM1 and SM3, increased during the study and reached 3.8 % and 2.6 % at day 121.

All other metabolites were each below 0.4 %.

In Gartenacker soil, the extractable radioactivity declined from 91.5 % at the beginning of the study to 20.5 % at day 121. The non-extractable radioactivity increased steadily to 18.9 % at the end of the study.

When an extracted soil sample was submitted to harsh extraction procedures, an amount of 1.5 % (day 121) was released by acidic harsh extraction. Soil organic matter fractionation of the bound radioactivity showed that 6.2 %, 0.3 %, and 10.7 % was associated with the fulvic acids, humic acids, and insoluble humin fraction, respectively.

Carbon dioxide increased as the study progressed and amounted to 55.8 % at day 121. Negligible amounts (< 0.1 %) of organic volatiles were generated. The test substance, NOA 459602, decreased from

91.5 % (day 0) to 8.1 % at day 121. Besides the test substance the metabolite SYN 501406 was found. It reached 12.6 %, its highest concentration, at day 28. After 121 days of incubation SYN 501406 accounted for 6.2 %. Metabolite SM1, accounted for a maximum of 8.0 % (day 61) and decreased as the study progressed to 4.4 % (day 121). Metabolite SM3, reached a maximum of 4.6 % (day 28) and decreased to 1.4 % at study end. All other metabolites were each below 1.5 %.

In Pappelacker soil, the extractable radioactivity declined from 93.0 % at the beginning of the study to 18.2 % at day 121. The non-extractable radioactivity increased steadily to 21.4 % at the end of the study.

When an extracted soil sample was submitted to harsh extraction procedures, an amount of 2.7 % (day 121) was released by acidic harsh extraction. Soil organic matter fractionation of the bound radioactivity showed that 8.4 %, 0.5 %, and 10.1 % was associated with the fulvic acids, humic acids, and insoluble humin fraction, respectively.

Carbon dioxide increased as the study progressed and amounted to 53.1 % at day 121. Negligible amounts (< 0.1 %) of organic volatiles were generated. The test substance, NOA 459602, decreased from 93.0 % (day 0) to 5.0 % at day 121. Besides the test substance the metabolite SYN 501406 was found. It reached 10.2 %, its highest concentration, at day 28. After 121 days of incubation SYN 501406 accounted for 3.5 %. Metabolite SM1, accounted for a maximum of 12.2 % (day 61) and decreased as the study progressed to 7.3 % (day 121). Metabolite SM3, reached a maximum of 8.1 % (day 28) and decreased to 2.1 % at study end.

All other metabolites were each below 0.5 %.

#### Degradation Kinetics of NOA 459602

The following degradation half-lives and DT<sub>90</sub>-values (90 % of degradation) of NOA 459602 were calculated:

**Table 2** Degradation half-lives and DT<sub>90</sub>-values (90 % of degradation) of NOA 459602

Soil	k (1 / days)	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
Borstel	0.0040 ± 0.0002	172.0*	571.4*
Gartenacker	0.0217 ± 0.0005	31.9	106.1
Pappelacker	0.0245 ± 0.0003	28.3	94.0

\* extrapolated

**Conclusion:** NOA 459602 was degraded with a half-life of 28.3 days in soil Pappelacker, 31.9 days in soil Gartenacker, and 172.0 days in soil Borstel. The endpoint of the metabolic pathway was the formation of carbon dioxide (up to 55.8 %, soil Gartenacker) and the formation of bound residues (up to 21.4 %, soil Pappelacker).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	20/09/04
Materials and Methods	<ul style="list-style-type: none"> <li> <div style="background-color: black; width: 100%; height: 1.2em; margin-bottom: 0.2em;"></div> <div style="background-color: black; width: 100%; height: 1.2em; margin-bottom: 0.2em;"></div> </li> </ul>

**Results and discussion**

- [Redacted]

- [Redacted]
- [Redacted]

**Conclusion**

**Reliability**

[Redacted]

**Acceptability**

[Redacted]

**Remarks**

98/8 section No.	Doc IIIA	7.2.2.2 / 01	Field soil dissipation and accumulation
91/414 Point addressed	Annex II	7.1.1.2.2	Rate of degradation in soil - field studies

1.2	<b>Title</b>	Residue Study with CGA 293343 in or on soil in South of France..
1.3	<b>Report and/or project N° Syngenta File N°(Desire)</b>	9731002 293343/746
1.4	<b>Lab. Report N°</b>	9731002
1.5	<b>Location in Dossier</b>	Section 5,
1.6	<b>Authors</b>	Report: Pointurier, R., ADME - Bioanalysis., Aigues-Vives, 30670- France
1.7	<b>Date of report</b>	01 October, 1998
1.8	<b>Published / owner</b>	Unpublished/Syngenta Crop Protection AG
2.1	<b>Testing facility</b>	Biological part: Novartis Agro S.A., F-30670 Aigues Vives, Analytical part: ADME - Bioanalysis Residue Laboratory, Aigues-Vives, F - 30670
2.2	<b>Dates of experimental work</b>	Field part:06 May 1997 - 05 May 1998 Analytical part:22 September 1998 -01 October 1998
3.	<b>Objectives</b>	Determination of the magnitude of residues of CGA 293343 and its metabolite CGA 322704 in soil after application of CGA 293343 as formulation WG 25
4.1	<b>Test substance</b>	ISO common name proposed :thiamethoxam. Company code CGA 293343
4.2	<b>Specification</b>	Formulation No.: A-9584 C
4.3	<b>Storage stability</b>	Not applicable
4.4	<b>Stability in vehicle</b>	Not applicable
4.5	<b>Homogeneity in vehicle</b>	Not applicable
4.6	<b>Validity</b>	Not applicable
4.7	<b>Vehicle / solvent</b>	Formulation type: WG 25
4.8	<b>Physical form</b>	Wetable granulate
5.1	<b>Test method</b>	The study was conducted in compliance with (not mentioned in the protocol and report): Commission Directive 95/36/EC of July 1995 amending Council Directive 91/414/EEC: Annex I: 7.1.1.2.2 Field Studies - Soil Dissipation Studies
5.2	<b>Justification</b>	Not applicable
5.3	<b>Copy of method</b>	Not applicable
6	<b>Choice of method</b>	Not applicable
7	<b>Deviations</b>	Not applicable
8.1	<b>Certified laboratory</b>	Yes
8.2	<b>Certifying authority</b>	Ministère de l'Industrie et d'Aménagement du Territoire, France
8.3	<b>GLP</b>	This study was performed in compliance with Good Laboratory Practice (GLP) in France. These procedures are based on the OECD Principles of GLP, adopted by Decision of the OECD Council [C (81) 30 (Final)] concerning Mutual Acceptance of Data in the Assessment of Chemicals. Parts not performed according to GLP-principles: The characterization of soil. The recording of weather data. These exceptions do not adversely affect the results of this study.
8.4	<b>Justification</b>	Not applicable
9.1	<b>GEP</b>	Not applicable

<b>9.2</b>	<b>Type of facility (official or officially recognised)</b>	Not applicable		
<b>9.3</b>	<b>Justification</b>	Not applicable		
<b>10</b>	<b>Test system</b>	Location: Marsillargues, France - 34590 Soil, ray grass application at stage 001 to 11 Soil characterisation for soil :		
		Parameter	Unit	Value (based on dry matter)
		pH	-log(H)	8.17
		org. matter	%	2.0
		CEC	meq/100g soil	16.0
		Clay (0-0.002 mm)	%	30.7
		Silt (0.002 - 0.05 mm)	%	64.0
		Sand (0.05 - 2.0 mm)	%	5.2
		Soil Texture (USDA)		clay loam,
		Water capacity	g/100g soil	23
<b>11</b>	<b>Statistics</b>	No statistical methods were used in this study		
<b>12</b>	<b>References (published)</b>	No references to literature were made in this summary		
<b>13</b>	<b>Unpublished data</b>	Residue method REM 179.03		

**Test system:** Soil residues of thiamethoxam and of the main metabolite CGA 322704 were determined in a field study performed in France in 1997. Thiamethoxam was applied in one dose to the 15 m<sup>2</sup> plot on which ray grass was sown about one month before application. A WG 25 formulation at a rate of 200g as/ha was used. Soil samples were taken in intervals up to one year and were analysed in 10 cm soil profile segments (0-30 cm) for parent thiamethoxam and for CGA 322704. Limit for determination for both compounds analysed was 0.002 mg/kg. The plots were irrigated during the summer months to prevent desiccation and to allow adequate growth of the grass. The grass was mowed regularly. Further details of the field plots are presented in Table 1.

**Table 1** Relevant soil characteristics and kinetic data for soil degradation of thiamethoxam

Location	France South Marsillargues
pH	8.2
C org. [%]	1.1
CEC pot. [meq/100g soil]	16.0
Clay (0-0.002 mm) [%]	30.7
Silt (0.002 - 0.05 mm) [%]	64.0
Sand (0.05 - 2.0 mm) [%]	5.2
Soil Texture (USDA)	Clay loam
Max. Water capacity *	23
Crop, stage at treatment (BBCH)	Ray grass, 1-11
Application date	6 May 1997
Rate (g as/ha), Volume [l/ha]	200 g in 400 L
Total rainfall during trial period [mm]	531
Total irrigation during trial period [mm]	296
<b>Kinetics for thiamethoxam</b>	
DT <sub>50</sub> (days)**	28
DT <sub>90</sub> (days)**	93

\* g water / 100g dry soil equivalents

\*\* 1st order decay calculated with Computerprogramme *Origin 5; Standardfunction: ExpDec1*

**Findings:** Results of the analysis of thiamethoxam and metabolite sampled during one year after application are summarised for the three trials in France in 1997 in Table 2. The degradation rates for thiamethoxam were calculated by applying first order kinetics. For this purpose the residue values in the individual soil layers were added. The resulting DT<sub>50</sub> and DT<sub>90</sub> values and the corresponding correlation coefficients are presented in Table 1. Parent thiamethoxam and the metabolite CGA 322704 were detected in the 10-20 cm soil layer beginning between day 14 and 28. thiamethoxam was not detected in the 20-30 cm soil layer except at sampling day 0 and 14 in the Marsillargues trial. This is attributed to contamination during sampling. Traces of the metabolite CGA 322704 were found in the 20-30 cm layer after one year in two trials.

**Table 2** Thiamethoxam Soil residue studies after application of 200 g/ha

Trial	Residues (mg/kg)			
	France South Marsillargues*			
	thiamethoxam	thiamethoxam	CGA 322704	CGA 322704
Day	0 - 10 cm	10 - 20 cm	0 - 10 cm	10 - 20 cm
0	0.120	<LOQ	<LOQ	<LOQ
7	0.142	<LOQ	0.006	<LOQ
14	0.083	<LOQ	0.004	<LOQ
28	0.048	0.006	0.002	<LOQ
56	0.026	0.012	0.003	<LOQ
112	0.012	0.014	0.009	0.003
364	0.006	0.009	0.005	0.004

- residues in 20-30 cm layer <0.002 mg/kg, except on day 0 and 14 thiamethoxam at 0.008 and 0.002 mg/kg, respectively.
-

<b>Evaluation by Competent Authorities</b>	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>	
<b>Date</b>	20/09/04
<b>Materials and Methods</b>	<b>Comments:</b> <ul style="list-style-type: none"><li>• [REDACTED]</li><li>█ [REDACTED]</li></ul>
<b>Results and discussion</b>	[REDACTED] d
<b>Conclusion</b>	
<b>Reliability</b>	█
<b>Acceptability</b>	[REDACTED]
<b>Remarks</b>	



98/8 section No.	Doc IIIA	7.2.2.2 / 02	Field soil dissipation and accumulation
91/414 Point addressed	Annex II	7.1.1.2.2	Rate of degradation in soil - field studies

- 1.2 **Title** Determination of Residues of CGA 293343 and the Metabolite CGA 322704 in Soil..
- 1.3 **Report and/or project N°** GR 66197  
**Syngenta File N°(Desire)** 293343/750
- 1.4 **Lab. Report N°** 1201/97
- 1.5 **Location in Dossier** Section 5,
- 1.6 **Authors** Report: Smith, J.A. Syngenta Agro GmbH, D-60323 Frankfurt/Main
- 1.7 **Date of report** 29 September, 1998
- 1.8 **Published / owner** Unpublished/Syngenta Crop Protection AG
- 2.1 **Testing facility** Biological part: Novartis Agro GmbH, Development, D-60323 Frankfurt/Main  
Analytical part: Novartis Crop Protection AG, Residue Analysis CP 2.53, CH-4002 Basel
- 2.2 **Dates of experimental work** Field part 30 May 1997 - 26 May 1998  
Analytical part: 18 November 1997 - 02 September 1998
3. **Objectives** Determination of the DT-50 and DT-90 values of the compound CGA 293343 and the metabolite CGA 322704 in soil after the application of the test product A-9584 C, WG25.
- 4.1 **Test substance** ISO common name proposed :thiamethoxam.  
Company code CGA 293343
- 4.2 **Specification** Formulation No.: A-9584 C (local German code: NAD 31030 I).
- 4.3 **Storage stability** Not applicable
- 4.4 **Stability in vehicle** Not applicable
- 4.5 **Homogeneity in vehicle** Not applicable
- 4.6 **Validity** Not applicable
- 4.7 **Vehicle / solvent** Formulation type: WG 25
- 4.8 **Physical form** Wettable granulate
- 5.1 **Test method** The study was conducted in compliance with:  
Richtlinie für die amtliche Prüfung von Pflanzenschutzmitteln Teil IV, 4-1, "verbleib von Pflanzenschutzmitteln im Boden - Abbau, Umwandlung und Metabolismus", BBA Braunschweig, federal republic of Germany 1990. and  
IVA Guidelines, Residue Studies, Industriverband Agrar, Frankfurt, Germany May 1994.
- 5.2 **Justification** Not applicable
- 5.3 **Copy of method** Not applicable
- 6 **Choice of method** Not applicable
- 7 **Deviations** Not applicable
- 8.1 **Certified laboratory** Yes
- 8.2 **Certifying authority** Hessisches Ministerium für Umwelt, Energie, Jugend, Familie und Gesundheit
- 8.3 **GLP** The biological part of the study was performed in compliance with Good Laboratory Practice (GLP) in Germany. The analytical part was performed in compliance with GLP in Switzerland issued by the Federal Department of the Interior. These procedures are based on the OECD Principles of GLP, adopted by Decision of the OECD Council [C (81) 30 (Final)] concerning Mutual Acceptance of Data in the Assessment of Chemicals.  
Parts not performed according to GLP-principles: The characterization of soil. The recording of weather data. These exceptions do not adversely affect the results of this study.
- 8.4 **Justification** Not applicable

9.1	<b>GEP</b>	Not applicable																											
9.2	<b>Type of facility (official or officially recognised)</b>	Not applicable																											
9.3	<b>Justification</b>	Not applicable																											
10	<b>Test system</b>	<p>Location: 23738 Riepsdorf, Germany          Soil, bare ground.          Soil characterisation for soil (LUFA, Speyer) sampled 02 June 1997:</p> <table border="0" style="margin-left: 40px;"> <thead> <tr> <th style="text-align: left;">Parameter</th> <th style="text-align: left;">Unit</th> <th style="text-align: left;">Value (based on dry matter)</th> </tr> </thead> <tbody> <tr> <td>pH</td> <td>-log(H)</td> <td>6.3</td> </tr> <tr> <td>org. carbon</td> <td>%</td> <td>1.25</td> </tr> <tr> <td>CEC</td> <td>meq/100g soil</td> <td>14</td> </tr> <tr> <td>Clay (0-0.002 mm)</td> <td>%</td> <td>14.2</td> </tr> <tr> <td>Silt (0.002 - 0.05 mm)</td> <td>%</td> <td>28.3</td> </tr> <tr> <td>Sand (0.05 - 2.0 mm)</td> <td>%</td> <td>57.5</td> </tr> <tr> <td>Soil Texture (USDA)</td> <td></td> <td>loamy sand</td> </tr> <tr> <td>Water capacity</td> <td>g/100g soil</td> <td>34.6</td> </tr> </tbody> </table>	Parameter	Unit	Value (based on dry matter)	pH	-log(H)	6.3	org. carbon	%	1.25	CEC	meq/100g soil	14	Clay (0-0.002 mm)	%	14.2	Silt (0.002 - 0.05 mm)	%	28.3	Sand (0.05 - 2.0 mm)	%	57.5	Soil Texture (USDA)		loamy sand	Water capacity	g/100g soil	34.6
Parameter	Unit	Value (based on dry matter)																											
pH	-log(H)	6.3																											
org. carbon	%	1.25																											
CEC	meq/100g soil	14																											
Clay (0-0.002 mm)	%	14.2																											
Silt (0.002 - 0.05 mm)	%	28.3																											
Sand (0.05 - 2.0 mm)	%	57.5																											
Soil Texture (USDA)		loamy sand																											
Water capacity	g/100g soil	34.6																											
11	<b>Statistics</b>	No statistical methods were used in this study																											
12	<b>References (published)</b>	No references to literature were made in this summary																											
13	<b>Unpublished data</b>	Residue method REM 179.03																											

**Test system:** Soil residues of thiamethoxam and of the main metabolite CGA 322704 were analysed in two bareground field studies performed in Germany in 1997 (Riepsdorf). Thiamethoxam was applied in one dose to the bare soil (60 m<sup>2</sup> plots) as a WG 25 formulation at a rate of 200g as/ha. Soil samples were taken in intervals up to one year and were analysed in 5 cm soil segments to a depth of 10 cm and in 10 cm segments for the 10 - 30 cm soil profile for parent thiamethoxam and for the metabolite CGA 322704. Limit for determination for both compounds analysed was 0.002 mg/kg. Further details of the field plots are presented in Table 1.

**Table 1** Relevant soil characteristics and kinetic data for soil degradation of thiamethoxam

<b>Location</b>	Riepsdorf, Germany
pH	6.3
C org. [%]	1.16 - 1.25
Clay [%]	9.6 - 14.2
Silt [%]	28.3 - 32.5
Sand [%]	57.5 - 57.9
Soil Texture	loamy sand
Cation exchange capacity [meq/100 g dry soil]	14
MWC [g water /100g dry soil ]	34.6
Application date	30 May 1997
<b>Kinetics for thiamethoxam (first order)</b>	
DT <sub>50</sub> [days]	72
DT <sub>90</sub> [days]	238
Correlation coefficient r <sup>2</sup>	0.85

**Findings:** Results of the analysis of thiamethoxam and metabolite sampled during one year after a single application of 200 g/ha thiamethoxam to bare soil plots are summarised Table 2. The degradation rates for thiamethoxam were calculated by applying first order kinetics. For this purpose the residue values in the individual soil layers were added and normalised to a 5 cm soil layer. The resulting DT<sub>50</sub> and DT<sub>90</sub> value and the corresponding correlation coefficients are presented in Table 1. Parent thiamethoxam and the metabolite CGA 322704 were detected in the 10-20 cm soil layer with increasing time, but did not leach into the 20-30 cm layer.

**Table 2** Thiamethoxam Soil residue studies after application of 200 g/ha

Trial	Residues (mg/kg)					
	Riepsdorf, Germany					
	thiame thoxa m	thiame thoxa m	thiame thoxa m	CGA 322704	CGA 322704	CGA 322704
Day*	0 - 5 cm	5 - 10 cm	10 - 20 cm	0 - 5 cm	5 - 10 cm	10 - 20 cm
0	0.079 (0-10 cm)		<LOQ	<LOQ		<LOQ
3	0.163	0.008	<LOQ	0.014	<LOQ	<LOQ
6	0.164	<LOQ	<LOQ	0.019	<LOQ	<LOQ
13	0.119	<LOQ	<LOQ	0.021	<LOQ	<LOQ
28(31)	0.144	0.010	<LOQ	0.021	<LOQ	<LOQ
59(60)	0.061	0.007	0.002	0.005	<LOQ	<LOQ
90(87)	0.064	0.010	0.006	0.008	0.002	<LOQ
118(116)	0.038	0.006	0.002	0.006	0.003	<LOQ
361	0.014	0.010	0.004	0.009	0.008	0.002

LOQ (limit of quantification) = 0.002 mg/kg

\*\* Residues in 20-30 cm layer <0.002 mg/kg, in samples of all time intervals

<b>Evaluation by Competent Authorities</b>	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>	
<b>Date</b>	10/10/2004

**Materials and Methods**

[REDACTED]

**Results and discussion**

[REDACTED]

[REDACTED]

**Conclusion**

[REDACTED]

**Reliability**

[REDACTED]

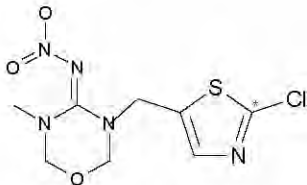
**Acceptability**

[REDACTED]

**Remarks**

98/8 section No.	Doc IIIA	7.2.2.4 / 01	Other soil degradation studies
91/414 Point addressed	Annex II	7.1.1.1.2 / 03	Supplementary soil degradation studies - soil photolysis

1. **Annex point(s)** IIA, 7.1.1.1.2 **Supplementary soil degradation studies, Soil Photolysis**
2. **Location in Dossier** Section 5,
3. **Authors (year)** Kay Sparrow (1997a)  
**Title** Photodegradation of (<sup>14</sup>C-thiazole)-CGA 293343 on Soil Under Artificial Light  
**Report No., Date** ABR-97011, July 7, 1997  
**Syngenta File N° (Desire)** 293343/374  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc Environmental Safety Department, Greensboro, NC 27419, USA
5. **Dates of work** Study Initiation: 31 October, 1996  
 Experimental Start: 5 November, 1996  
 Experimental Termination:  
 Study Completion: 7 July, 1997
6. **Test substance** ISO common name: thiamethoxam  
 Trade name: Not applicable  
 Batch: [REDACTED]  
<sup>14</sup>C-labelled test substance: Yes [ x ], <sup>14</sup>C-thiazole ring label  
 Specific activity of [.....] 1.5 MBq/mg  
 Radiochemical purity of the test substance: [REDACTED]  
 Structural formula:  
 (position of label)
 


- Formulation used for study: Yes [ ] No [ x ]
7. **Test method** The study was conducted in compliance with:  
 Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate:  
 540/9-82-021, Section 161-3, Photodegradation Studies on Soil. US Environmental Protection  
 Agency, October 18, 1982.
8. **Deviations** No deviations
9. **GLP** This study was performed in compliance with :  
 Environmental Protection Agency, Good Laboratory Practice Standards, 40 CFR Part 160.

**Test system:** The objectives of the soil photolysis study were to provide information on the photolytic degradation of thiamethoxam, when applied on a soil surface. Data were analysed for rate and pattern of decline of thiamethoxam and of formation and decline of photodegradation products and for the nature of the major photodegradation products.

Table: Soil characterisation for soil photolysis studies (Sparrow 1997a and b)

Origin of soil*:		Novartis CP Research Station, Sanger CA
Batch-No:		336-96-1
Classification (USDA):		Sandy loam
Particle size distribution:	% silt	27
	% sand	64
	% clay	9
Organic matter content:	(%)	0.9
pH:		6.5
Cation exchange capacity:	(meq/100g soil)	7.2
Moisture at 33 kPa (FMC)	%	10.8
Microbial biomass at start	(mg/100 g dry soil):	9.8

For this purpose, the thiazolyl labeled thiamethoxam was applied on viable, moist sandy loam soil (75% of FMC at pF 2.5). The soil was uniformly treated with a dose rate of 0.09 µg / g corresponding to a field use rate of 200 g / ha based on a soil depth of 15 cm and a bulk density of 1.5. The treated soil samples (7g aliquots in rectangular vials of 2x2x5 cm) were irradiated with a xenon arc light source for 12 hours per day at an average daily intensity of approximately 410 W/m<sup>2</sup>. UV glass filters were used to absorb wavelengths below 290 nm to simulate natural sunlight. Control samples were treated in the same way, except that they were kept in the dark during the testing period. In all experiments the temperature was kept at 25 ± 1.0°C.

Replicate samples were harvested at 0, 3, 7, 14, 21 and 30 days and extracted with acetonitrile and acetonitrile : 0.5 M HCl. Extracts were analyzed by TLC, by HPLC and mass spectroscopy.

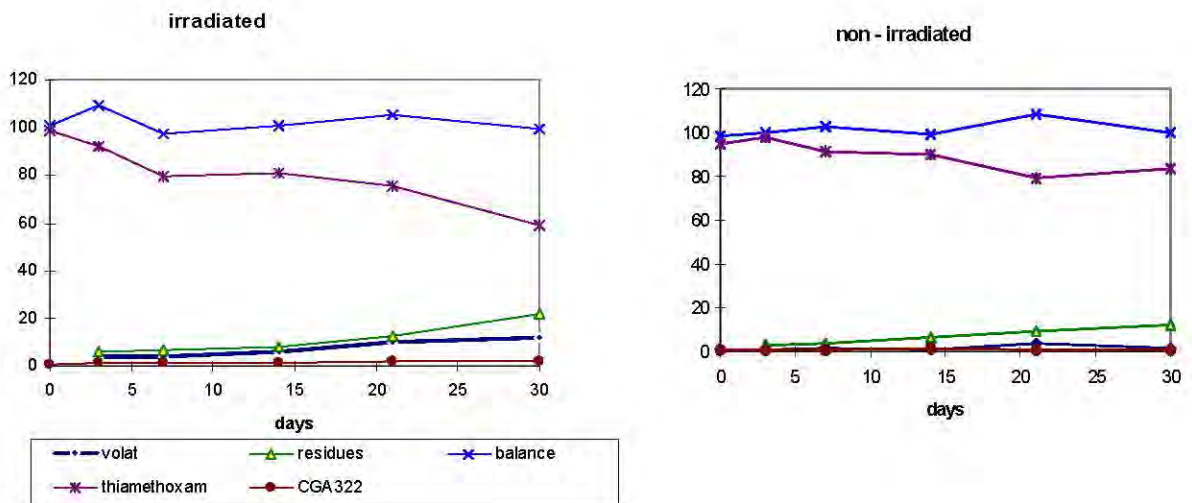
**Findings:** Degradation of <sup>14</sup>C-thiazolyl-thiamethoxam on soil indicated first-order kinetics with a half-life of 47 days for the irradiated incubations as opposed to 113 days for the non-irradiated incubations. Photolysis on soil appears to contribute to the degradation of thiamethoxam, however there was no major qualitative difference in the pattern of degradates observed in the irradiated and non-irradiated soil photolysis samples. Volatiles were present at an accumulative maximum average of 10.8% of total dose with carbon dioxide as the major component. Non extractable residues increased over time to an average of 12.7% and 9.2%, respectively for the irradiated and non-irradiated incubations on day 21. Photolytic degradation of <sup>14</sup>C- thiazolyl - thiamethoxam led to the formation of 14 degradates for the irradiated incubation as opposed to 13 degradates for the non-irradiated incubation. Thiamethoxam on soil appears to initially degrade to CGA 322704 (maximum of 2.1%) or to CGA 355190 (maximum of 0.9%) then to CGA 353968 (maximum of 0.5%) and to other multiple minor components (each <1%) and finally to carbon dioxide. Photolysis seems to increase the rate of degradation but does not appear to produce any significant new degradates.

**Table 1** Degradation pattern of  $^{14}\text{C}$ -thiazolyl-thiamethoxam on soil with and without irradiation

































Time after applic. [d]	Volatiles ( $\text{CO}_2$ )	CGA-293343 [%]	CGA-322704 [%]	CGA-355190 [%]	Non-extractables [%]	Balance [%]
<b>Irradiated</b>						
0	n.a.	98.51	0.68	n.d.	0.00	100.71
3	4.23	92.04	1.16	0.45	6.17	109.24
7	4.13	79.57	1.42	0.86	6.37	97.51
14	5.82	80.75	1.56	0.66	8.13	100.88
21	10.19	75.93	1.87	0.59	12.76	105.65
30	11.80	58.68	2.06	0.21	6.85	99.21
<b>Non-Irradiated</b>						
0	n.a.	95.19	0.70	n.d.	0.47	98.30
3	0.81	97.85	0.40	0.38	2.64	100.27
7	1.44	91.71	0.49	0.29	3.78	102.79
14	0.86	89.7	1.16	0.27	6.08	99.38
21	3.22	79.24	0.69	0.53	9.18	108.27
30	1.60	83.41	0.66	0.09	3.30	99.91

n.d.: not detected

**Figure 1:** Degradation pattern of  $^{14}\text{C}$ -thiazolyl-thiamethoxam on soil with and without irradiation





Evaluation by Competent Authorities		
7.2.2.4/01 Sparrow, ABR-97011		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	22/02/2005	
Materials and Methods		
		
		
		
		
		
		
		
		
		
		
		
		
		
		
		

**Results and discussion**

[Redacted]

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[Redacted]

[Redacted]

**Conclusion**

[Redacted]

**Reliability**

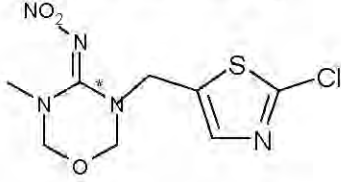
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**Acceptability**

[Redacted]

**Remarks**

98/8 section No.	Doc IIIA	7.2.2.4 / 02	Other soil degradation studies
91/414 Point addressed	Annex II	7.1.1.1.2 / 04	Supplementary soil degradation studies - soil photolysis

1. **Annex point(s)** IIA, 7.1.1.1.2 **Supplementary soil degradation studies, Soil Photolysis**
2. **Location in Dossier** Section 5,
3. **Authors (year)** Kay Sparrow (1997b)  
**Title** Photodegradation of (<sup>14</sup>C-Guanidine)-CGA 293343 on Soil Under Artificial Light
- Report No., Date** ABR-97012, July 7, 1997  
**Syngenta File N°(Desire)** 293343/376  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc Environmental Safety Department, Greensboro, NC 27419, USA
5. **Dates of work** Study Initiation: 29 August, 1996  
 Experimental Start: 17 September, 1996  
 Study Completion: 7 July, 1997
6. **Test substance** ISO common name: thiamethoxam  
 Trade name: Not applicable  
 Batch: [REDACTED]  
<sup>14</sup>C-labelled test substance: Yes [ x ], <sup>14</sup>C-oxadiazinyl ring label  
 Specific activity of [.....] 3.14 MBq/mg  
 Radiochemical purity of the test substance: [REDACTED]  
 Structural formula: **labeled in the oxadiazinring**  
 (position of label)
- 
- Formulation used for study: Yes [ ] No [ x ]
7. **Test method** The study was conducted in compliance with:  
 Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate:  
 540/9-82-021, Section 161-3, Photodegradation Studies on Soil. US Environmental  
 Protection Agency, October 18, 1982.
8. **Deviations** No deviations
9. **GLP** This study was performed in compliance with :  
**Environmental Protection Agency, Good Laboratory Practice Standards, 40 CFR  
 Part 160.**

**Test system:** This second soil photodegradation study was performed under identical conditions as the first study (7.2.2.4 / 01, Sparrow 1997a) but using guanidine-<sup>14</sup>C labelled thiamethoxam.

**Findings:** Degradation of <sup>14</sup>C-Guanidine-thiamethoxam on soil indicated first-order kinetics with a half-life of 54 days for the irradiated incubations as opposed to 124 days for the non-irradiated incubations. Photolysis on soil appears to contribute to the degradation of thiamethoxam (Table 1 and Figure 7.1.1.1.2-2), however there was no major qualitative difference in the degradates observed in the irradiated and non-irradiated soil photolysis samples. Volatiles accounted for up to an average of 4.7% of total dose with carbon dioxide as the major component. Non extractable residues increased over time to an average of 12.3% and 8.6%, respectively for the irradiated and non-irradiated incubations on day 21. Photolytic degradation of <sup>14</sup>C-Guanidine-thiamethoxam led to the formation of 14 degradates for the irradiated incubation as opposed to 10 degradates for the non-irradiated incubation. Four degradates, CGA 322704 (maximum of 2.4%), CGA 355190 (maximum of 2.2%), CGA 353968 (maximum of 1.1%) and CGA 282149 (maximum of 3.2%) were present in sufficient quantity to be identified. These metabolites were also observed under aerobic soil metabolism conditions.

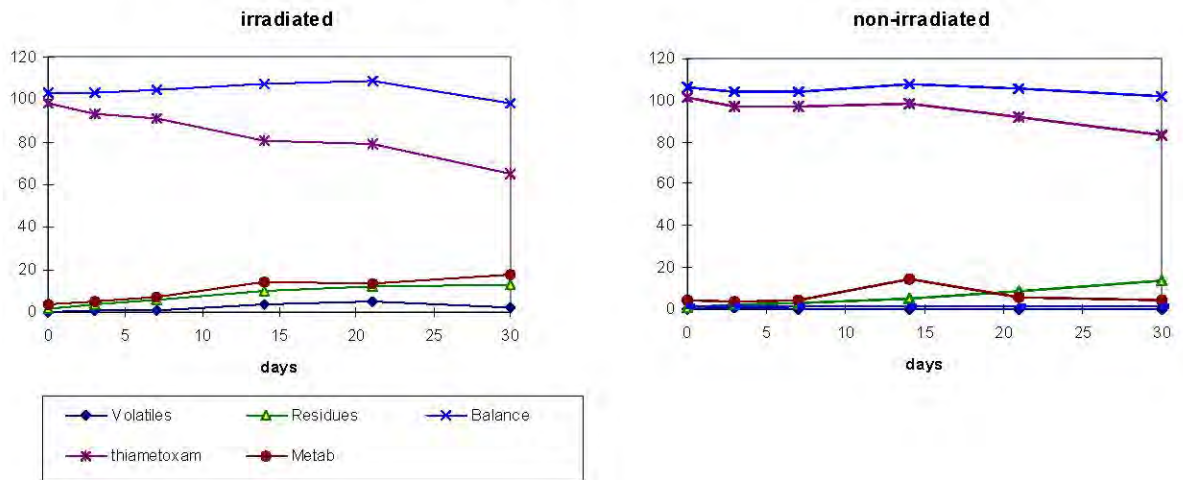
As in the first study, photolysis increases the rate of thiamethoxam degradation but does not appear to produce any significant new degradates. CGA 282149 was the only label specific degradate not observed in the study with <sup>14</sup>C-thiazolyl labelled material.

**Table 1: Degradation pattern of <sup>14</sup>C-guanidine-thiamethoxam on soil with and without irradiation (Sparrow 1997b)**

Time after applic. [d]	Volatiles (CO <sub>2</sub> )	CGA-293343 [%]	CGA-322704 [%]	CGA-355190 [%]	CGA-282149 [%]	Non-extractables [%]	Balance [%]
<b>Irradiated</b>							
0	n.p.	97.89	0.83	0.29	0	1.38	102.875
3	0.96	93.18	0.76	0.46	0	3.71	102.71
7	0.80	90.9	0.95	0.76	0	5.30	104.335
14	3.20	80.34	1.47	2.22	3.17	9.80	107.135
21	4.65	79.11	2.33	1.08	0.38	12.33	108.405
30	2.46	65.02	2.44	1.25	0.75	0.73	97.87
<b>Non-Irradiated</b>							
0	n.p.	101.51	1.12	0.4	0	0.655	106.435
3	0.72	97.33	0.95	0.17	0	2.255	104.195
7	0.245	96.86	0.77	0.38	0	3.05	104.48
14	0.275	98.28	0.98	0.37	0	5.38	107.655
21	0.01	91.99	1.02	0.31	0.07	8.58	105.68
30	0.115	83.38	1.02	0.28	0	1.02	102.04

n.d.: not detected; n.p. – not performed

Figure 1: Degradation pattern of <sup>14</sup>C-guanidine -thiamethoxam on soil with and without irradiation (Sparrow 1997b)



<b>Evaluation by Competent Authorities</b>	
	7.2.2.4/02 Sparrow, ABR-97012
	<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>
<b>Date</b>	22/02/2005
<b>Materials and Methods</b>	[REDACTED]
<b>Results and discussion</b>	[REDACTED]
<b>Conclusion</b>	[REDACTED]
<b>Reliability</b>	[REDACTED]
<b>Acceptability</b>	[REDACTED]
<b>Remarks</b>	

98/8 section No.	Doc IIIA	7.2.3.1 01	/	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Point addressed	Annex II	7.1.2 / 01		Adsorption and desorption

1. **Annex point(s)** II A, 7.1.2 **Adsorption and Desorption**
2. **Location in Dossier** Section 5
3. **Authors (year)** M.Concha (1998a)  
**Title** Soil adsorption / desorption of <sup>14</sup>C-guanidine-CGA 293343 by the batch equilibrium method  
**Report No., Date** Final report No. 612W, 02.11.1998  
**Syngenta File N°(Desire)** Syngenta File N° 293343-835  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** PTRL West, Inc., Richmond CA 94806, United States
5. **Dates of work** Study Initiation: December 23, 1996  
Experiment Completion: October 23, 1998  
Study Completion: November 2, 1998
6. **Test substance** ISO common name: thiamethoxam.  
Company Code: (<sup>14</sup>C-guanidine) CGA 293343, [REDACTED]  
specific radioactivity: 2.19 MBq/mg  
radiochemical purity: [REDACTED]
7. **Test method** The study was conducted in compliance with:  
Environmental Fate Data Requirement, 40 CFR 158, Subdivision N, Series 163-1, Leaching and Adsorption/Desorption Studies  
and with:  
Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada, section 6.2, B, 1 "Mobility, Adsorption/Desorption Measurements"
8. **Deviations** none
9. **GLP** Yes, EPA Good Laboratory Practice Standards (40 CFR Part 160)  
Exception:  
Clay mineralogy conducted at North Dakota University was not carried out according to GLP.

**Test system:** A second study to measure adsorption and desorption of thiamethoxam using a batch equilibrium was performed in USA. Aqueous test solutions of guanidine-<sup>14</sup>C labeled thiamethoxam in 0.01M calcium chloride were used at four concentrations ranging from 0.11 to 4.71 mg/liter. The study was conducted at 25°C by shaking 7.0 g soil and 12 mL test solution for 19 hours. After centrifugation and decanting the supernatants, desorption was done as above with fresh calcium chloride solution. The characteristics of the six soils used is shown in Table 1.



Table 1: Parameters of soils used for adsorption/desorption (Concha 1998a)

Name	Soil					
	Rignold	Honeywood	Hanford	Lakeland	Niagara	Niagara
Origin	Carman, Manitoba	Plattsville, Ontario	Sanger, California	Andersonville Georgia	Livingston New York	Livingston New York
Batch No.	629W-2	629W-4	627W-13	627W-14	627W-17	627W-19
Classification	Sandy clay loam	Loam	Sandy loam	Sand	Loam	Silty clay loam
Particle size:	23.0	19.0	10.0	3.0	24.0	38.0
clay (%)	13	35	31	4.0	46.0	43.0
silt (%)	64	46	59	93	30.0	19.0
sand (%)						
PH	6.2	6.2	7.6	5.4	7.2	6.5
WHC (%) at 33 kPa	26.9	25.6	9.9	2.7	28.0	30.7
Organic carbon (%)	3.0	1.7	0.4	0.5	1.7	2.4
CEC (meq/ 100g soil)	18.2	10.0	8.9	3.7	10.5	16.8

**Findings:** Overall recoveries comprising adsorption and desorption steps ranged from  $99.5 \pm 1.4\%$  to  $100.9 \pm 1.0\%$  for the four concentrations used. The stability of CGA 293334 during the process was confirmed by HPLC. The  $1/n$  values obtained indicate that a nonlinear relationship exists between concentrations in solution and adsorption. The Freundlich adsorption coefficient  $K_F$  varied between 0.22 mL/g for the sand and 2.32 mL/g for the sandy clay loam. The adsorption constants corrected for the organic carbon content ( $K_{OC}$ ) ranged from 33 to 177 mL/g with an average  $K_{OC}$  value of 70 mL/g. The desorption  $K_{OC}$  values were higher than the adsorption  $K_{OC}$  values with an average of 226 mL/g. This indicates that adsorption was not fully reversible. The data are presented in Table 2.

Table 2: Adsorption and desorption constants of thiamethoxam in US soils (Concha 1998a)

Soil texture	Adsorption (mL/g)			1 <sup>st</sup> Desorption (mL/g)		
	$K_F$	$K_{OC}$	N	$K_F$	$K_{OC}$	N
Carman Sandy clay loam	2.32	77.2	0.8334	3.64	121.3	0.8258
Plattsville Loam	0.9	53.1	0.8163	2.56	150.6	0.8724
Sanger Sandy loam	0.71	176.7	0.8389	2.79	697.5	0.9565
Andersonville Sand	0.22	43.0	0.8613	0.90	180.0	0.9279
Niagara Loam	0.65	38.3	0.7956	2.28	134.1	0.8469
Niagara Silty clay loam	0.79	33.1	0.8788	1.73	72.1	0.8666
<b>Average</b>	<b>0.93</b>	<b>70.2</b>	<b>0.8374</b>	<b>2.32</b>	<b>225.9</b>	<b>0.8827</b>



Conclusion

[REDACTED]

[REDACTED]

Reliability

[REDACTED]

Acceptability

[REDACTED]

Remarks

98/8 section No.	Doc IIIA	7.2.3.1 / 02	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Point addressed	Annex II	7.1.2 / 04	Adsorption and desorption

1. **Annex point(s)** II A, 7.1.2 **Adsorption and Desorption**
2. **Location in Dossier** Section 5
3. **Authors (year)** A. Keller (1996)  
**Title** Adsorption / Desorption of CGA 293343 in Various Soil Types  
**Report No., Date** 95AK03, June 12, 1996  
**Syngenta File N°(Desire)** 293343/78  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Ciba-Geigy Ltd  
Product Safety/Ecochemistry  
4002 Basel, Switzerland
5. **Dates of work** Study Initiation: September 1, 1995  
Study Completion: June 12, 1996
6. **Test substance** ISO common name: not yet available.  
Company code CGA 293343  
Company Code: <sup>14</sup>C-CGA 293343, Batch [REDACTED]  
specific radioactivity: 2.12 MBq/mg  
radiochemical purity: [REDACTED]
7. **Test method** The study was conducted in compliance with:  
OECD Guideline for Testing of Chemicals, 'Adsorption / Desorption', 106, adopted:  
12 May 1981
8. **Deviations** none
9. **GLP** This study was performed in compliance with Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, March 1986 [Verfahren und Grundsätze der Guten Laborpraxis (GLP) in der Schweiz, März 1986] issued by the Federal Department of the Interior and the Intercantonal Office for the Control of Medicaments, Switzerland. These procedures are based on OECD Principles of GLP adopted on 12 May 1981 by Decision of the OECD Council concerning Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30 (Final)].  
  
Exception:  
Soil characterization was performed by AgroLab AG, Ebikon / Root, Switzerland.

**Test system:** Adsorption and desorption of thiamethoxam were measured using a batch equilibrium procedure to determine the  $K_d$  and the  $K_{OC}$  values of thiazolyl-<sup>14</sup>C labelled thiamethoxam. From a pre-test the three soil types characterised in Table 1 were used. Analytical grade <sup>14</sup>C labelled thiamethoxam with a specific radioactivity of 2.12 MBq/mg and a radiochemical purity of > 95 % was prepared in aqueous 0.01 M CaCl<sub>2</sub> solution at 5 concentrations between 0.25 and 2.00 mg/litre. The solutions were added to soil and allowed to equilibrate in the dark while shaking in a controlled temperature incubator at 20°C for 24 hours. After equilibration the phases were separated by centrifugation and thiamethoxam concentrations determined by liquid scintillation counting (LSC) of the aqueous phases and by difference for the soil phases. The soil phases were next desorbed twice with 0.01 M CaCl<sub>2</sub> solution and concentrations determined by combustion of the soil and by LSC of the aqueous phases following centrifugation. All data were evaluated using the Freundlich equation and values for  $K_d$  (sorption constant),  $K_{OC}$  (sorption coefficient) and  $n$  were determined.

**Table 1: Parameters of soils used for adsorption/desorption (Keller 1996)**

	Soil
--	------

Name	Gartenacker	Vetroz	Illarsaz
Origin	CH/VS/Les Barges	CH/VS/Les Barges	CH/VS/Les Barges
Batch No.	10/93	3/75	4/75
Classification	Loam	Silt loam	Humic silt loam
Particle size: clay (%)	11.9	23.3	n.d.
silt (%)	48.0	58.5	n.d.
sand (%)	40.1	18.2	n.d.
pH	7.1	7.2	6.7
CaCO <sub>3</sub> (%)	7.4	56.0	6.1
Organic carbon (%)	2.0	4.7	19.8
CEC (meq/ 100g soil)	12.7	28.1	102.8

**Findings:** The Freundlich adsorption coefficient  $K_F$  varied between 0.66 mL/g for the loam and 6.94 mL/g for the humic soil. CGA 293334 is a compound with a low sorption capacity to most soils. The adsorption constants corrected for the organic carbon content ( $K_{OC}$ ) ranged from 32 to 35 mL/g with an average  $K_{OC}$  value of 33 mL/g. The data are presented in the Table below. The first desorption of CGA 293334 from the soils was nearly equal to adsorption as shown by the similar desorption coefficients (0.84 to 7.74 mL/g) calculated after the first desorption step. The values after the second step were higher thus demonstrating that adsorption was not fully reversible (Table 2).

**Table 2: Adsorption and desorption constants of thiamethoxam in various soil (Keller 1996)**

Soil texture	Adsorption (mL/g)			1 <sup>st</sup> Desorption (mL/g)			2 <sup>nd</sup> Desorption (mL/g)		
	$K_F$	$K_{OC}$	N	$K_F$	$K_{OC}$	N	$K_F$	$K_{OC}$	N
Gartenacker Loam	0.66	33	0.9126	0.84	42	0.9646	1.73	87	0.9819
Vetroz silt loam	1.53	32.5	0.9323	1.52	32	0.9596	1.76	38	0.9995
Illarsaz humic silt loam	6.94	35	0.9049	7.74	39	0.8915	9.48	48	0.9945

The <sup>14</sup>C material balance ranged between 98.4 and 99.5 % recovery for the three soils tested. Analysis of the extracts after the adsorption step showed that the radioactivity consisted entirely of parent compound.



Results and discussion

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[Redacted]

[Redacted]	[Redacted]			[Redacted]			[Redacted]		
	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
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[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Conclusion

[Redacted]

Reliability

[Redacted]

Acceptability

[Redacted]

Remarks

98/8 section No.	Doc IIIA	7.2.3.1 / 03	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Point addressed	Annex II	7.1.2 / 04	Adsorption and desorption

1. **Annex point(s)** II A, 7.1.2 **Adsorption and Desorption**
2. **Location in Dossier** Section 5
3. **Authors (year)** J. Peters (2000)  
**Title** Time Dependent Sorption of Technical and of 2SC Formulated (Thiazolyly-2-<sup>14</sup>C)-Labelled CGA 293343 in Two Different Soils  
**Report No., Date** 1200-99, March 28, 2000  
**Syngenta File N°(Desire)** 293343/1214  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc  
Environmental Safety Department  
Greensboro, NC 27419, USA
5. **Dates of work** Study Initiation: December 15, 1999  
Experimental Start: January 12, 2000  
Experimental termination: March 13, 2000  
Study Completion: March 28, 2000
6. **Test substance** ISO common name: thiamethoxam.  
Company Code: (2-<sup>14</sup>C-thiazolyly) CGA 293343,  
Batch [REDACTED] 34, specific radioactivity: 1.74 MBq/mg, radiochemical purity: [REDACTED]  
Batch [REDACTED], specific radioactivity: 1.05 MBq/mg, radiochemical purity: [REDACTED]
7. **Test method** The study was conducted in compliance with:  
Environmental Fate Data Requirement, 40 CFR 158, Subdivision N, Series 163-1,  
Leaching and Adsorption/Desorption Studies.
8. **Deviations** Supplemental study.
9. **GLP** Yes, EPA Good Laboratory Practice Standards (40 CFR Part 160)  
Exception:  
The soil collection procedure for the Florida muck was not conducted to fulfil GLP requirements.  
Agvise Laboratories sent soil samples to North Dakota State University for x-ray diffraction analysis for soil type determinations. The university is not a GLP facility.

**Test system:** This aged soil desorption study with thiazolyly-<sup>14</sup>C labeled thiamethoxam was designed to determine the effect of time on desorption. The study was conducted in two soil types, a muck and a sand. Soil characteristics are presented in Table 1.



**Table 1 Parameters of soils used for aged soil desorption study (Peters 2000)**

Name	Florida Muck	Florida Sand
Origin	Belle Glade, Florida	Oviedo, Florida
Batch No.	99-4098	99-4103
Classification	Organic Muck	Sand
Particle size: clay (%)	0	97
silt (%)	21	2
sand (%)	79	1
PH	7.8	8.1
Moisture (%) at 33 kPa	48	1.6
Organic carbon (%)	28.2	0.3
CEC (meq/ 100g soil)	57.4	2.9

For the time dependent sorption (aged  $K_d$ ) soil portions of 50 g were dosed with  $^{14}\text{C}$ -thiamethoxam at a rate of 0.582 mg/kg and in a second set of trials with 0.590 mg/kg of a 2SC formulation (soluble concentrate with 2 lb ai/gallon, equivalent to about 24 % w/v) of  $^{14}\text{C}$ -thiamethoxam. Incubation was up to 30 days at 75% of 33 kPa FMC and 25° C. Volatiles were collected during incubation. Duplicate samples were harvested after 0, 2, 7, 14, 21 and 30 days. Desorption was determined by suspending the soils in 75 mL 0.01M calcium chloride for 24 hours. The soils were subsequently extracted with 3:1 acetonitrile : 0.5N hydrochloric acid. The desorption solutions and the soil extracts were assayed and characterised by two dimensional TLC and HPLC. Total thiamethoxam remaining after incubation was determined and used for calculation of the desorption equilibrium constant.

A batch equilibrium adsorption / desorption study for thiamethoxam was conducted with the same two soils in a 0.01M calcium chloride solution at a concentration of 0.624 mg/l. For the Florida muck 1.75 g soil was equilibrated with 35 mL of the fortified calcium chloride solution. For the sand a soil:solution ratio of 1:1 was used.

**Findings:** Adsorption/desorption by the batch equilibrium method: Overall recoveries comprising adsorption and desorption ranged from 98.0% to 98.5. The stability of CGA 293334 during the process was confirmed by TLC and HPLC. The Freundlich adsorption and desorption coefficients  $K_d$  and the constants corrected for the organic carbon content ( $K_{oc}$ ) are shown in Table 2.

**Table 2 Freundlich adsorption and desorption values in Florida muck and sand (Peters 2000)**

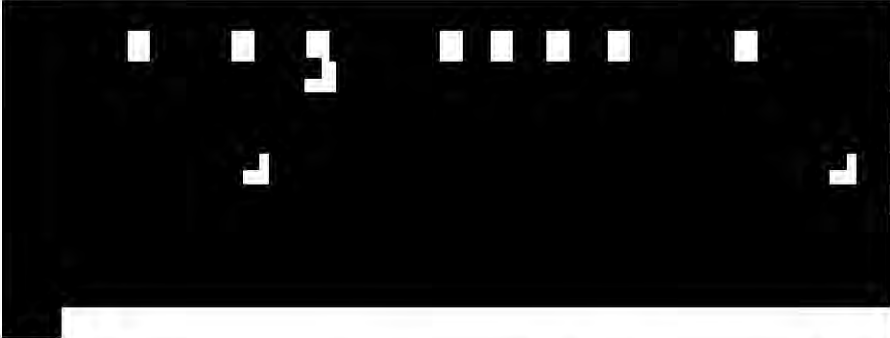





























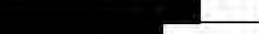








































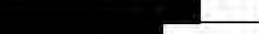







































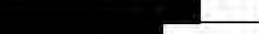










Soil	Adsorption		Desorption	
	$K_d$	$K_{oc}$	$K_d$	$K_{oc}$
Florida muck	16.49	58.4	29.85	105.7
Florida sand	0.13	37.4	0.74	213.5
Average	8.31	47.9	15.30	159.6

**Time dependent sorption:** For the trial dosed with active substance the material balance ranged from 93.4 to 102.4% throughout the study - i.e. incubation and desorption phase. The formation of volatiles accounted for a maximum of 0.19% during the 30 day incubation period. Unaltered thiamethoxam was the major component in the soil samples after 30 days. Minor degradation products observed were CGA 355190 and CGA 322704 besides other minor unknown products individually accounting for less than 3% of the applied dose. The  $K_d$  and  $K_{OC}$  values were calculated based on the amount of thiamethoxam desorbed by the 0.01M CaCl<sub>2</sub> relative to that of the soil residue. The  $K_d$  and  $K_{OC}$  values presented in Table 3 increased as a function of time. The increase was less significant for the muck and plateaued after 7 days of incubation. Similar results were observed for the samples dosed with 2SC formulated thiamethoxam. In this case the increase of the  $K_d$  values of the muck soil had reached a plateau after 2 days.

**Table 3 Maximum  $K_d$  and  $K_{OC}$  values for the time dependent sorption of thiamethoxam (Peters 2000)**

Soil	Time Interval	Material Applied	Desorption (Maximum Average)		$K_d$ Increased by Factor
			$K_d$	$K_{OC}$	
Muck	Day 0	Active substance	10.92	38.7	
Muck	Day 7	Active substance	16.73	59.2	1.5
Muck	Day 0	Formulated 2SC	14.82	52.5	
Muck	Day 2	Formulated 2SC	17.57	62.2	1.2
Sand	Day 0	Active substance	0.14	38.9	
Sand	Day 30	Active substance	0.43	122.6	3.2
Sand	Day 0	Formulated 2SC	0.14	41.3	
Sand	Day 30	Formulated 2SC	0.38	109.7	2.7

**In conclusion** the data generated in both soil types show that thiamethoxam does bind with aging. The  $K_d$  values increased by a factor of 1.2 to 3.2 over the course of 30 days incubation. The results indicate that soil adsorption is affected not only by the physical and chemical properties of the test substance and the soil but also by the residence time in soil. When evaluating the mobility of thiamethoxam the aging factor has to be considered.

Evaluation by Competent Authorities																																									
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Results and discussion

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Conclusion

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Reliability

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Acceptability

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Remarks

98/8 section No.	Doc IIIA	7.2.3.1 / 04	Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products
91/414 Point addressed	Annex II	7.1.2	Adsorption and desorption

1. **Annex point(s)** II A, 7.1.2 **Adsorption and Desorption**
2. **Location in Dossier** Section 5
3. **Authors (year)** Peters, J. (2001)  
**Title** Time Dependent Sorption of (Thiazolyl-2-<sup>14</sup>C)-Labelled CGA 293343 in Various Soils  
**Report No., Date Syngenta File N° Owner** Proj.No 200-00, May 08, 2001  
293343/1377  
Syngenta Crop Protection AG
4. **Testing facility** Novartis Crop Protection Inc  
Environmental Safety Department  
Greensboro, NC 27419, USA
5. **Dates of work** Experimental Start: October 30, 2000  
Experimental termination: March 1, 2001
6. **Test substance** Thiamethoxam.  
Company Code: (2-<sup>14</sup>C-thiazolyl) CGA 293343,  
Batch CL-XLVIII-34, specific radioactivity: 1.74 MBq/mg, radiochemical purity: 98.8 %
7. **Test method** The study was conducted in compliance with:  
  
Environmental Fate Data Requirement, 40 CFR 158, Subdivision N, Series 163-1,  
Leaching and Adsorption/Desorption Studies.
8. **Deviations** Supplemental study.
9. **GLP** Yes , EPA Good Laboratory Practice Standards (40 CFR Part 160)

**Test system:** This aged soil desorption study with thiazolyl-<sup>14</sup>C labeled thiamethoxam is a supplemental study designed to determine the effect of time on desorption. The study was conducted with five soil types from different locations. For characteristics of the soils used see Table 1. For the time dependent sorption (aged Kd) 50 g soil portions were dosed with active substance at a rate of 0.45 mg/kg. Incubation was up to 90 days at 75% of 33 kPa FMC and 25° C. Volatiles were collected during incubation. Duplicate samples were harvested after 0, 2, 7, 14, 21, 30, 45, and 90 days. Desorption was determined by suspending the soils in 75 mL 0.01M calcium chloride for 24 hours. The soils were subsequently extracted with 3:1 acetonitrile : 0.5N hydrochloric acid. The desorption solutions and the soil extracts were assayed and characterised by HPLC and two dimensional TLC. Total thiamethoxam remaining after incubation was determined and used for calculation of the desorption equilibrium constant.

A batch equilibrium adsorption / desorption study for thiamethoxam was conducted with the same five soils in a 0.01M calcium chloride solution at a concentration of 0.43 mg/l. 7 g soil were equilibrated with 12 mL of the fortified calcium chloride solution for each soil type, with the exception of the sand that required a soil:solution ratio of 1:1. After equilibration the supernatant was decanted and analysed by HPLC. Desorption was determined by resuspending the adsorbed test substance on the soil in 0.01 M calcium chloride solution. After centrifugation the supernatant was analysed by HPLC and the soil pellets were extracted.

**Table 1 Parameters of soils used for aged soil desorption study (Peters 2001)**

Name	Illinois Silt loam	California Loam	Mississippi Clay loam	Michigan Sandy loam	North Carolina Sand
Origin	Dewy, IL, USA	Coalinga, CA, USA	Winterville, MS, USA	Conklin, MI, USA	Wilson, NC, USA

Batch No.	00-2362	00-2379	00-2366	00-2374	00-2364
Classification	Silt loam	Loam	Clay loam	Sandy loam	Sand
Particle size: clay (%)	21	22	36	20	2
Particle size: silt (%)	54	36	40	28	6
Particle size: sand (%)	25	42	24	52	92
pH	6.2	7.8	7.1	7.6	6.2
Organic carbon (%)	2.09	0.52	0.87	1.10	0.35
CEC (meq/ 100g soil)	19.5	18.5	20.7	7.6	6.2

**Findings:** Adsorption/desorption by the batch equilibrium method: Overall recoveries comprising adsorption and desorption ranged from 94.8% to 98.0%. The stability of CGA 293334 during the process was confirmed by HPLC and TLC. The Freundlich adsorption and desorption coefficients  $K_d$  and the constants corrected for the organic carbon content ( $K_{OC}$ ) are shown in the Table 2.

Time dependent sorption: For the trial dosed with active substance the material balance ranged from 93.2 to 103.6% throughout the study - i.e. incubation and desorption phase. The formation of volatiles accounted for a maximum of 1.4% during the 90 day incubation period with the exception of the clay loam. For the clay loam a maximum average of 13.5% volatiles was found on day 45. Unaltered thiamethoxam was the major component in the soil samples after 90 days. Minor degradation products observed were CGA 355190, CGA 322704 and CGA 353968 besides other minor unknown products individually accounting for less than 3% of the applied dose. Only in the clay loam CGA 355190 represented a maximum average of 8.2% of the  $^{14}C$  dose on day 7 by HPLC. The  $K_d$  and  $K_{OC}$  values were calculated based on the amount of thiamethoxam desorbed by the 0.01M CaCl<sub>2</sub> relative to that of the soil residue. The  $K_d$  and  $K_{OC}$  values presented in Table 3 increased as a function of time. The  $K_d$  values over a period of 90 days increased by a factor of 3.1 (silt loam), 2.6 (loam), 2.6 (clay loam), 3.6 (sandy loam), and 7.6 (sand).

**Table 2: Freundlich adsorption and desorption values in five soils (Peters 2001)**

Soil	Adsorption		Desorption	
	$K_d$	$K_{OC}$	$K_d$	$K_{OC}$
Illinois Silt loam	1.60	76.8	3.71	177.5
California Loam	0.79	151.4	2.57	492.6
Mississippi Clay loam	1.27	145.6	3.55	408.2
Michigan Sandy loam	0.72	65.5	2.40	218.2
North Carolina sand	0.32	91.6	1.05	302.9
Average	0.94	106.2	2.66	319.9

**Table 3: Maximum  $K_d$  and  $K_{OC}$  values for the time dependent sorption of thiamethoxam (Peters 2001)**

Soil	Time Interval	Desorption (Maximum Average)		$K_d$ Increased by Factor
		$K_d$	$K_{OC}$	
Silt Loam	Day 0	1.09	52.4	3.1
Silt Loam	Day 90	3.39	162.5	
Loam	Day 0	0.56	108.0	2.6
Loam	Day 90	1.47	280.8	
Clay Loam	Day 0	0.93	107.3	2.6
Clay Loam	Day 90	2.39	274.8	
Sandy Loam	Day 0	0.57	51.5	3.6
Sandy Loam	Day 90	2.03	184.3	
Sand	Day 0	0.29	84.5	7.6
Sand	Day 90	2.22	638.4	

**In conclusion** the data generated in all soil types show that thiamethoxam does bind with aging. Depending on the soil, the  $K_d$  values increased by a factor of 2.6 - 7.6 over the course of the 90 day incubation period. The time dependent sorption trials with CGA 293343 have shown that

the residence time in the soil tends to significantly decrease the leaching potential of this compound.

<b>Evaluation by Competent Authorities</b>	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
<b>EVALUATION BY RAPPORTEUR MEMBER STATE</b>	
<b>Date</b>	23/02/05
<b>Materials and Methods</b>	[REDACTED]
<b>Results and discussion</b>	[REDACTED]
<b>Conclusion</b>	[REDACTED]
<b>Reliability</b>	[REDACTED]
<b>Acceptability</b>	[REDACTED]
<b>Remarks</b>	

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

1. **Annex point(s)** II A, 7.1.2 **Adsorption and Desorption**
2. **Location in Dossier** Section 5
3. **Authors (year)** Hein, W., Dorn, R. (2001a)  
**Title** Adsorption /Desorption of [Oxadiazin-4-<sup>14</sup>C]-CGA 293343 on Birkenheide Soil  
**Report No., Date** NOV18, 01 August, 2001  
**Syngenta File N°** 293343/1380  
**Owner** Syngenta Crop Protection AG
4. **Testing facility** Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau, 67435 Neustadt an der Weinstrasse, Germany
5. **Dates of work** Experimental Start: November 15, 2000  
Experimental termination: May 17, 2001
6. **Test substance** Thiamethoxam.  
Company Code: (oxadiazin-4-<sup>14</sup>C) CGA 293343,  
Batch: [REDACTED], specific radioactivity: 2.46 MBq/mg, radiochemical purity: [REDACTED]
7. **Test method** OECD Guideline for Testing of Chemicals, No 106 "Adsorption/Desorption", Jan. 21, 2000
8. **Deviations** Supplemental study.
9. **GLP** yes (Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau (SLFA), Breitenweg 71, D-67435 Neustadt/Weinst)

**Test system:** Adsorption and desorption of thiamethoxam were measured using a batch equilibrium procedure to determine the  $K_d$  and the  $K_{OC}$  values of oxadiazin-<sup>14</sup>C labelled thiamethoxam. The soil type used is characterised in Table 1. Analytical grade <sup>14</sup>C labelled thiamethoxam with a specific radioactivity of 2.46 MBq/mg and a radiochemical purity of 97.7 % was prepared in aqueous 0.01 M CaCl<sub>2</sub> solution at 5 concentrations between 0.01 and 5.00 mg/litre. The solutions were added to soil and allowed to equilibrate in the dark while shaking in a controlled temperature incubator at 20°C for 24 hours. After equilibration the phases were separated by centrifugation and thiamethoxam concentrations determined by liquid scintillation counting (LSC) of the aqueous phases and by difference for the soil phases. The soil phases were next desorbed twice with 0.01 M CaCl<sub>2</sub> solution and concentrations determined by combustion of the soil and by LSC of the aqueous phases following centrifugation. All data were evaluated using the Freundlich equation and values for  $K_d$  (sorption constant),  $K_{OC}$  (sorption coefficient) and  $n$  were determined.



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



		Soil
Name		Birkenheide
Origin		Rhineland Palatinate, Germany
Batch No.		10/2000
Classification		Weak loamy sand
Particle size:	clay (%)	6.0
	silt (%)	22.4
	sand (%)	71.6
pH (CaCl <sub>2</sub> )		6.0
pH (KCl)		6.3
CaCO <sub>3</sub> (%)		<0.1
Organic carbon (%)		0.90
CEC (meq/ 100g soil)		8

**Findings:** The Freundlich adsorption coefficient  $K_F$  was 0.30 mL/g. CGA 293334 is a compound with a low sorption capacity to most soils. The adsorption constants corrected for the organic carbon content ( $K_{OC}$ ) was 33 mL/g. The data are presented in Table 2. The first desorption of CGA 293334 from the soil was nearly equal to adsorption as shown by the similar desorption coefficient (0.37 mL/g) calculated after the first desorption step. The value after the second step was higher thus demonstrating that adsorption was not fully reversible.

The <sup>14</sup>C material balance ranged between 95.5 and 102.2 % recovery for the soil tested. Analysis of the extracts after the adsorption step showed that > 98% of the radioactivity consisted of parent compound.

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

Soil texture	Adsorption (mL/g)			1 <sup>st</sup> Desorption (mL/g)			2 <sup>nd</sup> Desorption (mL/g)		
	$K_F$	$K_{OC}$	N	$K_F$	$K_{OC}$	N	$K_F$	$K_{OC}$	N
Birkenheide Weak loamy sand	0.30	33	0.8929	0.37	41	0.8870	0.5040	56	0.9038

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	24/02/05
Materials and Methods	
Results and discussion	

	[REDACTED]
	[REDACTED]
<b>Conclusion</b>	[REDACTED]
<b>Reliability</b>	[REDACTED]
<b>Acceptability</b>	[REDACTED]
<b>Remarks</b>	[REDACTED]

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

1. **Annex point(s)** II A, 7.1.2 **Adsorption and Desorption**
2. **Location in Dossier** Section 5
3. **Authors (year)** Concha, M. (1998b):  
**Title** Adsorption /Desorption of (<sup>14</sup>C-thiazole) CGA 322704 by the Batch Equilibrium Method  
**Report No., Date Syngenta File N° Owner** Proj.No 419-96, November 30, 1998  
322704/0019  
Syngenta Crop Protection AG
4. **Testing facility** PTRL West Inc., Richmond, USA
5. **Dates of work** Experimental Start: September 1, 1998  
Experimental termination: November 3, 1998
6. **Test substance** CGA 322704 (metabolite of thiamethoxam)  
Company Code: (thiazol-4-<sup>14</sup>C) CGA 322704,  
Batch: [REDACTED], specific radioactivity: 1.99 MBq/mg, radiochemical purity: [REDACTED]
7. **Test method** Pesticide Assessment Guidelines, Subdivision N, Chemistry:  
Environmental Fate: 540/9-82-021, Series 163-1, Leaching and Adsorption/Desorption Studies. US Environmental Protection Agency, October 18, 1982.  
  
Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada, Section 6.2, B, 1 "Mobility, Adsorption/Desorption Measurements".
8. **Deviations** none
9. **GLP** yes

**Test system:** A study to measure adsorption and desorption of CGA 322704 using a batch equilibrium was performed in USA. Aqueous test solutions of thiazole-<sup>14</sup>C labeled CGA 322704 in 0.01M calcium chloride were used at four concentrations ranging from 0.08 to 5.36 µg/mL. The study was conducted at 25°C by shaking 7.0 g soil and 12 mL (17.5 mL for the Rignold sandy loam) test solution for 23 to 24 hours. After centrifugation and decanting the supernatants, desorption was done as above with fresh calcium chloride solution. The characteristics of the six soils used is shown in Table 1.

**Table 1 Parameters of soils used for adsorption/desorption (Concha 1998b)**

Name	Hanford	Niagara	Lakeland	Rignold	Honeywood	Niagara
Origin	Sanger, California	Livingston New York	Andersonville Georgia	Carman, Manitoba	Plattsville, Ontario	Livingston New York
Batch No.	635W-3	635W-5A	635W-6	635W-7A	635W-8A	635W-11
Classification	Sandy loam	Clay	Sand	Sandy loam	Loam	Silt loam
Particle size: sand (%)	60	18	90	62	40	29
Silt (%)	32	40	8	28	48	56
Clay (%)	8	42	2	10	12	15
PH	8.0	7.5	5.8	6.4	5.7	7.1
WHC (%) at 33 kPa	9.9	29.5	4.7	21.7	20.3	21.9
Organic matter (%)	0.7	3.5	1.0	6.6	3.0	2.7
CEC (meq/ 100g soil)	7.7	17.2	3.9	22.8	10.7	9.4