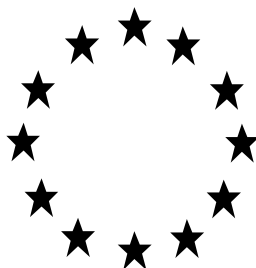


# Draft Assessment Report



## **DIFENOCONAZOLE**

### **Volume 3**

#### **Annex B.8**

#### **Environmental fate and behaviour**

Rapporteur Member State: Sweden

Draft May 2006

**Volume 1**

**Level 1: Statement of subject matter and purpose for which the monograph was prepared**

**Level 2: Reasoned statement of the overall conclusions drawn by the Rapporteur Member State**

Appendix 1: Standard terms and abbreviations

Appendix 2: Specific terms and abbreviations

Appendix 3: List of endpoints

**Level 3: Proposed decision with respect to the application for inclusion of the active substance in Annex I**

**Level 4: Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex 1**

**Volume 2**

**Annex A: List of the tests and studies submitted and of information available**

**Volume 3**

**Annex B: RMS summary, evaluation and assessment of the data and information**

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Annex B.2: Phys/chem.

Annex B.3: Data application and further information.

Annex B.4: Proposal for classification and labelling

Annex B.5: Analytical method

Annex B.6: Toxicology and metabolism

Annex B.7: Residues in crop

**Annex B.8: Fate and behaviour**

Annex B.9: Ecotoxicology

Appendix 1: Standard terms and abbreviations

Appendix 2: Specific terms and abbreviations

**Volume 4**

**Annex C: Confidential information and summary and assessment of information relating to the collective submission of dossiers**

**DIFENOCONAZOLE**  
Annex B.8: Environmental fate and behaviour

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## B.8 Environmental fate and behaviour

Difenoconazole is a broadspectrum systemic fungicide belonging to the triazole group of fungicides. The molecular structure of difenoconazole and positions of radiolabel used in different studies are shown on the next page.

The representative formulations are DIVIDEND 030 FS (code: A-9142 G), a flowable concentrate for seed treatment (content of difenoconazole 30 g/L), and SCORE 250 EC (code: A-7402 T), an emulsifiable concentrate intended for spray application (content of difenoconazole 250 g/L).

The representative use of DIVIDEND 030 FS is:

- cereal seed treatment application at 0.2 L product/100 kg seeds, equivalent to 6 g a.s./100 kg seeds. Depending on seeding rate the hectare dose is 5-12 g a.s./ha.

The representative uses of SCORE 250 EC are:

- 1-4 spray applications to pome fruit in Northern EU at growth stage BBCH 61. Application rate is 18.75-56.25 g a.s./ha, in 500-1500 L water/ha. Spray interval is 10-14 days.
- 1-4 spray applications to pome fruit in Southern EU at growth stage BBCH 61. Application rate is 37.5-75.0 g a.s./ha, in 500-1500 L water/ha. Spray interval is 10-14 days.
- 1-3 spray applications to carrot in N and S EU at growth stage BBCH 42/43. Application rate is 125 kg a.s./ha, in 100-500 L water/ha. Spray interval is 14 days.

Some studies were performed on an older formulation type of SCORE 250 EC (code: A-7402 G). The only compositional difference between these two variants, G and T, is the grade of solvent used (for A-7402 T a naphthalene depleted grade of the same aromatic hydrocarbon as in A-7402 G is used). This minor difference is not expected to have any significant effect on the results presented.

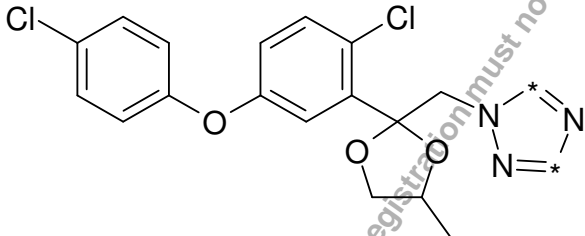
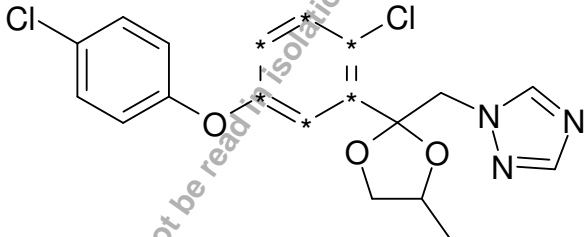
Some physical and chemical properties of difenoconazole, relevant for the fate and behaviour in the environment are:

Water solubility , 25°C	15 mg/L
pKa	Difenoconazole does not dissociate at environmentally relevant pH values.
Log Pow, 25°C	4.36
Vapour pressure, 25°C	$3.32 \times 10^{-8}$ Pa (extrapolated)
Henry's Law's Constant	$9.0 \times 10^{-7}$ Pa m <sup>3</sup> mol <sup>-1</sup> (calculated)

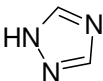
## DIFENOCONAZOLE

Annex B.8: Environmental fate and behaviour

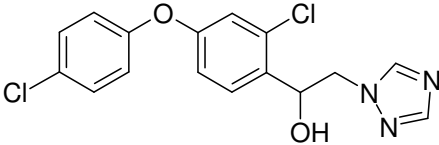
The chemical structure of difenoconazole (code: CGA 169374) is shown below. The metabolites that follow were identified in one or more studies on environmental fate of difenoconazole.

<b>CGA 169374</b>	<b>Chemical name:</b> 1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-4-methyl-[1,3]dioxolan-2-ylmethyl]-1H-[1,2,4]triazole (IUPAC) <b>Trivial name:</b> Difenoconazole (ISO)		
<b>Position of <math>^{14}\text{C}</math>-labelling:</b> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: left;"> <math>^{14}\text{C}</math>-triazole-radiolabel         </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 20px;"> <div style="text-align: left;"> <math>^{14}\text{C}</math>-chlorophenyl-radiolabel         </div> <div style="text-align: center;">  </div> </div>			
<b>Mol. formula:</b>	$\text{C}_{19}\text{H}_{17}\text{Cl}_2\text{N}_3\text{O}_3$	<b>Mol. weight:</b>	406.3
<b>Environmental compartments:</b>	Major residue in soil, aquatic environments and air.		

**DIFENOCONAZOLE**  
Annex B.8: Environmental fate and behaviour

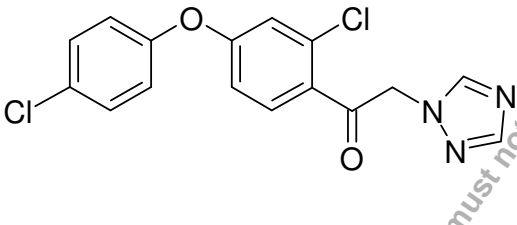
<b>CGA 71019</b>  Other codes: CA 469, R 45468, CGA 98020	<b>Chemical name:</b> 1H-1,2,4-triazole (IUPAC)  <b>Trivial name:</b> 1,2,4-Triazole  In some studies 4H-1,2,4-triazole was used as reference compound or test substance. As a reference or test substance this compound is considered to be equivalent to 1H-1,2,4-triazole since in solution, the position of the hydrogen atom and the double bonds are expected to alter and the precise structural configuration cannot be known.
	
<b>Mol. formula:</b> C <sub>2</sub> H <sub>3</sub> N <sub>3</sub>	<b>Mol. weight:</b> 69.1
<b>Environmental compartments*:</b>	<p><u>Soil:</u> Maximum amount formed in different soils/tests under aerobic conditions was 23.4% (day 271). During anaerobiosis found as max. 5.5% (day 1, possibly formed during aerobiosis).</p> <p>In soil samples treated with CGA 205375 (aerobic) formed as max. 32.4% (day 150). During anaerobiosis in sample treated with CGA 205375 found as max. 26.0%.</p> <p><u>Water/sediment:</u> In water/sediments treated with CGA 205375 formed as max. 14.1% (day 148).</p>

\* percentages are % of applied radioactivity

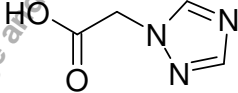
<b>CGA 205375</b>	<b>Chemical name:</b> 1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol (IUPAC)  <b>Trivial name:</b>
	
<b>Mol. formula:</b> -	<b>Mol. weight:</b> 350
<b>Environmental compartments:</b>	<p><u>Soil:</u> Maximum amount formed in different soils/tests under aerobic conditions was 9.7% (day 84). In soil photolysis study formed as max. 0.1%. During anaerobiosis found as max. 5.1% (day 1, possibly formed during aerobiosis).</p> <p>In field study max. amount was 10-12% of initial radioactivity (day 182).</p> <p><u>Water/sediment:</u> Max. amounts formed in different systems were 11.6% (day 90) in whole water/sediment systems at 20°.</p>

\* percentages are % of applied radioactivity, unless otherwise indicated

**DIFENOCONAZOLE**  
Annex B.8: Environmental fate and behaviour

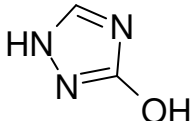
CGA 205374	<b>Chemical name:</b> 1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanone		
	<b>Trivial name:</b> -		
			
<b>Mol. formula:</b>	-	<b>Mol. weight:</b>	-
<b>Environmental compartments:</b>	<p><u>Soil:</u> In soil photolysis study formed as max. 0.2%.</p> <p>In soil samples treated with CGA 205375 (aerobic) formed as max. 2.7% (day 14). During anaerobiosis in sample treated with CGA 205375 found as max. 2.2%. In field study max. amount was 2.2% of initial radioactivity (day 28).</p> <p><u>Water/sediment:</u> Max. amount formed in water/sediment systems at 8°C was 7.5% (day 91). In water/sediments treated with CGA 205375 formed as max. 1.4% (day 62).</p>		

\* percentages are % of applied radioactivity unless otherwise indicated

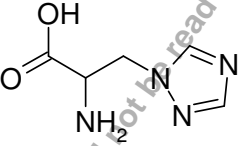
CGA 142856	<b>Chemical name:</b> 1,2,4-triazol-1-yl-acetic acid
	<b>Trivial name:</b> Triazole acetic acid
	
<b>Mol. formula:</b>	-
<b>Mol. weight:</b>	-
<b>Environmental compartments:</b>	<p><u>Soil:</u> In samples treated with CGA 71019 (aerobic) formed as max. 6.3% (days 7 and 14). Under anaerobic conditions in samples treated with CGA 71019 formed as max. 50.3% (day 126).</p> <p><u>Water/sediment:</u> -</p>

\* percentages are % of applied radioactivity

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<b>NOA 457654</b>	<b>Chemical name:</b>	1H-1,2,4-triazol-3-ol
	<b>Trivial name:</b>	Hydroxy triazole, Triazole-hydroxy, Triazolone
		
<b>Mol. formula:</b>	-	<b>Mol. weight:</b> -
<b>Environmental compartments:</b>	<u>Soil:</u> In samples treated with CGA 71019 (aerobic) formed as max. 2.2% (days 14 and 30).	
	<u>Water/sediment:</u> -	

\* percentages are % of applied radioactivity

<b>CGA 131013</b>	<b>Chemical name:</b>	2-amino-3- [1,2,4] triazol-1-yl-propionic acid
	<b>Trivial name:</b>	Triazole alanine
		
<b>Mol. formula:</b>	-	<b>Mol. weight:</b> -
<b>Environmental compartments:</b>	<u>Soil:</u> Under anaerobic conditions in samples treated with CGA 71019 formed as max. 3.4% (day 11).	
	<u>Water/sediment:</u> -	

\* percentages are % of applied radioactivity

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## 8.1 Route and rate of degradation in soil (Annex IIA 7.1.1; Annex IIIA 9.1.1)

### B.8.1.1 Aerobic degradation

<b>Reference:</b>	<b>Mamouni A (2000a)</b> Degradation and metabolism of CGA 169374 (14C-Triazole) in one soil incubated under aerobic conditions. RCC Ltd., Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. Report No. 738606. Syngenta File No. CGA169374/2101.
Test Material:	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99% (as determined by TLC before application: 100%), Batch No. ILS-244.1.
Guideline:	OECD Draft Guideline 1998: Aerobic and Anaerobic Transformation in Soil.
GLP:	Yes

#### Material and methods:

Test concentration:	0.188 mg a.s./kg soil (dw), corresponding to 141 g a.s./ha (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm <sup>3</sup> ).
Test system:	Route and rate of degradation was investigated in one freshly collected soil. Before use, soil was sieved through a 2 mm sieve and stored at 4°C in the dark. Prior to use, the soil was acclimated to room temperature for two weeks and moisture adjusted. Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO <sub>2</sub> and the systems were continuously ventilated with moistened air. The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. The flasks were incubated in the dark for 293 days.
Test conditions:	20±1°C, 40 % of MWHC.
Sampling time points:	Samples were taken for analysis after 0*, 3, 7*, 14, 28*, 56*, 84*, 100, 120*, 135, 190 and 293* days of incubation (* duplicate samples). Gas traps were exchanged every two weeks until day 42, thereafter approx. every three to four weeks.
Method of analysis:	Soil samples were extracted at room temperature by shaking three times with acetonitrile/water (4:1, v/v) and subsequently once with water. A Soxhlet extraction with acetonitrile/water (9:1, v/v) for at least four hours followed the cold extraction procedure from day 84 onwards. Extracts were combined and concentrated. The residual radioactivity in soil was determined by combustion and LSC. In addition, a soil sample from day 293 was submitted to organic matter fractionation (extraction in NaOH followed by separation of undissolved humin fraction, thereafter precipitation of extracted humic acids at pH 1 with fulvic acids remaining in the liquid phase). The identification and quantification of parent compound and metabolites was performed by HPLC and TLC. Reference compounds were: Difenoconazole, CGA 71019 (1H-1,2,4-triazole), CGA 131013, CGA 142856, CGA 205374 (=CGA 176459), CGA 205375 (=CGA 211391), CGA 107069.

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Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out on day 132 samples to confirm that radioactivity in NaOH trap consisted of  $^{14}\text{CO}_2$ .

Calculations: Degradation rate was calculated by non-linear regression applying first order reaction kinetics (MicroCal Origin software).

Soil Characteristics: See Table B.8.1.1-1

**Table B.8.1.1-1. Soil characteristics.**

Soil designation		Les Barges (Switzerland)
Soil type (USDA)		loam
Sand (>0.05 mm)	[%]	47.31
Silt (0.002-0.05 mm)	[%]	43.39
Clay (< 0.002 mm)	[%]	9.31
pH		7.18
Organic carbon	[%]	2.15
Cation exchange capacity	[meq/100 g]	12.84
Maximum water holding capacity (MWHC, pF 1.0)	[g/100 g]	64.6
40% MWHC	[g/100 g]	25.9
Field capacity (FC, pF 1.8)	[g/100 g]	46.6
Field capacity (FC, pF 2.5)	[g/100 g]	24.1
Biomass <sup>a</sup> - start of study	[mg C/100 g]	56.5
Biomass <sup>a</sup> - after 120 days	[mg C/100 g]	41.3
Biomass <sup>a</sup> - after 293 days	[mg C/100 g]	31.6

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. *Soil Biol. Biochem.*, 10: 215-221.

### Results:

The recovery, distribution and characterisation of radioactivity is summarised in Table B.8.1.1-2. Total recovery was  $93.7 \pm 3.8\%$  of the applied radioactivity.

Difenoconazole decreased from 94.5% of the applied radioactivity to 13.6% at study termination. Only one major metabolite was observed, CGA 71019, which reached a maximum of 21% of the applied radioactivity after 190 days incubation. The amount had declined to 18% at the end of the study (day 293). Only one other metabolite, CGA 205375, was identified in soil extracts at a maximum of 4.6% on day 56. Three unidentified metabolites (M2, M5 and M6) were separately quantified at a maximum of 2.1% of the applied radioactivity. Due to the small absolute amounts formed the structures of the metabolites were not determined.

Mineralisation from the  $^{14}\text{C}$ -triazole label was low, accounting for a maximum of 4.5% after 293 days of incubation. Organic volatiles are not included in the table because they always consisted of <0.1% of the applied radioactivity in individual traps. Unextracted radioactivity increased over the incubation up to 49% of the applied radioactivity. Most radioactivity was recovered by cold extraction while the Soxhlet extractions performed from day 84 onwards extracted max. 8.9% of the applied radioactivity.

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Organic matter fractionation of day 293 sample showed that about 25% of the applied radioactivity was incorporated into the less mobile humin and humic acid fraction (16 and 9.5% in each, respectively) and 24% were associated with the fulvic acid fraction.

**Table B.8.1.1-2. Recovery, distribution and characterisation of radioactivity in loam soil treated with <sup>14</sup>C-triazole labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	Difenoconazole	CGA 205375	M2	CGA 71019	M5	M6	Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
0	94.5	n.d.	n.d.	n.d.	n.d.	n.d.	3.8	n.d.	98.3
3	97.5	n.d.	n.d.	n.d.	n.d.	n.d.	3.4	n.d.	100.9
7	92.4	0.9	n.d.	n.d.	n.d.	n.d.	3.9	n.d.	96.6
14	88.5	0.7	n.d.	n.d.	n.d.	n.d.	4.4	n.d.	93.7
28	80.5	3.2	1.2	2.6	n.d.	n.d.	8.5	0.1	95.2
56	65.6	4.6	0.7	6.4	n.d.	n.d.	16.6	0.3	94.2
84	55.9	4.4	0.9	12.9	n.d.	n.d.	17.7	1.1	92.5
100	48.2	4.4	1.1	16.2	n.d.	n.d.	21.8	1.6	93.5
120	42.6	3.8	n.d.	16.9	n.d.	n.d.	27.1	1.7	91.9
135	37.6	3.4	n.d.	19.4	n.d.	n.d.	28.8	2.3	91.5
190	28.9	3.7	1.1	20.6	n.d.	n.d.	32.9	3.5	90.6
293	13.6	2.7	2.1	17.8	0.2	0.9	48.9	4.5	90.4

n.d. Not detected

DT<sub>50</sub> of difenoconazole was determined to 104 days, and DT<sub>90</sub> to 345 days ( $r^2$  0.999)<sup>1</sup>.

#### Comments by RMS:

The study is of acceptable quality. The above DT<sub>50</sub> and DT<sub>90</sub> will be used in the further assessment. The metabolite CGA 71019 is regarded as the only "major" metabolite (>10% of the applied radioactivity in this study). The metabolite CGA 205375 did not account for >5% of the applied radioactivity at any sampling interval and it was found at decreasing amount towards the end of the study.

Reference:	<b>Mamouni A (2000b)</b> Degradation and Metabolism of CGA 169374 [14C-Chlorophenyl] in one Soil incubated under Aerobic Conditions. RCC Ltd., Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. Report No. 738617. Syngenta File No. CGA169374/2102
Test Material:	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity 100%, Batch No. ILS-246.1A.
Guideline:	OECD Draft Guideline 1998: Aerobic and Anaerobic Transformation in Soil.
GLP:	Yes

#### Material and methods:

Test concentration: 0.190 mg a.s./kg soil (dw), corresponding to 143 g a.s./ha (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm<sup>3</sup>).

Test system: Route and rate of degradation was investigated in one freshly collected soil. Before use, soil was sieved through a 2 mm sieve and stored at 4°C in the dark. Prior to use, the soil was acclimated to room temperature for two weeks and moisture adjusted.

<sup>1</sup> "Model efficiency" rather than coefficient of determination since non-linear curve fitting was employed. RMS's comment.

**DIFENOCONAZOLE**

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	Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO <sub>2</sub> and the systems were continuously ventilated with moistened air. The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. The flasks were incubated in the dark for 293 days.
Test conditions:	20±1°C, 40 % of MWHC.
Sampling time points:	Samples were taken for analysis after 0*, 3, 7*, 14, 28*, 56*, 84*, 100, 120*, 190 and 293* days of incubation (* duplicate samples). Gas traps were exchanged every two weeks until day 57, thereafter every 15 to 68 days.
Method of analysis:	Soil samples were extracted at room temperature by shaking three times with acetonitrile/water (4:1, v/v) and subsequently once with water. A Soxhlet extraction with acetonitrile/water (9:1, v/v) for at least four hours followed the cold extraction procedure from day 84 onwards. Extracts were combined and concentrated. The residual radioactivity in soil was determined by combustion and LSC. In addition, a soil sample from day 293 was submitted to organic matter fractionation (extraction in NaOH followed by separation of undissolved humin fraction, thereafter precipitation of extracted humic acids at pH 1 with fulvic acids remaining in the liquid phase). The identification and quantification of parent compound and metabolites was performed by HPLC and TLC. Reference compounds were: Difenconazole, CGA 205374 (=CGA 176459), CGA 205375 (=CGA 211391), CGA 189138, and CGA 190978.  Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out on day 28, 132 and 293 samples to confirm that radioactivity in NaOH trap consisted of <sup>14</sup> CO <sub>2</sub> .
Calculations:	Degradation rate was calculated by non-linear regression applying first order reaction kinetics (MicroCal Origin software).
Soil Characteristics:	The same loam soil from Les Barges on Switzerland as used for the previous study, see Table B.8.1.1-1.

**Results:**

The recovery, distribution and characterisation of radioactivity is summarised in Table B.8.1.1-3. Total recovery was 96.5±7.9% of the applied radioactivity.

Difenconazole decreased from 100.7% of the applied radioactivity to 18.4% at study termination. Three minor metabolites were detected, M1, M2 and M4. M1 was characterised as CGA 205375, reaching at highest 5.1% of the radioactivity applied after 84 days of incubation and then declined. Due to the small absolute amounts formed, structures of M2 and M4 could not be determined.

Mineralisation from the chlorophenyl ring was significant with up to 23% of the applied radioactivity evolved as <sup>14</sup>CO<sub>2</sub> over 293 days of incubation. However, procedural losses during sample work-up in the later stages (see

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total recovery) mean this is an underestimate of the total evolved. Organic volatiles are not included in the table because they consisted of <0.1% of the applied radioactivity in individual traps, except on day 190 when 0.7% of the applied radioactivity was measured. Unextracted radioactivity increased over the incubation up to 38% of the applied radioactivity. Most radioactivity was recovered by cold extraction while the Soxhlet extractions performed from day 84 onwards extracted max. 5.7% of the applied radioactivity.

Organic matter fractionation of day 293 sample showed that about 26% of the applied radioactivity was incorporated into the less mobile humin and humic acid fraction (14 and 12% in each, respectively) and 13% were associated with the fulvic acid fraction.

**Table B.8.1.1-3. Recovery, distribution and characterisation of radioactivity in loam soil treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	Difenoconazole	CGA 205375	M2	M4	Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
0	100.7	n.d.	n.d.	n.d.	3.2	n.d.	103.9
3	100.2	n.d.	n.d.	n.d.	3.4	n.d.	103.6
7	98.3	0.3	0.4	n.d.	4.1	0.1	103.1
14	95.0	0.8	n.d.	n.d.	4.5	0.4	100.6
28	85.9	3.2	0.8	n.d.	8.5	1.7	100.1
56	72.2	4.5	0.4	n.d.	14.7	7.5	99.0
84	63.9	5.1	n.d.	n.d.	16.5	13.2	98.6
100	51.9	3.9	n.d.	1.0	22.8	18.1	97.7
120	49.9	4.1	n.d.	0.3	23.5	16.5	94.2
190	36.4	4.1	0.9	1.2	27.5	20.1	90.9
293	18.4	3.7	1.4	1.0	38.0	23.4	85.4

n.d. Not detected

DT<sub>50</sub> of difenoconazole was determined to 118 days, and DT<sub>90</sub> to 392 days (r<sup>2</sup> 0.998)<sup>2</sup>.

#### Comments by RMS:

The study is of acceptable quality. The above DT<sub>50</sub> and DT<sub>90</sub> will be used in the further assessment. No metabolite was identified as >10% of the applied radioactivity or as >5% at sequential measurements.

<b>Reference:</b>	<b>Gonzalez-Valero J (1992a)</b> Degradation of CGA 169374 in Soil under Aerobic Conditions at 20°C. CIBA-GEIGY Limited, Division Plant Protection, Basle, Switzerland. Report No. 4/92 (91-GJ-05). Syngenta File No. CGA169374/0606. Includes an Amendment No 1 to the Study report 4/92, dated June 1996, with re-evaluation of the data.
<b>Test Material:</b>	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity 93.7%, Batch No. CL-XVI-89.
<b>Guideline:</b>	BBA Guideline Part IV, 4-1, December 1986. Environmental Chemistry and Fate Guidelines for Registration of Pesticides in Canada; Section 6.2.C: Biotransformation; 1. Soil Degradation Pathways and Persistence, July 15, 1987. Danish Law of the Ministry of Environment, September 1, 1987. Dutch registration guideline, section G.1: Behaviour in soil; Question G.1.1: In-

<sup>2</sup> "Model efficiency" rather than coefficient of determination since non-linear curve fitting was employed. RMS's comment.

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formation about the nature of the metabolites and the rate at which these are formed.  
Ministry of Agriculture and Fisheries, Ministry of Public Health and environmental  
Hygiene, Ministry of Social Affairs, January 1987.

GLP: Yes

### Material and methods:

Test concentration: 0.1 mg a.s./kg soil (dw), corresponding to 75 g a.s./ha (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm<sup>3</sup>).

Test system: Rate of degradation was investigated in one soil. Before use, soil was stored in the greenhouse. The soil was air dried and sieved through a 2 mm sieve prior to use. The test substance (dissolved in acetone) was applied to a larger sample of soil, the soil mixed, and moisture adjusted. Thereafter sub-samples corresponding to 75 g soil (dw) were transferred to glass flasks connected to traps for <sup>14</sup>CO<sub>2</sub>. The samples were incubated for 106 days and the systems were continuously ventilated with moistened air.

Test conditions: 20±2°C, 40% MWHC

Sampling time points: Single samples were taken for analysis after 0, 14, 28, 49, 75 and 106 days of incubation. Gas traps were exchanged in about two weeks interval.

Method of analysis: Soil samples were extracted three times at room temperature by shaking with acetone and subsequently with acetone/water (4:1, v/v). A Soxhlet extraction with acetone for 8 hour followed the cold extraction procedure. Extracts were concentrated and combined. The residual radioactivity in soil was determined by combustion and LSC. The identification and quantification of parent compound and metabolites was performed by HPLC. Reference compounds were: Difenoconazole, CGA 205374, CGA 189138 and CGA 190978.

Calculations: Degradation rate was calculated by non-linear regression applying first order reaction kinetics (recalculated in Doc. M-II).

Soil Characteristics: See Table B.8.1.1-4.

**Table B.8.1.1-4. Soil characteristics.**

Soil designation		Neuhofen (SP 229) (Germany)
Soil type		sand
Sand	[%]	84.6
Silt	[%]	8.5
Clay	[%]	6.9
pH		5.0
Organic carbon	[%]	1.78
Cation exchange capacity	[meq/100 g]	11.5
Maximum water holding capacity (MWHC)	[g/100 g]	48.6
Field capacity (FC)	[g/100 g]	22.2
Biomass <sup>a</sup> - start of study	[mg C/100 g]	47.8
Biomass <sup>a</sup> - after 119 days	[mg C/100 g]	41.7

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. Soil Biol. Biochem., 10: 215-228.

## Results:

Recovery, distribution and characterisation of the radioactivity is presented in Table B.8.1.1-5. Total recovery ranged from 101 to 112% of the dose applied. In the stock solution and in the treated soil samples at least one impurity was detected. It could not be reliably quantified in the soil extracts and was not further characterised.

Difenoconazole decreased from 106% to 61% over the study. Two metabolites, M2 and M3, were determined reaching a maximum of 8.1 and 6.9% of the applied radioactivity. Due to the small absolute amounts formed, no structure could be determined. However, co-chromatography by HPLC showed that they were not any of the reference compounds used. CGA 205375 was not used as a marker in this study and may account for one of the unknown metabolites.

Mineralisation was low,  $^{14}\text{CO}_2$  accounted for a maximum of 4% after 106 days of incubation. Unextracted radioactivity increased over this time period up to 21% of the applied radioactivity.

**Table B.8.1.1-5. Recovery, distribution and characterisation of radioactivity in loam soil treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole. As % of applied radioactivity. Single replicates. Percentages for difenoconazole, M2 and M3 re-calculated by RMS based on raw data from HPLC analyses.**

Days after application	Difenoconazole <sup>a</sup>	M2 <sup>a</sup>	M3 <sup>a</sup>	Not analysed <sup>b</sup>	$^{14}\text{CO}_2$	Non-extractable	Total recovery
0	106.0	n.d.	n.d.	0.4	n.d.	0.6	111.9
14	87.6	7.1	n.d.	0.1	0.3	4.6	105.0
28	82.8	-- <sup>c</sup>	n.d.	0.1	0.6	7.3	106.3
49	72.2	6.2	6.9	1.3	1.7	11.6	103.7
75	62.1	-- <sup>c</sup>	-- <sup>c</sup>	0.1	2.5	14.9	100.7
106	61.2	8.1	6.6	0.2	3.7	20.6	103.6

n.d. Not detected

a All percentages of parent, M2 and M3 re-calculated by RMS based on peak responses corrected for background counts (see RMS's comments below).

b Radioactivity not further analysed.

c Metabolite detected but not quantifiable due to signal noise in HPLC.

The  $\text{DT}_{50}$  of difenoconazole was calculated to 138 days but this value is not considered reliable by the RMS (see below).

## Comments by RMS:

This study was of questionable quality but the results are considered acceptable for calculation of a degradation rate. In the original study report the peak responses in HPLC were not corrected for background counts (and the responses were sometimes very low in relation to the signal noise). In the amendment this was done and the limits of detection and quantification reconsidered, and it was concluded that for certain sampling points the two metabolites and the impurity were present at too low amounts to allow a reliable quantification. The RMS agrees to this. However the percentage radioactivity earlier attributed to these compounds were then allocated to the parent compound, and this is not considered as an appropriate approach. The RMS therefore re-calculated the percentages of parent and metabolites based on the peak responses corrected for background counts. After this evaluation it is concluded that the data obtained for difenoconazole can be used to calculate a degradation rate. The RMS used the ModelMaker ver. 4 program to calculate first order degradation rate.  $\text{DT}_{50}$  was 123 days and

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DT<sub>90</sub> 409 days ( $r^2$  0.913, model efficiency). The degradation rate is however uncertain since difenoconazole had only decreased to approx. 60% at study termination. The RMS agrees that one of the two identified metabolites (M2, M3) may have been CGA 205375. The other one is not further considered because of the uncertainty of the analytical part of the study and because more recent studies did not indicate presence of additional metabolites present as >5% at sequential measurements.

<b>Reference:</b>	<b>Gonzalez-Valero J (1992b)</b> Rate of Degradation of <sup>14</sup> C-CGA 169374 in Aerobic Soil at Various Conditions. CIBA-GEIGY Limited, Division Plant Protection, Basle, Switzerland. Report No. 12/92 (91GJ01 and 91GJ02). Syngenta File No. CGA169374/0713 Includes an Amendment No 1 to the Study report 12/92, dated September 1993, with confirmation of metabolite identity.
Test Material:	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 97.7%. Batch No. JAK-V-80. Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity 92.6%, Batch No. CL-XVI-89.
Guideline:	Danish Law of the Ministry of Environment, September 1, 1987. Dutch registration guideline, section G.1: Behaviour in soil; Question G.1.1: Information about the nature of the metabolites and the rate at which these are formed. 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 6.2.C: Biotransformation; 1. Soil Degradation Pathways and Persistence, July 15, 1987 US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 162-1. EPA, 540/9-82-021, October 1982.
GLP:	Yes

**Material and methods:**

Test concentration: 0.1 and 1.0 mg/kg soil (dw), corresponding to 75 and 750 g a.s./ha, respectively (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm<sup>3</sup>).

Test system: Rate of degradation was investigated in one soil but at various different conditions:

Label	Application rate	Incubation conditions
<sup>14</sup> C-triazole difenoconazole	1.0 mg/kg	60% FC; 20°C 60% FC; 30°C
<sup>14</sup> C-chlorophenyl difenoconazole	1.0 mg/kg	30% FC; 20°C 60% FC; 20°C 60% FC; 10°C
	0.1 mg/kg	60% FC; 20°C

Before use, soil was stored in biologically active in the greenhouse. The soil was air dried and sieved through a 2 mm sieve prior to use. The test substance (dissolved in acetone) was applied to larger samples of soil, the soil mixed, and moisture adjusted. Thereafter sub-samples corresponding to 75 g soil (dw) were transferred to glass flasks connected to traps for <sup>14</sup>CO<sub>2</sub>. The samples were incubated for 178-281 days and the systems were continuously ventilated with moistened air.

Test conditions: 10±2 °C, 20±2 °C and 30±2°C, 30 or 60% FC

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Sampling time points:	<p>Single samples were taken for analysis after the following days:</p> <p><sup>14</sup>C-triazole labelled samples: day 0, 19, 32, 60, 82, 91, 122, 150 and 178, and additionally after 273 days at incubation at 20°C.</p> <p><sup>14</sup>C-chlorophenyl labelled samples: day 0, 33, 60, 90, 118, 186, 238 and 281.</p> <p>Gas traps were exchanged in about two weeks interval during the first month and thereafter about monthly.</p>
Method of analysis:	<p>Soil samples were extracted at room temperature by shaking with acetone three times and subsequently with acetone/water (80:20, v/v) for 20 minutes. Both extracts were combined. A Soxhlet extraction with acetone for 8 hour followed the cold extraction procedure. The residual radioactivity was determined by combustion and LSC.</p> <p>The identification and quantification of parent compound and metabolites were performed by HPLC and TLC. Reference compounds were: Difenoconazole, CGA 205374, CGA 190169, CGA 189138, CGA 190978, CGA 207131. In an amendment the reference compound CGA 205375 was added.</p> <p>Soil samples of the <sup>14</sup>C-triazole ring labelled experiment (20°C, day 91; 30°C, day 122) and <sup>14</sup>C-chlorophenyl ring labelled experiment (20°C, day 118, 1 mg/kg and 0.1 mg/kg) were submitted to an additional extraction procedure, beginning with an extraction with methanol/water (9:1, v/v) at pH 5.5 by ultrasonic treatment and strong agitation, thereafter the procedure was repeated with dimethylformamid/oxalic acid (1:1, v/v). The harsh extraction procedure liberated only low amounts of radioactivity (0.1-2.5% of applied) and these residues were not further analysed.</p>
Calculations:	Degradation rates in the study report were calculated using one- or two-compartment models, first order kinetics. The values were recalculated in Doc. M-II using single first order equation, non-linear regression.
Soil Characteristics:	See Table B.8.1.1-6.

**Table B.8.1.1-6. Soil characteristics.**

Soil designation		Les Evouettes (Switzerland)
Soil type		silt loam
Sand	[%]	26.9
Silt	[%]	59.7
Clay	[%]	13.4
pH		7.2
Organic carbon	[%]	1.95
Cation exchange capacity	[meq/100 g]	13.7
Maximum water holding capacity (MWHC)	[g/100 g]	61.1
Field capacity (FC)	[g/100 g]	48.8
Biomass <sup>a</sup> - start of study day 0	[mg C/100 g]	80.5
Biomass <sup>a</sup> - day 90	[mg C/100 g]	53.2
Biomass <sup>a</sup> - day 199	[mg C/100 g]	50.1
Biomass <sup>a</sup> - day 280	[mg C/100 g]	46.2

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. *Soil Biol. Biochem.*, 10: 215-228.

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**Results:**

Recovery, distribution and characterisation of the radioactivity is summarised in Tables B.8.1.1-7 to B.8.1.1-12. Total recovery ranges from 87.5-125.9% of the applied radioactivity. The average recovery from all treatments was 101 %.

At the treatment rate equivalent to a normal field application (0.1 kg/ha) difenoconazole decreased from 111% of the applied radioactivity to 17.4% after 281 days. At ten times field rate under equivalent conditions degradation was much slower, with 51 and 61% difenoconazole remaining after 281 and 273 days. Incubation at lower temperature (10°C) or soil moisture (30% FC) predictably decreased the rate of degradation, whereas at higher temperature it was increased.

Several minor degradation products were detected. From a comparison with the original test substance it was concluded that V1, V2 and V3 were impurities in the original radiochemical preparation. Two other metabolites were separately quantified as M2 and M3 accounting for a maximum of 8.9 and 4.5% of the applied radioactivity after 33 and 238 days in the field rate treatment, respectively. The metabolite M2 was later identified (in the amendment to the report) as CGA 205375.

At normal field rate,  $^{14}\text{CO}_2$  from the  $^{14}\text{C}$ -chlorophenyl label accounted for a maximum of 33.4% the applied radioactivity after 281 days. As degradation of the parent at ten times field rate was slow, little  $^{14}\text{CO}_2$  was detected. Unextracted radioactivity increased to a maximum of 48% of the applied radioactivity after 238 days and decreased to 35% at 281 days in the field rate treatment. In the higher treatment rates unextracted radioactivity was correspondingly lower in line with the slower degradation of difenoconazole. This suggests that part of the unextracted radioactivity consisted of degradation products.

**Table B.8.1.1-7. Recovery, distribution and characterisation of radioactivity in silt loam treated with  $^{14}\text{C}$ -triazole labelled difenoconazole at 1 mg/kg and incubated at 60% FC and 20°C. As % of applied radioactivity. Single replicates.**

Days after application	Difenoconazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	$^{14}\text{CO}_2$	Non-extractable	Total recovery
0	93.7	n.d.	n.d.	1.7	2.2	n.d.	0.2	97.8
19	88.5	n.d.	n.d.	n.d.	2.1	<0.1	5.7	96.4
32	87.8	n.d.	n.d.	n.d.	2.7	<0.1	9.3	99.9
60	82.0	3.3	n.d.	3.4	n.d.	0.1	10.0	98.9
82	76.6	4.7	0.7	3.9	n.d.	0.2	13.3	99.4
91	81.6	4.9	n.d.	1.2	1.6	0.2	11.0	100.4
122	68.7	6.6	n.d.	3.5	n.d.	0.3	19.8	98.9
150	74.5	5.3	n.d.	5.5	n.d.	0.3	17.6	103.2
178	73.4	6.9	0.5	5.1	n.d.	0.5	18.9	105.3
273	60.6	7.3	0.3	2.9	n.d.	0.8	33.8	105.7

n.d. Not detected

a The impurities were mainly identified as V3.

b Extractable fractions containing <1% of the applied radioactivity were not analysed.

**Table B.8.1.1-8. Recovery, distribution and characterisation of radioactivity in silt loam treated with  $^{14}\text{C}$ -triazole labelled difenoconazole at 1 mg/kg and incubated at 60% FC and 30°C. As % of applied radioactivity. Single replicates.**

Days after application	Difenoconazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	$^{14}\text{CO}_2$	Non-extractable	Total recovery
0	90.2	n.d.	n.d.	1.5	2.3	n.d.	0.3	94.2

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Days after application	Difenoc-nazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
19	78.9	n.d.	n.d.	0.5	2.0	0.1	12.5	93.9
31	73.5	0.7	n.d.	0.9	1.7	0.1	19.7	96.6
60	65.7	4.0	n.d.	4.3	n.d.	0.3	20.7	95.0
82	61.7	5.2	n.d.	4.4	n.d.	0.4	23.4	95.1
91	61.7	6.0	n.d.	7.0	n.d.	0.6	25.2	100.4
122	55.8	3.9	n.d.	4.1	n.d.	0.7	23.4	87.9
150	46.4	7.0	0.3	5.6	n.d.	0.8	27.4	87.5
178	44.0	5.7	n.d.	6.3	n.d.	1.2	35.9	93.0

n.d. Not detected

a The impurities were mainly identified as V3.

b Extractable fractions containing <1% of the applied radioactivity were not analysed.

**Table B.8.1.1-9. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 1 mg/kg and incubated at 30% FC and 20°C. As % of applied radioactivity. Single replicates.**

Days after application	Difenoc-nazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	92.6	n.d.	n.d.	4.3	3.6	n.d.	0.1	100.6
33	92.7	n.d.	n.d.	n.d.	0.8	0.6	3.4	97.5
60	93.6	n.d.	n.d.	n.d.	<0.1	1.1	6.3	101.1
90	85.4	2.7	0.5	0.2	0.1	1.4	7.2	97.5
118	84.6	3.1	0.7	n.d.	0.1	1.8	8.2	98.4
186	86.1	3.0	0.4	n.d.	<0.1	2.3	9.1	101.0
238	72.7	5.0	2.8	0.2	<0.1	2.7	17.8	101.3
281	70.4	5.1	1.7	0.3	0.1	3.4	20.5	101.5

n.d. Not detected

a The only impurity identified was V1.

b Extractable fractions containing <1% of the applied radioactivity were not analysed.

**Table B.8.1.1-10. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 1 mg/kg and incubated at 60% FC and 20°C. As % of applied radioactivity. Single replicates.**

Days after application	Difenoc-nazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	95.3	n.d.	n.d.	5.1	3.2	n.d.	0.4	104.1
33	82.1	3.3	n.d.	n.d.	3.8	2.5	6.3	98.1
60	81.1	5.4	n.d.	n.d.	0.1	4.7	10.6	101.9
90	74.9	5.6	n.d.	n.d.	1.0	5.5	13.8	100.7
118	71.9	4.8	0.8	n.d.	0.3	8.4	13.9	100.0
186	65.5	6.9	0.5	0.1	0.1	12.3	15.8	101.0
238	58.0	4.1	n.d.	n.d.	0.1	14.0	22.1	98.3
281	50.9	4.0	0.4	2.1	0.1	16.5	27.7	101.7

n.d. Not detected

a The only impurity identified was V1.

b Extractable fractions containing <1% of the applied radioactivity were not analysed.

**Table B.8.1.1-11. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 1 mg/kg and incubated at 60% FC and 10°C. As % of applied radioactivity. Single replicates.**

Days after application	Difenoc-nazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	92.6	n.d.	n.d.	4.8	1.7	n.d.	0.4	99.4
33	95.6	2.2	n.d.	2.1	0.2	1.1	3.4	104.6
60	92.2	2.5	n.d.	1.9	0.2	1.9	6.7	105.4
90	86.6	4.8	0.4	n.d.	0.2	2.5	7.0	101.5
118	82.9	5.8	0.4	n.d.	0.2	3.7	8.9	101.8
186	76.6	3.9	0.3	2.2	n.d.	5.0	10.4	98.5
238	72.2	6.2	0.3	n.d.	0.1	5.2	20.5	104.5
281	70.5	5.2	0.3	1.2	0.1	5.8	15.2	98.1

n.d. Not detected

a The only impurity identified was V1.

b Extractable fractions containing <1% of the applied radioactivity were not analysed.

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**Table B.8.1.1-12. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 0.1 mg/kg and incubated at 60% FC and 20°C. As % of applied radioactivity. Single replicates.**

Days after application	Difenoconazole	CGA 205375	M3	V1-V3 <sup>a</sup>	Not Analysed <sup>b</sup>	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	111.0	n.d.	n.d.	6.1	3.2	n.d.	3.0	123.3
33	84.1	8.9	n.d.	2.3	0.5	7.5	22.6	125.9
60	52.8	4.7	4.4	2.7	0.5	15.0	29.7	109.9
90	47.2	7.2	2.4	n.d.	0.3	19.3	33.7	110.0
118	34.7	6.2	3.2	n.d.	0.2	23.9	36.2	108.3
186	27.3	3.3	3.1	0.2	0.1	28.8	41.3	104.1
238	24.3	4.4	4.5	1.5	<0.1	31.2	48.2	114.2
281	17.4	3.3	2.6	n.d.	2.7	33.4	35.4	94.8

n.d. Not detected

<sup>a</sup> The only impurity identified was V1.

<sup>b</sup> Extractable fractions containing <1% of the applied radioactivity were not analysed.

The first-order degradation rates of difenoconazole in each treatment are shown in Table B.8.1.1-13. Although the rates have been calculated also for the treatments at ten times field rate, these values should be regarded with caution as they are extrapolated well beyond the study timeframe.

**Table B.8.1.1-13. Degradation rates in Les Evouettes soil under various conditions (values from Doc. M-II).**

Position of radiolabel	Treatment: rate (mg/kg; moisture (%FC); temperature (°C)	DT <sub>50</sub> , days	DT <sub>90</sub> , days <sup>a</sup>	r <sup>2</sup> <sup>b</sup>
Triazole	1.0, 60, 20	456	>>273	0.892
	1.0, 60, 30	175	>>178	0.977
Chlorophenyl	1.0, 30, 20	709	>>281	0.855
	1.0, 60, 20	345	>>281	0.973
	1.0, 60, 10	602	>>281	0.952
	0.1, 60, 20	83	277	0.950

<sup>a</sup> DT<sub>90</sub> values inserted by RMS.

<sup>b</sup> r<sup>2</sup> represent model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

#### Comments by RMS:

The study is of acceptable quality. Treatment rate appears to have a large influence on the degradation rate. Therefore, only the DT<sub>50</sub> and DT<sub>90</sub> values from the experiment using the treatment rate of 0.1 mg/kg (corresponding to 100 g a.s./ha) will be used for calculation of mean values, since this rate is similar to the representative field rates. The metabolite CGA 205375 was found as max. 8.9% in the low treatment rate and as >5% at two sequential measurements. The absence of CGA 71019 (1,2,4-triazole) in samples treated with <sup>14</sup>C-triazole difenoconazole was a bit surprising but may be due to very slow formation because of the high treatment rate used (CGA 71019 was not used as reference substance however even if the amounts of the unknown M3 and the not analysed radioactivity are assumed to consist of CGA 71019 the amounts would still be low). The impurities V1-V3 are not further considered since there were no indications of impurities at the same levels in more recent studies.

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<b>Reference:</b>	<b>Völkel W (2000b)</b> Degradation of CGA 169374 [ <sup>14</sup> C-triazole] in one soil incubated under various conditions. RCC Ltd., Environmental Chemistry & Pharamanalytics Division, Itingen, Switzerland. Report No. 738628. Syngenta File No. CGA169374/2100.
<b>Test Material:</b>	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99% (as determined by HPLC before application: 100%), Batch No. ILS-244.1.
<b>Guideline:</b>	OECD Draft Guideline, October 1998: Aerobic and Anaerobic Transformation in soil. Requirement of Denmark for Pesticide registration (Statutory order from the Ministry of Environment No. 791, 1987). Dutch registration guideline; Section G. 1: Behaviour in soil, January 1987 BBA Guideline, Part IV, 4-1, December 1996
<b>GLP:</b>	Yes

**Material and methods:**

**Test concentration:** 0.171 and 0.0172 mg a.s./kg soil (dw), corresponding to 128 and 12.8 g a.s./ha (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm<sup>3</sup>).

**Test system:** Rate of degradation was investigated in one freshly collected soil, at different conditions:

<b>Treatment part</b>	<b>Appl. rate, g/ha</b>	<b>Moisture, %FC</b>	<b>Temperature, °C</b>
I Low humidity	128	30	20
II Low temperature	128	60	10
III Low dose	12.8	60	20
IV Sterile	128	60	20

Before use, soil was sieved through a 2 mm sieve and stored at 4°C in the dark. Prior to use, the soil was acclimated to room temperature for two weeks and moisture adjusted. For the sterile experiment, soil was autoclaved.

Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO<sub>2</sub> and the systems were continuously ventilated with moistened air.

The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. The flasks were incubated in the dark for 271 days. Soil moisture was adjusted every one to two weeks.

**Test conditions:** 20±2°C, 10±2°C, 30 and 60 % of FC.

**Sampling time points:** Single samples were taken for analysis after 0, 3 (part III only), 7, 21, 56, 90, 125, 177 and 271 days of incubation. Gas traps were exchanged at the respective sampling interval (except day 0) and approx. every two to seven weeks.

**Method of analysis:** Soil samples were extracted at room temperature by shaking with acetonitrile/water (8:2, v:v) up to four times, followed once with water. Beginning with sampling day 21 (III), 56 (I) and 177 (II and IV), samples were additionally Soxhlet extracted with acetonitrile/water (9:1, v:v) for at least four hours. The residual radioactivity was determined by combustion. Extracts were quantified by LSC and combined, concentrated and analysed again by LSC. All concentrates were then submitted to HPLC and TLC analysis. Reference compounds were: Difenoconazole, CGA 71019 (1H-1,2,4-triazole), CGA 131013, CGA 142856, CGA 205374 (=CGA 176459), CGA 205375 (=CGA 211391), CGA 107069.

WARNING: This document forms part of an EC evaluation data package and should not be used in isolation. Registration must not be granted on the basis of this document.

Soil samples from day 271 of parts I and III were also submitted to "harsh extraction" (reflux extractions with water/acetone and acetone/HCl (8:2 and 9:1, v/v) for about six hours) and organic matter fractionation (extraction in NaOH followed by separation of undissolved humin fraction, thereafter precipitation of extracted humic acids at pH 1 with fulvic acids remaining in the liquid phase).

Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out on day 177 and 271 samples to confirm that radioactivity in NaOH trap consisted of  $^{14}\text{CO}_2$ .

**Calculations:** Degradation rate was determined by non-linear regression applying first order reaction kinetics (MicroCal Origin software).

**Soil Characteristics:** The same loam soil from Les Barges in Switzerland as used for previous studies, see Table B.8.1.1-1. The moisture levels 30 and 60% FC used in this study equals 14.0 and 27.9 g water/100 g soil, respectively. The results of the microbial biomass determination (in mg C/100 g soil) for this study were:

Start of incubation: 51.0

After 140 (part I and II) and 114 (part III) days: 28.4 (I), 40.7 (II), 41.3 (III)

End of incubation: 27.2 (I), 46.9 (II), 31.6 (III).

## Results:

Recovery, distribution and characterisation of radioactivity is summarised in Tables B.8.1.1-14 to B.8.1.1-16. The mean total recoveries were  $97.3 \pm 4.8\%$  (part I),  $99.2 \pm 1.0\%$  (part II),  $97.4 \pm 3.3\%$  (part III) and  $99.2 \pm 2.3\%$  (part IV).

Difenoconazole decreased from 96.9% of the applied radioactivity to 4.6% by day 271 in the low dose treatment (0.0172 mg/kg). Low humidity (30% FC) only had a small effect on the degradation; difenoconazole decreased from 99.3% to 16.0% over the study. Low temperature (10°C) had a large influence on degradation; 55.6% of the applied radioactivity was still identified as difenoconazole at study termination.

Only one major metabolite was observed, CGA 71019, at a maximum of 23% of the applied radioactivity in the low dose application. Several other degradation products were detected, but only one could be identified as CGA 205375 (max 9% in the low temperature treatment). The remaining products, M2, M4, M6 and M7 individually never accounted for more than 2.6%, 8.6%, 1.9% and 0.9% of radioactivity applied. Due to the small absolute amounts formed, the structures could not be elucidated.

Mineralisation of the triazole ring was generally low with the maximum  $^{14}\text{CO}_2$  formed of 4.6% after 271 days in the low dose treatment. Organic volatiles are not included in the tables since they generally were detected only as  $>0.1\%$  of the applied radioactivity, and at a maximum of 0.4%. The amount of unextracted radioactivity corresponded to the level of difenoconazole breakdown, therefore the maximum of 54% of the applied radioactivity was observed in the low application rate treatment, at study termination. Soxhlet extraction liberated maximum 7.9% of the applied radioactivity.

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The "harsh extraction" carried out on day 271 samples (part I and III) released 9.0 and 16.2% of the applied radioactivity. The organic matter fractionation showed that about 19 and 21.5% of the applied radioactivity was incorporated into the less mobile humin and humic acid fraction (12.9-17.5% and 4.0-6.3% in each, respectively) and 15 and 16% were associated with the fulvic acid fraction.

**Table B.8.1.1-14. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-triazole labelled difenoconazole at 0.171 mg/kg and incubated at 30% FC and 20°C (treatment part I). As % of applied radioactivity. Single replicates.**

Days after application	Difenoc-nazole	CGA 205375	M2	CGA 71019	M4	M6	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	99.3	n.d.	n.d.	n.d.	n.d.	n.d.	n.p.	2.2	101.5
7	95.3	n.d.	n.d.	n.d.	n.d.	n.d.	<0.1	2.3	97.6
21	92.1	1.2	n.d.	n.d.	n.d.	n.d.	<0.1	4.8	98.1
56	82.3	3.4	n.d.	6.2	n.d.	n.d.	0.1	8.9	100.9
90	68.9	5.8	1.8	10.0	n.d.	n.d.	0.3	12.4	99.3
125	54.2	6.2	n.d.	15.0	n.d.	n.d.	1.0	21.5	97.8
177	44.0	6.1	1.2	18.1	n.d.	n.d.	1.3	27.0	97.6
271	16.0	4.0	1.2	15.9	1.7	1.9	2.2	42.8	86.1

n.d. Not detected

n.p. Not performed

**Table B.8.1.1-15. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-triazole labelled difenoconazole at 0.171 mg/kg and incubated at 60% FC and 10°C (treatment part II). As % of applied radioactivity. Single replicates.**

Days after application	Difenoc-nazole	CGA 205375	M2	CGA 71019	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	99.1	n.d.	n.d.	n.d.	n.p.	2.0	101.1
7	95.8	0.6	0.4	n.d.	<0.1	2.1	98.9
21	95.0	1.0	n.d.	n.d.	<0.1	3.1	99.1
56	84.7	3.5	2.0	1.7	<0.1	6.6	98.5
90	79.7	7.6	2.6	n.d.	<0.1	8.9	99.0
125	74.9	4.8	2.3	6.1	<0.1	11.0	99.1
177	70.9	6.7	1.5	5.2	0.1	13.1	97.5
271	55.6	8.9	2.6	8.6	3.2	20.9	99.9

n.d. Not detected

n.p. Not performed

**Table B.8.1.1-16. Recovery, distribution and characterisation of radioactivity in silt loam treated with <sup>14</sup>C-triazole labelled difenoconazole at 0.0172 mg/kg and incubated at 60% FC and 20°C (treatment part III). As % of applied radioactivity. Single replicates.**

Days after application	Difenoc-nazole	CGA 205375	M2	CGA 71019	M4	M7	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	96.9	n.d.	n.d.	n.d.	n.d.	n.d.	n.p.	3.8	100.7
3	99.0	n.d.	n.d.	n.d.	n.d.	n.d.	<0.1	3.2	102.2
7	87.9	n.d.	3.9	n.d.	n.d.	n.d.	0.2	5.0	97.0
21	70.6	6.5	n.d.	13.3	n.d.	n.d.	<0.1	8.4	98.8
56	45.3	7.4	n.d.	20.7	n.d.	n.d.	0.8	23.3	97.6
90	26.9	7.2	n.d.	19.8	1.8	n.d.	2.1	36.6	94.4
125	20.2	5.8	n.d.	19.2	5.1	0.9	3.9	38.9	93.9
177	15.9	4.2	n.d.	20.2	2.2	n.d.	3.9	46.1	92.5
271	4.6	1.9	2.2	23.4	8.6	n.d.	4.6	54.1	99.6

n.d. Not detected

n.p. Not performed

As determined by plate counts the sterile samples were maintained sterile at least until day 125. Difenoconazole decreased from 99.5% of the applied radioactivity day 0 to 92.2% day 125, and 84.8% by day 271. These results

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suggest that micro organisms mediate the initial breakdown of difenoconazole. Non-extractable radioactivity in sterile samples accounted for 3.6% of the applied radioactivity day 125 and 6.5% at study end.

The degradation rates are shown in Table B.8.1.1-17. The fastest degradation was observed in the low dose treatment (part III). The results can be considered together with those in Mamouni 2000a and Mamouni 2000b as they were carried out at a similar time and on the same soil. Lower soil moisture (30% FC) lead to a slightly lowered degradation (DT<sub>50</sub> 136 days) as compared to favourable moisture conditions (40% MWHC) under which DT<sub>50</sub> values of 104 and 118 days were established (Mamouni, 2000a and b).

**Table B.8.1.1-17. Degradation rates in Les Evouettes soil under various conditions.**

Treatment part	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> a
I Low humidity	136	452	0.986
II Low temperature	338	>1000	0.993
III Low dose	53	175	0.995
IV Sterile	>1000	>1000	0.982

a r<sup>2</sup> represent model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

#### Comments by RMS:

The study is of acceptable quality. The DT<sub>50</sub> and DT<sub>90</sub> values presented are used for the further assessment, however only the value obtained under standard conditions will be included in calculation of mean and median DT<sub>50</sub>. The metabolite CGA 71019 was found as max. 23.4% of the applied radioactivity. CGA 205375 was found as >5% at sequential measurements in all incubation variants and as max. 8.9% in samples incubated at 10°C.

<b>Reference:</b>	<b>Mamouni A (2002)</b> Degradation of CGA 169374 [ <sup>14</sup> C-Chlorophenyl] in three soils incubated under aerobic conditions. RCC Ltd., Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. Report No. 775438. Syngenta File No. CGA169374/2223.
Test Material:	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity 100%, Batch No. ILA-34-1.
Guideline:	OECD Draft Guideline 307, August 2000: Aerobic and Anaerobic Transformation in Soil.
GLP:	Yes

#### Material and methods:

Test concentration:	0.257 mg a.s./kg soil (dw), corresponding to 193 g a.s./ha. (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm <sup>3</sup> ).
Test system:	Rate of degradation was investigated in three freshly collected soils. Before use, soil was sieved through a 2 mm sieve and stored at 4°C in the dark. Prior to use, the soil was acclimated to room temperature for 10 days and moisture adjusted.  Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO <sub>2</sub> and the systems were continuously ventilated with moistened air. The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. The flasks were incubated in the dark for 228 days. Soil moisture was adjusted

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	weekly.
Test conditions:	20±2°C, 40% of MWHC.
Sampling time points:	Samples were taken for analysis after 0*, 14*, 28, 56, 84, 120*, 175 and 228 days of incubation (* duplicate samples). Gas traps were exchanged at the respective sampling interval (except day 0) and on days 27, 53, 81, 110, 173 and 197.
Method of analysis:	<p>Samples of the soils were extracted at room temperature up to four times with acetonitrile/water (4:1, v/v), followed by a Soxhlet extraction (except day 0 samples) with acetonitrile/water (9:1, v/v) for at least 4 hours. An additional extraction step using water only was performed on day 14 and 28 samples prior to Soxhlet extraction. Residual radioactivity was determined by combustion.</p> <p>All extracts were combined and concentrated before analysis by HPLC and TLC.</p> <p>Reference compounds were: Difenoconazole, CGA 205374 (=CGA 176459), CGA 205375 (=CGA 211391), CGA 189138, and CGA 190978.</p> <p>Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out on pooled aliquots of day 27-228 samples to confirm that radioactivity in NaOH trap consisted of <sup>14</sup>CO<sub>2</sub>.</p>
Calculations:	Degradation rate was determined by non-linear regression applying first order reaction kinetics (MicroCal Origin software).
Soil Characteristics:	See Table B.8.1.1-18.

**Table B.8.1.1-18. Soil characteristics.**

Soil designation		I Schanz (Switzerland)	II Pappelacker (Switzerland)	III Senozan (France)
Soil type (USDA)		sandy loam	sandy loam/ loamy sand	silty clay loam
Sand (>0.05 mm)	[%]	65.7	71.7	19.9
Silt (0.002-0.05 mm)	[%]	21.0	21.9	60.0
Clay (< 0.002 mm)	[%]	13.3	6.4	29.1
pH		7.4	7.5	6.7
Organic carbon	[%]	1.2	1.2	<0.30
Cation exchange capacity	[meq/100 g]	11.3	7.3	19.3
Maximum water holding capacity (MWHC, pF 1.0)	[g/100 g]	41.7	44.1	55.3
Field capacity (FC, pF 2.5)	[g/100 g]	28.1	34.3	30.1
Bulk density	[g/cm <sup>3</sup> ]	1.2	1.2	--
Biomass <sup>a</sup> - start of study	[mg C/100 g]	59.7	41.8	45.6
Biomass <sup>a</sup> - after 119 days	[mg C/100 g]	47.8	47.6	43.8
Biomass <sup>a</sup> - end of study (day 228)	[mg C/100 g]	30.4	24.4	30.5

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. *Soil Biol. Biochem.*, 10: 215-221.

## Results:

The recovery, distribution and characterisation of radioactivity in each soil is summarised in Tables B.8.1.1-19 to B.8.1.1-21. Total recovery of radioactivity from individual samples ranged from 93 to 102%. The total mean recovery was 97.5±2.4%, 98.2±1.6% and 98.7±2.0% for Schanz, Pappelacker and Senozan soil, respectively.

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Difenoconazole decreased from 98-99% of the applied radioactivity to 39% (Schanz soil), 51% (Pappelacker soil) and 45% (Senozan soil) at study termination. Only one metabolite was identified, CGA 205375 (M1), which reached a maximum of 9.7% (single sample) of the applied radioactivity after 84 days in Schanz soil then declined slightly. A similar pattern was observed in the other two soils. Four other metabolites, M2, M3, M4 and M5 were individually quantified but were not identified since they individually accounted for less than 2% of the applied radioactivity at all times in all three soils.

Approximately 20% of the applied radioactivity was evolved as  $^{14}\text{CO}_2$  over the incubation and unextracted radioactivity accounted for a maximum of 23% of the applied radioactivity by the end of the study. Volatile radioactivity not being  $^{14}\text{CO}_2$  did not exceed 0.5%.

**Table B.8.1.1-19. Recovery, distribution and characterisation of radioactivity in Schanz soil treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	Difenoconazole	CGA 205375	M2	M3	M4	M5	Non-extractable	$^{14}\text{CO}_2$	Total recovery
0	99.2	n.d.	n.d.	n.d.	n.d.	n.d.	0.9	n.p.	100.3
14	90.3	2.7	n.d.	n.d.	n.d.	n.d.	3.1	1.4	97.5
28	87.1	4.7	n.d.	n.d.	n.d.	n.d.	5.9	2.8	100.5
56	71.2	7.3	0.7	n.d.	n.d.	n.d.	10.6	6.6	96.4
84	63.2	9.7	1.4	n.d.	n.d.	n.d.	14.1	9.9	98.3
120	56.8	9.4	n.d.	1.6	n.d.	n.d.	17.4	11.3	96.4
175	46.3	9.0	n.d.	0.4	0.4	n.d.	22.2	17.5	95.9
228	38.7	9.0	1.5	0.9	n.d.	0.4	22.9	19.2	92.6

n.d. Not detected

n.p. Not performed.

**Table B.8.1.1-20. Recovery, distribution and characterisation of radioactivity in Pappelacker soil treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	Difenoconazole	CGA 205375	M2	M3	M4	M5	Non-extractable	$^{14}\text{CO}_2$	Total recovery
0	97.8	n.d.	n.d.	n.d.	n.d.	n.d.	1.2	n.p.	99.0
14	92.1	2.5	n.d.	n.d.	n.d.	n.d.	2.6	1.4	98.6
28	89.5	3.1	0.4	n.d.	n.d.	n.d.	4.7	2.4	100.1
56	73.3	5.8	n.d.	n.d.	n.d.	n.d.	11.2	6.1	96.4
84	70.4	5.7	0.6	n.d.	n.d.	n.d.	12.7	9.0	98.6
120	57.4	8.5	n.d.	n.d.	n.d.	n.d.	18.1	14.4	98.7
175	48.8	6.1	0.4	0.8	n.d.	n.d.	20.1	19.5	95.8
228	51.0	6.0	n.d.	n.d.	n.d.	n.d.	20.2	19.4	97.1

n.d. Not detected

n.p. Not performed.

**Table B.8.1.1-21. Recovery, distribution and characterisation of radioactivity in Senozan soil treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	Difenoconazole	CGA 205375	M2	M3	M4	M5	Non-extractable	$^{14}\text{CO}_2$	Total recovery
0	98.0	n.d.	n.d.	n.d.	n.d.	n.d.	0.9	n.p.	98.8
14	90.3	2.0	n.d.	n.d.	n.d.	n.d.	3.6	1.7	97.6
28	81.7	3.0	0.5	n.d.	n.d.	n.d.	7.6	4.2	97.0
56	76.9	3.0	n.d.	n.d.	n.d.	n.d.	13.1	8.4	101.5
84	71.9	2.7	0.5	n.d.	n.d.	n.d.	13.6	9.9	98.8
120	62.1	4.4	n.d.	n.d.	n.d.	n.d.	19.2	15.2	101.1
175	52.2	3.3	n.d.	n.d.	0.7	n.d.	22.2	19.3	98.0

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Days after application	Difenoconazole	CGA 205375	M2	M3	M4	M5	Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
228	44.7	2.7	n.d.	1.2	1.1	1.5	23.1	20.4	94.9

n.d. Not detected

n.p. Not performed.

The calculated degradation rates are presented in Table B.8.1.1-17. It was concluded that difenoconazole was degraded in all three soils with half-lives of 149, 186 and 187 days.

**Table B.8.1.1-17. Degradation rates in three soils.**

Soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> a
I Schanz	149	496	0.977
II Pappelacker	186	617	0.939
III Senozan	187	620	0.972

a r<sup>2</sup> represent model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

#### Comments by RMS:

The study is of acceptable quality. The DT<sub>50</sub> and DT<sub>90</sub> values will be used in the further assessment although the degradation rates are a bit uncertain since 39-51% of the applied difenoconazole still remained at study termination. The metabolite CGA 205375 was found as >5% at sequential measurements in two of the three soils tested.

The study report sometimes stated that the test item was <sup>14</sup>C-labelled in the "chlorophenoxy" ring, sometimes in the "chlorophenyl" ring. As pointed out by the notifier (response to comments, 19 August 2005) both "chlorophenyl rings" of the difenoconazole structure can also be called "chlorophenoxy rings", i.e. the terms are interchangeable in this case. The notifier also stated that the only positions of radiolabelling were those presented in the figures shown in the beginning of Section B.8. This explanation is accepted by the RMS and in any case the confusion of the study report does not compromise the results obtained concerning measured amounts of difenoconazole or any of the metabolites since all the reference compounds had both chlorophenyl ring structures intact.

#### B.8.1.2 Anaerobic degradation

<b>Reference:</b>	<b>Völkel W (2000a)</b> Degradation and metabolism of CGA 169374 [ <sup>14</sup> C-triazole] in one soil incubated under anaerobic conditions. RCC Ltd., Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. Report No. 738630. Syngenta File No. CGA169374/2099.
<b>Test Material:</b>	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99%, Batch No. ILS-244.1.
<b>Guideline:</b>	OECD Draft Guideline 1998: Aerobic and Anaerobic Transformation in Soil.
<b>GLP:</b>	Yes

#### Material and methods:

Test concentration: 0.171 mg a.s./kg soil (dw), corresponding to 128 g a.s./ha (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm<sup>3</sup>).

Test system:	<p>Route and rate of degradation was investigated under anaerobic conditions after 30 days of aerobic incubation in one freshly collected soil. Before use, soil was sieved through a 2 mm sieve and stored at 4°C in the dark. Prior to use, the soil was acclimated to room temperature for two weeks and moisture adjusted. Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO<sub>2</sub> and the systems were continuously ventilated with moistened air during aerobic incubation. The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. After 30 days of incubation in the dark the soil was waterlogged and the system flushed with nitrogen and incubated for a further 180 days. The system was ventilated with nitrogen regularly (4 times/day).</p> <p>Data for the aerobic portion of the study was taken from Völkel, 2000b, which was carried out at the same time.</p>
Test conditions:	20±2°C, 40 % of MWHC (moisture condition under 30 d aerobic incubation).
Sampling time points:	<p>Duplicate samples were taken for analysis after 1, 7, 29, 84, 110 and 180 days of anaerobic incubation. Gas traps were exchanged at each sampling interval.</p> <p>After flooding the soil, pH, oxygen concentration and redox potential in water and soil were measured at each sampling interval in the respective treated samples and in two untreated control samples.</p>
Method of analysis:	<p>The soil and water were separated. Soil samples were extracted at room temperature by shaking three times with acetonitrile/water (4:1, v/v), once with water and finally samples were Soxhlet extracted with acetonitrile/water (9:1, v/v) for at least four hours. Extracts were combined and concentrated. Water phases were lyophilised if necessary in order to concentrate samples. The residual radioactivity in soil was determined by combustion and LSC.</p> <p>The identification and quantification of parent compound and metabolites in water and soil was performed by HPLC and TLC. Reference compounds were: Difenoconazole, CGA 71019 (4H-1,2,4-triazole), CGA 131013, CGA 142856, CGA 205374 (=CGA 176459), CGA 205375 (=CGA 211391), and CGA 107069.</p> <p>Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out to confirm that radioactivity in NaOH trap consisted of <sup>14</sup>CO<sub>2</sub>.</p>
Calculations:	Degradation rate was not determined.
Soil Characteristics:	<p>The same loam soil from Les Barges on Switzerland as used for previous studies, see Table B.8.1.1-1. However, the results of the microbial biomass determination for this study were:</p> <p>At start of aerobic incubation: 48.7 mg C/100 g soil.</p> <p>At start of anaerobic incubation: 42.5 mg C/100 soil.</p> <p>At study end: 55.3 mg C/100 g soil.</p>

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**Results:**

The recovery, distribution and characterisation of radioactivity is summarised in Table B.8.1.2-1. Total recovery was 99.1±1.7% of the applied radioactivity throughout the study.

After flooding, virtually no radioactivity was transferred into the water phase; the total radioactivity in the water remained at a plateau value of approx. 1.5% of the applied radioactivity over the anaerobic incubation period. Amounts of extractable difenoconazole from the soil remained at similar levels of 80-87% until the end of the incubation. Small amounts (< 6% each) of three metabolites CGA 205375 (M1), unknown M2, and CGA 71019 (M3), principally formed during the aerobic incubation phase, were observed. However, the amounts remained relatively constant during the anaerobic phase.

Negligible <sup>14</sup>CO<sub>2</sub> was evolved and amounts of unextracted radioactivity remained at or below approx. 10% of the applied radioactivity. Organic volatiles never exceeded 0.1% of the radioactivity applied.

**Table B.8.1.2-1. Recovery, distribution and characterisation of radioactivity in loam soil treated with <sup>14</sup>C-triazole labelled difenoconazole and incubated under aerobic conditions for 30 days, thereafter under anaerobic (flooded) conditions. As % of applied radioactivity. Mean of duplicate samples.**

		Aerobic (days)		Anaerobic phase (days)					
		0	28	1	7	29	84	110	180
<b>Difenoconazole</b>	Water	n.a.	n.a.	n.d.	0.2	n.d.	0.2	n.d.	n.d.
	Soil	94.5	80.5	81.3	83.9	86.6	84.9	79.6	85.4
<b>CGA 205375</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Soil	n.d.	3.2	5.1	3.2	2.5	2.3	3.3	2.8
<b>M2</b>	Water	n.a.	n.a.	n.d.	0.1	n.d.	0.1	n.d.	n.d.
	Soil	n.d.	0.6	2.2	n.d.	n.d.	n.d.	0.5	0.4
<b>CGA 71019</b>	Water	n.a.	n.a.	n.d.	0.8	n.d.	0.8	n.d.	n.d.
	Soil	n.d.	2.5	5.5	2.7	0.6	1.1	1.9	1.3
<b><sup>14</sup>CO<sub>2</sub></b>		n.a.	<0.1	n.a.	<0.1	0.1	0.1	0.1	0.1
<b>Non-extractable</b>		3.8	8.5	6.3	5.1	7.5	9.9	11.6	7.7
<b>Total recovery</b>		<b>98.2</b>	<b>95.2</b>	<b>101.8</b>	<b>96.8</b>	<b>98.4</b>	<b>100.0</b>	<b>98.5</b>	<b>99.3</b>

n.d. Not detected

n.a. Not applicable

It was concluded that difenoconazole was stable under anaerobic conditions and no degradation rate could be determined.

The measurements of physicochemical conditions indicated that the systems were essentially anaerobic. Measured dissolved oxygen in the water phase of the treated samples was 0.6-2.1 mg/L or 6.6-23% of saturation (mean value 1.0±0.6 mg/L, or 11% of saturation). Redox potential varied between -20 and -160 mV in the aqueous phase (average -84±62 mV) and between -13 and -214 mV in the soil (average -77±71 mV). pH in the aqueous phase varied between 7.83 and 8.48.

**Comments by RMS:**

The study is of acceptable quality. The results show that difenoconazole is stable and that no major metabolites are formed under anaerobic conditions.

### B.8.1.3 Phototransformation on soil

<b>Reference:</b>	<b>Atkins RH (1994)</b> Soil Surface Photolysis of Phenyl- <sup>14</sup> C-CGA-169374 Under Artificial Sunlight. PTRL East, Inc., Richmond, Kentucky, USA. Report No. 791. Syngenta File No. CGA169374/1184.
Test material:	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity 99.5%, Batch No. CL-XXXII-94.
Guideline:	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental fate. Section 162-3. EPA 540/9-82-021, October 1982.
GLP:	Yes

#### Material and methods:

Test concentration: 10.22 mg/kg

Test system: The photolytic degradation of difenoconazole was investigated on an air dried slurry of soil and deionised water spread in Petri dishes (soil layer 0.5 mm thick, 3.1 g soil per dish). Test substance, dissolved in acetonitrile, was applied to the surface and after evaporation of the solvent the soil was brought to 75 % field capacity. The moisture level was adjusted daily during the experiment.

Samples were irradiated under a xenon arc lamp equipped with a borosilicate filter to absorb wavelengths less than 290 nm. Plates were exposed intermittently (12 hours light, 12 hours dark) to the light source for 30 days. The intensity of the lamps was continuously measured and the spectral distribution of the intensity was determined at the beginning and at the end of the study. Light energy was 2.90 W x min/cm<sup>2</sup>/day for each light/dark cycle, or 87.0 W x min/cm<sup>2</sup> for the 30-day study period. The spectrum of the xenon lamps was quite similar to that of natural sunlight. Filtered, humidified air was drawn through the chambers to a set of volatile traps. A similar apparatus using glass plates covered with black rubber was used for the dark control set.

Test conditions: 25°C, 75% of FC.

Sampling time points: Duplicate irradiated and dark control dishes were sampled on day 0, 1, 3, 5, 7, 11, 21 and 30. Volatile traps were replaced at the same sampling intervals.

Method of analysis: Soil samples were extracted with CaCl<sub>2</sub>, twice with methanol/water (8:2, v/v) and on days 21 and 30 samples finally with methanol/water (reflux, 9:1, v/v). Extracts were quantified by LSC and analysed by HPLC and TLC (except CaCl<sub>2</sub> extracts as little radioactivity was present). Reference compounds were: Difenoconazole, CGA 71019 (1H-1,2,4-triazole), CGA 131013, CGA 142856, GB-XLIII-42-1, CGA 189138, CGA 190169, CGA 190978, CGA 205374, CGA 205375. Residual radioactivity in the soils was determined by combustion. Solutions in traps for volatiles were radioassayed and polyurethane foam plugs extracted in methanol.

Soil Characteristics: See Table B.8.1.3-1.

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**Table B.8.1.3-1. Soil characteristics.**

Soil designation		Kentucky, USA	
Soil type (USDA)		sandy loam	
Sand (>0.05 mm)	[%]	67	
Silt (0.002-0.05 mm)	[%]	23	
Clay (< 0.002 mm)	[%]	10	
pH		6.8	
Organic carbon	[%]	1.0	
Cation exchange capacity	[meq/100 g]	5.5	
Field capacity (1/3 bar)	[g/100 g]	15.1	
Microbial biomass <sup>a</sup>		pre-study	post study
- aerobic bacteria	[CFU/g]	2.4 x 10 <sup>6</sup>	4.0 x 10 <sup>5</sup>
- actinomycetes	[CFU/g]	2.1 x 10 <sup>6</sup>	4.7 x 10 <sup>6</sup>
- fungi	[CFU/g]	2.0 x 10 <sup>3</sup>	2.8 x 10 <sup>3</sup>
- anaerobic bacteria	[CFU/g]	3.7 x 10 <sup>3</sup>	2.5 x 10 <sup>4</sup>

<sup>a</sup> Determined as Colony Forming Units/g soil.

**Results:**

Recovery, distribution and characterisation of radioactivity are presented in Tables B.8.1.3-2 and B.8.1.3-3 for irradiated and dark control samples, respectively. Mean total recovery was 98.8±2.4% throughout the study.

Under the conditions of the test, difenoconazole was virtually stable to photolysis. Several minor degradates were isolated at low levels (< 3%). Traces of CGA 205374 and CGA 205375 were noted but the identity of these compounds was only tentative. Evolution of <sup>14</sup>CO<sub>2</sub> reached maximum 0.2% of the applied radioactivity. In traps for other volatiles the radioactivity was always <0.1%. Non-extractable radioactivity ranged from 2.0-7.8% in individual samples.

**Table B.8.1.3-2. Recovery, distribution and characterisation of radioactivity in irradiated samples of sandy loam soil treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples unless degradation products were only detected in one of the replicates. In those cases the value given represents the maximum amount detected.**

	Sampling time (days)							
	0	1	3	5	7	11	21	30
Difenoconazole	97.7	94.6	91.5	90.6	90.3	89.0	94.5	91.4
CGA 205374	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.2	0.2
CGA 205375	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.1	n.d.
Unknown A	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.2
Unknown B	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	2.8 <sup>b</sup>	0.1
Unknown C	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Unknown D	n.d.	0.3	n.d.	n.d.	0.3	0.4	0.5	0.3
<sup>14</sup> CO <sub>2</sub>	n.a.	<0.1	<0.1	<0.1	0.1	0.1	0.2	0.2
Not analysed <sup>a</sup>	n.a.	n.a.	2.4	2.5	2.1	2.0	n.a.	n.a.
Non-extractable	2.8	3.4	4.4	5.5	6.8	7.4	4.0	3.7
Total recovery	100.5	98.1	98.4	98.5	99.4	98.8	100.6	95.8

n.d. Not detected

n.a. Not applicable

<sup>a</sup> Radioactivity in the first extract (CaCl<sub>2</sub>) was not analysed on sampling intervals days 3-11.

<sup>b</sup> Consisted of two peaks.

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**Table B.8.1.3-3. Recovery, distribution and characterisation of radioactivity in dark control samples of sandy loam soil treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole. As % of applied radioactivity. Mean of duplicate samples unless degradation products were only detected in one of the replicates. In those cases the value given represents the maximum amount detected.**

	Sampling time (days)							
	0	1	3	5	7	11	21	30
Difenoconazole	97.7	93.7	92.0	91.9	93.3	88.0	99.0	92.5
CGA 205374	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.2
CGA 205375	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Unknown A	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.8
Unknown B	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Unknown C	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.2
Unknown D	n.d.	0.4	n.d.	n.d.	0.3	0.3	0.3	0.3
$^{14}\text{CO}_2$	n.a.	<0.1	<0.1	<0.1	<0.1	<0.1	0.2	0.2
Not analysed <sup>a</sup>	n.a.	n.a.	2.6	2.3	2.1	1.5	n.a.	n.a.
Non-extractable	2.8	3.0	4.1	5.7	6.1	6.9	2.1	2.7
<b>Total recovery</b>	<b>100.5</b>	<b>97.1</b>	<b>98.5</b>	<b>99.8</b>	<b>101.9</b>	<b>96.9</b>	<b>101.4</b>	<b>96.6</b>

n.d. Not detected

n.a. Not applicable

<sup>a</sup> Radioactivity in the first extract ( $\text{CaCl}_2$ ) was not analysed on sampling intervals days 3-11.

It was concluded that difenoconazole was stable to photochemical transformation on soil surface on the conditions of the test.

#### Comments by RMS:

The study is of acceptable quality. It is concluded that photochemical transformation is not a significant route of degradation of difenoconazole on soil.

#### B.8.1.4 Aerobic and anaerobic transformation of metabolites

Reference:	<b>Slangen PJ (2000)</b> Degradation of 1,2,4-triazole in three soils under aerobic conditions. NOTOX B.V., 'S-Hertogenbosch, The Netherlands. Report No. NOTOX 278336. Syngenta File No. CGA64250/4345.
Test Material:	CGA71019 (1,2,4-triazole, more specifically 1H-1,2,4-triazole), 3,5- $^{14}\text{C}$ -radiolabel: Radiochemical purity >98%, Batch No. 337/1.
Guideline:	SETAC (1995) Procedures for assessing the environmental fate and ecotoxicity of pesticides, part 1, 1.1 Aerobic degradation, Ed. M. Lynch. Dutch Board for the Authorisation of Agrochemicals (CTB). G. 1.1.: Gegevens over de aard van de omzettingsprodukten en de snelheden waarmee deze worden gevormd (1995) US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 162-1. EPA, 540/9-82-021, October 1982. BBA Guideline Part IV, 4-1, December 1986.
GLP:	Yes

#### Material and methods:

Test concentration:	0.06 mg/kg soil (dw), corresponding to 45 g/ha (assuming even distribution in top 5 cm soil layer and density $1.5 \text{ g/cm}^3$ ).
Test system:	Route and rate of degradation of CGA 71019 was investigated in three freshly collected soils. Before use, soils were sieved and brought to approx. 40% WHC and stored for 7-8 weeks. Test systems were set up and acclimated to test conditions for a

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	about a week prior to treatment. Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO <sub>2</sub> and the systems were continuously ventilated with moistened air. The test substance (dissolved in water) was applied and the soil mixed. After 1 and 2 days the soils were again thoroughly mixed. The flasks were incubated in the dark for 120 days.
Test conditions:	20±2°C, 40 % of WHC.
Sampling time points:	Samples were taken for analysis after 0*, 1, 3, 7, 14*, 30, 61, 83 (Laacherhof A III only) and 120* days of incubation (* duplicate samples). Gas traps were analysed at the same sampling intervals and on day 85.
Method of analysis:	Soil samples were extracted at room temperature with methanol:water (4:1, v/v) and two times with methanol, and finally by methanol soxhlet for 1 hour. The cold extracts were combined and both samples were concentrated prior to analysis by TLC for triazole and its metabolites. Reference compounds were: CGA 71019 (1,2,4-triazole), NOA 457654 (1,2,4-triazole-hydroxy), CGA 142856 (1,2,4-triazole-1-yl-acetic acid), and CGA 131013 (2-amino-3-[1,2,4]triazol-1-yl-propionic acid). The residual radioactivity in soil was determined by combustion and LSC. Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out on day 120 samples to confirm that radioactivity in NaOH trap consisted of <sup>14</sup> CO <sub>2</sub> .
Calculations:	Degradation rate was calculated by non-linear regression applying both one-compartment first order reaction and first order multicompartment (FOMC) kinetics (Origin 5.0 software).
Soil Characteristics:	See Table B.8.1.4-1.

**Table B.8.1.4-1. Soil characteristics.**

Soil designation		Laacherhof AXXa (Germany)	Hanhofen (BBA 2.2) (Germany)	Laacherhof A III (Germany)
Soil type (USDA)		sandy loam	loamy sand	silt loam
Sand (>0.05 mm)	[%]	72.4	78.9	36.9
Silt (0.002-0.05 mm)	[%]	22.6	14.4	51.1
Clay (< 0.002 mm)	[%]	5.0	6.7	12.0
pH		6.4	5.8	6.7
Organic carbon	[%]	1.4	2.2	0.98
Cation exchange capacity	[meq/100 g]	9.6	11.0	8.0
Water holding capacity	[g/100 g]	34.4	50.0	36.4
Biomass <sup>a</sup> - start of study	[mg C/100 g]	33.4	29.4	25.2
Biomass <sup>a</sup> - end of study	[mg C/100 g]	19.8	13.8	13.8

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. Soil Biol. Biochem., 10: 215-221.

**Results:**

The recovery, distribution and characterisation of radioactivity is summarised for each soil in Tables B.8.1.4-2 to B.8.1.4-4. The values were presented as normalised to day 0 recoveries since these represented 101.4, 99.0 and 99.2% of the applied radioactivity in the three soils respectively. Mass balance ranged from 88 to 103% in

individual samples over the study except in one soil. Recoveries less than 80% were observed in the Laacherhof A III soil towards the end of the study and were explained by incomplete trapping of  $^{14}\text{CO}_2$ .

CGA 71019 decreased from 85-91% of the applied radioactivity on day 0 to 12, 31 and 2% at study termination. Hence, CGA 71019 degraded rapidly in all three soils. After seven days approximately 50% of the applied amount had been transformed into unextractable (bound) residues. The degradation rate slowed with increasing time and was therefore biphasic. Small amounts of degradation products were observed; CGA 142856 (1,2,4-triazol-1-yl acetic acid; max. 6.3%) and NOA 457654 (1,2,4-triazole-hydroxy; max. <3%) were identified; one other product (<1%) was also isolated but not identified. All the metabolites declined after the maximum was reached and were undetectable by the end of the study.

In the soils Laacherhof AXXa and Laacherhof A III the degradation of triazole entailed complete mineralisation with the formation of 15 and 33 %, respectively of  $^{14}\text{CO}_2$ . In the Hanhofen soil (BBA 2.2)  $^{14}\text{CO}_2$  evolution was very limited though the overall trends with regard to decline of triazole and increase of bound residues were found to be identical with the situation in the other soils. Volatile organic compounds were negligible ( $\leq 0.01\%$ ) in all three soils.

**Table B.8.1.4-2. Recovery, distribution and characterisation of radioactivity in Laacherhof AXXa soil treated with  $^{14}\text{C}$ -labelled 1,2,4-triazole (CGA 71019). Values normalised to % of mean radioactivity recovered on day 0. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	1,2,4-triazole	Triazole acetic acid	Triazole-hydroxy	Unknown <sup>a</sup>	$^{14}\text{CO}_2$	Non-extractable	Total recovery
0	91.0	n.d.	n.d.	0.5	n.p.	8.6	100.0 <sup>b</sup>
1	61.8	3.0	n.d.	0.7	0.04	31.2	96.9
3	37.4	4.8	n.d.	n.d.	0.4	58.4	100.9
7	30.8	6.3	n.d.	n.d.	0.9	56.1	94.2
14	27.7	6.3	0.3	n.d.	6.5	56.2	97.0
30	19.8	1.3	0.5	0.5	5.3	71.9	99.3
61	12.5	0.6	1.0	0.5	12.5	74.6	101.8
120	12.0	n.d.	n.d.	n.d.	15.4	64.7	92.0

n.d. Not detected

n.p. Not performed

<sup>a</sup> Unknown metabolite with  $R_f \leq 0.03$ .

<sup>b</sup> Total recovery of individual samples on day 0 was 101.21 and 98.79%..

**Table B.8.1.4-3. Recovery, distribution and characterisation of radioactivity in Hanhofen BBA 2.2 soil treated with  $^{14}\text{C}$ -labelled 1,2,4-triazole (CGA 71019). Values normalised to % of mean radioactivity recovered on day 0. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	1,2,4-triazole	Triazole acetic acid	Triazole-hydroxy	Unknown <sup>a</sup>	$^{14}\text{CO}_2$	Non-extractable	Total recovery
0	89.9	n.d.	n.d.	n.d.	n.p.	10.0	100.0 <sup>b</sup>
1	76.2	n.d.	n.d.	n.d.	0.01	24.3	100.5
3	52.4	n.d.	n.d.	n.d.	0.1	44.0	96.6
7	45.7	n.d.	n.d.	n.d.	0.1	49.7	95.6
14	39.6	1.5	n.d.	n.d.	0.3	52.3	93.7
30	31.8	0.4	n.d.	0.3	0.5	69.8	102.9
61	30.2	0.9	n.d.	0.6	1.0	65.4	98.2
120	31.0	n.d.	n.d.	n.d.	1.5	59.6	92.0

n.d. Not detected

n.p. Not performed

<sup>a</sup> Unknown metabolite with  $R_f \leq 0.03$ .

<sup>b</sup> Total recovery of individual samples on day 0 was 99.42 and 100.58%.

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**Table B.8.1.4-4. Recovery, distribution and characterisation of radioactivity in Laacherhof A III soil treated with <sup>14</sup>C-labelled 1,2,4-triazole (CGA 71019). Values normalised to % of mean radioactivity recovered on day 0. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	1,2,4-triazole	Triazole acetic acid	Triazole-hydroxy	Unknown <sup>a</sup>	<sup>14</sup> CO <sub>2</sub>	Non-extractable	Total recovery
0	85.0	n.d.	n.d.	n.d.	n.p.	15.0	100.0 <sup>b</sup>
1	75.4	n.d.	n.d.	n.d.	0.1	24.7	100.2
3	50.9	n.d.	n.d.	n.d.	0.6	44.2	95.7
7	45.2	n.d.	n.d.	n.d.	1.8	49.4	96.4
14	38.1	n.d.	2.2	n.d.	0.8	48.5	89.6
30	18.3	0.3	2.2	0.2	19.4	61.6	102.0
61	6.6	n.d.	1.5	n.d.	19.6	49.9	77.6
83	3.7	n.d.	n.d.	n.d.	24.6	59.3	87.5
120	2.1	n.d.	n.d.	n.d.	33.0	40.1	75.2

n.d. Not detected

n.p. Not performed

<sup>a</sup> Unknown metabolite with  $R_f \leq 0.03$ .

<sup>b</sup> Total recovery of individual samples on day 0 was 102.08 and 97.92%.

Calculated degradation rates are shown in Table B.8.1.4-5. Assuming first-order kinetics the half-lives were in the range of 10 days in all three soils. However, in the case of the Hanhofen soil (BBA 2.2) only the initial part of the trial with data points from day 0 to day 14 were included in the calculation. The slow degradation of triazole in the later stages indicated a biphasic process (hockey-stick type). Therefore, the half-lives in this soil as well as that in the soil Laacherhof AXXa were also calculated by first order multicompartment regression analysis. The authors suggested that the slower dissipation in Hanhofen soil (BBA 2.2) in the later stages of the experiment was caused by a combination of reduced bioavailability and reduced viability of the soil.

**Table B.8.1.4-5. Degradation rates for CGA 71019 in three soils under aerobic conditions.**

Soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2*</sup>
<b>One compartment first order (SFO)</b>			
Laacherhof AXXa	6.3	20.9 <sup>a</sup>	0.75
Hanhofen BBA 2.2	9.9 <sup>b</sup>	33.0 <sup>a</sup>	0.81
Laacherhof A III	12.3	40.8	0.95
<b>Mean DT<sub>50</sub> for PEC calculations</b>	<b>9.5</b>		
<b>First order multicompartment (FOMC)</b>			
Laacherhof AXXa	2.3	202	0.99
Hanhofen BBA 2.2	9.3	- <sup>c</sup>	0.97
Laacherhof A III	n.p.	n.p.	n.p.

n.p. Not performed.

\* r<sup>2</sup> represent model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

<sup>a</sup> DT<sub>90</sub> values from single first order equation for two soils inserted by RMS.

<sup>b</sup> Using data from all sampling points resulted in a poor fit, with r<sup>2</sup> of 0.51. Therefore only values up to day 14 were included in the analysis resulting in DT<sub>50</sub> 9.9 days.

<sup>c</sup> DT<sub>90</sub> not calculated in report presumably since 31% 1,2,4-triazole was still present at study termination..

#### Comments by RMS:

The study is of acceptable quality. The presentation of the results as normalised to day 0 recoveries is considered acceptable since the recoveries were all close to 100% of applied radioactivity. The single first order (SFO) degradation rates are used in the further assessment. For two of the soils it appears that better fits were obtained by the multicompartment model, however, the difference in terms of DT<sub>50</sub> is relatively minor. It seems reasonable to conclude that the viability of the Hanhofen (BBA 2.2) soil was reduced after the initial incubation period (at least from day 30 onwards). The metabolites CGA 142856 and NOA 457654 were found as max. 6.3 and 2.2%,

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respectively, however the principal fate of 1,2,4-triazole was incorporation into bound residues. To a limited degree these bound residues appear to be available for further degradation since the non-extractable fraction of the radioactivity decreased towards study termination.

The max. annual "application rate" of CGA 71019 was calculated to 15 g/ha following the representative use of difenoconazole (based on max. formation 23.4% and corrected for molecular weight). Test concentration thus exceeded the expected exposure to CGA 71019 following the representative use of difenoconazole.

<b>Reference:</b>	<b>Mamouni A (2003)</b> [ <sup>14</sup> C]-CGA 71019: Anaerobic Soil Degradation. RCC Ltd., Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. Report No. 798660. Syngenta File No. CGA169374/0062
Test Material:	CGA 71019 (1,2,4-triazole, more specifically 4H-1,2,4-triazole), 3,5- <sup>14</sup> C-radiolabel: Radiochemical purity 96.4% (as determined by RCC by TLC: 97.2%), Batch No. CFQ12197.
Guideline:	OECD Draft Guideline 307, August 2000; Aerobic and Anaerobic Transformation in Soil.
GLP:	Yes

#### Material and methods:

Test concentration:	0.061 mg 1,2,4-triazole/kg soil (dw), corresponding to 46 g/ha (assuming even distribution in top 5 cm soil layer and density 1.5 g/cm <sup>3</sup> ).
Test system:	Route and rate of degradation of the metabolite 1,2,4-triazole was investigated under anaerobic conditions after 4 days of aerobic incubation in one freshly collected soil. Before use, soil was sieved through a 2 mm sieve acclimated to room temperature for two weeks and moisture adjusted. Test systems consisted of 100 g samples in glass flasks connected to traps for organic volatiles and CO <sub>2</sub> and the systems were continuously ventilated with moistened air during aerobic incubation. The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. After 4 days of incubation in the dark the soil was flooded with distilled water and kept under oxygen free nitrogen for 122 days. The system was ventilated with nitrogen regularly (4 times/day).
Test conditions:	20±2°C, 40 % of MWHC (moisture condition under 4 d aerobic incubation).
Sampling time points:	Duplicate samples were taken day on 0, 3 (single replicate) and 4 of aerobic incubation and on day 5, 7, 14, 27 (single replicate), 60 and 122 of anaerobic incubation. Gas traps were exchanged at each sampling interval and additionally on days 18 and 105 of anaerobic incubation.  After flooding the soil, pH, oxygen concentration in water and redox potential in water and soil were measured at each sampling interval in the respective treated samples and in two untreated control samples.
Method of analysis:	After removal of the overlaying water, when necessary, treated soils were extracted

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at room temperature three times with acetonitrile/water (4:1, v/v), once with water and finally samples were Soxhlet extracted with acetonitrile/water (9:1, v/v) for at least four hours. Extracts were combined and concentrated. The residual radioactivity in soil was determined by combustion and LSC. The radioactivity in the water phase was quantified by LSC.

1,2,4-triazole and metabolites in water and soil were identified by TLC. Reference compounds were: CGA 71019 (note: 4H-1,2,4-triazole instead of 1H-1,2,4-triazole), CGA 131013, CGA 142856 and NOA 457654.

Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out to confirm that radioactivity in NaOH trap consisted of  $^{14}\text{CO}_2$ .

Calculations:

Degradation rate was calculated by non-linear regression applying first order reaction kinetics (MicroCal Origin software).

Soil Characteristics:

See Table B.8.1.4-6.

**Table B.8.1.4-6. Soil characteristics.**

Soil designation		Les Barges (Switzerland)
Soil type (USDA)		silt loam
Sand (>0.05 mm)	[%]	35.9
Silt (0.002-0.05 mm)	[%]	52.3
Clay (< 0.002 mm)	[%]	11.8
pH		7.31
Organic carbon	[%]	2.11
Cation exchange capacity	[meq/100 g]	13.9
Maximum water holding capacity (MWHC, pF 1.0)	[g/100 g]	68.3
40% MWHC	[g/100 g]	27.3
Field capacity (FC, pF 1.8)	[g/100 g]	47.9
Biomass <sup>a</sup> - start of aerobic incubation	[mg C/100 g]	29.8

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. *Soil Biol. Biochem.*, 10: 215-221.

## Results:

The recovery, distribution and characterisation of radioactivity is summarised in Table B.8.1.4-7. Total recovery was  $96.3 \pm 0.9\%$  of the applied radioactivity.

After flooding, radioactivity was transferred to the water phase where 31% of the applied radioactivity was measured after 5 days. This level remained more or less constant throughout the incubation.

1,2,4-Triazole degraded rapidly during the initial aerobic phase decreasing from 90 to 57% of the applied radioactivity over the 4 days. Degradation however, was slower after flooding and 21% remained as 1,2,4-triazole after 122 days.

The principle degradation product was identified as 1,2,4-triazol-1-yl acetic acid (CGA 142856, M1), which accumulated during the study to a maximum of 50% after 126 days. Six other compounds were observed each in

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amounts of less than approx. 3% of the applied radioactivity. Only one of these compounds was identified, as 2-amino-3-1,2,4-triazol-1-yl propionic acid (CGA 131013, M2).

Unextracted radioactivity increased to a maximum of 18% of the applied radioactivity after 4 days of aerobic incubation and then remained relatively constant until the end of the study. The only volatile product evolved was <sup>14</sup>CO<sub>2</sub> which reached a maximum of 1% of the applied radioactivity at the end of the aerobic incubation phase. Other volatiles never exceeded <0.2% of the applied radioactivity.

**Table B.8.1.4-7. Recovery, distribution and characterisation of radioactivity in silt loam soil treated with <sup>14</sup>C-labelled 1,2,4-triazole and incubated under aerobic conditions for 4 days, thereafter under anaerobic (flooded) conditions. As % of applied radioactivity. Mean of duplicate samples (exceptions day 3 aerobic and day 27 anaerobic).**

		Aerobic phase (days)			Anaerobic phase (days)					
Days after application		0	3	4	9	11	18	31	64	126
Days after flooding		-	-	0	5	7	14	27	60	122
<b>1,2,4-triazole</b>	Water	n.a.	n.a.	n.d.	20.0	22.4	15.0	13.6	9.0	4.6
	Soil	89.9	63.9	56.5	38.6	37.2	32.1	30.2	27.3	16.5
	Total	89.9	63.9	56.5	58.6	59.6	47.2	43.8	36.2	21.1
<b>CGA 142856 (=M1)</b>	Water	n.a.	n.a.	n.d.	10.6	11.5	14.6	15.1	20.1	30.0
	Soil	n.d.	7.8	15.2	7.9	6.8	8.7	9.6	10.9	20.3
	Total	n.d.	7.8	15.2	18.5	18.3	23.2	24.7	31.0	50.3
<b>CGA 131013 (=M2)</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.1
	Soil	0.5	2.7	3.3	2.9	3.4	2.6	2.5	0.9	1.2
	Total	0.5	2.7	3.3	2.9	3.4	2.6	2.5	0.9	1.4
<b>M3</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	0.1	n.d.	0.3	1.0
	Soil	0.9	0.5	1.0	1.7	1.7	2.6	3.1	2.3	1.9
	Total	0.9	0.5	1.0	1.7	1.7	2.6	3.1	2.5	2.9
<b>M4</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	0.4	0.3	n.d.
	Soil	n.d.	0.6	0.4	n.d.	0.2	0.7	0.9	1.1	0.7
	Total	n.d.	0.6	0.4	n.d.	0.2	0.7	1.3	1.4	0.7
<b>M5</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	0.2	0.4	0.1
	Soil	n.d.	0.8	0.8	0.4	0.6	0.8	1.7	0.5	0.5
	Total	n.d.	0.8	0.8	0.4	0.6	0.8	2.0	0.9	0.6
<b>M6</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	0.4	n.d.	n.d.
	Soil	n.d.	n.d.	0.3	0.6	0.2	0.2	1.2	0.5	n.d.
	Total	n.d.	n.d.	0.3	0.6	0.2	0.2	1.6	0.5	n.d.
<b>M7</b>	Water	n.a.	n.a.	n.d.	n.d.	n.d.	0.4	0.3	0.2	0.9
	Soil	n.d.	n.d.	n.d.	n.d.	0.1	0.3	0.4	0.4	n.d.
	Total	n.d.	n.d.	n.d.	n.d.	0.1	0.6	0.7	0.6	0.9
<b><sup>14</sup>CO<sub>2</sub></b>		n.a.	0.6	1.0	1.3	1.2	0.7	1.3	1.0	1.3
<b>Non-extractable</b>		5.3	17.1	17.6	12.5	11.6	16.8	16.2	21.4	16.3
<b>Total recovery</b>		<b>96.6</b>	<b>93.9</b>	<b>96.1</b>	<b>96.5</b>	<b>96.8</b>	<b>95.5</b>	<b>97.2</b>	<b>96.5</b>	<b>96.7</b>

n.d. Not detected

n.a. Not applicable

The DT<sub>50</sub> and DT<sub>90</sub> values calculated over the anaerobic phase was 81 days and 268 days (r<sup>2</sup> 0.972)<sup>3</sup>.

It was concluded that 1,2,4-triazole is degraded under anaerobic conditions principally to CGA 142856.

The measurements of physicochemical conditions indicated that the systems developed into anaerobic conditions over the study. Measured dissolved oxygen in the water phase of the treated samples decreased from 1.0-3.5 mg/L (day 5 of anaerobic incubation) to 0.0 or 0.10-0.30 mg/L at study termination (over the study the oxygen

<sup>3</sup> "Model efficiency" rather than coefficient of determination since non-linear curve fitting was employed. RMS's comment.

saturation was 1.1-38%). Redox potential in the water decreased from 185-206 mV (day 5 of anaerobic incubation) to -198 - -249 mV at study termination. In the soil, redox potential decreased from 141-145 mV (day 5) to -259 - -277 mV at study end. In both water and soil the values were negative from day 14 onwards. pH in the aqueous phase increased from about 7.2 to about 8.6.

#### Comments by RMS:

The study is of acceptable quality. It is concluded that 1,2,4-triazole is degraded slower under anaerobic conditions than under aerobic. The  $DT_{50}$  and  $DT_{90}$  will be used in the further assessment. 4H-1,2,4-triazole was used as test substance, not the metabolite of difenoconazole 1H-1,2,4-triazole. This is however considered acceptable since in solution the position of the hydrogen atom in 1,2,4-triazole is expected to alter between position 1 and 4 of the molecule. The metabolite CGA 142856 was present in higher amounts (max. 50.3% day 126) than under aerobic conditions and in addition the metabolite CGA 131013 was identified as max. 3.4%. Since 1,2,4-triazole was formed as max. 23.4% of the parent compound, the maximum theoretical formation of triazole acetic acid (CGA 142856) would be  $0.23 \times 0.50 = 12\%$  of the applied dose of difenoconazole. This assumes that further degradation of 1,2,4-triazole would take place under anaerobic conditions and this not a realistic assumption since 1,2,4-triazole is more rapidly degraded under aerobic than anaerobic conditions and CGA 142856 reached its max. formation only late in the anaerobic study. The RMS therefore concludes that triazole acetic acid (CGA 142856) does not need to be considered further.

The max. annual "application rate" of CGA 71019 was calculated to 15 g/ha following the representative use of difenoconazole (based on max. formation 23.4% and corrected for molecular weight). Test concentration thus exceeded the expected exposure to CGA 71019 following the representative use of difenoconazole.

<b>Reference:</b>	<b>Völkel W (2002a)</b> Degradation of CGA 205375 [ $^{14}\text{C}$ -Triazole] in three soils incubated under aerobic and anaerobic conditions. RCC Ltd., Environmental Chemistry & Pharamalytics Division, Itingen, Switzerland. Report No. 775451. Syngenta File No. CGA169374/2240.
<b>Test Material:</b>	CGA 205375 (1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol), $^{14}\text{C}$ -triazole-radiolabel: Radiochemical purity 99.4% (as determined by RCC by HPLC: 100.0%), Batch No. ILA-52.3A-1
<b>Guideline:</b>	OECD Draft Guideline 307, August 2000: Aerobic and Anaerobic Transformation in Soil.
<b>GLP:</b>	Yes

#### Material and methods:

**Test concentration:** 0.1 mg/kg soil (dw), corresponding to 75 g/ha (assuming even distribution in top 5 cm soil layer and density  $1.5 \text{ g/cm}^3$ ).

**Test system:** Route and rate of degradation of CGA 205375 was investigated in three freshly collected soils. Before use, soils were sieved through a 2 mm sieve acclimated to room temperature for about two weeks and moisture adjusted.

Test systems consisted of 100 g samples in glass flasks connected to traps for organic

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volatiles and CO<sub>2</sub> and the systems were continuously ventilated with moistened air. The test substance (dissolved in acetone/water) was applied dropwise and the soil mixed. The flasks were incubated in the dark for 228 days. Soil moisture was adjusted during incubation.

Anaerobic degradation was investigated in additional samples of Pappelacker soil. After 30 days of incubation in the dark the soil was flooded with purified water and ventilated with nitrogen. The flasks were incubated in the dark for 120 days. The system was ventilated with nitrogen regularly (2 times/day).

Test conditions: 20±2°C, 40% of MWHC (aerobic part).

Sampling time points: Aerobic incubation: Samples were taken for analysis after 0\*, 7, 14, 30\*, 58, 84, 150 and 210\*/228\* days of incubation (\* duplicate samples). Gas traps were exchanged at the respective sampling interval (except day 0) or about every two weeks until day 157 and thereafter on days 192, 219 and 228.

Anaerobic incubation: Single samples were taken 7, 28, 54 and 120 days after flooding. During anaerobic incubation, pH and oxygen concentration in water and redox potential in water and soil were measured at each sampling interval in the respective treated samples.

Method of analysis: Soil samples (after removal of the water phase where necessary) were sequentially extracted at room temperature with acetonitrile/water (3 times, 8:2, v/v), water and after day 14 additionally with a Soxhlet extraction in acetonitrile/water (9:1, v/v) for at least 4 hours. Residual radioactivity in the soil debris was quantified by combustion. Extracts were combined and concentrated. Concentrates and water phase samples were analysed by HPLC and TLC. Reference compounds were: CGA 205375 (=CGA 211391), CGA 205374 (=CGA 176459), and CGA 71019.

Radioactivity in gas traps was monitored by LSC. Barium hydroxide precipitations were carried out on selected samples to confirm that radioactivity in NaOH trap consisted of <sup>14</sup>CO<sub>2</sub>.

Calculations: Degradation rate was determined by non-linear regression applying first order reaction kinetics (MicroCal Origin software).

Soil Characteristics: See Table B.8.1.4-8.

**Table B.8.1.4-8. Soil characteristics.**

Soil designation		<b>I Schanz (Switzerland)</b>	<b>II Pappelacker (Switzerland)</b>	<b>III Senozan (France)</b>
Soil type (USDA)		sandy loam	sandy loam/ loamy sand	silt loam
Sand (>0.05 mm)	[%]	67.3	71.5	20.3
Silt (0.002-0.05 mm)	[%]	19.7	22.1	56.1
Clay (< 0.002 mm)	[%]	13.0	6.5	23.6
pH		7.4	7.5	5.8
Organic carbon	[%]	0.95	1.0	0.99
Cation exchange capacity	[meq/100 g]	10.4	6.2	15.5
Maximum water holding capacity (MWHC, pF 1.0)	[g/100 g]	41.7	44.1	55.4

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Soil designation		I Schanz (Switzerland)	II Pappelacker (Switzerland)	III Senozan (France)
Biomass <sup>a</sup> - start of study	[mg C/100 g]	62.3	46.4	36.9
Biomass <sup>a</sup> - after 119 days	[mg C/100 g]	27.7	20.7	29.0
Biomass <sup>a</sup> - end of study (day 228)	[mg C/100 g]	21.4	22.6	19.2

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. *Soil Biol. Biochem.*, 10: 215-221.

### Results:

Recovery, distribution and characterisation of radioactivity in the three soils incubated under aerobic conditions are presented in Tables 8.1.4-9 to B.8.1.4-11. The results from the anaerobic incubation of Pappelacker soil is summarised in Table B.8.1.4-12. The total recovery of radioactivity from individual samples ranged from 93 to 102% of applied throughout the study. The total mean recovery was  $96.2 \pm 2.6\%$ ,  $97.5 \pm 1.9\%$  and  $96.5 \pm 1.9\%$  for Schanz, Pappelacker (aerobic) and Senozan soil, respectively. During the aerobic and anaerobic incubation of Pappelacker soil the total mean recovery was  $96.8 \pm 1.4\%$ .

Under aerobic conditions CGA 205375 decreased from 96-97% of the applied radioactivity on day 0 to 28% (Schanz soil), 24% (Pappelacker soil) and 43% (Senozan soil) at study termination (day 210/228). Only one major metabolite was observed, CGA 71019, which accounted for up to a maximum of 32% of the applied radioactivity under aerobic conditions. Amounts of the CGA 71019 had declined from the maximum by the end of the study. Under anaerobic conditions (Table B.8.1.4-12) CGA 71019 initially partitioned equally between the water and soil phases, at the final sampling however, it was principally found in the soil. Amounts of CGA 71019 formed under anaerobic conditions were similar to those in aerobic soils.

Several other minor metabolites (CGA 205374, M3, M4, M5 and M6) were observed but at a maximum they were individually <3% of the applied radioactivity on all occasions. With the exception of CGA 205374 the other metabolites were not identified.

The mineralisation of CGA 205375, i.e. the formation of  $^{14}\text{CO}_2$  was significant in soils I (Schanz) and II (Pappelacker), reaching a maximum of 31% and 13% respectively. Mineralisation in soil III (Senozan) and after flooding soil II was very low (1%). Other volatile compounds collected in ethylene glycol did not exceed 0.5% of the applied radioactivity.

The level of unextracted radioactivity increased with incubation time to a maximum of 35% of the applied radioactivity at the end of the study (day 210/228). At the end of the anaerobic incubation non-extractable radioactivity accounted for 20%. Soxhlet extraction released maximum 19% of the radioactivity.

**Table B.8.1.4-9. Recovery, distribution and characterisation of radioactivity in Schanz soil treated with  $^{14}\text{C}$ -triazole labelled CGA 205375 and incubated under aerobic conditions. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	CGA 205375	CGA 205374	CGA 71019	M4	M5	M6	Non-extractable	$^{14}\text{CO}_2$	Total recovery
0	97.1	n.d.	n.d.	n.d.	n.d.	n.d.	2.0	n.p.	99.1
7	90.6	n.d.	2.6	n.d.	n.d.	n.d.	5.8	<0.1	99.1

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Days after application	CGA 205375	CGA 205374	CGA 71019	M4	M5	M6	Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
14	83.7	0.9	9.1	n.d.	n.d.	n.d.	3.9	0.2	97.8
30	72.2	1.0	14.0	n.d.	n.d.	n.d.	7.9	1.4	96.6
58	54.8	n.d.	15.8	n.d.	n.d.	n.d.	15.9	6.0	92.6
84	52.4	n.d.	15.6	n.d.	n.d.	n.d.	15.6	10.0	93.7
150	37.8	n.d.	13.6	n.d.	n.d.	n.d.	22.1	22.3	96.1
228	28.2	n.d.	4.6	1.4	0.8	1.0	26.0	31.4	93.6

n.d. Not detected

n.p. Not performed.

**Table B.8.1.4-10. Recovery, distribution and characterisation of radioactivity in Pappelacker soil treated with <sup>14</sup>C-triazole labelled CGA 205375 and incubated under aerobic conditions. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	CGA 205375	CGA 205374	CGA 71019	M4	M5	M6	Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
0	95.6	n.d.	n.d.	n.d.	n.d.	n.d.	2.8	n.p.	98.4
7	88.5	n.d.	2.2	n.d.	n.d.	n.d.	7.0	<0.1	97.7
14	84.8	2.7	6.4	n.d.	n.d.	n.d.	3.0	0.1	96.9
30	71.0	0.3	17.0	n.d.	n.d.	n.d.	7.4	0.6	96.4
58	57.7	n.d.	26.0	n.d.	n.d.	n.d.	10.9	1.9	96.7
84	44.9	n.d.	30.8	n.d.	n.d.	n.d.	17.2	2.8	96.2
150	31.5	n.d.	32.4	n.d.	n.d.	n.d.	22.8	7.1	94.2
210	24.0	n.d.	25.4	1.6	1.7	n.d.	31.9	13.4	100.4

n.d. Not detected

n.p. Not performed.

**Table B.8.1.4-11. Recovery, distribution and characterisation of radioactivity in Senozan soil treated with <sup>14</sup>C-triazole labelled CGA 205375 and incubated under aerobic conditions. As % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Days after application	CGA 205375	CGA 205374	CGA 71019	M3	M4	M5	M6	Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
0	96.8	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	2.2	n.p.	99.0
7	90.0	1.0	n.d.	n.d.	n.d.	n.d.	n.d.	5.9	<0.1	96.8
14	89.1	n.d.	2.8	n.d.	n.d.	n.d.	n.d.	3.4	<0.1	95.2
30	84.4	0.4	5.6	0.4	n.d.	n.d.	n.d.	6.0	0.1	96.8
58	73.5	n.d.	9.3	n.d.	n.d.	n.d.	n.d.	12.2	0.1	95.1
84	65.0	n.d.	13.3	n.d.	n.d.	n.d.	n.d.	15.6	0.2	94.4
150	48.2	n.d.	24.0	n.d.	n.d.	n.d.	n.d.	20.0	1.2	93.9
228	43.1	n.d.	18.7	n.d.	n.d.	n.d.	n.d.	34.3	0.8	97.0

n.d. Not detected

n.p. Not performed.

**Table B.8.1.4-12. Recovery, distribution and characterisation of radioactivity in Pappelacker soil treated with <sup>14</sup>C-triazole labelled CGA 205375 and incubated under aerobic and anaerobic conditions. As % of applied radioactivity. Single replicates except on day 0 (aerobic) and day 30 (aerobic).**

Days after application		CGA 205375		CGA 205374		CGA 71019		Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
aerobic	anaerobic	water	soil	water	soil	water	soil			
0	-	n.a.	95.6	n.a.	n.d.	n.a.	n.d.	2.8	n.p.	98.4
7	-	n.a.	88.5	n.a.	n.d.	n.a.	2.2	7.0	<0.1	97.7
14	-	n.a.	84.8	n.a.	2.7	n.a.	6.4	3.0	0.1	96.9
30	0	n.a.	71.0	n.a.	0.3	n.a.	17.0	7.4	0.6	96.4
37	7	1.2	69.5	n.d.	2.2	7.8	9.3	6.1	0.5	96.6
58	28	0.5	67.9	n.d.	n.d.	9.1	9.0	10.7	0.3	97.6
84	54	n.d.	58.7	n.d.	n.d.	10.4	11.3	13.3	0.6	94.3
150	120	0.8	47.7	n.d.	n.d.	6.5	19.5	19.7	1.1	95.2

n.d. Not detected.

n.p. Not performed.

n.a. Not applicable.

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Calculated rates of degradation are presented in Table B.8.1.4-13. It was concluded that the metabolite CGA 205375 is degraded more slowly under anaerobic conditions than under aerobic.

**Table B.8.1.4-13. Degradation rates for DGA 205375 in three soils under aerobic or anaerobic conditions.**

Soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> a
I Schanz, aerobic	93	309	0.980
II Pappelacker, aerobic	83	275	0.995
II Pappelacker, anaerobic	213	706	0.986
III Senozan, aerobic	152	504	0.996

a r<sup>2</sup> represent model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

#### Comments by RMS:

The study is of acceptable quality. The degradation rates obtained are uncertain, especially the rate calculated from the experiment under anaerobic conditions, due to relatively large amounts of test substance remaining at study termination. The results are nevertheless used in the further assessment as best available estimates. As for difenoconazole anaerobic degradation was slower than aerobic. The metabolite CGA 205374 was found as max. 2.7% and CGA 71019 as max. 32.4%. The level of 1,2,4-triazole (CGA 71019) do not exceed the levels expected from the results in studies on difenoconazole (max formation of CGA 71019 9.7% x 0.324 = 3%).

The max. annual "application rate" of CGA 205375 was calculated to 31 g/ha following the representative use of difenoconazole (based on max. formation 9.7% and corrected for molecular weight). Test concentration thus exceeded the expected exposure to CGA 205375 following the representative use of difenoconazole.

#### B.8.1.5 Field dissipation studies

<b>Reference:</b>	<p><b>Ressler H (1992a)</b> Field Soil Dissipation Rate Determination of CGA 169374. CIBA-GEIGY GmbH, Division Agro, Frankfurt/M, FRG. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, FRG. Report No. 96-88 B. Syngenta File No. CGA169374/2302.</p> <p><b>Ressler H (1992b)</b> Field Dissipation of Difenoconazole. CIBA-GEIGY GmbH Division Agro, Frankfurt/M, FRG. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, FRG. Report No. 43-89 B. Syngenta File No. CGA169374/0699.</p> <p><b>Ressler H (1992c)</b> Field Dissipation of Difenoconazole. CIBA-GEIGY GmbH Division Agro, Frankfurt/M, FRG. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, FRG. Report No. 45-89 B. Syngenta File No. CGA169374/0700.</p> <p><b>Ressler H (1992d)</b> Field Dissipation of Difenoconazole. CIBA-GEIGY GmbH Division Agro, Frankfurt/M, FRG. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, FRG. Report No. 46-89 B. Syngenta File No. CGA169374/0701.</p> <p><b>Harvey BR (2004)</b> Difenoconazole (CGA 169374): Summary of degradation rates in European field dissipation and residue trials. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Report No. RAJ0208B. Syngenta File No. CGA169374/2429.</p>
Test material:	EC 250 formulation (250 g difenoconazole/L).
Guideline:	BBA Guideline Part IV, 4-1, December 1986.
GLP:	No

#### Material and methods:

Treatment rate: 250 or 500 g a.s./ha.

Test system: The field dissipation of difenoconazole in soil after spray applications to bare ground

	was investigated at four locations in Germany. Plot size was 25 m <sup>2</sup> in each trial. Weed was mechanically controlled during the trials.
Applications:	<p><u>Freistett, Germany (Ressler, 1992a):</u> Application on 14 October 1988 (250 g a.s./ha in 400 L water/ha).</p> <p><u>Schornbusch, Germany (Ressler, 1992b):</u> Application on 17 May 1989 (500 g a.s./ha in 400 L water/ha).</p> <p><u>Lorsch, Germany (Ressler, 1992c):</u> Application on 18 May 1989 (500 g a.s./ha in 400 L water/ha).</p> <p><u>Platting-See, Germany (Ressler, 1992d):</u> Application on 5 May 1989 (500 g a.s./ha in 400 L water/ha).</p>
Weather:	<p><u>Freistett, Germany (Ressler, 1992a):</u> Rainfall from October 1988 to October 1989 was 618 mm. Range of monthly average air temperatures was 2.3°C (January) to 19.8°C (July).</p> <p><u>Schornbusch, Germany (Ressler, 1992b):</u> Rainfall during May-October 1989 was 270 mm. Monthly average air temperatures during this period was 12.0-18.7 °C.</p> <p><u>Lorsch, Germany (Ressler, 1992c):</u> Rainfall during May-October 1989 was 334 mm. Monthly average air temperatures during this period was 11.5-20.2 °C.</p> <p><u>Platting-See, Germany (Ressler, 1992d):</u> Rainfall during May-October 1989 was 512 mm. Monthly average air temperatures during this period was 8.7-17.8 °C.</p>
Sampling time points:	Soil samples were taken before application and at 7-9 intervals up to 124-336 days after treatment. At each sampling date, 20 soil cores were taken, to a depth of 20 cm. Samples were stored frozen (-18°C) until analysis.
Method of analysis:	Samples were cut into 10 cm sections (except Ressler, 1992a). Sections of the same depth were combined, sieved (2 mm mesh) and homogenised. Sub-samples were first refluxed with methanol/ammonium hydroxide (4:1), followed by dilution with water and sodium chloride and partition with dichloromethane. After concentration and clean-up, samples were analysed by GC-NPD with a limit of detection (LOD) of 0.02 mg/kg. Method was based on method no. AG-501. Mean procedural recoveries in fortified samples were 94.1±17.6% and the measured concentrations were not corrected for recovery.
Calculations:	In the study reports "best fit" dissipation rate was calculated according to Timme et al (1986) <sup>4</sup> . To provide a consistent approach and rates determined by single first order

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<sup>4</sup>Timme G, Frehse H and Lasko V (1986) Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenschutzmitteln - Rückständen II. Pflanzenschutz-Nachrichten Bayer, 39, 188-204.

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kinetics the data was reanalysed when necessary in a separate report (Harvey, 2004).

The curve-fitting program Model Manager ver. 1.1 was used for this purpose.

Soil Characteristics: See Table B.8.1.5-1.

**Table B.8.1.5-1. Soil characteristics<sup>a</sup>.**

Soil designation		Freistett (Germany) Ressler, 1992a	Schornbusch (Germany) Ressler, 1992b	Lorsch (Germany) Ressler, 1992c	Platting-See (Germany) Ressler, 1992d
Soil type (USDA)		silt loam	silt loam	loamy sand	silt loam
Sand (>0.05 mm)	[%]	17.1	13.3	81.1	4.4
Silt (0.002-0.05 mm)	[%]	68.3	72.5	12.1	78.3
Clay (< 0.002 mm)	[%]	14.6	14.2	6.8	17.3
pH		7.4	6.6	6.2	6.8
Organic carbon	[%]	1.71	1.2	1.05	1.35
Maximum water holding capacity (MWHC)	[g/100 g]	54.0	40.1	35.5	44.3
Biomass	[mg C/100 g]	59-78	18-26	24-25	27-51

<sup>a</sup> In Ressler (1992a) samples for soil characterisation were taken in October 1990, i.e. one year after study termination. In Ressler (1992b, 1992c and 1992d) samples for soil characterisation were taken in January 1989, i.e. 4 months prior to study start. RMS's comment.

### Results:

The measured concentrations of difenoconazole in each trial are presented in Tables B.8.1.5-2 to B.8.1.5-5.

Difenoconazole was mainly retained in the upper soil layer; in only one of the trials difenoconazole was detected in the 10-20 cm soil layer.

Calculated rates of dissipation are presented in Table B.8.1.5-6. Where relevant, residues below the top soil section were included in the analyses.

**Table B.8.1.5-2. Measured concentrations of difenoconazole in Freistett silt loam (Ressler, 1992a) following a single application of EC-formulation at 250 g a.s./ha to bare soil in October. Single analytical samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-20 cm soil layer	
Pre-application	<0.05 <sup>a</sup>	
0	1.22	
31	0.98	
152	0.86	
187	0.79	
214	0.45	
244	0.42	
272	0.27	
305	0.25	
336	0.10	

<sup>a</sup> This should presumably have been given as <0.02 mg/kg which was the stated LOD (RMS's comment).

**Table B.8.1.5-3. Measured concentrations of difenoconazole in Schornbusch silt loam (Ressler, 1992b) following a single application of EC-formulation at 500 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
Pre-application	<0.02	<0.02
0	0.31	<0.02
7	0.25	<0.02
15	0.21	<0.02
30	0.07	<0.02
61	0.07	<0.02

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Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
92	0.02	<0.02
124	<0.02	<0.02

**Table B.8.1.5-4. Measured concentrations of difenoconazole in Lorsch loamy sand (Resseler, 1992c) following a single application of EC-formulation at 500 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
Pre-application	<0.02	<0.02
0	0.32	<0.02
7	0.25	<0.02
14	0.18	<0.02
46	0.14	<0.02
76	0.15	<0.02
106	0.12	<0.02
138	<0.02	<0.02

**Table B.8.1.5-5. Measured concentrations of difenoconazole in Platting-See silt loam (Resseler, 1992d) following a single application of EC-formulation at 500 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
Pre-application	<0.02	<0.02
0	0.36	<0.02
14	0.18	0.03
31	0.19	<0.02
61	0.14	<0.02
91	0.13	<0.02
130	0.10	<0.02
152	0.05	<0.02

**Table B.8.1.5-6. Dissipation rates calculated from results of four soil dissipation trials in Germany. When necessary, data was re-analysed and rates calculated in a separate report (Harvey, 2004) and further re-analysed by the RMS. Where relevant also residues below the top soil section were included in the analyses. All dissipation rates were calculated using single first order kinetics.**

Location, soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> <sup>a</sup>	Reference
Freistett silt loam <sup>b</sup>	160	532	0.853	Resseler, 1992a
Schornbusch silt loam <sup>c</sup>	22	72	0.963	Resseler, 1992b
Lorsch loamy sand <sup>d</sup>	57	189	0.817	Resseler, 1992c
Platting-See silt loam <sup>e</sup>	64	211	0.885	Resseler, 1992d

<sup>a</sup> r<sup>2</sup> represents model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

<sup>b</sup> Values calculated in original study report and repeated in Harvey (2004) were calculated using log transformed measured data resulting in DT<sub>50</sub> 111 days, DT<sub>90</sub> 368 days r<sup>2</sup> 0.812. Values in table calculated by RMS (see comment below).

<sup>c</sup> Values from Harvey, 2004. In study report (Resseler, 1992b) values calculated by first order kinetics (best fit) using log transformed data.

<sup>d</sup> Value from study report calculated by first order kinetics (best fit) were DT<sub>50</sub> 47 days, DT<sub>90</sub> 156 days, r<sup>2</sup> 0.78, using log transformed data and not reanalysed in Harvey (2004). DT<sub>90</sub> erroneously quoted as 106 days in Harvey 2004 and in Doc. M-II. Values in table calculated by RMS (see comment below).

<sup>e</sup> In Harvey (2004) it seems that fixed day 0 concentration were used in fitting which resulted in DT<sub>50</sub> 51 days, DT<sub>90</sub> 169 days, r<sup>2</sup> 0.818. In the study report "best fit" degradation rate was calculated. Values in table calculated by RMS (see comment below).

#### Comments by RMS:

The studies are of acceptable quality, however, it should be noted that according to the study report samples for biomass determination and soil characterisation were not taken at start of the trials. The re-calculation of the "best fit" dissipation rates from the original study reports is accepted by the RMS since The Scientific Committee on Plants (opinion 24 September 1999) concluded "... the work of Timme et al (1986) has now been superseded and should not be cited." However, the re-analysis presented in Harvey (2004) was not carried out in a fully consistent way; sometimes log transformed measured data was used, sometimes not, and there was no justification provided

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for this approach. For one trial the day 0 concentration seems to have been "fixed" and not included in the optimisation and there was no clear reason for this. The RMS therefore recalculated some of the DT<sub>50</sub>s and DT<sub>90</sub>s so that all values presented in the Table B.8.1.5-6 are calculated without log transformation of the data and with inclusion of the day 0 concentration in all optimisations (ModelMaker ver. 4.0 was used). As judged by visual assessment and  $r^2$  values, the fit to the measured data was generally improved by this approach. The values in the table will be used in the further assessment.

In three of the studies (Ressler, 1992b, 1992c and 1992d) the maximum difenoconazole residue found on day 0 represented 94, 96 and 108% of the theoretical dose, respectively (0.33 mg/kg, based on application of 500 g a.s./ha, distribution within 0-10 cm soil layer and bulk density 1.5 g/cm<sup>3</sup>). In these trials the LOD corresponds to 6.0-6.1% of the theoretically applied dose. In the first study (Ressler, 1992a) the results were strange; the maximum residue found on day 0 represented 1465% (!) of the calculated theoretical dose (0.083 mg/kg, based on application of 250 g a.s./ha, distribution within 0-20 cm soil layer and bulk density 1.5 g/cm<sup>3</sup>), and in this study LOD corresponds to 24% of the theoretically applied dose. In fact, the maximum residue found, 1.22 mg/kg corresponds to an application of 3660 g a.s./ha. The measured residues were quite consistent and there is no reason to believe that the maximum residue was due to e.g., an error during analysis. The RMS suggests that it is likely that an error occurred during application resulting in an application rate far exceeding the intended rate. This is supported by the relatively slow rate of dissipation observed in this particular soil (as slower rate of degradation was indicated at high test concentration in the laboratory studies).

<b>Reference:</b>	<p><b>Ressler H (2001a)</b> Field Soil Dissipation of Difenoconazole. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, Germany. Report No. 44-89 B. Syngenta File No. CGA169374/2304.</p> <p><b>Ressler H (2001b)</b> Field Soil Dissipation of Difenoconazole. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, Germany. Report No. 40-90 B. Syngenta File No. CGA169374/2306.</p> <p><b>Ressler H (2001c)</b> Field Soil Dissipation of Difenoconazole. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, Germany. Report No. 41-90 B. Syngenta File No. CGA169374/2308.</p> <p><b>Ressler H (2001d)</b> Field Soil Dissipation Rate Determination of CGA169374. RCC Umweltchemie GmbH &amp; Co. KG, Roßdorf, Germany. Report No. 42-90 B. Syngenta File No. CGA169374/2310.</p> <p><b>Harvey BR (2004)</b> Difenoconazole (CGA 169374): Summary of degradation rates in European field dissipation and residue trials. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Report No. RAJ0208B. Syngenta File No. CGA169374/2429.</p>
Test material:	EC 250 formulation (250 g difenoconazole/L).
Guideline:	BBA Guideline Part IV, 4-1, December 1986.
GLP:	No (Ressler 2001a) Yes (Ressler 2001b, c and d)

**Material and methods:**

Treatment rate:	500 or 750 g a.s./ha.
Test system:	The field dissipation of difenoconazole in soil after spray applications to bare ground was investigated at four locations in Germany. Plot size was 25 m <sup>2</sup> in each trial. Weed

	was mechanically controlled during the trials.
Applications:	<u>Gnarrenburg-Brillit, Germany (Ressler, 2001a):</u> Application on 23 May 1989 (500 g a.s./ha in 400 L water/ha). <u>Oldenburg-Altratjensdorf, Germany (Ressler, 2001b):</u> Application on 10 May 1990 (750 g a.s./ha in 400 L water/ha). <u>Pleidelsheim, Germany (Ressler, 2001c):</u> Application on 4 May 1990 (750 g a.s./ha in 400 L water/ha). <u>Rheinau-Memprechtshofen, Germany (Ressler, 2001d):</u> Application on 4 May 1990 (750 g a.s./ha in 400 L water/ha).
Weather:	<u>Gnarrenburg-Brillit, Germany (Ressler, 2001a):</u> Rainfall during May-October 1989 was 335 mm. Range of monthly average air temperatures was 11.0°C to 17.6°C. <u>Oldenburg-Altratjensdorf, Germany (Ressler, 2001b):</u> Rainfall during May-October 1990 (presumably erroneously stated as 1989) was 341 mm. Range of monthly average air temperatures was 11°C to 17°C. <u>Pleidelsheim, Germany (Ressler, 2001c):</u> Rainfall during May-October 1990 was 376 mm. Range of monthly average air temperatures was 13°C to 21°C. <u>Rheinau-Memprechtshofen, Germany (Ressler, 2001d):</u> Rainfall during May-October 1990 was 425 mm. Range of monthly average air temperatures was 11°C to 20°C.
Sampling time points:	Soil samples were taken before application and at 7-13 intervals up to 356-474 days after treatment. At each sampling date, 20 soil cores were taken, to a depth of 20 or 30 cm (though all sections were not always analysed). Samples were stored frozen (-18°C) until analysis.
Method of analysis:	Samples were cut into 10 cm sections. Sections of the same depth were combined, sieved (2 mm mesh) and homogenised. Sub-samples were first refluxed with methanol/ammonium hydroxide (4:1), followed by dilution in water and sodium chloride and partition with hexane. After concentration and clean-up, samples were analysed by GC-NPD or GC-ECD with a limit of detection (LOD) of 0.05 mg/kg. Mean procedural recoveries in fortified samples were given as 89.7±12.0% (Ressler, 2001a) or 96.5±11.0% (Ressler, 2001b, 2001c and 2001d), and the measured concentrations were not corrected for recovery.
Calculations:	First order dissipation rates were calculated by use of the curve-fitting program ModelManager ver. 1.1 and according to Timme et al <sup>5</sup> in the original study reports. To

<sup>5</sup>Timme G, Frehse H and Lasko V (1986) Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenschutzmitteln - Rückständen II. Pflanzenschutz-Nachrichten Bayer, 39, 188-204.

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provide a consistent approach the data was reanalysed when necessary in a separate report (Harvey, 2004) using ModelManager ver. 1.1.

Soil Characteristics: See Table B.8.1.5-7.

**Table B.8.1.5-7. Soil characteristics<sup>a</sup>.**

Soil designation		<b>Gnarrenburg-Brillet (Germany) Ressler, 2001a</b>	<b>Oldenburg-Altratzendorf, (Germany) Ressler, 2001b</b>	<b>Pleidelsheim (Germany) Ressler, 2001c</b>	<b>Rheinau-Memprechtshofen (Germany) Ressler, 2001d</b>
Soil type (USDA)		loamy sand	sandy loam	silt loam	silt loam
Sand (>0.05 mm)	[%]	78.0	55.0	10.9	31.6
Silt (0.002-0.05 mm)	[%]	17.8	32.3	73.3	58.9
Clay (< 0.002 mm)	[%]	4.2	12.7	15.8	9.5
pH		5.6	6.0	6.0	5.7
Organic carbon	[%]	2.4	1.4	1.2	1.0
Cation exchange capacity	[meq/100 g]	n.d.	n.d.	13	10
Maximum water holding capacity (MWHC)	[g/100 g]	43.8	43	41	47
Biomass	[mg C/100 g]	23-40	32-44	58-44	18-33

*n.d.* Not determined.

*a* In Ressler (2001a and 2001b) samples for soil characterisation were taken in May 1989, with a second measurement of biomass in October 1989, i.e. for one trial about one year prior to study start. In Ressler (2001c) samples were taken in May 1990 and for biomass determination again in October 1990. In Ressler (2001d) a first sample for biomass determination was taken in October 1989, and second sample for biomass and soil characterisation was taken in May 1990. RMS's comment.

## Results:

The measured concentrations of difenoconazole in each trial are presented in Tables B.8.1.5-8 to B.8.1.5-11. In three of the trials difenoconazole was mainly retained in the upper soil layer, with sporadic detects in the 10-20 cm soil layer. In the Rheinau-Memprechtshofen silt loam difenoconazole findings in the 10-20 cm soil layer was more frequent. In Doc. M-II it was suggested that some contamination/poor sampling may have been a contributory factor in the distribution of the residue at Rheinau-Memprechtshofen since residues were measured in the 10-20 cm section already at zero time.

Calculated rates of dissipation are presented in Table B.8.1.5-12. Where relevant, residues below the top soil section were included in the analyses.

**Table B.8.1.5-8. Measured concentrations of difenoconazole in Gnarrenburg-Brillet loamy sand (Ressler, 2001a) following a single application of EC-formulation at 500 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.05 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw		
	0-10 cm soil layer	10-20 cm soil layer	20-30 cm soil layer
Pre-application	<0.05	<0.05	<0.05
0	0.49	<0.05	<0.05
7	0.38	<0.05	<0.05
20	0.28	<0.05	<0.05
65	0.29	<0.05	<0.05
94	0.11	<0.05	<0.05
329	0.35 <sup>a</sup>	n.a.	n.a.
356	0.22 <sup>a</sup>	n.a.	n.a.

*n.a.* Not analysed.

*a* In the study report, the results from the last two sampling points were assumed to be erroneous results either of an additional application by mistake the second year or of drift from the next field plot. Both values were considered as outliers not included in the kinetic analysis.

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**Table B.8.1.5-9. Measured concentrations of difenoconazole in Oldenburg-Altrajensdorf sandy loam (Ressler, 2001b) following a single application of EC-formulation at 750 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.05 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
Pre-application	<0.05	<0.05
0	0.39	<0.05
7	0.27	0.07
15	0.24	<0.05
29	0.24	<0.05
60	0.23	<0.05
92	0.22	<0.05
123	0.21	0.10
152	0.16	0.11
315	0.18	<0.05
343	0.11	<0.05
371	0.10	<0.05
421	0.08	n.a.
474	0.07	n.a.

n.a. Not analysed.

**Table B.8.1.5-10. Measured concentrations of difenoconazole in Pleidelsheim silt loam (Ressler, 2001c) following a single application of EC-formulation at 750 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.05 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
Pre-application	<0.05	<0.05
0	0.40	<0.05
7	0.22	<0.05
14	0.22	<0.05
28	0.22	<0.05
61	0.21	<0.05
90	0.19	0.06
126	0.15	<0.05
154	0.16	<0.05
354	0.08	n.a.
385	0.14	n.a.
437	0.08	n.a.

n.a. Not analysed.

**Table B.8.1.5-11. Measured concentrations of difenoconazole in Rheinau-Memprechtshofen silt loam (Ressler, 2001d) following a single application of EC-formulation at 750 g a.s./ha to bare soil in May. Single analytical samples. LOD 0.05 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm soil layer	10-20 cm soil layer
Pre-application	<0.05	<0.05
0	0.54	0.13
7	0.34	0.16
14	0.31	<0.05
28	0.32	0.05
61	0.20	0.15
94	0.19	0.08
126	0.19	<0.05
154	0.20	<0.05
353	0.10	n.a.
385	0.11	n.a.
444 <sup>a</sup>	0.07	n.a.

n.a. Not analysed.

<sup>a</sup> An additional sample was taken in the control plot day 503 showing <0.05 mg/kg in 0-10 cm soil..

**Table B.8.1.5-12. Dissipation rates calculated from results of four soil dissipation trials in Germany. When necessary, data was re-analysed and rates calculated in a separate report (Harvey, 2004) and further re-analysed by the RMS. Where relevant also residues below the top soil section were included in the analyses. All dissipation rates were calculated using single first order kinetics.**

Location, soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> <sup>a</sup>	Reference
Gnarrenburg-Brillit loamy sand <sup>b</sup>	63	211	0.766	Ressler, 2001a
Oldenburg-Altrajensdorf sandy loam <sup>c</sup>	265	879	0.752	Ressler, 2001b
Pleidelshheim silt loam <sup>d</sup>	241	802	0.652	Ressler, 2001c
Rheinau-Memprechtshofen silt loam <sup>e</sup>	116	384	0.810	Ressler, 2001d

<sup>a</sup> r<sup>2</sup> represents model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

<sup>b</sup> Values calculated in original study report and repeated in Harvey (2004). The study report included additional "best fit" values.

<sup>c</sup> Study report as well as Harvey (2004) seems to have used fixed day 0 concentration in fitting which resulted in DT<sub>50</sub> 191 days, DT<sub>90</sub> 636 days and r<sup>2</sup> 0.563. Additional "best fit" values were included in the study report. The values in the table were calculated by the RMS (see comment below).

<sup>d</sup> Harvey(2004) seems to have used fixed day 0 concentration and log transformed values in fitting which resulted in DT<sub>50</sub> 176 days, DT<sub>90</sub> 583 days and r<sup>2</sup> 0.321. In study report a similar approach was used but without log transformation of data. In addition other "best fit" values were reported in the study report. The values presented in the table were calculated by the RMS (see comment below).

<sup>e</sup> Study report as well as Harvey (2004) seems to have used weighted data and fixed day 0 concentration in fitting which resulted in DT<sub>50</sub> 102 days, DT<sub>90</sub> 339 days and r<sup>2</sup> 0.704. The values in the table were calculated by the RMS (see comment below).

#### Comments by RMS:

The studies are considered to be of acceptable quality. As a minor comment, samples for soil characterisation including biomass determination were in some of the trials not taken at the time point when the study started.

The re-calculation of the "best fit" dissipation rates from the original study reports is accepted by the RMS since The Scientific Committee on Plants (opinion 24 September 1999) concluded "... the work of Timme et al (1986) has now been superseded and should not be cited." However, the re-analyses presented in study report and in Harvey (2004) were not carried out in a fully consistent way. In Harvey (2004) log transformed measured data was used in one case, weighted data in another, and for three of the data sets the first measurement (day 0) was not included in the optimisation. There was no justification for deviation from the most straight-forward way for optimisation (to include all data in optimisation without log transformation or other means of weighting). The RMS recalculated some of the DT<sub>50</sub>s and DT<sub>90</sub>s so that all values presented in the Table B.8.1.5-12 are calculated without log transformation of the data and with inclusion of the day 0 concentration in all optimisations (curve fitting program ModelMaker ver. 4.0 was used). As judged by the r<sup>2</sup> values and visual assessment of the plots, the fit to the observed data was improved by the RMS's approach. The values in the table will be used in the further assessment. Again, a slower rate of dissipation was indicated at high treatment rates.

The maximum difenoconazole residues found on day 0 represented 163, 78, 80 and 136% of the theoretical dose applied in the four studies, respectively. Theoretical dose was calculated to 0.33 mg/kg in Ressler (2001a) based on application of 500 g a.s./ha, distribution within 0-10 cm soil layer and bulk density 1.5 g/cm<sup>3</sup>. In Ressler (2001b and 2001c) theoretical dose was calculated to 0.5 mg/kg (application of 750 g a.s./ha), and in Ressler (2001d) it was 0.25 mg/kg, based on application of 750 g a.s./ha, distribution within 0-20 cm soil layer and bulk density 1.5 g/cm<sup>3</sup>. These deviations from the target dose are considered to be acceptable. LOD corresponds to 15, 10, 10 and

20% of the theoretical dose in the four studies. This relatively high LOD makes conclusion on the potential for movement below the upper soil layers rather uncertain.

<b>Reference:</b>	<b>Walser M (1994)</b> Field Dissipation of CGA 169374 after Bareground Application of [Phenyl- <sup>14</sup> C] CGA 169374 labelled Material. CIBA-GEIGY Limited, Division Plant Protection, Basle, Switzerland. Report No. 92CN08. Syngenta File No. CGA169374/0920. <b>Harvey BR (2004)</b> Difenoconazole (CGA 169374): Summary of degradation rates in European field dissipation and residue trials. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Report No. RAJ0208B. Syngenta File No. CGA169374/2429.
Test material:	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity >95%, Batch No. JAK-5-79. In formulation SCORE EC 250 (code: A-7402 G).
Guideline:	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 164-1. EPA, 540/9-82-021, October 1982. US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 164-1. Addendum 2 on Data Reporting. October 1986. BBA Guideline Part IV, 4-1, December 1986.
GLP:	Yes

#### Material and methods:

Treatment rate:	125 g a.s./ha.
Test system:	The field dissipation of difenoconazole and the metabolite CGA 205375 in soil after spray application to bare ground was investigated at one location in Switzerland. Difenoconazole was applied to a 4 m <sup>2</sup> plot which was also used to grow rotational crops. During the last three years before the trial several different pesticides had been used on the plot (not SCORE). The plot was hand-weeded before application and one week before application the plot was planted with Phaseli. The plot was divided in 4 sections (1 m <sup>2</sup> each) which were subsequently planted with lettuce, winter wheat, corn and sugar beet after 99, 120, 343 and 370 days, respectively.
Application:	Application was done on 4 June 1992 (125 g a.s./ha in 500 L water/ha).
Weather:	Rainfall during April 1992 to October 1993 was 1469 mm. Tap water was occasionally added in summer to avoid soil cracks. During this period the average daily maximum air temperature per month ranged from 5.1 to 28.2°C and daily minimum air temperature per month ranged from -2.3 to 15.6°C.
Sampling time points:	Soil samples were taken at 10 intervals over a period of 369 days. At each sampling date, 5 soil cores were taken to a depth of 30 cm (though all sections were not always analysed).
Method of analysis:	Samples were cut into 0-5, 5-10, 10-20 and 20-30 cm sections and air dried and homogenised before analysis. Total residues were determined by combustion of triplicates, separately for each soil core and layer. For quantification of difenoconazole and its metabolites, soil samples were extracted with methanol/water (8:2, v/v) by

shaking for at least 4 hours, repeated up to five times until the amount extracted was below 5% of the applied radioactivity. Subsequently, a Soxhlet or a microwave (harsh) extraction using methanol or methanol/water (8:2, v/v) followed. Extracts from cold extraction procedure were analysed by TLC. Reference compounds were: Difenoconazole, CGA 205375, CGA 205374 and CGA 189138. Radioactivity in the extracted soil was determined by combustion. LOD 0.001 mg/kg.

**Calculations:** Bi-phasic first order dissipation rates were calculated by use of the curve-fitting program RS/1 (Release 4.4.1) in the original study report. To provide a consistent approach the data was reanalysed in a separate report (Harvey, 2004) using ModelManager ver. 1.1.

**Soil Characteristics:** See Table B.8.1.5-13.

**Table B.8.1.5-13. Soil characteristics.**

Soil designation		Klus (Switzerland)
Soil type (USDA)		clay loam
Sand (>0.05 mm)	[%]	24.8
Silt (0.002-0.05 mm)	[%]	47.1
Clay (< 0.002 mm)	[%]	27.0
pH		7.3
Organic carbon	[%]	2.26
Cation exchange capacity	[meq/100 g]	29.6

#### Results:

Distribution of radioactivity between different soil layers is shown in Table B.8.1.5-14. Up to sampling point day 279, the great majority of the recovered radioactivity was always in the upper 0-5 cm soil section. On the last sampling point day 369, 0.039 mg/kg and 0.014 mg/kg were measured in the 5-10 and 10-20 cm sections, respectively. Radioactivity recovered from the 20-30 cm section was generally at or below the limit of detection.

Total residues and distribution and characterisation of radioactivity in the 0-10 cm soil section is summarised in Table B.8.1.5-15. The total residue levels in the 0-10 cm section fell by approximately 50% within one year. Difenoconazole decreased from 0.076 mg/kg day 0 to 0.013 mg/kg after 1 year but it still accounted for about 25% of the recovered radioactivity. The metabolite CGA 205375 was detected in the 0-10 cm soil section at a maximum of approximately 10-12% of the initial concentration of difenoconazole (0.0076 mg/kg as parent equivalents) after 182 days. The amounts declined thereafter to approximately 5% of parent initial concentration by the end of the study. CGA 205374 and CGA 189138 were both observed but only at trace amounts; maximum 0.002 mg/kg and 0.0006 mg/kg, respectively (parent equivalents).

A maximum of 6.5% of the recovered radioactivity was unidentified. Radioactivity removed by the harsh extraction was generally below 5% of the recovered radioactivity and therefore not further characterised but reached a maximum of 11.2% at the last sampling point. Unextracted radioactivity increased during the study up

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to 0.038 mg/kg after 182 days then declined to 0.027 mg/kg by the end of the study. However, as percentage of recovered radioactivity the unextracted portion remained around 50% of the radioactivity over days 182-369.

It was concluded that difenoconazole dissipated in the field with the major products being CGA 205375 and unextracted residues. The total residues were mainly retained in the 0-10 cm soil layer.

**Table B.8.1.5-14. Distribution of total residues in different sections of Klus clay loam following a single application of EC-formulation containing  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole at 125 g a.s./ha in June. Values as mg/kg (parent equivalents) and as percentage of total residues in each layer recovered at each sampling date (set to 100%). Average of five soil cores, triplicate measurements.**

Days after application		Total residues			
		0-5 cm	5-10 cm	10-20 cm	20-30 cm
0	mg/kg	0.197	n.a.	n.a.	n.a.
	%	100	n.a.	n.a.	n.a.
7	mg/kg	0.176	0.008	0.001	<0.001
	%	93.9	4.5	1.2	0.4
14	mg/kg	0.163	0.011	0.001	0.003
	%	90.9	5.1	1.1	2.9
28	mg/kg	0.192	0.025	0.006	0.001
	%	83.3	10.9	5.0	0.8
89	mg/kg	0.131	0.022	0.004	<0.001
	%	84.1	11.9	3.6	0.4
126	mg/kg	0.097	0.022	0.006	<0.001
	%	71.3	16.8	11.0	0.8
151	mg/kg	0.09	0.034	0.006	<0.001
	%	62.8	27.0	9.3	0.9
182	mg/kg	0.111	0.032	0.007	<0.001
	%	70.3	19.4	9.8	0.4
279	mg/kg	0.081	0.031	0.008	0.001
	%	62.7	22.5	13.8	0.9
369	mg/kg	0.065	0.039	0.014	0.002
	%	45.8	25.3	23.8	5.1

n.a. Not analysed.

**Table B.8.1.5-15. Measured concentrations of difenoconazole and metabolites and distribution of radioactivity in Klus clay loam (0-10 cm section) following a single application of EC-formulation containing  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole at 125 g a.s./ha in June. Values as mg/kg (parent equivalents) and as percentage of recovery at each sampling date. Figures for total residues and difenoconazole calculated as half the measured concentrations in 0-5 cm layer (day 0) or the average concentrations in 0-5 and 5-10 cm layers (days 7-369). Total residues determined in triplicate, otherwise single analytical samples.**

Days after application	Total residue mg/kg (%)	Difenoconazole mg/kg (%)	CGA 205375 mg/kg (%)	CGA 205374 mg/kg (%)	CGA 189138 mg/kg (%)	Unidentified <sup>a</sup> mg/kg (%)	Harsh extraction <sup>b</sup> mg/kg (%)	Un-extracted mg/kg (%)	Recovery mg/kg (%)
0	0.100 (100.0)	0.076 (76.2)	0.0006 (0.9)	<0.001 (0)	0.0003 (0.34)	0.0062 (6.3)	0.0026 (2.6)	0.0071 (7.2)	0.0928 (93.5)
7	0.091 (100.0)	0.065 (71.2)	0.0026 (4.0)	0.0011 (1.2)	0.0004 (0.41)	0.0060 (6.5)	0.0019 (2.1)	0.0106 (11.5)	0.0876 (96.9)
14	0.084 (100.0)	0.058 (69.0)	0.0026 (3.0)	0.0013 (1.5)	0.0004 (0.48)	0.0029 (3.3)	0.0038 (4.4)	0.0087 (10.0)	0.0777 (91.7)
28	0.095 (100.0)	0.054 (58.7)	0.0052 (6.0)	0.0020 (2.2)	0.0005 (0.57)	0.0038 (4.1)	0.0039 (4.3)	0.0161 (17.8)	0.0855 (93.7)
89	0.073 (100.0)	0.025 (33.6)	0.0070 (9.3)	0.0008 (1.0)	0.0006 (0.78)	0.0027 (3.5)	0.0049 (6.4)	0.0279 (36.5)	0.0689 (91.1)
126	0.063 (100.0)	0.020 (32.1)	0.0072 (10.0)	0.0006 (1.0)	0.0006 (0.92)	0.0010 (1.9)	0.0010 (1.6)	0.0275 (46.2)	0.0579 (93.7)
151	0.060	0.020	0.0065	0.0005	0.0005	0.0018	0.0018	0.0257	0.0568

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Days after application	Total residue mg/kg (%)	Difenoconazole mg/kg (%)	CGA 205375 mg/kg (%)	CGA 205374 mg/kg (%)	CGA 189138 mg/kg (%)	Unidentified <sup>a</sup> mg/kg (%)	Harsh extraction <sup>b</sup> mg/kg (%)	Un-extracted mg/kg (%)	Recovery mg/kg (%)
	(100.0)	(33.6)	(9.6)	(0.9)	(0.86)	(3.0)	(2.9)	(41.5)	(92.4)
182	0.071 (100.0)	0.019 (27.3)	0.0076 (11.9)	0.0008 (1.1)	0.0006 (0.80)	0.0002 (2.6)	0.0018 (2.5)	0.0377 (52.7)	0.0677 (98.9)
279	0.055 (100.0)	0.016 (28.2)	0.0060 (11.1)	0.0005 (0.8)	0.0004 (0.64)	0.0013 (2.2)	0.0028 (5.0)	0.0275 (49.1)	0.0545 (97.0)
369	0.050 (100.0)	0.013 (25.4)	0.0040 (8.8)	0.0003 (0.5)	0.0004 (0.75)	0.0012 (2.3)	0.0058 (11.2)	0.0272 (52.3)	0.0519 (101.3)

<sup>a</sup> Radioactivity unresolved on TLC.

<sup>b</sup> Soxhlet or microwave extraction.

In Harvey (2004) single first order rate of dissipation was calculated using the measurements in the 0-10 cm soil layer: DT<sub>50</sub> 83.3 days, DT<sub>90</sub> 277 days, r<sup>2</sup> 0.934 (model efficiency). In the study report DT<sub>50</sub> was calculated to 50 days using a two-compartment model.

#### Comments by RMS:

The study is of acceptable quality. The rate of dissipation presented in Harvey (2004) is used in the further assessment. The concentration of difenoconazole in the 0-5 cm section on day 0 (0.152 mg/kg) was close to the theoretical dose of 0.17 mg/kg (based on application of 125 g a.s./ha, distribution in 0-5 cm layer, bulk density 1.5 g/cm<sup>3</sup>). LOD was low, representing 0.6% of the theoretical dose. The metabolite CGA 205375 was found at max. concentration (day 182) corresponding to 12% of the initial concentration of difenoconazole, close to the maximum percentage found in laboratory studies. CGA 205374 and CGA 189138 were found in concentrations representing 2.6% and 0.8% of the initial concentration of difenoconazole.

#### Reference:

- Kühne-Thu H (1990a)** Determination of residues of parent compound in soil after treatment with 'Difenoconazole EC 250' – field experiment. CIBA-GEIGY Agrochemicals, Cambridge, UK and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2097-89. Syngenta File No. CGA 169374/0335.
- Kühne-Thu H (1990b)** Determination of residues of parent compound in soil after treatment with 'Difenoconazole EC 250' – field experiment. CIBA-GEIGY Agrochemicals, Cambridge, UK and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2096-89. Syngenta File No. CGA 169374/0336.
- Kühne-Thu H (1990c)** Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. CIBA-GEIGY Agrochemicals, Utrera (Sevilla), Spain and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2024-89. Syngenta File No. CGA 169374/0341.
- Kühne-Thu H (1990d)** Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. CIBA-GEIGY Agrochemicals, Utrera (Sevilla), Spain and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2023-89. Syngenta File No. CGA 169374/0342.
- Kühne-Thu H (1991a)** Determination of residues of parent compound in soil after treatment with 'Difenoconazole EC 250' – field experiment. CIBA-GEIGY Agrochemicals, Cambridge, UK and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2040-89. Syngenta File No. CGA 169374/0337.
- Kühne-Thu H (1991b)** Determination of residues of parent compound in soil after treatment with 'Difenoconazole EC 250' – field experiment. CIBA-GEIGY

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Test material:	Agrochemicals, Cambridge, UK and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2039-89. Syngenta File No. CGA 169374/0338.
Guideline:	<b>Harvey BR (2004)</b> Difenoconazole (CGA 169374): Summary of degradation rates in European field dissipation and residue trials. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Report No. RAJ0208B. Syngenta File No. CGA169374/2429.
GLP:	EC 250 formulation (250 g difenoconazole/L), Batch No. (formulation) P 901011.
	-
	No (field part) Yes (analytical part)

**Material and methods:**

Treatment rate:	125, 150, 375 or 800 g a.s./ha
Test system:	The field dissipation of difenoconazole in soil after spray applications to bare ground was investigated in four trials in the United Kingdom and two trials in Spain. Plot size was 6 x 25 m in UK trials, 100 m <sup>2</sup> in duplicate in Spanish trials.
Applications:	<p><u>Kings Farm, UK (Kühne-Thu, 1990a):</u> Application on 14 June 1989 (375 g a.s./ha in 200 L water/ha).</p> <p><u>Kings Farm, UK (Kühne-Thu, 1990b):</u> Application on 14 June 1989 (125 g a.s./ha in 200 L water/ha).</p> <p><u>Utrera, Spain (Kühne-Thu, 1990c):</u> Application on 6 May 1989 (800 g a.s./ha in 500 L water/ha). Three weedings (15-20 cm) were done during the trial.</p> <p><u>Utrera, Spain (Kühne-Thu, 1990d):</u> Application on 6 May 1989 (150 g a.s./ha in 500 L water/ha). Weedings (15-20 cm) were done during the trial.</p> <p><u>Hill Farm, UK (Kühne-Thu, 1991a):</u> Application on 12 June 1989 (375 g a.s./ha in 200 L water/ha).</p> <p><u>Hill Farm, UK (Kühne-Thu, 1991b):</u> Application on 12 June 1989 (125 g a.s./ha in 200 L water/ha).</p>
Weather:	<p><u>Kings Farm, UK (Kühne-Thu, 1990a and 1990b):</u> Precipitation was stated to be below normal range (total 620 mm) and temperature above normal range; average daily max. 15.1°C, min. 6.5°C.</p> <p><u>Utrera, Spain (Kühne-Thu, 1990c and 1990d):</u> Total precipitation was 900 mm, temperature stated to be "average".</p> <p><u>Hill Farm, UK (Kühne-Thu, 1991a and 1991b):</u> Precipitation was stated to be below normal range (total 557 mm) and temperature above normal range; average daily max. 16.0°C, min. 6.3°C.</p>
Sampling time points:	Soil samples were taken at 6 intervals up to 375 days after application. At each sampling date, 20 soil cores were taken to a depth of 25 or 30 cm (though all sections were not always analysed).
Method of analysis:	Soil cores were cut into 0-10, 10-20 and 20-30 cm sections as appropriate, combined,

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mixed and stored frozen. Before analysis the samples were sieved (6 mm mesh) and homogenised. Sub-samples were first refluxed with methanol/ammonium hydroxide (8:2) followed by partition either with n-hexane and acetonitrile or dichloromethane. After concentration and clean-up samples were analysed by GC-ECD. LOD was 0.02 mg a.s./kg. The method was AG-514 modified or method AG-501 modified. Recoveries in fortified samples were 87-114% (Kühne-Thu, 1990a), 101-119% (Kühne-Thu, 1990b), 103-122% (Kühne-Thu, 1990c), 95-111% (Kühne-Thu, 1990d), 87-116% (Kühne-Thu, 1991a) and 87-117% (Kühne-Thu, 1991b) and the results were not corrected for recovery.

**Calculations:** Dissipation rates were calculated using the curve-fitting program ModelManager ver. 1.1 in a separate report (Harvey, 2004).

**Soil Characteristics:** See Table B.8.1.5-16. No soil characteristics were provided for the trial in Spain, apart from soil type; sandy loam.

**Table B.8.1.5-16. Soil characteristics.**

Soil designation		Kings Farm (UK)	Hill Farm (UK)
Soil type (USDA)		clay	sandy clay
Sand (>0.05 mm)	[%]	41	50
Silt (0.002-0.05 mm)	[%]	10.5	13
Clay (< 0.002 mm)	[%]	45.5	37
pH		7.6	8.2
Organic matter	[%]	3.4	3.1
Organic carbon <sup>a</sup>	[%]	2.0	1.8

<sup>a</sup> Calculated by RMS as % organic matter/1.724.

**Results:**

Measured concentrations of difenoconazole in each trial are given in Tables B.8.1.5-17 to B.8.1.5-22. Residues of difenoconazole were predominantly recovered from the 0-10 cm soil sections. Residues in the 10-20 and 20-30 cm soil sections were either below the LOD (0.02 mg/kg soil) or just above.

Calculated rates of dissipation are presented in Table B.8.1.5-23. The calculations were based on residues in 0-10 cm soil layer since measurements in deeper layer only rarely indicated residues above LOD.

**Table B.8.1.5-17. Measured concentrations of difenoconazole in Kings Farm clay (Kühne-Thu, 1990a) after a single application of EC-formulation at 375 g a.s./ha in June. Single analytical samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm	10-20 cm
0	0.49	n.a.
30	0.58	<0.02
65	0.51	<0.02
127	0.22	<0.02
267	0.19	<0.02
372	0.11	<0.02

n.a. Not analysed.

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**Table B.8.1.5-18. Measured concentrations of difenoconazole in Kings Farm clay (Kühne-Thu, 1990b) after a single application of EC-formulation at 125 g a.s./ha in June. Single analytical samples days 267 and 372, samples from days 0-127 were reanalysed for confirmation. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm	10-20 cm
0	0.115	n.a.
30	0.09	<0.02
65	0.09	<0.02
127	0.065	<0.02
267	0.07	<0.02
372	0.02	<0.02

n.a. Not analysed.

**Table B.8.1.5-19. Measured concentrations of difenoconazole in Utrera sandy loam (Kühne-Thu, 1990c) after a single application of EC-formulation at 800 g a.s./ha in May. Average of duplicate samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw		
	0-10 cm	10-20 cm	20-30 cm
0	0.825	n.a.	n.a.
31	0.495	0.07 <sup>a</sup>	0.04
61	0.235	0.05	<0.02
125	0.205	0.02	0.02
247	0.24	<0.02	<0.02
364	0.125	0.04	<0.02

n.a. Not analysed.

<sup>a</sup> Result from single sample since one of the replicates was unexpectedly high (0.23 mg/kg, confirmed in reanalysis). Believed to be due to an erroneous exchange of samples.

**Table B.8.1.5-20. Measured concentrations of difenoconazole in Utrera sandy loam (Kühne-Thu, 1990d) after a single application of EC-formulation at 150 g a.s./ha in May. Average of duplicate samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm	10-20 cm
0	0.22	n.a.
31	0.14 <sup>a</sup>	0.03
61	0.05	0.02
125	0.035	<0.02
247	0.03	<0.02
364	0.02	<0.02

n.a. Not analysed.

<sup>a</sup> Result from single sample since one of the replicates was unexpectedly low (0.04 mg/kg, confirmed in reanalysis). Believed to be due to an erroneous exchange of samples.

**Table B.8.1.5-21. Measured concentrations of difenoconazole in Hill Farm sandy clay (Kühne-Thu, 1991a) after a single application of EC-formulation at 375 g a.s./ha in June. Single analytical samples. LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm	10-20 cm
0	0.46	n.a.
30	0.25	<0.02
66	0.29	<0.02
129	0.18	<0.02
263	0.11	<0.02
375	0.10	<0.02

n.a. Not analysed.

**Table B.8.1.5-22. Measured concentrations of difenoconazole in Hill Farm sandy clay (Kühne-Thu, 1991b) after a single application of EC-formulation at 125 g a.s./ha in June. Single analytical samples (except day 263 0-10 cm average of three analyses, and day 375 10-20 cm average of two analyses). LOD 0.02 mg/kg.**

Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm	10-20 cm
0	0.21	n.a.
30	0.08	<0.02

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Days after application	Difenoconazole residue, mg/kg dw	
	0-10 cm	10-20 cm
66	0.07	<0.02
129	0.05	<0.02
263	0.15	<0.02
375	0.03	0.02

n.a. Not analysed.

**Table B.8.1.5-23. Dissipation rates calculated from results of four soil dissipation trials in UK, and two in Spain. Data was analysed and rates calculated in a separate report (Harvey, 2004) and further re-analysed by the RMS. Residues from 0-10 cm soil layer included in the analyses. All dissipation rates were calculated using single first order kinetics.**

Location, soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> <sup>a</sup>	Reference
Kings Farm clay	156	519	0.844	Kühne-Thu, 1990a
Kings Farm clay <sup>b</sup>	227	755	0.827	Kühne-Thu, 1990b
Utrera sandy loam	53.7	178	0.777	Kühne-Thu, 1990c
Utrera sandy loam <sup>c</sup>	38.4	128	0.937	Kühne-Thu, 1990d
Hill Farm sandy clay	133	442	0.840	Kühne-Thu, 1991a
Hill Farm sandy clay <sup>d</sup>	272	905	0.190	Kühne-Thu, 1991b

<sup>a</sup> r<sup>2</sup> represents model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

<sup>b</sup> Harvey (2004) used weighted data which resulted in DT<sub>50</sub> 162 days, DT<sub>90</sub> 537 days and r<sup>2</sup> 0.879. The values in the table were calculated by the RMS (see comments below).

<sup>c</sup> Harvey (2004) used an erroneous value for sampling day 31 (0.185 mg/kg) which resulted in DT<sub>50</sub> 45.9 days, DT<sub>90</sub> 151 days and r<sup>2</sup> 0.886. The values in the table were calculated by the RMS.

<sup>d</sup> Due to the high residue on sampling day 263 (0.15 mg/kg) there was a poor fit to the data. Exclusion of this data point resulted in DT<sub>50</sub> 38.6 days, DT<sub>90</sub> 128.3 days and r<sup>2</sup> 0.836. There is however no obvious reason to treat the day 263 value as an outlier (being the average of three analysis). Due to the poor fit the result from this trial will not be used in the further assessment.

#### Comments by RMS:

The studies were briefly reported but are considered acceptable as supplementary data. The dissipation rates in Table B.8.1.5-23 are used in the further assessment with the exception of the dissipation rate calculated for the trial at Hill Farm at low dose (Kühne-Thu 1991b), for which the optimised rate constant is considered as unreliable (poor visual fit and low r<sup>2</sup> 0.19). For two of the other trials the RMS recalculated the data because in one case an erroneous value was used for the original kinetic analysis and in another case measured data were weighted, without any justification provided, and with only a marginal improvement of the fit as a result.

Theoretical dose was calculated to 0.25 mg/kg, 0.083 mg/kg, 0.53 mg/kg, 0.1 mg/kg, 0.25 mg/kg and 0.083 mg/kg for the trials in Kühne-Thu 1990a-d and Kühne-Thu 1991a-b, respectively, based on application rate, distribution in 0-10 cm soil section and bulk density of 1.5 g/cm<sup>3</sup>. The maximum difenoconazole residues found, usually on day 0, represented 232, 138, 155, 220, 184 and 252% of the theoretical dose applied in the six trials, respectively. The deviations from the theoretical dose were sometimes high and may indicate problems at application or measurement, however, field studies often show some deviation from nominal dose and the calculated dissipation rates are considered acceptable as supportive data. LOD corresponds to 8, 24, 3.8, 20, 8 and 24% of the theoretical dose in the six trials, respectively. This sometimes high LOD in relation to dose makes conclusion on the potential for movement below the upper soil layers rather uncertain for some of the trials.

<b>Reference:</b>	<b>Kühne-Thu H (1992a)</b> Determination of residues of difenoconazole in asparagus and soil – field trial. CIBA-GEIGY Agrochemicals, Castenaso (BO), Italy and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2056-90. Syngenta File No. CGA 169374/0695.
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	<p><b>Kühne-Thu H (1992b)</b> Determination of residues of difenoconazole (CGA169374) in soil of sugar beet field – field trial. Bettinardi, Sarmego (VI), Las Morenas, Italy and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2054-90. Syngenta File No. CGA 169374/0696.</p> <p><b>Kühne-Thu H (1992c)</b> Determination of residues of difenoconazole (CGA169374) in soil of sugar beet field – field trial. Bettinardi, Sarmego (VI), Las Morenas, Italy and CIBA-GEIGY AG, Agro Division, Basel, Switzerland. Report No. RR-2149-90. Syngenta File No. CGA 169374/0694.</p> <p><b>Harvey BR (2004)</b> Difenoconazole (CGA 169374): Summary of degradation rates in European field dissipation and residue trials. Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, UK. Report No. RAJ0208B. Syngenta File No. CGA169374/2429.</p>
Test material:	SCORE EC 250 formulation (250 g difenoconazole/L).
Guideline:	-
GLP:	No (field part) Yes (analytical part)

### Material and methods:

Treatment rate:	6 x 125 g a.s./ha, 3 x 50 g a.s./ha, 3 x 100 g a.s./ha
Test system:	Field dissipation of difenoconazole in soil after multiple spray applications to cultivations of asparagus and sugar beets was investigated in three trials in Italy. Plot size was 10 or 12 m <sup>2</sup> in each trial.
Applications:	<p><u>Castenaso, Italy (Kühne-Thu, 1992a):</u></p> <p>Six applications from 3 July to 23 August 1990 at about 10-day intervals (6 x 125 g a.s./ha in 1000 L water/ha, in total 750 g a.s./ha) to asparagus. At the first application stage of development of the crop was 40 cm, at the last application 80 cm. Harvest was on 6 May 1991 (day 256 after the last application).</p> <p><u>Las Morenas, Italy (Kühne-Thu, 1992b):</u></p> <p>Three applications from 12 July to 10 August 1990 at 2-week intervals (3 x 50 g a.s./ha in 600 L water/ha, in total 150 g a.s./ha) to sugar beet. At all three applications, the development stage of the crop was given as 47-48 ZD (Zadok's decimal code).</p> <p><u>Las Morenas, Italy (Kühne-Thu, 1992c):</u></p> <p>Three applications from 12 July to 10 August 1990 at 2-week intervals (3 x 100 g a.s./ha in 600 L water/ha, in total 300 g a.s./ha) to sugar beet. At all three applications, the development stage of the crop was given as 47-48 ZD (Zadok's decimal code).</p>
Weather:	Precipitation and temperature was stated to be within the normal range over all three studies.
Sampling time points:	Soil samples were taken at 6 intervals up to 189 or 302 days after the last application. Samples were taken to a depth of 30 cm. Number of samples taken at each sampling interval was not stated.
Method of analysis:	Soil samples were stored frozen. Prior to analysis the samples were cut into 10 cm sections and mixed. Sub-samples were refluxed with methanol/ammonium hydroxide

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(8:2) and diluted with water and sodium chloride. Medium used for partitioning was not clearly stated. Samples were analysed by GC-ECD. LOD was 0.02 mg a.s./kg. Method AG-575 A modified was used. Recoveries in fortified samples of soil were 99-101% (Kühne-Thu, 1992a). In the two other trials the matrix (soil or crop) for the recovery of fortified samples was not clearly stated. None of the studies corrected the results for recovery.

**Calculations:** In a separate report (Harvey, 2004) dissipation rates were presented, calculated using the curve-fitting program ModelManager ver. 1.1.

**Soil Characteristics:** Castenaso, Italy (Kühne-Thu, 1992a):

Loam soil (32% sand, 44% silt, 24% clay).

Las Morenas, Italy (Kühne-Thu, 1992b and 1992c):

Sandy clay loam.

**Results:**

Measured concentrations of difenoconazole in each trial are given in Tables B.8.1.5-24 to B.8.1.5-26. Again, residues of difenoconazole were predominantly recovered from the 0-10 cm soil sections. Residues in the 10-20 and 20-30 cm soil sections were either below the LOD (0.02 mg/kg soil) or just above. In the trials at Las Morenas difenoconazole residues were <LOD at 60 days and thereafter in the 0-10 cm section.

Calculated rates of dissipation are presented in Table B.8.1.5-27, based on measurements in 0-10 cm soil section.

**Table B.8.1.5-24. Measured concentrations of difenoconazole in Castenaso loam (Kühne-Thu, 1992a) following six applications of EC-formulation to asparagus from July to August, each one as 125 g a.s./ha (total 750 g a.s./ha). Single analytical samples. LOD 0.02 mg/kg.**

Days after the last application	Difenoconazole residue, mg/kg dw		
	0-10 cm soil layer	10-20 cm soil layer	20-30 cm soil layer
0	0.39	<0.02	0.02
32	0.50	0.07	<0.02
61	0.49	<0.02	<0.02
92	0.30	<0.02	<0.02
183	0.23	<0.02	<0.02
302	0.12	0.03	<0.02

**Table B.8.1.5-25. Measured concentrations of difenoconazole in Las Morenas sandy clay loam (Kühne-Thu, 1992b) following three applications of EC-formulation to sugar beet from July to August, each one as 50 g a.s./ha (total 150 g a.s./ha). Single analytical samples. LOD 0.02 mg/kg.**

Days after the last application	Difenoconazole residue, mg/kg dw		
	0-10 cm soil layer	10-20 cm soil layer	20-30 cm soil layer
0	0.05	<0.02	<0.02
31	0.03	0.02	<0.02
60	<0.02	<0.02	<0.02
90	<0.02	<0.02	<0.02
189	<0.02	<0.02	<0.02

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**Table B.8.1.5-26. Measured concentrations of difenoconazole in Las Morenas sandy clay loam (Kühne-Thu, 1992c) following three applications of EC-formulation to sugar beet from July to August, each one as 100 g a.s./ha (total 300 g a.s./ha). Single analytical samples. LOD 0.02 mg/kg.**

Days after the last application	Difenoconazole residue, mg/kg dw		
	0-10 cm soil layer	10-20 cm soil layer	20-30 cm soil layer
0	0.05	0.02	0.02
31	0.09	<0.02	<0.02
60	<0.02	<0.02	<0.02
90	<0.02	<0.02	<0.02
189	<0.02	<0.02	<0.02

**Table B.8.1.5-27. Dissipation rates calculated from results of three soil dissipation trials in Italy. Data was analysed and rates calculated in a separate report (Harvey, 2004) and further re-analysed by the RMS. Residues measured in the 0-10 cm soil section were included in the analyses. All dissipation rates were calculated using single first order kinetics.**

Location, soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> <sup>a</sup>	Reference
Castenaso loam <sup>b</sup>	181	602	0.750	Kühne-Thu, 1992a
Las Morenas sandy clay loam <sup>c</sup>	-	-	-	Kühne-Thu, 1992b
Las Morenas sandy clay loam <sup>d</sup>	-	-	-	Kühne-Thu, 1992c

<sup>a</sup> r<sup>2</sup> represents model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

<sup>b</sup> Harvey (2004) used log transformed data which resulted in DT<sub>50</sub> 152 days, DT<sub>90</sub> 504 days and r<sup>2</sup> 0.888 (coefficient of determination). The values in the table were calculated by the RMS (see comments below).

<sup>c</sup> Harvey (2004) set residues for days 60-180 to 0.01 mg/kg (LOD/2) resulting in DT<sub>50</sub> 35.7 days, DT<sub>90</sub> 119 days and r<sup>2</sup> 0.909. See comment below.

<sup>d</sup> Harvey (2004) set residues for days 60-180 to 0.01 mg/kg (LOD/2) resulting in DT<sub>50</sub> 57.3 days, DT<sub>90</sub> 190 days and r<sup>2</sup> 0.436. See comment below.

#### Comments by RMS:

The studies were briefly reported and are considered acceptable only as supplementary data. The dissipation rate for the Castenaso soil seems to have been calculated using log transformed data in Harvey (2004). There was no justification provided for this. To keep a consistent approach the RMS recalculated the data in the table above without log transformation. In Las Morenas residues >LOD were only measured at two sampling intervals. It is not considered appropriate to include three sequential measurements <LOD in the kinetic analysis and the other alternative, to include only the first measurement <LOD, would leave too few sampling points to provide a reliable DT<sub>50</sub>. No conclusion on dissipation rate can be drawn from these two trials. The DT<sub>50</sub> for Castenaso soil given in the table above will be used in the further assessment.

In the trial at Castenaso the maximum difenoconazole residue found on day 32 represented 100% of the theoretical dose (calculated from the application rate, distribution in 0-10 cm soil section and bulk density of 1.5 g/cm<sup>3</sup>). LOD corresponded to 4% of the theoretically applied dose. In the two trials at Las Morenas the maximum concentrations of difenoconazole represented only 45 and 50% of the theoretically applied dose which probably reflect the development of the crop. LOD corresponded to 20 and 45% of the theoretical dose in each trial.

#### Reference:

**Purdy J (1997)** Dissipation and leaching movement of CGA 169374 residues in soil after application as a seed treatment on wheat seed. Novartis Crop Protection Inc., Mississauga, Ontario, Canada and Envirotech Laboratory, Edmonton, Alberta, Canada. Report No. CER 05306/94. Syngenta File No. CGA169374/1423.  
**Harvey BR (2004)** Difenoconazole (CGA 169374): Summary of degradation rates in European field dissipation and residue trials. Syngenta, Jealott's Hill International

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Test material:	Research Centre, Bracknell, Berkshire, UK. Report No. RAJ0208B. Syngenta File No. CGA169374/2429.
Guideline:	DIVIDEND 360 FS formulation (FL 940824) (35.6% w/w difenoconazole), Batch No. (formulation) 328-189.
GLP:	-
	Yes

### Material and methods:

Treatment rate: Nominal 240 mg a.s./kg seed (4 x the representative treatment rate), corresponding to 36-40 g a.s./ha.

Test system: The persistence and leaching of difenoconazole was measured in soil after application as Dividend 360 FS seed treatment on wheat seed at four trial sites across the prairie region of Western Canada. The trials were run for two seasons. Since the soil was not cultivated in the second season, the study was considered to represent a worst-case scenario for persistence.

The design for this study is based on application of the test substance on viable treated seed, so that the effects of the seed on the initial deposition of residues and the dispersion of residues in the soil profile would be included in the results, in addition to the environmental factors. As a result, the test application area was the area within the seed rows in each plot rather than uniform distribution across the treated plot area.

Applications: At each site, three plots were laid out on bare, well cultivated ground. One plot was planted with untreated wheat seed and two plots with treated seed.

The crop was allowed to grow and was maintained as for normal production.

#### Portage La Prairie, Manitoba:

Application on 27 May 1994; 161 kg seed/ha with 246 mg a.s./kg seed (39.5 g a.s./ha). 22.4 m<sup>2</sup> seeded/plot, row spacing 20 cm, planting depth approx. 3 cm.

Tralkoxydim, Bromoxynil/MCPA and Target herbicide were applied in May/June 1994.

#### Aberdeen, Saskatchewan:

Application on 24 May 1994; 150 kg seed/ha with 246 mg a.s./kg seed (36.9 g a.s./ha). 29.5 m<sup>2</sup> seeded/plot, row spacing 15 cm, planting depth approx. 2.5 cm.

Tralkoxydim was applied in June 1994.

#### Regina, Saskatchewan:

Application on 29 May 1995; 200 kg seed/ha with 180 mg a.s./kg seed (36.0 g a.s./ha). 19.2 m<sup>2</sup> seeded/plot, row spacing 17 cm, planting depth approx. 5-6 cm.

No other pesticides were used in 1995.

#### Calgary, Alberta:

Application on 27 May 1995; 204 kg seed/ha with 180 mg a.s./kg seed (36.0 g a.s./ha). 18.8 m<sup>2</sup> seeded/plot, row spacing 17 cm, planting depth approx. 1-2.5 cm.

Buctril was applied post-emergence 1995.

WARNING: This document forms part of an EC evaluation data (EC number should be inserted). Registration must not be granted on the basis of this document.

Weather:	<p><u>Portage La Prairie, Manitoba (10 km from weather station):</u></p> <p>Average monthly air temperature was 12.2°C in May 1994, increased to 18.4°C in July and decreased to -13.8°C in Jan. 1995. Highest monthly average was 19.5°C in June and July 1995. Precipitation May 1994-April 1995: 515 mm; May 1995-Oct. 1995: 262 mm.</p> <p><u>Aberdeen, Saskatchewan (40 km from weather station):</u></p> <p>Average monthly air temperature was 11.1°C in May 1994, increased to 17.5°C in July (highest monthly average during the study) and decreased to -14.6°C in Jan. 1995. Precipitation May 1994-April 1995: 406 mm; May 1995-Sept. 1995: 214 mm.</p> <p><u>Regina, Saskatchewan (5 km from weather station):</u></p> <p>Average monthly air temperature was 10.4°C in May 1995, increased to 18.5°C in July and decreased to -21.6°C in Jan. 1996. Highest monthly average was 19.1°C in Aug. 1996. Precipitation May 1995-April 1996: 520 mm; May 1996-Sept. 1996: 204 mm.</p> <p><u>Calgary, Alberta (25 km from weather station):</u></p> <p>Average monthly air temperature was 9.3°C in May 1995, increased to 15.5°C in July and decreased to -15.7°C in Jan. 1996. Highest monthly average was 16.9°C in Aug. 1996. Precipitation May 1995-April 1996: 454 mm; May 1996-Sept. 1996: 222 mm.</p>
Sampling time points:	<p>Soil samples were taken before application and at 10-11 intervals up to 505 days after treatment. The final set of samples at the trial sites in Regina and Calgary was collected after cultivation of the plots.</p> <p>The samples for each date were collected by taking at least 10 soil cores in a regular grid pattern directly in the seed rows within each plot. With the exception of day 0 samples (0-10 cm), all samples were taken to a depth of 50-60 cm (Ø 3.5 or 5 cm), and cut into 10 cm increments. Samples from each depth range from the same plot were combined. Hence, two sets of samples were processed further for each date and location. Analysis was performed in duplicate (day 0 samples in 4 replicates).</p>
Method of analysis:	<p>Soil samples were dried and processed with a soil grinder. Soil samples were extracted with 20% concentrated NH<sub>4</sub>OH/methanol under reflux, cooled to room temperature and centrifuged. An aliquot was partitioned with water/NaCl and twice with 30 % acetone/dichloromethane and dried with Na<sub>2</sub>SO<sub>4</sub>. The combined organic extract was then evaporated to dryness, dissolved with dichloromethane and analysed by GC/MS (LOQ 0.005 mg/kg). For analysis of metabolite CGA 205375, the organic extract was dissolved in acetonitrile/water, centrifuged, filtered and analysed by HPLC/MS (LOQ 0.005 mg/kg). Mean procedural recovery of difenoconazole in fortified samples were 75-100% (average 87±8.5%). Mean procedural recovery of CGA 205375 in fortified samples were 78-97% (average 86±8.3%). The results were not corrected for recovery. Vegetation samples were also collected and analysed for difenoconazole in grain, straw and foliage by GC/MS (LOQ 0.05 mg/kg). Those results are not further</p>

considered here.

Calculations: First order dissipation rates were calculated by linear regression (Excel 5.0 software).

Soil Characteristics: See Table B.8.1.5-28.

**Table B.8.1.5-28. Soil characteristics.**

Soil designation		Portage La Prairie (Manitoba)	Aberdeen (Saskatchewan)	Regina (Saskatchewan)	Calgary (Alberta)
Soil type (USDA) <sup>a</sup>		clay	clay loam	clay	clay loam
Sand (>0.05 mm)	[%]	14.5	30.6	7.5	35.8
Silt (0.002-0.05 mm)	[%]	32.0	37.3	16.4	35.7
Clay (< 0.002 mm)	[%]	53.5	32.2	76.2	28.4
pH		7.7	6.6	8.3	6.1
Organic matter	[%]	7.2	6.1	3.3	7.4
Organic carbon <sup>b</sup>	[%]	4.2	3.5	1.9	4.3
Bulk density	[g/cm <sup>3</sup> ]	1.15	1.20	1.34	0.93
Slope	[%]	0	1	0	0
Depth to water table	[m]	5.5	3.4	43	20

*a* Soil type in Aberdeen and Calgary was given as loam in study report.

*b* Calculated by RMS as % organic matter/1.724.

## Results:

The measured concentrations of difenoconazole and metabolite CGA 205375 at the four sites are presented in Tables B.8.1.5-29 to B.8.1.5-32. The results from the 10-20 cm soil segment are not shown in the tables since apart from four isolated occasions at which difenoconazole was measured (0.013 mg/kg day 1 and 27 at Aberdeen; 0.006 mg/kg day 120 at Regina, and 0.012 mg/kg day 366 at Regina) no residues were detected.

Calculated rates of dissipation are presented in Table B.8.1.5-33. Although clearly defined dissipation curves were obtained at all four sites it was noted that data was more variable in the time shortly after treatment. This may have been caused by localisation of residues around the seeds in the samples. However the amount of residue around each seed was also highly variable, and the residue levels did not correlate to the number of seeds present. Replicate analysis was done to reduce the impact of this variability. For Portage La Prairie and Regina a prominent delay of a week or more before degradation started was noted and supplementary dissipation rates excluding the first data points were provided in the study report.

The dissipation rate levelled off at the end of the first year (winter) and residues persisted in uncultivated soil until the fall of the second year. At the two trial sites where cultivation was done at the end of the study (Regina and Calgary), the residues decreased to levels at or below the limit of detection (with mean levels >LOQ). The presence of detectable residues after cultivation was attributed to persistence of localized residues on the seed coat. The inclusion of the residual seed coats in a sub-sample taken for analysis led to detectable residues.

The appearance of the metabolite CGA 205375 showed that biodegradation occurred at all four sites. CGA 2053 75 appeared after 1-3 weeks and reached maximum of up to 0.02 mg/kg. The metabolite was not detected in the samples from the second season. Neither the parent compound nor the metabolite were found to leach significantly below 10 cm.

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**Table B.8.1.5-29. Measured concentrations of difenoconazole and CGA 205375 in Portage Le Prairie clay (0-10 cm soil section) after a single application of difenoconazole as seed treatment at 40 g a.s./ha in May. Average of duplicate analysis of samples from duplicate plots (day 0; 4 analyses of samples from duplicate plots). LOQ 0.005 mg/kg.**

Days after application	Difenoconazole mg/kg dw	CGA 205375 mg/kg dw
0	0.20	<0.005
1	0.24	<0.005
5	0.19	<0.005
24	0.22	0.021
32	0.23	0.008
62	0.12	0.010
96	0.071	0.013
120	0.053	0.004
357	0.090	<0.005
489	0.030	<0.005

**Table B.8.1.5-30. Measured concentrations of difenoconazole and CGA 205375 in Aberdeen clay loam (0-10 cm soil section) after a single application of difenoconazole as seed treatment at 37 g a.s./ha in May. Average of duplicate analysis of samples from duplicate plots (day 0; 4 analyses of samples from duplicate plots). LOQ 0.005 mg/kg.**

Days after application	Difenoconazole mg/kg dw	CGA 205375 mg/kg dw
0	0.29	n.a.
1	0.22	<0.005
3	0.21	n.a.
7	0.15	0.003
14	0.14	<0.005
27	0.15	0.004
63	0.029	<0.005
93	0.057	0.009
121	0.023	<0.005
353	<0.015	<0.005
505	<0.015	<0.005

n.a. Not analysed.

**Table B.8.1.5-31. Measured concentrations of difenoconazole and CGA 205375 in Regina clay (0-10 cm soil section) after a single application of difenoconazole as seed treatment at 36 g a.s./ha in May. Average of duplicate analysis of samples from duplicate plots (day 0; 4 analyses of samples from duplicate plots). LOQ 0.005 mg/kg.**

Days after application	Difenoconazole mg/kg dw	CGA 205375 mg/kg dw
0	0.32	<0.005
2	0.35	<0.005
4	0.32	<0.005
11	0.40	0.017
28	0.27	0.018
73	0.16	0.015
120	0.10	0.015
366	0.076 <sup>b</sup>	<0.005
499	0.038 <sup>b</sup>	<0.005
500 <sup>a</sup>	<0.005	<0.005

<sup>a</sup> Last sample collected after cultivation of plot.

<sup>b</sup> Mean measured concentration day 366 was given as 0.24 mg/kg in summary table in study report and in Doc. M-II. However, from table showing the individual results it was noted that two sub-samples were biased high by presence of seeds. In addition, the sub-samples without seeds seemed to have been excluded from the mean. The RMS therefore re-calculated the mean measured concentration excluding the values from the sub-samples with seeds. A similar incidence was noted for day 499 samples; mean was given as 0.14 mg/kg in study report summary and Doc. M-II. The RMS re-calculated also this value excluding measurement biased high by presence of seed.

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**Table B.8.1.5-32. Measured concentrations of difenoconazole and CGA 205375 in Calgary clay loam (0-10 cm soil section) after a single application of difenoconazole as seed treatment at 36 g a.s./ha in May. Average of duplicate analysis of samples from duplicate plots (day 0; 4 analyses of samples from duplicate plots). LOQ 0.005 mg/kg.**

Days after application	Difenoconazole mg/kg dw	CGA 205375 mg/kg dw
0	0.48	<0.005
2	0.35	<0.005
4	0.25	<0.005
14	0.28	0.007
30	0.17	0.008
76	0.10	<0.005
118	0.09	<0.005
367	0.04	<0.005
502	0.07	<0.005
503 <sup>a</sup>	<0.005	<0.005

*a* Last sample collected after cultivation of plot.

**Table B.8.1.5-33. Dissipation rates calculated from results of four soil dissipation trials in Canada, based on measurements in the 0-10 cm soil section. Data was re-analysed by the RMS. All dissipation rates were calculated using single first order kinetics.**

Location, soil	DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup> <sup>a</sup>
Portage La Prairie clay <sup>b</sup>	87	289	0.741
Aberdeen clay loam <sup>c</sup>	28	92	0.895
Regina clay <sup>d</sup>	76	254	0.902
Calgary clay loam <sup>e</sup>	34	114	0.821

*a* r<sup>2</sup> represents model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

*b* In the study report dissipation rate was calculated to DT<sub>50</sub> 58 days and DT<sub>90</sub> 193 days (r<sup>2</sup> 0.893) using data from sampling points day 0-120. These values were also reported in Doc. M-II. The study report also gave a DT<sub>50</sub> of 41 days calculated on data from sampling points 32-120, since the data suggested a delay before dissipation started. The values in the table were calculated by the RMS using data from all sampling points (see comments below).

*c* In the study report dissipation rate was calculated to DT<sub>50</sub> 35 days and DT<sub>90</sub> 116 days (r<sup>2</sup> 0.857) using data from sampling points day 0-121. These values were also reported in Doc. M-II. The values in the table were calculated by the RMS including also the data from sampling point day 353 (set to 0.015/2) (see comments below).

*d* In the study report dissipation rate was calculated to DT<sub>50</sub> 71 days and DT<sub>90</sub> 236 days (r<sup>2</sup> 0.954) using data from sampling points day 0-120. These values were also reported in Doc. M-II. The study report also gave a DT<sub>50</sub> of 63 days calculated on data from sampling points 11-128, since the data suggested a delay before dissipation started. The values in the table were calculated by the RMS using data from all sampling points prior to cultivation, i.e. including data from days 0-499 and using the corrected values for days 366 and 499 (see comments below and note to Table 8.1.5-31).

*e* In the study report dissipation rate was calculated to DT<sub>50</sub> 49 days and DT<sub>90</sub> 163 days (r<sup>2</sup> 0.881) using data from sampling points day 0-118. These values were also reported in Doc. M-II. The values in the table were calculated by the RMS using data from all sampling points prior to cultivation, i.e. including data from days 0-502 (see comments below).

### Comments by RMS:

The study is of acceptable quality. The formulation used was not identical with DIVIDEND 030 FS but this is not considered to be of importance for the results. In the study report dissipation rates were calculated for the first season including only data points over the first four months. The RMS sees no reason to omit data from sampling points from the second season (the potential reduction in biological activity of soils sometimes encountered at the laboratory should not be a problem in field studies). To make use of all the data and to allow comparison with other field dissipation results the RMS therefore recalculated the dissipation rates including data from all sampling points (first value <0.015 mg/kg at Aberdeen entered as 0.015/2). For the Regina and Calgary results, data from samples collected after cultivation of soils were omitted from the analyses. ModelMaker ver. 4 was used and for consistency non-linear regression. Data from the initial sampling points at Portage La Prairie and Regina were included in the analyses since the apparent delay in degradation observed for these sites may have been due to the natural variability in residues during the initial phase of the trials. The resulting dissipation rates in the table above are considered useful for the assessment of seed treatments.

One-three seeds were often included in the sub-samples analysed. The RMS agrees to the inclusion of the measurements from these sub-samples in the calculation of mean residues to reflect realistic conditions. However, for two sampling points in the Regina soil, the residues were reported as being biased high due to the presence of seeds and the additional sub-samples taken on the same days were (presumably erroneously) excluded from the mean. The RMS corrected these two mean values by including the results from sub-samples without seeds, and excluding those with (see note to Table 8.1.5-31).

Calculation of max. measured residue and LOD as percentages of theoretical dose is not meaningful since sampling was carried out within the rows (i.e. measured residues were >> than the theoretical doses based on assumption of uniform distribution of hectare dose).

#### B.8.1.6 Freezer storage stability studies

<b>Reference:</b>	<b>Beidler WT (1991)</b> Stability of CGA-169374 residues in soil under freezer storage conditions for two years. CIBA-GEIGY Research Farm, Columbia, NY, USA; CIBA-GEIGY Corporation, Agricultural Division, Greensboro, NC, USA and BioAnalytika Laboratories, Raleigh, NC, USA. Report No. ABR-90068. Syngenta File No. CGA169374/0451.
Test material:	Difenoconazole: Purity 95.6%, Batch No. S85-0812.
Guideline:	-
GLP:	Yes

#### Material and methods:

Test concentration:	0.50 mg/kg (dw)
Test system:	Soil samples were fortified with difenoconazole and stored in a freezer along with untreated control samples at approximately -20°C for up to 2 years.
Sampling time points:	Immediately after fortification and after 1, 3, 6, 14, 18 and 24 months. Immediately after fortification, one control and two fortified samples were analysed. At later intervals, two fortified and two control samples were removed from the freezer and analysed after freshly fortifying one of the controls.
Method of analysis:	Analysis involved reflux extraction with methanol/ammonium hydroxide (4:1) and partition with dichloromethane. The amounts of difenoconazole were determined by GC-NPD with a LOD of 0.05 mg/kg. (Method AG-501 and AG-501 modified.)
Soil Characteristics:	Not provided (reference was made to a field study which was not further identified).

#### Results:

The recovery of difenoconazole in the freezer-stored soil samples averaged 125% (SD = 8.3, n=14) as compared to an average recovery of 122% (SD = 7.2, n=8) for the freshly fortified samples. In all freshly fortified as well as stored fortified samples the measured residues were within the range 0.55 to 0.69 mg/kg.

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It was concluded that difenoconazole residues are stable in soil stored at -20°C for at least up to 2 years.

**Comments by RMS:**

The study is of acceptable quality. The results show that storage of soil samples for at least up to 2 years under frozen conditions does not influence on the measured residues of difenoconazole.

<b>Reference:</b>	<b>Shadrick BA, Bloomberg AM and Helfrich KK (1999)</b> Freezer storage stability of 1H-1,2,4-triazole [3,5- <sup>14</sup> C] in soil. Bayer Corporation, Kansas City, USA. Report No. 108303. Syngenta File No. CGA71019/0068.
Test material:	CGA 71019 (1H-1,2,4-triazole, more specifically 1H-1,2,4-triazole), 3,5- <sup>14</sup> C-radiolabel: Radiochemical purity 99.1%, Batch No. C-485.
Guideline:	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 164-1. EPA, 540/9-82-021, October 1982.
GLP:	Yes

**Material and methods:**

Test concentration:	10.3 mg/kg (dw)
Test system:	Storage stability of <sup>14</sup> C-CGA 71019 in soil under freezer conditions was investigated. Treated samples and control samples were stored for 42 months (1258 days) at between -25 and -30°C.
Sampling time points:	Duplicate samples were analysed immediately after treatment and at 1, 3, 6, 12, 21 and 42 months after treatment. At each sampling interval, except day 0, a control sample was spiked with CGA 71019 and extracted concurrently with the treated samples.
Method of analysis:	Analysis involved repeated extraction with methanol/water (4:1) followed by extraction with methanol/NH <sub>4</sub> OH aqueous (7:3). Extracts were radioassayed by LSC and sub-samples were subject to TLC analysis (except samples from 1 and 3 months). Some samples were also analysed by HPLC. Remaining <sup>14</sup> C residues in solids were quantified by LSC after combustion.
Soil Characteristics:	A loamy sand (0.6% OM, pH 4.5) from Fresno, California, was used.

**Results:**

The total radioactive residues recovered was within the range 96.6-110.3% of the applied radioactivity throughout the study. The percentage of applied radioactivity recovered as 1,2,4-triazole averaged 96.3% over the study and was 94.6% in the fortified 42 month samples.

Analysis with HPLC with little or no sample concentration showed an average of 97% corresponding to the 1,2,4-triazole peak. The HPLC analysis showed that the test substance to some extent was volatilised during evaporation.

It was concluded that 1,2,4-triazole remained stable for the duration (42 months) of the study.

**Comments by RMS:**

The study is of acceptable quality. The results show that storage of soil samples for at least up to 3.5 years under frozen conditions does not influence on the measured residues of 1,2,4-triazole.

**B.8.1.7 Soil accumulation studies**

<b>Reference:</b>	<b>Tack TJ (1995)</b> The determination of difenoconazole (CGA 169374) residues in soil after successive applications of A7402G 250EC containing 250 g ai CGA 169374 applied as a foliar application to winter wheat and bare soil for three years. Ciba Agriculture, Hill Farm Road, Whittlesford, Cambridge, UK. Report No. CSTR 01:11. Syngenta File No. CGA169374/1205.
Test material:	PLOVER 250 EC formulation (A-7402 G) (250 g difenoconazole/L).
Guideline:	-
GLP:	Yes

**Material and methods:**

Treatment rate:	75 g a.s./ha and 150 g a.s./ha
Test system:	Potential for accumulation of difenoconazole residues in soil after annual applications to bare soil or winter wheat at two different sites in the UK was investigated over three years. There were two treated plots at each site treated at different rates (eight treated plots in total plus control plots).
Applications:	Annual applications in June-July at two different rates in different plots, both to bare ground and winter wheat.
Weather:	Graphical presentations of min and max temperature and rainfall were included in the study report (data from Whittlesford and Elmdon).
Sampling time points:	Samples were taken to a depth of 10 cm. Samples were stored frozen until analysis.
Method of analysis:	Samples were extracted with acetonitrile and cleaned up on a phenyl solid phase, eluted with methanol or diethyl ether and partitioned with hexane/ether (4:1, v/v) or tertiary butyl methyl ether. Analysis was by GC-ECD with an LOD of 0.02 mg as/kg. Method REM 7/86 with minor modifications was used. Mean procedural recovery of fortified samples was 86.5% (SD 13.23%, n=22) and the results were not corrected for recovery.
Calculations:	None performed, calculation of DT <sub>50/90</sub> not relevant.
Soil Characteristics:	Cambridgeshire: Sandy loam. Essex: Clay. No other data provided.

**Results:**

Measured residues of difenoconazole in plots to which the substance was applied to winter wheat and to bare ground are shown in Tables B.8.1.7-1 and B.8.1.7-2, respectively. In samples from untreated control plots collected prior to application year 1 (day -2) and after application year 3 (day 720) the measured residues were always <0.02 mg/kg.

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Residues of difenoconazole immediately after the application in the third year were not significantly different to those taken immediately after the application in the first year. There were no differences between the winter wheat plots and the bare soil other than the magnitude of the residue in the soil. It was concluded that there was no evidence of accumulation of residues of difenoconazole in soil after three annual applications at either 75 or 150 g a.s./ha.

**Table B.8.1.7-1. Difenoconazole residues in soil (0-10 cm layer) after application to winter wheat at two different rates (75 g a.s./ha or 150 g a.s./ha) at two sites in UK. Individual results from duplicate analyses. LOD 0.02 mg as/kg.**

Site	Date applied	Date sampled	Growth stage	Dose rate, g a.s./ha	Days after 1st application	Difenoconazole, mg/kg dw		Comment
Cambridge-shire sandy loam	10.07.91	10.07.91	75	75	0	0.04	0.03	after appl. yr 1
	19.06.92	19.06.92	65-71	75	345	<0.02	<0.02	prior to appl. yr 2
	26.06.93	29.06.93	65-71	75	720	0.02	0.02	after appl. yr 3
	10.07.91	10.07.91	75	150	0	0.05	0.06	after appl. yr 1
	19.06.92	19.06.92	65-71	150	345	<0.02	<0.02	prior to appl. yr 2
	26.06.93	29.06.93	65-71	150	720	0.05	0.05	after appl. yr 3
Essex clay	10.07.91	10.07.91	69-71	75	0	<0.02	<0.02	after appl. yr 1
	19.06.92	19.06.92	60-65	75	345	<0.02	<0.02	prior to appl. yr 2
	26.06.93	29.06.93	65-69	75	720	0.02	0.03	after appl. yr 3
	10.07.91	10.07.91	69-71	150	0	0.02	0.02	after appl. yr 1
	19.06.92	19.06.92	60-65	150	345	<0.02	<0.02	prior to appl. yr 2
	26.06.93	29.06.93	65-69	150	720	0.04	0.04	after appl. yr 3

**Table B.8.1.7-2. Difenoconazole residues in soil (0-10 cm layer) after application to bare soil at two different rates (75 g a.s./ha or 150 g a.s./ha) at two sites in UK. Individual results from duplicate analyses. LOD 0.02 mg as/kg.**

Site	Date applied	Date sampled	Dose rate, g a.s./ha	Days after 1st application	Difenoconazole, mg/kg dw		Comment
Cambridge-shire sandy loam	10.07.91	10.07.91	75	0	0.07	0.07	after appl. yr 1
	19.06.92	19.06.92	75	345	<0.02	<0.02	prior to appl. yr 2
	26.06.93	29.06.93	75	720	0.06	0.06	after appl. yr 3
	10.07.91	10.07.91	150	0	0.13	0.15	after appl. yr 1
	19.06.92	19.06.92	150	345	0.04	0.04	prior to appl. yr 2
	26.06.93	29.06.93	150	720	0.04	0.04	after appl. yr 3
Essex clay	10.07.91	10.07.91	75	0	0.06	0.06	after appl. yr 1
	19.06.92	19.06.92	75	345	0.02	0.02	prior to appl. yr 2
	26.06.93	29.06.93	75	720	0.07	0.06	after appl. yr 3
	10.07.91	10.07.91	150	0	0.10	0.11	after appl. yr 1
	19.06.92	19.06.92	150	345	0.05	0.05	prior to appl. yr 2
	26.06.93	29.06.93	150	720	0.10	0.11	after appl. yr 3

#### Comments by RMS:

The study is considered acceptable only as supplementary data. It was briefly described, e.g., lacking information on agricultural practice. In the RMS evaluation of the method (section B.5) it was concluded that LOQ was 0.05 mg/kg and the difference was explained by lack of explicit link between LOQ and the lowest fortification level at the time of the field trial. Furthermore, the method was not considered as a fully validated quantitative method because there was no data available on linearity. The notifier has agreed (4 April 2006) to the RMS's comments on the method but argues that the comments do not materially affect the field trial, only the potential use of the method for monitoring purposes. The RMS concludes that lack of linearity data should not be of crucial

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importance for the interpretation of the results, since the measured concentrations all fall within a rather narrow range.

Since sampling was limited to the upper 0-10 cm no clear conclusions on the potential for accumulation can be drawn by comparing the measured residues from individual years (presumably the sites were cultivated and residues hence "diluted" into additional soil sections from year to year). However, there was no indication of accumulation in the 0-10 cm section. In bare soil, residues of up to 0.05 mg/kg remained in soil one year after application but the residues after the 3rd year were not different from those in the first year.

The residues found after each application to bare soil represented <40-150% of the theoretical dose (calculated from the application rates, distribution in 0-10 cm soil section and bulk density of 1.5 g/cm<sup>3</sup>). The LOD was relatively high, corresponding to 40% (low dose 75 g a.s./ha) or 20% (high dose, 150 g a.s./ha) of the theoretical dose.

Application to winter wheat is not included in the representative area of use. The application rate used was lower than the maximum application rate of SCORE 250 EC in carrot (up to 3 times at 125 g a.s./ha). In the study report, one of the tables showing the results from bare soil erroneously showed the results from winter wheat plots.

<b>Reference:</b>	<b>Kühne-Thu H (2000)</b> Long term study on fate and behaviour of difenoconazole (CGA 169374) in soil in Switzerland. Novartis Crop Protection AG, Residue Analysis, Basel, Switzerland. Report No. 2031-89-98. Syngenta File No. CGA169374/0652.
Test material:	EC 250 formulations (250 g difenoconazole/L): A-7402 A (1989-1991, Batch No. P 901011, P 911014, OP 102013), A-7402 F (1992-1993, Batch No. P 111003), A-7402 G (1994-1998, Batch No. P 111003, OP 305008, P 210005, 404019, 501026, P 612076).
Guideline:	BBA Guideline Part IV, 4-1, December 1986. Commission of the European Communities, 7029/VI/95 (rev. 5, working document). General recommendations for the design, preparation and realization of residue trials. July 1997.
GLP:	Yes

**Material and methods:**

Treatment rate:	125 g a.s./ha annually (total amount over the 10 year period was 1500 g a.s./ha). In the last season, the wheat seed used was also treated with the test compound.
Test system:	Potential for accumulation of difenoconazole residues in soil after annual applications to a plot of arable land in a typical agricultural area in Switzerland was investigated over ten seasons (1989 to 1998). The plot was 180 m <sup>2</sup> (in some of the interim reports described as 2 replicates of 90 m <sup>2</sup> each). A number of additional pesticides were used over the study (Faneron extra, Elocron, Gramoxon, Reglon, Betanal compact, Trammat Flow, Goltix, Duplosan, Firoadal, Faneron, Duplosan KV-combi, Azur, and Thiram and Isofenphos (both for seed treatment).

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Applications:	Year	Date of application	Treatment rate (g a.s./ha)	Crop	Growth stage
	1989	19 June	125	wheat	BBCH 59
	1990	17 May	125	rape	end of blossom
	1991	19 June	125	wheat	BBCH 59
	1992	15 July, 14 Aug., 15 Sept.	3 x 125	sugar beet	BBCH 52, 46-47, 48
	1993	8 June	125	wheat	BBCH 60
	1994	13 June	125	wheat	BBCH 60
	1995	20 June	125	wheat	BBCH 60
	1996	22 May	125	rape	BBCH 69
	1997	26 May	125	wheat	BBCH 59
	1998	4 June	125	wheat	treated seed + BBCH 59

**Weather:** Weather data were shortly provided for the periods from application to the last sampling date each year (total precipitation, max and min average daily temperature).

**Sampling time points:** Samples of soil were taken before the first application (except in the first three years), immediately after the last application and after harvest. The soil was sampled to a depth of 30 cm on all occasions and to 60 cm on three occasions (Ø 5 cm except in the second year; 8 cm). Number of soil cores/specimen were 10 (1989), 3 (1990), 10 (1991), 20 (1992-1998) and 1-10 samples taken from control plots. Samples were stored frozen until analysis.

**Method of analysis:** Samples were split into 10 cm sections prior to analysis and the separate layers were combined, mixed and homogenised. Besides difenoconazole, CGA 205375 was analysed in years 1993 to 1998 and free CGA 71019 and total 1,2,4-triazole (includes bound residues) were analysed in years 1996 to 1998. Analysis of difenoconazole involved extraction with methanol/ammonium hydroxide under reflux and partitioning into hexane and acetonitrile (omitted in later analyses). Method was AG-514 modified (first year) or AG-575A modified.

CGA 205375 was analysed by method REM 147.04 modified and CGA 71019 by method REM 130.04 modified.

Total triazoles (total 1,2,4-triazoles including bound residues) were analysed by method REM 107.06 modified, which (according to Doc. M-II, Section 2, and evaluation in section B.5) involves extraction in methanol/ammonium hydroxide under reflux, oxidation of the extract by refluxing with alkaline potassium permanganate and adjustment to pH 9. Finally, 1,2,4-triazole is derivatised to CGA 213291 with 2,4-dinitrofluorbenzene.

Samples were analysed by GC-ECD (difenoconazole) or HPLC (metabolites) with LOD 0.02 mg/kg (difenoconazole and CGA 205375), 0.01 mg/kg (CGA 71019), and 0.009 mg/kg (total triazoles).

Recovery of fortified samples were 103-107% (AG-514 modified); 85-115% (AG-575A modified); 95-135% (REM 147.04 modified); 58-78% (REM 130.04 modified); 53-101% (REM 107.06). Results were not corrected for recovery.

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Calculations: None performed, calculation of DT<sub>50/90</sub> not relevant.

Soil Characteristics: See Table B.8.1.7-3.

**Table B.8.1.7-3. Soil characteristics.**

Soil designation		Les Barges (Switzerland)
Soil type (USDA)		sandy loam
Sand	[%]	54.2
Silt	[%]	37.9
Clay	[%]	7.9
pH		7.5 (1989-1995) 7.8 (1996-1998)
Organic matter	[%]	3.5 (1989-1995) 2.3 (1996-1998)
Organic carbon <sup>a</sup>	[%]	2.0 (1989-1995) 1.3 (1996-1998)
Cation exchange capacity	[meq/100 g]	8.6

<sup>a</sup> Calculated by RMS as % organic matter/1.724.

### Results:

Measured residues of difenoconazole are shown in Table B.8.1.7-4. Residues of the metabolites CGA 205375 and CGA 71019 are shown in Tables B.8.1.7-5 and B.8.1.7-6, respectively. Measured residues of total 1,2,4-triazoles, including bound material, are shown in Table B.8.1.7-7. In samples from untreated control plots collected at the same sampling intervals, residues of difenoconazole were always <0.02 mg/kg.

Highest residues of difenoconazole were observed shortly after application (maximum 0.11 mg a.s./kg). Except in one case residues at harvest were at or below the limit of detection (0.02 mg/kg). Residues in the soil before the first application of the following year were always below the LOD. There was therefore no sign of accumulation under the conditions of this trial. Occasional (three) detections of parent were made in 20-30 cm soil sections but are not thought to represent actual movement of difenoconazole, more likely due to the sampling technique.

CGA 205375 was not detected above the LOD (0.02 mg/kg) at any time during the last six years of the trial.

Neither was free CGA 71019 detected above the LOD (0.01 mg/kg) at any time during the last three years of the trial.

The total 1,2,4-triazole residue, which includes bound material, was observed at a maximum of 0.017 mg/kg in the upper soil layer. Several detections of 1,2,4-triazole at all depths were made at around the LOD (0.009 mg/kg).

The lack of any free CGA 71019 in these samples suggests the material is closely associated with the soil matrix.

**Table B.8.1.7-4. Difenoconazole residues in soil after annual applications to crop at 125 g a.s./ha (3 x 125 g a.s./ha in 1992) at a field in Switzerland. Individual analytical samples. LOD 0.02 mg as/kg.**

Year	Sampling time	Difenoconazole residue, mg/kg dw				
		0-10 cm	10-20 cm	20-30 cm	30-50 cm	50-60 cm
1989	7 DALA	0.09, 0.11	<0.02, <0.02	<0.02, <0.02	n.a.	n.a.
	14 DALA	0.05, 0.10	<0.02, <0.02	<0.02, <0.02	n.a.	n.a.
	46 DALA	0.04, 0.03	<0.02, <0.02	<0.02, <0.02	n.a.	n.a.
1990	54 DALA	<0.02, 0.03	<0.02, <0.02	<0.02, <0.02	<0.02, <0.02	<0.02, <0.02
1991	50 DALA	<0.02, <0.02	<0.02, <0.02	<0.02, <0.02	n.a.	n.a.
1992	1 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	0.04	<0.02	<0.02	n.a.	n.a.

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Year	Sampling time	Difenoconazole residue, mg/kg dw				
		0-10 cm	10-20 cm	20-30 cm	30-50 cm	50-60 cm
	21 DALA	0.10	<0.02	<0.02	n.a.	n.a.
1993	1 DBFA	<0.02	<0.02	0.02	n.a.	n.a.
	0 DALA	0.02	<0.02	0.02	n.a.	n.a.
	50 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1994	3 DBFA	<0.02	<0.02	0.02	n.a.	n.a.
	0 DALA	0.02	<0.02	<0.02	n.a.	n.a.
	44 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1995	1 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	0.05	<0.02	<0.02	n.a.	n.a.
	38 DALA	0.02	<0.02	<0.02	n.a.	n.a.
1996	1 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	50 DALA	0.02	<0.02	<0.02	n.a.	n.a.
1997	0 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	0.04	<0.02	<0.02	n.a.	n.a.
	64 DALA	0.02	<0.02	<0.02	n.a.	n.a.
1998	1 DBFA	<0.02	<0.02	<0.02	<0.02	<0.02
	0 DALA	0.05	<0.02	<0.02	n.a.	n.a.
	47 DALA	0.02	<0.02	<0.02	<0.02	<0.02

DBFA Days Before First Application

DALA Days After Last Application

n.a. Not analysed

**Table B.8.1.7-5. Metabolite CGA 205375 residues in soil after annual applications of difenoconazole to crop at 125 g a.s./ha (3 x 125 g a.s./ha in 1992) at a field in Switzerland. Individual analytical samples. LOD 0.02 mg as/kg.**

Year	Sampling time	CGA 205375 residue, mg/kg dw				
		0-10 cm	10-20 cm	20-30 cm	30-50 cm	50-60 cm
1993	1 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	50 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1994	3 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	44 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1995	1 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	38 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1996	1 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	50 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1997	0 DBFA	<0.02	<0.02	<0.02	n.a.	n.a.
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	64 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
1998	1 DBFA	<0.02	<0.02	<0.02	<0.02	<0.02
	0 DALA	<0.02	<0.02	<0.02	n.a.	n.a.
	47 DALA	<0.02	<0.02	<0.02	<0.02	<0.02

DBFA Days Before First Application

DALA Days After Last Application

n.a. Not analysed

**Table B.8.1.7-6. Metabolite CGA 71019 residues in soil after annual applications of difenoconazole to crop at 125 g a.s./ha (3 x 125 g a.s./ha in 1992) at a field in Switzerland. Individual analytical samples. LOD 0.01 mg as/kg.**

Year	Sampling time	CGA 71019 residue, mg/kg dw				
		0-10 cm	10-20 cm	20-30 cm	30-50 cm	50-60 cm
1996	1 DBFA	<0.01	<0.01	<0.01	n.a.	n.a.
	0 DALA	<0.01	<0.01	<0.01	n.a.	n.a.
	50 DALA	<0.01	<0.01	<0.01	n.a.	n.a.
1997	0 DBFA	<0.01	<0.01	<0.01	n.a.	n.a.
	0 DALA	<0.01	<0.01	<0.01	n.a.	n.a.
	64 DALA	<0.01	<0.01	<0.01	n.a.	n.a.

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Year	Sampling time	CGA 71019 residue, mg/kg dw				
		0-10 cm	10-20 cm	20-30 cm	30-50 cm	50-60 cm
1998	1 DBFA	<0.01	<0.01	<0.01	<0.01	<0.01
	0 DALA	<0.01	<0.01	<0.01	n.a.	n.a.
	47 DALA	<0.01	<0.01	<0.01	<0.01	<0.01

DBFA Days Before First Application

DALA Days After Last Application

n.a. Not analysed

**Table B.8.1.7-7. Measured residues of total (including bound) 1,2,4-triazole residues in soil after annual applications of difenoconazole to crop at 125 g a.s./ha (3 x 125 g a.s./ha in 1992) at a field in Switzerland. Individual analytical samples. LOD 0.009 mg as/kg.**

Year	Sampling time	Total 1,2,4-triazole (incl. bound) residue, mg/kg dw				
		0-10 cm	10-20 cm	20-30 cm	30-50 cm	50-60 cm
1996	1 DBFA	0.009	0.009	0.009	n.a.	n.a.
	0 DALA	0.009	0.009	0.009	n.a.	n.a.
	50 DALA	0.011	<0.009	0.009	n.a.	n.a.
1997	0 DBFA	<0.009	<0.009	<0.009	n.a.	n.a.
	0 DALA	0.010	<0.009	<0.009	n.a.	n.a.
	64 DALA	0.011	0.010	0.009	n.a.	n.a.
1998 <sup>a</sup>	1 DBFA	0.010	<0.009	<0.009	<0.009	0.009
	0 DALA	0.016	0.014	0.011	n.a.	n.a.
	47 DALA	0.017	0.011	<0.009	<0.009	<0.009

DBFA Days Before First Application

DALA Days After Last Application

n.a. Not analysed

<sup>a</sup> The results for total triazoles in the last year were corrected for average recovery from fortified samples. Otherwise no results for any of the compounds were corrected for recovery.

#### Comments by RMS:

The study is of acceptable quality. There was no indication of accumulation of difenoconazole or its metabolites CGA 205375 and CGA 71019. However, there was an indication of potential accumulation of total 1,2,4-triazole residues since 0.09 and 0.010 mg/kg was detected before application in years 1996 and 1998. It is however agreed that a major part of these residues are likely to be bound to soil. The aerobic laboratory study carried out on CGA 71019 (1,2,4-triazole) showed a high degree of incorporation into bound residues (max. 60-75% of the applied radioactivity) and the analytical method used for determination of total 1,2,4-triazole residues in the soil accumulation study released bound material. The total triazole residues measured in the study are therefore only expected to be bioavailable to a limited degree.

The application rate used was usually lower than the maximum application rate of SCORE 250 EC in carrot (up to 3 times at 125 g a.s./ha). This is considered acceptable given the long duration of the study.

<b>Reference:</b>	<b>Zelger R (2001)</b> Ricerche sul comportamento dei residui di difenoconazolo in frutticoltura. Centro per la Sperimentazione Agraria e Forestale, Laimburg (Bolzano), Italy. Syngenta File No. CGA169374/2043. Translation to English: Research into Difenoconazole Residue Behaviour in Fruit Growing. (Received by RMS August, 2005)
Test material:	SCORE 25 EC formulation (250 g difenoconazole/L).
Guideline:	-
GLP:	No

**Material and methods:**

Treatment rate:	4 x 62.5 g a.s./ha per year (total amount over the 4 year period was 1000 g a.s./ha).
Test system:	The deposition and potential accumulation in soil was investigated in an established apple orchard in Northern Italy over four years. Height of trees was approx. 3 m, and distance between trees was 3.5 x 1.3 m. The trees were spindle trained. Four rows of trees were used and each plot consisted of 15 adjacent trees in each row.
Applications:	62.5 g a.s./ha (in 500 l water/ha) was applied with an axial air-blast sprayer on: 22 April, 29 April, 22 May, 26 May 1997, 23 April, 2 May, 10 May, 25 May 1998, 21 April, 30 April, 12 May, 21 May 1999, 10 May, 26 May, 5 June, 16 June 2000. On each occasion the whole orchard was treated. The soil between the rows was grassed (cut 5-6 times per year and left on the surface). In the rows weeds were controlled along a strip (approx. 0.8 m wide) by treatment with glyphosate and MCPA in June, July and October.
Weather:	Weather data was collected 200 m from the test area. Total annual precipitation was 739-1050 mm. Highest average monthly air temperature was 21-22.0°C in July-August and lowest average monthly air temperature was -1-1°C in December/January. The study author concluded that the weather conditions varied widely during the trial and interpreted the results in relation to the weather conditions.
Sampling time points:	Samples of the apple foliage, grass (inter row) and soil (inter and intra row, to 10 cm deep) were taken immediately before the first treatment in each year (April/May), soon after the last application (June/July) and also in October in each year. A final sampling was performed in April 2001. An additional sample was taken immediately after the first application in the first year (1997) to provide a reference to the typical maximum residues. 30 inter and 30 intra row soil samples were taken from each plot at each sampling occasion. Samples from each plot were combined before analysis.
Method of analysis:	Leaves, grass and soil were extracted with acetone, partitioned with methylene chloride, dried and re-suspended in acetone (standard method S19). Analysis of difenoconazole residues in the solutions was by GC-ECD with a LOD of 0.01 mg/kg dry weight. Recovery from two soil samples were stated to be 71.74%.
Calculations:	None presented, calculation of DT <sub>50/90</sub> not relevant.
Soil Characteristics:	Sandy loam with pH 7.3 and 1.7% organic matter in topsoil.

**Results:**

Measured residues of difenoconazole are shown in Table B.8.1.7-8. Amounts of difenoconazole in the soil either between (inter) or within (intra) rows of apple trees after treatment at typical agricultural rates were only at or slightly above the LOD (0.01 mg ai/kg) on all occasions. Residues in the soil soon after the last application were

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similar each year and generally fell to less than the LOD in the following year prior to the next treatment. After 16 applications over four years, no indication of accumulation was found.

**Table B.8.1.7-8. Difenoconazole residues in foliage, grass and soil (0-10 cm depth) as results of four annual applications of 62.5 g a.s./ha (250 g a.s./ha per year) over four years to an apple orchard in Northern Italy. Mean concentrations of four replicates. LOD 0.01 mg as/kg.**

Year	Sampling date	Difenoconazole residue, mg/kg dw			
		Foliage	Grass (inter row)	Soil (intra row)	Soil (inter row)
1997	21 April	n.p.	n.p.	n.p.	n.p.
	22 April	27.5	14.0	0.01	0.01
	12 June	0.57	0.72	0.02	0.01
	20 October	0.03	0.25	0.01	0.01
1998	22 April	n.p.	0.11	0.01	0.01
	17 June	0.13	0.13	0.01	0.01
	27 October	0.09	0.01	0.01	0.01
1999	19 April	n.p.	n.d.	n.d.	n.d.
	1 July	0.03	0.04	n.d.	n.d.
	29 October	n.p.	n.p.	n.p.	n.p.
2000	9 May	n.p.	n.p.	n.p.	n.p.
	8 July	0.28	0.03	0.01	0.01
	24 October	n.d.	n.d.	0.01	n.d.
2001	17 April	n.p.	n.p.	n.d.	n.p.

n.p. Not present.

n.d. Not detectable.

#### Comments by RMS:

The study is of acceptable quality. However, the difference between "not present" and "not detectable" in the table of results was a bit obscure. Presumably, "not present" meant that no residues were detected and "not detectable" meant that traces not possible to quantify were present. The analytical method used could be questioned since the recovery reported was unusually low (71.74%). In any case, and even if the measured concentrations would be corrected for recovery, there was no indication of accumulation soil.

The residues measured in grass prior to application in 1998 are surprising and seem to indicate that soil residues are taken up by plants. There was no explanation in the study report for the results from different years other than differences in weather conditions. The application rate used was in between the maximum rates recommended for Southern EU and Northern EU.

<b>Reference:</b>	<b>Molinari GP (2002)</b> Soil dissipation of difenoconazole. (English translation of report: Dissipazione nel suolo del fungicida difenoconazole). Azienda Agricola Tramelli, Località Busazza, San Pietro in Cerro (Piacenza), Italy and Università Cattolica del Sacro Cuore, Faculty of Agriculture, Department of Environmental and Agricultural Chemistry – Section of Soil Chemistry, Piacenza, Italy. Report No. NOVARTIS/99/01/Bietola. Syngenta File No. CGA169374/2044.
Test material:	SCORE 25 EC formulation (250 g difenoconazole/L).
Guideline:	-
GLP:	Yes

**Material and methods:**

Treatment rate:	3 x 75 g a.s./ha per year (total amount over the 4 year period was 900 g a.s./ha).
Test system:	The dissipation and potential for accumulation of difenoconazole applied to sugar beet was studied in the Piacenza region of Italy over a period of four years. The trial site consisted of two a ha large fields, one treated and one serving as control. Three sampling plots (10 x 6 m) were located within each of the fields.
Applications:	<p>63-83 g a.s./ha was sprayed to the fields on:</p> <p>23 June, 10 July, 29 July 1997, 15 June, 7 July, 28 July 1998, 21 June, 13 July, 4 August 1999, 25 July, 11 August, 29 August 2000.</p> <p>The treated plots were maintained under the same regime as the local conditions and practises required. Metolachlor, Chloridazon, Phenmedipham, Metamitron and Lenacil were also used on the experimental field during the trial.</p>
Weather:	Weather data (air temperature, humidity, rainfall) were recorded in Fiorenzuola (Piacenza) but not included in the study report.
Sampling time points:	<p>Five soil cores (to a depth of 40 cm) were collected within each of the three replicates according to the following schedule (not all samples were taken each year):</p> <p>T1 - Just before first application T2 - 1 day after first application T3 - 1 day before second application T4 - Just after second application T5 - 1 day before third application T6 - Just after third application T7 - 10 days after third application T8 - At harvest T9 - 1 year after third treatment (in the last year)</p> <p>The 0-10 cm and 10-40 cm sections from each replicate were combined and stored frozen until extraction.</p>
Method of analysis:	Soil samples were extracted with methanol/NaOH (8:2, v/v) reflux at 50°C for 4 hours. Sample clean-up was by liquid/liquid partition with n-hexane. The residues were finally resuspended in acetonitrile and stored frozen until analysis by GC-NPD with a LOD of 0.01 mg/kg. Recoveries in fortified samples were reported as 91-97% (95±3%, n=3).
Calculations:	<p>When calculating the mean measured residues not detectable (&lt;0.01 mg/kg) were set to 0.001 mg/kg (however, in table below each individual result is presented).</p> <p>Calculation of DT<sub>50/90</sub> not relevant</p>
Soil Characteristics:	See Table 8.1.7-9.

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**Table B.8.1.7-9. Soil characteristics.**

Soil designation		San Pietro in Cerro, Piacenza (Italy)
Soil type (USDA)		silty clay
Sand	[%]	3.57
Silt	[%]	52.87
Clay	[%]	43.56
pH		7.7
Organic carbon	[%]	not stated
Cation exchange capacity	[meq/100 g]	21.77

**Results:**

Measured residues of difenoconazole are shown in Table B.8.1.7-10. Difenoconazole was never detected in control field.

Difenoconazole residues in soil were low at all sampling times. Maximum residues (up to 0.03 mg/kg) were detected after the 2nd or 3rd applications. Residues in soil one year after application were always below the LOD (0.01 mg/kg) in each individual sampling plot except in the last year (2001) at which residues >LOD in individual sampling plot(s) were indicated (though mean residues were <LOD). There was therefore no indication of accumulation of difenoconazole.

Sporadic detections of difenoconazole were made in the 10-40 cm soil section, but except on one occasion (T4, 2000 mean 0.011 mg/kg), the average of the three areas sampled was less than the LOD.

Based on the results of mean measured residues, it was concluded that low residues were observed in soil and that no residues were detected in samples taken one year after application and that there was no significant movement of difenoconazole beyond the 0-10 cm soil depth.

**Table B.8.1.7-10. Difenoconazole residues in soil after annual applications to crop at 3 x 75 g a.s./ha at a sugar beet field in Piacenza region, Italy. Individual analytical samples; residues above marked LOD in bold. LOD 0.01 mg as/kg.**

Year	Time of sampling	Sampling date	Difenoconazole residue, mg/kg dw	
			0-10 cm	10-40 cm
1997	T1 - before 1st application	17 Jun	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T2 - 3 h after 1st app.	23 Jun	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T4 - 3 h after 2nd app.	10 Jul	<0.01, <b>0.027</b> , <0.01	<0.01, <0.01, <0.01
	T6 - 3 h after 3rd app.	29 Jul	<b>0.032, 0.017</b> , <0.01	<0.01, <0.01, <0.01
	T8 - 21 d after 3rd app.	19 Aug	<b>0.021, 0.011</b> , <0.01	<0.01, <0.01, <0.01
1998	T1 - before 1st application	09 Jun	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T2 - 3 h after 1st app.	15 Jun	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T4 - 3 h after 2nd app.	07 Jul	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T6 - 3 h after 3rd app.	28 Jul	<b>0.017, 0.025, 0.054</b>	<0.01, <b>0.010</b> , <0.01
	T8 - 22 d after 3rd app.	19 Aug	<b>0.013, 0.012, 0.016</b>	<0.01, <0.01, <0.01
1999	T1 - before 1st application	09 Jun	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T2 - 3 h after 1st app.	22 Jun	<0.01, <0.01, <b>0.011</b>	<0.01, <0.01, <0.01
	T4 - 3 h after 2nd app.	14 Jul	<0.01, <0.01, <b>0.013</b>	<0.01, <b>0.015</b> , <0.01
	T6 - 3 h after 3rd app.	05 Aug	<b>0.023</b> , <0.01, <b>0.018</b>	<0.01, <0.01, <0.01
	T7 - 14 d after 3rd app.	19 Aug	<b>0.02</b> , <b>0.01</b> , <0.01	<0.01, <0.01, <0.01
2000	T1 - before 1st application	20 Jul	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T2 - 3 h after 1st app.	25 Jul	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T3 - before 2nd appl.	11 Aug	<0.01, <b>0.026, 0.029</b>	<0.01, <0.01, <0.01
	T4 - 3 h after 2nd app.	11 Aug	<0.01, <0.01, <b>0.013</b>	<b>0.034</b> , <0.01, <0.01

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Year	Time of sampling	Sampling date	Difenoconazole residue, mg/kg dw	
			0-10 cm	10-40 cm
2001	T5 - before 3rd appl.	29 Aug	<0.01, <b>0.011</b> , <0.01	<0.01, <0.01, <0.01
	T6 - 3 h after 3rd app.	29 Aug	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T7 - 7 d after 3rd app.	05 Sep	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01
	T9 - 365 d after 3rd appl.	10 Jul	(<0.01) <sup>a</sup>	<0.01, <0.01, <0.01

*a Results from individual sub-plots not presented in study report. Value given indicates that residues >LOD were presented in individual sampling plot(s) but that the mean residues were <0.01 mg/kg.*

#### Comments by RMS:

The study is of acceptable quality. There was no indication of accumulation of difenoconazole in soil following application to sugar beet according to normal practice. The growth stage of plants at timing of application was not stated however the data indicate that only small amounts reached the soil due to crop development. A statistical analysis presented in the study report was not reproduced herein since it is not considered to add any significant information. The application rate used was lower than the maximum application rate of SCORE 250 EC in carrot (up to 3 times at 125 g a.s./ha).

#### B.8.1.8 Summary and assessment of studies on route and rate of degradation in soil

##### B.8.1.8.1 Route of degradation

The degradation of difenoconazole in soil is principally mediated by micro organisms under aerobic conditions; studies under sterile or anaerobic conditions and soil surface photolysis study demonstrated little or no degradation of difenoconazole.

The proposed degradation pathway in soil is presented in Figure B.8.1.8.1-1. The degradation of difenoconazole in soil is considered to proceed by hydrolysis of the dioxolane ring of the parent molecule to the alcohol CGA 205375 (maximum formation 9.7%) or the ketone CGA 205374. As CGA 205374 was observed only in soil photolysis study and in study using CGA 205375 as test item, and then only at trace levels (max. 2.7%), it is presumed to be essentially unstable. It is also possible that CGA 205374 and CGA 205375 are inter-convertible. In a field study using <sup>14</sup>C-chlorophenyl radiolabelled difenoconazole CGA 205375 was found at max. concentration corresponding to 10-12% of the initial concentration of difenoconazole, close to the maximum percentage found in laboratory studies. In the same study CGA 205374 was found at max. concentration representing 2.2% of the initial concentration of difenoconazole.

Bridge cleavage between the triazole and phenyl moieties results in CGA 71019 (1,2,4-triazole, maximum formation 23.4% in studies on <sup>14</sup>C-triazole-labelled difenoconazole) and the acid metabolite CGA 189138 (2-chloro-4-(4-chloro-phenoxy)-benzoic acid), although this compound was not observed in any of the soil metabolism studies despite being used as a reference compound in a number of the studies. However, in the field study using <sup>14</sup>C-chlorophenyl radiolabelled difenoconazole trace amounts of CGA 189138 was found, representing max. 0.8% of the initial concentrations of difenoconazole.

Since rate of degradation of difenoconazole appears to be related to test concentration (see below), some of the results indicating low rate of formation of CGA 205375 and CGA 71019 may be considered as less relevant.

In aerobic study on 1,2,4-triazole (CGA 71019), two metabolites were identified under aerobic conditions; triazole acetic acid (CGA 142856, max. 6.3%) and hydroxy triazole (NOA 457654, max. 2.2%). The principal fate of CGA 71019 under aerobic conditions was formation of bound residues (max. 62-75% after 30-61 days) and mineralisation (max 15-33%  $^{14}\text{CO}_2$  at study termination). Under anaerobic conditions, larger amounts (max. 50.3%) of triazole acetic acid was formed from CGA 71019, and in addition triazole alanine (CGA 131013) was formed (max. 3.4%). The high amounts of triazole acetic acid (CGA 142856) observed in anaerobic study on 1,2,4-triazole (CGA 71019) are not expected to be formed under natural conditions (see RMS's comment to Mamouni, 2003).

In aerobic and anaerobic studies on CGA 205375, the only metabolite measured as >10% of the applied radioactivity was CGA 71019 (max. 32%).

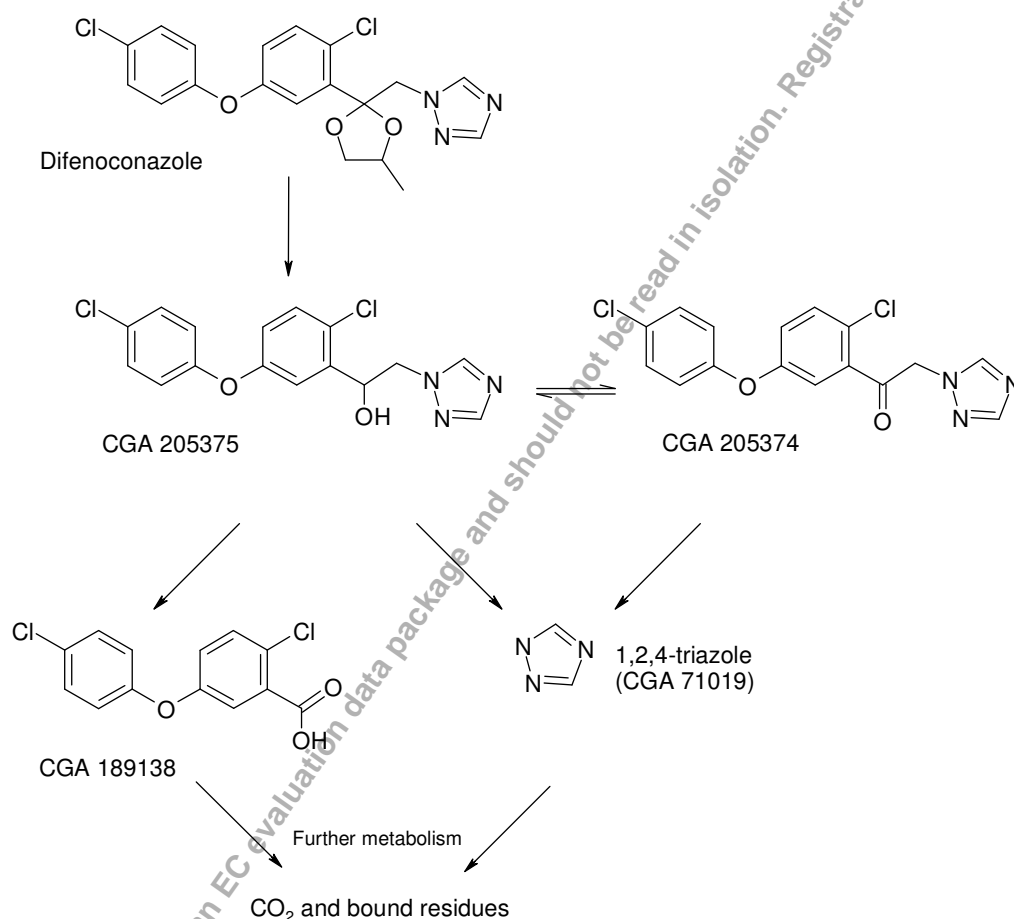
In various studies with both  $^{14}\text{C}$ -chlorophenyl and  $^{14}\text{C}$ -triazole labelled difenoconazole, a number of unidentified products have been observed at low levels, suggesting the degradation of the molecule beyond the initial steps is complex. In recent studies these unknown products individually accounted for <5% of the radioactivity, except in one study in which unknown M4 was identified at max. 8.6% (it was however not found above 5% at two consecutive measurements). Further investigation of the nature of these compounds is not considered necessary due to the low levels found and the sometimes sporadic occurrence of them. In one old study considered to be of lower quality two unidentified metabolites were present at greater than 5% of the applied radioactivity (and less than 10%) on two consecutive occasions. It can be inferred from later studies that one of these was probably CGA 205375. In another old study unidentified impurities V1-V3 were found up to 7.0%. However, since no product were observed at these levels in any of the other and more recent studies these unknown compounds are not considered further.

A significant proportion of the radioactivity was unextractable from soil. The maximum amounts of bound material formed from the chlorophenyl and triazole moieties of the molecule were similar at 48.2 and 54.1% respectively after 238-271 days (see more detailed figures on % bound residues in Table B.8.1.8.2-1 below). As relatively harsh extraction methods were usually employed it can be assumed that this unextracted radioactivity is principally bound or incorporated into the soil organic material. As the main route of breakdown is via bridge cleavage and high amounts of bound residues were rapidly formed in the aerobic study of 1,2,4-triazole (CGA 71019) it is suggested that the identity of at least part of the non-extractable residues is different in samples treated with difenoconazole labelled in different position. Highest amounts of bound residues were found in samples treated at low concentration in which degradation of difenoconazole was more rapid than at higher treatment rates. Organic matter fractionation of  $^{14}\text{C}$ -triazole-difenoconazole treated samples showed that approximately half of the bound radioactivity was associated with the humin and humic acid fractions of the soil organic matter, the

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remainder with the fulvic acid fraction. In samples treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole less radioactivity was associated with the fulvic acid fraction (13%) than with the humin and humic acids fractions (26%). This supports that the bound residues are likely to be heterogenous in nature.

The divergences in the routes of breakdown are evidenced by the considerable differences between the amounts of mineralisation in the two portions of the molecule. Up to 33.4% of the  $^{14}\text{C}$ -chlorophenyl radiolabel was evolved as  $^{14}\text{CO}_2$  after 281 days whereas only max. 4.6% was evolved in the corresponding  $^{14}\text{C}$ -triazole treatments after 271 days (see more detailed figures on %  $^{14}\text{CO}_2$  formed in Table B.8.1.8.2-1 below). Since degradation appears to be dependent on treatment rate (see below), only the percentages of  $\text{CO}_2$  and bound residues which were obtained at relevant treatment rates are transferred to the list of endpoints.



**Figure B.8.1.8.1-1. Proposed degradation pathway for difenoconazole in soil (from Doc. M-II).**

#### **B.8.1.8.2 Rate of degradation**

Rate of degradation was investigated in six different soils and at different temperature, moisture level and test concentrations. Results from all laboratory studies with difenoconazole as test substance are presented in Table B.8.1.8.2-1 and those results used to calculate mean values and values normalised to reference temperature and moisture are also given in Table B.8.1.8.2-2. Some of the DT<sub>50</sub> and DT<sub>90</sub> values presented in the tables are uncertain due to high amounts of difenoconazole remaining at study termination, however, the values are considered acceptable as best available estimates. Median DT<sub>50</sub> at 20°C was 120 days, after normalisation with respect to moisture 86 days.

Organic carbon content varied from <0.3% to 2.15% and pH from 5.0 to 7.5, and within these ranges there was no indication of influence of these parameters on the degradation rate. Also, soil type had little influence on the rate of degradation. Comparing the rates of degradation at 30°C and 10°C to those at 20°C shows that they give faster or slower rates respectively in line with expectations, i.e. approximately a two-fold change although the data does not allow an exact figure to be estimated. At high treatment rate lower soil moisture caused a significant slowing of the degradation rate. At rates corresponding to the representative field rates the effect of moisture was however minimal.

The results suggests that the rate of degradation of difenoconazole is influenced by treatment rate. In Document M-II it was shown that the increase in degradation rate with increased treatment rate is not linear and it was suggested that the longer half-lives obtained at high treatment rate are more likely to be the result of a gradual saturation of microbial degradative capacity, rather than any toxic effect over the soil concentrations tested. Concentrations from 0.0172 to 1.0 mg/kg were used in the studies, corresponding to 12.8 to 750 g a.s./ha (assuming distribution in 0-5 cm soil layer and density of 1.5 g/cm<sup>3</sup>). In the representative use as seed treatment the maximum exposure is 12 g a.s./ha. In the representative uses with spray applications, difenoconazole is applied 1-4 times to pome fruit at 18.75-56.25 g/ha (N EU) or 37.5-75.0 g/ha (S EU) and 1-3 times to carrot at 125 g/ha. Total exposure during one season may hence be maximum 375 g/ha. It therefore seems reasonable not to use the DT<sub>50</sub> and DT<sub>90</sub> derived from samples treated at the highest test concentration (corresponding to 750 g a.s./ha) for calculation of mean and median DT<sub>50</sub> and DT<sub>90</sub> - regardless of the mechanism for the slower degradation rate observed at these test concentrations. In addition to values obtained at highest treatment rate, also two values obtained in samples incubated at low moisture conditions (30% FC) and low temperature (10°C) are excluded from the mean and median because in the same study degradation rate was also investigated on the same loam soil under standard conditions.

The same selection of data based on treatment rate was done for percentages CO<sub>2</sub> and non-extractable radioactivity transferred to the list of endpoint.

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**Table B.8.1.8.2-1. Summary of laboratory studies on degradation of difenoconazole in soil. All DT<sub>50</sub> and DT<sub>90</sub> values were calculated by single first order kinetics.**

Study/Soil	Treatment rate <sup>a</sup>		Moisture	Temp.	DT <sub>50</sub>	DT <sub>90</sub>	CO <sub>2</sub>	Non-extractable
	mg/kg	g/ha	%	°C	days	days	% (at days)	% (at days)
<b>AEROBIC CONDITIONS</b>								
<b>Mamouni, 2000a</b>								
loam	0.188	141	40% MWHC	20	104	345	1.6 (100) <sup>b</sup>	21.8 (100) <sup>b</sup>
<b>Mamouni, 2000b</b>								
loam	0.190	143	40% MWHC	20	118	392	18.1 (100) <sup>c</sup>	22.8 (100) <sup>c</sup>
<b>Gonzalez-Valero, 1992a</b>								
sand	0.1	75	40% MWHC	20	123	409	3.7 (106) <sup>c</sup>	20.6 (106) <sup>c</sup>
<b>Gonzalez-Valero, 1992b</b>								
silt loam	1.0	750	60% FC	20	456	>>273	0.2 (91) <sup>b</sup>	11.9 (91) <sup>b</sup>
silt loam	1.0	750	60% FC	30	175	>>178	0.6 (91) <sup>b</sup>	25.2 (91) <sup>b</sup>
silt loam	1.0	750	30% FC	20	709	>>281	1.4 (90) <sup>c</sup>	7.2 (90) <sup>c</sup>
silt loam	1.0	750	60% FC	20	345	>>281	5.5 (90) <sup>c</sup>	13.8 (90) <sup>c</sup>
silt loam	1.0	750	60% FC	10	602	>>281	2.5 (90) <sup>c</sup>	7.0 (90) <sup>c</sup>
silt loam	0.1	75	60% FC	20	83	277	19.3 (90) <sup>c</sup>	33.7 (90) <sup>c</sup>
<b>Völkel, 2000b</b>								
loam	0.171	128	30% FC	20	136	452	0.3 (90) <sup>b</sup>	12.4 (90) <sup>b</sup>
loam	0.171	128	60% FC	10	338	>1000	<0.1 (90) <sup>b</sup>	8.9 (90) <sup>b</sup>
loam	0.0172	12.8	60% FC	20	53	175	2.1 (90) <sup>b</sup>	36.6 (90) <sup>b</sup>
loam sterile	0.171	128	60% FC	20	>1000	>1000	0.1 (90) <sup>b</sup>	3.7 (90) <sup>b</sup>
<b>Mamouni, 2002</b>								
sandy loam	0.257	193	40% MWHC	20	149	496	11.3 (120) <sup>c</sup>	17.4 (120) <sup>c</sup>
sandy loam/loamy sand	0.257	193	40% MWHC	20	186	617	14.4 (120) <sup>c</sup>	18.1 (120) <sup>c</sup>
silty clay loam	0.257	193	40% MWHC	20	187	620	15.2 (120) <sup>c</sup>	19.2 (120) <sup>c</sup>
<b>ANAEROBIC CONDITIONS</b>								
<b>Völkel, 2000a</b>								
loam	0.171	128	n.a.	20	stable	stable	0.1 (110) <sup>b</sup>	11.6 (110) <sup>b</sup>
<b>SOIL PHOTOLYSIS</b>								
<b>Atkins, 1994</b>								
sandy loam	10.22	-	75% FC	25	stable	stable	0.2 (30) <sup>c</sup>	3.7 (30) <sup>c</sup>

n.a. Not applicable

a Treatment rate used in the studies, in mg/kg soil and recalculated in g a.s./ha, assuming distribution in 0-5 cm soil layer and bulk density of 1.5 g/cm<sup>3</sup>.

b <sup>14</sup>C-triazole labelled difenoconazole was used as test substance.

c <sup>14</sup>C-chlorophenyl labelled difenoconazole was used as test substance.

**Table B.8.1.8.2-2. Soil laboratory DT<sub>50</sub> and DT<sub>90</sub> values, as derived from the studies and standardised to 20°C and pF2, according to FOCUS Groundwater Report (2002).<sup>a</sup>**

Reference	Soil	Temp., °C	Moisture, %	DT <sub>50</sub> , days	DT <sub>90</sub> , days	Standardised DT <sub>50</sub> , days
Mamouni, 2000a	loam	20	40% MWHC	104	345	64
Mamouni, 2000b	loam	20	40% MWHC	118	392	72
Gonzalez-Valero, 1992a	sand	20	40% MWHC	123	409	105
Gonzalez-Valero, 1992b	silt loam	20	60% FC	83	277	58
Völkel, 2000b	loam	20	60% FC	53	175	37
Mamouni, 2002	sandy loam	20	40% MWHC	149	496	100
	sandy loam/loamy sand	20	40% MWHC	186	617	133
	silty clay loam	20	40% MWHC	187	620	107
<b>Range</b>				<b>53-187</b>	<b>175-620</b>	<b>37-133</b>
<b>Median</b>				<b>120</b>	<b>400</b>	<b>86</b>
<b>Geometric mean</b>				<b>117</b>	<b>388</b>	<b>79</b>
<b>Arithmetic mean</b>				<b>125</b>	<b>416</b>	<b>84</b>

a In Doc. M-II the results from Völkel (2000b) obtained on the loam soil at 10°C; 60% FC and 20°C; 30% FC were also normalised to reference conditions and included in mean/median values. In addition, the DT<sub>50</sub> obtained from Gonzalez-Valero (1992a) was slightly different than the value used by the RMS. Hence, the median/mean normalised DT<sub>50</sub> values presented in Doc. M-II (median 86 days, geometric mean 80 days, arithmetic mean 86 days) were slightly different than the values presented by the RMS in the table.

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Results from laboratory studies on the two principle metabolites identified, CGA 205375 and CGA 71019 are given in Table B.8.1.8.2-3. The degradation of CGA 71019 was rapid in aerobic soil with a mean  $DT_{50}$  of 9.5 days. The aerobic degradation rate of CGA 205375 was faster than that of its parent on the same soils (compare Völkel, 2002a and Mamouni, 2002). For CGA 205375 the  $DT_{50}$  and  $DT_{90}$  values may be less certain due to high amounts remaining at study termination but the values are still considered sufficiently reliable for risk assessment. Compared with the maximum amounts formed of CGA 205375 and CGA 71019 in studies on difenoconazole, exaggerated test concentrations were used in the studies in which these compounds were applied as parent material.

**Table B.8.1.8.2-3. Summary of laboratory studies on degradation of metabolites of difenoconazole, CGA 205375 and CGA 71019, in soil. All  $DT_{50}$  and  $DT_{90}$  values were calculated by single first order kinetics.**

Study/Soil	Treatment rate <sup>a</sup>		Moisture %	Temp. °C	DT <sub>50</sub> days	DT <sub>90</sub> days	CO <sub>2</sub> % (at days)	Non-extractable % (at days)
	mg/kg	g/ha						
CGA 71019, AEROBIC CONDITIONS								
Slangen, 2000								
sandy loam	0.06	45	40% MWHC	20	6.3	21	15.4 (120)	64.7 (120)
loamy sand <sup>b</sup>	0.06	45	40% MWHC	20	9.9	33	1.5 (120)	59.6 (120)
silt loam	0.06	45	40% MWHC	20	12	41	33.0 (120)	40.1 (120)
Arithmetic mean					9.5	32		
CGA 71019, ANAEROBIC CONDITIONS								
Mamouni, 2003								
silt loam	0.061	46	n.a.	20	81	268	1.3 (122)	16.3 (122)
CGA 205375, AEROBIC CONDITIONS								
Völkel, 2002a								
sandy loam	0.1	75	40% MWHC	20	93	309	10.0 (84) <sup>c</sup>	15.6 (84) <sup>c</sup>
sandy loam/loamy sand	0.1	75	40% MWHC	20	83	275	2.8 (84) <sup>c</sup>	17.2 (84) <sup>c</sup>
silt loam	0.1	75	40% MWHC	20	152	504	0.2 (84) <sup>c</sup>	15.6 (84) <sup>c</sup>
Arithmetic mean					109	363		
CGA 205375, ANAEROBIC CONDITIONS								
Völkel, 2002a								
sandy loam/loamy sand	0.1	75	n.a.	20	213	706	0.6 (84) <sup>c</sup>	13.3 (84) <sup>c</sup>

n.a. Not applicable

a Treatment rate used in the studies, in mg/kg soil and recalculated in g a.s./ha, assuming distribution in 0-5 cm soil layer and bulk density of 1.5 g/cm<sup>3</sup>.

b The viability of this soil was probably reduced with time, therefore only data from initial sampling points were used to calculate  $DT_{50}$  and  $DT_{90}$ .

c <sup>14</sup>C-chlorophenyl labelled CGA 205375 was used as test substance.

The  $DT_{50}$ s for the metabolites were normalised to reference conditions in the reports on PEC<sub>gw</sub>, PEC<sub>sw</sub> and PEC<sub>sd</sub> (Turner and Beulke, 2003, and Beulke and Brown, 2003). These results are shown in Table B.8.1.8.2-4.

**Table B.8.1.8.2-4. Metabolites CGA 71019 and CGA 205375; Soil laboratory  $DT_{50}$  and  $DT_{90}$  values, as derived from the studies and standardised to 20°C and pF2, according to FOCUS Groundwater Report (2002).**

Reference	Soil	Temp., °C	Moisture, %	$DT_{50}$ , days	$DT_{90}$ , days	Standardised $DT_{50}$ , days
<b>CGA 71019</b>						
Slangen, 2000	sandy loam	20	40% MWHC	6.3	21	4.3
	loamy sand	20	40% MWHC	9.9	33	7.6
	silt loam	20	40% MWHC	12	41	7.5
<b>Arithmetic mean</b>						<b>6.45</b>
<b>CGA 205375</b>						
Völkel, 2002a	sandy loam	20	40% MWHC	93	309	62.7
	sandy loam/ loamy sand	20	40% MWHC	83	275	59.5

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Reference	Soil	Temp., °C	Moisture, %	DT <sub>50</sub> , days	DT <sub>90</sub> , days	Standardised DT <sub>50</sub> , days
	silt loam	20	40% MWHC	152	504	92.4
<b>Arithmetic mean</b>						<b>74.5</b>

Results from all field dissipation studies on difenoconazole are given in Table B.8.1.8.2-5. All studies except Purdy (1997) used spray application. Timing of application was in May or June except at the location in Freiset where spraying was carried out in October and at the trials in Italy where crops were treated in July-August. The pH of the soils ranged from 5.6 to 8.3 and the % organic carbon from 1.0 to 4.3. Within these ranges there was no obvious influence of these parameters on the rate of dissipation. Neither was the dissipation rate correlated to soil type. The tendency to slower degradation at high test concentrations observed at the laboratory was also indicated in the field studies performed at high treatment rates. In all trials, the majority of the residues were always recovered from the 0-10 cm soil depth but where relevant, measured residues in all soil sections (i.e. including residues below the top layer) were included in the calculations of dissipation rates. However, the DT<sub>50/90</sub> values were often recalculated by the RMS (see comments to the individual studies).

**Table B.8.1.8.2-5. Summary of field dissipation studies on difenoconazole. All DT<sub>50</sub> and DT<sub>90</sub> values were calculated by single first order kinetics.**

Study/Location and Soil	Country	Application rate, g a.s./ha	Bare ground or crop	DT <sub>50</sub> , days	DT <sub>90</sub> , days
<b>Ressler, 1992a-d</b>					
Freistett silt loam	Germany	>>250 <sup>a</sup>	bare	160	532
Schornbusch silt loam	Germany	500	bare	22	72
Lorsch loamy sand	Germany	500	bare	57	189
Platting-See silt loam	Germany	500	bare	64	211
<b>Ressler, 2001a-d</b>					
Gnarrenburg-Brillet loamy sand	Germany	500	bare	63	211
Oldenburg-Altratjensdorf sandy loam	Germany	750	bare	265	879
Pleidelshheim silt loam	Germany	750	bare	241	802
Rheinau-Memprechtshofen silt loam	Germany	750	bare	116	384
<b>Walser, 1994</b>					
Klus clay loam	Switzerland	125	bare	83	277
<b>Kühne-Thu, 1990a-d, 1991a-b</b>					
Kings Farm clay	UK	375	bare	156	519
Kings Farm clay	UK	125	bare	227	755
Utrera sandy loam	Spain	800	bare	54	178
Utrera sandy loam	Spain	150	bare	38	128
Hill Farm sandy clay	UK	375	bare	133	442
Hill Farm sandy clay	UK	125	bare	not reliable <sup>b</sup>	not reliable <sup>b</sup>
<b>Kühne-Thu, 1992a-c</b>					
Castenaso loam	Italy	6 x 125	asparagus	181	602
Las Morenas sandy clay loam	Italy	3 x 50	sugar beet	not reliable <sup>c</sup>	not reliable <sup>c</sup>
Las Morenas sandy clay loam	Italy	3 x 100	sugar beet	not reliable <sup>c</sup>	not reliable <sup>c</sup>
<b>Purdy, 1997</b>					
Portage la Prairie clay	Canada	40	treated seed	87	289
Aberdeen clay loam	Canada	37	treated seed	28	92
Regina clay	Canada	36	treated seed	76	254
Calgary clay loam	Canada	36	treated seed	34	114

<sup>a</sup> The nominal treatment rate was 250 g a.s./ha however the maximum residue recovered (1.22 mg/kg) corresponds to a treatment rate of 3660 g a.s./ha (calculated by RMS assuming distribution in 0-10 cm soil layer and bulk density of 1.5 g/cm<sup>3</sup>).

<sup>b</sup> Due to poor fit of the data to first order kinetic model the DT<sub>50/90</sub> values calculated are not used (r<sup>2</sup> 0.19, model efficiency). The reason for the poor fit was a deviating value for which there was no clear reason to treat as an outlier and omit from the analysis.

<sup>c</sup> Data was not sufficient to calculate reliable DT<sub>50/90</sub> values since residues >LOD were only measured on two sampling intervals.

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Median and mean values and were appropriate 90th percentiles of different sets of results are given in Table B.8.1.8.2-6. In Doc. M-II the notifier regarded the studies by Ressler (1992a-d, 2001a-d) and Walser (1994) as main studies and the studies by Kühne-Thu (1990a-d, 1991a-b, 1992a-c) and Purdy (1997) as supplementary studies, providing supporting data for conclusions drawn from the main studies. With regard to the studies by Kühne-Thu the RMS agrees to this approach since these studies were generally only briefly reported. The results from Purdy (1997) performed under Canadian conditions (north prairie) should be considered separately since difenoconazole was applied as seed treatment in this study. Since dissipation rate seemed to be influenced by treatment rate the RMS also calculated separate mean and median values for low and high treatment rates (up to or above 500 g a.s./ha, respectively). However, for the further assessment, the 90th percentile (DT<sub>50</sub> 246 days and DT<sub>90</sub> 817 days) from the main studies using spray application and the whole range of treatment rates is used to provide robust estimates covering different conditions of use. Median DT<sub>50</sub> and DT<sub>90</sub> are 83 and 277 days, respectively. The 90th percentile values of 246 and 817 days are longer than those from the supplementary studies by Kühne-Thu and Purdy. It should be noted that for seed treatment applications and applications at low rates, these 90th percentile values probably represent overestimations of the persistence of difenoconazole.

**Table B.8.1.8.2-6. Median and mean values and (where appropriate) 90th percentile of DT<sub>50</sub> and DT<sub>90</sub> values from field dissipation studies on difenoconazole. Only main studies using spray application or seed treatment included. Values in bold used in the further assessment.**

Basis for calculation	Range	Median	Geometric mean	Arithmetic mean	90th percentile
<b>Studies using spray application (Ressler, 1992a-d and 2001a-d and Walser, 1994):</b>					
DT <sub>50</sub>	22-265 (n=9)	83	92	119	<b>246</b>
DT <sub>90</sub>	72-879 (n=9)	277	307	395	<b>817</b>
<b>Studies using spray application at ≤500 g/ha (Ressler, 1992b-d and 2001a and Walser, 1994):</b>					
DT <sub>50</sub>	22-83 (n=5)	63	53	58	n.a.
DT <sub>90</sub>	72-277 (n=5)	211	176	192	n.a.
<b>Studies using spray application at &gt;500 g/ha (Ressler, 1992a and 2001b-d):</b>					
DT <sub>50</sub>	116-265 (n=4)	200	186	196	n.a.
DT <sub>90</sub>	384-879 (n=4)	667	616	649	n.a.
<b>Studies using seed treatment (Purdy, 1997):</b>					
DT <sub>50</sub>	28-87 (n=4)	55	50	56	n.a.
DT <sub>90</sub>	92-289 (n=4)	184	167	187	n.a.

n.a. Not applicable (relatively few values).

Since field DT<sub>50</sub> > 3 months and field DT<sub>90</sub> > 1 year were observed, soil accumulation studies with annual applications were provided. One 3-year study on bare soil and winter wheat in the UK considered as supplementary (Tack, 1995), one 10-year study on plot with crop rotation in Switzerland (Kühne-Thu, 2000), one 4-year study in an apple orchard in northern Italy (Zelger, 2001), and finally a 4-year study on sugar beet in Italy (Molinari, 2002). None of the studies used application rates equal to the maximum annual application rate (375 g a.s./ha) following the representative uses. Based on the available data, difenoconazole or the two principal metabolites (CGA 205375 and CGA 71019) are not expected to accumulate in soil following normal agricultural practice. No indication of accumulation in soil was indicated by the study in the UK following application to wheat at 75 or 150 g a.s./ha. After application to bare soil low residues (up to 0.05 mg/kg) remaining from the previous season were found but the residues after the 3rd treatment were not different to the first year. However, measurements were limited to the 0-10 cm soil section in this study and the results are only used as support to other studies. The long-term study on field crops in Switzerland, usually with applications of 125 g a.s./ha each

year, gave no indication of accumulation of difenoconazole, CGA 205375 or CGA 71019 to a soil depth of 30 cm. In the last year analyses were done on samples to a depth of 60 cm with no residues of these compounds above LOD. However, there was an indication of potential accumulation of total, including bound, 1,2,4-triazole residues since up to 0.009-0.010 mg/kg were found immediately before application of difenoconazole. Since the majority of these residues are likely to be bound to the soil matrix and hence expected to be bioavailable only to a limited degree these residues are not considered as an area of concern. In the Italian study with annual applications of 4 x 62.5 g a.s./ha to an apple orchard, residues remaining from the previous season was only measurable in the second out of four years, at 0.01 mg/kg in soil (inter as well as intra rows). Finally, the Italian study with applications of 3 x 75 g a.s./ha to sugar beets gave no indication of accumulation in soil.

#### **B.8.1.8.3 Overall conclusions on route and rate of degradation in soil**

The information provided is considered sufficient and no further studies are considered necessary. Difenoconazole is slowly degraded in soil under aerobic conditions, and stable under anaerobic conditions. High treatment rate appears to result in slower degradation. Laboratory studies carried out at relevant treatment rates resulted in DT<sub>50</sub>s in the range 53 to 187 days (n=8) with a median value of 120 days.

The metabolite CGA 205375 was identified as maximum 9.7% of the applied radioactivity and as >5% at two or more sequential measurements in laboratory studies. It was also measured under field conditions as maximum 10-12% of the initial radioactivity. The metabolite CGA 71019 was identified as maximum 23.4% of the applied radioactivity in laboratory studies. No other metabolites are considered to require further assessment. Studies were provided on the aerobic and anaerobic rate of degradation of CGA 205375 and CGA 71019. Aerobic DT<sub>50</sub>s obtained were 83-152 days for CGA 205375 and 6.3-12 days for CGA 71019. A relatively large portion of the radioactivity was non-extractable in the studies on difenoconazole. The bound material is believed to be heterogeneous in nature. Mineralisation rate differs between different positions of radiolabel, with higher amounts of <sup>14</sup>C<sub>2</sub> measured from the chlorophenyl portion of the molecule than from the triazole ring.

Also in the field studies, a tendency for longer half-lives were noticed when high treatment rates were applied. Under field conditions with a wide range of application rates the main studies resulted in DT<sub>50</sub>s of 22-265 days (median 83 days, 90th %-ile 246 days), with DT<sub>90</sub>s in the range 72-879 days (median 277 days, 90th %-ile 817 days). The results were supported by additional supplementary studies involving spray application. Following seed treatment DT<sub>50</sub>s were 28-87 days, DT<sub>90</sub>s 92-289 days.

From the results of soil accumulation studies carried out over 3-10 years on various crops and bare soil difenoconazole or the two principal metabolites (CGA 205375 and CGA 71019) are not expected to accumulate in soil following normal agricultural practice.

The 90th %-ile field DT<sub>50</sub> of 246 days (Table B.8.1.8.2-6) is used to calculate PEC<sub>soil</sub>. For PEC<sub>gw</sub>, PEC<sub>sw</sub> and PEC<sub>sd</sub> the arithmetic mean of normalised DT<sub>50</sub> values for difenoconazole and metabolites were used (Tables B.8.1.8.2-2 and B.8.1.8.2-4).

## **B.8.2 Adsorption, desorption and mobility in soil (Annex IIA 7.1.2 and 7.1.3; Annex IIIA 9.1.2)**

### **B.8.2.1 Adsorption/desorption studies**

<b>Reference:</b>	<b>Atkins RH (1991a)</b> CGA 169374: Soil adsorption/desorption of [ <sup>14</sup> C] CGA 169374 by the batch equilibrium method. PTRL East, Inc., Richmond, Kentucky, USA. Report No. 495. Syngenta File No. CGA169374/0477.
<b>Test material:</b>	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99.0% (as determined for definitive study: 98.7%), Batch No. JAK-IV-82.
<b>Guideline:</b>	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 163-1. EPA, 540/9-82-021, October 1982.
<b>GLP:</b>	Yes

#### **Material and methods:**

<b>Test concentration:</b>	0.1, 0.2, 0.4, 0.7 and 1.0 mg/L.
<b>Test system:</b>	Adsorption and desorption isotherms with <sup>14</sup> C-difenoconazole were determined using four different soil types, and duplicate samples. Test solutions were prepared in 0.01 M calcium chloride. 2.5 g of the sand soil, and 0.5 g of the remaining soils, respectively, were mixed with 30 mL of the dosing solution (soil/solution ratio 1:12 for the sand soil, 1:60 for the other soils). The adsorption phase was conducted for approximately 24 hours in a shaking water bath, followed by centrifugation and decanting of the supernatant for analysis. After decanting the supernatant, desorption isotherms were determined by re-suspending each of the soil pellets with 0.01 M CaCl <sub>2</sub> solution (volume added was equivalent to volume of adsorption solution decanted). The tubes were then placed into the shaking water bath for an additional 24 hours, followed by centrifugation as above. Preliminary tests were performed to determine the appropriate soil to water ratio and equilibration time.
<b>Test conditions:</b>	25±0.0°C, in the dark.
<b>Method of analysis:</b>	LSC quantitation of supernatant radiocarbon. After the desorption phase, the soil pellets were air dried at room temperature and combusted for quantitation of radiocarbon.
<b>Soil Characteristics:</b>	See Table B.8.2.1-1.

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**Table B.8.2.1-1. Soil characteristics.**

Soil designation		Agricultural sand (USA)	Sandy loam (USA)	Silt loam (USA)	Silty clay loam (USA)
Soil type (USDA)		sand	sandy loam	silt loam	silty clay loam
Sand	[%]	88	69	17	15
Silt	[%]	11	21	66	51
Clay	[%]	1	10	17	34
pH		7.9	7.8	6.5	6.9
Organic matter	[%]	0.62	3.40	3.00	1.16
Organic carbon <sup>a</sup>	[%]	0.36	1.98	1.74	0.67
Cation exchange capacity	[meq/100 g]	3.0	10.0	16.0	30.0
Bulk density	[g/cm <sup>3</sup> ]	1.49	1.24	1.37	1.59
Field capacity (FC, 1/3 bar)	[g/100 g]	8.7	16.0	38.0	42.9

<sup>a</sup> calculated by RMS, dividing % organic matter by 1.72.

**Results:**

The overall mean mass balance or recovery for the definitive study was 102.6±6.6% of applied radioactivity. The adsorption and desorption constants are summarised in the tables below. The adsorption coefficients ( $K_f$  values, referred to as  $K_d$  in the study) for difenoconazole ranged from 12.8 in the sand to 63 in the sandy loam soil. The Freundlich adsorption constants corrected for the soil organic matter ( $K_{foc}$  values) ranged from 3470 in the silt loam to 7730 in the silty clay loam soil. Desorption constant values were higher than the corresponding adsorption values. It was concluded that difenoconazole is strongly adsorbed to soil.

**Table B.8.2.1-2. Freundlich adsorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for difenoconazole in four soils. Mean of duplicate samples.**

	$K_f$ (mL/g)	$K_{foc}$ (mL/g)	1/n
Sand	12.8	3870	0.74
Sandy loam	63.0	3520	0.76
Silt loam	54.8	3470	0.85
Silty clay loam	47.2	7730	0.91
<b>Mean</b>	<b>44.4</b>	<b>4648</b>	<b>0.82</b>

**Table B.8.2.1-3. Freundlich desorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for difenoconazole in four soils. Mean of duplicate samples.**

	$K_{f, des}$ (mL/g)	$K_{foc}$ (mL/g)	1/n
Sand	18.6	5620	0.75
Sandy loam	95.2	5320	0.80
Silt loam	57.2	3620	0.76
Silty clay loam	71.4	11700	0.93
<b>Mean</b>	<b>60.6</b>	<b>6565</b>	<b>0.81</b>

**Comments by RMS:**

The analytical method used (LSC) cannot differentiate difenoconazole and possible transformation products. However, difenoconazole is not expected to be rapidly transformed and therefore the total radioactivity in this case is considered to represent the parent compound only. The study is considered to be well performed and reported and is considered as valid for the risk assessment.

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<b>Reference:</b>	<b>Spare WC (1988)</b> CGA 169374: Adsorption/desorption of <sup>14</sup> C-CGA 169374. Agrisearch Incorporated, Frederick, Maryland, USA. Report No. 12115. Syngenta File No. CGA169374/0476.
<b>Test material:</b>	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99%, Batch No. BPM-V-41.
<b>Guideline:</b>	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 163-1. EPA, 540/9-82-021, October 1982.
<b>GLP:</b>	Yes

#### Material and methods:

Test concentration: 0.02, 0.05, 0.1, 0.5 and 1.0 mg/L.

Test system: Adsorption/desorption isotherms with <sup>14</sup>C-difenoconazole were determined using four different soil types. Test solutions were prepared in 0.01 M calcium acetate. 5 g each of the sandy loam and sand soils were mixed with 25 mL solution (soil/solution ratio 1:5), and 0.5 g each of the silt loam and clay soils were mixed with 50 mL solution (soil/solution ratio 1:100). The adsorption phase was conducted in duplicate for approx. 8 hours in a shaking water bath. After 8 hours adsorption isotherms were determined by centrifugation with subsequent analysis of the supernatant. After decanting the supernatant, desorption isotherms were determined by re-suspending each of the soil pellets with 0.01 M calcium acetate solution (volume added was equivalent to volume of adsorption solution decanted). The tubes were then placed into the shaking water bath for an additional 8 hours. After centrifugation, supernatants were decanted and analysed. A range finding test was performed prior to the definitive test to determine the appropriate soil to water ratio and equilibration time.

Test conditions: 24-25°C, in the dark.

Method of analysis: LSC quantitation of supernatant radiocarbon. The stability of difenoconazole in solutions from the adsorption and desorption phases was determined by TLC. The soil pellets were air dried at room temperature and combusted for quantitation of radiocarbon.

Soil Characteristics: See Table B.8.2.1-4.

**Table B.8.2.1-4. Soil characteristics.**

Soil designation		Maryland I (USA)	Maryland II (USA)	Mississippi (USA)	California (USA)
Soil type (USDA)		clay	sand	silt loam	sandy loam
Sand	[%]	25.2	95.6	39.5	67.0
Silt	[%]	32.8	2.2	54.2	27.0
Clay	[%]	42.0	2.2	6.3	6.0
pH		5.9	6.5	7.5	8.5
Organic matter	[%]	4.8	0.9	1.0	1.0
Organic carbon <sup>a</sup>	[%]	2.79	0.52	0.58	0.58
Cation exchange capacity	[meq/100 g]	24.3	1.8	9.7	10.4
Bulk density	[g/cm <sup>3</sup> ]	1.25	1.65	1.34	1.84
Field capacity (FC, 1/3 bar)	[g/100 g]	35.9	3.8	16.5	10.1

<sup>a</sup> calculated by RMS, dividing % organic matter by 1.72.

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**Results:**

The overall mass balance or recovery for the definitive study was between 88.8 and 94.6% of applied radioactivity. No degradation of the parent in any of the solutions was detected. The adsorption and desorption constants are summarised in the tables below. The adsorption coefficients ( $K_f$  values, referred to as  $K_d$  values in the study) for difenoconazole ranged from 2 in a sand to 98 in a clay soil. The Freundlich adsorption constants corrected for the soil organic matter ( $K_{foc}$  values) ranged from 400 in the sand to 5660 in the silt loam soil. Desorption constant values were higher than the corresponding adsorption values. It was concluded that difenoconazole was moderately to strongly adsorbed to soil.

**Table B.8.2.1-5. Freundlich adsorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for difenoconazole in four soils. Mean of duplicate samples.**

	$K_f$ (mL/g)	$K_{foc}$ (mL/g)	1/n
Maryland I Clay	97.8	3470	0.89
Maryland II Sand	2.1	400	0.80
Mississippi Silt loam	35.0	5660	0.88
California Sandy loam	11.5	1960	0.94
<b>Mean</b>	<b>36.6</b>	<b>2872</b>	<b>0.88</b>

**Table B.8.2.1-6. Freundlich desorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for difenoconazole in four soils. Mean of duplicate samples.**

	$K_{f, des}$ (mL/g)	$K_{foc}$ (mL/g)	1/n
Maryland I Clay	119.1	4220	0.86
Maryland II Sand	4.2	790	0.85
Mississippi Silt loam	66.7	10800	0.89
California Sandy loam	17.3	2940	0.94
<b>Mean</b>	<b>51.8</b>	<b>4688</b>	<b>0.88</b>

**Comments by RMS:**

Based on results from a range-finding study (up to 48 hours), it seems unlikely that equilibrium was reached after the 8 hours in the definitive test. After 24 hours the average amount remaining in solution was 88% of the amount in solution after 8 hours shaking (set to 100%); after 48 hours the average percentage remaining in solution was 84% of the amount in solution after 8 hours. However, since sorption increased with time the proposed adsorption constants may be used as a worst case regarding the potential for leaching to groundwater.

<b>Reference:</b>	<b>Völkel W (2002b)</b> Adsorption/desorption of CGA 205375 [14C-triazole] on soils. RCC Ltd, Environmental Chemistry & Pharamanalytics Division, Itingen, Switzerland. Report No. 798647. Syngenta File No. CGA205375/0013.
<b>Test material:</b>	CGA 205375 (1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol), <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99.4% (as determined by HPLC before application: 100%), Batch No. ILA-52.3A-1.
<b>Guideline:</b>	OECD Guideline 106: Adsorption/Desorption using a batch equilibrium method. Adopted January 21, 2000.
<b>GLP:</b>	Yes

**Material and methods:**

Test concentration: 0.005, 0.02, 0.10, 0.26 and 0.5 mg/L.

Test system: Adsorption/desorption isotherms for the soil metabolite <sup>14</sup>C-CGA 205375 were determined using five different soil types. Test solutions were prepared in 0.01 M calcium chloride. 1 g of soil was mixed with 25 mL solution (soil/solution ratio 1:25). The adsorption phase was conducted for approx. 48 hours on a shaker. Duplicate samples were used. After 24 hours adsorption isotherms were determined by centrifugation with subsequent assay of supernatant radiocarbon. After decanting the supernatant, desorption isotherms were determined by re-suspending each of the soil pellets with 0.01 M calcium chloride solution (volume added was equivalent to volume of adsorption solution decanted). The tubes were then placed on to the shaker for an additional 48 hours. A preliminary test was performed on two soils at 0.47 mg/l to select the optimal soil/solution ratio, determine the equilibration time, determine the adsorption to test vessels and the stability of the test item, and to determine mass balance. A screening test was also performed on five soils at a single concentration (0.46 mg/l, soil/solution ratio 1:25). Below mainly the results from the advanced test are presented.

Test conditions: 20±2°C, in the dark.

Method of analysis: LSC quantitation of supernatant radiocarbon. The stability and recovery of the compound in the test system was determined during the preliminary range finding test. The aqueous solutions were analysed directly by HPLC. The residual soil was first extracted with acetonitrile/water (4:1, v/v) and the combined extracts were analysed by HPLC and the remaining radioactivity in the soil determined by LSC after combustion.

Soil Characteristics: See Table B.8.2.1-7.

**Table B.8.2.1-7. Soil characteristics.**

Soil designation		Soil I Speyer 2.2 (Germany)	Soil II Senozan (France)	Soil III Itingen (Switzerland)	Soil IV Schanz (Switzerland)	Soil V Mechthilds- hausen (Germany)
Soil type (USDA)		loamy sand	silty clay loam	clay	sandy loam	loam
Sand	[%]	77.1	19.2	13.7	65.7	50.9
Silt	[%]	15.4	52.6	40.0	21.0	34.7
Clay	[%]	7.5	28.2	46.3	13.3	14.4
pH (CaCl <sub>2</sub> )		5.7	6.6	6.7	6.8	7.6
Organic carbon	[%]	2.17	1.16	2.63	1.17	1.22
Cation exchange capacity	[meq/100 g]	11.0	18.0	32.5	11.3	9.6

**Results:**

The overall mass balance or recovery in the preliminary study was 99.3 (soil I) and 103.2% (soil II) of applied radioactivity. No degradation of CGA 205375 in any phase was detected. The adsorption and desorption constants

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are summarised in the tables below. The Freundlich adsorption coefficient ( $K_f$  values) for CGA 205375 ranged from 23 in a sandy loam to 188 in a loamy sand soil. The Freundlich adsorption constants corrected for the soil organic matter ( $K_{foc}$  values) ranged from 1680 in the clay to 5440 in the loamy sand soil. Desorption constant values were higher than the corresponding adsorption values. It was concluded that CGA 205375 was strongly adsorbed to soil.

**Table B.8.2.1-8. Freundlich adsorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for CGA 2053 75 in five soils. Mean of duplicate samples.**

	$K_f$	$K_{foc}$ (mL/g)	1/n
Soil I loamy sand	118.0	5440	0.81
Soil II silty clay loam	45.5	3920	0.76
Soil III clay	44.1	1680	0.76
Soil IV sandy loam	22.6	1930	0.72
Soil V loam	23.6	1930	0.77
<b>Mean</b>	<b>50.8</b>	<b>2980</b>	<b>0.76</b>

**Table B.8.2.1-9. Freundlich desorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for CGA 2053 75 in five soils. Mean of duplicate samples.**

	$K_{f, des}$	$K_{foc}$ (mL/g)	1/n
Soil I loamy sand	157.5	7260	0.87
Soil II silty clay loam	49.4	4260	0.79
Soil III clay	53.5	2030	0.76
Soil IV sandy loam	25.2	2150	0.75
Soil V loam	34.9	2860	0.83
<b>Mean</b>	<b>64.1</b>	<b>3712</b>	<b>0.80</b>

**Comments by RMS:**

The study was well performed and reported, and the results are considered to be valid for the risk assessment.

<b>Reference:</b>	<b>Hawkins DR (1988)</b> Soil adsorption and desorption of 1,2,4-Triazole. Rohm and Haas Company, Spring House, Pennsylvania, USA. Report No. 34S-88-27. Syngenta File No. CGA71019/0014.
<b>Test material:</b>	CGA 71019 (1,2,4-triazole, more specifically 1H-1,2,4-triazole), 3,5- <sup>14</sup> C-radiolabel: Radiochemical purity >95%, Batch No. 674.0001.
<b>Guideline:</b>	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 163-1. EPA, 540/9-82-021, October 1982.
<b>GLP:</b>	Yes

**Material and methods:**

Test concentration: 0.0043, 0.0085, 0.043 and 0.086 mg/L.

Test system: The adsorption/desorption isotherms of <sup>14</sup>C-CGA 71019 were determined in 5 US soils in a batch equilibrium experiment. Test solutions were prepared in aqueous calcium chloride (0.01 M). The test solutions were added to the soils in solution/soil ratios of between 1:2 and 1:5. The soils were equilibrated for 95 hours then centrifuged to separate the soil and solutions prior to analysis of the

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liquid phase. Preliminary work had shown that one day was sufficient to reach about 90% of the equilibrium adsorption but to be certain of reaching equilibrium the tubes were shaken for almost four days. Two sequential desorption steps were performed for 46 hours and 24 hours, respectively, changing the  $\text{CaCl}_2$  solutions at each step. Freundlich adsorption constants  $K_f$  and  $K_{\text{foc}}$  (referred to as  $K_d$  and  $K_{\text{oc}}$  in the report) and the corresponding  $1/n$  value were determined from a plot of  $-\log$  concentration in soil versus  $-\log$  concentration in solution.

Test conditions:  $25 \pm 1^\circ\text{C}$ , in the dark.

Method of analysis: LSC quantitation of supernatant radiocarbon. The stability of CGA 71019 through the experiment was monitored by HPLC of samples from the supernatant solutions. Radioactivity remaining in the soil after the second desorption was determined by oxidation.

Soil Characteristics: See Table B.8.2.1-10.

**Table B.8.2.1-10. Soil characteristics.**

Soil designation		Alpaugh (USA)	Hollister (USA)	Lakeland (USA)	Lawrenceville (USA)	Pachappa (USA)
Soil type (USDA)		silty clay	clay loam	sand	silty clay loam	sandy loam
Sand	[%]	11	26	91	9	62
Silt	[%]	44	46	0	62	21
Clay	[%]	45	28	9	29	17
pH		8.8	6.9	4.8	7.0	6.9
Organic matter	[%]	1.2	3.0	0.2	1.2	1.4
Organic carbon	[%]	0.70	1.74	0.12	0.70	0.81
Cation exchange capacity	[meq/100 g]	30.5	16.9	1.2	6.6	11.1

*a calculated by RMS, dividing % organic matter by 1.72.*

### Results:

Material balance during the study was good with  $99 \pm 8\%$  of applied radioactivity. CGA 71019 was stable throughout the experiment, the average recovery (by HPLC) was  $102 \pm 7\%$ . The Freundlich adsorption constants ( $K_f$ ) for the various soils ranged from 0.23 for the Lakeland sand to 0.83 for the Alpaugh silty clay. The adsorption adjusted for the organic carbon content of the soils,  $K_{\text{foc}}$ , ranged from 43 for the Hollister clay loam to 202 for the Lakeland sand. However, due to the very low organic carbon content of the Lakeland soil its high value for  $K_{\text{foc}}$  was proposed to be not representative of CGA 71019 behaviour in soil, and therefore for risk assessment purposes it was disregarded. As a result, the average  $K_{\text{foc}}$  for the four remaining soils was 89 mL/g. A summary of the data is shown in the table below. The desorption equilibrium constants were much higher compared to the adsorption constants and amounted to approximately 1.2 and 4.6 for the first and second desorption cycle, respectively. The average percentage of radioactivity remaining in the aqueous phase after adsorption amounted to 78%. This fraction decreased to approximately 67 and 47% after the first and second desorption, respectively. This indicates that a portion of the CGA 71019 was irreversibly bound to the soil, and this was proposed to reduce the potential for leaching. It was concluded that CGA 71019 was weakly adsorbed to soil.

**Table B.8.2.1-11. Freundlich adsorption and desorption coefficients, coefficients normalised to organic carbon content and Freundlich exponent (1/n) for CGA 71019 in five soils. Adsorption parameters mean of triplicate samples; desorption parameters single samples.**

Soil		1/n	K <sub>f</sub> (mL/g)	K <sub>oc</sub> (mL/g)
Alpaugh Silty clay	Adsorption	<b>0.897</b>	<b>0.83</b>	<b>120</b>
	1 <sup>st</sup> Desorption	0.968	2.13	306
	2 <sup>nd</sup> Desorption	1.015	7.93	1139
Hollister Clay loam	Adsorption	<b>0.827</b>	<b>0.75</b>	<b>43</b>
	1 <sup>st</sup> Desorption	0.811	1.14	66
	2 <sup>nd</sup> Desorption	0.826	1.86	107
Lakeland Sand	Adsorption	0.885	0.23	202
	1 <sup>st</sup> Desorption	1.015	0.61	526
	2 <sup>nd</sup> Desorption	1.244	7.60	6551
Lawrenceville Silty clay loam	Adsorption	<b>0.922</b>	<b>0.72</b>	<b>104</b>
	1 <sup>st</sup> Desorption	0.843	0.82	117
	2 <sup>nd</sup> Desorption	0.876	2.04	293
Pachappa Sandy loam	Adsorption	<b>1.016</b>	<b>0.72</b>	<b>89</b>
	1 <sup>st</sup> Desorption	0.972	1.07	131
	2 <sup>nd</sup> Desorption	1.010	3.49	430
<b>Mean<sup>a</sup></b>		<b>0.91</b>	<b>0.75</b>	<b>89</b>

*a Mean values do not include the value for Lakeland soil due to its exceptionally low organic matter content.*

#### Comments by RMS:

The RMS agrees that the Lakeland soil may not be representative for European agricultural soils, and that the results from this soil should be omitted in the risk assessment. The study was well performed and reported, and is considered as valid for the risk assessment.

#### B.8.2.2 Column leaching studies

Since reliable adsorption studies are available for a sufficient number of soils, column leaching studies are not formally required. However, the notifier has submitted a study on the potential for leaching of the parent compound. The study was not evaluated in detail by RMS, but below is a summary provided by the notifier.

<b>Reference:</b>	<b>Mani J (1991a)</b> Leaching model study with <sup>14</sup> C-CGA 169374 in four soils under laboratory conditions. CIBA-GEIGY Limited, Agricultural Division, Basle, Switzerland. Report No. 23-91. Syngenta File No. CGA169374/0467.
Test material:	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 97.6%, Batch No. RAF-VIII-45-1.
Guideline:	BBA Guideline Part IV, 4-2, December 1986. Dutch Registration Guideline, Section G.1.2: Data about the Mobility of the Product and the most important Metabolites in the Soil. Ministry of Agriculture and Fisheries, Ministry of Public Health and Environmental Hygiene, Ministry of Social Affairs, January 1987.
GLP:	Yes

**Material and methods:** A column leaching study was carried out with four different soils. Soils were packed according to their bulk density into columns to a height of 30 cm. <sup>14</sup>C-Difenoconazole was applied to the top of the columns at an exaggerated rate equivalent to 5300 g a.s./ha and eluted with the equivalent of 200 mm of rain in a

period of two days.

Leachate was collected and the radioactivity quantified by LSC. After elution the soil columns were split into 2 cm segments and the total radioactive content determined by combustion. Segments with significant radioactivity (>0.5% of the applied radioactivity) were exhaustively extracted in a Soxhlet apparatus with acetone. Radioactive content was determined by LSC and the extracts were analysed by HPLC for difenoconazole and breakdown products.

Soil Characteristics: See Table B.8.2.1-12.

**Table B.8.2.1-12. Soil characteristics.**

Soil designation		Collombey (USA)	Lakeland (USA)	Les Evouettes (Switzerland)	Vetroz (Switzerland)
Soil type (USDA)		loamy sand	sand	loam	silt loam
Sand	[%]	78.7	96.5	42.5	18.4
Silt	[%]	17.1	1.0	42.3	56.8
Clay	[%]	4.2	2.5	15.2	24.8
pH		7.0	5.7	5.7	7.1
Organic carbon	[%]	0.8	0.4	1.4	4.4
Bulk density	[g/cm <sup>3</sup> ]	1.53	1.72	1.30	0.96
Cation exchange capacity	[meq/100 g]	6.35	3.41	12.7	30.7

#### Results:

Total recovery of radioactivity ranged from 90 to 101% of applied radioactivity. Difenoconazole did not move out of the zone of application (0-2 cm segment) in any soil. All the radioactivity in the 0-2 cm segment was shown to be difenoconazole. Less than 0.1% of the applied radioactivity was detected in the leachate. It was concluded that difenoconazole is not mobile in soil.

#### Comments by RMS:

The results support the conclusions from available adsorption/desorption studies that difenoconazole has a low potential for mobility in soil. The study is considered acceptable as providing supporting information.

#### B.8.2.3 Summary and assessment of adsorption, desorption and mobility in soil

A summary of the available studies on adsorption/desorption of difenoconazole and major metabolites in soil is given in Table B.8.2.3-1. The results from available studies indicate that difenoconazole and the metabolite CGA 205375 have a strong sorption and a low potential for mobility in soil, while the metabolite CGA 71019 (1,2,4-triazole) has a weak sorption and is more likely to leach through the soil profile. However, CGA 71019 was also shown to be rapidly degraded in soil and to a large extent incorporated into the soil matrix (see section B.8.1) why its potential for mobility is reduced.

The extent of adsorption of difenoconazole seemed to depend only on soil organic matter and there was no obvious relationship with other soil parameters, within the range tested.

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In the extensive package of field trials (sections B.8.1.5 and B.8.1.7), some covering several years of applications, difenoconazole was only rarely detected below 10 cm in soil. Since reliable adsorption/desorption data were available for difenoconazole, CGA 205375 and CGA 71019, "fresh" or "aged" soil column leaching are not formally required. A soil column study with "freshly" applied difenoconazole was however submitted and the result supports the conclusion of low mobility of difenoconazole in soil.

**Table B.8.2.3-1. Summary of studies on adsorption/desorption on difenoconazole and its metabolites in soil CGA 205375 and CGA 71019.**

Study/Soil	pH	Org. C %	Adsorption			Desorption		
			K <sub>f</sub> (mL/g)	1/n	K <sub>foc</sub> (mL/g)	K <sub>f, des</sub> (mL/g)	1/n	K <sub>foc</sub> (mL/g)
Difenoconazole								
Atkins, 1991a								
Sand	7.9	0.36 <sup>a</sup>	12.8	0.74	3870	18.6	0.75	5620
Sandy loam	7.8	1.98 <sup>a</sup>	63.0	0.76	3520	95.2	0.80	5320
Silt loam	6.5	1.74 <sup>a</sup>	54.8	0.85	3470	57.2	0.76	3620
Silty clay loam	6.9	0.67 <sup>a</sup>	47.2	0.91	7730	71.4	0.93	11700
Spare, 1988								
Clay	5.9	2.79 <sup>a</sup>	97.8	0.89	3470	119	0.86	4220
Sand	6.5	0.52 <sup>a</sup>	2.1	0.80	400	4.2	0.85	790
Silt loam	7.5	0.58 <sup>a</sup>	35.0	0.88	5660	66.7	0.89	10800
Sandy loam	8.5	0.58 <sup>a</sup>	11.5	0.94	1960	17.3	0.94	2940
Median	-	-	41.1	0.87	3495	62.0	0.85	4770
Mean	-	-	40.5	0.85	3760	56.2	0.85	5626
CGA 205375								
Völkel, 2002b								
Loamy sand	5.7	2.17	118	0.81	5440	157.5	0.87	7260
Silty clay loam	6.6	1.16	45.5	0.76	3920	49.4	0.79	4260
Clay	6.7	2.63	44.1	0.76	1680	53.5	0.76	2030
Sandy loam	6.8	1.17	22.6	0.72	1930	25.2	0.75	2150
Loam	7.6	1.22	23.6	0.77	1930	34.9	0.83	2860
Median			44.1	0.76	1930	49.4	0.79	2860
Mean	-	-	50.8	0.76	2980	64.1	0.80	3712
CGA 71019								
Hawkins, 1988								
Silty clay	8.8	0.70 <sup>a</sup>	0.83	0.90	120	7.93	1.01	1139
Clay loam	6.9	1.74 <sup>a</sup>	0.75	0.83	43	1.86	0.83	107
Sand	4.8	0.12 <sup>a</sup>	- <sup>b</sup>	- <sup>b</sup>	- <sup>b</sup>	- <sup>b</sup>	- <sup>b</sup>	- <sup>b</sup>
Silty clay loam	7.0	0.70 <sup>a</sup>	0.72	0.92	104	2.04	0.88	293
Sandy loam	6.9	0.81 <sup>a</sup>	0.72	1.02	89	3.49	1.01	430
Median			0.74	0.91	81.5	2.76	0.94	623
Mean		-	0.75	0.91	89	3.83	0.93	492

*a* calculated by RMS, dividing % organic matter by 1.72.

*b* Results not considered reliable due to very low content of organic matter.

As a conclusion, sufficient information was available on adsorption/desorption and potential mobility in soil of difenoconazole and its two major metabolites in soil CGA 205375 and CGA 71019. The mean values for adsorption K<sub>foc</sub> (3760 for difenoconazole, 2980 for CGA 205375 and 89 for CGA 71019) and 1/n given in the table above are used in the further assessment.

### B.8.3 Predicted environmental concentrations in soil (PECs) (Annex IIIA 9.1.3)

#### B.8.3.1 DIVIDEND 030 FS: PECsoil

**Reference:** Harvey B (2004c) A-9142 G Difenoconazole (DIVIDEND 030 FS). Document M-III, Section 5. Fate and Behaviour in the Environment. ERA5713.

##### Active ingredient:

PECsoil was calculated based on a standard scenario of a single sowing of treated seed. From the proposed use pattern of DIVIDEND 030 FS (A-9142 G) on small seed crops such as wheat and barley, the maximum rate of difenoconazole is 12.3 g a.s./ha, based on a seed planting rate of 205 kg seed/ha and a seed coating of 6 g a.s./100 kg seeds.

PECsoil were calculated for the 0-5 cm soil layer, and a value of 1.5 g/cm<sup>3</sup> for bulk density was used. For calculation of actual and time weighted average (TWA) PECsoil, a 90th percentile field dissipation DT<sub>50</sub> of 179 days was used by the notifier. Since the RMS re-calculated several of the individual DT<sub>50</sub>s the 90th percentile was changed to 246 days during this evaluation. The short and long term PECsoil presented below are therefore not those presented in Doc. M-III but produced by the RMS. Apart from DT<sub>50</sub> the same scenarios and assumptions as proposed by the notifier were used.

The initial and the short and long term actual and TWA PECsoil for difenoconazole are shown in Table B.8.3.1-1.

**Table B.8.3.1-1. Initial PECsoil and actual and time weighted average (TWA) PECsoil for difenoconazole following application (planting) of seeds treated with DIVIDEND 030 FS at a rate of 6 g a.s./100 kg seed. Seed planting rate 205 kg seed/ha. Short and long term PECsoil re-calculated by the RMS using 90th percentile DT<sub>50</sub> 246 days instead of 179 days, as proposed by the notifier.**

Days from last application	Actual PECsoil, mg/kg	TWA PECsoil, mg/kg
0	0.016	-
1	0.016	0.016
2	0.016	0.016
4	0.016	0.016
7	0.016	0.016
14	0.016	0.016
21	0.015	0.016
28	0.015	0.016
50	0.014	0.015
100	0.012	0.014

##### Metabolites:

For the metabolites CGA 205375 and CGA 71019 initial PECsoil was calculated according to the following equation:

$$\text{PECsoil (mg/kg)} = \text{Max. Parent PECsoil} \times \text{Max. metabolite in soil} \times \text{Mol. Wt. fraction}$$

Where:

Max. metabolite in soil = maximum percentage (as a fraction) observed in laboratory soil metabolism studies

Mol. Wt. Fraction = ratio of molecular weights of metabolite to difenoconazole.

For CGA 205375 the max. percentage in soil was 10% and the molecular weight fraction  $350/406=0.862$ .

For CGA 71019 the max. percentage in soil was 23% and the molecular weight fraction  $69/406=0.170$ .

For use as seed treatment the max. parent PECsoil of 0.016 mg/kg was used.

The initial PECsoil for the metabolites following planting of seeds (205 kg/ha) treated with difenoconazole at a rate of 6 g/100 kg seed were:

CGA 205375:  $0.016 \times 0.1 \times 0.862 = 0.0014$  mg/kg

CGA 71019:  $0.016 \times 0.23 \times 0.170 = 0.0006$  mg/kg

#### Comments by RMS:

The values presented above are used for risk assessment for DIVIDEND 030 FS. The choice to use the 90th percentile field  $DT_{50}$  for difenoconazole is considered justified by the high number of field studies provided (9 main studies, and 13 supplementary). The difference in  $DT_{50}$  value used (notifier 179 days vs. RMS 246 days) produced only a negligible difference.

#### B.8.3.2 SCORE 250 EC: PECsoil

<b>Reference:</b>	<b>Harvey B (2004b)</b> A-7402 T Difenoconazole (SCORE 250 EC). <b>Document M-III</b> , Section 5. Fate and Behaviour in the Environment. ERA5695.
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#### Active ingredient:

During a growing season, SCORE 250 EC (A-7402 T) may be applied up to a maximum of 4 x 75 g a.s./ha on apples (S EU) and 3 x 125 g a.s./ha on carrots (N and S EU) giving a maximum of 300 g and 375 g difenoconazole/ha/year respectively. PECsoil for difenoconazole were calculated for these two areas of use, representing the worst-case situation. An interval of 7 days (minimum) between spray to apples was assumed, an interval of 14 days to carrots. Initial PECsoil following a single application were also calculated, for the formulated product and the active ingredient.

As a fungicide A-7402 T will always be applied to growing crops; the earliest application will be at BBCH 61 for apples (growth stage also referred to as flowering) and BBCH 42-43 for carrots. Estimates of crop interception of 65% (apples) and 80% (carrots) as proposed in FOCUS Groundwater Report (2002) were used. Since applications later in the season will have greater interception the calculations represent the worst case in this respect. PECsoil were calculated for the 0-5 cm soil layer, and a value of  $1.5 \text{ g/cm}^3$  for bulk density was used.

A 90th percentile field dissipation  $DT_{50}$  of 179 days was used by the notifier. Since the RMS re-calculated several of the individual  $DT_{50}$ s the 90th percentile was changed to 246 days during this evaluation. The results presented below for multiple applications are therefore not those presented in Doc. M-III but produced by the RMS. Apart from  $DT_{50}$  the same scenarios and assumptions as proposed by the notifier were used.

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The initial PECsoil of difenoconazole following a single application at the maximum rate to apples and carrots is shown in Table B.8.3.2-1. Short and long term actual and TWA PECsoil for the use in apples and carrots are shown in Tables B.8.3.2-2 and B.8.3.2-3, respectively.

**Table B.8.3.2-1. Initial PECsoil for product and active ingredient following a single application of SCORE 250 EC (A-7402 T) to apples and carrots, at the maximum application rate. Crop interception 65% (apples) and 80% (carrots).**

Product/Active ingredient	Crop	Application rate, g/ha	Initial PECsoil, mg/kg
A-7402 T	Apples	323 <sup>a</sup>	0.151
A-7402 T	Carrots	538 <sup>b</sup>	0.144
Difenoconazole	Apples	75	0.035
Difenoconazole	Carrots	125	0.033

*a* Maximum application rate 0.3 L/ha, density of formulation 1076 g/L (20°).

*b* Maximum application rate 0.5 L/ha, density of formulation 1076 g/L (20°).

**Table B.8.3.2-2. Initial PECsoil and actual and time weighted average (TWA) PECsoil for difenoconazole following multiple applications of SCORE 250 EC to apples at maximum application rate 4 x 75 g a.s./ha. Spray intervals 7 days. Crop interception 65%. Re-calculated by the RMS using 90th percentile DT<sub>50</sub> 246 days instead of 179 days, as proposed by the notifier.**

Days from last application	Actual PECsoil, mg/kg	TWA PECsoil, mg/kg
0	0.136	-
1	0.136	0.136
2	0.135	0.136
4	0.134	0.135
7	0.133	0.135
14	0.131	0.133
21	0.128	0.132
28	0.126	0.131
50	0.118	0.127
100	0.103	0.118

**Table B.8.3.2-3. Initial PECsoil and actual and time weighted average (TWA) PECsoil for difenoconazole following multiple applications of SCORE 250 EC to carrots at maximum application rate 3 x 125 g a.s./ha. Spray intervals 14 days. Crop interception 80%. Re-calculated by the RMS using 90th percentile DT<sub>50</sub> 246 days instead of 179 days, as proposed by the notifier.**

Days from last application	Actual PECsoil, mg/kg	TWA PECsoil, mg/kg
0	0.096	-
1	0.096	0.096
2	0.096	0.096
4	0.095	0.096
7	0.094	0.095
14	0.092	0.094
21	0.091	0.093
28	0.089	0.092
50	0.084	0.090
100	0.072	0.084

#### Metabolites:

For the metabolites CGA 205375 and CGA 71019 initial PECsoil was calculated according to the following equation:

$$\text{PECsoil (mg/kg)} = \text{Max. Parent PECsoil} \times \text{Max. metabolite in soil} \times \text{Mol. Wt. fraction}$$

Where:

Max. metabolite in soil = maximum percentage (as a fraction) observed in laboratory soil metabolism studies

Mol. Wt. Fraction = ratio of molecular weights of metabolite to difenoconazole.

For CGA 205375 the max. percentage in soil was 10% and the molecular weight fraction  $350/406=0.862$ .

For CGA 71019 the max. percentage in soil was 23% and the molecular weight fraction  $69/406=0.170$ .

For use in apples the max. parent PECsoil of 0.134 mg/kg was used. The corresponding figure for use in carrots was 0.095 mg/kg. Since the RMS re-calculated the PECsoil for the parent for the multiple applications scenarios using a different  $DT_{50}$ , the initial PECsoil was also re-calculated by the RMS using max. parent PECsoil values of 0.136 mg/kg (apples) and 0.096 mg/kg (carrots).

The initial PECsoil for the metabolites (re-calculated by the RMS) following application to apples at 4 x 75 g a.s./ha were:

CGA 205375:  $0.136 \times 0.1 \times 0.862 = 0.012$  mg/kg

CGA 71019:  $0.136 \times 0.23 \times 0.170 = 0.0053$  mg/kg

The initial PECsoil for the metabolites (re-calculated by the RMS) following application of to carrots at 3 x 125 g a.s./ha were:

CGA 205375:  $0.096 \times 0.1 \times 0.862 = 0.0083$  mg/kg

CGA 71019:  $0.096 \times 0.23 \times 0.170 = 0.0038$  mg/kg

#### Comments by RMS:

The values presented above are used for risk assessment for SCORE 250 EC. The choice to use the 90th percentile field  $DT_{50}$  for difenoconazole is considered justified by the high number of field studies provided (9 main studies, and 13 supplementary). The difference in  $DT_{50}$  value used (notifier 179 days vs. RMS 246 days) produced only minor differences (e.g., PECinitial after the last application to apples was 0.134 mg/kg in Doc. M-III as compared to 0.136 mg/kg in the table above; for the use in carrots the corresponding figure presented by the notifier was 0.095 mg/kg compared to 0.096 mg/kg as calculated by the RMS in the table above).

Since field  $DT_{50} > 3$  months and field  $DT_{90} > 1$  year were observed, the RMS calculated a plateau PECsoil for difenoconazole. The scenario with 4 applications at 75 g a.s./ha to apples with spray interval was considered. The 90th percentile field  $DT_{50}$  of 246 days was used and the PECsoil 0.136 mg/kg presented above used as a starting point year 1. Since the orchard scenario was considered with little expected cultivation of the soil, the plateau PECsoil was calculated for a soil depth of only 5 cm. The plateau PECsoil were 0.076 mg/kg just before each annual application (lower part of "saw-teeth" curve) and 0.212 mg/kg just after the annual treatments (upper part of "saw-teeth" curve). These values would theoretically be reached after 7 years of annual treatment. Based on the results of the soil accumulation studies difenoconazole is however not expected to accumulate in soil, and the plateau PECsoil calculated are therefore not used for risk assessment.

## B.8.4 Fate and behaviour in water (Annex IIA 7.2.1; Annex IIIA 9.2.1, 9.2.3)

### B.8.4.1 Hydrolysis

<b>Reference:</b>	<b>Atkins RH (1991b)</b> Hydrolysis of [ <sup>14</sup> C] CGA-169374 at pH 5, 7 and 9. PTRL East Inc., Kentucky, USA. Report No. 494. Syngenta File No. CGA169374/0488.
Test material:	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99.2%, Batch No. JAK-IV-82
Guideline:	US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 161-1. EPA, 540/9-82-021, October 1982.
GLP:	Yes

#### Material and methods:

Test concentration:	2 mg/L
Test system:	<sup>14</sup> C-difenoconazole solution was prepared in acetonitrile and aliquots mixed with sterile buffers which were incubated for 30 days. The test systems were set up in triplicate.
Test conditions:	25±0.0°C, darkness.
pH (buffer system):	pH 5, 7 and 9.
Sampling time points:	Samples were taken at 0, 2, 7, 12, 16, 19, 23, 27 and 30 days of incubation.
Method of analysis:	Recoveries were determined by radio assay (LSC). Quantitative analysis was done by HPLC and confirmatory GC-MS was used to analyse day 30 samples. Reference compounds: Difenoconazole.

#### Results:

After 30 days of incubation at 25°C 95.2%, 100.5% and 101.9% of added radiocarbon remained as difenoconazole. The calculated half-lives for difenoconazole were significantly greater than 30 days (extrapolated to > 1000 days). Two unknown degradates were detected throughout the study in quantities <1.2% of applied radiocarbon. Total radioactive recoveries were between 101 and 103% of applied. The high recoveries indicated that no volatile products could have been produced. Difenoconazole was concluded to be hydrolytically stable in solutions at pH 5 to 9 at 25°C.

#### Comments by RMS:

The study was well performed and reported and is considered to be valid for the risk assessment. The study was also reported in section B.2.1.9.

<b>Reference:</b>	<b>van der Gaauw A (2001)</b> CGA 205375 [ <sup>14</sup> C-triazole]: Hydrolysis at three different pH values. RCC Ltd, Environmental Chemistry & Pharamanalysis Division, Itingen, Switzerland. Report No. 798658. Syngenta File No. CGA205375/0010.
Test material:	CGA 205375 (1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-

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Guideline:	yl]-ethanol), <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 98.3% (as determined by HPLC before application: 100%), Batch No. ILA-52.3A-1. OECD Guideline 111: Hydrolysis as a function of pH. Adopted May 12, 1981. Directive 92/69/EEC Part C.7. Abiotic degradation: Hydrolysis as a function of pH; L 383 A. December 1992.
GLP:	US EPA Guideline OPPTS 835.2110 – Hydrolysis as a function of pH, 1996. Yes

**Material and methods:**

Test concentration:	0.23 mg/L
Test system:	<sup>14</sup> C-CGA 205375 solution was prepared in acetonitrile and aliquots were mixed with sterile buffer solutions.
Test conditions:	50.1±0.1°C, darkness.
pH (buffer system):	4, 7 and 9.
Sampling time points:	After 0 (single sample) and 2.4 hours, 1 and 5 days of incubation (duplicate samples).
Method of analysis:	Radioactivity was quantified by LSC and the amounts of CGA 205375 and any degradates determined by HPLC. Selected samples were subject to confirmatory analysis by TLC. Reference compounds: CGA 205375, CGA 205374, CGA 71019, CGA 131013, CGA 142856 and NOA 457654.

**Results:**

Total radioactive recoveries were between 98.3 and 104.1% of applied. The high recoveries indicated that no volatile products could have been produced. Little or no degradation of CGA 205375 occurred, the parent accounted for between 103.2 and 104.1% of applied radioactivity in the solutions after 5 days. No degradates were observed. The results indicate that CGA 205375 is hydrolytically stable in solutions at pH 4 to 9 at 50°C.

**Comments by RMS:**

The study was well performed and reported, and the conclusion that CGA 205375 is stable towards hydrolysis is considered to be valid.

<b>Reference:</b>	<b>Spare WC (1983)</b> Determination of the Hydrolysis Rate Constants of 1,2,4-H-Triazole. Biospherics Incorporated, Rockville, Maryland, USA. Report No. 83-E-074. Syngenta File No. CGA71019/0033.
Test material:	CGA 71019 (1,2,4-triazole), 3,5- <sup>14</sup> C-radiolabel: Radiochemical purity 98.6%, Batch No. GB-XXVI-45.
Guideline:	-
GLP:	No

**Material and methods:**

Test concentration:	10 mg/L
Test system:	<sup>14</sup> C-CGA 71019 was dissolved in deionised water and added to sterile buffers.

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	Each dosed buffer was split into two replicates.
Test conditions:	25±1°C, in darkness.
pH (buffer system):	5, 7 and 9.
Sampling time points:	Triplicate samples were taken at days 0, 1, 3, 6, 13 and 30 of incubation.
Method of analysis:	At each sampling interval two samples were removed from each buffer incubation. One sample was used for TLC analysis, the second for LSC.

**Results:**

Total recovery from TLC was 74.0-98.3% of total radioactivity spotted. Of this, CGA 71019 accounted for 90.8-94.2% day 0 and 89.6-92.6% day 30. Hence no significant degradation had occurred during the test. The test substance was concluded to be hydrolytically stable at pH 5 to 9 at 25°C.

**Comments by RMS:**

The total recovery from TLC at day 0 in a first analysis was only 55-84% of the total radioactivity, so the values reported above were derived from a repeated analyses. Although not a GLP study, and the recovery analyses seemed to be a bit uncertain, the overall conclusion that CGA 71019 is hydrolytically stable is considered as valid. The test method was generally in accordance with OECD Test Guideline No. 111.

**B.8.4.2 Phototransformation in water**

<b>Reference:</b>	<b>van der Gaauw A (2002a)</b> Aqueous Photolysis of CGA 169374 [14C-Triazole] under laboratory conditions. RCC Ltd, Environmental Chemistry & Pharamanalysis Division, Itingen, Switzerland. Report No. 815635. Syngenta File No. CGA169374/2209.
Test material:	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 100%, Batch No. ILS-244.1
Guideline:	SETAC (1995) Procedures for Assessing the Environmental Fate and Ecotoxicology of Pesticides. OECD/GD(97)21: Guidance Document on Direct Phototransformation of Chemical in Water. OECD Series on Testing and Assessment No. 7, 1997. EPA OPPTS 835.2210: Direct Photolysis Rate in Water by Sunlight, 1996.
GLP:	Yes

**Material and methods:**

Test concentration:	1.5 mg/L
Test system:	Photochemical transformation of difenoconazole in aqueous solution was investigated. Simulated sunlight from a SUNTEST apparatus equipped with a xenon arc lamp, with filters to remove wavelengths below 290 nm and having an intensity of 52 W/m <sup>2</sup> (compared to a typical temperate latitude natural summer sunlight irradiation of 42 W/m <sup>2</sup> ) within the range of 300 to 400 nm of the light spectrum, was used to irradiate solutions of <sup>14</sup> C-difenoconazole (dissolved in acetonitrile) in sterilised aqueous buffer (pH 7). The irradiation was carried out for a continuous period of 15 days. Filtered, humified air was passed through the

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incubation vessels and volatiles collected in traps. Corresponding control samples were maintained under the same conditions but in the dark.

Test conditions: 25.1±0.2°C

Sampling time points: Duplicate irradiated samples were taken at 0, 3, 6, 8, 10 and 15 days.

Methods of analysis: Recoveries were determined by radio assay (LSC) and chromatographic analysis was done by HPLC and TLC. Reference compounds were difenoconazole, CGA 71019, CGA 131013, CGA 142856, CGA 205374, CGA 205375 and CGA 107069.

### Results:

A summary of the results is shown in Tables B.8.4.2-1 and B.8.4.2-2. The total mean recovery from the irradiated solutions during the 15-day incubation period was 99.1±3.1% of applied radioactivity. For the dark control, individual recoveries ranged between 95.1% and 100.9% of applied radioactivity. No significant phototransformation of difenoconazole (<10% degradation) was observed in buffer solution at pH 7. After 15 days of continuous irradiation, difenoconazole represented 90.9% of the applied radioactivity. Besides difenoconazole, three other radioactive fractions were detected (M2 to M4), however, none exceeded 6.3% of the applied radioactivity. Co-chromatography using HPLC showed that none of the fractions corresponded to the available reference compounds. In the dark control samples, no degradation was observed. It was concluded that difenoconazole is stable to direct photolysis in aqueous systems.

**Table B.8.4.2-1. Recovery and characterisation of radioactivity in irradiated <sup>14</sup>C-difenoconazole in aqueous buffer. As % of applied radioactivity. Mean of duplicate samples.**

Compound	Sampling interval, days					
	0	3	6	8	10	15
Difenoconazole	100.0	102.6	94.3	101.3	91.7	90.9
Unknown M2	n.d.	n.d.	n.d.	n.d.	1.4	0.8
Unknown M3	n.d.	n.d.	n.d.	n.d.	6.3	3.7
Unknown M4	n.d.	n.d.	n.d.	n.d.	n.d.	1.0

n.d. Not detected.

**Table B.8.4.2-2. Recovery of <sup>14</sup>C-difenoconazole in aqueous buffer in dark control samples. As % of applied radioactivity. Mean of duplicate samples.**

Compound	Sampling interval, days		
	0	10	15
Difenoconazole	100.0	100.9	95.4

### Comments by RMS:

The study is of acceptable quality. It was also reported in section B.2.1.9. The result is in good agreement with the fact that difenoconazole has a very low absorption above 290 nm (see section B.2.1.5).

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<b>Reference:</b>	<b>van der Gaauw A (2002b)</b> Aqueous Photolysis of CGA 205375 [ <sup>14</sup> C-triazole] under laboratory conditions. RCC Ltd, Environmental Chemistry & Pharamanalsys Division, Itingen, Switzerland. Report No. 815657. Syngenta File No. CGA205375/0018.
Test material:	CGA 205375 (1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol), <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 99.3% (determined before application), 100% (determined after application), Batch No. ILA-52.3A-1.
Guideline:	SETAC (1995) Procedures for Assessing the Environmental Fate and Ecotoxicology of Pesticides. OECD/GD(97)21: Guidance Document on Direct Phototransformation of Chemical in Water. OECD Series on Testing and Assessment No. 7, 1997. EPA OPPTS 835.2210: Direct Photolysis Rate in Water by Sunlight, 1996.
GLP:	Yes

**Material and methods:**

Test concentration:	1.0 mg/L
Test system:	Photochemical transformation of CGA 205375 in aqueous solution was investigated. Simulated sunlight from a SUNTEST apparatus equipped with a xenon arc lamp, with filters to remove wavelengths below 290 nm and having an intensity of 44.5 W/m <sup>2</sup> (compared to a typical temperate latitude natural summer sunlight irradiation of 42 W/m <sup>2</sup> ) within the range of 300 to 400 nm of the light spectrum, was used to irradiate solutions of CGA 205375 (dissolved in acetonitrile) in sterilised aqueous buffer (pH 7). The irradiation was carried out for a continuous period of 15 days. Filtered, humified air was passed through the incubation vessels and volatiles collected in traps. Corresponding control samples were maintained under the same conditions but in the dark.
Test conditions:	24.8±0.3°C
Sampling time points:	Duplicate irradiated samples were taken at 0, 3, 5, 7, 10 and 15 days.
Methods of analysis:	Recoveries were determined by radio assay (LSC) and chromatographic analysis was done by HPLC and TLC. Reference compounds were CGA 205375, CGA 205374, CGA 71019, CGA 131013, CGA 142856, and NOA 457654.

**Results:**

The total mean recovery from the irradiated solutions during the incubation period was 98.6±3.1% of the applied radioactivity. For the dark control, individual recoveries ranged between 100.0% and 103.7% of applied. No significant photo-degradation of CGA 205375 (<10% degradation) was observed in buffer solution at pH 7. After 15 days of continuous irradiation, CGA 205375 represented 90.3% of the applied radioactivity. Besides CGA 205375, five other radioactive fractions were detected (M2 to M6), however, none exceeded 4.2% of the applied radioactivity. Co-chromatography using HPLC showed that none of the fractions corresponded to the available reference items. In the dark control samples, no degradation was observed. It was concluded that CGA 205375 is stable to direct photolysis in aqueous systems.

**Comments by RMS:**

The study was well performed and reported, and the results are considered as valid for the risk assessment.

<b>Reference:</b>	<b>Hennecke D (2002a)</b> Quantum yield of photochemical degradation of CGA 169374 in aqueous solution. Fraunhofer-Institut für Molekularbiologie und Angewandte Ökologie, Schmallenberg, Germany. Report No. SYN-001/7-05a. Syngenta File No. CGA169374/2208.
Test material:	Difenoconazole: Chemical purity 99.3%, Batch No. AMS 255/3.
Guideline:	OECD Draft Test Guideline: Phototransformation of chemicals in water, direct and indirect photolysis. August 2000
GLP:	Yes

**Material and methods:**

Test concentration:	18.9 and 36.8 mg/L (for determination of decadic molar extinction coefficient), 10.1, 20.0 and 41.1 mg/L (for determination of quantum yield).
Test system:	The decadic molar extinction coefficient $\epsilon(\lambda)$ of difenoconazole was determined in purified un-buffered water with 10% of acetonitrile as inert co-solvent. Determinations were done in intervals of 2.5 nm at wavelengths above 270 nm. For determination of the quantum yield difenoconazole was dissolved in purified, de-ionised water containing 10% of acetonitrile. Based on the assumption that the quantum yield is independent of the wavelength for a discrete absorption band, the irradiation experiments were performed at $290 \pm 4$ nm with the intention to measure higher degradation rates because absorption decreases rapidly at higher wavelengths. Samples were irradiated for 0.5, 1, 2, 3, 4 and 6 hours in a Quantacount apparatus (450 W xenon lamp) providing monochromatic light. After 6 hours irradiation the observed degradation was approximately 37% on all tested concentrations. Therefore these samples were not used for determination of quantum yield (0-30% transformation was used as criteria since otherwise degradation products may disturb the correct determination). Control samples were prepared and stored in the dark.
Test conditions:	$25 \pm 1^\circ\text{C}$ (irradiated); $22^\circ\text{C}$ (dark controls).
Methods of analysis:	Irradiated samples and corresponding dark control samples were analysed by HPLC.
Calculations:	Environmental half-lives were calculated using program ABIWAS based on method by Frank and Klöpffer (1989) <sup>6</sup> . Tabular solar irradiance for $52^\circ\text{N}$ latitude were used. The calculation was performed for pure water with an assumed depth of 10 cm. Additional calculations by program GCSOLAR were included in an Appendix.

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**Results:**

The maximum absorption was at approximately 272.5 nm showing an absorption band which tails into the spectrum of sunlight (wavelengths >290 nm), but no separate absorption band above 290 nm was observed. The molar absorption coefficient at 290 nm ( $\epsilon_{290}$ ) was  $552.1 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$  and at 295 nm ( $\epsilon_{295}$ ) was  $139.3 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$ . At wavelengths above 317.5 nm the absorbance was in the range of the experimental error.

The quantum yield was determined to be 0.0155. Calculated environmental half-lives were between 11.8 years and >10000 years, depending on the season.

It was concluded that direct photolysis is an insignificant process for degradation of difenoconazole in surface water.

**Comments by RMS:**

The study is of acceptable quality. It was also reported in section B.2.1.9. The result is in agreement with the results of the study by van der Gaauw A (2002a) above.

<b>Reference:</b>	<b>Hennecke D (2002b)</b> Quantum yield of photochemical degradation of CGA 205375 in aqueous solution. Fraunhofer-Institut für Molekularbiologie und Angewandte Ökologie, Schmallenberg, Germany. Report No. SYN-001/7-05b. Syngenta File No. CGA205375/0017.
Test material:	CGA 205375 (1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol): Chemical purity 99.0%, Batch No. MLA-421/2.
Guideline:	OECD Draft Test Guideline: Phototransformation of chemicals in water, direct and indirect photolysis. August 2000
GLP:	Yes

**Material and methods:**

Test concentration:	20.2 and 39.0 mg/L (for determination of decadic molar extinction coefficient), 11.2, 20.2 and 42.0 mg/L (for determination of quantum yield).
Test system:	The decadic molar extinction coefficient $\epsilon(\lambda)$ of CGA 205375 was determined in purified un-buffered water with 10% of acetonitrile as inert co-solvent. Determinations were done in intervals of 2.5 nm at wavelengths above 270 nm. For determination of the quantum yield difenoconazole was dissolved in purified, de-ionised water containing 10% of acetonitrile. Based on the assumption that the quantum yield is independent of the wavelength for a discrete absorption band, the irradiation experiments were performed at $290 \pm 4$ nm with the intention to measure higher degradation rates because absorption decreases rapidly at higher wavelengths. Samples were irradiated for 0.5, 1, 1.5, 2, 3 and 4 hours in a Quantacount apparatus (450 W xenon lamp) providing monochromatic light.

<sup>6</sup> Frank K and Klöpffer W (1989) A Convenient Model and Program for the Assessment of Abiotic Degradation of Chemicals in Natural Waters. *Ecotox. Environ. Safety*, 17; 323-332.

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After 3 hours irradiation the observed degradation was between 24 and 33% and these samples were used for determination. Control samples were prepared and stored in the dark.

Test conditions: 25±1°C (irradiated); 22°C (dark controls).

Methods of analysis: Irradiated and corresponding dark control samples were analysed by HPLC.

Calculations: Environmental half-lives were calculated using program ABIWAS based on method by Frank and Klöpffer (1989)<sup>7</sup>. Tabular solar irradiance for 52°N latitude were used. The calculation was performed for pure water with an assumed depth of 10 cm. Additional calculations by program GCSOLAR were included in an Appendix.

### Results:

The maximum absorption was at approximately 275 nm showing an absorption band which tails into the spectrum of sunlight (wavelengths >290 nm), but no separate absorption band above 290 nm was observed. The molar absorption coefficient at 290 nm ( $\epsilon_{290}$ ) was 688 L x mol<sup>-1</sup> x cm<sup>-1</sup> and at 295 nm ( $\epsilon_{295}$ ) was 118 L x mol<sup>-1</sup> x cm<sup>-1</sup>. At wavelengths above 317.5 nm the absorbance was very low.

The quantum yield for CGA 205375 was determined to be 0.0266. Calculated environmental half-lives were between 14 years and >10000 years, depending on the season.

It was concluded that direct photolysis is an insignificant process for degradation of CGA 205375 in surface water.

### Comments by RMS:

The study is of acceptable quality. The result is in agreement with the results of the study by van der Gaauw A (2002b) above.

### B.8.4.3 Biological degradation

#### B.8.4.3.1 Ready biodegradability

<b>Reference:</b>	<b>Baumann W (1993)</b> Report on the test for ready biodegradability of CGA 169374 tech. in the carbon dioxide evolution test. CIBA-GEIGY Ltd., Product Safety, Basel, Switzerland. Report No. 933652. Syngenta File No. CGA169374/0813.
<b>Test material:</b>	Difenoconazole: Purity 91.8%, Batch No. P. 807002.
<b>Guideline:</b>	92/69/EEC C.4-C: Ready biodegradability, Carbon dioxide evolution test (corresponding to OECD Test Guideline No. 301B)
<b>GLP:</b>	Yes

<sup>7</sup> Frank K and Klöpffer W (1989) A Convenient Model and Program for the Assessment of Abiotic Degradation of Chemicals in Natural Waters. *Ecotox. Environ. Safety*, 17; 323-332.

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**Material and methods:**

Test concentration:	26.0 and 26.7 mg/L
Reference substance:	Sodium benzoate.
Test system:	Activated sludge collected from a sewage treatment plant prepared in accordance with the guideline was dosed with difenoconazole and incubated for 29 days in duplicate. Evolved carbon dioxide was trapped in sodium hydroxide.
Test conditions:	22±2°C
Sampling time points:	The CO <sub>2</sub> traps were sampled on days 0, 3, 6, 8, 10, 15, 20, 24, 28 and 29 and the carbon content determined in a carbon analyser.
Calculations:	Percentage biodegradation was calculated from content of inorganic carbon in absorption flask (corrected for blank) over the calculated theoretical organic carbon content.

**Results:**

No biodegradation of difenoconazole was found after 29 days. Biodegradation of reference compound was >70% after 6 days. It was concluded that difenoconazole was not biodegradable under the conditions of the test.

**Comments by RMS:**

The study is of acceptable quality. It is concluded that difenoconazole is not readily biodegradable in accordance with the OECD criteria.

**B.8.4.3.2 Degradation in water sediment system**

<b>Reference:</b>	<b>Gonzalez-Valero J (1993)</b> Metabolism of CGA 169374 under aerobic conditions in aquatic systems. CIBA-GEIGY Limited, Division Plant Protection, Basle, Switzerland. Report No. 34/92. Syngenta File No. CGA 169374/0746.
Test material:	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel: Radiochemical purity 92.6%, Batch No. CLXVI-89.
Guideline:	BBA Guideline Part IV; 5-1, December 1990. Dutch Registration Guideline, Section G.2: Behaviour in Water; Ministry of Agriculture and Fisheries, Ministry of Public Health and Environmental Hygiene, Ministry of Social Affairs, January 1987. US EPA Pesticide Assessment Guidelines, Subdivision N. Chemistry: Environmental Fate: Section 162-4. EPA 540/9-82-021, October, 1982.
GLP:	Yes

**Material and methods:**

Test concentration:	0.17 mg/L (corresponding to direct over spray of 100 g a.s./ha, , 0.06 m deep water) or related to sediment; 1.5 mg/kg dw (pond system), 0.47 mg/kg dw (river system)
Test system:	Route and rate of degradation of difenoconazole in pond and river systems was investigated. Each test systems consisted of 2-2.5 cm wet sediment (54 and 177 g based on sediment dry weight for pond and river, respectively) and water to a height of about 6 cm (500 mL). The systems were connected to traps for organic volatiles

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and  $^{14}\text{CO}_2$ . The test substance (dissolved in acetone) was applied to the water phase. The systems were incubated for 183 days, with the water phases maintained under aerobic conditions.

Test conditions: 20.0±0.3°C, in the dark.

Sampling time points: Water and sediment samples were taken at 0, 1, 3, 7, 14, 22, 32, 59, 90, 127 and 183 days after treatment. The solutions in gas traps were first exchanged in about 2-weeks interval, later approx. once a month. Redox potential and temperature was recorded in sediment and water, and the water was also monitored for oxygen content and pH.

Method of analysis: Radioactivity in the water phases was quantified by LSC. Sub-samples of water were adjusted to pH 4 and passed through a C-18 cartridge (pre-treated with methanol and water), thereafter the radioactivity was eluted with acetonitrile and analysed by HPLC. Remaining aqueous phases containing >1% of the applied radioactivity were concentrated and analysed by HPLC and TLC. The sediments were extracted sequentially with 3 x acetone (cold shake), acetone/water (4:1, v/v, cold shake) and finally with acetone Soxhlet. Extracts were combined (except for Soxhlet extracts with <1% of the applied radioactivity), liquid/liquid partitioned with dichloromethane and finally analysed by HPLC and TLC. Reference compounds were: Difenoconazole, CGA 205374, CGA 205375, CGA 190169, CGA 189138 and CGA 190978.  $^{14}\text{C}$ - in the residual sediment was determined after combustion.

Calculations: Degradation rates were calculated by applying first order rate equation.

Water/Sediment See Table B.8.4.3.2-1.

Characteristics:

**Table B.8.4.3.2-1. Characteristics of sediments and water.**

System designation		Pond (Tugbach, Switzerland)	River (Rhine, Switzerland)
		Sediment	
Sediment type (USDA)		silty clay loam	sandy loam
Sand	[%]	6.1	74.8
Silt	[%]	66.2	15.7
Clay	[%]	27.7	9.5
pH (KCl)		6.9	7.2
Organic carbon	[%]	6.3	0.6
Cation exchange capacity	[meq/100 g]	35.8	5.1
CaCO <sub>3</sub>	[%]	59.7	23.4
Nitrogen, total	[%]	0.56	0.12
Biomass	[mg C/100 g]	234	104
		Water	
Phosphorus	[mg/L]	0.1	0.1
Nitrogen	[mg/L]	2.0	9.2
CO <sub>3</sub>	[mg/L]	192.8	152.3
Total organic carbon	[mg/L]	3.5	3.0
Hardness	[meq/L]	3.4	2.9

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. Soil Biol. Biochem., 10: 215-228, modified for the application to sediments. Samples taken prior to treatment.

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**Results:**

Percentage of the applied radioactivity recovered in the water phase of each systems is shown in Table B.8.4.3.2-2. The rate of dissipation of radioactivity from the water phase was calculated to 1-2 days in the two different systems (see Table B.8.4.3.2-5).

**Table B.8.4.3.2-2. Radioactivity in the water phase after treatment of two aquatic systems with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole at 0.17 mg/L and incubated at 20°C, as % of applied radioactivity. Single samples.**

Sampling time, days	Pond system	River system
0	87.7	79.8
1	40.1	47.7
3	20.3	32.1
7	5.9	19.1
14	5.1	8.1
22	3.4	5.0
32	2.5	2.7
59	1.0	3.0
90	1.8	2.5
127	1.7	2.9
183	2.1	2.9

In the study report the distribution and characterisation of radioactivity was expressed in terms of combined water and sediment phases. These results are shown in Tables B.8.4.3.2-3 (pond system) and B.8.4.3.2-4 (river system). Total recovery was 94.5-107.4% in the pond system, 91.1-105.8% in the river system (mean recovery 100%).

Difenoconazole decreased from 89-96% of the applied radioactivity day 0 to 61-71% at study termination, day 183. CGA 205375 was the only major metabolite formed, at a maximum of 11.6% of the applied radioactivity on day 90 in the river system. CGA 205375 was present mainly in the sediment phase. Two other metabolites (M3, M4) were separately quantified (maximum 7.8%) but levels were too low to allow further characterisation, they did not however, chromatograph with other available reference standards. M3 was present in both water and sediment. Analysis of the stock solution showed a purity of 92.6% and presence of two impurities V1 (5.6%) and V2 (1.2%), and of these V1 was measured also in the two test systems.

Besides  $^{14}\text{CO}_2$  no other volatile compounds were measured. Up to 3.9% of the applied radioactivity was evolved as  $^{14}\text{CO}_2$ . Bound residues increased to maximum 13.9% at study termination in the pond system.

Calculated rates of degradation in the whole water/sediment systems are shown in Table B.8.4.3.2-5. As shown by the extrapolated  $\text{DT}_{50}$  and  $\text{DT}_{90}$  values, degradation of difenoconazole was slow after adsorption to sediment.

**Table B.8.4.3.2-3. Recovery, distribution and characterisation of radioactivity in pond system treated with  $^{14}\text{C}$ -chlorophenyl labelled difenoconazole at 0.17 mg/L and incubated at 20°C, as % of applied radioactivity. Single samples.**

Sampling time, days	Difenoconazole	V1 <sup>a</sup>	CGA 205375	M3	M4	Not analysed <sup>b</sup>	$\text{CO}_2$	Non-extractable	Total recovery
0	96.2	3.3	1.9	0.0	0.0	0.3	0.0	0.0	101.8
1	94.8	3.9	1.9	0.0	0.0	0.8	<0.05	0.3	101.8
3	95.9	3.8	2.2	0.0	0.0	0.3	<0.05	0.5	102.7
7	95.9	4.1	2.8	0.0	0.0	0.2	0.1	1.2	104.3
14	89.5	4.4	2.8	0.3	0.0	0.2	<0.05	1.5	98.8
22	95.9	4.5	4.1	0.2	0.0	0.2	0.4	2.1	107.4

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Sampling time, days	Difenoconazole	V1 <sup>a</sup>	CGA 205375	M3	M4	Not analysed <sup>b</sup>	CO <sub>2</sub>	Non-extractable	Total recovery
32	91.5	3.9	4.9	2.0	0.0	0.1	0.2	4.0	106.5
59	82.9	3.5	4.6	2.4	0.0	0.1	0.4	5.6	99.4
90	77.1	2.1	3.7	3.3	0.6	0.1	0.9	11.9	99.8
127	66.1	2.2	4.9	5.7	0.5	0.1	2.0	13.0	94.5
183	71.2	2.1	6.2	7.8	0.3	0.1	3.0	13.9	104.7

*a* Radioactive impurity in original stock solution.

*b* Radioactivity in extracts, not analysed.

**Table B.8.4.3.2-4. Recovery, distribution and characterisation of radioactivity in river system treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 0.17 mg/L and incubated at 20°C, as % of applied radioactivity. Single samples.**

Sampling time, days	Difenoconazole	V1 <sup>a</sup>	CGA 205375	M3	M4	Not analysed <sup>b</sup>	CO <sub>2</sub>	Non-extractable	Total recovery
0	89.8	4.0	1.7	0.0	0.0	1.0	0.0	0.0	96.7
1	90.6	4.4	2.7	0.0	0.0	0.3	<0.05	0.2	98.3
3	90.2	4.1	2.6	0.0	0.0	1.2	<0.05	0.4	98.4
7	90.1	4.1	3.0	0.0	0.0	1.1	<0.05	0.8	99.2
14	87.0	4.2	4.2	0.2	0.0	9.2 <sup>c</sup>	<0.05	1.4	105.8
22	88.9	3.3	8.4	0.4	0.0	0.9	0.1	1.6	103.5
32	83.5	3.7	6.2	0.3	0.0	0.6	0.3	3.5	98.2
59	77.0	2.9	8.1	0.7	0.4	1.2	0.6	5.1	96.2
90	69.5	2.7	11.6	1.8	0.0	0.6	1.4	7.6	95.2
127	70.1	2.5	10.5	2.0	0.4	0.6	1.7	6.2	94.0
183	61.3	2.3	11.4	2.3	0.4	0.7	3.9	8.7	91.1

*a* Radioactive impurity in original stock solution.

*b* Radioactivity in extracts, not analysed.

*c* This measurement includes two fractions (Z1 and Z2 in study report) at 6.0 and 2.4% of the applied radioactivity, thought to be artefacts.

**Table B.8.4.3.2-5. Rate of dissipation of radioactivity from water phase, and rate of degradation of difenoconazole in whole pond and river water/sediment systems. Values presented in study report, calculated by first order kinetic equation.**

System		DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup>
<b>Pond</b>	Dissipation from water	1.0	3.3	0.987
	Degradation in whole system	324	1076	0.998
<b>River</b>	Dissipation from water	2.0	6.6	0.968
	Degradation in whole system	307	1020	0.999

The measurements of physicochemical conditions indicated that the water columns were aerobic throughout the study, while the sediments were more anaerobic. Dissolved oxygen in the water increased over the study, from 5.8 to 8.5 mg/L and from 5.2 to 8.9 mg/L from day 0 to day 181 for pond and river water, respectively. The mean content of dissolved oxygen in the water over the whole study (from 7 days pre treatment to day 181) was 6.3±1.7 mg/L (69% of saturation) in the pond system, 6.4±1.8 mg/L (71% of saturation) in the river system. pH in both systems also increased slightly, from 8.2-8.3 at day 0 to 8.5 at study termination. Mean pH over the whole study (-7 days before treatment until day 181) was 8.3 in both systems. Redox potential in the water column was 115-209 mV (mean 151±26 mV) in the pond system, 115-222 mV (mean 160±30 mV) in the river system. In the sediments, the redox potential was always negative; -64 - -205 (mean -126±35 mV) in the pond system, -78 - -217 (mean -140±62 mV) in the river system.

#### Comments by RMS:

The study is of acceptable quality. CGA 205375 was the only metabolite identified as >10% of the applied radioactivity. The degradation rates are considered to be uncertain since >50% of the applied substance was still

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undegraded at study termination but the values are accepted as best available estimates and used in the further assessment (DT<sub>90</sub> set to >1000 days).

The studies on metabolism in soil indicated that the rate of degradation is slower at high treatment rates. Compared to the test concentrations used in the soil studies, the test concentration (related to sediment dry weight) was relatively high in the pond system (1.5 mg/kg dw). However, there was no apparent difference in degradation date between the pond and the river systems which would indicate a dependence on test concentration, and hence the estimated degradation rates are considered to be representative.

<b>Reference:</b>	<b>Ulbrich R (1997)</b> Metabolism of <sup>14</sup> C labelled CGA 169374 in Aquatic Systems under Aerobic Conditions at 8°C. Novartis Crop Protection AG, Environmental Safety / Ecochemistry, Basel, Switzerland. Report No. 94UL03. Syngenta File No. CGA169374/1357.
Test material:	Difenoconazole, <sup>14</sup> C-chlorophenyl-radiolabel; Radiochemical purity 92.6%, Batch No. NV-XVII-56A-1.
Guideline:	Agriculture Canada: Environmental Chemistry and fate. Guidelines for registration of pesticides in Canada, 15 July 1987. 6.2 Laboratory Studies, C. Biotransformation, 2. Aquatic - Anaerobic and Aerobic. SETAC (1995) Procedures for assessing the environmental fate and ecotoxicity of pesticides, part 1, 1.1 Aerobic degradation, Ed. M. Lynch.
GLP:	Yes

**Material and methods:**

Test concentration:	0.1 mg/L (corresponding to direct over spray of 100 g a.s./ha, 0.1 m deep water), or as related to sediment; 0.49 mg/kg dw (pond) and 0.34 mg/kg dw (river system)
Test system:	Dissipation and degradation of difenoconazole in pond and river systems at low temperature was investigated. Each test systems consisted of 2-2.5 cm wet sediment (139 and 96 g based on sediment dry weight for pond and river, respectively) and water to a height of about 6 cm (500 mL). The systems were connected to traps for organic volatiles and <sup>14</sup> CO <sub>2</sub> . The test substance (dissolved in acetone) was applied to the water phase. The systems were incubated for 181/183 days, with the water phases maintained under aerobic conditions.
Test conditions:	8±1°C, in the dark.
Sampling time points:	Water and sediment samples were taken on days 0*, 1, 3, 7*, 14*, 28, 42*, 91, 120*/122* and 181*/183 (* in duplicate). Absorption solution in gaps were exchanged about weekly during the first month, thereafter in about two weeks intervals. pH and oxygen content of the water, and redox potential of water and sediment were monitored over the study.
Method of analysis:	Radioactivity in the water phases was quantified by LSC. Sub-samples of water were adjusted to pH 4 and passed through a C-18 cartridge (pre-treated with methanol and water), thereafter the radioactivity was eluted with acetonitrile and analysed by

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HPLC. The sediments were extracted sequentially with 3 x acetone (cold shake), acetone/water (4:1, v/v, cold shake) and finally with acetone Soxhlet. Extracts were combined (except for Soxhlet extracts with <1% of the applied radioactivity), liquid/liquid partitioned with dichloromethane and finally analysed by HPLC.

Reference compounds were: Difenconazole, CGA 205374 and CGA 205375.

Radioactivity in the residual sediment was determined by LSC after combustion.

## Calculations:

Degradation rates for the whole systems were calculated in accordance with first order degradation equation. Dissipation rates from the water phase were calculated by applying both single first order kinetics (SFO) and a two-compartment model (DFOP, double first order in parallel).

## Water/Sediment

See Table B.8.4.3.2-6.

## Characteristics:

**Table B.8.4.3.2-6. Characteristics of sediments and water.**

System designation		Pond (Switzerland)	River (Rhine, Switzerland)
		<b>Sediment</b>	
Sediment type (USDA)		loam	silt loam
Sand (0.05-2.0 mm)	[%]	29.7	10.3
Silt (0.002-0.05 mm)	[%]	46.8	67.1
Clay (<0.002 mm)	[%]	23.5	22.6
pH (KCl)		7.2	7.2
Organic carbon	[%]	3.5	3.8
Cation exchange capacity	[meq/100 g]	23.9	23.6
Phosphorus, total	[ppm]	617	762
Nitrogen, total	[%]	0.27	0.35
Maximum Water Holding Capacity	[g/100 g]	50.2	68.3
Biomass	[mg C/100 g]	125	149
		<b>Water</b>	
Phosphorus	[mg/L]	0.1	0.1
Nitrogen	[mg/L]	3.4	1.5
CO <sub>3</sub>	[mg/L]	167	61
Total organic carbon	[mg/L]	16.4	6.4
Hardness		middle hard	middle hard

*a Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. Soil Biol. Biochem. 10: 215-228, modified for the application to sediments. Samples taken prior to treatment.*

**Results:**

Recovery and distribution in the pond and river systems are shown in Tables B.8.4.3.2-7 and B.8.4.3.2-8, respectively. Total recovery of radioactivity ranged from 98 to 111% of the radioactivity applied with a mean of 104%. The radioactivity rapidly disappeared from the water column, most rapidly in the pond system. Low amounts of <sup>14</sup>CO<sub>2</sub> evolved, with maximum amounts of 1.9 and 2.9% in the two systems at the end of incubation. No other volatile products were detected. Unextracted radioactivity increased over the study, to maximum 11.4 and 9.8% at study termination (days 181/183).

Characterisation of radioactivity in the two systems is shown in Tables B.8.4.3.2-9 and B.8.4.3.2-10.

Difenconazole rapidly adsorbed on to the sediment with half-lives of 1 and 3 days in the pond and river water

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phases respectively, see Table B.8.4.3.2-11. At 8°C, degradation as expected, was very slow in the sediment with extrapolated half-lives of approximately 3 and 2 years in the pond and river systems respectively.

Analysis of the stock solution showed a purity of 92.6% and presence of an impurity of 7.4% M(15.0). This impurity was also present in the two test systems. As little parent degraded there were no major metabolites formed in this study. Small amounts (maximum 7.5% of the applied radioactivity) of CGA 205374 were observed.

**Table B.8.4.3.2-7. Recovery and distribution of radioactivity in pond system treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 0.1 mg/L and incubated at 8°C, as % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Incubation time, days	Water	Sediment Extractable	Sediment Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
0	90.2	9.6	0.2	-	100.0
1	37.8	65.8	0.8	<0.1	104.3
3	17.5	88.9	1.2	<0.1	107.6
7	8.3	97.1	2.0	0.04	107.4
14	2.4	99.7	3.4	0.1	105.6
28	1.4	100.0	3.7	0.2	105.3
42	1.0	104.1	4.3	0.3	109.8
91	0.6	91.0	5.5	1.4	98.5
120	0.7	94.7	7.1	1.1	103.6
183	1.1	88.1	11.4	1.9	102.0

**Table B.8.4.3.2-8. Recovery and distribution of radioactivity in river system treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 0.1 mg/L and incubated at 8°C, as % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Incubation time, days	Water	Sediment Extractable	Sediment Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
0	95.2	5.7	0.1	-	100.0
1	56.0	45.2	0.9	n.d.	102.0
3	36.0	65.4	1.0	n.d.	102.4
7	17.9	78.9	1.5	<0.1	98.3
14	12.8	84.2	2.4	0.1	99.6
28	6.9	99.2	2.6	0.4	109.1
42	5.6	101.1	3.5	0.6	110.9
91	4.1	90.9	5.7	1.6	102.2
122	2.4	93.2	6.9	1.8	104.3
181	1.8	88.1	9.8	2.9	102.6

n.d. Not detected.

**Table B.8.4.3.2-9. Characterisation of radioactivity in pond system treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 0.1 mg/L and incubated at 8°C, as % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Incubation time, days	Compartment	Difenoconazole	Unknown M(11.0)	CGA 205374 M(14.1)	Impurity M(15.0)
0	Water	83.3	n.d.	n.d.	6.9
	Sediment	9.6	n.d.	n.d.	n.d.
	Total	92.9	n.d.	n.d.	6.9
1	Water	37.8	n.d.	n.d.	n.d.
	Sediment	60.4	n.d.	n.d.	5.4
	Total	98.1	n.d.	n.d.	5.4
3	Water	15.4	n.d.	n.d.	1.8
	Sediment	83.1	n.d.	n.d.	5.8
	Total	98.5	n.d.	n.d.	7.6
7	Water	7.4	n.d.	0.2	0.8
	Sediment	91.1	n.d.	n.d.	6.0

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Incubation time, days	Compartment	Difenoconazole	Unknown M(11.0)	CGA 205374 M(14.1)	Impurity M(15.0)
	Total	98.4	n.d.	0.2	6.8
14	Water	2.3	n.d.	0.1	0.6
	Sediment	94.2	n.d.	n.d.	5.6
	Total	96.4	n.d.	0.1	6.2
28	Water	1.4	n.d.	n.d.	n.d.
	Sediment	93.5	n.d.	n.d.	6.5
	Total	94.9	n.d.	n.d.	6.5
42	Water	n.d.	n.d.	n.d.	n.d.
	Sediment	99.8	n.d.	n.d.	4.4
	Total	99.8	n.d.	n.d.	4.4
91	Water	n.d.	n.d.	n.d.	n.d.
	Sediment	86.0	n.d.	n.d.	5.1
	Total	86.0	n.d.	n.d.	5.1
120	Water	n.d.	n.d.	n.d.	n.d.
	Sediment	92.9	n.d.	n.d.	3.5
	Total	92.9	n.d.	n.d.	3.5
183	Water	n.d.	n.d.	n.d.	n.d.
	Sediment	86.8	n.d.	n.d.	2.5
	Total	86.8	n.d.	n.d.	2.5

n.d. Not detected (<LOD).

**Table B.8.4.3.2-10. Characterisation of radioactivity in river system treated with <sup>14</sup>C-chlorophenyl labelled difenoconazole at 0.1 mg/L and incubated at 8°C, as % of applied radioactivity. Mean of duplicate samples where applicable (see Material and methods above).**

Incubation time, days	Compartment	Difenoconazole	Unknown M(11.0)	CGA 205374 M(14.1)	Impurity M(15.0)
0	Water	87.3	n.d.	n.d.	7.0
	Sediment	5.7	n.d.	n.d.	n.d.
	Total	93.0	n.d.	n.d.	7.0
1	Water	56.0	n.d.	n.d.	n.d.
	Sediment	43.1	n.d.	n.d.	2.1
	Total	99.1	n.d.	n.d.	2.1
3	Water	36.0	n.d.	n.d.	n.d.
	Sediment	62.0	n.d.	n.d.	3.5
	Total	98.0	n.d.	n.d.	3.5
7	Water	17.2	n.d.	n.d.	1.4
	Sediment	74.3	n.d.	n.d.	4.6
	Total	91.5	n.d.	n.d.	6.0
14	Water	11.8	0.1	n.d.	0.9
	Sediment	79.8	n.d.	n.d.	4.4
	Total	91.7	0.1	n.d.	5.3
28	Water	6.4	n.d.	n.d.	0.6
	Sediment	93.4	n.d.	n.d.	5.9
	Total	99.8	n.d.	n.d.	6.5
42	Water	5.2	0.2	n.d.	0.3
	Sediment	96.5	n.d.	n.d.	4.6
	Total	101.7	0.2	n.d.	4.9
91	Water	3.7	0.3	n.d.	0.1
	Sediment	83.4	n.d.	7.5	n.d.
	Total	87.1	0.3	7.5	0.1
122	Water	1.9	0.5	0.2	n.d.
	Sediment	87.1	n.d.	4.9	1.2
	Total	88.9	0.5	5.1	1.2
181	Water	n.d.	n.d.	n.d.	n.d.
	Sediment	82.2	0.9	5.4	n.d.
	Total	82.2	0.9	5.4	n.d.

n.d. Not detected (<LOD).

**Table B.8.4.3.2-11. Rate of dissipation of difenoconazole from the water phase of pond and river water/sediment systems. Values presented in study report, calculated by both single first order kinetics (SFO) and a two-compartment model (DFOP, double first order in parallel).**

System		DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2</sup>
<b>Pond</b>	Dissipation from water, SFO	1.0	3.4	0.991
	Dissipation from water, DFOP	2.6	8.5	0.975
<b>River</b>	Dissipation from water, SFO	0.8	6.2	0.999
	Dissipation from water, DFOP	1.9	24.7	0.996

The measurements of physicochemical conditions indicated that the water columns were aerobic throughout the study, while the sediments were more anaerobic. Dissolved oxygen content in the water phases was relatively constant over the study in both systems; mean values over day 0 to 181 were 9.8±1.4 mg/L in the pond system and 10.5±1.7 mg/L in the river system, corresponding to 83 and 89% of oxygen saturation. Mean pH over the incubation period were 8.2±0.2 in the pond water and 8.2±0.1 in the river water. Redox potential in the water column was 227-281 mV (mean 243±17 mV) in the pond system, 205-252 mV (mean 228±15 mV) in the river system. In the sediments, the redox potential was always negative; -398 - -438 (mean -415±13 mV) in the pond system, -193 - -432 (mean -358±66 mV) in the river system.

#### Comments by RMS:

The study is of acceptable quality. No metabolites were identified as >10% of the applied radioactivity. The rates of dissipation from the water phase as shown in the table above are used in the further assessment. The degradation rates are considered to be very uncertain due to extrapolation far beyond the study duration. It is clear however that difenoconazole is very persistent in sediments at low temperature.

<b>Reference:</b>	<b>Völkel S (2002c)</b> CGA 205375 [14C-triazole]: Route and Rate of Degradation in aerobic aquatic systems. RCC Ltd, Environmental Chemistry & Pharamanalytics Division, Itingen, Switzerland. Report No. 798636. Syngenta File No. CGA205375/0016.
<b>Test material:</b>	CGA 205375 (1-[2-[2-chloro-4-(4-chloro-phenoxy)-phenyl]-2-1H-[1,2,4]triazol-yl]-ethanol), <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 100%, Batch No. ILA-52.3A-1.
<b>Guideline:</b>	OECD Draft Guideline: Aerobic and Anaerobic Transformation in Water/Sediment Systems. August 2000.
<b>GLP:</b>	Yes

#### Material and methods:

<b>Test concentration:</b>	0.10 mg/L (corresponding to direct over spray of 100 g a.s./ha, , 0.1 m deep water). or related to sediment weight; 0.86 mg/kg dw (pond), 0.47 mg/kg dw (river system).
<b>Test system:</b>	Route and rate of degradation of the metabolite CGA 205375 in pond and river systems was investigated. Each test systems consisted of 2-2.5 cm wet sediment (corresponding to a wet weight of approx. 150 g) and water to a height of about 6 cm (500 mL). The systems were connected to traps for organic volatiles and <sup>14</sup> CO <sub>2</sub> . The test substance (dissolved in acetone) was applied drop wise to the water phase. The systems were incubated for 148 days, with the water phases maintained under

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	aerobic conditions.
Test conditions:	20±2°C, in the dark.
Sampling time points:	Water and sediment samples were taken in duplicate at days 0, 1, 3, 7, 14, 28, 62, 101 and 148 days after treatment. The solutions in gas traps were exchanged at the same intervals or about every four weeks (whichever was shortest). Redox potential was recorded in sediment and water, and the water was also monitored for oxygen content and pH.
Method of analysis:	Radioactivity in the water phases was quantified by LSC. Sub-samples of water were concentrated and analysed by TLC and HPLC (selected samples). The sediments were extracted sequentially with acetonitrile/water (8:2, up to 4 times, cold shake) and additionally with an acetonitrile/water Soxhlet (9:1) from day 14 or 62 for the River and Pond systems respectively. Extracts were combined (except for extracts with <1% of the applied radioactivity), concentrated and analysed by TLC and HPLC. Reference compounds were: CGA 205375, CGA 205374, CGA 71019, CGA 131013, CGA 142856 and NOA 457654. Radioactivity in the residual sediment was determined by LSC after combustion.
Calculations:	Dissipation and degradation rates were determined by non-linear regression applying first order reaction kinetics (MicroCal Origin and ModelMaker ver. 3.04 software).
Water/Sediment	See Table B.8.4.3.2-12.
Characteristics:	

**Table B.8.4.3.2-12. Characteristics of sediments and water.**

System designation		Pond (Ormalingen, Switzerland)	River (Rhine, Switzerland)
		Sediment	
Sediment type (USDA)		silty clay loam	sandy loam
Sand (>0.05 mm)	[%]	7.5	77.5
Silt (0.002-0.05 mm)	[%]	61.8	14.1
Clay (<0.002 mm)	[%]	30.7	8.4
pH (CaCl <sub>2</sub> )		7.09	7.46
Organic carbon	[%]	6.6	0.71
Cation exchange capacity	[meq/100 g]	44.8	5.9
Sediment dry mass	[kg wet/kg dry]	2.6	1.4
Phosphorus, total	[g/kg]	0.79	0.68
Nitrogen, total	[g/kg]	0.70	0.07
Biomass <sup>a</sup> , start of acclimation	[mg C/100 g]	240	51.1
Biomass <sup>a</sup> , start of incubation	[mg C/100 g]	161.6	41.9
Biomass <sup>a</sup> , after 62 days	[mg C/100 g]	68.2	30.8
Biomass <sup>a</sup> , after 144 days	[mg C/100 g]	155.9	54.8
Biomass <sup>a</sup> , end of incubation	[mg C/100 g]	88.0	60.5
		Water	
pH <sup>b</sup>		7.97	8.1
Phosphorus <sup>b</sup>	[mg/L]	0.12	0.06
Nitrogen <sup>c</sup>	[mg/L]	2.0	2.5
Total organic carbon <sup>c</sup>	[mg/L]	16.0	6.0
Hardness <sup>b</sup>	[°dH]	25	14

<sup>a</sup> Determined according to Anderson JPE and Domsch KH (1978) A physiological method for the quantitative measurement of microbial biomass in soils. Soil Biol. Biochem., 10: 215-221, modified for the application to sediments.

<sup>b</sup> Determined at sampling at the sampling location.

*c Determined at the laboratory before acclimation.*

### Results:

Recovery and distribution in the pond and river systems are shown in Tables B.8.4.3.2-13 and B.8.4.3.2-14, respectively. Total recovery of radioactivity in individual samples ranged from 95 to 103% of the radioactivity applied. Total mean recoveries were  $98.1 \pm 1.6\%$  for the pond system and  $99.9 \pm 1.3\%$  for the river system. The radioactivity rapidly disappeared from the water column, most rapidly in the pond system. Towards the end of the study, the radioactivity in the water increased again, to 11.4% in the river system, most probably due to the dissolution of the metabolite CGA 71019. Low amounts of  $^{14}\text{CO}_2$  evolved, with maximum amounts of 0.5 and 0.4% in the two systems at the end of incubation. No other volatile products were detected. Unextracted radioactivity increased over the study, to maximum 8.2 and 13.0% at study termination (day 148).

Characterisation of radioactivity in the two systems is shown in Tables B.8.4.3.2-15 and B.8.4.3.2-16. CGA 205375 rapidly adsorbed on to the sediment with half-lives of 1 and 3 days in the pond and river water phases respectively, see Table B.8.4.3.2-17. Degradation was very slow with extrapolated half-lives for the whole systems of 630 and 301 days in pond and river, respectively.

Only one major metabolite, CGA 71019, was observed at a maximum of 14.1% of the applied radioactivity in the river system (whereof 10% in the water phase) at the end of the study. Amounts of CGA 71019 in the pond system reached a maximum of 3.2% in the same time. Small amounts (maximum 1.4% of the applied radioactivity) of CGA 205374 were observed. Several other metabolites were observed (M3-M11) but the maximum recovered was 2% or less in either phase.

**Table B.8.4.3.2-13. Recovery and distribution of radioactivity in pond system treated with  $^{14}\text{C}$ -triazole labelled CGA 205375 at 0.1 mg/L and incubated at 20°C, as % of applied radioactivity. Mean of duplicate samples.**

Incubation time, days	Water	Sediment Extractable	Sediment Non-extractable	$^{14}\text{CO}_2$	Total recovery
0	97.5	2.8	0.9	n.p.	101.2
1	43.4	51.8	2.4	<0.1	97.6
3	33.6	60.9	3.3	<0.1	97.8
7	5.0	91.1	2.1	<0.1	98.1
14	4.3	93.4	3.2	<0.1	97.9
28	1.5	93.8	3.1	<0.1	98.4
62	1.9	94.2	3.1	0.2	99.3
101	2.4	89.8	4.5	0.4	97.1
148	3.0	83.9	8.2	0.5	95.5

*n.p.* Not performed.

**Table B.8.4.3.2-14. Recovery and distribution of radioactivity in river system treated with  $^{14}\text{C}$ -triazole labelled CGA 205375 at 0.1 mg/L and incubated at 20°C, as % of applied radioactivity. Mean of duplicate samples.**

Incubation time, days	Water	Sediment Extractable	Sediment Non-extractable	$^{14}\text{CO}_2$	Total recovery
0	96.8	4.2	1.0	n.p.	101.9
1	90.7	9.1	1.0	<0.1	100.8
3	51.3	44.9	2.5	<0.1	98.7
7	16.9	75.0	8.4	<0.1	100.3
14	9.1	87.3	2.6	<0.1	99.1
28	5.9	90.2	4.3	0.1	100.5

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Incubation time, days	Water	Sediment Extractable	Sediment Non-extractable	<sup>14</sup> CO <sub>2</sub>	Total recovery
62	5.3	87.8	7.0	0.3	100.4
101	7.2	80.6	10.2	0.3	98.2
148	11.4	74.7	13.0	0.4	99.6

n.p. Not performed.

**Table B.8.4.3.2-15. Characterisation of radioactivity in pond system treated with <sup>14</sup>C-triazole labelled CGA 205375 at 0.1 mg/L and incubated at 20°C, as % of applied radioactivity. Mean of duplicate samples.**

Incubation time, days	Compartment	CGA 205375	CGA 205374	CGA 71019	M4	M5	M7	M8	M9
0	Water	97.0	n.d.	n.d.	n.d.	n.d.	n.d.	0.5	n.d.
	Sediment	2.8	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Total	99.8	n.d.	n.d.	n.d.	n.d.	n.d.	0.5	n.d.
1	Water	42.2	n.d.	n.d.	n.d.	n.d.	n.d.	1.1	n.d.
	Sediment	51.3	n.d.	n.d.	n.d.	n.d.	n.d.	0.5	n.d.
	Total	93.7	n.d.	n.d.	n.d.	n.d.	n.d.	1.6	n.d.
3	Water	32.3	0.4	n.d.	n.d.	n.d.	n.d.	0.9	n.d.
	Sediment	60.2	0.3	n.d.	n.d.	n.d.	n.d.	0.4	n.d.
	Total	92.5	0.7	n.d.	n.d.	n.d.	n.d.	1.2	n.d.
7	Water	4.3	<0.1	0.2	0.1	0.1	<0.1	0.1	0.1
	Sediment	88.8	0.7	n.d.	0.8	0.6	n.d.	0.2	n.d.
	Total	93.1	0.7	0.2	0.9	0.7	<0.1	0.3	0.1
14	Water	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.d.
	Sediment	89.2	1.2	0.7	0.9	0.5	n.d.	0.9	n.d.
	Total	89.2	1.2	0.7	0.9	0.5	n.a.	0.9	n.d.
28	Water	0.9	<0.1	0.2	0.1	0.1	0.1	<0.1	<0.1
	Sediment	89.9	0.4	0.6	1.1	1.2	n.d.	0.7	n.d.
	Total	90.8	0.5	0.7	1.1	1.2	0.1	0.7	<0.1
62	Water	1.0	<0.1	0.3	n.d.	<0.1	0.4	0.1	<0.1
	Sediment	90.6	1.4	n.d.	0.7	0.7	n.d.	n.d.	0.3
	Total	91.6	1.4	0.3	0.7	0.7	0.4	0.1	0.3
101	Water	0.9	<0.1	0.5	n.d.	0.1	0.7	<0.1	n.d.
	Sediment	83.6	1.2	1.7	2.0	1.1	n.d.	0.3	n.d.
	Total	84.5	1.2	2.2	2.0	1.2	0.7	0.3	n.d.
148	Water	0.8	n.d.	1.2	0.1	0.2	0.6	0.1	0.9
	Sediment	78.0	1.0	2.0	0.6	1.4	n.d.	n.d.	n.d.
	Total	78.7	1.0	3.2	0.7	1.6	0.6	0.1	0.9

n.d. Not detected or <LOQ.

n.a. Not analysed due to low amount detected in the water phase (1.3% of the applied radioactivity was measured in the water phase on day 14 but not analysed).

**Table B.8.4.3.2-16. Characterisation of radioactivity in river system treated with <sup>14</sup>C-triazole labelled CGA 205375 at 0.1 mg/L and incubated at 20°C, as % of applied radioactivity. Mean of duplicate samples.**

Incubation time, days	Compartment	CGA 205375	CGA 205374	CGA 71019	M4	M5	M6	M7	M8	M9
0	Water	95.7	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.0	n.d.
	Sediment	4.2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Total	99.9	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.0	n.d.
1	Water	89.9	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.7	n.d.
	Sediment	9.1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Total	99.1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.7	n.d.
3	Water	50.0	n.d.	0.3	0.2	0.2	n.d.	0.2	0.4	n.d.
	Sediment	44.3	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.6	n.d.
	Total	94.3	n.d.	0.3	0.2	0.2	n.d.	0.2	1.1	n.d.
7	Water	15.4	n.d.	0.3	0.1	0.1	0.3	0.1	0.1	0.6
	Sediment	73.6	n.d.	n.d.	0.3	0.5	n.d.	n.d.	0.4	0.1
	Total	89.0	n.d.	0.3	0.5	0.6	0.3	0.1	0.5	0.7
14	Water	8.0	n.d.	0.3	0.1	0.2	0.2	0.1	0.1	0.1
	Sediment	85.0	n.d.	0.3	0.5	0.4	n.d.	n.d.	1.3	n.d.
	Total	93.0	n.d.	0.6	0.6	0.5	0.2	0.1	1.4	0.1

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Incubation time, days	Compartment	CGA 205375	CGA 205374	CGA 71019	M4	M5	M6	M7	M8	M9
28	Water	4.2	<0.1	0.5	0.2	0.2	0.2	0.2	0.2	0.1
	Sediment	87.1	0.6	0.4	0.4	0.7	n.d.	n.d.	0.5	0.5
	Total	91.2	0.6	0.9	0.6	0.9	0.2	0.2	0.7	0.6
62	Water	1.7	0.1	2.8	<0.1	0.1	n.d.	0.3	0.2	0.1
	Sediment	82.7	0.8	2.2	1.1	1.0	n.d.	n.d.	n.d.	n.d.
	Total	84.3	0.9	4.9	1.1	1.1	n.d.	0.3	0.2	0.1
101	Water	1.3	n.d.	5.3	<0.1	0.2	n.d.	0.3	0.1	n.d.
	Sediment	75.5	0.6	1.9	0.9	0.3	n.d.	n.d.	0.4	1.1
	Total	76.7	0.6	7.2	0.9	0.5	n.d.	0.3	0.5	1.1
148	Water	0.9	n.d.	10.0	n.d.	0.2	n.d.	n.d.	0.3	n.d.
	Sediment	67.5	1.0	4.1	0.9	0.6	n.d.	n.d.	0.6	n.d.
	Total	68.4	1.0	14.1	0.9	0.8	n.d.	n.d.	0.9	n.d.

n.d. Not detected or <LOQ.

**Table B.8.4.3.2-17. Rate of dissipation of CGA 205375 from the water phase of pond and river water/sediment systems, and rate of degradation in whole systems. Values presented in study report, calculated by single first order kinetics.**

System		DT <sub>50</sub> , days	DT <sub>90</sub> , days	r <sup>2a</sup>
<b>Pond</b>	Dissipation from water	1.4	4.7	0.958
	Degradation whole system	630	>1000	0.765
<b>River</b>	Dissipation from water	3.1	10.2	0.985
	Degradation whole system	301	>1000	0.932

a r<sup>2</sup> represent model efficiency rather than coefficient of determination, since non-linear regression was employed (RMS's comment).

The measurements of physicochemical conditions indicated that the water columns were aerobic throughout the study, while the sediments were more anaerobic. Dissolved oxygen content in the water phases was relatively constant over the study in both systems; mean values over day 0 to 148 were 6.6±0.9 mg/L in the pond system and 7.1±0.9 mg/L in the river system, corresponding to 73 and 78% of oxygen saturation. Mean pH over the incubation period were 7.97±0.14 in the pond water and 8.18±0.11 in the river water. Redox potential in the water column was 216-268 mV (mean 243±20 mV) in the pond system, 193-276 mV (mean 247±24 mV) in the river system. In the sediments, the redox potential was always negative; -84 - -139 (mean -111±15 mV) in the pond system, -38 - -109 (mean -77±16 mV) in the river system.

#### Comments by RMS:

The study is of acceptable quality. The study supplements the studies carried out on difenoconazole, since none of those studies used <sup>14</sup>C-triazole labelled test substance. In this study on CGA 205375 the only metabolite identified as >10% of the applied radioactivity was CGA 71019 (1,2,4-triazole, max. 14.1% at study termination).

The rates of dissipation from the water phase and degradation in the whole systems as shown in the table above are used in the further assessment. The degradation rates are considered to be uncertain since >50% of the applied substance was still undegraded at study termination but the values are accepted as best available estimates.

#### B.8.4.4 Summary and assessment of studies on fate and behaviour in water

Difenoconazole as well as its metabolites CGA 205375 and CGA 71019 (1,2,4-triazole) were shown to be stable to hydrolytic degradation at environmentally relevant pH values. Studies on direct photochemical degradation in

aqueous solutions and determinations of molar decadic extinction coefficients and quantum yield all showed that difenoconazole as well as CGA 205375 are stable to photolysis.

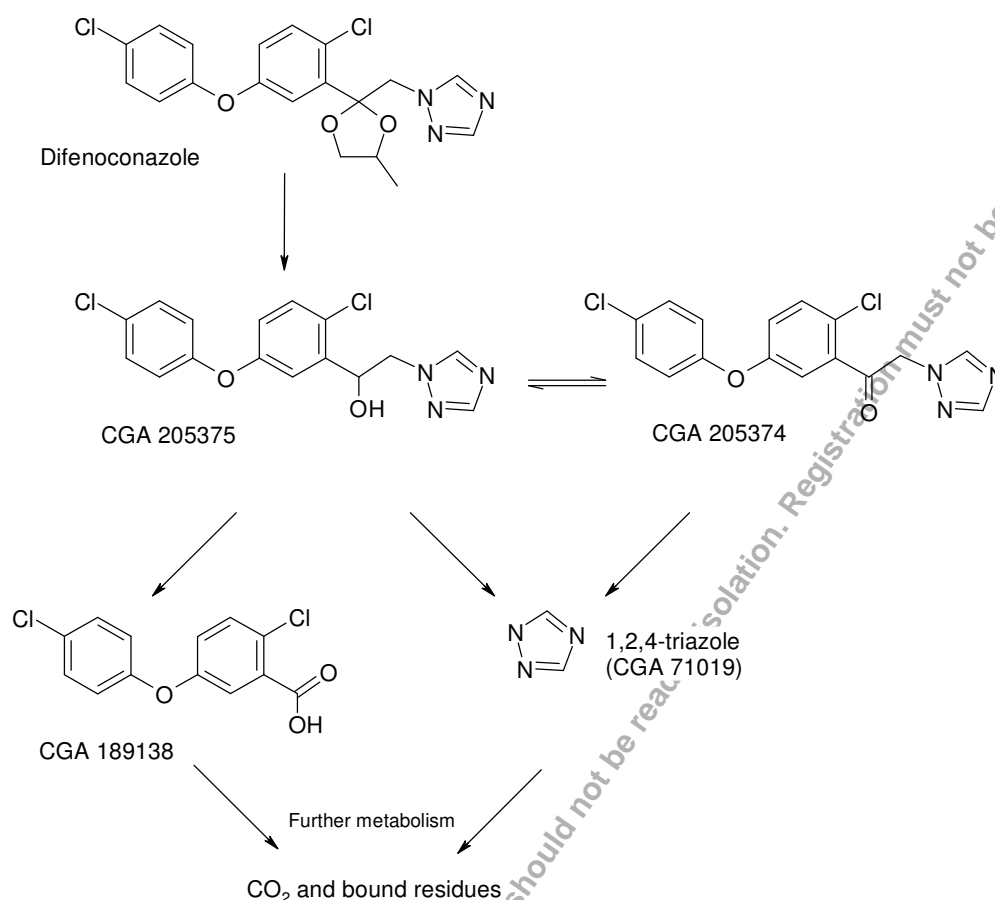
Difenoconazole was not readily biodegradable in accordance with the OECD criteria. Two water/sediment studies on difenoconazole ( $^{14}\text{C}$ -chlorophenyl label) were submitted, one carried out at 20°C, the other at 8°C. An additional study on the metabolite CGA 205375 ( $^{14}\text{C}$ -triazole label) was submitted. The conditions in all studies were maintained aerobic in the water phase with more anaerobic conditions in the sediment phase. The proposed degradation pathway is shown in Figure B.8.4.4-1. In the difenoconazole study at 20°C CGA 205375 was the only metabolite measured as >10 % of the applied radioactivity; max. 4.9% in pond system days 32 and 127, and max. 11.6% in river system on day 90. In the river system, the amounts of CGA 205375 were fairly constant over days 90-183 (11.6-11.4%) and hence seemed to have reached a plateau. Amounts of individual compounds were only presented for the combined water plus sediment system, however, based on the log Pow of 3.81 for CGA 205375, it seems reasonable to assume that it was present mainly in the sediment phase. In the water/sediment study with CGA 205375 added as test item it behaved similarly to difenoconazole, with rapid adsorption to sediment.

The metabolite CGA 71019 (1,2,4-triazole) found in soil studies could not be detected in the water/sediment studies on difenoconazole due to the position of radio labelling. However, in the study on  $^{14}\text{C}$ -triazole labelled CGA 205375, 1,2,4-triazole was detected as max. 14.1% of the applied radioactivity in the river system, max. 3.2% in the pond system, both values recorded at study termination (day 148). If it is assumed that CGA 71019 is only formed from difenoconazole via degradation of CGA 205375, the maximum formation of CGA 71019 from difenoconazole would be:  $0.116 \times 0.141 = 1.6\%$ . However, the amounts of CGA 71019 did not seem to have reached a plateau at study termination and therefore a worst-case rate of formation of CGA 71019 is calculated, assuming that all CGA 205375 remaining at study termination (68.4% in the river system) eventually would be transformed into CGA 71019. Thus, the worst-case max. formation of CGA 71019 from degradation of difenoconazole would be:  $0.116 \times (0.684 + 0.141) = 9.6\%$ .

Several unidentified metabolites were also measured in the water/sediment studies. They were usually only present at levels up to 2% of the applied radioactivity in the whole systems, with the exception of M3 measured at max. 7.8% in the study on difenoconazole at 20°C. CGA205374 was measured as max. 7.5% in the study on difenoconazole at 8°C. None of these metabolites are considered to require any further assessment.

Small amounts of  $^{14}\text{CO}_2$  evolved over the studies; max. 3.9% of the applied radioactivity after 183 days in the study on difenoconazole ( $^{14}\text{C}$ - chlorophenyl label) at 20°C, and max. 0.5% after 148 days in the study on CGA 205375 ( $^{14}\text{C}$ -triazole label) at 20°C. In the same studies the amounts of bound residues increased over the studies to max. 13.9% of the applied radioactivity after 183 days, and to max. 13.0% after 148 days.

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**Figure B.8.4.4-1. Proposed degradation pathway for difenoconazole in aquatic systems (from Doc. M-II).**

The estimated rates of dissipation from the water phase and rates of degradation in the whole systems are summarised in Table B.8.4.4-1. Difenoconazole was very rapidly adsorbed to sediment and was only slowly degraded in that state. Temperature had little effect on the rate of loss of difenoconazole from water to sediment; however, degradation was considerably slowed at 8°C. Similarly to the parent compound, CGA205375 was only slowly degraded. All degradation rates estimated are uncertain since >50% of the applied test substance remained undegraded at study termination. However, the results are considered acceptable as best available estimates.

Mean DT<sub>50</sub> for degradation of difenoconazole in the whole systems was 316 days at 20°C. In the study performed at 8°, DT<sub>50s</sub> for degradation in the whole systems were estimated to 3 and 2 years, for pond and river system, respectively. This is consistent with calculated DT<sub>50s</sub> at 8°C of 2.2-2.3 years using a default Q<sub>10</sub> of 2.2. Mean DT<sub>50</sub> for degradation of CGA 205375 in the whole systems at 20°C was 466 days.

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**Table B.8.4.4-1. Summary of laboratory studies on degradation of difenoconazole and metabolite CGA 205375 in aquatic systems. All DT<sub>50</sub> and DT<sub>90</sub> values were calculated by single first order kinetics.**

Study/System	Treatment rate	OC	Temp.	DT <sub>50</sub>	DT <sub>90</sub>	CO <sub>2</sub>	Non-extractable
	mg/L	%	°C	days	days	% (at days)	% (at days)
<b>Difenoconazole</b>							
<b>Gonzalez-Valero, 1993</b>							
Pond system	0.17	6.3	20	1.0 (water) <sup>a</sup> ca 324 (total) <sup>b</sup>	3.3 (water) <sup>a</sup> >1000 (total) <sup>b</sup>	3.0 (183)	13.9 (183)
River system	0.17	0.6	20	2.0 (water) <sup>a</sup> ca 307 (total) <sup>b</sup>	6.6 (water) <sup>a</sup> >1000 (total) <sup>b</sup>	3.9 (183)	8.7 (183)
<b>Ulbrich, 1997</b>							
Pond system	0.1	3.5	8	1.0 (water) <sup>a</sup> ca 3 yrs (total) <sup>b</sup>	3.4 (water) <sup>a</sup> > 3 yrs (total) <sup>b</sup>	1.9 (183)	11.4 (183)
River system	0.1	3.8	8	0.8 (water) <sup>a</sup> ca 2 yrs (total) <sup>b</sup>	6.2 (water) <sup>a</sup> > 2 yrs (total) <sup>b</sup>	2.9 (181)	9.8 (181)
<b>CGA 205375</b>							
<b>Völkel, 2002c</b>							
Pond system	0.1	6.6	20	1.4 (water) <sup>a</sup> ca 630 (total) <sup>b</sup>	4.7 (water) <sup>a</sup> >1000 (total) <sup>b</sup>	0.5 (148)	8.2 (148)
River system	0.1	0.71	20	3.1 (water) <sup>a</sup> ca 301 (total) <sup>b</sup>	10.2 (water) <sup>a</sup> >1000 (total) <sup>b</sup>	0.4 (148)	13.0 (148)

*a* Rate of dissipation from water phase.

*b* Rate of degradation in whole water/sediment system.

Neither difenoconazole nor its degradates are likely to leach to groundwater, therefore studies in the saturated zone were not submitted. This is considered acceptable.

As a conclusion, difenoconazole and the metabolite expected to be formed as >10% of the dose, CGA 205375, are only slowly degraded in aquatic systems. Abiotic degradation of difenoconazole, CGA 205375 and CGA 71019 is not significant under environmental conditions. Disappearance from the water phase is rapid due to adsorption to sediment for both difenoconazole and CGA 205375. The metabolite CGA 71019 (1,2,4-triazole) which was also a major metabolite in soil was observed only at levels representing 2% of the difenoconazole dose in aquatic system performed with CGA 205375 (no study using <sup>14</sup>C-triazole label of difenoconazole was submitted). The RMS estimated a worst-case maximum formation of CGA 71019 of 9.6% of the difenoconazole dose in water/sediment systems. From the results of the studies on water/sediments CGA 205375 is the only metabolite which needs to be considered further. However, due to its presence in soil, also CGA 71019 needs to be further considered for the aquatic environment. No studies on rate of degradation of CGA 71019 in water/sediment systems were submitted but this is considered acceptable provided that conservative assumptions are used for risk assessment.

#### B.8.5 Impact on water treatment procedures (Annex IIIA 9.2.2)

<b>Reference:</b>	<b>Harvey B (2004c)</b> A-9142 G Difenoconazole (DIVIDEND 030 FS). <b>Document M-III</b> , Section 5. Fate and Behaviour in the Environment. ERA5713. <b>Harvey B (2004b)</b> A-7402 T Difenoconazole (SCORE 250 EC). <b>Document M-III</b> , Section 5. Fate and Behaviour in the Environment. ERA5695.
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The use of the products according to the rules of 'Good Agricultural Practice' might lead, in worst cases only, to traces of the active ingredient and relevant metabolites in surface water. These will be subject to a large degree of

dilution, in the case of surface waters, prior to any abstraction procedures. Entry into ground water is not considered to be likely (evaluated in section B.8.6.1).

In *drinking water treatment*, traces of difenoconazole will have no impact on typical treatment procedures. They are expected to be removed, at least partially, depending on the initial aeration, flocculation and filtration processes, and nearly completely eliminated in case of oxidation/sterilization procedures with ozone/hydrogen peroxide followed by adsorption and filtration on activated carbon/sand filter beds.

In *sewage treatment*, traces of difenoconazole should not interfere with biological performance, as shown with activated sludge experiments, where even high rates of difenoconazole had no significant effects on the aerobic respiration of micro organisms in sewage sludge (evaluated in section B.9.10).

It was concluded that use of A-9142 G or A-7402 T as directed will not result in any exposure of drinking water or sewage treatment plants. Nevertheless, the available data demonstrate that effects of difenoconazole on sewage treatment processes are likely to be negligible.

#### Comments by RMS:

The statement is considered acceptable and no further data is required.

### **B.8.6 Predicted environmental concentrations in surface water and in groundwater (PEC<sub>sw</sub>, PEC<sub>gw</sub>) (Annex IIIA9.2.1, 9.2.3)**

#### **B.8.6.1 Predicted environmental concentrations in groundwater**

##### **B.8.6.1.1 DIVIDEND 030 FS: PEC<sub>gw</sub>**

<b>Reference:</b>	<b>Harvey B (2004c)</b> A-9142 G Difenoconazole (DIVIDEND 030 FS). <b>Document M-III</b> , Section 5. Fate and Behaviour in the Environment. ERA5713.
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In Doc. M-III on DIVIDEND 030 FS reference was made to the PEC<sub>gw</sub> simulations for SCORE 250 EC (presented below). The conclusion was that since the application rates used in those standard FOCUS scenarios are far in excess of those possible from seed treatments, the results illustrate the wide margin of safety from applications of difenoconazole as A-9142 G seed treatment.

#### Comments by RMS:

The statement is accepted and no further data is required. Use of difenoconazole in seed treatment is not expected to result in leaching of difenoconazole or its soil metabolites to groundwater (see PEC<sub>gw</sub> for SCORE 250 EC below).

#### B.8.6.1.2 SCORE 250 EC: PEC<sub>gw</sub>

<b>Reference:</b>	<b>Turner NL, Beulke S (2003)</b> Estimation with FOCUS PEARL 2.2.2 of predicted concentrations of difenoconazole and its metabolites CGA 205'375 and 1,2,4-triazole in groundwater (PEC <sub>GW</sub> ) following application to sugar beet, sunflower, apple and carrot crops. Cranfield Centre for EcoChemistry, Cranfield University, Silsoe, Beds., UK. Report No. 03/MOD/040. Syngenta File No. CGA169374/2427.
<b>Guideline:</b>	FOCUS (2000). FOCUS ground water scenarios in the EU review of active substances. Report of the FOCUS Ground water Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev. 2

#### Method:

The simulation model FOCUS PEARL 2.2.2 was used to assess the potential for leaching to groundwater of the fungicide difenoconazole and its metabolites CGA 205375 and 1,2,4-triazole (CGA 71019), using the FOCUS groundwater scenarios.

The leaching potential was assessed for the proposed application to apple and carrot crops using the relevant FOCUS groundwater soil and weather scenarios and crop parameters. Additional crops were included in the report (sugar beet and sunflowers) but are not relevant to this assessment. This resulted in a total of 15 scenarios for each compound (9 for apples and 6 for carrots). Application details for each crop are summarised in Table B.8.6.1.2-1.

The fate of the parent and the metabolites were simulated in separate model runs with the metabolites applied on the same dates as the parent compound. Application rates for the metabolites were calculated taking the maximum accumulation of CGA 205375 (9.4%) and CGA 71019 (23.4%) in soil degradation studies and differences between molecular weights of the three compounds into account. Each substance was assumed to be applied in each of 26 successive years, with the final 20 years being considered for the assessment.

In the simulations of the use in apples, the first application was made one week after the start of leaf development (from 22 March to 17 May in the different scenarios), followed by three weekly intervals. In order to match the application scheme with that used in surface water modelling (Beulke and Brown, 2003) where for one scenario in the modelling two annual crops were required for vegetable (carrot), two crops were assumed also for groundwater simulations. Hence, two carrot crops were assumed to be grown each season in all six scenarios except Jokioinen. The date of the last application to carrots was set to two weeks before the harvest date for each scenario. For the scenarios with two carrot crops per season the first application of the year was 10-19 April, followed by two additional fortnightly treatments with the last one on 8-17 May. For the second crop the first application was made from 30 July to 3 September in the different scenarios, followed by two additional fortnightly treatments with the last one on 27 August to 1 October.

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**Table B.8.6.1.2-1. Application scenarios used for FOCUS groundwater modelling of difenoconazole and metabolites CGA 205375 and CGA 71019 (1,2,4-triazole).**

Crop	BBCH growth stage	Individual application rate, g/ha	No of applications	Interval, days	Annual application rate, g/ha	Crop interception
<b>Difenoconazole</b>						
Apples	61	75	4	7	300	65
Carrots (one annual crop)	42-43	125	3	14	375	70 <sup>a</sup>
Carrots (two annual crops)	42-43	125	6	14	750	70 <sup>a</sup>
<b>CGA 205375</b>						
Apples	61	6.07	4	7	24.29	65
Carrots (one annual crop)	42-43	10.12	3	14	30.37	70 <sup>a</sup>
Carrots (two annual crops)	42-43	10.12	6	14	60.73	70 <sup>a</sup>
<b>CGA 71019</b>						
Apples	61	2.98	4	7	11.92	65
Carrots (one annual crop)	42-43	4.97	3	14	14.90	70 <sup>a</sup>
Carrots (two annual crops)	42-43	4.97	6	14	29.80	70 <sup>a</sup>

*a Crop interception was 60% for growth stages 20-39 and 80% for growth stages 40 and later. Average interception for the three applications made to carrot was estimated to be 70%.*

The chemical characteristics of difenoconazole and its two metabolites used for modelling are shown in Table B.8.6.1.2-2. Arithmetic mean values of laboratory soil DT<sub>50</sub> and adsorption parameters were used. The DT<sub>50</sub> values were first normalised to reference conditions (20°C and pF2) in accordance with FOCUS recommendations. Koc values were converted to Kom values (as required by PEARL) by dividing Koc by 1.724. Other pesticide parameters input to the programme were kept at the default values.

**Table B.8.6.1.2-2. Input parameters used for FOCUS groundwater modelling of difenoconazole and its metabolites.**

Compound	Mol. weight, g/mol	Solubility, mg/L	Soil DT <sub>50</sub> , days	Koc, mL/g	Kom, mL/g	1/n
Difenoconazole	406	15 <sup>a</sup>	86.0	3759.4	2180.6	0.8
CGA 205375	350	- <sup>a</sup>	71.5	2979.4	1728.2	0.8
CGA 71019	69	- <sup>a</sup>	6.45	89.0	51.6	0.9

*a Measured value for difenoconazole at 25°C; solubility of metabolites set to that for parent as measured data not available at the time of modelling.*

### Results:

The predicted 80th percentile annual average concentration in leachate at 1 m depth in each scenario is shown in Table 8.6.1.2-3.

**Table 8.6.1.2-3. Results of FOCUS groundwater simulations for difenoconazole and its metabolites CGA 205375 and CGA 71019, as 80th percentile annual average concentrations in leachate at 1 m depth. Applications to apples and carrots at maximum rates; 4 x 75 g a.s./ha in apples (7 d interval) and 3 x 125 g a.s./ha in carrots (14 d interval). For most scenarios 2 carrot crops per season was assumed (resulting a total of 6 applications/year).**

Crop	FOCUS scenario	Difenoconazole, µg/L	CGA 205375, µg/L	CGA 71019, µg/L
Apples	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001

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Crop	FOCUS scenario	Difenoconazole, µg/L	CGA 205375, µg/L	CGA 71019, µg/L
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Carrots	Châteaudun <sup>a</sup>	< 0.001	< 0.001	< 0.001
	Hamburg <sup>a</sup>	< 0.001	< 0.001	< 0.001
	Jokioinen <sup>b</sup>	< 0.001	< 0.001	< 0.001
	Kremsmünster <sup>a</sup>	< 0.001	< 0.001	< 0.001
	Porto <sup>a</sup>	< 0.001	< 0.001	< 0.001
	Thiva <sup>a</sup>	< 0.001	< 0.001	< 0.001

*a* Two annual crops, total application 750 g a.s./ha/year.

*b* One annual crop, total application 375 g a.s./ha/year.

It was concluded that it is unlikely that difenoconazole or its metabolites CGA 205375 and 1,2,4-triazole (CGA 71019) will leach to groundwater at concentrations >0.1 µg/L, and that PEC<sub>gw</sub> can be set to <0.001 µg/L.

#### Comments by RMS:

The simulations performed and the results are considered acceptable. Following the RMS's evaluation the mean DT<sub>50</sub> value changed slightly (see section B.8.1.8.2) however this should have a negligible effect on the results. The maximum formation observed of CGA 205375 was erroneously set to 9.4% for the calculation of application rate (should be 9.7%) however the effect of this error on the results should also be negligible. Based on the results use of difenoconazole in apples or carrots is not expected to result in leaching of difenoconazole or its soil metabolites CGA 205375 and 1,2,4-triazole (CGA 71019) to groundwater.

#### B.8.6.2 Predicted environmental concentrations in surface water

##### B.8.6.2.1 DIVIDEND 030 FS: PEC<sub>sw</sub> and PEC<sub>sed</sub>

<b>Reference:</b>	<b>Harvey B (2004c)</b> A-9142 G Difenoconazole (DIVIDEND 030 FS). <b>Document M-III</b> , Section 5. Fate and Behaviour in the Environment. ERA5713.
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#### Method:

FOCUS Steps 1 and 2 surface water modelling was used to examine the potential for difenoconazole and its metabolites CGA 205375 and 1,2,4-triazole (CGA 71019) to reach surface water following use of difenoconazole as seed treatment in DIVIDEND 030 FS (A-9142 G). Following this use surface water contamination can only occur via runoff, erosion and drainage. Therefore the 'no drift' option was used in the modelling.

Sowing of treated seed can take place in the autumn in northern Europe or in spring in both the south and north of Europe. FOCUS Surface Water Step 1 calculations are independent of seasonal and geographic considerations; Step 2 was run with all three scenarios.

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Application rate of difenoconazole was 12.3 g/ha (based on seed planting rate of 205 kg/ha and seed coating of 6 g a.s./100 kg seed). The "application rates" for the metabolites were calculated internally by FOCUS SW Step 1-2 based on maximum percentage found in soil and molecular weight relative the parent (see Table B.8.6.2.1-1).

Substance specific chemical properties used as input to the simulations are shown in Table B.8.6.2.1-1. Arithmetic mean values of adsorption parameters and laboratory DT<sub>50</sub>s in soil and water/sediment systems were used. The DT<sub>50</sub> values for soil were first normalised to reference conditions (20°C and pF2) in accordance with FOCUS recommendations. Degradation in the separate water and sediment phases were both set to degradation rate in the whole water/sediment systems. For CGA 71019 (1,2,4-triazole) DT<sub>50</sub> 1000 days was used as a worst-case assumption since no degradation half-life in water/sediment was available. The maximum occurrence of CGA 71019 in water/sediment systems was estimated to:

11.6% (formation of CGA 205375 from difenoconazole) x 10% (formation of CGA 71019 from CGA 205375) = 1.16%. A conservative estimate of 3% was used for the simulations.

**Table B.8.6.2.1-1. Input parameters used for FOCUS surface water modelling of difenoconazole and its metabolites.**

	Difenoconazole	CGA 205375	CGA 71019
Molecular weight (g mol <sup>-1</sup> )	406	350	69
Solubility in water at 25°C (mg L <sup>-1</sup> )	15	- <sup>a</sup>	730
Saturated vapour pressure at 20°C (Pa)	0 <sup>b</sup>	0 <sup>b</sup>	0 <sup>b</sup>
K <sub>FOC</sub> (mL g <sup>-1</sup> )	3759.4	2979.4	89
1/n	0.8	0.8	0.9
Soil half-life (days)	86.0	71.5	6.45
Water degradation half-life (days)	315.5	465.5	1000 <sup>c</sup>
Sediment degradation half-life (days)	315.5	465.5	1000 <sup>c</sup>
Max. formation in soil (%)	-	9.4	23.4
Max. formation in water (%)	-	11.6	3 <sup>d</sup>

<sup>a</sup> Value not available at the time of modelling, 100 mg/L assumed.

<sup>b</sup> Value not available, worst-case assumption.

<sup>c</sup> Worst-case assumption as degradation half-life in water/sediment system not available.

<sup>d</sup> Value not available, estimated.

## Results:

### STEP 1

The maximum and time weighted average (TWA) Step 1 PEC<sub>sw</sub> for difenoconazole, CGA 205375 and CGA 71019 are shown in Table B.8.6.2.1-2. Corresponding PEC<sub>sed</sub> are shown in Table B.8.6.2.1-3.

**Table B.8.6.2.1-2. Maximum and time weighted average (TWA) PEC<sub>sw</sub> for difenoconazole and metabolites CGA 205375 and CGA 71019 at FOCUS Step 1 assessment. Application of difenoconazole as seed treatment (12.3 g a.s./ha).**

Com- pound	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Difeno- conazole	0.693	0	0.692	0.692	0.690	0.688	0.682	0.677	0.672	0.662	0.622
CGA 205375	0.0679	0	0.0679	0.0678	0.0677	0.0675	0.0672	0.0669	0.0665	0.0658	0.0631
CGA 71019	0.148	0	0.148	0.148	0.148	0.148	0.147	0.147	0.147	0.146	0.143

<sup>a</sup> From time of application.

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**Table B.8.6.2.1-3. Maximum and time weighted average (TWA) PECsed for difenoconazole and metabolites CGA 205375 and CGA 71019 at FOCUS Step 1 assessment. Application of difenoconazole as seed treatment (12.3 g a.s./ha).**

Com- pound	PECsw, µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Difeno- conazole	26.0	0	26.0	26.0	26.0	25.8	25.7	25.5	25.3	24.9	23.4
CGA 205375	2.02	0	2.02	2.02	2.02	2.01	2.00	1.99	1.98	1.96	1.88
CGA 71019	0.132	0	0.132	0.132	0.132	0.132	0.131	0.131	0.131	0.130	0.127

<sup>a</sup> From time of application.

## STEP 2

The maximum Step 2 PECsw and PECsed for difenoconazole, CGA 205375 and CGA 71019 for each of the three scenarios ( Northern EU spring planting, Northern EU autumn planting, Southern EU spring planting) are shown in Table B.8.6.2.1-4.

The maximum Step 2 PECsw after planting of seeds treated with DIVIDEND 030 FS (A-9142 G) were 0.34, 0.03 and 0.05 µg/L for difenoconazole, CGA 205375 and CGA 71019, respectively. The corresponding values for PECsed were 12.6, 0.97 and 0.04 µg/kg.

Time weighted average (TWA) PECsw for difenoconazole, CGA 205375 and CGA 71019 for the scenario which showed highest initial PECsw (N EU autumn conditions) are shown in Table B.8.6.2.1-5. Corresponding PECsed are shown in Table B.8.6.2.1-6.

**Table B.8.6.2.1-4. Step 2 PECsw and PECsed for difenoconazole, CGA 205375 and CGA 71019. Application of difenoconazole as seed treatment (12.3 g a.s./ha) in N/S EU, spring/autumn conditions where applicable.**

Region and season /Compound	Max PECsw, µg/L	on day	Max PECsed, µg/kg	on day
<b>Difenoconazole</b>				
N EU spring planting	0.134	4	5.04	4
N EU autumn planting	0.336	4	12.6	4
S EU spring planting	0.268	4	10.1	4
<b>CGA 205375</b>				
N EU spring planting	0.0131	4	0.389	4
N EU autumn planting	0.0327	4	0.973	4
S EU spring planting	0.0261	4	0.778	4
<b>CGA 71019</b>				
N EU spring planting	0.0193	4	0.0172	4
N EU autumn planting	0.0482	4	0.0429	4
S EU spring planting	0.0385	4	0.0343	4

**Table B.8.6.2.1-5. Maximum and time weighted average (TWA) PECsw for difenoconazole and metabolites CGA 205375 and CGA 71019 at FOCUS Step 2 assessment. Autumn application of difenoconazole as seed treatment (12.3 g a.s./ha), Northern EU.**

Com- pound	PECsw, µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Difeno- conazole	0.336	4	0.335	0.335	0.334	0.333	0.330	0.328	0.325	0.320	0.301

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Com- pound	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
CGA 205375	0.0327	4	0.0326	0.0326	0.0326	0.0325	0.0323	0.0322	0.0320	0.0317	0.0303
CGA 71019	0.0482	4	0.0482	0.0482	0.0481	0.0481	0.0480	0.0478	0.0477	0.0475	0.0466

*a From time of application.*

**Table B.8.6.2.1-6. Maximum and time weighted average (TWA) PEC<sub>sw</sub> and PEC<sub>sed</sub> for difenoconazole and metabolites CGA 205375 and CGA 71019 at FOCUS Step 1 assessment. Autumn application of difenoconazole as seed treatment (12.3 g a.s./ha), Northern EU.**

Com- pound	PEC <sub>sed</sub> , µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
Difeno- conazole	12.6	4	12.6	12.6	12.6	12.5	12.4	12.3	12.2	12.0	11.3
CGA 205375	0.973	4	0.972	0.972	0.970	0.968	0.963	0.958	0.953	0.943	0.904
CGA 71019	0.0429	4	0.0429	0.0429	0.0428	0.0428	0.0427	0.0426	0.0425	0.0423	0.0414

*a From time of application.*

#### Comments by RMS:

The simulations performed and the results are considered acceptable and the PEC<sub>sw</sub> and PEC<sub>sed</sub> presented in the tables above are used for risk assessment.

The maximum amount of CGA 71019 (1,2,4-triazole) formed in water/sediment study on CGA 205375 was erroneously set to 10%. A maximum of 14.1% was observed at study termination and hence the max. formation based on this figure would be  $11.6 \times 14.1 = 1.6\%$ . However, the amounts of CGA 71019 did not seem to have reached a plateau at termination of the study on degradation of CGA 205375 in water/sediment. The RMS therefore calculated a worst-case max. formation of CGA 71019 in aquatic systems to 9.6% (see section B.8.4.4) based on the assumption that all CGA 205375 formed by degradation of difenoconazole and remaining at study termination (max. 68.4%) eventually would be transformed into CGA 71019. The RMS also re-calculated the PEC<sub>sw</sub> and PEC<sub>sed</sub> assuming 9.6% formation in water/sediment, however this did not produce any higher PEC<sub>sw</sub> and PEC<sub>sed</sub> than the values presented in the tables above, presumably because for seed treatments the PEC<sub>sw</sub> for metabolites are mainly governed by the fate of the parent in soil, not in water/sediment.

A few additional and minor comments could be made on the input values used. Following the RMS's evaluation the mean DT<sub>50</sub> for soil changed slightly (see section B.8.1.8.2) however this should have a negligible effect on the results. The assumption of DT<sub>50</sub> 1000 days for degradation of CGA 71019 in water/sediment is considered to represent a worst-case since the DT<sub>50</sub> in soil was so much shorter. The maximum formation observed of CGA 205375 was erroneously set to 9.4% for the calculation of application rate (should be 9.7%) however the effect of this error on the results should also be negligible. The water solubility of CGA 205375 has been determined to 12 mg/L (see section B.2), and with respect to PEC<sub>sw</sub> the assumed value of 100 mg/L should represent a worst-case.

#### B.8.6.2.2 SCORE 250 EC: PEC<sub>sw</sub> and PEC<sub>sed</sub>

In the original dossier, FOCUS Steps 1-3 simulations were presented for multiple applications of difenoconazole, as well as Steps 1-2 simulations for the metabolites CGA 71019 and CGA 205375 (Beulke and Brown, 2003). Later, the dossier was supplemented with FOCUS Step 3 simulations for difenoconazole following a single application and FOCUS Step 4 simulations for difenoconazole following single and multiple applications (Takacs, 2006).

<b>Reference:</b>	<b>Beulke S, Brown C (2003)</b> FOCUS Step 1-3 modelling to estimate predicted environmental concentrations in surface water (PEC <sub>sw</sub> ) and sediment (PEC <sub>sed</sub> ) for difenoconazole and its metabolites CGA 205375 and 1,2,4-triazole following use on sugar beet, apples and carrots. Cranfield Centre for EcoChemistry, Cranfield University, Silsoe, Beds., UK. Report No. 03/MOD/044. Syngenta File No. CGA169374/2418.
<b>Guideline:</b>	FOCUS (2001) FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC, report of the FOCUS Working Group on surface water scenarios workgroup, EC document reference Sanco/4802/2001 rev. 1, 221pp.

#### Method:

FOCUS surface water modelling was used to examine the potential for difenoconazole and its metabolites CGA 205375 and 1,2,4-triazole (CGA 71019) to reach surface water following application to apple and carrot crops. Additional crops were included in the report but are not relevant to this assessment.

All three compounds were assessed using FOCUS Steps 1 and 2. In addition, Step 3 modelling using the FOCUS surface water models (SWASH ver. 1.1, Drift calculator ver. 1.1, PRZM\_SW ver. 1.1.1, MACRO ver. 4.4.2 and TOXSWA ver. 1.1.1) was carried out for the parent compound. The modelling was done in accordance with FOCUS recommendations. Application details for each crop are summarised in Table B.8.6.2.2-1.

At Step 2 the region assumed was Southern Europe and the period assumed was March-May. Under these conditions run-off and drainage losses are assumed to be 4% of the soil residue. Concentrations for North, March to May would be smaller due to a smaller percentage of run-off and drainflow losses (2%).

At Step 2 recommended crop interception of 70% was used for both apples (late growth stages) and carrot, as recommended by FOCUS (at Step 1 no crop interception is assumed, at Step 3 interception is calculated by the models internally based on application dates set).

The Step 3 scenarios considered for the use of difenoconazole were:

Apples: D3, D4, D5, R1, R2, R3 and R4,

Carrot (vegetable root crop): D3, D6, R1, R2, R3 and R4.

For one scenario (R2) modelling of two annual crops was required for vegetable (carrot) use.

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Dates for the first application to apples were between 1 March and 18 April. For carrots, the end of the application window was set to two weeks before harvest, and as a result the first application to carrots was made between 2 March and 15 June in the different scenarios. The first application to the second carrot crop at R2 was made on 4 August.

**Table B.8.6.2.2-1. Application scenarios used for FOCUS surface water modelling of difenoconazole and metabolites CGA 205375 and CGA 71019 (1,2,4-triazole).**

Crop	BBCH growth stage	Individual application rate, g/ha	No of applications	Interval, days	Annual application rate, g/ha
<b>Difenoconazole</b>					
Apples	61	75	4	7	300
Carrots (one annual crop)	42-43	125	3	14	375
Carrots (two annual crops) <sup>a</sup>	42-43	125	6	14	750

*a At Step 3 modelling of difenoconazole, application to two carrot crops per season was also simulated for the scenario R2.*

Substance specific chemical properties used as input to the simulations are shown in Table B.8.6.2.2-2. Arithmetic mean values of adsorption parameters and laboratory DT<sub>50</sub> in soil and water/sediment systems were used. The DT<sub>50</sub> values for soil were first normalised to reference conditions (20°C and pF2) in accordance with FOCUS recommendations. Degradation in the separate water and sediment phases were both set to degradation rate in the whole water/sediment systems. For CGA 71019 (1,2,4-triazole) DT<sub>50</sub> 1000 days was used as a worst-case assumption since no degradation half-life in water/sediment was available. The maximum occurrence of CGA 71019 in water/sediment systems was estimated to:

11.6% (formation of CGA 205375 from difenoconazole) x 10% (formation of CGA 71019 from CGA 205375) = 1.16%. A conservative estimate of 3% was used for the simulations.

**Table B.8.6.2.2-2. Input parameters used for FOCUS surface water modelling of difenoconazole and its metabolites.**

	Difenoconazole	CGA 205375	CGA 71019
Molecular weight (g mol <sup>-1</sup> )	406	350	69
Solubility in water at 25°C (mg L <sup>-1</sup> )	15	- <sup>a</sup>	730
Saturated vapour pressure at 20°C (Pa)	0 <sup>b</sup>	0 <sup>b</sup>	0 <sup>b</sup>
K <sub>FOC</sub> (mL g <sup>-1</sup> )	3759.4	2979.4	89
1/n	0.8	0.8	0.9
Soil half-life (days)	86.0	71.5	6.45
Water degradation half-life (days)	315.5	465.5	1000 <sup>c</sup>
Sediment degradation half-life (days)	315.5	465.5	1000 <sup>c</sup>
Max. formation in soil (%)	-	9.4	23.4
Max. formation in water (%)	-	11.6	3 <sup>d</sup>

*a Value not available at the time of modelling, 100 mg/L assumed.*

*b Value not available, worst-case assumption.*

*c Worst-case assumption as degradation half-life in water/sediment system not available.*

*d Value not available, estimated.*

## Results:

### STEP 1

The maximum Step 1 PEC<sub>sw</sub> and PEC<sub>sd</sub> for difenoconazole, CGA 205375 and CGA 71019 at the representative use in apples and carrots are shown in Table B.8.6.2.2-3.

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**Table B.8.6.2.2-3. Step 1 PEC<sub>sw</sub> and PEC<sub>sed</sub> for difenoconazole, CGA 205375 and CGA 71019. Applications of difenoconazole to apples and carrots at maximum rates; 4 x 75 g a.s./ha in apples and 3 x 125 g a.s./ha in carrots.**

Crop	Max PEC <sub>sw</sub> , µg/L	on day	Max PEC <sub>sed</sub> , µg/kg	on day
<b>Difenoconazole</b>				
Apples	32.4	0	722	1
Carrot	24.2	0	801	0
<b>CGA 205375</b>				
Apples	3.20	0	57.8	1
Carrot	2.38	0	62.6	1
<b>CGA 71019</b>				
Apples	3.76 <sup>a</sup>	0	3.11 <sup>b</sup>	1
Carrot	4.43 <sup>c</sup>	0	3.89 <sup>d</sup>	1

*a* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 3.64 µg/L.

*b* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 3.23 µg/kg.

*c* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 4.46 µg/L.

*d* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 3.97 µg/kg.

**STEP 2**

The maximum Step 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for difenoconazole, CGA 205375 and CGA 71019 at the representative use in apples and carrots are shown in Table B.8.6.2.2-4. The maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> for CGA 205375 were calculated for the use in apples and were 0.46 µg/L and 11 µg/kg, respectively. For CGA 71019, the maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> were 0.17 µg/L and 0.15 µg/kg, respectively, calculated for the use in apples.

**Table B.8.6.2.2-4. Step 2 PEC<sub>sw</sub> and PEC<sub>sed</sub> for difenoconazole, CGA 205375 and CGA 71019. Applications of difenoconazole to apples and carrots at maximum rates; 4 x 75 g a.s./ha in apples (7 d interval) and 3 x 125 g a.s./ha in carrots (14 d interval). Southern Europe, spring applications.**

Crop	Max PEC <sub>sw</sub> , µg/L	on day	Max PEC <sub>sed</sub> , µg/kg	on day
<b>Difenoconazole</b>				
Apples	4.23	21	128	26
Carrot	2.73	32	96.5	32
<b>CGA 205375</b>				
Apples	0.457	21	11.0	26
Carrot	0.274	32	7.61	33
<b>CGA 71019</b>				
Apples	0.272 <sup>a</sup>	25	0.237 <sup>b</sup>	26
Carrot	0.176 <sup>c</sup>	32	0.155 <sup>d</sup>	33

*a* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 0.172 µg/L.

*b* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 0.152 µg/kg.

*c* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 0.159 µg/L.

*d* Value in table calculated by RMS assuming 9.6% max. formation of CGA 71019 formed by degradation of difenoconazole (see comment below). Value presented in study report (based on max. formation 3%) was 0.141 µg/kg.

**STEP 3**

Global maximum and time weighted average (TWA) PEC<sub>sw</sub> and PEC<sub>sed</sub> following 4 applications to apples at the highest recommended rate of 75 g a.s./ha are shown in Tables B.8.6.2.2-5 and B.8.6.2.2-6, respectively. Maximum PEC<sub>sw</sub> was 1.9 µg/L in R3 stream scenario. Maximum PEC<sub>sed</sub> was 4.0 µg/kg in D5 pond scenario.

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**Table B.8.6.2.2-5. Maximum and time weighted average (TWA) PEC<sub>sw</sub> for difenoconazole at FOCUS Step 3 assessment. Application to apples at 4 x 75 g a.s./ha (7 d interval). Maximum value in bold.**

Scenario	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	1.789	43	1.469	1.048	0.562	0.326	0.251	0.206	0.191	0.148	0.081
D4: Pond	0.241	24	0.237	0.234	0.228	0.219	0.202	0.193	0.185	0.170	0.133
D4: Stream	1.677	7	0.126	0.063	0.032	0.018	0.016	0.015	0.015	0.010	0.004
D5: Pond	0.240	30	0.237	0.233	0.227	0.219	0.202	0.192	0.185	0.171	0.134
D5: Stream	1.806	30	0.139	0.070	0.035	0.020	0.019	0.019	0.014	0.011	0.005
R1: Pond	0.227	39	0.223	0.220	0.214	0.205	0.189	0.179	0.172	0.157	0.120
R1: Stream	1.372	19	0.237	0.118	0.059	0.034	0.030	0.029	0.023	0.020	0.012
R2: Stream	1.819	29	0.154	0.077	0.039	0.026	0.022	0.022	0.019	0.017	0.007
R3: Stream	<b>1.943</b>	25	0.624	0.329	0.227	0.130	0.110	0.103	0.096	0.064	0.027
R4: Stream	1.380	41	0.426	0.321	0.163	0.093	0.060	0.040	0.036	0.030	0.021

<sup>a</sup> From time of first application.

**Table B.8.6.2.2-6. Maximum and time weighted average (TWA) PEC<sub>sd</sub> for difenoconazole at FOCUS Step 3 assessment. Application to apples at 4 x 75 g a.s./ha (7 d interval). Maximum value in bold.**

Scenario	PEC <sub>sd</sub> , µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	3.875	45	3.868	3.848	3.788	3.686	3.457	3.259	3.111	2.958	2.366
D4: Pond	3.937	98	3.937	3.937	3.937	3.937	3.936	3.934	3.932	3.926	3.882
D4: Stream	0.255	24	0.254	0.252	0.248	0.242	0.230	0.219	0.209	0.198	0.160
D5: Pond	<b>4.033</b>	109	4.033	4.033	4.033	4.033	4.032	4.031	4.029	4.024	3.981
D5: Stream	0.287	30	0.285	0.282	0.277	0.271	0.256	0.244	0.232	0.218	0.171
R1: Pond	3.723	95	3.723	3.723	3.723	3.723	3.721	3.718	3.714	3.702	3.612
R1: Stream	0.718	77	0.716	0.712	0.705	0.695	0.672	0.652	0.634	0.612	0.551
R2: Stream	1.568	101	1.566	1.563	1.557	1.548	1.528	1.510	1.492	1.457	1.335
R3: Stream	1.849	26	1.839	1.823	1.789	1.740	1.638	1.557	1.489	1.372	1.104
R4: Stream	1.761	76	1.752	1.742	1.720	1.690	1.627	1.571	1.522	1.458	1.442

<sup>a</sup> From time of first application.

Global maximum and time weighted average (TWA) PEC<sub>sw</sub> and PEC<sub>sd</sub> following 3 applications to carrots at the highest recommended rate of 125 g a.s./ha (and for R2 also 6 x 125 g a.s./ha) are shown in Tables B.8.6.2.2-7 and B.8.6.2.2-8, respectively. Maximum PEC<sub>sw</sub> was 0.71 µg/L in R4 stream scenario. Maximum PEC<sub>sd</sub> was 147 µg/kg in R2 stream scenario following 6 applications (i.e. two carrot crops grown per season).

**Table B.8.6.2.2-7. Maximum and time weighted average (TWA) PEC<sub>sw</sub> for difenoconazole at FOCUS Step 3 assessment. Application to carrots at 3 x 125 g a.s./ha (14 d interval). At scenario R2 also 6 x 125 g a.s./ha assumed (two carrot crops grown per season). Maximum value in bold.**

Scenario	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	0.573	40	0.457	0.309	0.162	0.093	0.047	0.059	0.044	0.041	0.018
D6: Ditch	0.570	0	0.425	0.262	0.133	0.076	0.038	0.026	0.026	0.017	0.009
R1: Pond	0.082	163	0.081	0.080	0.078	0.076	0.071	0.068	0.066	0.064	0.061
R1: Stream	0.376	37	0.191	0.095	0.079	0.057	0.039	0.030	0.025	0.019	0.014
R2: Stream 1st crop	0.504	46	0.080	0.042	0.022	0.015	0.009	0.007	0.006	0.006	0.004
R2: Stream 2nd crop	0.504	0	0.056	0.039	0.028	0.022	0.017	0.014	0.012	0.012	0.009
R3: Stream	0.530	40	0.322	0.174	0.087	0.050	0.042	0.030	0.025	0.023	0.017
R4: Stream	<b>0.713</b>	57	0.561	0.470	0.238	0.190	0.130	0.088	0.085	0.078	0.040

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*a From time of first application.*

**Table B.8.6.2.2-8. Maximum and time weighted average (TWA) PECsed for difenoconazole at FOCUS Step 3 assessment. Application to carrots at 3 x 125 g a.s./ha (14 d interval). At scenario R2 also 6 x 125 g a.s./ha assumed (two carrot crops grown per season). Maximum value in bold.**

Scenario	PECsed, µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	0.979	40	0.978	0.973	0.960	0.937	0.886	0.840	0.800	0.734	0.598
D6: Ditch	0.428	50	0.427	0.424	0.418	0.410	0.391	0.374	0.362	0.361	0.328
R1: Pond	3.908	261	3.906	3.904	3.899	3.892	3.877	3.854	3.818	3.712	3.401
R1: Stream	23.00	234	22.98	22.96	22.92	22.86	22.72	22.59	22.49	21.99	20.73
R2: Stream 1st crop	62.88	340	62.83	62.79	62.69	62.54	61.98	61.09	60.84	60.32	58.68
R2: Stream 2nd crop	<b>146.6</b>	157	146.4	146.2	145.8	145.3	144.0	143.1	142.8	142.3	137.1
R3: Stream	7.356	272	7.350	7.343	7.330	7.314	7.277	7.249	7.234	7.211	6.947
R4: Stream	18.15	83	18.12	18.07	17.97	17.85	17.66	17.45	17.19	16.71	16.24

*a From time of first application.*

### Comments by RMS:

The simulations performed and the results are considered acceptable and the PECsw and PECsed presented in the tables above are used for risk assessment. No TWA concentrations were presented for Step 1 and 2, this is however acceptable since initial PECsw and PECsed are used for risk assessment.

The maximum amount of CGA 71019 (1,2,4-triazole) formed in water/sediment study on CGA 205375 was erroneously set to 10%. A maximum of 14.1% was observed at study termination and hence the max. formation based on this figure would be  $11.6 \times 14.1 = 1.6\%$ . Furthermore, the amounts of CGA 71019 did not seem to have reached a plateau at termination of the study on degradation of CGA 205375 in water/sediment. The RMS therefore calculated a worst-case max. formation of CGA 71019 in aquatic systems to 9.6% (see section B.8.4.4) based on the assumption that all CGA 205375 formed by degradation of difenoconazole and remaining at study termination (max. 68.4%) eventually would be transformed into CGA 71019. The RMS therefore re-calculated the PECsw and PECsed for CGA 71019 in Steps 1 and 2 assuming 9.6% formation in water/sediment, and the results are included in the tables above.

A few additional and minor comments could be made on the input values used. Following the RMS's evaluation the mean  $DT_{50}$  for soil changed slightly (see section B.8.1.8.2) however this should have a negligible effect on the results. The assumption of  $DT_{50}$  1000 days for degradation of CGA 71019 in water/sediment is considered to represent a worst-case since the  $DT_{50}$  in soil was so much shorter. The maximum formation observed of CGA 205375 was erroneously set to 9.4% for the calculation of application rate (should be 9.7%) however the effect of this error on the results should also be negligible. The water solubility of CGA 205375 has been determined to 12 mg/L (see section B.2), and with respect to PECsw the assumed value of 100 mg/L should represent a worst-case.

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<b>Reference:</b>	<b>Takacs M (2006)</b> Difenoconazole (CGA 169374): A European fate assessment using the FOCUS Surface water scenarios at Steps 3 and 4 for carrots and apples. Syngenta, Jealott's Hill International Research Centre, Bracknell, UK. Report No. RAJ0410B. Syngenta File No. CGA169374/2821.
<b>Guideline:</b>	FOCUS (2001) FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC, report of the FOCUS Working Group on surface water scenarios workgroup, EC document reference Sanco/4802/2001 rev. 1, 221pp. FOCUS (2003) FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC, report of the FOCUS Working Group on surface water scenarios workgroup. EC document reference SANCO/4802/2001 rev. 2 final, 238 pp.

**Method:**

FOCUS surface water modelling Steps 3 and 4 was used to examine the potential for difenoconazole to reach surface water following single and multiple applications to apple and carrot crops. The FOCUS surface water model was used, comprising SWASH ver. 1.1, Drift calculator ver. 1.1, PRZM SW ver. 1.1.1, MACRO ver. 4.4.2 and TOXSWA ver. 2.2.1. The modelling was done in accordance with FOCUS recommendations. The Step 3 modelling was intended to repeat the earlier work by Beulke and Brown (2003, see above) and in addition PEC<sub>sw</sub> and PEC<sub>sd</sub> from single applications to apples and carrots were modelled. The substance specific input parameters used were the same as those previously used (see parameters for difenoconazole in Table B.8.6.2.2-2).

Application details are summarised in Table B.8.6.2.2-9. The scenarios considered were:

Apples: D3, D4, D5, R1, R2, R3 and R4,

Carrot (vegetable root crop): D3, D6, R1, R2, R3 and R4.

For one scenario (R2) modelling of two annual crops was required for vegetable (carrot) use.

Dates for the first application to apples were between 1 March and 6 April. For carrots, the first application was made between 2 March and 3 June in the different scenarios. The first application to the second carrot crop at R2 was made on 3 August.

**Table B.8.6.2.2-9. Application scenarios used for FOCUS surface water Steps 3 and 4 modelling of difenoconazole.**

Crop	BBCH growth stage	Individual application rate, g/ha	No of applications	Interval, days	Annual application rate, g/ha
Apples	61	75	1	n.a.	75
Apples	61	75	4	7	300
Carrots	42-43	125	1	n.a.	125
Carrots (one annual crop)	42-43	125	3	14	375
Carrots (two annual crops) <sup>a</sup>	42-43	125	6	14	750

n.a. Not applicable.

<sup>a</sup> Application to two carrot crops per season was also simulated for the scenario R2.

At Step 4, a 5 m vegetative filter strip was used for spray drift and run-off mitigation for the use in carrots. The application schemes in TOXSWA were modified using the FOCUS drift calculator with the TOXSWA GUI<sup>8</sup> to reduce the mass loadings input to the model. At Step 4 the drift loadings for the stream scenarios were manually increased by 20% from the values calculated by the FOCUS drift calculator to account for inputs from the

<sup>8</sup> Graphical User Interface.

upstream catchment (at Step 3 this is automatically done by the SWASH model). The run-off loading from the treated fields in the stream scenarios was reduced by 50% with reference given to literature<sup>9</sup> on the mitigation effect of buffer strips on run-off.

For the use in apples, spray-drift was reduced by buffer strips (14 and 20 m wide) at Step 4 in the same way as for carrots. The results from Step 3 indicated that the route of entry to surface water from the use in orchards is dominated by spray drift and therefore run-off mitigation was not considered for apples.

## Results:

### STEP 3

Maximum and TWA PEC<sub>sw</sub> and PEC<sub>sd</sub> from the Step 3 modelling assuming one single application (75 g a.s./ha) to apples are presented in Tables 8.6.2.2-10 and 8.6.2.2-11, respectively. The results from Step 3 modelling of one single application (125 g a.s./ha) to carrots are presented in Tables 8.6.2.2-12 and 8.6.2.2-13. The maximum PEC<sub>sw</sub> and PEC<sub>sd</sub> following a single application to apples were 2.93 µg/L (R3 stream) and 1.90 µg/kg (D3 ditch), respectively. Maximum PEC<sub>sw</sub> and PEC<sub>sd</sub> following a single application to carrots were 0.783 µg/L (D3 ditch) and 67.3 µg/kg (R2 stream, 2nd crop), respectively.

Actual short- and long-term PEC<sub>sw</sub> and PEC<sub>sd</sub> were also presented in the report but not re-produced herein.

All results from the modelling with multiple applications were essentially the same as those previously presented (Beulke and Brown, 2003, see above) and they are therefore not repeated here.

**Table B.8.6.2.2-10. Maximum and time weighted average (TWA) PEC<sub>sw</sub> for difenoconazole at FOCUS Step 3 assessment. Single application to apples at 75 g a.s./ha. Maximum value in bold.**

Scenario	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	2.72	0	2.05	1.28	0.651	0.373	0.188	0.126	0.095	0.064	0.027
D4: Pond	0.121	0	0.119	0.117	0.113	0.107	0.097	0.088	0.081	0.071	0.049
D4: Stream	2.46	0	0.140	0.070	0.035	0.020	0.010	0.007	0.005	0.003	0.001
D5: Pond	0.121	0	0.119	0.117	0.113	0.107	0.096	0.088	0.081	0.071	0.050
D5: Stream	2.49	0	0.094	0.047	0.024	0.014	0.007	0.005	0.003	0.002	0.001
R1: Pond	0.121	0	0.119	0.117	0.113	0.107	0.096	0.087	0.080	0.069	0.047
R1: Stream	2.08	0	0.359	0.179	0.090	0.051	0.026	0.017	0.013	0.009	0.004
R2: Stream	2.76	0	0.234	0.117	0.058	0.033	0.017	0.011	0.008	0.006	0.003
R3: Stream	<b>2.93</b>	0	0.801	0.401	0.200	0.115	0.057	0.038	0.031	0.021	0.009
R4: Stream	2.08	0	0.361	0.180	0.090	0.052	0.026	0.017	0.013	0.009	0.005

<sup>a</sup> Single application modelled, max. PEC<sub>sw</sub> always on the day of application.

**Table B.8.6.2.2-11. Maximum and time weighted average (TWA) PEC<sub>sd</sub> for difenoconazole at FOCUS Step 3 assessment. Single application to apples at 75 g a.s./ha. Maximum value in bold.**

Scenario	PEC <sub>sd</sub> , µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	<b>1.90</b>	2	1.90	1.88	1.85	1.79	1.66	1.55	1.46	1.31	0.963

<sup>9</sup> Klöppel H, Kördel W and Stein B (1997) Herbicide Transport by Surface Runoff and Herbicide Retention in a Filter Strip - Rainfall and Runoff Simulation Studies. Chemosphere, Vol 35, No ½, pp 129-141.

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Scenario	PECsed, $\mu\text{g/kg}$		Time weighted average concentration, $\mu\text{g/kg}$								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D4: Pond	1.51	80	1.51	1.51	1.51	1.51	1.51	1.51	1.51	1.50	1.48
D4: Stream	0.102	0	0.102	0.101	0.100	0.098	0.093	0.089	0.086	0.079	0.062
D5: Pond	1.53	85	1.53	1.53	1.53	1.53	1.53	1.53	1.53	1.53	1.51
D5: Stream	0.067	0	0.066	0.066	0.065	0.064	0.061	0.059	0.056	0.052	0.041
R1: Pond	1.43	67	1.43	1.43	1.43	1.43	1.43	1.43	1.43	1.42	1.39
R1: Stream	0.272	0	0.270	0.267	0.263	0.256	0.242	0.229	0.220	0.214	0.204
R2: Stream	0.416	362	0.415	0.415	0.414	0.413	0.401	0.377	0.373	0.365	0.344
R3: Stream	0.605	1	0.602	0.596	0.584	0.567	0.530	0.499	0.497	0.486	0.402
R4: Stream	0.477	76	0.475	0.473	0.470	0.464	0.452	0.442	0.435	0.422	0.414

<sup>a</sup> From time of application.

**Table B.8.6.2.2-12. Maximum and time weighted average (TWA) PECsw for difenoconazole at FOCUS Step 3 assessment. Single application to carrots at 125 g a.s./ha. At scenario R2 also one application at 125 g a.s./ha assumed for a second carrot crop grown the same season. Maximum value in bold.**

Scenario	PECsw, $\mu\text{g/L}$		Time weighted average concentration, $\mu\text{g/L}$								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	<b>0.783</b>	0	0.582	0.356	0.181	0.104	0.052	0.035	0.026	0.018	0.008
D6: Ditch	0.781	0	0.582	0.358	0.183	0.105	0.053	0.035	0.027	0.018	0.008
R1: Pond	0.029	0	0.028	0.028	0.027	0.025	0.025	0.023	0.022	0.021	0.017
R1: Stream	0.517	0	0.108	0.054	0.030	0.017	0.013	0.009	0.007	0.007	0.005
R2: Stream 1st crop	0.682	0	0.059	0.030	0.015	0.009	0.006	0.006	0.005	0.003	0.002
R2: Stream 2nd crop	0.694	0	0.077	0.039	0.019	0.011	0.006	0.005	0.004	0.004	0.003
R3: Stream	0.725	0	0.212	0.106	0.053	0.043	0.021	0.018	0.013	0.009	0.006
R4: Stream	0.510	0	0.178	0.111	0.056	0.045	0.031	0.026	0.020	0.021	0.012

<sup>a</sup> Single application modelled, max. PECsw always on the day of application.

**Table B.8.6.2.2-13. Maximum and time weighted average (TWA) PECsed for difenoconazole at FOCUS Step 3 assessment. Single application to carrots at 125 g a.s./ha. At scenario R2 also one application at 125 g a.s./ha assumed for a second carrot crop grown the same season. Maximum value in bold.**

Scenario	PECsed, $\mu\text{g/kg}$		Time weighted average concentration, $\mu\text{g/kg}$								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	0.535	2	0.534	0.531	0.522	0.509	0.479	0.452	0.429	0.389	0.292
D6: Ditch	0.540	2	0.538	0.536	0.528	0.515	0.485	0.459	0.436	0.397	0.298
R1: Pond	1.23	261	1.23	1.23	1.23	1.23	1.23	1.22	1.21	1.19	1.11
R1: Stream	7.92	234	7.91	7.91	7.89	7.88	7.83	7.79	7.76	7.58	7.11
R2: Stream 1st crop	24.1	284	24.2	24.2	24.1	24.1	23.8	23.5	23.4	23.1	22.4
R2: Stream 2nd crop	<b>67.3</b>	148	67.2	67.1	66.9	66.7	66.2	65.7	65.7	65.4	63.2
R3: Stream	2.78	272	2.78	2.78	2.77	2.77	2.76	2.75	2.74	2.74	2.64
R4: Stream	5.19	274	5.18	5.18	5.17	5.15	5.13	5.13	5.11	5.07	4.92

<sup>a</sup> From time of application.

#### STEP 4

First, the results of Step 4 modelling of single applications is briefly summarised in Table 8.6.2.2-14. The

maximum PECsw following a single application to apples and using a 14 m buffer was 0.578  $\mu\text{g/L}$  (R3 stream).

This figure was reduced to 0.314  $\mu\text{g/L}$  using a 20 m buffer. The maximum PECsed following a single application

to apples and using a 14 m buffer was 0.699  $\mu\text{g/kg}$  (D5 pond). Using 20 m buffer the max. PECsed was reduced to

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0.469 µg/kg. In carrots, a single application resulted in maximum PEC<sub>sw</sub> of 0.264 µg/L (R3 stream), using a 5 m vegetative buffer. Maximum PEC<sub>sed</sub> was 33.9 µg/kg (R2 stream, 2nd crop).

Presented short and long term actual and TWA PEC<sub>sw</sub> and PEC<sub>sed</sub> from single application modelling are not reproduced herein.

**Table B.8.6.2.2-14. Maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> for difenoconazole at FOCUS Step 4 assessment. Single applications to apples at 75 g a.s./ha and carrots at 125 g a.s./ha. At scenario R2 also one application at 125 g a.s./ha assumed for a second carrot crop grown the same season. Two different buffers (14 m or 20 m) in apple crops to reduce loading by spray drift; in carrot crop a vegetative buffer strip (5 m) to reduce spray drift and run-off. Maximum values in bold.**

Crop	Max PEC <sub>sw</sub> , µg/L	on day <sup>a</sup>	Max PEC <sub>sed</sub> , µg/kg	on day <sup>a</sup>
<b>Apples, 14 m buffer</b>				
D3: Ditch	0.464	0	0.329	2
D4: Pond	0.053	0	0.689	77
D4: Stream	0.486	0	0.020	0
D5: Pond	0.053	0	<b>0.699</b>	84
D5: Stream	0.492	0	0.013	0
R1: Pond	0.053	0	0.660	67
R1: Stream	0.410	0	0.133	57
R2: Stream	0.544	0	0.400	361
R3: Stream	<b>0.578</b>	0	0.226	24
R4: Stream	0.410	0	0.425	172
<b>Apples, 20 m buffer</b>				
D3: Ditch	0.252	0	0.179	2
D4: Pond	0.035	0	0.462	76
D4: Stream	0.264	0	0.011	0
D5: Pond	0.035	0	<b>0.469</b>	84
D5: Stream	0.267	0	0.007	0
R1: Pond	0.035	0	0.446	69
R1: Stream	0.223	0	0.120	57
R2: Stream	0.295	0	0.398	361
R3: Stream	<b>0.314</b>	0	0.188	24
R4: Stream	0.223	0	0.420	172
<b>Carrots, 5 m buffer</b>				
D3: Ditch	0.211	0	0.146	2
D6: Ditch	0.211	0	0.147	2
R1: Pond	0.024	0	0.721	261
R1: Stream	0.188	0	4.01	234
R2: Stream 1st crop	0.248	0	12.29	340
R2: Stream 2nd crop	0.253	0	<b>33.9</b>	156
R3: Stream	<b>0.264</b>	0	1.41	272
R4: Stream	0.186	0	2.64	274

<sup>a</sup> From time of application

Maximum and TWA PEC<sub>sw</sub> and PEC<sub>sed</sub> from the Step 4 modelling assuming multiple applications (4 x 75 g a.s./ha) to apples are presented in Tables 8.6.2.2-15 and 8.6.2.2-16, respectively, including the results of use of both 14 m and 20 m buffers. Maximum PEC<sub>sw</sub> using 14 as well as 20 m buffer was 0.444 µg/L (R4 stream)<sup>10</sup>. Maximum PEC<sub>sed</sub> was 1.78 µg/kg (D5 pond) using 14 m buffer, and 1.50 µg/kg (R2 stream) using 20 m buffer.

<sup>10</sup> This result was questioned by the RMS since use of 20 m buffer would have been expected to produce a lower PEC<sub>sw</sub> than that calculated using a 14 m buffer. The notifier responded that while surface water PEC was driven by spray drift at FOCUS Step 3, introduction of a 14 m

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The results from Step 4 modelling of multiple applications (3 x 125 g a.s./ha) to carrots using a 5 m vegetative buffer strip are presented in Tables 8.6.2.2-17 and 8.6.2.2-18. The maximum PEC<sub>sw</sub> was 0.392 µg/L (R4 stream) and the maximum PEC<sub>sed</sub> was 74.1 µg/kg (R2 stream 2nd crop).

Actual short- and long-term PEC<sub>sw</sub> and PEC<sub>sed</sub> for multiple applications in apples and carrots were also presented in the report but not re-produced herein.

**Table B.8.6.2.2-15. Maximum and time weighted average (TWA) PEC<sub>sw</sub> for difenoconazole at FOCUS Step 4 assessment. Application to apples at 4 x 75 g a.s./ha (7 days interval). Two different buffers (14 m or 20 m) to reduce loading by spray drift. Maximum values in bold.**

Scenario	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
<b>14 m buffer</b>											
D3: Ditch	0.326	43	0.268	0.191	0.102	0.059	0.046	0.037	0.035	0.027	0.015
D4: Pond	0.101	24	0.100	0.098	0.095	0.092	0.084	0.080	0.077	0.070	0.054
D4: Stream	0.351	7	0.026	0.013	0.007	0.004	0.003	0.003	0.003	0.002	0.001
D5: Pond	0.101	30	0.099	0.098	0.095	0.091	0.084	0.080	0.077	0.070	0.055
D5: Stream	0.378	30	0.029	0.015	0.007	0.004	0.004	0.004	0.003	0.002	0.001
R1: Pond	0.095	38	0.093	0.092	0.089	0.086	0.079	0.074	0.072	0.065	0.050
R1: Stream	0.287	19	0.156	0.078	0.039	0.022	0.012	0.010	0.010	0.009	0.005
R2: Stream	0.381	28	0.080	0.040	0.020	0.012	0.008	0.007	0.006	0.005	0.002
R3: Stream	0.407	25	0.263	0.141	0.103	0.059	0.039	0.032	0.028	0.019	0.008
R4: Stream	<b>0.444</b>	75	0.426	0.321	0.163	0.093	0.060	0.040	0.036	0.025	0.019
<b>20 m buffer</b>											
D3: Ditch	0.325	30	0.259	0.174	0.090	0.052	0.036	0.028	0.024	0.018	0.009
D4: Pond	0.064	24	0.063	0.062	0.060	0.058	0.053	0.051	0.049	0.044	0.034
D4: Stream	0.183	7	0.014	0.007	0.003	0.002	0.002	0.002	0.002	0.001	0.000
D5: Pond	0.064	30	0.063	0.062	0.060	0.058	0.053	0.051	0.049	0.044	0.034
D5: Stream	0.197	30	0.015	0.008	0.004	0.002	0.002	0.002	0.002	0.001	0.000
R1: Pond	0.067	38	0.066	0.065	0.063	0.061	0.056	0.054	0.052	0.048	0.037
R1: Stream	0.230	53	0.156	0.078	0.039	0.022	0.012	0.009	0.010	0.008	0.004
R2: Stream	0.198	28	0.080	0.040	0.020	0.011	0.007	0.005	0.005	0.004	0.002
R3: Stream	0.292	23	0.263	0.141	0.088	0.050	0.030	0.023	0.020	0.013	0.006
R4: Stream	<b>0.444</b>	75	0.426	0.321	0.163	0.093	0.060	0.040	0.036	0.024	0.019

a. From time of first application.

**Table B.8.6.2.2-16. Maximum and time weighted average (TWA) PEC<sub>sed</sub> for difenoconazole at FOCUS Step 4 assessment. Application to apples at 4 x 75 g a.s./ha (7 days interval). To different buffers (14 m or 20 m) to reduce loading by spray drift. Maximum values in bold.**

Scenario	PEC <sub>sed</sub> , µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
<b>14 m buffer</b>											
D3: Ditch	0.777	45	0.776	0.773	0.764	0.748	0.711	0.677	0.647	0.615	0.500
D4: Pond	1.74	95	1.74	1.74	1.74	1.74	1.74	1.74	1.74	1.74	1.72
D4: Stream	0.056	24	0.056	0.055	0.055	0.054	0.052	0.050	0.048	0.045	0.038
D5: Pond	<b>1.78</b>	106	1.78	1.78	1.78	1.78	1.78	1.78	1.78	1.78	1.76
D5: Stream	0.062	30	0.062	0.062	0.061	0.060	0.057	0.055	0.053	0.050	0.041
R1: Pond	1.68	95	1.68	1.68	1.68	1.68	1.68	1.68	1.68	1.67	1.63
R1: Stream	0.508	76	0.506	0.504	0.499	0.492	0.478	0.464	0.452	0.431	0.387

buffer reduced the spray drift inputs sufficiently so that run-off became the dominating route. As no run-off mitigation was used for apples at Step 4 there was no further reduction in the surfacere water PEC with increasing buffer distance.

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Scenario	PEC <sub>sd</sub> , µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
R2: Stream	1.51	361	1.51	1.50	1.50	1.50	1.46	1.41	1.39	1.36	1.28
R3: Stream	0.769	26	0.766	0.761	0.751	0.737	0.709	0.685	0.661	0.621	0.510
R4: Stream	1.52	76	1.51	1.51	1.49	1.46	1.41	1.36	1.34	1.32	1.29
<b>20 m buffer</b>											
D3: Ditch	0.515	45	0.514	0.513	0.507	0.497	0.474	0.453	0.444	0.425	0.338
D4: Pond	1.14	94	1.14	1.14	1.14	1.14	1.14	1.14	1.14	1.13	1.12
D4: Stream	0.030	24	0.030	0.029	0.029	0.029	0.028	0.027	0.026	0.025	0.021
D5: Pond	1.16	104	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.16	1.14
D5: Stream	0.033	30	0.033	0.033	0.032	0.032	0.031	0.030	0.029	0.027	0.022
R1: Pond	1.26	95	1.26	1.26	1.26	1.26	1.26	1.26	1.26	1.25	1.22
R1: Stream	0.478	76	0.477	0.475	0.470	0.464	0.451	0.438	0.427	0.407	0.368
R2: Stream	<b>1.50</b>	361	1.50	1.50	1.50	1.49	1.45	1.39	1.38	1.35	1.28
R3: Stream	0.623	25	0.621	0.618	0.611	0.601	0.583	0.565	0.547	0.517	0.432
R4: Stream	1.49	76	1.48	1.47	1.45	1.43	1.38	1.34	1.33	1.30	1.27

<sup>a</sup> From time of first application.

**Table B.8.6.2.2-17. Maximum and time weighted average (TWA) PEC<sub>sw</sub> for difenoconazole at FOCUS Step 4 assessment. Application to carrots at 3 x 125 g a.s./ha (14 d interval). At scenario R2 also 6 x 125 g a.s./ha assumed (two carrot crops grown per season). Vegetative buffer strip (5 m) to reduce spray drift and run-off. Maximum value in bold.**

Scenario	PEC <sub>sw</sub> , µg/L		Time weighted average concentration, µg/L								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	0.151	40	0.120	0.081	0.043	0.024	0.012	0.015	0.012	0.011	0.005
D6: Ditch	0.150	0	0.112	0.069	0.035	0.020	0.010	0.007	0.007	0.005	0.002
R1: Pond	0.044	37	0.043	0.043	0.042	0.040	0.038	0.037	0.036	0.033	0.031
R1: Stream	0.162	26	0.103	0.052	0.043	0.031	0.021	0.016	0.014	0.009	0.007
R2: Stream 1st crop	0.180	46	0.044	0.023	0.012	0.007	0.004	0.003	0.003	0.003	0.002
R2: Stream 2nd crop	0.180	0	0.026	0.022	0.015	0.012	0.009	0.008	0.006	0.006	0.005
R3: Stream	0.206	49	0.178	0.097	0.048	0.028	0.023	0.016	0.013	0.013	0.008
R4: Stream	<b>0.392</b>	57	0.309	<b>0.259</b>	0.132	0.105	0.072	0.049	0.047	0.043	0.022

<sup>a</sup> From time of first application.

**Table B.8.6.2.2-18. Maximum and time weighted average (TWA) PEC<sub>sd</sub> for difenoconazole at FOCUS Step 4 assessment. Application to carrots at 3 x 125 g a.s./ha (14 d interval). At scenario R2 also 6 x 125 g a.s./ha assumed (two carrot crops grown per season). Vegetative buffer strip (5 m) to reduce spray drift and run-off. Maximum value in bold.**

Scenario	PEC <sub>sd</sub> , µg/kg		Time weighted average concentration, µg/kg								
	Max.	on day <sup>a</sup>	1 d	2 d	4 d	7 d	14 d	21 d	28 d	42 d	100 d
D3: Ditch	0.273	42	0.273	0.272	0.269	0.263	0.252	0.241	0.231	0.214	0.176
D6: Ditch	0.123	50	0.122	0.122	0.120	0.118	0.114	0.110	0.106	0.105	0.095
R1: Pond	2.20	261	2.20	2.19	2.19	2.19	2.18	2.17	2.15	2.10	1.95
R1: Stream	11.7	234	11.6	11.6	11.6	11.6	11.5	11.5	11.4	11.2	10.5
R2: Stream 1st crop	32.0	340	32.0	32.0	31.9	31.8	31.5	31.1	30.9	30.7	29.8
R2: Stream 2nd crop	<b>74.1</b>	158	74.0	73.9	73.7	73.5	72.9	72.4	72.3	72.0	69.6
R3: Stream	3.73	272	3.73	3.72	3.72	3.71	3.69	3.68	3.67	3.66	3.53
R4: Stream	9.24	83	9.22	9.20	9.15	9.09	8.99	8.88	8.76	8.52	8.29

<sup>a</sup> From time of first application.

### Comments by RMS:

The simulations performed and the results obtained are considered acceptable and PEC<sub>sw</sub> and PEC<sub>sed</sub> presented are used for risk assessment.

The risk mitigation measure introduced at Step 4 to reduce run-off from the use in carrots (50% reduction by 5 m vegetative untreated strip) is considered acceptable. Although not yet formally adopted, the literature review provided in the Draft FOCUS Report Landscape and Mitigation Factors in Aquatic Ecological Risk Assessment (SANCO/10422/2005, ver. 1.0, March, 2005) supports the approach taken in that vegetated buffer strips may reduce run-off by 50%. For the use in apples, the Step 4 calculations presented can be considered as worst-case estimates since no mitigation effect on run-off was assumed by introducing 14/20 m buffer strips (this was only assumed to have a mitigation effect on spray drift). Under field conditions untreated buffer strips are likely to reduce the run-off also from orchards.

Again, a minor comment is that the mean DT<sub>50</sub> in soil used for the simulation changed slightly from the RMS's evaluation of the data (see section B.8.1.8.2) but the minor difference is not likely to have any significant impact on the PEC<sub>sw</sub>/PEC<sub>sed</sub>.

### B.8.6.3 Monitoring data

No study on environmental monitoring data on difenoconazole was presented, and is not required.

## B.8.7 Fate and behaviour in air (Annex II A 7.2.2; Annex III A 9.3)

### B.8.7.1 Volatilisation

<b>Reference:</b>	<b>Mani J (1991b)</b> Volatilisation of CGA 169374 from Soil under Laboratory Conditions. CIBA-GEIGY Limited, Agricultural Division, Basle, Switzerland. Report No. 13/91. Syngenta File No. CGA169374/0468.
<b>Test material:</b>	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity 93.2%, Batch No. RAF-VIII-45.
<b>Guideline:</b>	BBA Guideline Part IV, 6-1, July 1990 (provisional). US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate. Section 163-2. EPA, 540/9-82-021, October 1982.
<b>GLP:</b>	Yes

### Material and methods:

<b>Test concentration:</b>	1 µg/cm <sup>2</sup> , corresponding to 100 g a.s./ha
<b>Test system:</b>	Volatilisation of difenoconazole from soil surface in volatilisation chambers was investigated under three different conditions (A, B and C). Soil (50 g dw) was wetted to 60% of MWHC and placed onto the bottom of the volatilisation chamber. The soil layer had a thickness of ca 1 cm. Difenoconazole (dissolved in acetone) was applied

over the surface and the system ventilated with an air flow of 60 mL/min (12.6 air changes per hour). The effluent air was passed through liquid adsorption traps (containing ethyleneglycol) to collect any volatile radioactivity.

Test conditions:	A: 20°C, 35% air humidity B: 20°C, dry air stream C: 40°C, 35% air humidity
Sampling time points:	Each run (A, B and C) consisted of five units which were worked up after 0, 1, 3, 6 and 24 hours of exposure.
Method of analysis:	Radioactivity in gas traps and in soil samples (after combustion) was determined by LSC in duplicate.
Soil characteristics:	German standard sandy soil 2.1 (Speyer): pH 6.8, 0.72% organic matter, 3.9% clay, 4.8% silt, 91.3% sand, moisture content at Maximum Water Holding Capacity 28.2 g water/100 g soil.

#### Results:

Total recovery of radioactivity varied from 90.8 to 119.6% of the applied radioactivity at all sampling points and all treatments. After 24 hours total recovery was between 101.4-115.9%. Radioactivity in absorption traps was reported as <0.05% of the applied radioactivity over 1-24 hours at all treatments. It was concluded that difenoconazole was not volatile from soil surface under the conditions of the test.

#### Comments by RMS:

The study was of acceptable quality. Based on the results, difenoconazole is not expected to volatilise significantly from soil.

Reference:	<b>Sandmeier P (1992)</b> Volatilisation of CGA 169374 from plant and soil after postemergent spray application of [ <sup>14</sup> C-triazole] labelled material on wheat under indoor conditions. CIBA-GEIGY Limited, Division Plant Protection, Basle, Switzerland. Report No. 8/92. Syngenta File No. CGA169374/0651.
Test material:	Difenoconazole, <sup>14</sup> C-triazole-radiolabel: Radiochemical purity >95%, Batch No. JAK-V-80, formulated as EC 250 (A-7402 F blank formulation).
Guideline:	BBA Guideline Part IV, 6-1, July 1990.
GLP:	Yes

#### Material and methods:

Test concentration:	23.0 mg/m <sup>2</sup> , corresponding to 230 g a.s./ha
Test system:	Volatilisation of difenoconazole from plant and soil surface after postemergent spray application was investigated. Before application soil was wetted to approx. 60% of MWHC. 25 pots (6x6 cm) each containing 10 wheat plants at the 2-leaf stage were arranged in rows and difenoconazole formulated as an EC 250 was applied by spray. After treatment the plants were transferred to a growth chamber (17.3 m <sup>3</sup> ) with

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	controlled conditions.
Test conditions:	<p>Illumination: 12 h light, 10 h dark, 2 h light (light at 4400 lux)</p> <p>Temperature: 19-21°C</p> <p>Humidity: 40-44% Relative Humidity</p> <p>Ventilation: approx. 220 air changes/hour</p>
Sampling time points:	<p>Whole samples (plant and soil) were removed after 15 min. and 1, 3, 6 and 24 hours.</p> <p>Five pots were sampled at each interval.</p>
Method of analysis:	<p>Plants and soil were separated and the plants washed twice with methanol. The radioactivity in the washings was determined by LSC and in the plant material by combustion. Washed plants at the last interval were homogenised in methanol prior to combustion. Soil samples were extracted in acetone twice and the radioactivity in the extracts was quantified by LSC and that remaining in the soil by combustion.</p> <p>At each interval, pooled plant washings and soil extracts as well as pooled extracts of plants of the last interval were analysed by TLC.</p>
Soil characteristics:	<p>German standard sandy soil 2.1 (Speyer);</p> <p>pH 4.8, 0.48% organic carbon, 5.3% clay, 8.5% silt, 86.2% sand, moisture content at Maximum Water Holding Capacity 20.1 g water/100 g soil.</p>

### Results:

Total residues of the whole pot (sum of plant and soil radioactivity) were set to 100% at the first sampling interval, and total residues recovered decreased to 91.2% of the total initial residues after 24 hours, see Table 8.7.1-1. The overall volatilisation of difenoconazole was therefore <9% in 24 h. Losses were small from plants as well as soil.

**Table 8.7.1-1. Distribution of radioactivity after application of <sup>14</sup>C-triazole labelled difenoconazole as 250 EC formulation to wheat plants and soil.**

Interval	Sample	Recovery, % <sup>a</sup>	±SD, %	<sup>14</sup> C-on plant, % <sup>b</sup>	Parent, % <sup>c</sup>	<sup>14</sup> C- in plant, % <sup>b</sup>			Total, % <sup>b</sup>
15 min	Plant	22.9	7.9	98.7	97.4	1.3			100
	Soil	77.1							
	Total	100.0							
1 hour	Plant	22.1	5.1	98.7	98.1	1.3			100
	Soil	73.5							
	Total	95.6							
3 hours	Plant	22.8	7.6	98.3	97.4	1.7			100
	Soil	75.3							
	Total	98.1							
6 hour	Plant	24.1	10.2	97.0	97.8	3.0			100
	Soil	74.7							
	Total	98.8							
24 hours						Extract <sup>b</sup>	Parent <sup>c</sup>	Unextracted <sup>b</sup>	
	Plant	19.2		93.9	97.2	5.9	78.2	0.2	100
	Soil	72.0				88.9	98.6	11.1	100
	Total	91.2	8.9						

<sup>a</sup> As percentage of total recovery (soil + plant) at the first sampling interval (set to 100%).

<sup>b</sup> Percentage of recovery found in or on the plants.

<sup>c</sup> Percentage difenoconazole of radioactivity in surface washings or plant or soil extracts.

Only low penetration of difenoconazole into leaves was observed: 93.9% of recovered radioactivity was found on the surface 24 h after application. No degradation of difenoconazole on the plant surface was observed: 97.2% of the surface radioactivity consisted of unchanged parent. After 24 hours 78.2% of the penetrated radioactivity remained as difenoconazole.

It was concluded that only very small amounts of difenoconazole are volatilised from soil and plant surfaces after spray application of difenoconazole in EC 250 formulation.

**Comments by RMS:**

The results were briefly reported however the study is of acceptable quality. Although volatilisation was measured as loss from plants and soil the results were consistent and it is concluded that small amounts of difenoconazole may volatilise after spray application to plants.

**B.8.7.2 Phototransformation in air**

<b>Reference:</b>	<b>Stamm E (1998)</b> Atmospheric oxidation of difenoconazole CGA 169374 by hydroxyl radicals; rate estimation. Novartis Crop Protection AG, Environmental Safety/Chemodynamics, Basel, Switzerland. Report No. 95A98108SM. Syngenta File No. CGA169374/1669.
Test material:	Difenoconazole.
Guideline:	-
GLP:	Not applicable.

**Material and methods:** The rate of atmospheric oxidation of difenoconazole by hydroxy radicals was calculated by the method of Atkinson<sup>11</sup>. The Atmospheric Oxidation Program ver. 1.85 (1997)<sup>12</sup> was used. Assumed hydroxyl radical concentration was  $1.5 \times 10^6$  radicals/cm<sup>3</sup> and assumed day length was 12 hours.

**Results:**

The estimated half-life of difenoconazole in the atmosphere (by hydroxyl radical oxidation) was approximately 5 hours (0.40 days). Overall degradation rate constant for difenoconazole was  $26.38 \times 10^{-12}$  cm<sup>3</sup>/molecule-sec. It was concluded that difenoconazole is rapidly transformed in the atmosphere.

**Comments by RMS:**

The results are considered acceptable (also reported under B.2.1.10). Based on the results, photochemical oxidative transformation in air is expected to be rapid.

<sup>11</sup> Atkinson R (1988) *Environ. Toxicol. Chem.* 7, 435.

<sup>12</sup> Program commercially available from Syracuse Research Corporation, Syracuse, NY, USA.

### **B.8.7.3 Summary and assessment of fate and behaviour in air**

The vapour pressure of difenoconazole was determined to be  $3.32 \times 10^{-8}$  Pa at 25 °C (extrapolated value). The Henry's Law Constant was determined as  $9.0 \times 10^{-7}$  Pa m<sup>3</sup>/mol (25°C, calculated value). Both values indicate a low potential for volatility. No volatilisation of difenoconazole from moist soil surface was observed in experiment with measurement of volatile radioactivity over 24 hours. In study with measurement of volatility as percentage loss of radioactivity from plant and soil only a small loss (<9% of initial radioactivity) was observed over 24 hours. Based on the presented data, no significant volatilisation of difenoconazole is expected. Photochemical oxidative degradation was rapid with a calculated half-life of 5 hours in significant and any residues that may occur in the atmosphere are therefore expected to be rapidly degraded.

CGA 71019 (1,2,4-triazole) has a relatively high vapour pressure of  $3.4 \times 10^{-1}$  Pa (25°C, extrapolated). The value of Henry's Law Constant is  $3 \times 10^{-5}$  Pa m<sup>3</sup>/mol (25°C, calculated value). No volatile products were observed in soil degradation study on CGA 71019. Therefore, no significant volatilisation of CGA 71019 formed in soil is expected.

### **B.8.8 Predicted environmental concentrations in air (PEC<sub>a</sub>) (Annex IIIA 9.3)**

The predicted environmental concentration of difenoconazole in air (PEC<sub>a</sub>) is expected to be negligible.

### **B.8.9 Definition of the residue (Annex IIA 7.3)**

#### **Soil:**

Besides difenoconazole, two metabolites were identified close to or above 10% of the applied radioactivity in laboratory metabolism studies, CGA 205375 and CGA 71019. The RMS suggests that difenoconazole and the metabolite CGA 205375 are included in the definition of the residue for soil, with the final decision on CGA 205375 pending a long term risk assessment for soil dwelling organisms when studies have been made available.

#### Justification:

CGA 205375 was present as max. 9.7% in laboratory study on degradation of difenoconazole in soil. This metabolite was also measured as 10-12% of the initial radioactivity in one field study. Sufficient data on degradation and adsorption/desorption of this metabolite was available. Ecotox studies (acute study earthworms and study on micro organisms) on CGA 205375 were also submitted and used for risk assessment in section B.9. In terms of Toxicity to Exposure Ratios (TERs) or % effect, no risks above those specified in the criteria of Annex VI to Directive 91/414/EEC were identified. There were however no long-term study on soil dwelling organisms submitted. The notifier has made a commitment to provide such data on earthworms and Collembola (expected June 2006). The RMS suggests to include these data in an Addendum to the DAR.

CGA 71019 was present as max. 23.4% in laboratory study degradation of difenoconazole in soil. Sufficient data on degradation and adsorption/desorption of this metabolite was available. Ecotox studies (acute and long term

studies on earthworms, long-term study on Collembola, and study on micro organisms) on CGA 71019 were provided and used for risk assessment in section B.9. In terms of Toxicity to Exposure Ratios (TERs) or % effect, no risks above those specified in the criteria of Annex VI to Directive 91/414/EEC were identified.

#### **Groundwater:**

Besides difenoconazole, two metabolites were identified close to or above 10% of the applied radioactivity in laboratory soil metabolism studies, CGA 205375 and CGA 71019. The RMS suggests that difenoconazole alone is included in the definition of the residue for groundwater.

#### Justification:

Data on adsorption/desorption and potential mobility of difenoconazole indicated a strong adsorption and low potential for mobility in soil. The PEC<sub>gw</sub> was <0.001 µg/L in all relevant FOCUS scenarios (9 for apples, 6 for carrots) following simulation of leaching after annual applications to apples and carrots in accordance with the representative use (also at twice the recommended application rate in carrots).

CGA 205375 was present as max. 9.7% in laboratory study on degradation of difenoconazole in soil. This metabolite was also measured as 12% of the initial radioactivity in one field study. Sufficient data on degradation and adsorption/desorption of this metabolite was available. Data on adsorption/desorption and potential mobility of CGA 205375 indicated a strong adsorption and low potential for mobility in soil. The PEC<sub>gw</sub> was <0.001 µg/L in all relevant FOCUS scenarios (9 for apples, 6 for carrots) following simulation of leaching after annual application of difenoconazole to apples and carrots in accordance with the representative use (also at twice the recommended application rate in carrots).

CGA 71019 was present as max. 23.4% in laboratory study degradation of difenoconazole in soil. Sufficient data on degradation and adsorption/desorption of this metabolite was available. Data on adsorption/desorption and potential mobility of CGA 71019 indicated a weak adsorption and hence a potential for mobility in soil. The substance is however also expected to be rapidly degraded and incorporated into soil bound material which should reduce the potential for leaching. The PEC<sub>gw</sub> was <0.001 µg/L in all relevant FOCUS scenarios (9 for apples, 6 for carrots) following simulation of leaching after annual application of difenoconazole to apples and carrots in accordance with the representative use (also at twice the recommended application rate in carrots).

#### **Surface water and sediment:**

Besides difenoconazole, the potential impact of metabolites CGA 205375 and CGA 71019 on aquatic environments was assessed. The RMS suggests that difenoconazole alone is included in the definition of the residue for surface water and sediment.

#### Justification:

CGA 205375 was the only compound identified as >10% of the applied radioactivity in water/sediment studies.

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A study on route and rate of degradation in water/sediment systems was provided and PEC<sub>sw</sub> and PEC<sub>sed</sub> were calculated. Ecotox studies on fish (acute), invertebrates (acute daphnia and chronic Chironomus) and algae were submitted. For the representative use as seed treatment as well as spray applications to apples and carrots the acute and chronic Toxicity to Exposure Ratios based on FOCUS Step 1 calculations of PEC<sub>sw</sub> and PEC<sub>sed</sub> were above the criteria of Annex VI to Directive 91/414/EEC and no further refinement was necessary.

CGA 71019 could not be identified in studies on difenoconazole due to position of radio labelling but it was identified as max 14.1% of the applied radioactivity in a water/sediment study on CGA 205375. The RMS calculated as worst-case max. formation of CGA 71019 of 9.6% from the degradation of difenoconazole via CGA 205375. No study on route and rate of degradation in water/sediment systems was provided but a conservative estimate was used for calculating PEC<sub>sw</sub> and PEC<sub>sed</sub>. Ecotox studies on fish (acute and chronic), daphnia (acute) and algae were submitted. For the representative use as seed treatment as well as spray applications to apples and carrots the acute and chronic Toxicity to Exposure Ratios based on FOCUS Step 1 calculations of PEC<sub>sw</sub> and PEC<sub>sed</sub> were above the criteria of Annex VI to Directive 91/414/EEC and no further refinement was necessary.

#### **Air:**

The RMS suggests that difenoconazole alone is included in the definition of the residue for air.

#### **Justification:**

Volatilisation of difenoconazole is expected to be low and atmospheric concentrations expected to be negligible. As a consequence potential concentrations of transformation products in the atmosphere are expected to be negligible. From data provided on the metabolite CGA 71019, no significant volatilisation from soil is expected.

#### **B.8.10 References relied on**

<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Data Protection Claimed * Y/N</b>	<b>Owner **</b>
IIA 7	Harvey B	2004a	Difenoconazole. Document M-II, Section 5. Fate and Behaviour in the Environment. ERA5677.	-	SYN
KIIA 7.1.1.1/01 and 7.1.1.2.1	Mamouni, A.	2000a	Degradation and metabolism of CGA 169374 (14C-Triazole) in one soil incubated under aerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738606. GLP Not Published Syngenta File N° CGA169374/2101	Y	SYN

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Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed * Y/N	Owner **
KIIA 7.1.1.1.1/02 and 7.1.1.2.1	Mamouni, A.	2000b	Degradation and metabolism of CGA 169374 (14C-Chlorophenyl) in one soil incubated under aerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738617. GLP Not Published Syngenta File N° CGA169374/2102	Y	SYN
KIIA 7.1.1.1.1 and 7.1.1.2.1/01	Gonzalez-Valero, J.	1992a	CGA 169374 Degradation in soil under aerobic conditions at 20°C. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 91-GJ-05. GLP Not Published Syngenta File N° CGA169374/0606	N	SYN
KIIA 7.1.1.1.1 and 7.1.1.2.1/02	Gonzalez-Valero, J.	1992b	Rate of degradation of 14C-CGA 169374 in aerobic soil at various conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 12-92. GLP Not Published Syngenta File N° CGA169374/0713	N	SYN
KIIA 7.1.1.1.1 and 7.1.1.2.1/03	Völkel, W.	2000b	Degradation of CGA 169374 (14C-Triazole) in one soil incubated under various conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738628. GLP Not Published Syngenta File N° CGA169374/2100	Y	SYN
KIIA 7.1.1.1.1 and 7.1.1.2.1/04	Mamouni, A.	2002	Degradation of CGA169374 [14C-Chlorophenyl] in three Soils incubated under Aerobic Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 775438. GLP Not Published Syngenta File N° CGA169374/2223	Y	SYN
KIIA 7.1.1.1.1 and 7.1.1.2.1/06	Slangen, P.J.	2000	Degradation of 1,2,4-triazole in Three Soils under Aerobic Conditions. Novartis Crop Protection AG, Basel, Switzerland. NOTOX B.V., 'S Hertogenbosch, Netherlands, Report No NOTOX 278336. GLP Not Published Syngenta File N° CGA64250/4345	Y	TDMG

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KIIA 7.1.1.1.1, 7.1.1.1.2.1 and 7.1.1.2.1/05	Völkel, W	2002a	Degradation of CGA205375 [14C-triazole] in three soils incubated under aerobic and anaerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 775451. GLP Not Published Syngenta File N° CGA169374/2240	Y	SYN
KIIA 7.1.1.1.2.1/01	Völkel, W.	2000a	Degradation and metabolism of CGA 169374 (14C-Triazole) in one soil incubated under anaerobic conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 738630. GLP Not Published Syngenta File N° CGA169374/2099	Y	SYN
KIIA 7.1.1.1.2.1/02	Mamouni, A	2003	[14C]-CGA71019: Anaerobic soil degradation. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798660. GLP Not Published Syngenta File N° CGA71019/0062	Y	SYN
KIIA 7.1.1.1.2.2/01	Atkins, R.H.	1994	CGA 169374, Soil surface photolysis of Phenyl-14C-CGA-169374 under artificial sunlight. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 791. GLP Not Published Syngenta File N° CGA169374/1184	N	SYN
KIIA 7.1.1.2.2/01	Harvey, B. R.	2004	Difenoconazole (CGA169374) Summary of degradation rates in European field dissipation and residue trials. Syngenta Crop Protection AG, Basel, Switzerland. Syngenta, Jealott's Hill, United Kingdom, Report No RAJ0208B. Not GLP (not applicable) Not Published Syngenta File N° CGA169374/2429	Y	SYN
KIIA 7.1.1.2.2/02 and IIIA 9.1.1.2	Ressler, H	1992a	Field Dissipation of Difenaconazole. Test Report - Field Experiment. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 96-88 B. Not GLP Not Published Syngenta File N° CGA169374/2302	N	SYN

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<b>Annex point / reference number</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not</b>	<b>Data Protection Claimed * Y/N</b>	<b>Owner **</b>
KIIA 7.1.1.2.2/03 and IIIA 9.1.1.2	Resseler, H.	1992b	Field dissipation of difenoconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 43-89B. Not GLP Not Published Syngenta File N° CGA169374/0699	N	SYN
KIIA 7.1.1.2.2/04 and IIIA 9.1.1.2	Resseler, H.	1992c	Field dissipation of difenoconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 45-89B. Not GLP Not Published Syngenta File N° CGA169374/0700	N	SYN
KIIA 7.1.1.2.2/05 and IIIA 9.1.1.2	Resseler, H.	1992d	Field dissipation of difenoconazole. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy GmbH, Frankfurt a.Main, Germany, Report No 46-89B. Not GLP Not Published Syngenta File N° CGA169374/0701	N	SYN
KIIA 7.1.1.2.2/06 and IIIA 9.1.1.2	Resseler, H	2001a	Field Dissipation of Difenaconazole - Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 44-89B. Not GLP Not Published Syngenta File N° CGA169374/2304	Y	SYN
KIIA 7.1.1.2.2/07 and IIIA 9.1.1.2	Resseler, H	2001b	Field Dissipation of Difenaconazole Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 40-90B. GLP Not Published Syngenta File N° CGA169374/2306	Y	SYN
KIIA 7.1.1.2.2/08 and IIIA 9.1.1.2	Resseler, H	2001c	Field Dissipation of Difenaconazole Test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 41-90B. GLP Not Published Syngenta File N° CGA169374/2308	Y	SYN
KIIA 7.1.1.2.2/09 and IIIA 9.1.1.2	Resseler, H	2001d	Field Dissipation of Difenaconazole. test Report - Field Experiment. Syngenta Agro GmbH, Frankfurt/Main, Germany, Report No 42-90B. GLP Not Published Syngenta File N° CGA169374/2310	Y	SYN

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Annex point / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or not	Data Protection Claimed * Y/N	Owner **
KIIA 7.1.1.2.2/10 and IIIA 9.1.1.2	Walser, M.	1994	Field Dissipation of CGA 169374 after Bareground Application of [Phenyl-14C] CGA 169374 labelled Material. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 92CN08. GLP Not Published Syngenta File N° CGA169374/0920	N	SYN
KIIA 7.1.1.2.2/11 and IIIA 9.1.1.2	Kühne-Thu, H.	1990a	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2097-89. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0335	N	SYN
KIIA 7.1.1.2.2/12 and IIIA 9.1.1.2	Kühne-Thu, H.	1990b	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2096-89. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0336	N	SYN
KIIA 7.1.1.2.2/13 and IIIA 9.1.1.2	Kühne-Thu, H.	1990c	Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2024-89. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0341	N	SYN
KIIA 7.1.1.2.2/14 and IIIA 9.1.1.2	Kühne-Thu, H.	1990d	Determination of residues of parent compound in soil after treatment with fungicide 'CGA169374 EC 250'. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2023-89. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0342	N	SYN

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KIIA 7.1.1.2.2/15 and IIIA 9.1.1.2	Kühne-Thu, H.	1991a	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - Field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2040-89. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0337	N	SYN
KIIA 7.1.1.2.2/16 and IIIA 9.1.1.2	Kühne-Thu, H.	1991b	Determination of residues of parent compound in soil after treatment with 'Difenaconazole EC 250' - field experiment. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No RR-2039-89. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0338	N	SYN
KIIA 7.1.1.2.2/17 and IIIA 9.1.1.2	Kühne-Thu, H.	1992a	Determination of residues difenoconazole in asparagus and soil - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2056-90. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0695	N	SYN
KIIA 7.1.1.2.2/18 and IIIA 9.1.1.2	Kühne-Thu, H.	1992b	Determination of residues difenoconazole in soil of sugar beet - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2054-90. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0696	N	SYN
KIIA 7.1.1.2.2/19 and IIIA 9.1.1.2	Kühne-Thu, H.	1992c	Determination of residues difenoconazole in soil of sugar beet field - field trial - Italy. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 2149-90. GLP (analytical phase) Not Published Syngenta File N° CGA169374/0694	N	SYN
KIIA 7.1.1.2.2/20 and IIIA 9.1.1.2	Purdy, J.	1997	Dissipation and leaching movement of CGA 169374 residues in soil after application as a seed treatment on wheat seed. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection Inc., Mississauga, Canada, Report No CER 05306/94. GLP Not Published Syngenta File N° CGA169374/1423	N	SYN

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KIIA 7.1.1.2.2/21	Beidler, W.T.	1991	Stability of CGA 169374 residues in soil under freezer storage conditions for 2 years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States, Report No ABR-90068. GLP Not Published Syngenta File N° CGA169374/0451	N	SYN
KIIA 7.1.1.2.2/22	Shadrick, BA, Bloomberg, AM, Helfrich, KK	1999	Freezer Storage Stability of 1H-1,2,4-Triazole[3,5-14C] in Soil. Syngenta Crop Protection AG, Basel, Switzerland. Bayer Corporation, Kansas City, United States, Report No 108303. GLP Not Published Syngenta File N° CGA71019/0068	N	SYN
KIIA 7.1.1.2.2/23 and IIIA 9.1.1.2	Tack, T.J.	1995	The determination of Difenoconazole (CGA 169374) residues in soil after successive applications of A7402G 250EC containing 250 g ai CGA 169374 applied as a foliar applicaion to winter wheat and bare soil for three years. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No CSTR 01:11. GLP Not Published Syngenta File N° CGA169374/1205	N	SYN
KIIA 7.1.1.2.2/24 and IIIA 9.1.1.2	Kühne-Thu, H.	2000	Long term study on fate and behaviour of Difenoconazole (CGA 169374) in soil in Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 2031/89-98. GLP Not Published Syngenta File N° CGA169374/0652	Y	SYN
KIIA 7.1.1.2.2/25 and IIIA 9.1.1.2	Zelger, R.	2001	Ricerche sul comportamento dei residui di Difenoconazolo nel frutteto. Novartis Crop Protection AG, Basel, Switzerland. Report No Final report after 4th year incl. interi. Translation to English: Research into Difenoconazole Residue Behaviour in Fruit Growing. Not GLP Not Published Syngenta File N° CGA169374/2043	Y	SYN

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KIIA 7.1.1.2.2/26 and IIIA 9.1.1.2	Molinari, G.P.	2002	Soil dissipation of difenoconazole (Dissipazione nel suolo del fungicida Difenoconazole). Novartis Crop Protection AG, Basel, Switzerland. Report No CIBA/96/01. GLP Not Published Syngenta File N° CGA169374/2044	Y	SYN
KIIA 7.1.2/01	Atkins, R.H.	1991a	CGA 169374, Soil adsorption/desorption of 14C-CGA-169374 by the batch equilibrium method. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 495. GLP Not Published Syngenta File N° CGA169374/0477	N	SYN
KIIA 7.1.2/02	Spare, W.C.	1988	CGA 169374, Adsorption/Desorption of 14C-CGA-169374. Novartis Crop Protection AG, Basel, Switzerland. Agriseach Inc., Frederick, United States, Report No 12115. GLP Not Published Syngenta File N° CGA169374/0476	N	SYN
KIIA 7.1.2/03	Volkel, W.	2002b	Adsorption/Desorption of CGA205375 [14C-Triazole] on Soils. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798647. GLP Not Published Syngenta File N° CGA205375/0013	Y	SYN
KIIA 7.1.2/04	Hawkins, D.R.	1988	Soil adsorption and desorption of 1,2,4- Triazole. Novartis Crop Protection AG, Basel, Switzerland. Rohm and Haas, Philadelphia, United States, Report No 34S-88-27. GLP Not Published Syngenta File N° CGA71019/0014	N	TDMG
KIIA 7.1.3.1/01	Mani, J.	1991a	Leaching mobil study with 14C-CGA 169374 in four soil under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 23-91. GLP Not Published Syngenta File N° CGA169374/0467	N	SYN

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KIIA 7.2.1.1/01	Atkins, R.H.	1991b	Hydrolysis of 14C CGA169374 at pH 5, 7 and 9. Novartis Crop Protection AG, Basel, Switzerland. PTRL East, Inc., Richmond, United States, Report No 494. GLP Not Published Syngenta File N° CGA169374/0488	N	SYN
KIIA 7.2.1.1/02	Van, Der Gaauw A.	2001	CGA 205375 [14C-Triazole]: Hydrolysis at three different pH Values. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 798658. GLP Not Published Syngenta File N° CGA205375/0010	Y	SYN
KIIA 7.2.1.1/03	Spare, W.C.	1983	Determination of the hydrolysis rate constants of 1,2,4-H-Triazole (CGA 71019). Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Corp., Greensboro, United States, Report No 83-E-074. Not GLP Not Published Syngenta File N° CGA71019/0033	N	TDMG
KIIA 7.2.1.2/01	Van, der Gaauw A.	2002a	Aqueous Photolysis of CGA169374 [14C-Triazole] under Laboratory Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 815635. GLP Not Published Syngenta File N° CGA169374/2209	Y	SYN
KIIA 7.2.1.2/02	Van, der Gaauw A.	2002b	Aqueous Photolysis of CGA205375 [14C-Triazole] under Laboratory Conditions. Syngenta Crop Protection AG, Basel, Switzerland. RCC Ltd., Itingen, Switzerland, Report No 815657. GLP Not Published Syngenta File N° CGA205375/0018	Y	SYN
KIIA 7.2.1.2/03	Hennecke, D.	2002a	Quantum Yield of the photochemical degradation of CGA169374 in aqueous solution. Syngenta Crop Protection AG, Basel, Switzerland. Fraunhofer Institut für Umweltchemie und Oekotoxikologie, Schmallenberg, Germany, Report No SYN-001/7-05. GLP Not Published Syngenta File N° CGA169374/2208	Y	SYN

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KIIA 7.2.1.2/04	Hennecke, D.	2002b	Quantum yield of the photochemical degradation of CGA205375 in aqueous solution. Syngenta Crop Protection AG, Basel, Switzerland. Fraunhofer Institut für Umweltchemie und Oekotoxikologie, Schmallenberg, Germany, Report No SYN-001/7-05. GLP Not Published Syngenta File N° CGA205375/0017	Y	SYN
KIIA 7.2.1.3.1/01	Baumann, W.	1993	Report on the test for ready biodegradability of CGA 169374 tech. in the carbon dioxide evolution test. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Basel, Oekotoxikologie, Basel, Switzerland, Report No 933652. GLP Not Published Syngenta File N° CGA169374/0813	N	SYN
KIIA 7.2.1.3.2/01	Gonzalez-Valero, J.	1993	Metabolism of CGA 169374 Under Aerobic Conditions in Aquatic Systems. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 34/92 91GJ04. GLP Not Published Syngenta File N° CGA169374/0746	N	SYN
KIIA 7.2.1.3.2/02	Ulbrich, R.	1997	Metabolism of <sup>14</sup> C labeled CGA 169374 in aquatic systems under aerobic conditions at 8°C. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 94UL03. GLP Not Published Syngenta File N° CGA169374/1357	N	SYN
KIIA 7.2.1.3.2/03	Völkl, S.	2002c	CGA205375 [ <sup>14</sup> C-Triazole]: Route and Rate of Degradation in Aerobic Aquatic Systems. Syngenta Crop Protection AG, Basel, Switzerland, Report No 798636. GLP Not Published Syngenta File N° CGA205375/0016	Y	SYN
KIIA 7.2.2/01	Mani, J.	1991b	Volatilization of CGA 169374 from soil under laboratory conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 13-91. GLP Not Published Syngenta File N° CGA169374/0468	N	SYN

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KIIA 7.2.2/02 and KIIIA 9.3	Sandmeier, P.	1992	Volatilization of CGA169374 from plant and soil after postemergent application of 14C-triazole) labelled material on wheat under indoor conditions. Novartis Crop Protection AG, Basel, Switzerland. Ciba-Geigy Ltd., Basel, Switzerland, Report No 8-92. GLP Not Published Syngenta File N° CGA169374/0651	N	SYN
KIIA 7.2.2/03	Stamm, E.	1998	Atmospheric oxidation of Difenconazole CGA 169374 by hydroxyl radicals; rate estimation. Novartis Crop Protection AG, Basel, Switzerland. Novartis Crop Protection AG, Basel, Switzerland, Report No 98SM18. Not GLP (not applicable) Not Published Syngenta File N° CGA169374/1669	N	SYN
IIIA 9	Harvey B	2004b	A-7402 T Difenconazole (SCORE 250 EC). Document M-III, Section 5. Fate and Behaviour in the Environment. ERA5695.	-	SYN
IIIA 9	Harvey B	2004c	A-9142 G Difenconazole (DIVIDEND 030 FS). Document M-III, Section 5. Fate and Behaviour in the Environment. ERA5713.	-	SYN
KIIIA 9.2.1/01	Turner, N. L., Beulke, S.	2003	Estimation with FOCUS PEARL 2.2.2 of predicted concentrations of difenconazole and its metabolites CGA205375 and 1,2,4-triazole in groundwater (PECGW) following application to sugar beet, sunflower, apple and carrot crops. Syngenta Crop Protection AG, Basel, Switzerland. Cranfield University, Silsoe, United Kingdom, Report No Modelling Study 03/MOD/040. Not GLP (not applicable) Not Published Syngenta File N° CGA169374/2427	Y	SYN
KIIIA 9.2.3/01	Beulke, S., Brown, C.	2003	FOCUS Step 1-3 modelling to estimate predicted environmental concentrations in surface water (PEC <sub>sw</sub> ) and sediment (PEC <sub>sed</sub> ) for difenconazole and its metabolites CGA205375 and 1,2,4-triazole following use on sugar beet, apples and carrots. Syngenta Crop Protection AG, Basel, Switzerland. Cranfield University, Silsoe, United Kingdom, Report No 03/MOD/044. Not GLP (not applicable) Not Published Syngenta File N° CGA169374/2418	Y	SYN

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KIII 9.2.3/01	Takacs M	2006	Difenoconazole (CGA169374): A European Fate Assessment using FOCUS Surface Water Scenarios at Steps 3 and 4 for Carrots and Apples. Syngenta Jealotts Hill International Research Centre, Bracknell, UK. Report No RAJ0410B Not published Not GLP (not applicable) Syngenta File No. CGA169374/2821	Y	SYN

\* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted to any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization of a plant protection product before the date of submission of the dossier to the Rapporteur Member State.

\*\* Owner's code identifications and names (Code identification: SYN, Name: Syngenta, TDMG, Name: Triazole Derivative Metabolite Group).

The notifier carried out a literature search on the 12th February 2004 using a number of databases. These were searched for references to difenoconazole and its triazole, triazole alanine and triazole acetic acid metabolites associated with several different keywords. A list of references found was included in Doc. M-II. The RMS did not expect any of these studies from the open literature to provide relevant information that would change the conclusions drawn from the material submitted and none of the studies were requested. In addition, Doc. L-II presented a list of references owned by Syngenta or Triazole Derivative Metabolite Group but not submitted. Justifications were provided for why they were not submitted. The RMS requested two of these studies (vapour pressure and Henry's Law constant for CGA 71019) which were included in the DAR. Otherwise the RMS agreed to the justifications provided.

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