



Document Title

**Summary of the fate and behaviour in the environment for
Trifloxystrobin**

Data Requirements

EU Regulation 1107/2009 & EU Regulation 283/2013

Document MCA

Section 7: Fate and behaviour in the environment

According to the guidance document, SANCO 10781/2013, for preparing dossiers for the approval of a chemical active substance

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Version history

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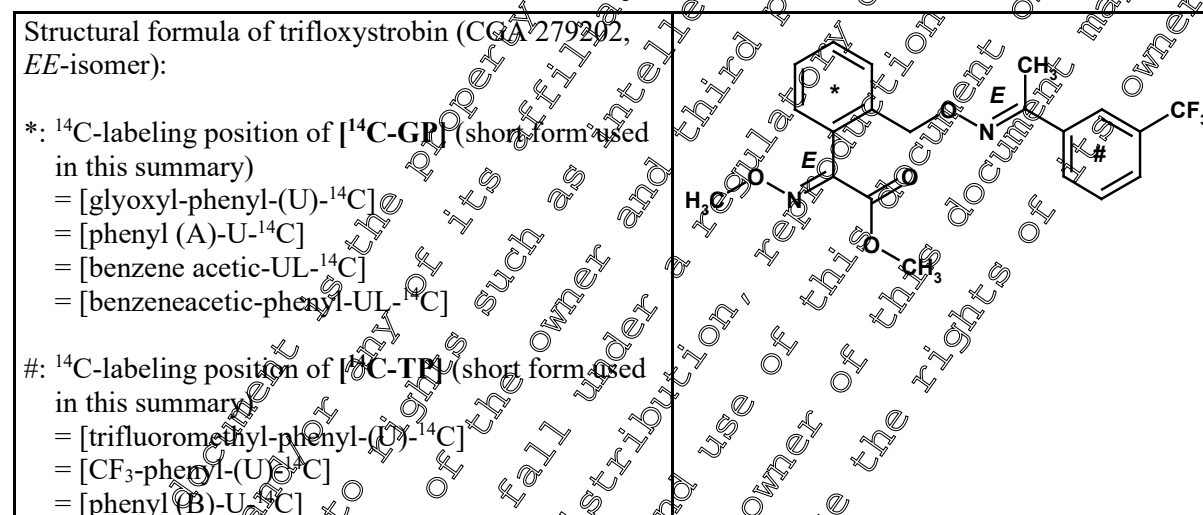
Table of Contents

	Page
CA 7	FATE AND BEHAVIOUR IN THE ENVIRONMENT 5
CA 7.1	Fate and behaviour in soil..... 7
CA 7.1.1	Route of degradation in soil..... 8
CA 7.1.1.1	Aerobic degradation 10
CA 7.1.1.2	Anaerobic degradation..... 10
CA 7.1.1.3	Soil photolysis 11
CA 7.1.2	Rate of degradation in soil..... 2
CA 7.1.2.1	Laboratory studies 8
CA 7.1.2.1.1	Aerobic degradation of the active substance 59
CA 7.1.2.1.2	Aerobic degradation of metabolites, breakdown and reaction products..... 83
CA 7.1.2.1.3	Anaerobic degradation of the active substance 147
CA 7.1.2.1.4	Anaerobic degradation of metabolites, breakdown and reaction products 150
CA 7.1.2.2	Field studies..... 170
CA 7.1.2.2.1	Soil dissipation studies..... 175
CA 7.1.2.2.2	Soil accumulation studies 212
CA 7.1.3	Adsorption and desorption on soil..... 213
CA 7.1.3.1	Adsorption and desorption..... 213
CA 7.1.3.1.1	Adsorption and desorption of the active substance 215
CA 7.1.3.1.2	Adsorption and desorption of metabolites, breakdown and reaction products 215
CA 7.1.3.2	Aged sorption 245
CA 7.1.4	Mobility in soil..... 245
CA 7.1.4.1	Column leaching studies..... 248
CA 7.1.4.1.1	Column leaching of the active substance 248
CA 7.1.4.1.2	Column leaching of metabolites, breakdown and reaction products 248
CA 7.1.4.2	Lysimeter studies..... 248
CA 7.1.4.3	Field leaching studies 249
CA 7.2	Fate and behaviour in water and sediment..... 249
CA 7.2.1	Route and rate of degradation in aquatic systems (chemical and photochemical degradation) 253
CA 7.2.1.1	Hydrolytic degradation 253
CA 7.2.1.2	Direct photochemical degradation 254
CA 7.2.1.3	Indirect photochemical degradation 254
CA 7.2.2	Route and rate of biological degradation in aquatic systems..... 260
CA 7.2.2.1	"Ready biodegradability"..... 260
CA 7.2.2.2	Aerobic mineralisation in surface water 260
CA 7.2.2.3	Water/sediment study 266
CA 7.2.2.4	Irradiated water/sediment study..... 272
CA 7.2.3	Degradation in the saturated zone..... 272
CA 7.3	Fate and behaviour in air 272
CA 7.3.1	Route and rate of degradation in air 272
CA 7.3.2	Transport via air..... 274
CA 7.3.3	Local and global effects..... 274
CA 7.4	Definition of the residue 274
CA 7.4.1	Definition of the residue for risk assessment..... 274
CA 7.4.2	Definition of the residue for monitoring..... 274
CA 7.5	Monitoring data 274

CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Data on the fate and behaviour of trifloxystrobin (CGA 279202) in soil, water, sediment and air were submitted within the EU Dossier (Baseline Dossier), which resulted in the Annex I inclusion under Directive 91/414/EEC in 2003. In the Supplemental Dossier for renewal of approval of trifloxystrobin presented here only those environmental fate studies are described in sections 7.1 to 7.5, which were not submitted within the Baseline Dossier. However, for a better understanding of the behaviour of trifloxystrobin in soil, water and sediment, short summaries including the results of all environmental fate studies are given additionally in this summary in sections [CA 7.1](#), [CA 7.1.3.1](#) and [CA 7.2](#).

The studies concerning the fate and behaviour of trifloxystrobin in the environment were conducted using two different radiolabel positions, [¹⁴C-GPI] and [¹⁴C-TP], as well as unlabelled trifloxystrobin. These radiolabel positions are sufficient to define the route of degradation of trifloxystrobin. The structure of trifloxystrobin and the positions of the different radiolabels are as follows:



The results of the studies are summarized in the following sections 7.1 to 7.5. The proposed degradation pathways in soil, water and sediment are given in [Figure 7.1.1- 1](#) and [Figure 7.2- 1](#), respectively.

Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

In addition, studies have been performed with the radiolabelled and unlabelled major degradation products CGA 357261, CGA 321113, CGA 373466, CGA 381318, NOA 413161, NOA 413263, CGA 357276 and NOA 409480:

<p>Structural formula of CGA 357261 (<i>ZE</i>-isomer):</p> <p>#: ^{14}C-labeling position of [^{14}C-TP] (short form used in this summary) = [CF₃-phenyl-(U)-^{14}C] = [phenyl-(B)-U-^{14}C]</p>	
<p>Structural formula of CGA 321113 (<i>EE</i>-isomer):</p> <p>*: ^{14}C-labeling position of [^{14}C-GP] (short form used in this summary) = [glyoxyl-phenyl-U-^{14}C] = [benzeneacetic-phenyl-UL-^{14}C]</p>	
<p>Structural formula of CGA 373466 (<i>ZE</i>-isomer):</p> <p>*: ^{14}C-labeling position of [^{14}C-GP] (short form used in this summary) = [glyoxyl-phenyl-(U)-^{14}C] = [benzeneacetic-phenyl-UL-^{14}C]</p>	
<p>Structural formula of CGA 381318 (<i>ZZ</i>-isomer):</p> <p>*: ^{14}C-labeling position of [^{14}C-GP] (short form used in this summary) = [benzeneacetic-phenyl-UL-^{14}C]</p>	
<p>Structural formula of NOA 413161 (<i>ZE</i>-isomer):</p> <p>*: ^{14}C-labeling position of [^{14}C-GP] (short form used in this summary) = [glyoxyl-phenyl-U-^{14}C] = [(U)-^{14}C-phenyl)-acetic acid] = [benzeneacetic-phenyl-UL-^{14}C]</p>	

Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

<p>Structural formula of NOA 413163 (<i>EE</i>-isomer):</p> <p>*: ¹⁴C-labeling position of [¹⁴C-GP] (short form used in this summary)</p> <ul style="list-style-type: none"> = [glyoxyl-phenyl-(U)-¹⁴C] = [(UL-¹⁴C-phenyl)-acetic acid] = [benzeneacetic-phenyl-UL-¹⁴C] 	
<p>Structural formula of CGA 357276 (<i>E</i>-isomer):</p> <p>#: ¹⁴C-labeling position of [¹⁴C-TP] (short form used in this summary)</p> <ul style="list-style-type: none"> = [CF₃-phenyl-(U)-¹⁴C] = [phenyl (B)-U-¹⁴C] 	
<p>Structural formula of NOA 409480 (<i>Z</i>-isomer):</p> <p>*: ¹⁴C-labeling position of [¹⁴C-GP] (short form used in this summary)</p> <ul style="list-style-type: none"> = [benzonitrile-ring-UL-¹⁴C] 	

In original reports study authors may have used different names or codes for degradation products of trifloxystrobin. In this summary, a single name or a single code is used for each degradation product. A full list containing structural formula, various names, short forms, codes and occurrences of degradation products is provided as Document N3.

CA 7.1 Fate and behaviour in soil

Trifloxystrobin (*EE*) is rapidly degraded in soil to the major degradation products carbon dioxide, CGA 321113 (*EE*), NOA 413161 (*ZE*) and CGA 357276 (*E*), and non-extractable residues. In presence of light, the major *E/Z* isomers (in this summary referred to as “photodegradation products”) CGA 357261 (*ZE*), CGA 373466 (*ZE*), CGA 381318 (*ZZ*), NOA 413163 (*EE*) and NOA 409480 (*Z*) of trifloxystrobin (*EE*) and its major degradation products CGA 321113 (*EE*), NOA 413161 (*ZE*) and CGA 357276 (*E*) are observed, as well as the major volatile degradation product CGA 107170. However, the degradation of trifloxystrobin in soil is driven by microbial degradation under typical conditions in the environment and photodegradation plays only a minor role in the overall fate of trifloxystrobin. More details for the route and rates of degradation of trifloxystrobin and its major degradation products in soil are given in section CA 7.1.1 and section CA 7.1.2, respectively.



CA 7.1.1 Route of degradation in soil

The route of degradation of trifloxystrobin in soil was studied using two different radiolabel positions, [^{14}C -GP] and [^{14}C -TP]. The studies have been performed in a number of soils in the laboratory at different temperatures and soil moistures, and under semi-field conditions (lysimeters and field plot). The maximum occurrences of degradation products in percentage of applied radioactivity [% AR] are given as means of duplicates and may slightly differ from the List of Endpoints (SANCO/4339/2000-Final, 7 April 2003).

Under aerobic conditions in the dark in the laboratory, trifloxystrobin (*EE*) was degraded to carbon dioxide with a range of 4.3 to 63.5% AR for the [^{14}C -GP]-label and a maximum amount of 56.6% AR for the [^{14}C -TP]-label. Besides the formation of carbon dioxide, three major degradation products were identified with the following maximum amounts: CGA 321113 (*EE*) with 96.8% AR, NOA 413161 (*ZE*) with 13.6% AR (dark samples of soil photolysis) and CGA 357276 (*E*) with 5.6% AR. Non-extractable residues (NER) ranged from 8.8 to 29.4% AR for the [^{14}C -GP]-label and reached a maximum amount of 26.8% AR for the [^{14}C -TP]-label. CGA 357276 (*E*) is newly addressed as soil degradation product in this Supplemental Dossier.

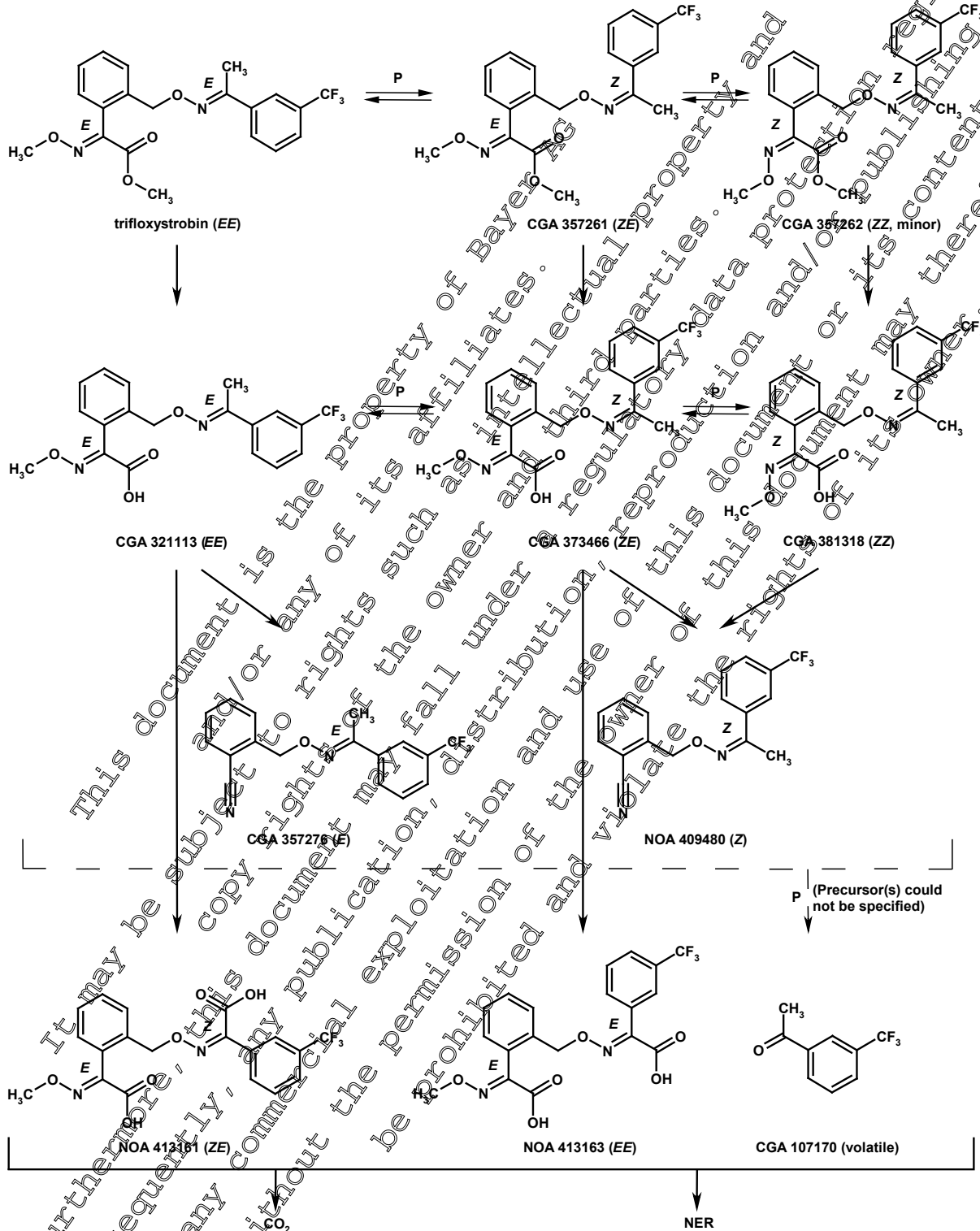
Under anaerobic conditions in the dark in the laboratory, CGA 321113 (*EE*) was identified as the single major degradation product with a maximum amount of 97.0% AR. Formation of carbon dioxide was very low with a maximum amount of 0.4% AR. NER reached a maximum amount of 6.8% AR.

Under photolytic conditions in the laboratory, the rate of degradation of trifloxystrobin (*EE*) was mainly influenced by biotic processes, but the route of degradation differed with regard to *E/Z* isomerization (in this summary referred to as 'photodegradation products'). Trifloxystrobin (*EE*) isomerized to its major *E/Z* isomer CGA 357261 (*ZE*) with max. 15.5% AR and to its minor *E/Z* isomer CGA 357262 (*ZZ*) with max. 5.1% AR. The maximum amount of 5.1% AR of CGA 357262 (*ZZ*) was found only at one single sampling interval and was below 5% AR at all following sampling intervals. Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to the major degradation product CGA 321113 (*EE*) with max. 57.4% AR and its major *E/Z* isomers CGA 373466 (*ZE*) with max. 42.5% AR and CGA 380318 (*ZZ*) with max. 6.2% AR by microbial ester cleavage and *E/Z* isomerization. Further microbial degradation led to the major photodegradation products NOA 413163 (*EE*) with max. 6.0% AR and NOA 409480 (*Z*) with max. 9.3% AR. Furthermore, the major volatile degradation product CGA 107170 was formed with a maximum amount of 7.9% AR by cleavage of the bridge between the aromatic ring systems. Formation of carbon dioxide was low with a maximum amount of 1.9% AR. NER reached a maximum amount of 26.1% AR. CGA 380318 (*ZZ*), NOA 409480 (*Z*) are newly addressed as soil degradation products and CGA 107170 (volatile) with regard to air in this Supplemental Dossier.

Under semi-field conditions in presence of light, the degradation products CGA 357261 (*ZE*), CGA 357262 (*ZZ*), CGA 321113 (*EE*), CGA 373466 (*ZE*), NOA 413161 (*ZE*) and NOA 413163 (*EE*) were identified as the most important ones.

The proposed degradation pathway of trifloxystrobin in soil is shown in [Figure 7.1.1- 1](#).

Figure 7.1.1- 1: Proposed degradation pathway of trifloxystrobin in soil (major degradation products)



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CA 7.1.1.1 Aerobic degradation

The route of degradation of trifloxystrobin in soil under aerobic conditions in the laboratory and under semi-field conditions (lysimeters and field plot) was evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.1.1 /01	[REDACTED]	1997	M-033008-01-1
KCA 7.1.1.1 /02	[REDACTED]	1997	M-033147-01-1
KCA 7.1.1.1 /03	[REDACTED]	1997	M-033394-01-1
KCA 7.1.1.1 /04	[REDACTED]	1997	M-033459-01-1
KCA 7.1.1.1 /05	[REDACTED]	1997	M-033453-01-1
KCA 7.1.1.1 /06	[REDACTED]	1997	M-033705-01-1
KCA 7.1.1.1 /07	[REDACTED]	1998	M-051722-04
KCA 7.1.1.1 /08	[REDACTED]	1997	M-033523-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. The degradation product CGA 57276 is newly addressed as soil degradation product in this Supplemental Dossier because it was formed above the new identification triggers in aerobic soil degradation study M-033394-01-1 (Baseline Dossier, KCA 7.1.1.1 /03). A summary of the route of degradation of trifloxystrobin in soil is given in section CA 7.1.1 and Figure 7.1.1-1.

CA 7.1.1.2 Anaerobic degradation

The route of degradation of trifloxystrobin in soil under anaerobic conditions in the dark in the laboratory was evaluated during the Annex I inclusion using one radiolabel position, [¹⁴C-GP], and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.1.2 /01	[REDACTED]	1996	M-033427-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the route of degradation of trifloxystrobin in soil is given in section CA 7.1.1 and Figure 7.1.1-1.

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CA 7.1.1.3 Soil photolysis

The route of degradation of trifloxystrobin in soil under photolytic conditions in the laboratory was evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP] and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.1.3 /01	[REDACTED]	1997	M-033490-01
KCA 7.1.1.3 /02	[REDACTED]	1997	M-033420-01

Two additional studies have been performed for trifloxystrobin and are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP]. A summary of the route of degradation of trifloxystrobin in soil is given in section CA 7.1.1 and Figure 7.1.1- 1.

Report:	KCA 7.1.1.3 /03 [REDACTED], S. P. 1997
Title:	Photodegradation of [Phenyl (B)-U- ¹⁴ C]-CGA-279202 on a Loamy sand under Artificial Sunlight Irradiation
Report No:	31-95
Document No:	M-049459-01-1
Guidelines:	- US EPA Pesticide Assessment Guidelines, Subdivision N, Section 161-3
GLP:	Yes
Justification:	New data guideline requirement: Degradation products: NOA 409480 (soil) and CGA 107170 (volatile) formed above the new identification triggers

Executive Summary

The photolytic route and rate of degradation of [¹⁴C-TP] trifloxystrobin were studied in one soil under exposure to simulated sunlight in the laboratory for 30 days at 25 ± 1 °C and a soil moisture of 75% of the field capacity at 0.3 bar.

Soil	Source	Texture (USDA)	pH	OC [%]
North Carolina	Louisburg, USA	loamy sand	7.3	0.3

A study application rate of approximately 2.0 mg per kg soil dry weight was applied.

30 days of incubation under exposure to simulated sunlight were equivalent to 32.0 and 49.5 days in Phoenix (Arizona, USA) and Athens (Greece), respectively. For comparison, additional samples were incubated in the dark.

Mean material balances ranged from 85.8 to 99.2% of applied radioactivity [% AR] for irradiated samples and from 98.7 to 102.0% AR for dark samples.

The maximum amount of carbon dioxide was 1.3 and 2.7% AR at study end (DAT-30) in irradiated and dark samples, respectively. The maximum amount of volatile organic compounds was 9.6 and 0.7% AR at DAT-30 in irradiated and dark samples, respectively. The volatile degradation product CGA 107170 was identified in irradiated samples with a maximum amount of 7.9% AR at DAT-30.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Extractable residues decreased from study start (DAT-0) to DAT-30 from 97.5 to 73.4% AR in irradiated samples and from 96.8 to 88.9% AR in dark samples.

Non-extractable residues remained constant from DAT-0 to DAT-30 at approximately 2% AR in irradiated samples and increased from 1.8 to 6.2% AR in dark samples.

The amount of trifloxystrobin in the soil extracts decreased from DAT-0 to DAT-30 from 97.5 to 12.7% AR in irradiated samples and from 96.8 to 11.5% AR in dark samples, thus not indicating a significant difference in the rate of degradation. However, the route of degradation of trifloxystrobin differed between irradiated and dark samples with regard to *E/Z* isomerization.

In irradiated samples, trifloxystrobin (*EE*) isomerized to its *E/Z* isomers CGA 357261 (*ZE*) (max. 9.3% AR at DAT-21), CGA 357262 (*ZZ*) (max. 4.1% AR at DAT-21) and CGA 331409 (*EZ*) (max. 3.4% AR at DAT-14). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to CGA 321113 (*EE*) (max. 17.2% AR at DAT-2) and its *E/Z* isomer CGA 373466 (*ZE*) (max. 24.8% AR at DAT-30) by microbial ester cleavage and *E/Z* isomerization. Furthermore, NOA 409489 (*Z*) (max. 9.5% AR at DAT-21) was formed.

In dark samples, trifloxystrobin (*EE*) was degraded to CGA 321113 (*EE*) (max. 72.3% AR at DAT-7) and NOA 413161 (*ZE*) (max. 13.6% AR at DAT-30).

The DT_{50} values were calculated using single first order kinetics, resulting in experimental half-lives for trifloxystrobin of 2.1 and 2.3 days in the irradiated and dark samples, respectively. Thus, the net photodegradation rate constant was calculated to 0.038 day^{-1} , resulting in a net photolytic half-life of 18.2 days. Based on the experimental DT_{50} value of 2.1 days for irradiated samples, the DT_{50} value of trifloxystrobin under environmental conditions is calculated to be e.g. 4.5 and 6.9 solar summer days at Phoenix and Athens, respectively.

It is concluded that the degradation of trifloxystrobin is driven by microbial degradation under typical conditions in the environment and photodegradation plays only a minor role in the overall fate of trifloxystrobin.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[phenyl (B)-U-¹⁴C]-CGA 279202
 Reference No: SAS-VIII-53-1
 Specific Activity: 1.70 MBq/mg (46.00 Ci/mg)
 Radiochemical Purity: 97.9%
 Chemical Purity: 97.7%

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2. Test Soil

One soil was used (see Table 7.1.1.3- 1), which was sampled freshly from the field and sieved to a particle size of ≤ 2 mm.

Table 7.1.1.3- 1: Physico-chemical properties of test soil

Parameter	Results / Units
Soil Designation	North Carolina
Geographic Location	
City	Louisburg
State	North Carolina
Country	USA
Soil Taxonomic Classification (USDA)	no information available
Soil Series	no information available
Textural Class (USDA)	loamy sand
Sand [50 μ m - 2 mm]	81%
Silt [2 μ m - 50 μ m]	10%
Clay [$<$ 2 μ m]	9%
pH	7.3
Organic Carbon	0.3%
Organic Matter ¹	0.5%
Cation Exchange Capacity [meq/100 g]	3.9
Water Holding Capacity at 1/3 bar (pF 2.5)	8.3%
Bulk Density (disturbed) [g/cm ³]	1.20
Microbial Viability [CFU/g soil DW]	
DAT-0	6.3 x 10 ⁶
DAT-30, irradiated sample	7.4 x 10 ⁶
DAT-30, dark sample	2.0 x 10 ⁶

¹ % organic matter = % organic carbon x 1.724
 CFU: colony forming units
 DAT: days after treatment
 DW: dry weight
 USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The flow-through test system for photolytic degradation in soil consisted of a proprietary soil photolysis apparatus containing a water-jacketed chamber with 12 steel plates. The chamber was closed with a quartz glass cover and a flow of humidified air was maintained. The air-flow output was connected to a series of trapping solutions (toluene, ethylene glycol and 2 N potassium hydroxide) for adsorption of volatile organic compounds (VOC) and carbon dioxide.

For preparation of the test systems, 7 g dry weight equivalents of the sieved soil (equilibrated at 25 °C and a soil moisture of 75% field capacity (FC) at 1/3 bar) were weighed into each steel plate, resulting in a soil layer of approximately 2 mm thickness. For the DAT-0 samples, the soil was weighed directly into soil extraction vials.

The study application rate (SAR) was approximately 2.8 mg per kg soil dry weight, resulting in a SAR of 19.5 μ g [¹⁴C-TP]trifloxystrobin per steel plate or soil extraction vial.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

The test item was applied dropwise onto the soil surface of the respective steel plates or soil extraction vials in 75 µL acetonitrile using a syringe.

The irradiated test systems were incubated with a 12-hour light / 12-hour dark artificial sunlight cycle for 30 days at $25 \pm 1^\circ\text{C}$ and a soil moisture of 75% FC at 1/3 bar in a Suntest® unit containing a Xenon lamp simulating natural sunlight. The light emission was filtered with a 290 nm cut-off UV-filter, which eliminated all wavelengths < 290 nm. The intensity of the Xenon lamp was determined at the beginning and the end of the overall test period using a radiometer and photodetector assembly and was calculated as 765 W/m^2 for 300 to 2450 nm. The radiation intensity and exposure time under experimental conditions can be related to natural solar radiation at e.g. Phoenix (Arizona, USA), representing extraordinary conditions, or Athens (Greece). At this light intensity, it takes 11.3 and 7.3 hours in the Suntest® unit to equal one solar summer day at Phoenix and Athens, respectively. Therefore, the equivalent of 30 solar days is achieved by this design using a 12-hour light / 12-hour dark cycle for approximately 28.2 and 18.3 days for Phoenix and Athens, respectively.

The dark test systems were incubated in the dark for 30 days at $25 \pm 1^\circ\text{C}$ and a soil moisture of 75% FC at 1/3 bar in an incubator.

2. Sampling

Six sampling intervals were distributed over the entire incubation period of 30 days. Duplicate samples (steel plates or soil extraction vials) were processed and analysed 0, 2, 4, 14, 21 and 30 days after treatment (DAT) for both irradiated and dark samples. Trapping solutions for adsorption of VOC and carbon dioxide were sampled and replaced at each sampling interval. In the irradiated test system, the toluene trapping solutions were also sampled and replaced on DAT-9 and DAT-12. Microbial viability of the soil was determined at DAT-0 and DAT-30.

3. Analytical Procedures

The radioactivity content of the toluene, ethylene glycol and 2 N potassium hydroxide trapping solutions was determined by liquid scintillation counting (LSC).

The entire soil of each sample was extracted six times using a sonicator bath, three times using acetonitrile/water, pH 4 4/1 (v/v) and three times using acetone/2M acetic acid 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation and decantation. The radioactivity content of the combined acetonitrile soil extracts and the combined acetone soil extracts was determined by LSC. Aliquots of the soil extracts were filtered, concentrated and analysed by reversed phase HPLC/radiodetection. The limit of detection for HPLC/radiodetection analysis of the soil extracts was 0.03% AR.

Non-extractable residues were determined by combustion/LSC.

Test item and degradation products were identified by HPLC and 2D-TLC co-chromatography with reference items and by HPLC-MS.

The degradation kinetics of the test item was determined using single first order kinetics. Input datasets were the mean residual amounts found at each sampling interval. DT_{50} values were calculated from the resulting parameters.



II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained over the duration of the laboratory study.

A. DATA

Table 7.1.1.3- 2: Photodegradation of trifloxystrobin in soil North Carolina (mean values expressed as % AR)

Compound	Mean	DAT					
		0	2	7	14	21	30
trifloxystrobin (EE)	irradiated	97.5	49.5	40.0	28.2	27.3	17.5
	dark	66.8	53.1	25.0	26.9	25.0	11.5
CGA 331409 (EZ)	irradiated	n.d.	1.3	3.1	3.4	2.9	1.6
	dark	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
CGA 357262 (ZZ)	irradiated	n.d.	2.1	3.3	4.0	4.2	2.2
	dark	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
CGA 357276 (E)	irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.	n.d.	0.9
CGA 357261 (ZE) + NOA 409480 (Z) ¹	irradiated	n.d.	13.6	35.5	17.2	18.5 ¹	9.4
	dark	n.d.	1.5	n.d.	n.d.	1.1	n.d.
CGA 321113 (EE)	irradiated	n.d.	47.2	15.3	15.1	13.9	16.2
	dark	n.d.	43.9	7.3	67.2	64.1	56.1
CGA 373466 (ZE)	irradiated	n.d.	1.3	16.4	15.8	16.9	24.8
	dark	n.d.	1.9	0.4	0.8	0.8	0.3
NOA 413161 (E)	irradiated	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	1.1	1.3	13.6
Non-Extractable Residues	irradiated	1.7	1.3	1.4	2.2	2.0	1.6
	dark	1.8	0.9	2.2	4.2	4.1	6.2

n.d.: not detected, n.a.: not analysed, DAT: days after treatment

¹ Resolving into two photodegradation products by TLC with approximately equal proportions and therefore a maximum amount of 9.3% AR at DAT-21 for each photodegradation product.

Table 7.1.1.3- 3: Photodegradation of trifloxystrobin in soil North Carolina – distribution of volatiles (expressed as % AR)

Traps	Mean	DAT							Cumulative
		2	7	9	12	14	21	30	
Toluene ¹	irradiated	0.4	1.1	0.5	1.5	0.9	0.3	3.1	7.9 ¹
	dark	n.d.	0.1	N/A	N/A	0.1	n.d.	n.d.	0.3
Ethylene Glycol	irradiated	n.d.	0.3	N/A	N/A	0.1	n.d.	1.1	1.7
	dark	0.1	0.0	N/A	N/A	0.2	n.d.	n.d.	0.4
Potassium Hydroxide	irradiated	0.3	0.2	N/A	N/A	0.3	0.3	0.2	1.3
	dark	0.3	0.5	N/A	N/A	0.6	0.5	0.8	2.7
Daily Total	irradiated	0.7	1.6	0.5	1.5	1.4	0.7	4.5	10.9
	dark	0.4	0.7	N/A	N/A	1.0	0.5	0.8	3.4

n.d.: not detected, N/A: not applicable, DAT: days after treatment

¹ CGA 101170 was identified as volatile degradation product in toluene trap of irradiated test system.



B. MATERIAL BALANCE

Mean material balances ranged from 85.8 to 99.2% of applied radioactivity [% AR] for irradiated samples and from 98.7 to 102.3% AR for dark samples.

C. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES

Extractable residues decreased from study start (DAT-0) to study end (DAT-30) from 97.5 to 73.4% AR in irradiated samples and from 96.8 to 88.9% AR in dark samples. Non-extractable residues remained constant from DAT-0 to DAT-30 at approximately 2% AR in irradiated samples and increased from 1.8 to 6.2% AR in dark samples.

D. VOLATILES

The maximum amount of carbon dioxide was 1.3 and 2.7% AR at DAT-30 in irradiated and dark samples, respectively. The maximum amount of volatile organic compounds was 9.6 and 0.7% AR at DAT-30 in irradiated and dark samples, respectively. The volatile degradation product CGA 107170 was identified in irradiated samples with a maximum amount of 7.9% AR at DAT-30.

The results are included in the summary of the route of degradation of trifloxystrobin in soil given in section CA 7.1.1 and Figure 7.1.1-1. The degradation of CGA 107170 in air is addressed in section CA 7.3.1.

E. DEGRADATION OF PARENT COMPOUND

The amount of trifloxystrobin in the soil extracts decreased from DAT-0 to DAT-30 from 97.5 to 12.7% AR in irradiated samples and from 96.8 to 11.5% AR in dark samples, thus not indicating a significant difference in the rate of degradation. However, the route of degradation of trifloxystrobin differed between irradiated and dark samples with regard to *E/Z* isomerization.

In irradiated samples, trifloxystrobin (*EE*) isomerized to its *E/Z* isomers CGA 357261 (*ZE*) (max. 9.3% AR at DAT-21), CGA 357262 (*ZZ*) (max. 4.1% AR at DAT-21) and CGA 331409 (*EZ*) (max. 3.4% AR at DAT-14). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to CGA 321113 (*EE*) (max. 17.2% AR at DAT-2) and its *E/Z* isomer CGA 3373466 (*ZE*) (max. 24.8% AR at DAT-30) by microbial ester cleavage and *E/Z* isomerization. Furthermore, NOA 409480 (*Z*) (max. 9.3% AR at DAT-21) was formed.

In dark samples, trifloxystrobin (*EE*) was degraded to CGA 321113 (*EE*) (max. 72.3% AR at DAT-7) and NOA 413161 (*ZE*) (max. 13.6% AR at DAT-30).



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The experimental DT₅₀ values of trifloxystrobin in irradiated and dark samples were calculated using single first order (SFO) kinetics (see Table 7.1.1.3- 4).

Table 7.1.1.3- 4: Photodegradation kinetics of trifloxystrobin in soil North Carolina

Test System	DT ₅₀ (exp.) [days]	Rate Constant [day ⁻¹]	SFO ¹	
			DT ₅₀ under natural conditions [days]	Net Photodegradation Rate Constant ² [day ⁻¹ / days]
Irradiated	2.1	0.34	4.8 (Phoenix, USA) 6.9 (Athens, Greece)	0.038 / 0.2
Dark	2.3	0.30	no conversion	

¹ SFO: single first order

² net photodegradation rate constant = rate constant of irradiated samples – rate constant of dark samples

III. CONCLUSIONS

Trifloxystrobin was rapidly degraded in soil (experimental half-life of 2.1 days) when being exposed to simulated sunlight in the laboratory. The experimental half-life for dark samples was 2.3 days, resulting in a net experimental photolytic half-life of 18.2 days.

The rate of degradation of trifloxystrobin (*EE*) was therefore mainly influenced by biotic processes, but the route of degradation (see Figure 7.1.1-1 for degradation pathway) differed with regard to *E/Z* isomerization (in this summary referred to as “photodegradation products”). In irradiated samples, trifloxystrobin (*EE*) isomerized to its major *E/Z* isomer, CGA 357261 (*ZE*). Trifloxystrobin (*EE*) and its *E/Z* isomer were degraded to the major degradation product CGA 321113 (*EE*) and its major *E/Z* isomer CGA 373466 (*ZE*) by microbial ester cleavage and *E/Z* isomerization. Further microbial degradation of CGA 373466 (*ZE*) led to the major photodegradation product NOA 409480 (*Z*). Furthermore, the major volatile degradation product CGA 107170 was formed by cleavage of the bridge between the aromatic ring systems. In dark samples, trifloxystrobin (*EE*) was degraded to the major microbial degradation products CGA 321113 (*EE*) and NOA 413161 (*ZE*). Formation of carbon dioxide was low.

It is concluded that the degradation of trifloxystrobin is driven by microbial degradation under typical conditions in the environment and photodegradation plays only a minor role in the overall fate of trifloxystrobin.

The results are in good agreement with the proposed photodegradation pathway of trifloxystrobin on soil known from studies included in the Baseline Dossier. The photodegradation product NOA 409480 and the volatile degradation product CGA 107170 are newly addressed in soil and air in this Supplemental Dossier, respectively, because they were formed above the new identification triggers.

The results are included in the summary of the route of degradation of trifloxystrobin in soil given in section CA 7.1.1 and Figure 7.1.1-1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.1.3 /04; [REDACTED]; [REDACTED]; 2013
Title:	[Benzeneacetic-phenyl-UL- ¹⁴ C]Trifloxystrobin: Phototransformation on Soil
Report No:	EnSa-12-0699
Document No:	M-462074-01-1
Guidelines:	- SETAC Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides - OECD DRAFT Test Guideline: Phototransformation of Chemicals on Soil Surfaces - US EPA OCSPP Test Guideline No. 835.2410 - Canadian PMRA Guideline DAG 8.2.3.3.1
GLP:	Yes
Justification:	New data / guideline requirement: Identification of degradation product M2 formed above the new identification triggers in soil photolysis study M-033410-01-1 Baseline Dossier, KCA 7.1.1.3 /01)

Executive Summary

The photolytic route and rate of degradation of [¹⁴C-GP]trifloxystrobin were studied in one soil under exposure to simulated sunlight in the laboratory for 11 days at 20.1 °C and a soil moisture of 52.5% of the maximum water holding capacity.

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	4a, Burscheid, Germany	silt loam	6.3	1.8

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

A nominal study application rate of 31.6 µg per test system (10.5 mg per kg soil dry weight) was applied based on a single field application rate of trifloxystrobin of 310 g per hectare.

11 days of incubation under exposure to simulated sunlight were equivalent to 30.8 and 47.8 solar summer days in Phoenix (Arizona, USA) and Athens (Greece), respectively. For comparison, additional samples were incubated in the dark.

Mean material balances were 99.6% of applied radioactivity [% AR] (range from 95.3 to 103.5% AR) for irradiated samples and 101.9% AR (range from 96.0 to 104.9% AR) for dark samples.

The maximum amount of carbon dioxide was 0.3 and 0.6% AR at study end (DAT-11) in irradiated and dark samples, respectively. Formation of volatile organic compounds was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals for both irradiated and dark samples.

Extractable residues decreased from 103.4% AR at study start (DAT-0) to 85.6 and 98.4% AR at DAT-11 in irradiated and dark samples, respectively.

Non-extractable residues increased from 0.1% AR at DAT-0 to 9.2 and 2.3% AR at DAT-11 in irradiated and dark samples, respectively.

The amount of trifloxystrobin in the soil extracts decreased from 101.0% AR at DAT-0 to 4.2 and 3.5% AR at DAT-11 in irradiated and dark samples, respectively, thus not indicating a significant difference in the rate of degradation. However, the route of degradation of trifloxystrobin differed between irradiated and dark samples with regard to E/Z isomerization.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

In irradiated samples, trifloxystrobin (*EE*) isomerized to its *E/Z* isomers CGA 357261 (*ZE*) (max. 5.1% AR at DAT-4), CGA 357262 (*ZZ*) and CGA 331409 (*EZ*) (both max. 1.1% AR at DAT-4 and DAT-7). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to CGA 321113 (*EE*) (max. 57.4% AR at DAT-2) and its *E/Z* isomers CGA 373466 (*ZE*) (max. 35.6% AR at DAT-11), CGA 381318 (*ZZ*) (max. 6.2% AR at DAT-11) and CGA 373465 (*EZ*) (max. 3.5% AR at DAT-11) by microbial ester cleavage and *E/Z* isomerization. Furthermore, NOA 413163 (*EE*) (max. 0.4% AR at DAT-11), CGA 357276 (*E*) (max. 1.7% AR at DAT-11) and its *E/Z* isomer NOA 409480 (*Z*) (max. 3.5% AR at DAT-11) were formed. The total unidentified residues amounted to a maximum of 3.1% AR with no one component exceeding 1.6% AR at any sampling interval.

In dark samples, trifloxystrobin (*EE*) was degraded to CGA 321113 (*EE*) (max. 91.6% AR at DAT-10) and NOA 413161 (*ZE*) (max. 0.6% AR at DAT-01). The total unidentified residues amounted to a maximum of 2.0% AR with no one component exceeding 1.6% AR at any sampling interval.

The DT₅₀ and DT₉₀ values were calculated using single first order kinetics, resulting in experimental half-lives for trifloxystrobin of 1.3 and 1.7 days in the irradiated and dark samples, respectively. Thus, the net photodegradation rate constant was calculated to 0.16 day⁻¹ resulting in a net photolytic half-life of 4.6 days. Based on the experimental DT₅₀ value of 1.3 days for irradiated samples, the DT₅₀ value of trifloxystrobin under environmental conditions is calculated to be e.g. 3.6 and 5.6 solar summer days at Phoenix and Athens, respectively.

It is concluded that the degradation of trifloxystrobin is driven by microbial degradation under typical conditions in the environment and photodegradation plays only a minor role in the overall fate of trifloxystrobin.

The degradation product M2 formed above the new identification triggers in irradiated samples of soil photolysis study M 033410-01-1 (Baseline Dossier, KCA 7.11.3 /01), was identified as NOA 413163.

1. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzeneacetic-phenyl-UK-¹⁴C]trifloxystrobin
 Sample ID: KML 9251
 Specific Activity: 3.01 MBq/mg / 81.4 µCi/mg
 Radiochemical Purity: 98%
 Chemical Purity: 98%

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

2. Test Soil

One soil was used (see Table 7.1.1.3- 5), representative for an agricultural use area. No plant protection products were used for the previous 5 years. The soil was sampled freshly from the field (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

Table 7.1.1.3- 5: Physico-chemical properties of test soil

Parameter	Results / Units
Soil Designation	[redacted] 4a
Geographic Location	
City	[redacted]
State	North-Rhine Westphalia
Country	Germany
GPS Coordinates	[redacted]
Soil Taxonomic Classification (USDA)	loamy mixed mesic Typic Argudalf
Soil Series	no information available
Textural Class (USDA)	silt loam
Sand [50 µm - 2 mm]	05%
Silt [2 µm - 50 µm]	66%
Clay [< 2 µm]	19%
pH (soil/0.01 M CaCl ₂ 1/2)	6.3
pH (soil/water 1/1)	6.7
pH (saturated paste)	6.8
pH (soil/1 N KCl 1/1)	6.1
Organic Carbon (combustion)	1.8%
Organic Matter	3.1%
Cation Exchange Capacity [meq/100 g]	11.0
Water Holding Capacity maximum [g H ₂ O ad 100 g soil DW] at 0.1 bar (pF 2.0)	61.7 26.9%
Bulk Density (disturbed) [g/cm ³]	1.01
Microbial Biomass [mg microbial carbon per kg soil DW]	488

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

USDA: United States Department of Agriculture

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B. STUDY DESIGN

1. Experimental Conditions

The static test system for photolytic degradation on soil consisted of a quartz glass vessel (36 mm inner diameter, 35 mm height, inner surface area 10.2 cm²) with a glass neck attached to the side of the wall. Each vessel was closed with a round quartz glass cover. Additionally, the glass neck of each vessel was equipped with a trap attachment (permeable for oxygen), containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds (VOC).

For preparation of the test systems, 3 g dry weight equivalents of the sieved soil were weighed into each vessel, resulting in a soil layer of approximately 3 mm thickness. Soil moisture was adjusted to 55 ± 5% of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water.

The study application rate (SAR) was based on a field application rate of 310 g per hectare given in soil photolysis study M-033410-01-1 (Baseline Dossier, KCA 7.1.1.1/01), resulting in a nominal SAR of 31.6 µg [¹⁴C-GP]trifloxystrobin per test system (10.5 mg per kg soil dry weight).

The test item was applied dropwise onto the soil surface of the respective test systems in 50 µL methanol using a pipette. After evaporation of the application solvent, the test vessels (except DAT-0 samples) were closed with quartz glass covers and equipped with trap attachments.

The irradiated test systems were continuously irradiated for 11 days at 20.1 °C and a soil moisture of 52.5% MWHC in a Suntest[®] unit containing a Xenon lamp simulating natural sunlight. The light emission was filtered with a 290 nm cut-off UV-filter, which eliminated all wavelengths < 290 nm. The intensity of the Xenon lamp was determined at the beginning and the end of the overall test period using an irradiance monitor and was calculated as 1006 W/m² for 300 to 2450 nm. The radiation intensity and exposure time under experimental conditions can be related to natural solar radiation at e.g. Phoenix (Arizona, USA), representing extraordinary conditions, or Athens (Greece). At this light intensity, it takes 8.6 and 5.5 hours in the Suntest[®] unit to equal one solar summer day at Phoenix and Athens, respectively. Therefore, the equivalent of 30 solar days is achieved by this design using continuous irradiation for approximately 10.8 and 6.9 days for Phoenix and Athens, respectively.

The dark test systems were incubated in the dark for 11 days at 20.1 °C and a soil moisture of 53.3% MWHC in a walk-in climatic chamber.

2. Sampling

Eight sampling intervals were distributed over the entire incubation period of 11 days. Duplicate samples were processed and analysed 0, 0.17, 0.33, 1, 2, 4, 7 and 11 days after treatment (DAT) for both irradiated and dark samples. Microbial soil biomass was determined once for the test soil.



3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped in a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The PU foam plugs were extracted with ethyl acetate in an ultrasonic bath to desorb VOC. The radioactivity content was determined by LSC.

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker followed by one accelerated extraction using a microwave at 70 °C with a magnetic stirrer using acetonitrile/water 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation (> 4500 x g) and decantation. The radioactivity content of the combined ambient soil extracts and the microwave soil extract was determined by LSC. Aliquots of the soil extracts were combined, concentrated and analysed by reversed phase HPLC/radiodetection. The limit of detection and limit of quantitation for HPLC/radiodetection analysis of the combined soil extracts were 0.2 and 0.6% AR, respectively.

The exhaustive extracted soils were air-dried and non-extractable residues were determined by combustion/LSC.

Test item and degradation products were identified by HPLC co-chromatography with reference items and by HPLC-MS/MS including accurate mass determination. For identification of the degradation product M2, formed above the new identification trigger in irradiated samples of soil photolysis study M-033410-01-1 (Baseline Dossier, MCA 77.1.3 /01), additional investigations by TLC were performed.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with a single first order kinetic model. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial total recovery (material balance) at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

¹ FOCUS kinetics (2006): "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration", Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.



II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained over the duration of the laboratory study.

A. DATA

Table 7.1.1.3- 6: Photodegradation of trifloxystrobin in soil (mean values and SD expressed as % AR)

Compound	Mean SD	DAT			
		0	0.17	0.33	1
trifloxystrobin (EE)	irradiated	101.0 ± 0.4	86.7 ± 0.9	86.2 ± 2.0	56.9 ± 1.9
	dark	101.0 ± 0.4	94.9 ± 1.9	82.7 ± 2.0	61.1 ± 4.8
CGA 331409 (EZ)	irradiated	< LOD	< LOD	0.5 ± 0.1	0.9 ± 0.1
	dark	< LOD	n.d.	n.d.	n.d.
CGA 357262 (ZZ)	irradiated	< LOD	n.d.	n.d.	0.5 ± 0.0
	dark	< LOD	n.d.	n.d.	n.d.
CGA 357276 (E)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.
CGA 357261 (ZE)	irradiated	0.4 ± 0.0	2.2 ± 0.0	3.2 ± 0.4	5.0 ± 1.1
	dark	0.4 ± 0.0	0.4 ± 0.0	0.4 ± 0.0	0.3 ± 0.0
NOA 409480 (Z)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.
CGA 373465 (EZ)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.
CGA 321113 (EE)	irradiated	n.d.	8.4 ± 1.4	10.4 ± 0.6	30.3 ± 6.0
	dark	n.d.	8.1 ± 0.0	17.4 ± 1.5	38.6 ± 4.6
CGA 381318 (ZZ)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.
CGA 373466 (ZE)	irradiated	n.d.	LOD	0.4 ± 0.0	4.9 ± 1.2
	dark	n.d.	n.d.	n.d.	0.3 ± 0.0
NOA 413163 (EE)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.
NOA 413161 (Z)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	n.d.	n.d.	n.d.
Sum of Unif./Diff. Residues ¹	irradiated	1.3 ± 0.1	1.4 ± 0.2	1.7 ± 0.1	1.7 ± 0.4
	dark	1.3 ± 0.1	1.1 ± 0.2	1.4 ± 0.0	1.3 ± 0.2
Total Extractable Residues ²	irradiated	102.9 ± 0.4	99.0 ± 2.2	102.3 ± 1.8	100.0 ± 2.1
	dark	102.9 ± 0.4	104.5 ± 0.6	104.9 ± 0.5	101.7 ± 0.0
Carbon Dioxide	irradiated	n.a.	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0
	dark	n.a.	< 0.1 ± 0.0	< 0.1 ± 0.0	0.1 ± 0.0
Volatile Organic Compounds ³	irradiated	n.a.	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0
	dark	n.a.	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0
Non-Extractable Residues ⁴	irradiated	0.1 ± 0.0	0.5 ± 0.0	0.4 ± 0.0	1.0 ± 0.1
	dark	0.1 ± 0.0	n.a. ⁴	n.a. ⁴	n.a. ⁴
Total Recovery ²	irradiated	103.0 ± 0.4	99.5 ± 2.2	102.8 ± 1.8	101.1 ± 2.0
	dark	103.0 ± 0.4	104.5 ± 0.6	104.9 ± 0.5	101.8 ± 0.0



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.1.3- 6 (continued)

Compound	Mean SD	DAT			
		2	4	7	10
trifloxystrobin (EE)	irradiated	20.7 ± 10.5	26.9 ± 0.6	10.3 ± 4.1	4.2 ± 0.9
	dark	47.9 ± 1.5	21.5 ± 1.6	7.5 ± 0.4	3.5 ± 0.4
CGA 331409 (EZ)	irradiated	0.4 ± 0.0	1.1 ± 0.3	1.1 ± 0.2	0.9 ± 0.1
	dark	n.d.	n.d.	n.d.	n.d.
CGA 357262 (ZZ)	irradiated	< LOD	1.1 ± 0.1	1.1 ± 0.1	0.9 ± 0.1
	dark	n.d.	n.d.	n.d.	n.d.
CGA 357276 (E)	irradiated	0.3 ± 0.0	LOD	0.8 ± 0.3	1.7 ± 0.3
	dark	n.d.	n.d.	n.d.	n.d.
CGA 357261 (ZE)	irradiated	2.8 ± 2.0	5.1 ± 0.2	2.5 ± 1.0	1.4 ± 0.2
	dark	0.2 ± 0.0	n.d.	n.d.	n.d.
NOA 409480 (Z)	irradiated	< LOD	< LOD	0.3 ± 0.8	3.5 ± 0.8
	dark	n.d.	n.d.	n.d.	n.d.
CGA 373465 (EZ)	irradiated	1.6 ± 0.6	0.8 ± 0.1	2.1 ± 0.6	3.3 ± 0.1
	dark	n.d.	n.d.	n.d.	n.d.
CGA 321113 (EE)	irradiated	57.4 ± 7.9	36.4 ± 4.3	32.3 ± 0.1	24.4 ± 1.4
	dark	54.4 ± 0.1	41.2 ± 0.2	86.6 ± 0.1	91.6 ± 1.9
CGA 381318 (ZZ)	irradiated	0.5 ± 0.0	0.9 ± 0.0	3.3 ± 1.1	6.2 ± 0.2
	dark	n.d.	n.d.	n.d.	n.d.
CGA 373466 (ZE)	irradiated	15.7 ± 3.1	20.2 ± 1.5	33.0 ± 3.7	35.6 ± 2.4
	dark	0.4 ± 0.0	0.5 ± 0.0	0.3 ± 0.0	0.6 ± 0.0
NOA 413163 (EE)	irradiated	n.d.	n.d.	< LOD	0.4 ± 0.1
	dark	n.d.	n.d.	n.d.	n.d.
NOA 413161 (ZE)	irradiated	n.d.	n.d.	n.d.	n.d.
	dark	n.d.	LOD	0.5 ± 0.1	0.6 ± 0.1
Sum of Unid. Diff. Residues	irradiated	1.4 ± 0.6	2.6 ± 0.1	2.5 ± 0.1	3.1 ± 0.2
	dark	0.7 ± 0.0	0.0 ± 0.0	1.5 ± 0.3	2.0 ± 0.0
Total Extractable Residues ²	irradiated	109.5 ± 9.4	95.1 ± 0.5	90.5 ± 1.6	85.6 ± 3.2
	dark	105.6 ± 1.4	94.3 ± 1.6	96.6 ± 1.7	98.3 ± 2.3
Carbon Dioxide ³	irradiated	0.1 ± 0.0	0.1 ± 0.1	0.3 ± 0.0	1.3 ± 0.1
	dark	0.1 ± 0.0	0.2 ± 0.0	0.4 ± 0.0	0.6 ± 0.0
Volatile Organic Compounds ³	irradiated	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0
	dark	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0	< 0.1 ± 0.0
Non-Extractable Residues ³	irradiated	2.0 ± 0.6	n.a.	5.0 ± 1.3	9.2 ± 0.8
	dark	n.a.	1.1 ± 0.0	1.9 ± 0.0	2.3 ± 0.0
Total Recovery ²	irradiated	102.6 ± 0.2	95.2 ± 0.6	95.9 ± 3.0	96.2 ± 2.5
	dark	103.8 ± 1.4	95.7 ± 1.6	98.9 ± 1.6	101.2 ± 2.4

n.d.: not detected, n.a.: not analysed, DAT: days after treatment, SD: standard deviation

¹ Minor degradation products are summed up to sum of unidentified / diffuse residues, with no one component exceeding 1.6% GR.

² Difference to Material Balance values due to rounding errors as well as clean up and chromatographic losses.

³ Values taken from Material Balance.

⁴ Samples were lost due to a malfunction of the oxidizer during quantitation of the NER by combustion/LSC.



B. MATERIAL BALANCE

Mean material balances were 99.6% of applied radioactivity [% AR] (range from 95.3 to 103.5% AR) for irradiated samples and 101.9% AR (range from 96.0 to 104.9% AR) for dark samples. The complete material balances found at all sampling intervals for both irradiated and dark samples demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

C. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES

Extractable residues decreased from 103.4% AR at study start (DAT-0) to 85.6 and 98.4% AR at study end (DAT-11) in irradiated and dark samples, respectively. Non-extractable residues increased from 0.1% AR at DAT-0 to 9.2 and 2.3% AR at DAT-11 in irradiated and dark samples, respectively.

D. VOLATILES

The maximum amount of carbon dioxide was 1.3 and 0.6% AR at DAT-11 in irradiated and dark samples, respectively. Formation of volatile organic compounds was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for both irradiated and dark samples.

E. DEGRADATION OF PARENT COMPOUND

The amount of trifloxystrobin in the soil extracts decreased from 101.0% AR at DAT-0 to 4.2 and 3.5% AR at DAT-11 in irradiated and dark samples, respectively, thus not indicating a significant difference in the rate of degradation. However, the route of degradation of trifloxystrobin differed between irradiated and dark samples with regard to *E/Z* isomerization.

In irradiated samples, trifloxystrobin (*EE*) isomerized to its *E/Z* isomers CGA 357261 (*ZE*) (max. 5.1% AR at DAT-4), CGA 357262 (*ZZ*) and CGA 331409 (*EZ*) (both max. 1.1% AR at DAT-4 and DAT-7). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to CGA 321113 (*EE*) (max. 57.4% AR at DAT-2) and its *E/Z* isomers CGA 373466 (*ZE*) (max. 35.6% AR at DAT-11), CGA 381318 (*ZZ*) (max. 6.2% AR at DAT-11) and CGA 373465 (*EZ*) (max. 3.3% AR at DAT-11) by microbial ester cleavage and *E/Z* isomerization. Furthermore, NOA 413163 (*EE*) (max. 0.4% AR at DAT-11), CGA 357276 (*E*) (max. 1.7% AR at DAT-11) and its *E/Z* isomer NOA 409480 (*Z*) (max. 3.5% AR at DAT-11) were formed. The total unidentified residues amounted to a maximum of 3.1% AR with no one component exceeding 1.6% AR at any sampling interval.

In dark samples, trifloxystrobin (*EE*) was degraded to CGA 321113 (*EE*) (max. 91.6% AR at DAT-11) and NOA 413161 (*ZE*) (max. 0.6% AR at DAT-11). Furthermore, the *E/Z* isomer CGA 357261 (*ZE*) of trifloxystrobin (*EE*) and the *E/Z* isomer CGA 373466 (*ZE*) of CGA 321113 (*EE*) were found with very low maximum amounts of 0.4% AR for CGA 357261 (*ZE*) from DAT-0 to DAT-0.33 and 0.6% AR for CGA 373466 (*ZE*) at DAT-11. Both are presumably formed by light during the sample processing. The total unidentified residues amounted to a maximum of 2.0% AR with no one component exceeding 1.6% AR at any sampling interval.

The experimental DT_{50} and DT_{90} values of trifloxystrobin in irradiated and dark samples were calculated using single first order (SFO) kinetics (see [Table 7.1.1.3- 7](#)).



Table 7.1.1.3- 7: Photodegradation kinetics of trifloxystrobin in soil [redacted] 4a according to FOCUS

Test System	DT ₅₀ (exp.) [days]	DT ₉₀ (exp.) [days]	Chi ² Error [%]	SFO ¹		Net Photodegradation Rate Constant ² / DT ₅₀ [day ⁻¹ / days]
				Rate Constant [day ⁻¹]	DT ₅₀ under natural conditions [days]	
Irradiated	1.3	4.2	13.2	0.55	5.6 (Phoenix, USA) 5.6 (Athens, Greece)	0.15 / 4.6
Dark	1.7	5.8	4.4	0.40	no conversion	

¹ SFO: single first order

² net photodegradation rate constant = rate constant of irradiated samples - rate constant of dark samples

The degradation product M2, formed above the new identification triggers in irradiated samples of soil photolysis study M-033410-01-1 (Baseline Dossier, KCA 7.1.1.3 /01), was identified as NOA 413163 by the comparison of TLC retardation factors and chromatographic profiles of this study with those of M-033410-01-1 (Baseline Dossier, KCA 7.1.1.3 /01).

III. CONCLUSIONS

Trifloxystrobin was rapidly degraded in soil (experimental half-life of 1.3 days) when being exposed to simulated sunlight in the laboratory. The experimental half-life for dark samples was 1.7 days, resulting in a net experimental photolytic half-life of 4.6 days.

The rate of degradation of trifloxystrobin (EE) was therefore mainly influenced by biotic processes, but the route of degradation (see Figure 7.1.1-1 for degradation pathway) differed with regard to E/Z isomerization (in this summary referred to as “photodegradation products”). In irradiated samples, trifloxystrobin (EE) isomerized to its major E/Z isomer CGA 35261 (ZE) and its minor E/Z isomer CGA 357262 (ZZ). Trifloxystrobin (EE) and its E/Z isomers were degraded to the major degradation product CGA 321103 (EE) and its major E/Z isomers, CGA 373466 (ZE) and CGA 381318 (ZZ) by microbial ester cleavage and E/Z isomerization. CGA 321103 (EE) was observed as the single major degradation product in dark samples. Formation of carbon dioxide was low.

It is concluded that the degradation of trifloxystrobin is driven by microbial degradation under typical conditions in the environment and photodegradation plays only a minor role in the overall fate of trifloxystrobin.

The results are in good agreement with the proposed photodegradation pathway of trifloxystrobin on soil known from studies included in the Baseline Dossier. The photodegradation product CGA 381318 is newly addressed in soil in this Supplemental Dossier because it was formed above the new identification triggers. The degradation product M2, formed above the new identification triggers in irradiated samples of soil photolysis study M-033410-01-1 (Baseline Dossier, KCA 7.1.1.3 /01), was identified as NOA 413163.

The results are included in the summary of the route of degradation of trifloxystrobin in soil given in section 7.1.1 and Figure 7.1.1-1.



CA 7.1.2 Rate of degradation in soil

Trifloxystrobin was rapidly degraded in soil under aerobic and anaerobic conditions in the laboratory as well as under field conditions. The kinetic models and DT_{50} values in soil of trifloxystrobin and its major degradation products used for modelling purpose and trigger evaluation (best-fit) as well as the formation fractions in soil for major degradation products are summarized in sections [CA 7.1.2.1](#) and [CA 7.1.2.2](#).

Modelling input values for the calculation of predicted environmental concentrations (PECs) of trifloxystrobin and its major degradation products in soil (PEC_{soil}), groundwater (PEC_{gw}) and surface water (PEC_{sw}) were derived from studies and kinetic evaluations (according to FOCUS kinetics (2006) ¹⁾ summarized in sections [CA 7.1.1](#), [CA 7.1.2](#) and [CA 7.2](#), and are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. The DT_{50} values and maximum occurrences / formation fractions in soil and aquatic systems of trifloxystrobin and its major degradation products used as modelling input values for the calculation of PECs are summarized in [Table 7.1.2- 1](#) to [Table 7.1.2- 3](#).

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2- 1: DT₅₀ values and maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for calculation of PEC_{soil}

Modelling Input Parameter	Endpoint	Comment
trifloxystrobin (EE)		
DT ₅₀ in soil [days]	1.43	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	100	worst case
CGA 357264 (ZE)		
DT ₅₀ in soil [days]	36.9	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	13.5	field, soil surface applied
CGA 321113 (EE)		
DT ₅₀ in soil [days]	358.0	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	51.2	field, soil surface applied
CGA 373466 (ZE)		
DT ₅₀ in soil [days]	72.3	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	31.0	field, soil surface applied
CGA 381318 (ZE)		
DT ₅₀ in soil [days]	22.8	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	6	laboratory, soil photolysis
NOA 413161 (ZE)		
DT ₅₀ in soil [days]	90.0	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	5.7	field, soil surface applied
NOA 413163 (ZE)		
DT ₅₀ in soil [days]	68.6	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	6.0	laboratory, soil photolysis
CGA 357276 (E)		
DT ₅₀ in soil [days]	7.0	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	2.3	field, soil incorporated
NOA 409480 (Z)		
DT ₅₀ in soil [days]	5.3	laboratory, non-normalised, worst case
maximum occurrence in soil [%]	9.3	laboratory, soil photolysis

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2- 2: DT₅₀ values and formation fraction / maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for calculation of PEC_{gw}

Modelling Input Parameter	Endpoint	Comment
trifloxystrobin (EE)		
DT ₅₀ in soil [days]	0.37	median laboratory and field, normalised
CGA 357261 (ZE)		
DT ₅₀ in soil [days]	0.13	median laboratory and field, normalised
FF trifloxystrobin → CGA 357261 in soil	1.000	worst case assumption
CGA 321113 (EE)		
DT ₅₀ in soil [days]	46.8	bias-corrected geomean field, normalised
FF trifloxystrobin → CGA 321113 in soil	0.707	arithmetic mean field
CGA 373466 (ZE)		
DT ₅₀ in soil [days]	20.5	bias-corrected geomean field, normalised
FF CGA 357261 → CGA 321113 in soil	0.853	arithmetic mean field
CGA 381308 (ZZ)		
DT ₅₀ in soil [days]	19.2	bias-corrected geomean laboratory, normalised
maximum occurrence in soil [%]	6	laboratory, soil photolysis
NOA 413161 (ZE)		
DT ₅₀ in soil [days]	38	bias-corrected geomean field, normalised
FF CGA 321113 → NOA 413161 in soil	0.145	arithmetic mean field
NOA 413163 (EE)		
DT ₅₀ in soil [days]	378	median laboratory and field, normalised
FF CGA 373466 → NOA 413163 in soil	0.276	arithmetic mean laboratory and field
CGA 357276 (E)		
DT ₅₀ in soil [days]	50.9	median laboratory and field, normalised
FF CGA 321113 → CGA 357276 in soil	0.059	arithmetic mean laboratory and field
NOA 409480 (Z)		
DT ₅₀ in soil [days]	5.9	median laboratory and field, normalised
FF CGA 373466 → NOA 409480 in soil	0.028	arithmetic mean field

FF: formation fraction

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2- 3: DT₅₀ values and maximum occurrences in soil and aquatic systems of trifloxystrobin and its major degradation products used as modelling input values for calculation of PEC_{sw}

Modelling Input Parameter	Endpoint	Comment
trifloxystrobin (EE)		
DT ₅₀ in soil [days]	0.37	median laboratory and field, normalised
DT ₅₀ in water [days]	0.8	geometric mean
DT ₅₀ in sediment [days]	2.5	geometric mean
DT ₅₀ in total water/sediment system [days]	1.7	geometric mean
max. occurrence in sediment [%]	12.3	
CGA 357261 (ZE)		
DT ₅₀ in soil [days]	0.13	median laboratory and field, normalised
max. occurrence in soil [%]	13.5	field, soil surface applied
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	not a major degradation product in water/sediment systems
max. occurrence in aquatic systems [%]	3.5	aqueous photolysis
CGA 357262 (ZZ)		
DT ₅₀ in soil [days]	1000	default, no major degradation product in soil
max. occurrence in soil [%]	0	no major soil degradation product
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment systems
max. occurrence in aquatic systems [%]	100	Aqueous photolysis
CGA 320113 (EE)		
DT ₅₀ in soil [days]	468	bias-corrected geomean field, normalised
max. occurrence in soil [%]	50.2	field, soil surface applied
DT ₅₀ in water [days]	209.7	geometric mean
DT ₅₀ in sediment [days]	502.2	geometric mean
DT ₅₀ in total water/sediment system [days]	388.0	geometric mean
max. occurrence in total water/sediment system [%]	100	
max. occurrence in aquatic systems [%]	100	100% aerobic mineralisation surface water 100% in hydrolysis (pH 9 and 25 °C) 57.4% in aqueous photolysis
CGA 373466 (ZE)		
DT ₅₀ in soil [days]	20.5	bias-corrected geomean field, normalised
max. occurrence in soil [%]	31.0	field, soil surface applied
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment systems
max. occurrence in aquatic systems [%]	34.7	aqueous photolysis



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2- 3 (continued)

Modelling Input Parameter	Endpoint	Comment
CGA 381318 (ZZ)		
DT ₅₀ in soil [days]	19.2	bias-corrected geometric mean laboratory, normalised
max. occurrence in soil [%]	6.2	laboratory, soil photolysis
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment and aquatic systems
max. occurrence in aquatic systems [%]	0	
NOA 413162 (ZE)		
DT ₅₀ in soil [days]	38.7	bias-corrected geometric mean field, normalised
max. occurrence in soil [%]	5.7	field, soil surface applied
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment and aquatic systems
max. occurrence in aquatic systems [%]	0	
NOA 413163 (EE)		
DT ₅₀ in soil [days]	37.8	median laboratory and field, normalised
max. occurrence in soil [%]	6.0	laboratory, soil photolysis
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment and aquatic systems
max. occurrence in aquatic systems [%]	0	
CGA 357276 (E)		
DT ₅₀ in soil [days]	50.9	median laboratory and field, normalised
max. occurrence in soil [%]	2.3	field, soil incorporated
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment systems
max. occurrence in aquatic systems [%]	10.4	hydrolysis (only at pH 7 and 60 °C)
NOA 409480 (Z)		
DT ₅₀ in soil [days]	35.9	median laboratory and field, normalised
max. occurrence in soil [%]	9.3	laboratory, soil photolysis
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment and aquatic systems
max. occurrence in aquatic systems [%]	0	



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2- 3 (continued)

Modelling Input Parameter	Endpoint	Comment
CGA 107170 (volatile)		
DT ₅₀ in soil [days]	1000	default, no major degradation product in soil
max. occurrence in soil [%]	0	no major soil degradation product
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment systems
max. occurrence in aquatic systems [%]	53.8	aqueous photolysis (39.5% in hydrolysis only at pH 5 and 40 °C)
2-hydroxymethylbenzotrile		
DT ₅₀ in soil [days]	1000	default, no major degradation product in soil
max. occurrence in soil [%]	0	no major soil degradation product
DT ₅₀ in water [days]	1000	default
DT ₅₀ in sediment [days]	1000	default
DT ₅₀ in total water/sediment system [days]	1000	default
max. occurrence in total water/sediment system [%]	0	no major degradation product in water/sediment systems
max. occurrence in aquatic systems [%]	20.1	aqueous photolysis

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Report:	KCA 7.1.2 /01; ; ; ; 2013
Title:	Derivation of Kinetic Input Parameter of Trifloxystrobin and its Metabolites for Soil Risk Assessment in the EU
Report No:	EnSa-13-0895
Document No:	M-469501-01-1
Guidelines:	- FOCUS kinetics (2006) ¹ - FOCUS kinetics (2011) ² - EFSA kinetics (2010) ³
GLP:	No
Justification:	New data / guideline requirement: Derivation of kinetic modelling input values for calculation of predicted environmental concentrations of trifloxystrobin and its major degradation products in soil

Executive Summary

The DT₅₀ values and maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in soil (PEC_{soil}) are summarized in [Table 7.1.2-1](#).

I. METHODS

DT₅₀ values and maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in soil (PEC_{soil}) were derived from studies and kinetic evaluations (according to FOCUS kinetics (2006) ¹) summarized in sections [CA 7.1.1](#) and [CA 7.1.2](#).

Modelling input values for the DT₅₀ values in soil were derived from laboratory studies (see section [CA 7.10.1](#)). The DT₅₀ values were calculated as DT₅₀3.32 in case of the first order multi compartment kinetic model and from the slow k_{rate} in case of the double first order in parallel and hockey stick kinetic models. The worst case DT₅₀ values of trifloxystrobin and its major degradation products were used as modelling input values for the calculation of PEC_{soil}. The DT₅₀ values were averaged (geometric means) for the same soil types. Box and whisker plot analyses of the individual DT₅₀ values were performed in cases where DT₅₀ values were clearly outside a 3-sigma range. Additional outlier tests were performed in these cases for the soil averaged DT₅₀ values (geometric means) based on Grubbs' test also called the ESD method (extreme studentized deviate), to determine whether the most extreme values are significant outliers (t-test < 0.05) from the other values.

² FOCUS kinetics (2011): "Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration", version 1.0, 436 pp., 23 November 2011.

³ EFSA kinetics (2010): "Guidance for evaluating laboratory and field dissipation studies to obtain DegT₅₀ values of plant protection products in soil", EFSA Panel of Plant Protection Products and their Residues (PPR), European Food Safety Authority (EFSA), Parma, Italy, EFSA Journal, 2010, 8 (12), 1936.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Modelling input values for the maximum occurrences in soil of major degradation products have been selected based on the available data from laboratory and field dissipation studies (see sections CA 7.1.1 and CA 7.1.2.2.1) in the following order:

1. maximum occurrence under field conditions in presence of light after soil surface application of trifloxystrobin
2. maximum occurrence under field conditions after soil incorporation of trifloxystrobin
3. maximum occurrence under laboratory conditions

The observed maximum occurrences in soil of major degradation products after soil incorporation are worst case for field conditions in presence of light as the photodegradation route is suppressed due to soil incorporation. The maximum occurrences in soil of major degradation products under field conditions are given as applied trifloxystrobin equivalents and are referenced to the recovered residues at day 0.

II. RESULTS

Table 7.1.2- 4: Maximum occurrences in soil of major trifloxystrobin degradation products (expressed as percentage of the applied parent equivalent)

Degradation Product	Laboratory Studies		Field Dissipation Studies	
	Dark [%]	Photolysis [%]	Soil Incorporation (Dark) [%]	Presence of Light [%]
CGA 357261 (ZE)	-	15.0	-	13.5 ¹
CGA 321113 (EE)	96.8	3.4	98.5	51.2 ¹
CGA 373466 (ZE)	-	42.5	-	31.0 ¹
CGA 381318 (ZE)	-	6.2 ¹	-	-
NOA 413161 (ZE)	13.6	-	16.0	5.7 ¹
NOA 413163 (EE)	-	6.0 ¹	-	-
CGA 357076 (E)	5.6	1.7	2.3 ¹	-
NOA 409480 (Z)	-	9.3	-	-

¹ maximum occurrences in bold used as modelling input values

Table 7.1.2- 5: DT₅₀ values in soils of trifloxystrobin (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	loam	1.43
	silt loam	0.93
	loamy sand	0.83
	loamy sand	0.70
	sandy loam	0.90
	sandy loam	0.80
	sandy loam	70.8 ¹
	sandy loam	0.24
	sandy loam	0.37
4a	silt loam	0.52
	clay loam	0.53
modelling input value (worst case)		1.43

¹ outlier not considered for selection of worst case DT₅₀ for PEC_{soil} calculation



Table 7.1.2- 6: DT₅₀ values in soils of CGA 357261 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	sandy loam	0.08
	sandy loam	36.9
4a	silt loam	2.45
	clay loam	0.24
modelling input value (worst case)		36.9

Table 7.1.2- 7: DT₅₀ values in soils of CGA 321113 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	loam	257.2
	silt loam	143.6
	loamy sand	755.8 ¹
	loamy sand	198.1
	sandy loam	358.0
	sandy loam	162.0
	sandy loam, loamy sand	201.4
	sandy loam	370.1
	sandy loam	71.6
4a	silt loam	55.5
	clay loam	77.4
modelling input value (worst case)		358.0

¹ outlier not considered for selection of worst case DT₅₀ for PEC_{soil} calculation

Table 7.1.2- 8: DT₅₀ values in soils of CGA 373466 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	sandy loam	31.3
	sandy loam	44.6
4a	silt loam	44.7
	clay loam	72.3
modelling input value (worst case)		72.3

Table 7.1.2- 9: DT₅₀ values in soils of CGA 381318 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	sandy loam	11.9
	loamy sand	22.8
4a	silt loam	22.8
	loam	20.4
modelling input value (worst case)		22.8



Table 7.1.2- 10: DT₅₀ values in soils of NOA 413161 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	loamy sand	235.7 ¹
	sandy loam	90.0
	sandy loam	48.1
4a	silt loam	72.4
	clay loam	51.2
modelling input value (worst case)		90.0

¹ outlier not considered for selection of worst case DT₅₀ for PEC_{soil} calculation

Table 7.1.2- 11: DT₅₀ values in soils of NOA 413163 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ ¹ [days]
	sandy loam	68.6
	sandy loam	39.6
4a	sandy loam / silt loam	39.8
	loam / clay loam	27.1
modelling input value (worst case)		68.6

Table 7.1.2- 12: DT₅₀ values in soils of CGA 357276 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	sandy loam	66.5
	loamy sand	71.9
4a	silt loam	79.0
	loam	21.6
modelling input value (worst case)		79.0

Table 7.1.2- 13: DT₅₀ values in soils of NOA 409480 (non-normalised)

Soil	Texture (USDA)	DT ₅₀ [days]
	sandy loam	45.3
	sandy loam	39.3
4a	silt loam	24.9
	clay loam	19.1
modelling input value (worst case)		45.3

III. CONCLUSIONS

The worst case DT₅₀ values and maximum occurrences in soil of trifloxystrobin and its major degradation product used as modelling input values for the calculation of predicted environmental concentrations in soil (PEC_{soil}) were derived from laboratory and field dissipation studies. The results are summarized in Table 7.1.2- 1.



Report:	KCA 7.1.2 /02; ; ; ; ; 2013
Title:	Derivation of Kinetic Input Parameter of Trifloxystrobin and its Metabolites for Groundwater Risk Assessment in the EU
Report No:	EnSa-13-0894
Document No:	M-469352-01-1
Guidelines:	<ul style="list-style-type: none"> - FOCUS kinetics (2006) ¹ - FOCUS kinetics (2011) ² - EFSA kinetics (2010) ³ - EFSA Q₁₀ (2007) ⁴ - FOCUS groundwater (2009) ⁵ - FOCUS groundwater (2012) ⁶
GLP:	No
Justification:	New data / guideline requirement: Derivation of kinetic modelling input values for calculation of predicted environmental concentrations of trifloxystrobin and its major degradation products in groundwater

Executive Summary

The DT₅₀ values and formation fractions / maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in groundwater (PEC_{gw}) are summarized in [Table 7.1.2-9](#).

I. METHODS

DT₅₀ values and formation fraction / maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in groundwater (PEC_{gw}) were derived from studies and kinetic evaluations (according to FOCUS kinetics (2006) ¹) summarized in sections [CA 7.1.1](#) and [CA 7.1.2](#).

⁴ EFSA Q₁₀ (2007): “Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default Q₁₀ value used to describe the temperature effect on transformation rates of pesticides in soil”, EFSA Journal, 622, 1-32.
⁵ FOCUS groundwater (2009): “Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU”, Final report of the Ground Water Working Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USE). vers. 1, 13. June 2009, EC Document Reference SANGO/13144/2010, v1.
⁶ FOCUS groundwater (2012): “Generic guidance for Tier 1 FOCUS groundwater water assessments”, version 2.1, 64 pp., December, 2012.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Degradation rates in soil from laboratory studies (see section CA 7.1.2.1) were normalised to 20 °C and field capacity using the Q₁₀ rule (based on the Arrhenius equation and a default Q₁₀ factor of 2.58) and the Walker equation (default value of 0.7 for the moisture exponent), respectively. The field dissipation data were normalised before performing kinetic analysis using the time-step normalisation (see section CA 7.1.2.2). The DT₅₀ values were averaged (geometric means) for the same soil types in order to select the relevant population to calculate the modelling input DT₅₀ values, the null hypothesis that laboratory and field dissipation values are equal, was tested. The statistical significance of differences in the laboratory and field dissipation DT₅₀ values was checked with Student's t-test at a 5% significance level. If the t-test value (t) was lower than the t-quantile of t-distribution (t_{(n-1), 1-α}), the null hypothesis was not rejected and the DT₅₀ values were pooled from both laboratory and field dissipation studies. If the null hypothesis was rejected, the DT₅₀ values from field dissipation studies were used as modelling input values for the calculation of PEC_{gw}. For the major degradation product CGA 381318, only laboratory DT₅₀ values and maximum occurrence in soil were available and used as modelling input values for the calculation of PEC_{gw}. If > 10 DT₅₀ values were available, the median DT₅₀ value in soil was used as modelling input value. If less than 10 DT₅₀ values were available, the bias-corrected geometric mean as estimator of the median was used as modelling input value.

The formation fractions of major degradation products were averaged (arithmetic means) for the same soil types. The modelling input formation fractions in soil of major degradation products used for the calculation of PEC_{gw} were selected based on the outcome of the population test for laboratory and field dissipation DT₅₀ values.

III. RESULTS

Table 7.1.2- 14: DT₅₀ values of trifloxystrobin in soils (normalised to 20 °C and field capacity)

Laboratory/Field Study	Soil/ Site	Texture (USDA)	DT ₅₀ [days]
Laboratory		Loam	0.99
Laboratory		silt loam	0.37
Laboratory		loamy sand	0.31
Laboratory		loamy sand	0.28
Laboratory		sandy loam	0.33
Laboratory		sandy loam	0.18
Laboratory		sandy loam	2.83
Laboratory		sandy loam	0.13
Laboratory		sandy loam	0.15
Laboratory	4a	silt loam	0.18
Laboratory		clay loam	0.30
Field		Loam	1.13
Field		sandy loam	1.66
Field		silt loam	1.69
Field		silt loam	2.73
Field		Loam	1.10
Field		silty clay loam	2.49
modelling input value			0.37¹

median (n = 17) from laboratory and field dissipation DT₅₀ values



Table 7.1.2- 15: DT₅₀ values of CGA 357261 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
Laboratory		sandy loam	0.06
Laboratory		sandy loam	0.07
Laboratory	4a	silt loam	0.08
Laboratory		clay loam	0.14
Field		loam	0.09
Field		sandy loam	0.61
Field		silt loam	0.13
Field		silt loam	1.35
Field		loam	0.95
Field		silty clay loam	0.88
modelling input value			0.13 ¹

¹ median (n = 10) from laboratory and field dissipation DT₅₀ values

Table 7.1.2- 16: DT₅₀ values and formation fractions of CGA 321113 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]	Formation Fraction
laboratory		loam	299.6	0.822
laboratory		silt loam	87.0	0.971
laboratory		loamy sand	106.8	0.944
laboratory		loamy sand	105.2	0.961
laboratory		sandy loam	206.3	0.946
laboratory		sandy loam	80.4	0.979
laboratory		sandy loam loamy sand	219.5	0.983
laboratory		sandy loam	70.8	0.917
laboratory		sandy loam	72.3	0.996
laboratory	4a	silt loam	52.0	0.973
laboratory		clay loam	78.1	0.961
field		loam	52.4	0.680
field		sandy loam	24.7	0.830
field		silt loam	53.0	0.556
field		silt loam	95.8	0.688
field		loam	23.7	0.488
field		silty clay loam	79.8	1.000
modelling input value			46.8 ¹	0.707 ²

¹ bias-corrected geometric mean (n = 6) from field dissipation DT₅₀ values

² arithmetic mean (n = 6) from field dissipation formation fractions



Table 7.1.2- 17: DT₅₀ values and formation fractions of CGA 373466 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]	Formation Fraction
laboratory		sandy loam	31.9	0.980 ¹
laboratory		sandy loam	45.5	1.000
laboratory	4a	silt loam	43.2	1.000
laboratory		clay loam	73.7	1.000
field		loam	60.8	0.640
field		sandy loam	27.5	1.000
field		silt loam	29.1	0.618
field		silt loam	90.9	1.000
field		loam	47.5	0.860
field		silty clay loam	56.1	1.000
modelling input value			20.5¹	0.853²

¹ bias-corrected geometric mean (n = 6) from field dissipation DT₅₀ values

² arithmetic mean (n = 6) from field dissipation formation fractions

Table 7.1.2- 18: DT₅₀ values and formation fractions of CGA 381318 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]	Formation Fraction
laboratory		sandy loam	12.2	N/A
laboratory		loamy sand	23.5	N/A
laboratory	4a	silt loam	23.5	N/A
laboratory		clay loam	32.0	N/A
modelling input value			19.2¹	6.2%²

N/A: not applicable

¹ bias-corrected geometric mean (n = 4) from laboratory DT₅₀ values

² maximum occurrence in soil photolysis study M-462074-01-1 (Supplemental Dossier, KCA 7.1.1.3 /04)

Table 7.1.2- 19: DT₅₀ values and formation fractions of NOA 413161 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]	Formation Fraction
laboratory		loamy sand	221.1	N/A
laboratory		sandy loam	90.4	0.135
laboratory		sandy loam	48.6	0.164
laboratory	4a	silt loam	70.1	0.132
laboratory		clay loam	51.5	0.213
field		loam	66.1	0.071
field		sandy loam	30.7	0.263
field		silt loam	- ³	- ³
field		silt loam	26.0	0.078
field		loam	34.9	0.259
field		silty clay loam	50.8	0.055
modelling input value			38.7¹	0.145²

N/A: not applicable



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

- ¹ bias-corrected geometric mean (n = 5) from field dissipation DT₅₀ values
- ² arithmetic mean (n = 5) from field dissipation formation fractions
- ³ value excluded due to unreliable statistical parameters

Table 7.1.2- 20: DT₅₀ values and formation fractions of NOA 413163 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]	Formation Fraction
laboratory		sandy loam	69.3	0.229
laboratory		sandy loam	54.6	0.246
laboratory	4a	silt loam / sandy loam	29.1	0.162
laboratory		clay loam / loam	27.7	0.260
field		loam	53.0	- ³
field		sandy loam	87.4	0.457
field		silt loam	29.9	0.198
field		silt loam	36.5	0.185
field		loam	23.2	0.333
field		silty clay loam	18.7	0.115
modelling input value			37.8	0.276²

- ¹ median (n = 10) from laboratory and field dissipation DT₅₀ values
- ² arithmetic mean (n = 9) from laboratory and field dissipation formation fractions
- ³ value excluded due to unreliable statistical parameters

Table 7.1.2- 21: DT₅₀ values and formation fractions of CGA 357276 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]	Formation Fraction
laboratory		sandy loam	65.9	0.043
laboratory		loamy sand / sandy loam	71.2	0.027
laboratory	4a	silt loam	69.2	- ³
laboratory		loam	21.4	- ³
field		loam	36.5	0.072
field		sandy loam	80.2	0.098
field		silt loam	36.1	0.062
field		silt loam	- ³	- ³
field		loam	45.5	0.077
field		silty clay loam	76.5	0.032
modelling input value			50.9¹	0.059²

N/A not applicable

- ¹ bias-corrected geometric mean (n = 9) from laboratory and field dissipation DT₅₀ values
- ² arithmetic mean (n = 7) from laboratory and field dissipation formation fractions
- ³ value excluded due to unreliable statistical parameters

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Table 7.1.2- 22: DT₅₀ values and formation fractions of NOA 409480 in soils (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ (days)	Formation Fraction
laboratory		sandy loam	42.8	N/A
laboratory		sandy loam	37.1	N/A
laboratory	4a	silt loam	23.5	N/A
laboratory		clay loam	15.2	N/A
field		loam	97.3	0.006
field		sandy loam	25.5	0.041
field		silt loam	34.7	0.025
field		silt loam	111	- ³
field		loam	11.1	0.035
field		clay loam	29.7	0.035
modelling input value			35.9	0.028

N/A: not applicable

¹ median (n = 10) from laboratory and field dissipation DT₅₀ values

² arithmetic mean (n = 5) from field dissipation formation fractions

³ value excluded due to unreliable statistical parameters

III. CONCLUSIONS

The DT₅₀ values and formation fractions / maximum occurrences in soil of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in groundwater (PEC_{gw}) were derived from laboratory and field dissipation studies. The results are summarized in Table 7.1.3.2.

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Report:	KCA 7.1.2 /03; ; ; ; 2013
Title:	Derivation of Kinetic Input Parameter of Trifloxystrobin and its Metabolites for Surface Water Risk Assessment in the EU
Report No:	EnSa-13-0930
Document No:	M-469771-01-1
Guidelines:	<ul style="list-style-type: none"> - FOCUS kinetics (2006) ¹ - FOCUS kinetics (2011) ² - EFSA kinetics (2010) ³ - EFSA Q₁₀ (2007) ⁴ - FOCUS surface water (2003) ⁷ - FOCUS surface water (2012) ⁸
GLP:	No
Justification:	New data / guideline requirement: Derivation of kinetic modelling input values for calculation of predicted environmental concentrations of trifloxystrobin and its major degradation products in surface water

Executive Summary

The DT₅₀ values and maximum occurrences in soil and aquatic systems of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in surface water (PEC_{sw}) are summarized in [Table 7.1.2-9](#).

I. METHODS

DT₅₀ values and maximum occurrences in soil and aquatic systems of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in surface water (PEC_{sw}) were derived from studies and kinetic evaluations (according to FOCUS kinetics (2006) ¹) summarized in sections [CA 7.1.1](#), [CA 7.1.2](#) and [CA 7.2](#).

⁷ FOCUS surface water (2003): "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC", Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANGO/4802/2001-rev2.

⁸ FOCUS surface water (2012): "Generic Guidance for FOCUS Surface Water Scenarios", version 1.2, 357 pp., December 2012.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

Degradation rates from laboratory studies in soil (see section CA 7.1.2.1) were normalised to 20 °C and field capacity using the Q₁₀ rule (based on the Arrhenius equation and a default Q₁₀ factor of 2.58) and the Walker equation (default value of 0.7 for the moisture exponent), respectively. The field dissipation data were normalised before performing kinetic analysis using the time-step normalisation (see section CA 7.1.2.2). The DT₅₀ values were averaged (geometric means) for the same soil types and water/sediment systems. In order to select the relevant population to calculate the modelling input DT₅₀ values, the null hypothesis that laboratory and field dissipation values are equal, was tested. The statistical significance of differences in the laboratory and field dissipation DT₅₀ values was checked with Student's t-test at a 5% significance level. If the t-test value (t) was lower than the t-quantile of t-distribution (tdf, 1- α), the null hypothesis was not rejected and the DT₅₀ values were pooled from both laboratory and field dissipation studies. If the null hypothesis was rejected, the DT₅₀ values from field dissipation studies were used as modelling input values for the calculation of PEC_w. For the major degradation product CGA 381318, only laboratory DT₅₀ values and maximum occurrence in soil were available and used as modelling input values for the calculation of PEC_w. If >10 DT₅₀ values were available, the median DT₅₀ value in soil was used as modelling input value. If less than 10 DT₅₀ values were available, the bias-corrected geometric mean as estimator of the median was used as modelling input value.

Modelling input values for the maximum occurrences in soil of major degradation products have been selected based on the available data from laboratory and field dissipation studies (see sections CA 7.1.1 and CA 7.1.2.1) in the following order:

1. maximum occurrence under field conditions in presence of light after soil surface application of trifloxystrobin
2. maximum occurrence under field conditions after soil incorporation of trifloxystrobin
3. maximum occurrence under laboratory conditions

The observed maximum occurrences in soil of major degradation products after soil incorporation are worst case for field conditions in presence of light as the photodegradation route is suppressed due to soil incorporation. The maximum occurrences of major degradation products in soil under field conditions are given as applied trifloxystrobin equivalents and are referenced to the recovered residues at day 0.

DT₅₀ values and maximum occurrences from water/sediment studies were only available for trifloxystrobin and its major degradation product CGA 371113 (see section CA 7.2). The geometric means of DT₅₀ values in water, sediment and total system were used as modelling input values. Modelling input values for the maximum occurrences of major degradation products in aquatic systems were derived from studies summarized in section CA 7.2.



II. RESULTS

Table 7.1.2- 23: Maximum occurrences in soil of major trifloxystrobin degradation products (expressed as percentage of applied parent equivalent)

Degradation Product	Laboratory Studies		Field Dissipation Studies	
	Dark [%]	Photolysis [%]	Soil Incorporation (Dark) [%]	Presence of Light [%]
CGA 357261 (ZE)	-	15.5	-	13.5 ²
CGA 357262 (ZZ) ¹	-	-	-	-
CGA 321113 (EE)	96.8	57.4	58.5	51.2 ²
CGA 373466 (ZE)	-	42.5	-	31.0 ²
CGA 381318 (ZZ)	-	6.2 ²	-	-
NOA 413161 (ZE)	13.6	-	16.0	5.7 ²
NOA 413163 (EE)	-	6.0 ²	-	-
CGA 357276 (E)	5.6	1.7	2.3 ²	-
NOA 409480 (Z)	-	9.3 ²	-	-
CGA 107170 (volatile) ¹	-	-	-	-
2-hydroxymethylbenzotrile ¹	-	-	-	-

¹ not a major degradation product in soil² maximum occurrences in bold used as modelling input values

Table 7.1.2- 24: Maximum occurrences in aquatic systems of trifloxystrobin and its major degradation products expressed as percentage of applied parent equivalent)

Degradation Product	Water/Sediment [%]	Aerobic Mineralisation [%]	Photolysis [%]	Hydrolysis [%]
trifloxystrobin (ZE)	42.3 (in sediment)	-	-	-
CGA 357261 (ZE)	-	-	51.5 ²	-
CGA 357262 (ZZ)	-	-	10.1 ²	-
CGA 321113 (EE)	100 ²	100	57.4	100 ^{2,5}
CGA 373466 (ZE)	-	-	21.1 ³	-
CGA 381318 (ZZ)	-	-	34.7 ^{2,4}	-
NOA 413161 (ZE)	-	-	-	-
NOA 413163 (EE) ¹	-	-	-	-
CGA 357276 (E)	-	-	-	10.4 ^{2,6}
NOA 409480 (Z)	-	-	-	-
CGA 107170 (volatile)	-	-	53.8 ²	39.5 ⁷
2-hydroxymethylbenzotrile	-	-	20.1 ²	-

¹ not a major degradation product in aquatic systems² maximum occurrences in bold used as modelling input values³ from trifloxystrobin⁴ from CGA 321113: 60.0%; calculated as worst case from trifloxystrobin: 57.4% x 60.5% = 34.7%⁵ pH 9 and 25 °C⁶ only at pH 7 and 60 °C, assessed as thermal decomposition product⁷ only at pH 7 and 40 °C



Table 7.1.2- 25: DT₅₀ values in soils of trifloxystrobin (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		loam	0.99
laboratory		silt loam	0.37
laboratory		loamy sand	0.31
laboratory		loamy sand	0.28
laboratory		sandy loam	0.33
laboratory		sandy loam	0.18
laboratory		sandy loam	2.83
laboratory		sandy loam	0.13
laboratory		sandy loam	0.15
laboratory	4a	silt loam	0.08
laboratory		clay loam	0.30
field		loam	1.14
field		sandy loam	1.96
field		silt loam	0.69
field		silt loam	2.73
field		loam	1.00
field		silty clay loam	2.49
modelling input value			0.37¹

¹ median (n = 17) from laboratory and field dissipation DT₅₀ values

Table 7.1.2- 26: DT₅₀ values in soils of CGA 352261 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		sandy loam	0.06
laboratory		sandy loam	0.07
laboratory	4a	silt loam	0.08
laboratory		clay loam	0.14
field		loam	0.09
field		sandy loam	0.61
field		silt loam	0.12
field		silt loam	1.35
field		loam	0.95
field		silty clay loam	0.88
modelling input value			0.13¹

¹ median (n = 10) from laboratory and field dissipation DT₅₀ values



Table 7.1.2- 27: DT₅₀ values in soils of CGA 321113 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		loam	209.0
laboratory		silt loam	81.0
laboratory		loamy sand	406.0
laboratory		loamy sand	105.2
laboratory		sandy loam	206.3
laboratory		sandy loam	80.4
laboratory		sandy loam / loamy sand	219.5
laboratory		sandy loam	70.8
laboratory		sandy loam	72.3
laboratory	4a	silt loam	52.0
laboratory		clay loam	78.1
field		loam	52.4
field		sandy loam	24.7
field		silt loam	53.0
field		silt loam	95.8
field		loam	23.7
field		silty clay loam	79.8
modelling input value			46.8¹

¹ bias-corrected geometric mean (n = 6) from field dissipation DT₅₀ values

Table 7.1.2- 28: DT₅₀ values in soils of CGA 373466 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		sandy loam	31.9
laboratory		sandy loam	45.5
laboratory	4a	silt loam	43.2
laboratory		clay loam	73.7
field		loam	6.86
field		sandy loam	8.57
field		silt loam	29.1
field		silt loam	90.9
field		loam	14.5
field		silty clay loam	56.1
modelling input value			20.5¹

¹ bias-corrected geometric mean (n = 6) from field dissipation DT₅₀ values

Table 7.1.2- 29: DT₅₀ values in soils of CGA 381318 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		sandy loam	11.9
laboratory		loamy sand	22.8
laboratory	4a	silt loam	22.8
laboratory		clay loam	20.4
modelling input value			19.2¹

¹ bias-corrected geometric mean (n = 4) from laboratory DT₅₀ values



Table 7.1.2- 30: DT₅₀ values in soils of NOA 413161 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		loamy sand	22.1
laboratory		sandy loam	90.4
laboratory		sandy loam	48.6
laboratory	4a	silt loam	70.1
laboratory		clay loam	51.5
field		loam	66.6
field		sandy loam	30.7
field		silt loam	- ²
field		silt loam	26.0
field		loam	34.9
field		silty clay loam	29.8
modelling input value			38.7 ¹

¹ bias-corrected geometric mean (n = 5) from field dissipation DT₅₀ values

² value excluded due to unreliable statistical parameters

Table 7.1.2- 31: DT₅₀ values in soils of NOA 431630 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		sandy loam	69.3
laboratory		sandy loam	54.6
laboratory	4a	silt loam / sandy loam	39.1
laboratory		clay loam / loam	27.7
field		loam	53.0
field		sandy loam	87.4
field		silt loam	29.9
field		silt loam	36.5
field		loam	25.2
field		silty clay loam	28.7
modelling input value			37.8 ¹

¹ median (n = 16) from laboratory and field dissipation DT₅₀ values

Table 7.1.2- 32: DT₅₀ values in soils of CGA 357276 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		sandy loam	65.9
laboratory		loamy sand / sandy loam	71.2
laboratory	4a	silt loam	69.2
laboratory		loam	21.4
field		loam	36.5
field		sandy loam	80.2
field		silt loam	36.1
field		silt loam	- ²
field		loam	45.5
field		silty clay loam	76.5



modelling input value	50.9¹
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- ¹ bias-corrected geometric mean (n = 9) from laboratory and field dissipation DT₅₀ values
- ² value excluded due to unreliable statistical parameters

Table 7.1.2- 33: DT₅₀ values in soils of NOA 409480 (normalised to 20 °C and field capacity)

Laboratory / Field Study	Soil / Site	Texture (USDA)	DT ₅₀ [days]
laboratory		sandy loam	42.8
laboratory		sandy loam	37.4
laboratory	4a	silt loam	23.5
laboratory		clay loam	15.2
field		loam	97.3
field		sandy loam	93.5
field		silt loam	34.7
field		silt loam	111.1
field		loam	18.1
field		silt clay loam	29.7
modelling input value			35.9¹

- ¹ median (n = 10) from laboratory and field dissipation DT₅₀ values

Table 7.1.2- 34: DT₅₀ values in water/sediment systems of trifloxystrobin and CGA 321113

Water/Sediment System	trifloxystrobin			CGA 321113		
	Water DT ₅₀ [days]	Sediment DT ₅₀ [days]	Total System DT ₅₀ [days]	Water DT ₅₀ [days]	Sediment DT ₅₀ [days]	Total System DT ₅₀ [days]
Rhine	0.77	3.57	2.45	285.1	570.9	423.1
Rhine	0.57	4.08	2.63	379.9	441.8	362.9
Pond	0.90	1.48	1.25	154.6	- ²	341.1
Pond	0.86	1.67	1.14	137.1	- ³	432.7
modelling input value	0.76¹	2.45¹	1.69¹	209.7¹	502.2¹	388.0¹

- ¹ geometric mean
- ² no clear dissipation observed in sediment
- ³ DT₅₀ could not be calculated due to a too low number of data

III. CONCLUSIONS

The DT₅₀ values and maximum occurrences in soil and aquatic systems of trifloxystrobin and its major degradation products used as modelling input values for the calculation of predicted environmental concentrations in surface water (PEC_{sw}) were derived from laboratory and field dissipation studies. The results are summarized in Table 7.1.2- 3.



CA 7.1.2.1 Laboratory studies

The degradation rates of trifloxystrobin and its major degradation products in soil were studied using two different radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and unlabelled compounds. The studies have been performed in a number of soils in the dark in the laboratory at temperatures between 16 to 25 °C and different soil moistures. The kinetic models and DT₅₀ values used for modelling purpose (non-normalised) and trigger evaluation (best-fit) as well as formation fractions for major degradation products are summarized in Table 7.1.2.1- 1 to Table 7.1.2.1- 26. The DT₅₀ and DT₉₀ values for trigger evaluation (best-fit) were taken from study reports and may slightly differ from the List of Endpoints (SANCO/4339/2000-Final, 7 April 2003).

Table 7.1.2.1- 1: Summary of DT₅₀ values for degradation of trifloxystrobin in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ ² [days]
25		loam	KCA 7.1.2.1.1 /16	FOMC	0.8
20		silt loam	KCA 7.1.2.1.1 /14	FOMC	0.49
		loam	KCA 7.1.2.1.1 /15	SFO	0.41
	A	silt loam	KCA 7.1.2.1.1 /11	FOMC	0.49
	B ³	silt loam	KCA 7.1.2.1.1 /11	FOMC	0.89
	D	silt loam	KCA 7.1.2.1.1 /11	FOMC	0.64
		loamy sand	KCA 7.1.2.1.1 /12	FOMC	0.57
		loamy sand	KCA 7.1.2.1.1 /12	FOMC	0.73
		sand loam	KCA 7.1.2.1.1 /12	FOMC	0.58
		silty loam	KCA 7.1.2.1.1 /16	SFO	0.82
		loamy sand	KCA 7.1.2.1.1 /19	FOMC	0.46
	A	sandy loam	KCA 7.1.2.1.1 /17	FOMC	0.34
	B	sandy loam	KCA 7.1.2.1.1 /17	FOMC	0.40
		loamy sand	KCA 7.1.2.1.1 /17	FOMC	0.44
		sandy loam	KCA 7.1.2.1.1 /13	DFOP	4.35
		sandy loam	KCA 7.1.2.1.1 /18	FOMC	0.13
		sandy loam	KCA 7.1.2.1.1 /18	FOMC	0.15
	4a	silt loam	KCA 7.1.2.1.1 /18	FOMC	0.19
		clay loam	KCA 7.1.2.1.1 /18	FOMC	0.30
10		silt loam	KCA 7.1.2.1.1 /11	FOMC	1.05

¹ SFO: single first order, FOMC: first order multi-compartment, DFOP: double first order in parallel

² for FOMC: DT₅₀ was not calculated as DT₉₀ is 32, DT₅₀ is based on fit of the decline curve

for DFOP: DT₅₀ was not calculated from the slow K_{rate}, DT₅₀ is based on fit of the decline curve

³ soil moisture of 30% of the field capacity at 1/3 bar

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Table 7.1.2.1- 2: Summary of DT₅₀ and DT₉₀ values for degradation of trifloxystrobin in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
25		loam	KCA 7.1.2.1.1 /03	SFO	2.0	n.c.
20		silt loam	KCA 7.1.2.1.1 /01	SFO	0.6	1.8
		loam	KCA 7.1.2.1.1 /02	SFO	0.4	1.4
		silt loam	KCA 7.1.2.1.1 /04	SFO	0.6-1.2	2.0-3.5
		loamy sand	KCA 7.1.2.1.1 /05	SFO	0.7	2.4
		loamy sand	KCA 7.1.2.1.1 /05	SFO	0.8	2.7
		sandy loam	KCA 7.1.2.1.1 /05	SFO	0.7	2.4
		silty loam	KCA 7.1.2.1.1 /08	SFO	0.7	2.3
		loamy sand	KCA 7.1.2.1.1 /06	SFO	0.9	2.9
		sandy loam	KCA 7.1.2.1.1 /07	SFO	0.5-0.6	1.8-2.0
		loamy sand	KCA 7.1.2.1.1 /07	SFO	0.7	2.3
		sandy loam	KCA 7.1.2.1.1 /08	FOTC	3.7	162
		loamy sand	KCA 7.1.2.1.1 /09	FOMC	0.1	80.5
		sandy loam	KCA 7.1.2.1.1 /10	DFOP	0.1	0.7
		sandy loam	KCA 7.1.2.1.1 /10	FOMC	0.2	1.3
10	4a	silt loam	KCA 7.1.2.1.1 /10	FOMC	0.2	1.8
		clay loam	KCA 7.1.2.1.1 /10	FOMC	0.3	1.8
		silt loam	KCA 7.1.2.1.1 /04	SFO	1.0	2.0-3.5

n.c.: not calculated

¹ SFO: single first order, FOTC: first order two compartment (Newton-Raphson method), FOMC: first order multi compartment, DFOP: double first order in parallel

Table 7.1.2.1- 3: Summary of DT₅₀ values for degradation of CGA 357261 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ ² [days]
20		sandy loam	KCA 7.1.2.1.2 /25	N/A	FOMC	0.06
		sandy loam	KCA 7.1.2.1.2 /25	N/A	DFOP	0.07
	4a	silt loam	KCA 7.1.2.1.2 /25	N/A	DFOP	0.08
		clay loam	KCA 7.1.2.1.2 /25	N/A	FOMC	0.14

N/A: not applicable

¹ FOMC: first order multi compartment, DFOP: double first order in parallel

² for FOMC: DT₅₀ was not calculated as DT₉₀ of 0.32, DT₅₀ is based on fit of the decline curve

for DFOP: DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve

Table 7.1.2.1- 4: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 357261 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /10	DFOP	0.1	0.3
		sandy loam	KCA 7.1.2.1.2 /10	DFOP	0.1	0.3
		silt loam	KCA 7.1.2.1.2 /10	DFOP	0.1	0.4
	4a	clay loam	KCA 7.1.2.1.2 /10	FOMC	0.1	0.9

¹ FOMC: first order multi compartment, DFOP: double first order in parallel



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Table 7.1.2.1- 5: Summary of DT₅₀ values and formation fractions for degradation of CGA 321113 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
25		loam	KCA 7.1.2.1.2 /22	0.822	SFO	257.2
20		silt loam	KCA 7.1.2.1.2 /20	0.969	SFO	80.3
		loam	KCA 7.1.2.1.2 /21	0.947	SFO	99.2
	A	silt loam	KCA 7.1.2.1.2 /17	0.951	SFO	120.0
	B ²	silt loam	KCA 7.1.2.1.2 /17	1.000	SFO	262.7
	D	silt loam	KCA 7.1.2.1.2 /17	1.000	SFO	335.1
		loamy sand	KCA 7.1.2.1.2 /18	0.944	SFO	755.0
		loamy sand	KCA 7.1.2.1.2 /18	0.970	SFO	428.4
		sandy loam	KCA 7.1.2.1.2 /18	0.946	SFO	358.0
		silty loam	KCA 7.1.2.1.2 /32	0.935	SFO	386.4
		loamy sand	KCA 7.1.2.1.2 /21	0.913	SFO	115.3
	A	sandy loam	KCA 7.1.2.1.2 /23	1.000	SFO	312.4
	B	sandy loam	KCA 7.1.2.1.2 /23	0.955	SFO	235.0
		loamy sand	KCA 7.1.2.1.2 /28	1.000	SFO	157.4
		loamy sand	KCA 7.1.2.1.2 /16	N/A	SFO	223.2
		sandy loam	KCA 7.1.2.1.2 /19	0.985	SFO	380.4
		sandy loam	KCA 7.1.2.1.2 /24	0.917	SFO	70.1
		sandy loam	KCA 7.1.2.1.2 /24	0.996	SFO	71.6
		4a silt loam	KCA 7.1.2.1.2 /24	0.973	SFO	55.5
		clay loam	KCA 7.1.2.1.2 /24	0.961	SFO	77.4
10	C	silt loam	KCA 7.1.2.1.2 /17	0.996	SFO	369.5

N/A: not applicable

¹ SFO: single first order

² soil moisture of 30% of the field capacity at 1/3 bag

Table 7.1.2.1- 6: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 321113 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	
25		loam	KCA 7.1.2.1.2 /03	SFO	301	n.c.	
20		silt loam	KCA 7.1.2.1.2 /01	SFO	83.9	279	
		loam	KCA 7.1.2.1.2 /02	SFO	101	340	
		silt loam	KCA 7.1.2.1.2 /04	SFO	32.9-259	n.c.	
		loamy sand	KCA 7.1.2.1.2 /05	SFO	493	n.c.	
		loamy sand	KCA 7.1.2.1.2 /05	SFO	394	n.c.	
		sandy loam	KCA 7.1.2.1.2 /05	SFO	277	n.c.	
		silty loam	KCA 7.1.2.1.2 /06	SFO	101	n.c.	
		loamy sand	KCA 7.1.2.1.2 /06	SFO	295	n.c.	
			sandy loam	KCA 7.1.2.1.2 /07	SFO	112-267	371-886
			loamy sand	KCA 7.1.2.1.2 /07	SFO	169	562
		loamy sand	KCA 7.1.2.1.2 /08	SFO	210	n.c.	
10		silt loam	KCA 7.1.2.1.2 /04	SFO	305	n.c.	

n.c.: not calculated

¹ SFO: single first order



Table 7.1.2.1- 7: Summary of DT₅₀ values and formation fractions for degradation of CGA 373466 in aerobic soils for and modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /25	0.980	SFO	31.3
		sandy loam	KCA 7.1.2.1.2 /25	1.000	SFO	44.6
	4a	silt loam	KCA 7.1.2.1.2 /25	1.000	SFO	44.7
		clay loam	KCA 7.1.2.1.2 /25	1.000	SFO	72.3

¹ SFO: single first order

Table 7.1.2.1- 8: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 373466 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /25	SFO	31.3	104
		sandy loam	KCA 7.1.2.1.2 /25	SFO	44.6	154
	4a	silt loam	KCA 7.1.2.1.2 /25	SFO	44.7	152
		clay loam	KCA 7.1.2.1.2 /25	SFO	72.3	240

¹ SFO: single first order

Table 7.1.2.1- 9: Summary of DT₅₀ values for degradation of CGA 381318 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /31	N/A	SFO	11.9
		loamy sand	KCA 7.1.2.1.2 /31	N/A	SFO	22.8
	4a	silt loam	KCA 7.1.2.1.2 /31	N/A	SFO	22.8
		loam	KCA 7.1.2.1.2 /31	N/A	SFO	20.4

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 10: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 381318 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /11	DFOP	11.3	43.3
		loamy sand	KCA 7.1.2.1.2 /11	DFOP	20.4	95.7
	4a	silt loam	KCA 7.1.2.1.2 /11	SFO	22.8	75.9
		loam	KCA 7.1.2.1.2 /11	SFO	20.4	67.8

¹ SFO: single first order, DFOP: double first order in parallel



Table 7.1.2.1- 11: Summary of DT₅₀ values and formation fractions for degradation of NOA 413161 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /24	0.155	SFO	90.4
		sandy loam	KCA 7.1.2.1.2 /24	0.164	SFO	48.1
	4a	silt loam	KCA 7.1.2.1.2 /24	0.132	SFO	35.1
		clay loam	KCA 7.1.2.1.2 /24	0.213	SFO	36.9
		loamy sand	KCA 7.1.2.1.2 /29	N/A	SFO	53.7
		sandy loam	KCA 7.1.2.1.2 /28	N/A	SFO	89.6
	4a	silt loam	KCA 7.1.2.1.2 /28	N/A	SFO	149.6
		clay loam	KCA 7.1.2.1.2 /28	N/A	SFO	85.0

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 12: Summary of DT₅₀ and DT₉₀ values for degradation of NOA 413161 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model	DT ₅₀ [days]	DT ₉₀ [days]
20		loamy sand	KCA 7.1.2.1.2 /09	SFO	253	840
		sandy loam	KCA 7.1.2.1.2 /12	DFOP	82.8	> 1000
	4a	silt loam	KCA 7.1.2.1.2 /12	DFOP	173	713
		clay loam	KCA 7.1.2.1.2 /12	DFOP	80.9	305

¹ SFO: single first order, DFOP: double first order in parallel

Table 7.1.2.1- 13: Summary of DT₅₀ values and formation fractions for degradation of NOA 413163 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /25	0.229	SFO	76.0
		sandy loam	KCA 7.1.2.1.2 /25	0.246	SFO	53.6
	4a	silt loam	KCA 7.1.2.1.2 /25	0.162	SFO	40.0
		clay loam	KCA 7.1.2.1.2 /25	0.260	SFO	25.4
		sandy loam	KCA 7.1.2.1.2 /27	N/A	SFO	61.9
	4a	sandy loam	KCA 7.1.2.1.2 /27	N/A	SFO	39.6
		loam	KCA 7.1.2.1.2 /27	N/A	SFO	29.6

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 14: Summary of DT₅₀ and DT₉₀ values for degradation of NOA 413163 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20		sandy loam	KCA 7.1.2.1.2 /13	DFOP	53.6	> 1000
	4a	sandy loam	KCA 7.1.2.1.2 /13	FOMC	37.3	158
		loam	KCA 7.1.2.1.2 /13	FOMC	27.7	113

¹ FOMC: first order multi compartment, DFOP: double first order in parallel



Table 7.1.2.1- 15: Summary of DT₅₀ values and formation fractions for degradation of CGA 357276 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ ² [days]
20	[redacted]	sandy loam	KCA 7.1.2.1.2 /24	0.043	- ³	
		sandy loam	KCA 7.1.2.1.2 /24	0.027		66.5
		sandy loam	KCA 7.1.2.1.2 /30	N/A	HS	71.9
		loamy sand	KCA 7.1.2.1.2 /30	N/A	DFOP	71.9
		4a silt loam	KCA 7.1.2.1.2 /30	N/A	DFOP	21.6
		loam	KCA 7.1.2.1.2 /30	N/A	FOMC	

N/A: not applicable

¹ FOMC: first order multi compartment, DFOP: double first order in parallel, HS: hockey stick

² for FOMC: DT₅₀ was calculated as DT₉₀/3.32

for DFOP and HS: DT₅₀ was calculated from the slow k-rate

³ degradation rate could not be calculated

Table 7.1.2.1- 16: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 357276 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20	[redacted]	sandy loam	KCA 7.1.2.1.2 /14	FOMC	22.0	190
		loamy sand	KCA 7.1.2.1.2 /14	FOMC	21.5	237
		silt loam	KCA 7.1.2.1.2 /14	FOMC	21.3	123
		4a loam	KCA 7.1.2.1.2 /14	FOMC	12.0	71.8

¹ FOMC: first order multi compartment

Table 7.1.2.1- 17: Summary of DT₅₀ values for degradation of NOA 409480 in aerobic soils for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20	[redacted]	sandy loam	KCA 7.1.2.1.2 /26	N/A	SFO	45.3
		sandy loam	KCA 7.1.2.1.2 /26	N/A	SFO	39.3
		silt loam	KCA 7.1.2.1.2 /26	N/A	SFO	24.9
		4a clay loam	KCA 7.1.2.1.2 /26	N/A	SFO	19.1

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 18: Summary of DT₅₀ and DT₉₀ values for degradation of NOA 409480 in aerobic soils for trigger evaluation

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
[redacted]	[redacted]	sandy loam	KCA 7.1.2.1.2 /15	FOMC	27.8	275
		sandy loam	KCA 7.1.2.1.2 /15	FOMC	30.2	239
		4a silt loam	KCA 7.1.2.1.2 /15	FOMC	20.1	113
		clay loam	KCA 7.1.2.1.2 /15	SFO	19.1	63.4

¹ SFO: single first order, FOMC: first order multi compartment



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Table 7.1.2.1- 19: Summary of DT₅₀ values for degradation of trifloxystrobin in anaerobic soil for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]
25	North Carolina	loamy sand	KCA 7.1.2.1.3 /02	HS	0.6

¹ HS: hockey stick

Table 7.1.2.1- 20: Summary of DT₅₀ and DT₉₀ values for degradation of trifloxystrobin in anaerobic soil (best-fit)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
25	North Carolina	loamy sand	KCA 7.1.2.1.3 /01	SFO	0.7	n.c.

n.c.: not calculated

¹ SFO: single first order

Table 7.1.2.1- 21: Summary of DT₅₀ values and formation fractions for degradation of CGA 321113 in anaerobic soil for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
25	North Carolina	loamy sand	KCA 7.1.2.1.4 /04	1.000	SFO	> 1000
20		silt loam	KCA 7.1.2.1.4 /02	N/A	SFO	356

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 22: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 321113 in anaerobic soils (best-fit)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
25	North Carolina	loamy sand	KCA 7.1.2.1.4 /01	SFO	> 1000	n.c.
20		silt loam	KCA 7.1.2.1.4 /02	SFO	356	> 1000

n.c.: not calculated

¹ SFO: single first order; FOMC: first order multi compartment

Table 7.1.2.1- 23: Summary of DT₅₀ values for degradation of NOA 413161 in anaerobic soil for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20		silt	KCA 7.1.2.1.4 /05	N/A	SFO	976.4

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 24: Summary of DT₅₀ and DT₉₀ values for degradation of NOA 413161 in anaerobic soil (best-fit)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20		silt	KCA 7.1.2.1.4 /03	SFO	976	> 1000

¹ SFO: single first order



Table 7.1.2.1- 25: Summary of DT₅₀ values for degradation of NOA 413163 in anaerobic soil for modelling purpose (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DT ₅₀ [days]
20	[REDACTED]	silt	KCA 7.1.2.1.4 /05	N/A	SFO	206.1

N/A: not applicable

¹ SFO: single first order

Table 7.1.2.1- 26: Summary of DT₅₀ and DT₉₀ values for degradation of NOA 413163 in anaerobic soil (best-fit)

Temp. [°C]	Soil	Texture (USDA)	Annex Point / Reference No	Kinetic Model	DT ₅₀ [days]	DT ₉₀ [days]
20	[REDACTED]	silt	KCA 7.1.2.1.4 /03	SFO	206	68

¹ SFO: single first order

CA 7.1.2.1.1 Aerobic degradation of the active substance

The degradation rate of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory was evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.2.1.1 /01	[REDACTED]	1997	M-033008-01-1
KCA 7.1.2.1.1 /02	[REDACTED]	1997	M-033147-01-1
KCA 7.1.2.1.1 /03	[REDACTED]	1997	M-033394-01-1
KCA 7.1.2.1.1 /04	[REDACTED]	1997	M-033459-01-1
KCA 7.1.2.1.1 /05	[REDACTED]	1997	M-033453-01-1
KCA 7.1.2.1.1 /06	[REDACTED]	1997	M-033599-01-1
KCA 7.1.2.1.1 /07	[REDACTED]	1997	M-033464-01-1
KCA 7.1.2.1.1 /08	[REDACTED]	2001	M-073242-01-1
KCA 7.1.2.1.1 /09	[REDACTED]	2001	M-069897-01-1

An additional study has been performed for trifloxystrobin and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using unlabelled trifloxystrobin. Furthermore, updated kinetic evaluations of the degradation behaviour of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory have been performed according to FOCUS kinetics (2006)¹ to derive kinetic parameters suitable for modelling purpose and environmental risk assessment. A summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory is given in section CA 7.1.2.1.1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.1 /10; [REDACTED]; [REDACTED]; 2013
Title:	Formation Fraction of NOA 413161 from Trifloxystrobin in Four European Soils
Report No:	EnSa-12-0410
Document No:	M-464420-01-1
Guidelines:	- OECD Test Guideline No. 307
GLP:	Yes
Justification:	Determination of formation fraction in soil of major degradation product NOA 413161 for modelling purpose

Executive Summary

The formation fraction of NOA 413161, a degradation product of trifloxystrobin, was studied in four soils under aerobic conditions in the dark in the laboratory for 120 days at 20.1 and 53.4% of the maximum water holding capacity:

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Mönheim, Germany	sandy loam	5.1	0.8
[REDACTED]	Mönheim, Germany	sandy loam	5.0	1.5
[REDACTED] 4a	Burscheid, Germany	silt loam	6.2	1.6
[REDACTED]	Blankenheim, Germany	clay loam	7.1	4.8

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

Additionally, kinetic data for a possible evaluation of the formation fractions of the trifloxystrobin degradation products CGA 321113 and CGA 357276 were determined.

A study application rate of 480 µg trifloxystrobin per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 187.5 g per hectare.

The amount of trifloxystrobin in the soil extracts decreased from 103.8, 99.4, 102.8 and 100.3% of applied amount [% AA] at study start (DAT-0) to < LOD (limit of detection) at DAT-58, DAT-120 (study end), DAT-93 and DAT-30 in soils [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED]. Degradation of trifloxystrobin was accompanied by the formation of its degradation products CGA 321113, NOA 413161 and CGA 357276.

CGA 321113 amounted to maxima (trifloxystrobin equivalents) of 92.0% AA (DAT-3), 96.9% AA (DAT-3), 91.6% AA (DAT-3) and 91.5% AA (DAT-3) in soils [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

NOA 413161 amounted to maxima (trifloxystrobin equivalents) of 5.3% AA (DAT-93 and DAT-120), 4.9% AA (DAT-93), 3.6% AA (DAT-58 and DAT-93) and 4.2% AA (DAT-58 and DAT-93) in soils [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

CGA 357276 amounted to maxima (trifloxystrobin equivalents) of 2.4% AA (DAT-120), 1.9% AA (DAT-120) and 1.0% AA (DAT-120) in soils [REDACTED], [REDACTED] and [REDACTED] 4a, respectively. In soil [REDACTED] the amounts of CGA 357276 were < LOD for all sampling intervals.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The experimental data could be well described by a double first order in parallel (DFOP) kinetic model for soil [redacted] and a first order multi compartment (FOMC) kinetic model for soils [redacted], [redacted] 4a and [redacted]. The half-life of trifloxystrobin under aerobic conditions was 0.1, 0.2, 0.2 and 0.3 days (corresponding to approximately 2 to 7 hours) in soil [redacted], [redacted], [redacted] 4a and [redacted], respectively.

It is concluded that trifloxystrobin and its degradation products have no potential for accumulation in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled trifloxystrobin
Certificate of Analysis: AZ 15228
Batch Code: AE C642802 00 1B98 00002
Chemical Purity: 99.6% w/w

2. Test Soils

Four soils were used (see [Table 7.1.2.11](#), 1). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled freshly from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2.1.1- 1: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation	[REDACTED]	[REDACTED]	[REDACTED] 4a	[REDACTED]
Geographic Location				
City	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambudoll	loamy, mixed, mesic, Typic Argudalf	fine loamy, mixed, acidic, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USDA)	sandy loam	sandy loam	silt loam	clay loam
Sand [50 µm – 2 mm]	53%	75%	15%	41%
Silt [2 µm – 50 µm]	30%	16%	70%	26%
Clay [< 2 µm]	17%	9%	15%	33%
pH (soil/0.01 M CaCl ₂ 1/2)	5.1	5.9	6.2	7.1
pH (soil/water 1/1)	5.3	6.1	6	7.2
pH (saturated paste)	5.3	6.1	6.4	7.2
pH (soil/1 N KCl 1/1)	4.7	5.6	5.8	6.8
Organic Carbon	1.8%	1.5%	1.6%	4.8%
Organic Matter ¹	3.1%	2.6%	2.8%	8.3%
Cation Exchange Capacity [meq/100 g]	10.6	8.7	11.7	20.7
Water Holding Capacity				
maximum [g H ₂ O / 100 g soil DW]	55.0	42.7	54.8	81.6
at 0.1 bar (pF 2.0)	26.8%	14.7%	32.5%	36.1%
Bulk Density (disturbed) [g/cm ³]	1.16	1.26	1.09	0.97
Microbial Biomass [mg microbial carbon per kg soil DW] ²				
DAT-0 (BIO-) ³	267	188	231	942
DAT-58 (BIO- / BIO+)	493 / 563	398 / 392	424 / 496	1948 / 1885
DAT-120 (BIO- / BIO+)	390 / 449	298 / 328	338 / 428	1731 / 1575

¹ % organic matter = % organic carbon x 1.724

² BIO- samples were left untreated, BIO+ samples were applied with solvent of application solution (400 µL acetone/water 1/1 (v/v)).

³ The values determined at DAT-0 are too low compared to DAT-58 and DAT-120, but the reason is unclear. However, determinations of microbial biomass demonstrated that the used soils were microbial viable.

DAT: days after treatment

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a polyurethane (PU) foam plug allowing for oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with PU foam plugs and equilibrated to study conditions for 10 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 187.5 g per hectare, resulting in a nominal SAR of $500 \mu\text{g}$ trifloxystrobin per kg soil dry weight.

The test item was applied dropwise onto the soil surface of the respective test systems in $400 \mu\text{L}$ acetone/water 1/1 (v/v) using a pipette. After application, the test vessels (except DAT-0, DAT-0.08 and DAT-0.25 samples) were closed with PU foam plugs.

The test systems were incubated in the dark for 120 days at 20.1°C and a soil moisture of 53.4% MWHC in a walk-in climatic chamber.

2. Sampling

11 sampling intervals were distributed over the entire incubation period of 120 days. Duplicate samples were processed and analysed 0, 0.08, 0.25, 1, 3, 7, 14, 30, 58, 93 and 120 days after treatment (DAT). Microbial soil biomass was determined at start, middle and end of the study (DAT-0, DAT-58 and DAT-120).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil (██████████) with test item trifloxystrobin and reference items CGA 321113, NOA 413161 and CGA 357276 at LOQ level (corresponding to 3% of the nominal SAR (test item equivalents)) and application rate level (corresponding to 100%, 100%, 50% and 50% of the nominal SAR (test item equivalents)) for trifloxystrobin, CGA 321113, NOA 413161 and CGA 357276, respectively. Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker and acetonitrile/water 4/1 (v/v). Furthermore, two accelerated extraction steps using a microwave with a magnetic stirrer were performed, first with acetonitrile/water 1/1 (v/v) at 70°C and second with methanol/water 1/1 (v/v) at 50°C . After each extraction step, extract and soil were separated by centrifugation ($2560 \times g$) and decantation. The soil extracts were combined, internal stable-labelled standards (ISTDs) added (nominal concentrations of ISTDs were 10% of the nominal SAR (test item equivalents)) and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in selected reaction monitoring mode. Concurrent recovery samples were processed and analysed analogously. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC-MS/MS analysis of the combined soil extracts corresponded to 1 and 3% of the nominal SAR (test item equivalents), respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization selected reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent. Therefore, multi-point calibration curves using ISTDs were established covering a range from 1% to 120%, 120%, 60% and 60% of the nominal SAR (test item equivalents) for trifloxystrobin, CGA 321113, NOA 413161¹ and CGA 357276, respectively. The nominal concentrations of the ISTDs were 10% of the nominal SAR (test item equivalents). The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with test item trifloxystrobin and reference items CGA 321113, NOA 413161, and CGA 357276 at LOQ level (corresponding to 3% of the nominal SAR (test item equivalents)) and application rate level (corresponding to 100%, 100%, 50% and 50% of the nominal SAR (test item equivalents) for trifloxystrobin, CGA 321113, NOA 413161 and CGA 357276, respectively). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT=0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the χ^2 scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameter.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 7.1.2.1.1- 2: Degradation of trifloxystrobin in soil [redacted] under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	93	120
trifloxystrobin	Mean	103.8	67.3	41.9	8.8	3.2	2.0	1.6	1.4	<LOD	<LOD	<LOD
	SD	±0.3	±1.7	±0.3	±0.5	±0.1	±0.0	±0.1	±0.1			
CGA 321113	Mean	<LOD	34.9	71.1	91.1	92.0	86.4	79.2	70.1	49.4	40.3	34.5
	SD		±1.1	±2.8	±3.5	±0.3	±0.5	±1.8	±3.5	±0.3	±1.6	±0.6
NOA 413161	Mean	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	1.7	2.8	4.5	5.3	5.3
	SD							±0.1	±0.4	±0.1	±0.4	±0.0
CGA 357276	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	1.2	1.6	2.0	2.4
	SD								±0.1	±0.0	±0.0	±0.2

n.d.: not detected; DAT: days after treatment, SD: standard deviation

¹ trifloxystrobin equivalents



Table 7.1.2.1.1- 3: Degradation of trifloxystrobin in soil [redacted] under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean ¹ SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	93	120
trifloxystrobin	Mean	99.4	68.9	34.7	13.7	4.7	3.1	2.3	1.6	1.4	1.2	<LOD
	SD	±0.9	±0.8	±1.5	±0.1	±0.4	±0.1	±0.0	±0.0	±0.1	±0.0	
CGA 321113	Mean	<LOD	34.7	63.1	92.9	96.9	88.7	82.9	73.4	55.5	41.8	34.9
	SD		±1.2	±0.3	±1.7	±0.8	±0.5	±0.0	±0.2	±0.2	±0.2	±0.8
NOA 413161	Mean	<LOD	<LOD	n.d.	<LOD	<LOD	<LOD	1.8	3.5	4.5	4.9	4.5
	SD							±0.0	±0.0	±0.0	±0.2	±0.2
CGA 357276	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	1.0	1.0	1.0
	SD									±0.1	±0.0	±0.1

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ trifloxystrobin equivalents

Table 7.1.2.1.1- 4: Degradation of trifloxystrobin in soil [redacted] 4a under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean ¹ SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	93	120
trifloxystrobin	Mean	102.8	74.6	43.7	17.5	5.7	3.0	3.1	2.0	1.3	<LOD	<LOD
	SD	±0.0	±0.7	±1.4	±2.2	±0.5	±0.2	±0.4	±0.3	±0.2		
CGA 321113	Mean	<LOD	28.4	59.9	91.4	91.6	87.5	84.4	70.4	50.2	30.0	23.5
	SD		±0.1	±1.4	±1.7	±0.8	±0.1	±0.2	±0.4	±1.6	±0.6	±1.2
NOA 413161	Mean	n.d.	n.d.	n.d.	<LOD	<LOD	1.1	1.0	3.4	3.6	3.6	3.1
	SD						±0.1	±0.1	±0.0	±0.2	±0.0	±0.3
CGA 357276	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	<LOD	1.0
	SD											±0.0

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ trifloxystrobin equivalents

Table 7.1.2.1.1- 5: Degradation of trifloxystrobin in soil [redacted] under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean ¹ SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	93	120
trifloxystrobin	Mean	100.3	80.3	55.9	19.7	5.0	2.0	1.2	<LOD	<LOD	<LOD	<LOD
	SD	±1.5	±2.0	±1.9	±0.5	±0.3	±0.1	±0.1				
CGA 321113	Mean	<LOD	20.4	43.6	81.2	91.5	87.6	84.1	72.1	54.7	43.3	36.4
	SD		±1.3	±1.5	±1.2	±0.5	±1.3	±1.0	±0.1	±0.5	±1.0	±0.5
NOA 413161	Mean	n.d.	n.d.	n.d.	<LOD	<LOD	1.1	2.3	3.4	4.2	4.2	3.8
	SD						±0.1	±0.1	±0.0	±0.0	±0.0	±0.1
CGA 357276	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	SD											

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ trifloxystrobin equivalents



B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficients (R^2) of the multi-point calibration curves ranged from 0.9999 to 0.0000. The recovery rates ranged from 91.5 to 109.3% of applied amount [% AA] for all soils, analytes and concentrations. The relative standard deviations for each recovery set ranged from 0.7 to 4.0%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 30% of the limit of quantitation in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recoveries were 101.5% AA (range from 96.2 to 114.1% AA) for trifloxystrobin, 102.1% AA (range from 97.1 to 110.0% AA) for CGA 321113, 100.5% AA (range from 94.5 to 108.1% AA) for NOA 413161 and 100.8% AA (range from 96.2 to 110.7% AA) for CGA 357276.

C. DEGRADATION OF PARENT COMPOUND

The amount of trifloxystrobin in the soil extracts decreased from 103.8, 99.4, 102.8 and 100.3% AA at study start (DAT-0) to < LOD (limit of detection) at DAT-58, DAT-120 (study end), DAT-93 and DAT-30 in soils [redacted], [redacted], [redacted] 4a and [redacted]. Degradation of trifloxystrobin was accompanied by the formation of its degradation products CGA 321113, NOA 413161 and CGA 357276.

CGA 321113 amounted to maxima (trifloxystrobin equivalents) of 92.0% AA (DAT-3), 96.9% AA (DAT-3), 91.6% AA (DAT-3) and 91.5% AA (DAT-3) in soils [redacted], [redacted] 4a and [redacted], respectively.

NOA 413161 amounted to maxima (trifloxystrobin equivalents) of 5.3% AA (DAT-93 and DAT-120), 4.9% AA (DAT-93), 3.6% AA (DAT-58 and DAT-93) and 4.2% AA (DAT-58 and DAT-93) in soils [redacted], [redacted] 4a and [redacted], respectively.

CGA 357276 amounted to maxima (trifloxystrobin equivalents) of 2.4% AA (DAT-120), 1.9% AA (DAT-120) and 1.0% AA (DAT-120) in soils [redacted], [redacted] and [redacted] 4a, respectively. In soil [redacted] the amounts of CGA 357276 were < LOD for all sampling intervals.

The degradation of trifloxystrobin followed double first order in parallel (DFOP) kinetics in soil [redacted] and first order multi-compartment (FOMC) kinetics in soils [redacted], [redacted] 4a and [redacted] according to the lowest χ^2 error values and visual assessments. [Table 7.2.1.6](#) summarizes the best-fit results of the DT_{50} and DT_{90} calculations.



Table 7.1.2.1.1- 6: Best-fit degradation kinetics of trifloxystrobin in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	Visual Assessment ²
	DFOP	0.1	0.7	3.1	+
	FOMC	0.2	1.3	6.9	+
4a	FOMC	0.2	1.8	3.8	+
	FOMC	0.3	1.8	0.9	+

¹ FOMC: first order multi compartment, DFOP: double first order in parallel

² visual assessment: + = good

III. CONCLUSIONS

Trifloxystrobin was rapidly degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-lives were between 0.1 and 0.3 days (corresponding to approximately 1 to 7 hours) in the tested soils. The major degradation products CGA 321113 and NOA 413164 were formed and declined towards study end.

It is concluded that trifloxystrobin and its degradation products have no potential for accumulation in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.1.1; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa_13-074
Document No:	M-467655-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	%
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033459-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /04 and KCA 7.1.2.1.2 /04) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted] under aerobic conditions in the dark in the laboratory at different temperatures (20 and 10 °C), soil moistures (60 and 30% of the field capacity at 1/3 bar (FC)) and test concentrations (1.0 and 0.1 mg/kg).

Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The half-life of trifloxystrobin was 0.49 days (20 °C, 60% FC, 1.0 mg/kg), 0.89 days (20 °C, 30% FC, 1.0 mg/kg), 1.05 days (10 °C, 60% FC, 1.0 mg/kg) and 0.64 days (20 °C, 60% FC, 0.1 mg/kg).

I. METHODS

Soil residue data from the aerobic soil degradation study M-033459-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /04 and KCA 7.1.2.1.2 /04) were used. In this study, the degradation of trifloxystrobin was studied in soil [REDACTED] (silt loam) under aerobic conditions in the dark in the laboratory for up to 287 days at different temperatures (20 and 10 °C), soil moistures (60 and 30% of the field capacity at 1/3 bar) and test concentrations (1.0 and 0.1 mg/kg).

The kinetic analysis was performed according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fit, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀/3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.

II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [REDACTED]. Table 7.1.2.1.1- 7 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 7: Kinetic parameters for the degradation of trifloxystrobin in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test ³	Visual Assessment ⁴
[REDACTED] A	FOMC	0.49	2.2	4.16 x 10 ⁻⁸	+
[REDACTED] B ⁶	FOMC	0.89	5.7	1.44 x 10 ⁻⁴	+
[REDACTED] C ⁷	FOMC	1.05	10.6	2.28 x 10 ⁻⁵	+
[REDACTED] D ⁸	FOMC	0.64	5.6	2.77 x 10 ⁻⁶	+

¹ FOMC: first order multi compartment

² for FOMC: DT₅₀ was not calculated as DT₉₀/3.32, DT₅₀ is based on fit of the decline curve

³ for FOMC worst case value of rate parameters alpha and beta

⁴ visual assessment: + = good

⁵ 20 °C, 60% of the field capacity at 1/3 bar, 1.0 mg/kg

⁶ 20 °C, 30% of the field capacity at 1/3 bar, 1.0 mg/kg

⁷ 10 °C, 60% of the field capacity at 1/3 bar, 1.0 mg/kg

⁸ 20 °C, 60% of the field capacity at 1/3 bar, 0.1 mg/kg

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory were between 0.49 and 1.05 days in the tested soils.



The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.1 /12; [REDACTED]; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0716
Document No:	M-467663-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033453-01-1 (Baseline Dossier, KCA 7.1.2.1.1/05 and KCA 7.1.2.1.2/05) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soils [REDACTED] and [REDACTED] under aerobic conditions in the dark in the laboratory at 20 °C, 40% of the maximum water holding capacity and a test concentration of 1.0 mg/kg.

The half-life of trifloxystrobin was 0.57 days in soil [REDACTED], 0.75 days in soil [REDACTED] and 0.58 days in soil [REDACTED].

I. METHODS

Soil residue data from the aerobic soil degradation study M-033453-01-1 (Baseline Dossier, KCA 7.1.2.1.1/05 and KCA 7.1.2.1.2/05) were used. In this study, the degradation of trifloxystrobin was studied in soils [REDACTED] (loamy sand), [REDACTED] (loamy sand) and [REDACTED] (sandy loam) under aerobic conditions in the dark in the laboratory for up to 204 days at 20 °C, 40% of the maximum water holding capacity and a test concentration of 1.0 mg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀/3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.

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II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soils [redacted], [redacted] and [redacted]. Table 7.1.2.1.1- 8 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 8: Kinetic parameters for the degradation of trifloxystrobin in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test ³	Visual Assessment
[redacted]	FOMC	0.58	11.9	1.99 x 10 ⁻⁵	+
[redacted]	FOMC	0.73	5.4	1.00 x 10 ⁻⁵	+
[redacted]	FOMC	0.58	4.2	3.48 x 10 ⁻⁹	+

¹ FOMC: first order multi compartment

² for FOMC: DT₅₀ was not calculated as DT₉₀/3.32, DT₅₀ is based on A_t of the decline curve

³ for FOMC: worst case value of rate parameters alpha and beta

⁴ visual assessment: + = good

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory were between 0.5 and 0.73 days in the tested soils.

Report:	KCA 7.1.2.1.1 /13; [redacted]; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0717
Document No:	M-467664-01
Guidelines:	- FOCUS kinetics (2006)
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-073242-01-1 (Baseline Dossier, KCA 7.1.2.1.1/08) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

Double first order in parallel was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted] under aerobic conditions in the dark in the laboratory at 20 °C, 40% of the maximum water holding capacity and a test concentration of 337 µg/kg.



The half-life of trifloxystrobin was 4.35 days.

I. METHODS

Soil residue data from the aerobic soil degradation study M-073242-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /08) were used. In this study, the degradation of trifloxystrobin was studied in soil [redacted] (sandy loam) under aerobic conditions in the dark in the laboratory for 120 days at 20 °C, 40% of the maximum water holding capacity and a test concentration of 337 µg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi²-scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the double first order in parallel model was not calculated from the slow k-rate as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.

II. RESULTS

Double first order in parallel (DFOP) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted]. Table 7.1.2.1.1- 9 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 9: Kinetic parameters for the degradation of trifloxystrobin in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test	Visual Assessment ³
[redacted]	DFOP	4.35	0.0	k ₂ : < 2 x 10 ⁻¹⁶	+

¹ DFOP: double first order in parallel

² for DFOP: DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve

³ visual assessment: + good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory was 4.35 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.1 /14; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0718
Document No:	M-468172-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033008-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /01 and KCA 7.1.2.1.2 /01) was performed, with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [REDACTED] under aerobic conditions in the dark in the laboratory at 19 °C, 75% of the field capacity and a test concentration of 1.0 mg/kg.

The half-life of trifloxystrobin was 0.49 day.

1. METHODS

Soil residue data from the aerobic soil degradation study M-033008-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /01 and KCA 7.1.2.1.2 /01) were used. In this study, the degradation of trifloxystrobin was studied in soil [REDACTED] (silt loam) under aerobic conditions in the dark in the laboratory for 364 days at 19 °C, 75% of the field capacity and a test concentration of 1.0 mg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀/3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.



II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted]. Table 7.1.2.1.1- 10 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 10: Kinetic parameters for the degradation of trifloxystrobin in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test ³	Visual Assessment
[redacted]	FOMC	0.49	5.1	7.4 x 10 ⁻⁶	+

¹ FOMC: first order multi compartment

² for FOMC: DT₅₀ was not calculated as DT₅₀ = 3.32 / DT₅₀ is based on fit of the decline curve

³ for FOMC: worst case value of rate parameters alpha and beta

⁴ visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory was 0.49 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.1/15; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI Tool
Report No:	EnSa-13-0719
Document No:	M-468202-01-1
Guidelines:	- FOCUS Kinetics (2006) ¹
GLP:	0
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033147-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /02 and KCA 7.1.2.1.2 /02) was performed with the software KinGUI 2 according to FOCUS Kinetics (2006)¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted] under aerobic conditions in the dark in the laboratory at 19 °C, 75% of the field capacity and a test concentration of 1.0 mg/kg.

The half-life of trifloxystrobin was 0.41 days.



I. METHODS

Soil residue data from the aerobic soil degradation study M-033147-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /02 and KCA 7.1.2.1.2 /02) were used. In this study, the degradation of trifloxystrobin was studied in soil [redacted] (loam) under aerobic conditions in the dark in the laboratory for 365 days at 19 °C, 75% of the field capacity and a test concentration of 1.0 mg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model.

II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted]. Table 7.1.2.1.1- 11 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 11: Kinetic parameters for the degradation of trifloxystrobin in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	0.41	7	< 2 x 10 ⁻¹⁶	o

¹ SFO: single first order

² visual assessment: o = moderate

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory was 0.41 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.1 /16; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolites under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0720
Document No:	M-468203-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation products CGA 321113 and CGA 357276 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033394-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /03 and KCA 7.1.2.1.2 /03) was performed, with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation products CGA 321113 and CGA 357276 as well as formation fractions for CGA 321113 and CGA 357276, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [REDACTED] under aerobic conditions in the dark in the laboratory at 25 °C, 75% of the field capacity at 1/3 bar and a test concentration of 0.5 mg/kg.

The half-life of trifloxystrobin was 0.85 days.

I. METHODS

Soil residue data from the aerobic soil degradation study M-033394-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /03 and KCA 7.1.2.1.2 /03) were used. In this study, the degradation of trifloxystrobin was studied in soil [REDACTED] (loam) under aerobic conditions in the dark in the laboratory for 365 days at 25 °C, 75% of the field capacity at 1/3 bar and a test concentration of 0.5 mg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀/3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.



II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted]. Table 7.1.2.1.1- 12 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 12: Kinetic parameters for the degradation of trifloxystrobin in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test ³	Visual Assessment
[redacted]	FOMC	0.35	7.9	2.79 x 10 ⁻⁴	+

¹ FOMC: first order multi compartment

² for FOMC: DT₅₀ was not calculated as DT₅₀ = 3.32 / DT₅₀ is based on fit of the decline curve

³ for FOMC: worst case value of rate parameters alpha and beta

⁴ visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory was 0.35 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.1/17; [redacted]; [redacted], 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI Tool
Report No:	EnSa-13-07213
Document No:	M-468174-01-1
Guidelines:	- FOCUS Kinetics (2006) ¹
GLP:	0
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033464-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /07 and KCA 7.1.2.1.2 /07) was performed with the software KinGUI 2 according to FOCUS Kinetics (2006)¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soils [redacted] and [redacted] under aerobic conditions in the dark in the laboratory at 19.2 °C, 40% of the maximum water holding capacity and test concentrations of 0.3 and 1.0 mg/kg.

The half-life of trifloxystrobin was 0.34(0.3 mg/kg) and 40 days (1.0 mg/kg) in soil [redacted] and 0.44 days in soil [redacted].



I. METHODS

Soil residue data from the aerobic soil degradation study M-033464-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /07 and KCA 7.1.2.1.2 /07) were used. In this study, the degradation of trifloxystrobin was studied in soils [redacted] (sandy loam) and [redacted] (loamy sand) under aerobic conditions in the dark in the laboratory for 105 days at 19.2 °C, 40% of the maximum water holding capacity and test concentrations of 0.3 and 1.0 mg/kg..

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, χ^2 -scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀ 3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.

II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soils [redacted] and [redacted]. Table 7.1.2.1.1- 13 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 13: Kinetic parameters for the degradation of trifloxystrobin in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² -Error [%]	t-test ³	Visual Assessment ⁴
[redacted]	FOMC	0.34	2.5	2.05 x 10 ⁻⁶	+
B ⁶	FOMC	0.40	4.1	1.85 x 10 ⁻⁵	+
[redacted]	FOMC	0.44	4.8	1.37 x 10 ⁻⁶	+

¹ FOMC: first order multi compartment

² for FOMC: DT₅₀ was not calculated as DT₉₀ 3.32, DT₅₀ is based on fit of the decline curve

³ for FOMC: worst case value of rate parameters alpha and beta

⁴ Visual assessment: + = good.

⁵ test concentration of 0.3 mg/kg

⁶ test concentration of 1.0 mg/kg

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory were between 0.34 and 0.44 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.1 /18; [REDACTED]; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolites under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0724
Document No:	M-467669-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation products CGA 321113, NOA 413161 and CGA 357276 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-464420-01-1 (Supplemental Dossier, KCA 7.1.2.1.1 /10) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation products CGA 321113, NOA 413161 and CGA 357276 as well as formation fractions for CGA 321113, NOA 413161 and CGA 357276, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soils [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED] under aerobic conditions in the dark in the laboratory at 20.1 °C, 53.4% of the maximum water holding capacity and a test concentration of 480 µg/kg.

The half-life of trifloxystrobin was 0.13 days in soil [REDACTED], 0.15 days in soil [REDACTED], 0.19 days in soil [REDACTED] 4a and 0.30 days in soil [REDACTED].

I. METHODS

Soil residue data from the aerobic soil degradation study M-464420-01-1 (Supplemental Dossier, KCA 7.1.2.1.1 /10) were used. In this study, the degradation of trifloxystrobin was studied in soils [REDACTED] (sandy loam), [REDACTED] (sandy loam), [REDACTED] 4a (silt loam) and [REDACTED] (clay loam) under aerobic conditions in the dark in the laboratory for 120 days at 20.1 °C, 53.4% of the maximum water holding capacity and a test concentration of 480 µg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, χ^2 scaled error criterion, t-test, significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀/3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.



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II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soils [redacted], [redacted] and [redacted] 4a and [redacted]. Table 7.1.2.1.1- 14 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 14: Kinetic parameters for the degradation of trifloxystrobin in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test	Visual Assessment
[redacted]	FOMC	0.13 ³	4.3	1.67 x 10 ⁻¹¹	+
[redacted]	FOMC	0.15	6.5	8.54 x 10 ⁻¹¹	+
[redacted] 4a	FOMC	0.19	5	4.74 x 10 ⁻¹⁶	+
[redacted]	FOMC	0.30	1.4	1.25 x 10 ⁻¹¹	+

¹ FOMC: first order multi compartment

² for FOMC: DT₅₀ was not calculated as DT₉₀ is 32, DT₅₀ is based on all of the decline curve

³ for FOMC: worst case value of rate parameters alpha and beta

⁴ visual assessment: + = good

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory were between 0.13 and 0.30 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.1 /19; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnS-13-073
Document No:	M-068177-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aged residues column leaching / aerobic soil degradation study M-033599-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /06 and KCA 7.1.2.1.2 /06) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted] and first order multi compartment in soil [redacted] under aerobic conditions in the dark in the laboratory at 20 °C, different soil moistures (75% of the field capacity at 1/3 bar for soil [redacted] and 40% of the maximum water holding capacity for soil [redacted]) and a test concentration of 1.0 mg/kg.

The half-life of trifloxystrobin was 0.82 days in soil [redacted] and 0.46 days in soil [redacted].

I. METHODS

Soil residue data from the aged residues column leaching/aerobic soil degradation study M-033599-01-1 (Baseline Dossier, KCA 7.1.2.01/06 and KCA 7.02.1.2/06) were used. In this study, the degradation of trifloxystrobin was studied in soils [redacted] (silty loam) and [redacted] (loamy sand) under aerobic conditions in the dark in the laboratory for 230 days at 20 °C, different soil moistures (75% of the field capacity at 1/3 bar for soil [redacted] and 40% of the maximum water holding capacity for soil [redacted]) and a test concentration of 1.0 mg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the first order multi compartment model was not calculated as DT₉₀/3.32 as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound which however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated value from KinGUI 2.

II. RESULTS

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil [redacted] and first order multi compartment in soil [redacted]. Table 7.1.2.1.1- 15 summarizes the results of the kinetic analysis.

Table 7.1.2.1.1- 15: Kinetic parameters for the degradation of trifloxystrobin in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ ² [days]	Chi ² Error [%]	t-test ³	Visual Assessment ⁴
[redacted]	SFO	0.82	4.6	1.76 x 10 ⁻¹²	+
[redacted]	FOMC	0.46	3.6	1.43 x 10 ⁻³	+

¹ SFO: single first order, FOMC: first order multi compartment
² for FOMC, DT₅₀ was not calculated as DT₉₀/3.32, DT₅₀ is based on fit of the decline curve
³ for FOMC: worst case value of rate parameters alpha and beta
⁴ visual assessment: + = good



III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of trifloxystrobin in soil under aerobic conditions in the dark in the laboratory were between 0.46 and 0.82 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

CA 7.1.2.1.2 Aerobic degradation of metabolites, breakdown and reaction products

The degradation rates of the major degradation products CGA 320113 and NOA 413161 in soil under aerobic conditions in the dark in the laboratory were evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.2.1.2 /01	[REDACTED]	1997	M-033008-01-1
KCA 7.1.2.1.2 /02	[REDACTED]	1997	M-033147-01-1
KCA 7.1.2.1.2 /03	[REDACTED]	1997	M-033394-01-1
KCA 7.1.2.1.2 /04	[REDACTED]	1997	M-033459-01-1
KCA 7.1.2.1.2 /05	[REDACTED]	1997	M-033453-01-1
KCA 7.1.2.1.2 /06	[REDACTED]	1999	M-033599-01-1
KCA 7.1.2.1.2 /07	[REDACTED]	1997	M-033464-01-1
KCA 7.1.2.1.2 /08	[REDACTED]	2001	M-069897-01-1
KCA 7.1.2.1.2 /09	[REDACTED]	2001	M-068260-01-1

Six additional studies have been performed for major degradation products and are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using unlabelled CGA 357261, CGA 381318, NOA 413161, NOA 413163, CGA 357276 and NOA 409480. Furthermore, updated kinetic evaluations of the degradation behaviours of major degradation products in soil under aerobic conditions in the dark in the laboratory have been performed according to FOCUS kinetics (2006)¹ to derive kinetic parameters suitable for modelling purpose and environmental risk assessment. A summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory is given in section CA 7.1.2.1.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.2 /10; [REDACTED]; [REDACTED]; 2013
Title:	Formation Fraction of NOA 413163 from CGA 357261 in Four European Soils
Report No:	EnSa-12-0409
Document No:	M-459997-01-1
Guidelines:	- OECD Test Guideline No. 307
GLP:	Yes
Justification:	Determination of formation fraction in soil of major photodegradation product NOA 413163 for modelling purpose and degradation rates of major photodegradation products CGA 357261 and CGA 373466

Executive Summary

The formation fraction of NOA 413163 derived from CGA 357261, a photodegradation product of trifloxystrobin, was studied in four soils under aerobic conditions in the dark in the laboratory for 121 days at 20.2 °C and 55 ± 5% of the maximum water holding capacity.

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Monheim, Germany	sandy loam	5.9	1.8
[REDACTED]	Monheim, Germany	sandy loam	5.9	1.5
[REDACTED] 4a	Burscheid, Germany	silt loam	6.2	1.6
[REDACTED]	Blankenheim, Germany	clay loam	7.0	4.8

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

Additionally, kinetic data for a possible evaluation of the formation fractions of the trifloxystrobin photodegradation products CGA 373466 and NOA 409480, which are also derived from CGA 357261, were determined.

A study application rate of 494 µg CGA 357261 per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 187.5 g per hectare.

The amount of CGA 357261 in the soil extracts decreased from 100.6, 100.1, 98.4 and 99.0% of applied amount [% AA] at study start (DAT-0) to < LOD (limit of detection) at DAT-58, DAT-121 (study end), DAT-90 and DAT-30 in soils [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED]. Degradation of CGA 357261 was accompanied by the formation of its degradation products CGA 373466, NOA 413163 and NOA 409480.

CGA 373466 amounted to maxima (CGA 357261 equivalents) of 96.5% AA (DAT-1), 94.1% AA (DAT-1), 95.7% AA (DAT-1) and 96.6% AA (DAT-3) in soils [REDACTED], [REDACTED] [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

NOA 413163 amounted to maxima (CGA 357261 equivalents) of 12.2% AA (DAT-58), 9.6% AA (DAT-90), 5.9% AA (DAT-58) and 5.6% AA (DAT-58) in soils [REDACTED], [REDACTED] [REDACTED] 4a and [REDACTED], respectively.

NOA 409480 amounted to values above LOD only in soil [REDACTED] with maxima (CGA 357261 equivalents) of 1.1% AA (DAT-58 to DAT-121).



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The experimental data could be well described by a double first order in parallel kinetic model for soils [redacted], [redacted] and [redacted] 4a and a first order multi compartment kinetic model for soil [redacted]. The half-life of CGA 357261 under aerobic conditions was 0.1 days (corresponding to approximately 2 hours) in all soils.

It is concluded that CGA 357261 and its degradation products have no potential for accumulation in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled CGA 357261
Certificate of Analysis: AZ 17556
Batch Code: AE 1393224-PU-01
Chemical Purity: 99.4% w/w

2. Test Soils

Four soils were used (see Table 7.1.2.1.2- 1). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled freshly from the fields (upper horizon of 0 to 5 cm) and sieved to a particle size of 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2.1.2- 1: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation	[REDACTED]	[REDACTED]	[REDACTED] 4a	[REDACTED]
Geographic Location				
City	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambodoll	loamy, mixed, mesic, Typic Argudalf	fine-loamy, mixed, active, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USDA)	sandy loam	sandy loam	silt loam	clay loam
Sand [50 µm – 2 mm]	53%	5%	15%	41%
Silt [2 µm – 50 µm]	30%	16%	70%	26%
Clay [< 2 µm]	17%	9%	15%	33%
pH (soil/0.01 M CaCl ₂ 1/2)	5.9	5.9	6.2	7.1
pH (soil/water 1/1)	5.3	6.1	6.3	7.2
pH (saturated paste)	5.3	6.1	6.4	7.2
pH (soil/1 N KCl 1/2)	4.7	5.6	5.8	6.8
Organic Carbon	1.8%	1.5%	1.6%	4.8%
Organic Matter	3.1%	2.6%	2.8%	8.3%
Cation Exchange Capacity [meq/100 g]	10.9	8.9	11.7	20.7
Water Holding Capacity maximum [g H ₂ O added/100 g soil DW] at 0.1 bar (pF 2.0)	55.0	42.6	54.8	81.6
	26.9%	14.7%	32.5%	36.1%
Bulk Density (disturbed) [g/cm ³]	1.06	1.26	1.09	0.97
Microbial Biomass [mg microbial carbon per kg soil DW] ²				
DAT-0 (BIO-) ³	323	253	378	1074
DAT-5 (BIO- / BIO+)	333 / 568	393 / 404	377 / 461	1954 / 1377
DAT-21 (BIO- / BIO+)	315 / 327	274 / 252	276 / 314	356 / 348

¹ % organic matter = % organic carbon x 1.24

² BIO- samples were left untreated, BIO+ samples were applied with solvent of application solution (400 µL acetone/water 2/1 (v/v)).

³ Due to an experimental error, the samples were shaken at a lower velocity. This was considered in the calculation of the microbial biomass.

DAT: days after treatment

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a polyurethane (PU) foam plug allowing for oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with PU foam plugs and equilibrated to study conditions for 4 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 187.5 g per hectare, resulting in a nominal SAR of $500 \mu\text{g CGA 357261 per kg soil dry weight}$.

The test item was applied dropwise onto the soil surface of the respective test systems in $400 \mu\text{L acetone/water 1/1 (v/v)}$ using a pipette. After application, the test vessels (except DAT-0, DAT-0.08 and DAT-0.25 samples) were closed with PU foam plugs.

The test systems were incubated in the dark for 121 days at 20.2°C and a soil moisture of $55 \pm 5\%$ MWHC in a walk-in climatic chamber.

2. Sampling

11 sampling intervals were distributed over the entire incubation period of 121 days. Duplicate samples were processed and analysed 0, 0.08, 0.25, 1, 3, 7, 14, 30, 58, 90 and 121 days after treatment (DAT). Microbial soil biomass was determined at start, middle and end of the study (DAT-0, DAT-58 and DAT-121).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil (██████████) with test item CGA 357261 and reference items CGA 373466, NOA 413163 and NOA 409480 at LOQ level (corresponding to 3% of the nominal SAR (test item equivalents)) and application rate level (corresponding to 100%, 100%, 50% and 50% of the nominal SAR (test item equivalents) for CGA 357261, CGA 373466, NOA 413163 and NOA 409480, respectively). Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker and acetonitrile/water 4/1 (v/v). Furthermore, two accelerated extraction steps using a microwave with a magnetic stirrer were performed, first with acetonitrile/water 1/1 (v/v) at 70°C and second with methanol/water 1/1 (v/v) at 50°C . After each extraction step, extract and soil were separated by centrifugation ($2560 \times g$) and decantation. The soil extracts were combined, internal stable-labelled standards (ISTDs) added (nominal concentrations of ISTDs were 10% of the nominal SAR (test item equivalents)) and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in selected reaction monitoring mode. Concurrent recovery samples were processed and analysed analogously. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC-MS/MS analysis of the combined soil extracts corresponded to 1 and 3% of the nominal SAR (test item equivalents), respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization selected reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent. Therefore, multi-point calibration curves using ISTDs were established covering a range from 1% to 120%, 120%, 60% and 60% of the nominal SAR (test item equivalents) for CGA 357261, CGA 373466, NOA 413163 and NOA 409480, respectively. The nominal concentrations of the ISTDs were 10% of the nominal SAR (test item equivalents). The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with test item CGA 357261 and reference items CGA 373466, NOA 413163 and NOA 409480 at LOQ level (corresponding to 3% of the nominal SAR (test item equivalents)) and application rate level (corresponding to 100%, 100%, 50% and 50% of the nominal SAR (test item equivalents) for CGA 357261, CGA 373466, NOA 413163 and NOA 409480, respectively). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT=0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the χ^2 scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT_{50} and DT_{90} values were calculated from the resulting kinetic parameter.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 1.2.1.2- 2: Degradation of CGA 357261 in soil [redacted] under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	90	121
CGA 357261	Mean	100.6	3.2	1.1	0.3	0.1	2.0	1.5	1.0	<LOD	<LOD	<LOD
	SD	±0.5	±0.8	±0.3	±0.2	±0.0	±0.4	±0.3	±0.1			
CGA 373466	Mean	<LOD	58.2	91.9	96.5	92.2	84.7	66.9	47.9	28.7	17.4	12.5
	SD		±0.5	±0.1	±0.6	±1.2	±1.1	±0.2	±0.6	±0.7	±0.0	±0.0
NOA 413163	Mean	n.d.	n.d.	LOD	LOD	1.2	3.8	5.5	9.6	12.2	11.0	10.6
	SD					±0.1	±0.3	±0.2	±0.1	±0.9	±0.4	±1.0
NOA 409480	Mean	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	<LOD	1.1	1.1	1.1
	SD									±0.1	±0.0	±0.0

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ CGA 357261 equivalents



Table 7.1.2.1.2- 3: Degradation of CGA 357261 in soil [redacted] under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean ¹ SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	90	121
CGA 357261	Mean	100.1	48.2	14.2	6.3	4.0	2.8	2.6	2.1	1.4	1.4	<LOD
	SD	±2.1	±1.1	±0.1	±0.0	±0.2	±0.1	±0.5	±0.2	±0.2	±0.2	
CGA 373466	Mean	<LOD	54.1	90.2	94.1	93.7	90.2	77.3	62.9	39.8	26.0	17.0
	SD		±1.2	±0.9	±1.3	±0.0	±1.5	±0.5	±0.2	±0.1	±0.8	±0.2
NOA 413163	Mean	n.d.	n.d.	<LOD	<LOD	4.1	2.7	4.6	7.3	9.2	9.6	8.6
	SD					±0.1	±0.1	±0.1	±0.1	±0.3	±0.0	±0.3
NOA 409480	Mean	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	SD											

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ CGA 357261 equivalents

Table 7.1.2.1.2- 4: Degradation of CGA 357261 in soil [redacted] 4a under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean ¹ SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	90	121
CGA 357261	Mean	98.4	49.9	16.2	6.4	3.9	2.3	1.7	1.4	1.1	<LOD	<LOD
	SD	±0.6	±0.3	±1.0	±0.2	±0.5	±0.3	±0.0	±0.0	±0.1		
CGA 373466	Mean	<LOD	51.8	89.1	95.7	95.0	94.0	79.5	65.4	41.1	25.6	16.3
	SD		±1.9	±0.3	±0.6	±0.1	±0.7	±0.7	±0.2	±0.6	±0.2	±0.2
NOA 413163	Mean	n.d.	n.d.	<LOD	<LOD	<LOD	1.8	2.8	4.5	5.9	5.1	4.4
	SD						±0.3	±0.1	±0.0	±0.1	±0.0	±0.4
NOA 409480	Mean	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	SD											

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ CGA 357261 equivalents

Table 7.1.2.1.2- 5: Degradation of CGA 357261 in soil [redacted] under aerobic conditions (mean values and SD expressed as % AA)

Compound	Mean ¹ SD	DAT										
		0	0.08	0.25	1	3	7	14	30	58	90	121
CGA 357261	Mean	99.0	65.4	33.4	7.9	3.2	1.7	1.1	<LOD	<LOD	<LOD	<LOD
	SD	±1.6	±1.4	±1.1	±0.5	±0.1	±0.0	±0.0				
CGA 373466	Mean	<LOD	36.0	70.2	93.2	96.6	94.7	84.7	74.2	55.1	43.0	35.2
	SD		±1.2	±1.1	±1.6	±0.2	±1.3	±0.2	±0.3	±0.3	±0.1	±0.3
NOA 413163	Mean	n.d.	n.d.	<LOD	<LOD	n.d.	1.3	2.5	4.1	5.6	4.8	3.6
	SD						±0.1	±0.2	±0.1	±0.1	±0.1	±0.3
NOA 409480	Mean	n.d.	n.d.	n.d.	n.d.	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	SD											

n.d.: not detected, DAT: days after treatment, SD: standard deviation

¹ CGA 357261 equivalents



B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficients (R^2) of the multi-point calibration curves ranged from 0.9997 to 0.0000. The recovery rates ranged from 72.5 to 113.7% of applied amount [% AA] for all soils, analytes and concentrations. The relative standard deviations for each recovery set ranged from 0.4 to 10.8%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 30% of the limit of quantitation in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recoveries were 99.6% AA (range from 95.1 to 103.5% AA) for CGA 357261, 100.2% AA (range from 97.1 to 105% AA) for CGA 373466, 92.7% AA (range from 76.0 to 103.6% AA) for NOA 413163 and 90.9% AA (range from 93.9 to 105.3% AA) for NOA 409480.

C. DEGRADATION OF PARENT COMPOUND

The amount of CGA 357261 in the soil extracts decreased from 100%, 100%, 98.4 and 99.0% AA at study start (DAT-0) to < LOD (limit of detection) at DAT-58, DAT-121 (study end), DAT-90 and DAT-30 days in soils [redacted] 4a and [redacted]. Degradation of CGA 357261 was accompanied by the formation of its degradation products CGA 373466, NOA 413163 and NOA 409480.

CGA 373466 amounted to maxima (CGA 357261 equivalents) of 96.5% AA (DAT-1), 94.1% AA (DAT-1), 95.7% AA (DAT-1) and 96.6% AA (DAT-3) in soils [redacted] 4a and [redacted], respectively.

NOA 413163 amounted to maxima (CGA 357261 equivalents) of 42.2% AA (DAT-58), 9.6% AA (DAT-90), 5.9% AA (DAT-58) and 5.5% AA (DAT-58) in soils [redacted] 4a and [redacted], respectively.

NOA 409480 amounted to values above LOD only in soil [redacted] with maxima (CGA 357261 equivalents) of 1.1% AA (DAT-58 to DAT-121).

The degradation of CGA 357261 followed double first order in parallel (DFOP) kinetics in soils [redacted] and [redacted] 4a and first order multi compartment (FOMC) kinetics in soil [redacted] according to the lowest χ^2 error values and visual assessments. [Table 7.1.2.02- 6](#) summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.



Table 7.1.2.1.2- 6: Best-fit degradation kinetics of CGA 357261 in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	Visual Assessment ²
	DFOP	0.1	0.3	4.0	+
	DFOP	0.1	0.3	4.3	+
4a	DFOP	0.1	0.4	3.4	+
	FOMC	0.1	0.9	2.5	+

¹ FOMC: first order multi compartment, DFOP: double first order in parallel

² visual assessment: + = good

III. CONCLUSIONS

CGA 357261, a major photodegradation product of trifloxystrobin, was rapidly degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-life was 0.1 days (corresponding to approximately 2 hours) in the tested soils. The major trifloxystrobin photodegradation products CGA 373466 and NOA 413163, which are derived from CGA 357261, were formed and declined towards study end.

It is concluded that CGA 357261 and its degradation products have no potential for accumulation in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 / 11; [redacted]; 2013
Title:	BCS-CU98569 (Sodium Salt of CGA 381318): Aerobic Degradation in Four European Soils
Report No.:	EnSa-12-067
Document No.:	M-462102/01-1
Guidelines:	- OECD Test Guideline No. 307 DRAFT SANCO 11802/2010 rev 1 in accordance with Regulation (EC) No 1107/2009
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rate of major photodegradation product CGA 381318

Executive Summary

The degradation rate of BCS-CU98569 (sodium salt of CGA 381318, a photodegradation product of trifloxystrobin) was studied in four soils under aerobic conditions in the dark in the laboratory for 122 days at 20.3 °C and 54.5% of the maximum water holding capacity:

Soil	Source	Texture (USDA)	pH *	OC [%]
	Monheim, Germany	sandy loam	5.2	1.9
	Monheim, Germany	loamy sand	5.9	1.8
4a	Burscheid, Germany	silt loam	6.2	2.2
	Blankenheim, Germany	loam	7.2	5.1

* pH value was derived from aqueous 0.01 M CaCl₂ suspension



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

A study application rate of 35.7 µg per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 187.5 g per hectare and a maximum formation of approximately 7% of CGA 381318 in a trifloxystrobin soil photolysis study.

The amount of BCS-CU98569 in the soil extracts decreased from study start (DAT-0) to study end (DAT-122) from 96.9 to 4.0% of applied amount [% AA] in soil [redacted], from 97.0 to 8.4% AA in soil [redacted], from 93.9 to 4.9% AA in soil [redacted] 4a and from 97.2 to 2.9% AA in soil [redacted].

The experimental data could be well described by a double first order, in parallel kinetic model for soils [redacted] and [redacted] and a single first order kinetic model for soils [redacted] 4a and [redacted]. The half-life of BCS-CU98569 under aerobic conditions was 11.3, 20.4, 22.8 and 20.4 days in soil [redacted] 4a and [redacted], respectively.

It is concluded that BCS-CU98569 and therefore also CGA 381318 have no potential for accumulation in the environment.

MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled BCS-CU98569 (sodium salt of CGA 381318)
Certificate of Analysis: AZ 73880
Batch Code: BCS-CU98569-PU-01
Chemical Purity: > 94% w/w

2. Test Soils

Four soils were used (see Table 7.1.2.1.2- 7). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled freshly from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2.1.2- 7: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation			4a	
Geographic Location				
City				
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates				
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambodoll	loamy, mixed, mesic, Typic Argudalf	fine-loamy, mixed, active, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USDA)	sandy loam	loamy sand	silt loam	loam
Sand [50 µm – 2 mm]	55%	29%	25%	39%
Silt [2 µm – 50 µm]	28%	14%	62%	36%
Clay [< 2 µm]	17%	7%	13%	25%
pH (soil/0.01 M CaCl ₂ 1/2)	5.5	5.9	6.2	7.2
pH (soil/water 1/1)	5.4	6.1	6.4	7.4
pH (saturated paste)	5.6	6.3	6.6	7.5
pH (soil/1 N KCl 1/2)	4.9	5.7	6.0	7.1
Organic Carbon	1.9%	1.8%	2.2%	5.1%
Organic Matter	3.3%	3.1%	3.8%	8.8%
Cation Exchange Capacity [meq/100 g]	10.1	9.4	11.3	20.0
Water Holding Capacity				
maximum [g H ₂ O added/100 g soil DW]	58.2	53.9	65.3	81.0
at 0.1 bar (pF 2.0)	20.1%	13.9%	29.9%	42.6%
Bulk Density (disturbed) [g/cm ³]	1.69	1.23	1.05	0.95
Microbial Biomass [mg microbial carbon per kg soil DW] ²				
DAT-0 (BIO-)	78	896	1156	2832
DAT-60 (BIO- / BIO+)	468 / 397	464 / 450	622 / 630	1904 / 1979
DAT-122 (BIO- / BIO+)	217 / 329	368 / 343	557 / 477	1867 / 2059

¹ % organic matter = % organic carbon x 1.724

² BIO- samples were applied with 200 µL water, BIO+ samples were applied with solvent of application solution (400 µL methanol/water 1/1 (v/v)).

DAT: days after treatment

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a polyurethane (PU) foam plug allowing for oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with PU foam plugs and equilibrated to study conditions for 3 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 187.5 g per hectare and a maximum formation of approximately 7% of CCA 381618 in soil photolysis study M-462074-01-1 (Supplemental Dossier, KCC 7.1.1.9/04), resulting in a nominal SAR of 36 μg BCS-CU98569 per kg soil dry weight.

The test item was applied dropwise onto the soil surface of the respective test systems in 400 μL methanol/water 1/1 (v/v) using a pipette. After application, the test vessels (except DAT-0 samples) were closed with PU foam plugs.

The test systems were incubated in the dark for 122 days at 20 $^{\circ}\text{C}$ and a soil moisture of 54.5% MWHC in a walk-in climatic chamber.

2. Sampling

Eight sampling intervals were distributed over the entire incubation period of 122 days. Duplicate samples were processed and analysed on 3, 7, 14, 30, 60, 91 and 122 days after treatment (DAT). Microbial soil biomass was determined at start, middle and end of the study (DAT-0, DAT-63 and DAT-122).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil () with the test item at LOQ level (corresponding to 5% of the nominal SAR) and application rate level (corresponding to 100% of the nominal SAR). Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker and acetonitrile/water 4/1 (v/v). Furthermore, two accelerated extraction steps using a microwave with a magnetic stirrer were performed, first with acetonitrile/water 1/1 (v/v) at 70 $^{\circ}\text{C}$ and second with methanol/water 1/1 (v/v) at 50 $^{\circ}\text{C}$. After each extraction step, extract and soil were separated by centrifugation ($>3000 \times g$) and decantation. The soil extracts were combined and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in selected reaction monitoring mode using matrix-matched external multi-point calibration curves. Concurrent recovery samples were processed and analysed analogously. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC-MS/MS analysis of the combined soil extracts corresponded to 1 and 5% of the nominal SAR, respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization selected reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent and in blank soil matrix solutions (matrix-matched). Therefore, multi-point external calibration curves were established covering a range from 1 to 125% of the nominal SAR. The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with the test item at LOQ level (corresponding to 5% of the nominal SAR) and at application rate level (corresponding to 100% of the nominal SAR). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 7.1.2.1.2.8: Degradation of BCS-CU98569 in soils under aerobic conditions (mean values and SD expressed as % AA)

Soil	Mean SD	DAT							
		0	14	30	60	91	122		
[Redacted]	Mean SD	96.9 ± 1.6	78.7 ± 0.7	61.4 ± 0.0	42.9 ± 2.6	16.0 ± 1.6	6.4 ± 0.4	4.1 ± 0.4	4.0 ± 0.2
[Redacted]	Mean SD	97.0 ± 0.8	86.6 ± 0.8	77.0 ± 0.3	60.8 ± 1.3	35.2 ± 1.4	16.8 ± 0.6	9.5 ± 0.7	8.4 ± 0.1
[Redacted]	Mean SD	93.9 ± 0.2	83.1 ± 0.4	71.4 ± 1.6	64.2 ± 0.2	34.4 ± 0.1	15.1 ± 0.9	7.1 ± 0.0	4.9 ± 0.2
[Redacted]	Mean SD	99.2 ± 0.3	89.2 ± 1.4	79.4 ± 0.4	65.1 ± 4.7	32.5 ± 5.0	11.3 ± 0.4	5.6 ± 1.0	2.9 ± 0.0

DAT: days after treatment, SD: standard deviation



B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficients (R^2) of the multi-point external calibration curves ranged from 0.9981 to 1.0000. The recovery rates ranged from 70.4 to 108.6% of applied amount [% AA] for all soils and concentrations. The relative standard deviations for each recovery set ranged from 0.7 to 5.7%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 30% of the LOQ in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recovery was 95.7% AA (range from 83.3 to 109.5% AA).

C. DEGRADATION OF PARENT COMPOUND

The amount of BCS-CU98569 (sodium salt of CGA 381318) in the soil extracts decreased from study start (DAT-0) to study end (DAT-129) from 96.9 to 4.0% AA in soil [redacted], from 97.0 to 8.4% AA in soil [redacted], from 93.9 to 4.9% AA in soil [redacted] 4a and from 97.2 to 2.9% AA in soil [redacted].

The degradation of BCS-CU98569 followed double first order in parallel (DFOP) kinetics in soils [redacted] and [redacted] and single first order (SFO) kinetics in soils [redacted] 4a and [redacted] according to the lowest χ^2 error values and visual assessments. Table 7.1.2.1.2-9 summarizes the best-fit results of the DT_{50} and DT_{90} calculations.

Table 7.1.2.1.2-9: Best-fit degradation kinetics of BCS-CU98569 in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-Fit Kinetic Model ¹	DT_{50} [days]	DT_{90} [days]	Chi ² Error [%]	Visual Assessment ²
[redacted]	DFOP	11.3	43.3	2.3	+
[redacted]	DFOP	20.4	95.7	1.6	+
[redacted] 4a	SFO	22.8	75.9	4.1	+
[redacted]	SFO	20.4	67.8	3.5	+

¹ SFO: single first order, DFOP: double first order in parallel

² visual assessment: + = good

III. CONCLUSIONS

BCS-CU98569 (sodium salt of CGA 381318, a major photodegradation product of trifloxystrobin) was well degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-lives were between 11.3 and 22.8 days in the tested soils.

It is concluded that BCS-CU98569 and therefore also CGA 381318 have no potential for accumulation in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



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Report:	KCA 7.1.2.1.2 /12; [redacted]; 2010
Title:	NOA 413161: Aerobic Degradation in Three European Soils
Report No:	MEF-09/460
Document No:	M-371172-01-1
Guidelines:	- OECD Test Guideline No. 307 - Commission Directive 95/36/EC amending Council Directive 91/414/EEC
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rate of major degradation product NOA 413161

Executive Summary

The degradation rate of NOA 413161, a degradation product of trifloxystrobin, was studied in three soils under aerobic conditions in the dark in the laboratory for 120 days at 20.0 °C and 52.9% of the maximum water holding capacity:

Soil	Source	Texture (USDA)	pH *	OC [%]
[redacted]	Monheim, Germany	sandy loam	5.2	2.0
[redacted] 4a	Burscheid, Germany	silt loam	6.5	2.5
[redacted]	Blankenheim, Germany	clay loam	7.1	5.0

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

A study application rate of 66.4 µg per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 250 g per hectare and a maximum formation of approximately 10% of NOA 413161.

The amount of NOA 413161 in the soil extracts decreased from study start (DAT-0) to study end (DAT-120) from 92.8 to 46.3% of applied amount [% AA] in soil [redacted], from 91.3 to 55.7% AA in soil [redacted] 4a and from 91.2 to 32.9% AA in soil [redacted].

The experimental data could be well described by a double first order in parallel kinetic model for all soils. The half-life of NOA 413161 under aerobic conditions was 82.8, 173 and 80.9 days in soil [redacted], [redacted] 4a and [redacted], respectively.

It is concluded that NOA 413161 will be degraded in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled NOA 413161
Certificate of Analysis: A-15123
Batch code: AE 1344143 00 1C92 0001
Chemical Purity: 91.8% w/w



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

2. Test Soils

Three soils were used (see Table 7.1.2.1.2- 10). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled fresh from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

Table 7.1.2.1.2- 10: Physico-chemical properties of test soils

Parameter	Results / Units		
Soil Designation	[redacted]	[redacted]	[redacted]
Geographic Location			
City	[redacted]	[redacted]	[redacted]
State	North-Rhine Westphalia Germany	North-Rhine Westphalia Germany	North-Rhine Westphalia Germany
Country	Germany	Germany	Germany
GPS Coordinates	[redacted]	[redacted]	[redacted]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	loamy, mixed, mesic, Typic Argudalf	no information available
Soil Series	no information available		
Textural Class (USDA)	sandy loam	silt loam	clay loam
Sand	53%	27%	29%
Silt	36%	54%	38%
Clay	19%	19%	33%
pH (soil/0.01 M CaCl ₂ 1/2)	5.3	6.7	7.1
pH (soil/water D1)	5.5	6.7	7.2
pH (saturated paste)	5.3	6.6	7.1
pH (soil/1 N KCl 1/1)	4.9	6.2	6.9
Organic Carbon	2.0%	2.5%	5.0%
Organic Matter ¹	3.4%	4.3%	8.6%
Cation Exchange Capacity [meq/100 g]	10.5	13.7	27.4
Water Holding Capacity maximum [g H ₂ O at 100 g soil DW] at 0.33 bar (pF 2.5)	56.7	66.9	79.0
	16.2%	21.1%	32.0%
Bulk Density (disturbed) [g/cm ³]	1.10	0.99	0.97
Microbial Biomass [mg microbial carbon per g soil DW] ²			
DAT-0	1314	1422	3228
DAT-120	143	767	2596

¹ % organic matter = % organic carbon x 1.724

² Mean of duplicates, microbial biomass samples were applied with solvent of application solution (500 µL methanol/water 1/1 (v/v)).

DAT: days after treatment

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a cotton wool plug allowing free oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with cotton wool plugs and equilibrated to study conditions for 4 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 250 g per hectare and a maximum formation of approximately 10% of NOA 413161, resulting in a nominal SAR of $69 \mu\text{g}$ NOA 413161 per kg soil dry weight.

The test item was applied dropwise onto the soil surface of the respective test systems in 100 μL methanol/water 1/1 (v/v) using a pipette. After application, the test vessels were closed with cotton wool plugs.

The test systems were incubated in the dark for 120 days at $20.0 \text{ }^\circ\text{C}$ and a soil moisture of 52.9% MWHC in a climatic cabinet.

2. Sampling

Ten sampling intervals were distributed over the entire incubation period of 120 days. Duplicate samples were processed and analysed 0, 3, 7, 14, 21, 30, 45, 62, 90 and 120 days after treatment (DAT). Microbial soil biomass was determined at start and end of the study (DAT-0 and DAT-120).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil (██████████) with the test item at LOQ level (corresponding to 5% of the nominal SAR) and application rate level (corresponding to 100% of the nominal SAR). Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker, once using water and twice using acetonitrile/water 1/2 (v/v). After each extraction step, extract and soil were separated by centrifugation ($4450 \times g$) and decantation. The soil extracts were combined and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in multiple reaction monitoring mode using matrix-matched external multi-point calibration curves. Concurrent recovery samples were processed and analysed analogously. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC-MS/MS analysis of the combined soil extracts corresponded to 1 and 5% of the nominal SAR, respectively.



The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization multiple reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent and in blank soil matrix solutions (matrix-matched). Therefore, multi-point external calibration curves were established covering a range from 1 to 120% of the nominal SAR. The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with the test item at LOQ level (corresponding to 5% of the nominal SAR) and at application rate level (corresponding to 100% of the nominal SAR). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 1.1 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 7.1.2.1.2-11: Degradation of NOA 413161 in soils under aerobic conditions (mean values expressed as % AA)

Soil	Mean	DAT									
		0	3	7	14	21	30	45	62	90	120
	Mean	92.8	95.3	96.0	81.4	72.5	68.3	56.2	51.1	50.8	46.3
	4a Mean	91.5	92.4	89.9	81.9	76.2	78.9	69.4	68.4	57.2	55.7
	Mean	91.2	86.1	80.3	77.4	69.6	66.0	59.8	52.4	44.1	32.9

B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficients (R²) of the multi-point external calibration curves ranged from 0.9997 to 0.9999. The recovery rates ranged from 79 to 106% of applied amount [% AA] for all soils and concentrations. The relative standard deviations for each recovery set ranged from 3.4 to 6.7%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 30% of the limit of quantitation in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recovery was 94% AA (range from 86 to 103% AA).



C. DEGRADATION OF PARENT COMPOUND

The amount of NOA 413161 in the soil extracts decreased from study start (DAT-0) to study end (DAT-120) from 92.8 to 46.3% AA in soil [redacted], from 91.3 to 55.7% AA in soil [redacted] 4a and from 91.2 to 32.9% AA in soil [redacted].

The degradation of NOA 413161 followed double first order in parallel (DFOP) kinetics in all soils according to the lowest chi² error values and visual assessments. Table 7.1.2.1.2- 12 summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.

Table 7.1.2.1.2- 12: Best-fit degradation kinetics of NOA 413161 in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]
[redacted]	DFOP	82.8	1000	4.2
[redacted] 4a	DFOP	173	713	2.7
[redacted]	DFOP	80.9	306	1.1

¹ DFOP: double first order in parallel

III. CONCLUSIONS

NOA 413161, a major degradation product of trifloxystrobin, was moderately degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-lives were between 80.9 and 173 days in the tested soil.

It is concluded that NOA 413161 will be degraded in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.2 /13; [REDACTED]; 2010
Title:	NOA 413163: Aerobic Degradation in Three European Soils
Report No.:	MEF-09/461
Document No.:	M-387169-01-1
Guidelines:	- OECD Test Guideline No. 307 - Commission Directive 95/36/EC amending Council Directive 91/414/EEC
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rate of major photodegradation product NOA 413163

Executive Summary

The degradation rate of NOA 413163, a photodegradation product of trifloxystrobin, was studied in three soils under aerobic conditions in the dark in the laboratory for 120 days at 20.0 °C and 52.1% of the maximum water holding capacity:

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Monheim, Germany	sandy loam	5.0	1.9
[REDACTED] 4a	Burscheid, Germany	sandy loam	6.8	2.6
[REDACTED]	Blankenheim, Germany	loam	7.3	5.2

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

A study application rate of 73.2 µg per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 250 g per hectare and a maximum formation of approximately 10% of NOA 413163.

The amount of NOA 413163 in the soil extracts decreased from study start (DAT-0) to study end (DAT-120) from 74.0 to 25.9% of applied amount [% AA] in soil [REDACTED], from 82.1 to 14.8% AA in soil [REDACTED] 4a and from 79.2 to 7.1% AA in soil [REDACTED].

The experimental data could be well described by a first order multi compartment kinetic model for soils [REDACTED] 4a and [REDACTED] and by a double first order in parallel kinetic model for soil [REDACTED]. The half-life of NOA 413163 under aerobic conditions was 54, 37 and 280 days in soil [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

It is concluded that NOA 413163 will be degraded in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled NOA 413163
Certificate of Analysis: AZ 15124
Batch Code: AE 1344149 00 1B98 0001
Chemical Purity: 99.2% w/w



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

2. Test Soils

Three soils were used (see Table 7.1.2.1.2- 13). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled fresh from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

Table 7.1.2.1.2- 13: Physico-chemical properties of test soils

Parameter	Results / Units		
Soil Designation	[redacted]	[redacted]	[redacted]
Geographic Location			
City	[redacted]	[redacted]	[redacted]
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany
GPS Coordinates	[redacted]	[redacted]	[redacted]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic Typic Argudalf	loamy, mixed, mesic Typic Argudalf	no information available
Soil Series	no information available		
Textural Class (USDA)	sandy loam	sandy loam	loam
Sand	39%	49%	33%
Silt	36%	50%	42%
Clay	25%	1%	25%
pH (soil/0.01 M CaCl ₂ 1/2)	5.6	6.0	7.3
pH (soil/water 1/1)	5.7	7.0	7.5
pH (saturated paste)	5.7	6.9	7.4
pH (soil/1 N KCl 1/1)	4.1	6.5	7.0
Organic Carbon	1.0%	2.6%	5.2%
Organic Matter ¹	3.3%	4.5%	9.0%
Cation Exchange Capacity [meq/100 g]	10.8	14.9	28.5
Water Holding Capacity maximum [g H ₂ O at 100 g soil DW] at 0.33 bar (pF 2.5)	58.6 16.4%	69.0 23.1%	85.7 35.7%
Bulk Density (disturbed) [g/cm ³]	1.10	1.02	0.98
Microbial Biomass [mg microbial carbon per kg soil DW] ²			
DAT-0	695	1059	3467
DAT-120	234	518	2180

¹ % organic matter = % organic carbon x 1024

² Mean of duplicates, microbial biomass samples were applied with solvent of application solution (500 µL methanol/water 1/1 (v/v)).

DAT: days after treatment

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a cotton wool plug allowing free oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with cotton wool plugs and equilibrated to study conditions for 14 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 250 g per hectare and a maximum formation of approximately 10% of NOA 413163, resulting in a nominal SAR of 69 μg NOA 413163 per kg soil dry weight.

The test item was applied dropwise onto the soil surface of the respective test systems in 100 μL methanol/water 1/1 (v/v) using a pipette. After application, the test vessels were closed with cotton wool plugs.

The test systems were incubated in the dark for 120 days at 20.0 °C and a soil moisture of 52.9% MWHC in a climatic cabinet.

2. Sampling

Ten sampling intervals were distributed over the entire incubation period of 120 days. Duplicate samples were processed and analysed 0, 3, 7, 14, 21, 30, 45, 62, 90 and 120 days after treatment (DAT). Microbial soil biomass was determined at start and end of the study (DAT-0 and DAT-120).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil (██████████ 2a) with the test item at LOQ level (corresponding to 5% of the nominal SAR) and application rate level (corresponding to 100% of the nominal SAR). Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker and methanol/water 1/1 (v/v). After each extraction step, extract and soil were separated by centrifugation (450 x g) and decantation. The soil extracts were combined and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in multiple reaction monitoring mode using matrix-matched external multi-point calibration curves. Concurrent recovery samples were processed and analysed analogously. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC-MS/MS analysis of the combined soil extracts corresponded to 1 and 5% of the nominal SAR, respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization multiple reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent and in blank soil matrix solutions (matrix-matched). Therefore, multi-point external calibration curves were established covering a range from 1 to 120% of the nominal SAR. The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with the test item at LOQ level (corresponding to 5% of the nominal SAR) and at application rate level (corresponding to 100% of the nominal SAR). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 1.1 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 7.1.2.1.2-14: Degradation of NOA 413163 in soils under aerobic conditions (mean values expressed as % AA)

Soil	Mean	DAT									
		0	3	7	14	21	30	45	62	90	120
	Mean	74.0	73.3	65.8	62.9	57.5	51.5	40.5	29.7	29.9	25.9
	4a Mean	82.1	84.5	79.1	65.0	59.1	47.0	37.2	28.2	20.2	14.8
	Mean	79.2	76.9	66.1	63.4	49.1	38.1	27.4	19.4	11.6	7.1

B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficients (R²) of the multi-point external calibration curves ranged from 0.9999 to 1.0000. The recovery rates ranged from 70 to 90% of applied amount [% AA] for all soils and concentrations. The relative standard deviations for each recovery set ranged from 0.6 to 3.4%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 30% of the limit of quantitation in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recovery was 80% AA (range from 72 to 87% AA).



C. DEGRADATION OF PARENT COMPOUND

The amount of NOA 413163 in the soil extracts decreased from study start (DAT-0) to study end (DAT-120) from 74.0 to 25.9% AA in soil [redacted], from 82.1 to 14.8% AA in soil [redacted] 4a and from 79.2 to 7.1% AA in soil [redacted].

The degradation of NOA 413163 followed first order multi compartment (FOMC) kinetics in soils [redacted] 4a and [redacted] and double first order in parallel (DFOP) kinetics in soil [redacted] according to the lowest chi² error values and visual assessments. Table 7.1.2.1.2- 15 summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.

Table 7.1.2.1.2- 15: Best-fit degradation kinetics of NOA 413163 in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]
[redacted]	DFOP	53.6	> 1000	4.0
[redacted] 4a	FOMC	27.3	138	3.8
[redacted]	FOMC	27.7	113	2.7

¹ FOMC: first order multi compartment, DFOP: double first order in parallel

III. CONCLUSIONS

NOA 413163, a major photodegradation product of trifloxystrobin, was well degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-lives were between 27.7 and 53.6 days in the tested soils.

It is concluded that NOA 413163 will be degraded in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.2 /14; [REDACTED]; [REDACTED]; 2013
Title:	CGA 357276: Aerobic Degradation in Four European Soils
Report No:	EnSa-13-0413
Document No:	M-465697-01-1
Guidelines:	- OECD Test Guideline No. 307 - DRAFT SANCO 11802/2010/rev 0 - DRAFT SANCO 11844/2010/rev 0
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rate of major degradation product CGA 357276

Executive Summary

The degradation rate of CGA 357276, a degradation product of trifloxystrobin, was studied in four soils under aerobic conditions in the dark in the laboratory for 120 days at 19.9 °C and 55.4% of the maximum water holding capacity:

Soil	Source	Texture (USDA)	pH	OC [%]
[REDACTED]	Monheim, Germany	sandy loam	6.0	2.0
[REDACTED]	Monheim, Germany	loamy sand	6.0	2.1
[REDACTED]	Bürscheid, Germany	silt loam	6.4	1.7
[REDACTED]	Blankenheim, Germany	loam	6.3	4.8

* pH value was derived from aqueous 0.01M CaCl₂ suspension.

A study application rate of 23.0 µg per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 187.5 g per hectare and a maximum formation of approximately 6% of CGA 357276 in a trifloxystrobin aerobic soil degradation study.

The amount of CGA 357276 in the soil extracts decreased from study start (DAT-0) to study end (DAT-120) from 102.7 to 18.8% of applied amount [%AA] in soil [REDACTED], from 104.4 to 17.6% AA in soil [REDACTED], from 103.9 to 11.9% AA in soil [REDACTED] 4a and from 99.2 to 5.9% AA in soil [REDACTED].

The experimental data could be well described by a first order multi compartment kinetic model for all soils. The half-life of CGA 357276 under aerobic conditions was 22.0, 21.5, 21.3 and 12.0 days in soil [REDACTED] 4a and [REDACTED], respectively.

It is concluded that CGA 357276 has no potential for accumulation in the environment.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled CGA 357276
Certificate of Analysis: AZ 16891
Batch Code: BCS-AB39835-PU-01
Chemical Purity: 97.8% w/w



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

2. Test Soils

Four soils were used (see Table 7.1.2.1.2- 16). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled fresh from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

Table 7.1.2.1.2- 16: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation				
Geographic Location				
City				
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates				
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambudoll	loamy, mixed, mesic, Typic Argudalf	fine-loamy, mixed, active, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USD)	sandy loam	loamy sand	silt loam	loam
Sand [50 μ m – 2 mm]	69%	41%	25%	43%
Silt [2 μ m – 50 μ m]	27%	41%	57%	33%
Clay [< 2 μ m]	14%	8%	18%	24%
pH (soil/0.01 M CaCl ₂ 1/2)	5.3	6.0	6.4	7.3
pH (soil/water 1/1)	5.3	6.2	6.6	7.4
pH (saturated paste)	5.4	6.4	6.7	7.4
pH (soil/1 N KCl 1/2)	4.7	5.8	6.0	7.0
Organic Carbon	3.9%	2.1%	1.7%	4.8%
Organic Matter ¹	3.4%	3.6%	2.9%	8.3%
Cation Exchange Capacity [meq/100 g]	10.8	9.7	10.9	20.4
Water Holding Capacity maximum [g H ₂ O ad 100 g soil DW]	60.3	49.4	56.6	79.7
at 0.1 bar (pF 2.0)	28.6	21.6%	37.1%	43.3%
Bulk Density (disturbed) [g cm ³]	1.08	1.21	1.08	1.01
Microbial Biomass [mg microbial carbon per kg soil DW] ²				
DAT-0 (BIO-)	418	660	532	2439
DAT-52 (BIO- / BIO+)	187 / 206	378 / 385	407 / 400	1929 / 1865
DAT-120 (BIO- / BIO+)	114 / 121	275 / 258	253 / 239	1576 / 1574

¹ % organic matter = % organic carbon x 1.724

² BIO- samples were left untreated, BIO+ samples were applied with solvent of application solution (400 μ L methanol/water 1/1 (v/v)).

DAT: days after treatment

DW: dry weight

GPS: global positioning system



USDA: United States Department of Agriculture

B. STUDY DESIGN**1. Experimental Conditions**

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a polyurethane (PU) foam plug allowing free oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with PU foam plugs and equilibrated to study conditions for 10 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 187.5 g per hectare and a maximum formation of approximately 6% of CGA 357276 in aerobic soil degradation study M-033394-01-1 (Baseline Dossier, KCA 7.1.1.1 /03), resulting in a nominal SAR of 25 μg CGA 357276 per kg soil dry weight.

The test item was applied dropwise onto the soil surface of the respective test systems in 400 μL methanol/water 1/1 (v/v) using a pipette. After application, the test vessels (except DAT-0 samples) were closed with PU foam plugs.

The test systems were incubated in the dark for 120 days at 19.9 °C and a soil moisture of 55.4% MWHC in a walk-in climatic chamber.

2. Sampling

Eight sampling intervals were distributed over the entire incubation period of 120 days. Duplicate samples were processed and analysed 0, 3, 7, 15, 29, 52, 85 and 120 days after treatment (DAT). Microbial soil biomass was determined at start, middle and end of the study (DAT-0, DAT-53 and DAT-120).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil (██████████) with the test item at LOQ level (corresponding to 5% of the nominal SAR) and application rate level (corresponding to 100% of the nominal SAR). Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker and acetonitrile/water 4/1 (v/v). Furthermore, two accelerated extraction steps using a microwave with a magnetic stirrer were performed, first with acetonitrile/water 1/1 (v/v) at 70 °C and second with methanol/water 1/1 (v/v) at 90 °C. After each extraction step, extract and soil were separated by centrifugation (4200 g) and decantation. The soil extracts were combined and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in selected reaction monitoring mode using a matrix-matched external multi-point calibration curve. Concurrent recovery samples were processed and analysed analogously. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC-MS/MS analysis of the combined soil extracts corresponded to 1 and 5% of the nominal SAR, respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization selected reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent and in blank soil matrix solutions (matrix-matched). Therefore, multi-point external calibration curves were established covering a range from 1 to 150% of the nominal SAR. The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with the test item at LOQ level (corresponding to 5% of the nominal SAR) and at application rate level (corresponding to 100% of the nominal SAR). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 7.1.2.1.2-17: Degradation of CGA 357276 in soils under aerobic conditions (mean values and SD expressed as % AA)

Soil	Mean SD	DAT							
		0	15	29	52	85	120		
[Redacted]	Mean SD	102.7 ± 2.6	96.6 ± 2.4	82.6 ± 1.7	61.5 ± 0.6	43.4 ± 0.5	29.9 ± 0.0	21.6 ± 0.4	18.8 ± 0.3
[Redacted]	Mean SD	104.4 ± 2.3	92.0 ± 2.0	77.9 ± 1.8	60.5 ± 0.2	45.6 ± 0.3	33.0 ± 2.1	22.3 ± 0.3	17.6 ± 0.6
[Redacted]	Mean SD	103.3 ± 0.5	97.2 ± 0.5	79.3 ± 2.2	62.5 ± 0.2	44.3 ± 0.6	25.7 ± 1.1	16.4 ± 0.0	11.9 ± 0.5
[Redacted]	Mean SD	99.7 ± 0.3	91.7 ± 2.2	64.1 ± 2.0	43.9 ± 0.6	25.7 ± 0.1	13.3 ± 0.2	8.0 ± 0.0	5.9 ± 0.0

DAT: days after treatment, SD: standard deviation



B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficient (R^2) of the multi-point external calibration curve was 0.9998. The recovery rates ranged from 89.8 to 117.3% of applied amount [% AA] for all soils and concentrations. The relative standard deviations for each recovery set ranged from 1.4 to 5.4%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 30% of the limit of quantitation in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recovery was 96.7% AA (range from 70.9 to 108.7% AA).

C. DEGRADATION OF PARENT COMPOUND

The amount of CGA 357276 in the soil extracts decreased from study start (DAT-0) to study end (DAT-120) from 102.7 to 18.8% AA in soil [redacted], from 104.4 to 17.6% AA in soil [redacted], from 103.3 to 14.9% AA in soil [redacted] 4a and from 99.2 to 5.9% AA in soil [redacted].

The degradation of CGA 357276 followed first order multi compartment (FOMC) kinetics in all soils according to the lowest χ^2 error values and visual assessments. Table 7.1.2.1.2-18 summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.

Table 7.1.2.1.2- 18: Best-fit degradation kinetics of CGA 357276 in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-Fit Kinetic Model	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	Visual Assessment ²
[redacted]	FOMC	22.0	100	3.4	+
[redacted]	FOMC	21.5	237	1.2	+
[redacted] 4a	FOMC	21.3	123	2.6	+
[redacted]	FOMC	12.0	71.8	1.8	+

¹ FOMC: first order multi compartment

² visual assessment: + = good

III. CONCLUSIONS

CGA 357276, a major degradation product of trifloxystrobin, was well degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-lives were between 12.0 and 22.0 days in the tested soils.

It is concluded that CGA 357276 has no potential for accumulation in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.2 /15; [REDACTED]; 2012; amended 2013-01-08
Title:	Amendment No 1 to Report – NOA 409480: Aerobic Degradation in Four European Soils
Report No:	S11-01625
Document No:	M-445349-02-1
Guidelines:	- OECD Test Guideline No. 307
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rate of major photodegradation product NOA 409480

Executive Summary

The degradation rate of NOA 409480, a photodegradation product of trifloxystrobin, was studied in four soils under aerobic conditions in the dark in the laboratory for 115 days at 19.4 °C and 55 ± 5% of the maximum water holding capacity:

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Monheim, Germany	sandy loam	5.0	2.1
[REDACTED]	Monheim, Germany	sandy loam	7.0	1.9
[REDACTED] 4a	Burscheid, Germany	silt loam	6.1	1.8
[REDACTED]	Blankenheim, Germany	clay loam	7.2	5.0

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

A study application rate of 71.4g per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 187.5 g per hectare and a maximum formation of approximately 9% of NOA 409480 in a trifloxystrobin soil photolysis study.

The amount of NOA 409480 in the soil extracts decreased from study start (DAT-0) to study end (DAT-115) from 79.2 to 18.1% of applied amount [%AA] in soil [REDACTED], from 107.4 to 26.0% AA in soil [REDACTED], from 73.1 to 10.2% AA in soil [REDACTED] 4a and from 2.7 to 4.9% AA in soil [REDACTED].

The experimental data could be well described by a first order multi compartment kinetic model for soils [REDACTED] and [REDACTED] 4a and a single first order kinetic model for soil [REDACTED]. The half-life of NOA 409480 under aerobic conditions was 27.8, 30.2, 20.1 and 19.1 days in soil [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

It is concluded that NOA 409480 has no potential for accumulation in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled NOA 409480
Certificate of Analysis: AZ 17177
Batch Code: BCS-CR74871-01-01
Chemical Purity: 98.7%



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

2. Test Soils

Four soils were used (see Table 7.1.2.1.2- 19). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled fresh from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of ≤ 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

Table 7.1.2.1.2- 19: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation	[redacted]	[redacted]	[redacted] 4a	[redacted]
Geographic Location				
City	[redacted]	[redacted]	[redacted]	[redacted]
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates	[redacted]	[redacted]	[redacted]	[redacted]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambuoll	loamy, mixed, mesic, Typic Argudalf	fine-loamy, mixed, active, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USDA)	sandy loam	loamy sand	silt loam	clay loam
Sand [50 μ m – 2 mm]	55%	75%	23%	27%
Silt [2 μ m – 50 μ m]	30%	16%	60%	42%
Clay [$<$ 2 μ m]	15%	9%	17%	31%
pH (soil/0.01 M CaCl ₂ 1/2)	5.0	5.5	6.1	7.2
pH (soil/water 1/1)	5.5	5.9	6.4	7.3
pH (saturated paste)	5.3	6.0	6.4	7.3
pH (soil/1 N KCl 1/1)	4.7	5.5	5.8	6.9
Organic Carbon	2.0%	1.9%	1.8%	5.0%
Organic Matter ¹	3.6%	3.3%	3.1%	8.6%
Cation Exchange Capacity [meq/100 g]	11.0	9.8	11.8	22.0
Water Holding Capacity				
maximum [g H ₂ O ad 100 g soil DW]	57.7	47.5	53.8	85.5
at 0.33 bar (pF 2.5)	16.7%	10.9%	21.3%	32.2%
Bulk Density (disturbed) [g cm ⁻³]	1.13	1.24	1.09	1.00
Microbial Biomass [mg microbial carbon per kg soil DW] ²				
DAT-0	284	324	297	354
DAT-30	290	315	326	455
DAT-125	190	135	206	412

¹ % organic matter = % organic carbon x 1.724

² Microbial biomass samples were left untreated.

DAT: days after treatment

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under aerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). Each flask was closed with a cotton wool plug allowing free oxygen exchange.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soils were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then closed with cotton wool plugs and equilibrated to study conditions for 6 days prior to application.

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 187.5 g per hectare, a maximum formation of approximately 9% of NOA 409480 in soil photolysis study M-049459-01-1 (Supplemental Dossier, KCA 7-1.3 /03) and a 2-fold application rate due to analytical reasons, resulting in a nominal SAR of 72 μg NOA 409480 per kg soil dry weight.

The test item was applied dropwise onto the soil surface of the respective test systems in 200 μL acetone/water 1/1 (v/v) using a pipette.

The test systems were incubated in the dark for 115 days at 19.4 °C and a soil moisture of $55 \pm 5\%$ MWHC in a climatic cabinet.

2. Sampling

Eight sampling intervals were distributed over the entire incubation period of 115 days. Duplicate samples were processed and analysed on 3, 7, 14, 29, 58, 87 and 115 days after treatment (DAT). Microbial soil biomass was determined at start, middle and end of the study (DAT-0, DAT-30 and DAT-115).

At each sampling interval, concurrent recovery samples were prepared freshly by fortification of a representative soil () with the test item at LOQ level (corresponding to 10% of the nominal SAR) and at 11-fold LOQ level (corresponding to 110% of the nominal SAR). Duplicate samples were prepared and processed in parallel to the degradation samples of the respective sampling interval for each fortification level.

3. Analytical Procedures

The entire soil of each test system was extracted twice at ambient temperature using a shaker and acetonitrile/water 4/1 (v/v). Furthermore, two accelerated extraction steps using a microwave were performed, first with acetonitrile/water 4/1 (v/v) at 60 to 70 °C and second with methanol/water 1/1 (v/v) at 50 °C. After each extraction step, extract and soil were separated by centrifugation (1295 x g) and decantation. The soil extracts were combined and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in selected reaction monitoring mode using matrix-matched external multi-point calibration curves. Concurrent recovery samples were processed and analysed analogously.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The mass selective detector was operated in the positive electrospray ionization selected reaction monitoring mode, tuned for the mass transitions of parent and a significant product ion. The linearity range of the mass spectrometer was tested in pure extraction solvent and in blank soil matrix solutions (matrix-matched). Therefore, multi-point external calibration curves were established covering a range from approximately 1 to 175% of the nominal SAR. The accuracy and precision of the method was assessed on the basis of the recovery rates determined for each soil after fortification with the test item at LOQ level (corresponding to 10% of the nominal SAR) and at 11-fold LOQ level (corresponding to 110% of the nominal SAR). The fortified samples were processed and analysed as described for the degradation samples. Blank soil matrix solutions were used to determine the background abundance of the test item in the respective soils.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI 1.1 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

A. DATA

Table 7.1.2.1.2-20: Degradation of NOA 409480 in soils under aerobic conditions (mean values and SD expressed as % AA)

Soil	Mean SD	DAT							
		0	14	29	58	87	115		
[Redacted]	Mean SD	9.2 ± 5.8	73.3 ± 0.6	66.6 ± 4.0	52.7 ± 2.4	37.6 ± 1.7	26.4 ± 3.0	19.4 ± 1.1	18.1 ± 0.3
[Redacted]	Mean SD	107.4 ± 1.9	107.1 ± 3.9	99.5 ± 1.8	79.1 ± 1.1	53.1 ± 0.6	30.5 ± 7.7	29.2 ± 1.5	26.0 ± 0.5
[Redacted]	Mean SD	73.1 N/A	69.0 ± 5.8	65.1 ± 1.9	46.5 ± 0.8	25.7 ± 7.6	17.1 ± 1.4	11.3 ± 0.7	10.2 ± 1.6
[Redacted]	Mean SD	72.0 ± 4.9	65.2 ± 2.1	64.9 ± 1.6	43.6 ± 4.4	22.0 ± 5.6	11.0 ± 2.6	5.4 ± 0.1	4.9 ± 0.9

DAT: days after treatment, SD: standard deviation, N/A: not applicable

¹ One replicate was an outlier and was not used for evaluation, therefore no SD could be calculated.



B. METHOD VALIDATION

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. The correlation coefficients (r) of the multi-point external calibration curves were ≥ 0.995 . The recovery rates ranged from 78.6 to 111.5% of applied amount [% AA] for all soils and concentrations. The relative standard deviations for each recovery set ranged from 1.5 to 13.8%, showing a good repeatability of this method. Background abundance in blank soil matrix was far below 20% of the limit of quantitation in all soils and no interference by other matrix components occurred. The combination of the selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

In addition, the extraction efficiency was demonstrated by concurrent recovery samples at each sampling interval. The overall mean concurrent recovery was 100.5% AA (range from 96.5 to 105.8% AA).

C. DEGRADATION OF PARENT COMPOUND

The amount of NOA 409480 in the soil extracts decreased from study start (DAT-0) to study end (DAT-115) from 79.2 to 18.1% AA in soil [redacted], from 107.4 to 26.0% AA in soil [redacted], from 73.4 to 10.2% AA in soil [redacted] and from 72.7 to 4.9% AA in soil [redacted].

The degradation of NOA 409480 followed first order multi compartment (FOMC) kinetics in soils [redacted] and [redacted] 4a and single first order (SFO) kinetics in soil [redacted] according to the lowest χ^2 error values and visual assessments. Table 7.1.2.1-21 summarizes the best-fit results of the DT_{50} and DT_{90} calculations.

Table 7.1.2.1-21: Best-fit degradation kinetics of NOA 409480 in soils under aerobic conditions for trigger evaluation according to FOCUS

Soil	Best-Fit Kinetic Model ¹	DT_{50} [days]	DT_{90} [days]	Chi ² Error [%]	Visual Assessment ²
[redacted]	FOMC	27.8	275	2.6	+
[redacted]	FOMC	30.2	239	4.7	+
[redacted] 4a	FOMC	20.1	113	7.2	+
[redacted]	SFO	19.1	63.4	7.5	+

¹ SFO: single first order, FOMC: first order multi compartment

² visual assessment: + = good

III. CONCLUSIONS

NOA 409480, a major photodegradation product of trifloxystrobin, was well degraded in soil under aerobic conditions in the dark in the laboratory. The calculated best-fit half-lives were between 19.1 and 30.2 days in the tested soils.

It is concluded that NOA 409480 has no potential for accumulation in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.2 /16; [REDACTED]; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite CGA 321113 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0714
Document No:	M-467654-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-069897-01-1 (Baseline Dossier, KCA 7.1.2.1.2 /08) was performed according to FOCUS kinetics (2006) to derive half-lives for CGA 321113, a degradation product of trifloxystrobin, which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of CGA 321113 in soil [REDACTED] under aerobic conditions in the dark in the laboratory at 20 °C and 40% of the maximum water holding capacity.

The half-life of CGA 321113 was 223.2 days.

1. METHODS

Soil residue data from the aerobic soil degradation study M-069897-01-1 (Baseline Dossier, KCA 7.1.2.1.2 /08) were used. In this study the degradation of CGA 321113, a degradation product of trifloxystrobin, was studied in soil [REDACTED] (loamy sand) under aerobic conditions in the dark in the laboratory for 120 days at 20 °C and 40% of the maximum water holding capacity.

The degradation kinetics was determined according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled error criterion, t-test significance correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.

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II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of CGA 321113 in soil [redacted]. Table 7.1.2.1.2- 22 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 22: Kinetic parameters for the degradation of CGA 321113 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment
[redacted]	SFO	223.2	1.8	2.43 x 10 ⁻²	+

¹ SFO: single first order

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory was 223.2 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section 7.1.2.1.

Report:	KCA 7.1.2.1.2 / 04; [redacted]; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0715
Document No:	M-467655-014
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033459-01-1 (Baseline Dossier, KCA 7.1.2.1.2 / 04 and KCA 7.1.2.1.2 / 04) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted] under aerobic conditions in the dark in the laboratory at different temperature (20 and 10 °C), soil moistures (60 and 30% of the field capacity at 1/3 bar (FC)) and test concentrations (1.0 and 0.1 mg/kg).



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The half-life of CGA 321113 was 120.0 days (20 °C, 60% FC, 1.0 mg/kg), 262.7 days (20 °C, 30% FC, 1.0 mg/kg), 369.5 days (10 °C, 60% FC, 1.0 mg/kg) and 35.1 days (20 °C, 60% FC, 0.1 mg/kg).

The formation fraction of CGA 321113 was 0.951 (20 °C, 60% FC, 1.0 mg/kg), 1.000 (20 °C, 30% FC, 1.0 mg/kg), 0.996 (10 °C, 60% FC, 1.0 mg/kg) and 1.000 (20 °C, 60% FC, 0.1 mg/kg).

I. METHODS

Methods are summarized under KCA 7.1.2.1.1 / 11 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted]. Table 7.1.2.1.2- 23 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 23: Kinetic parameters for degradation of CGA 321113 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted] A ³	0.951	SFO	120.0	2.3	$< 2 \times 10^{-16}$	+
[redacted] B ⁴	1.000	SFO	262.7	2.7	2×10^{-16}	+
[redacted] C ⁵	0.996	SFO	369.5	4.3	9.76×10^{-12}	+
[redacted] D ⁶	1.000	SFO	35.1	9.5	$< 2 \times 10^{-16}$	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + good

³ 20 °C, 60% of the field capacity at 1/3 bar, 1.0 mg/kg

⁴ 20 °C, 30% of the field capacity at 1/3 bar, 1.0 mg/kg

⁵ 10 °C, 60% of the field capacity at 1/3 bar, 1.0 mg/kg

⁶ 20 °C, 60% of the field capacity at 1/3 bar, 0.1 mg/kg

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory were between 35.1 and 369.5 days in the tested soils. The formation fractions were between 0.951 and 1.000.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.2 /18; [redacted]; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0716
Document No:	M-467663-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-036453-01.1 (Baseline Dossier, KCA 7.1.2.1.1 /05 and KCA 7.1.2.1.2 /05) was performed, with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soils [redacted], [redacted] and [redacted] under aerobic conditions in the dark in the laboratory at 20 °C, 40% of the maximum water holding capacity and a test concentration of 1.0 mg/kg.

The half-life of CGA 321113 was 755.6 days in soil [redacted], 428.4 days in soil [redacted] and 358.0 days in soil [redacted].

The formation fraction of CGA 321113 was 0.944 in soil [redacted], 0.970 in soil [redacted] and 0.946 in soil [redacted].

I. METHODS

Methods are summarized under KCA 7.1.2.1.1.12 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soils [redacted], [redacted] and [redacted]. Table 7.1.2.1.2- 24 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2-24: Kinetic parameters for degradation of CGA 321113 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	0.944	SFO	755.6	0.9	< 2 x 10 ⁻¹⁶	+
[redacted]	0.970	SFO	428.4	1.2	< 2 x 10 ⁻¹⁶	+
[redacted]	0.946	SFO	358.0	1.5	< 2 x 10 ⁻¹⁶	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good



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III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory were between 358.0 and 755.6 days in the tested soils. The formation fractions were between 0.944 and 0.970.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 /19; [REDACTED]; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0717
Document No:	M-467664-01-1
Guidelines:	- FOCUS kinetics (2006)
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-073242-01-1 (Baseline Dossier KCA 7.1.2.1.2 /08) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) to derive half-lives for trifloxystrobin and its degradation product CGA 321113, as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [REDACTED] under aerobic conditions in the dark in the laboratory at 20 °C, 40% of the maximum water holding capacity and a test concentration of 337 µg/kg.

The half-life of CGA 321113 was 380.4 days.

The formation fraction of CGA 321113 was 0.983.

4. METHODS

Methods are summarized under KCA 7.1.2.1.1 /13 of the Supplemental Dossier.



II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted]. Table 7.1.2.1.2- 25 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 25: Kinetic parameters for degradation of CGA 321113 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	0.983	SFO	80.4	2	6.11 x 10 ⁻⁶	

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory was 380.4 days in the tested soil. The formation fraction was 0.983.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section 7.1.2.1.

Report:	KCA 7.1.2.1.2 /20; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	E05a-13-0718
Document No:	M-468172-014
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033008-01-1 (Baseline Dossier, KCA 7.1.2.1.2 /01 and KCA 7.1.2.1.2 /01) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted] under aerobic conditions in the dark in the laboratory at 19 °C, 75% of the field capacity and a test concentration of 1.0 mg/kg.

The half-life of CGA 321113 was 80.3 days.

The formation fraction of CGA 321113 was 0.969.



I. METHODS

Methods are summarized under KCA 7.1.2.1.1 /14 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted]. Table 7.1.2.1.2-26 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 26: Kinetic parameters for degradation of CGA 321113 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	D ₁₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	0.969	SFO	80.3	3.2	$\times 10^{-16}$	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory was 80.3 days in the tested soil. The formation fraction was 0.969.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 /21; [redacted]; [redacted], 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI2 Tool
Report No:	EnSa-13-071
Document No:	M-468202-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement. Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033147-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /02 and KCA 7.1.2.1.2 /02) was performed with the software KinGUI2 according to FOCUS kinetics (2006)¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted] under aerobic conditions in the dark in the laboratory at 19 °C, 5% of the field capacity and a test concentration of 1.0 mg/kg.

The half-life of CGA 321113 was 99.2 days.

The formation fraction of CGA 321113 was 0.947.

I. METHODS

Methods are summarized under KCA 7.1.2.1.1 /15 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil [redacted]. Table 7.1.2.1.2- 27 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 27: Kinetic parameters for degradation of CGA 321113 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	0.947	SFO	99.2	1.7	2 x 10 ⁻⁴	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory was 99.2 days in the tested soil. The formation fraction was 0.947.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

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Report:	KCA 7.1.2.1.2 /22; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolites under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0720
Document No:	M-468203-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation products CGA 321113 and CGA 357276 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-036394-01.1 (Baseline Dossier, KCA 7.1.2.1.1 /03 and KCA 7.1.2.1.2 /03) was performed, with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation products CGA 321113 and CGA 357276 as well as formation fractions for CGA 321113 and CGA 357276, which are suitable for modelling purpose. Only the results for CGA 321113 and CGA 357276 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 and CGA 357276 in soil [REDACTED] under aerobic conditions in the dark in the laboratory at 25 °C, 75% of the field capacity at 1/3 bar and a test concentration of 0.5 mg/kg.

The half-life of CGA 321113 was 257.2 days and could not be calculated for CGA 357276.

The formation fraction of CGA 321113 was 0.822 and could not be calculated for CGA 357276.

I. METHODS

Methods are summarized under KCA 7.1.2.1.1 /16 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 and CGA 357276 in soil [REDACTED]. No valid half-life and formation fraction could be derived for CGA 357276. Table 7.1.2.1.2-28 summarizes the results of the kinetic analysis for CGA 321113.

Table 7.1.2.1.2- 28: Kinetic parameters for degradation of CGA 321113 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[REDACTED]	0.822	SFO	257.2	1.7	7.64 x 10 ⁻¹⁶	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good



III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory was 257.2 days in the tested soil. The formation fraction was 0.822. No valid half-life and formation fraction could be derived for the major trifloxystrobin degradation product CGA 357276.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 /23; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0721
Document No:	M-468174-01-1
Guidelines:	- FOCUS kinetics (2006)
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-033464-01-1 (Baseline Dossier KCA 7.1.2.1.2 /07 and KCA 7.1.2.1.2 /07) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soils [REDACTED] and [REDACTED] under aerobic conditions in the dark in the laboratory at 19.2 °C, 40% of the maximum water holding capacity and test concentrations of 0.3 and 1.0 mg/kg.

The half-life of CGA 321113 was 12.4 days (0.3 mg/kg) and 235.0 days (1.0 mg/kg) in soil [REDACTED] and 157.4 days in soil [REDACTED].

The formation fraction of CGA 321113 was 1.000 (0.3 mg/kg) and 0.957 (1.0 mg/kg) in soil [REDACTED] and 1.000 days in soil [REDACTED].

I. METHODS

Methods are summarized under KCA 7.1.2.1.1 /17 of the Supplemental Dossier.



II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soils [redacted] and [redacted]. Table 7.1.2.1.2- 29 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 29: Kinetic parameters for degradation of CGA 321113 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted] A ³	1.000	SFO	112.4	2.4	2.68 x 10 ⁻¹³	+
[redacted] B ⁴	0.957	SFO	235.0	2.1	1.35 x 10 ⁻¹³	+
[redacted] ³	1.000	SFO	151.4	0.6	2 x 10 ⁻⁶	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

³ test concentration of 0.3 mg/kg

⁴ test concentration of 1.0 mg/kg

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory were between 112.4 and 235.0 days in the tested soils. The formation fractions were between 0.957 and 1.000.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA.1.2.1.

Report:	KCA 7.1.2.1.2 /24- [redacted]; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolites under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No.:	EnS-13-0724
Document No.:	M-467660-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation products CGA 321113, NOA 413161 and CGA 357276 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-464420-01-1 (Supplemental Dossier, KCA 7.1.2.1.1 /10) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) to derive half-lives for trifloxystrobin and its degradation products CGA 321113, NOA 413161 and CGA 357276 as well as formation fractions for CGA 321113, NOA 413161 and CGA 357276, which are suitable for modelling purpose. Only the results for CGA 321113, NOA 413161 and CGA 357276 are described here.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113, NOA 413161 and CGA 357276 in soils [redacted], [redacted], [redacted] 4a and [redacted] under aerobic conditions in the dark in the laboratory at 20.1 °C, 53.4% of the maximum water holding capacity and a test concentration of 480 µg/kg.

The half-life of CGA 321113 was 70.1 days in soil [redacted], 71.6 days in soil [redacted], 55.5 days in soil [redacted] 4a and 77.4 days in soil [redacted]. The half-life of NOA 413161 was 90.4 days in soil [redacted], 48.1 days in soil [redacted], 35.1 days in soil [redacted] 4a and 30.9 days in soil [redacted]. The half-life of CGA 357276 could not be calculated.

The formation fraction of CGA 321113 was 0.917 in soil [redacted], 0.996 in soil [redacted], 0.973 in soil [redacted] 4a and 0.961 in soil [redacted]. The formation fraction of NOA 413161 was 0.135 in soil [redacted], 0.164 in soil [redacted], 0.132 in soil [redacted] 4a and 0.213 in soil [redacted]. The formation fraction of CGA 357276 was 0.043 in soil [redacted] and 0.027 in soil [redacted].

I. METHODS

Methods are summarized under KOA 7.1.2.1.1.6 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113, NOA 413161 and CGA 357276 in soils [redacted], [redacted], [redacted] 4a and [redacted]. Table 7.1.2.1.2- 30 to Table 7.1.2.1.2- 32 are summarizing the results of the kinetic analysis.

Table 7.1.2.1.2- 30: Kinetic parameters for degradation of CGA 321113 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model	D ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	0.917	SFO	70.1	4.6	< 2 x 10 ⁻¹⁶	+
[redacted]	0.996	SFO	71.6	3.6	< 2 x 10 ⁻¹⁶	+
[redacted] 4a	0.973	SFO	55.5	1.9	< 2 x 10 ⁻¹⁶	+
[redacted]	0.961	SFO	77.4	2.9	< 2 x 10 ⁻¹⁶	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good



Table 7.1.2.1.2- 31: Kinetic parameters for degradation of NOA 413161 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment
[redacted]	0.135	SFO	90.4	3.3	5.39 x 10 ⁻⁷	+
[redacted]	0.164	SFO	48.1	5.1	4.48 x 10 ⁻¹⁵	+
[redacted] 4a	0.132	SFO	35.1	4.0	< 2 x 10 ⁻¹⁵	+
[redacted]	0.213	SFO	30.9	2.7	< 2 x 10 ⁻¹⁶	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

Table 7.1.2.1.2- 32: Kinetic parameters for degradation of CGA 357276 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil ¹	Formation Fraction
[redacted]	0.043
[redacted]	0.027

¹ No kinetic parameters could be derived for CGA 357276 in soils [redacted]

[redacted] 4a and [redacted] due to insufficient number of measured data.

² CGA 357276 residues did not reach the maximum until the end of the study, thus no degradation rates could be estimated

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation products CGA 32113 and NOA 413161 in soil under aerobic conditions in the dark in the laboratory were between 55.5 and 77.4 days for CGA 32113 and between 30.9 and 90.4 days for NOA 413161 in the tested soils. The half-lives for the major trifloxystrobin degradation product CGA 357276 could not be calculated. The formation fractions were between 0.917 and 0.996 for CGA 32113, between 0.132 and 0.213 for NOA 413161 and between 0.027 and 0.043 for CGA 357276.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

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Report:	KCA 7.1.2.1.2 /25; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite CGA 357261 and its Metabolites under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0725
Document No:	M-468206-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of the major trifloxystrobin photodegradation products CGA 357261, CGA 373466 and NOA 413163 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-45997-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /10) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for the trifloxystrobin photodegradation products CGA 357261, CGA 373466 and NOA 413163 as well as formation fractions for CGA 373466 and NOA 413163, which are suitable for modelling purpose. CGA 373466 and NOA 413163 are derived from CGA 357261.

First order multi compartment was the most appropriate kinetic model for modelling purpose for the degradation of CGA 357261 in soils [redacted] and [redacted] as well as double first order in parallel in soils [redacted] and [redacted] 4a under aerobic conditions in the dark in the laboratory at 20.2 °C, 55% of the maximum water holding capacity and a test concentration of 494 µg/kg. The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 373466 and NOA 413163. The kinetic analysis was also suitable to derive half-lives for trigger evaluation.

The half-life of CGA 357261 was 0.06 days in soil [redacted], 0.07 days in soil [redacted], 0.08 days in soil [redacted] 4a and 0.14 days in soil [redacted]. The half-life of CGA 373466 was 31.3 days in soil [redacted], 44.6 days in soil [redacted], 44.7 days in soil [redacted] 4a and 72.3 days in soil [redacted]. The half-life of NOA 413163 was 76.0 days in soil [redacted], 53.6 days in soil [redacted], 30.0 days in soil [redacted] 4a and 25.4 days in soil [redacted].

The formation fraction of CGA 373466 was 0.989 in soil [redacted], 1.000 in soil [redacted] 4a and 1.000 in soil [redacted]. The formation fraction of NOA 413163 was 0.229 in soil [redacted], 0.246 in soil [redacted], 0.162 in soil [redacted] 4a and 0.260 in soil [redacted].

I. METHODS

Soil residue data from the aerobic soil degradation study M-45997-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /10) were used. In this study, the degradation of trifloxystrobin was studied in soils [redacted] (sandy loam), [redacted] (sandy loam), [redacted] 4a (silt loam) and [redacted] (clay loam) under aerobic conditions in the dark in the laboratory for 121 days at 20.2 °C, 55% of the maximum water holding capacity and a test concentration of 494 µg/kg.



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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fit, chi-scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ values from the first order multi compartment and double first order in parallel models were not calculated as DT₉₀/3.32 and from the slow k-rate, respectively, as recommended by FOCUS. These procedures produce the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling are based on the iteratively calculated values from KinGUI 2.

II. RESULTS

First order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose for the degradation of CGA 357261 in soils [redacted] and [redacted], as well as double first order in parallel (DFOP) in soils [redacted] and [redacted] 4a. The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 373466 and NOA 413163. The kinetic analysis was also suitable to derive half-lives for trigger evaluation. Table 7.1.2.1.2- 33 to Table 7.1.2.1.2- 35 are summarizing the results of the kinetic analysis.

Table 7.1.2.1.2- 33: Kinetic parameters for degradation of CGA 357261 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test ³	Visual Assessment ⁴
[redacted]	FOMC	0.06	6.5	3.26 x 10 ⁻³	+
[redacted]	DFOP	0.07	5.3	k ₂ : 6.66 x 10 ⁻³	+
[redacted] 4a	DFOP	0.08	7.9	k ₂ : 2.10 x 10 ⁻²	o
[redacted]	FOMC	0.14	3.1	2.73 x 10 ⁻⁹	+

¹ FOMC: first order multi compartment, DFOP: double first order in parallel
² for FOMC: DT₅₀ was not calculated as DT₉₀/3.32, DT₅₀ is based on fit of the decline curve
for DFOP: DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve
³ for FOMC: worst case value of rate parameters alpha and beta
⁴ visual assessment: + = good, o = moderate

Table 7.1.2.1.2- 34: Kinetic parameters for degradation of CGA 373466 in soils under aerobic conditions for trigger evaluation and modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	0.980	SFO	31.3	103.8	4.7	< 2 x 10 ⁻¹⁶	+
[redacted]	1.000	SFO	44.6	154.2	1.7	< 2 x 10 ⁻¹⁶	+
[redacted] 4a	1.000	SFO	44.7	152.2	1.9	< 2 x 10 ⁻¹⁶	+
[redacted]	1.000	SFO	72.3	240.2	2.5	< 2 x 10 ⁻¹⁶	+



FF: formation fraction
1 SFO: single first order
2 visual assessment: + = good

Table 7.1.2.1.2- 35: Kinetic parameters for degradation of NOA 413163 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment
[redacted]	0.229	SFO	75.0	5.0	3.8 x 10 ⁻¹⁶	+
[redacted]	0.246	SFO	53.6	3.7	< 2 x 10 ⁻¹⁶	+
[redacted]	0.162	SFO	40.0	6.2	< 2 x 10 ⁻¹⁶	+
[redacted] 4a	0.260	SFO	25.4	6.2	< 2 x 10 ⁻¹⁶	+

FF: formation fraction
1 SFO: single first order
2 visual assessment: + = good

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin photodegradation products CGA 357261, CGA 373466 and NOA 413163 in soil under aerobic conditions in the dark in the laboratory were between 0.65 and 0.14 days for CGA 357261, between 31.3 and 72.3 days for CGA 373466 and between 25.4 and 75.0 days for NOA 413163 in the tested soils. The formation fractions were between 0.980 and 1.000 for CGA 373466 and between 0.162 and 0.260 for NOA 413163.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2/26; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite NOA 409480 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0725
Document No:	M-445349-02-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement Kinetic analysis of the degradation of major photodegradation product NOA 409480 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-445349-02-1 (Supplemental Dossier, KCA 7.1.2.1.2/15) was performed according to FOCUS kinetics (2006) ¹ to derive half-lives for NOA 409480, a photodegradation product of trifloxystrobin, which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of NOA 409480 in soils [redacted], [redacted], [redacted] 4a



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

and [redacted] under aerobic conditions in the dark in the laboratory at 20 °C, 55% of the maximum water holding capacity and a test concentration of 71 µg/kg.

The half-life of NOA 409480 was 45.3 days in soil [redacted], 39.3 days in soil [redacted], 24.9 days in soil [redacted] 4a and 19.1 days in soil [redacted].

I. METHODS

Soil residue data from the aerobic soil degradation study M-445309-02-1 (Supplemental Dossier, KCA 7.1.2.1.2 /15) were used. In this study, the degradation of NOA 409480, a photodegradation product of trifloxystrobin, was studied in soils [redacted] (sandy loam), [redacted] (sandy loam), [redacted] 4a (silt loam) and [redacted] (clay loam) under aerobic conditions in the dark in the laboratory for 115 days at 20 °C, 55% of the maximum water holding capacity and a test concentration of 70 µg/kg.

The degradation kinetics was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.

II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of NOA 409480 in soils [redacted] 4a and [redacted]. Table 7.1.2.1.2- 36 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 36: Kinetic parameters for the degradation of NOA 409480 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	45.3	9.2	2.20 x 10 ⁻⁷	o
[redacted]	SFO	39.3	8.2	1.84 x 10 ⁻⁸	o
[redacted] 4a	SFO	24.9	9.1	2.67 x 10 ⁻⁷	o
[redacted]	SFO	19.1	7.5	5.26 x 10 ⁻⁹	o

¹ SFO: single first order
² visual assessment: o = moderate

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin photodegradation product NOA 409480 in soil under aerobic conditions in the dark in the laboratory were between 19.1 and 45.3 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



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Report:	KCA 7.1.2.1.2 /27; [REDACTED]; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite NOA 413163 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0727
Document No:	M-467678-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of major photodegradation product NOA 413163 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-387169-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /13) was performed according to FOCUS kinetics (2006) to derive half-lives for NOA 413163, a photodegradation product of trifloxystrobin which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413163 in soils [REDACTED] 4a and [REDACTED] under aerobic conditions in the dark in the laboratory at 20 °C, 55% of the maximum water holding capacity and a test concentration of 69 µg/kg.

The half-life of NOA 413163 was 61.9 days in soil [REDACTED] 39.6 days in soil [REDACTED] 4a and 29.6 days in soil [REDACTED].

I. METHODS

Soil residue data from the aerobic soil degradation study M-387169-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /13) were used. In this study, the degradation of NOA 413163, a photodegradation product of trifloxystrobin, was studied in soils [REDACTED] (sandy loam), [REDACTED] 4a (sandy loam) and [REDACTED] (loam) under aerobic conditions in the dark in the laboratory for 120 days at 20 °C, 55% of the maximum water holding capacity and a test concentration of 69 µg/kg.

The degradation kinetics was determined according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT=0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.



II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413163 in soils [redacted], [redacted] 4a and [redacted]. Table 7.1.2.1.2- 37 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 37: Kinetic parameters for the degradation of NOA 413163 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	Dt ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	61.9	5.9	9.12 x 10 ⁻¹²	o
[redacted] 4a	SFO	39.6	4.4	1.82 x 10 ⁻¹⁶	+
[redacted]	SFO	29.6	3.2	2 x 10 ⁻¹⁶	++

¹ SFO: single first order

² visual assessment: ++ = good, o = moderate

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin photodegradation product NOA 413163 in soil under aerobic conditions in the dark in the laboratory were between 29.6 and 61.9 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 /28; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite NOA 413161 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa 413-0728
Document No:	M-467683-01-1
Guidelines:	FOCUS kinetics (2006) ¹
GLP:	No
Justification:	No data guideline requirement: Kinetic analysis of the degradation of major degradation product NOA 413161 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-371172-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /12) was performed according to FOCUS kinetics (2006) ¹ to derive half-lives for NOA 413161, a degradation product of trifloxystrobin, which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413161 in soils [redacted], [redacted] 4a and [redacted] under aerobic conditions in the dark in the laboratory at 20 °C, 55% of the maximum water holding capacity and a test concentration of 69 µg/kg.



The half-life of NOA 413161 was 89.6 days in soil [redacted], 149.3 days in soil [redacted] 4a and 85.0 days in soil [redacted].

I. METHODS

Soil residue data from the aerobic soil degradation study M-371172-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /12) were used. In this study, the degradation of NOA 413161, a degradation product of trifloxystrobin, was studied in soils [redacted] (sandy loam), [redacted] 4a (sandy loam) and [redacted] (loam) under aerobic conditions in the dark in the laboratory for 120 days at 20 °C, 55% of the maximum water holding capacity and a test concentration of 89 µg/kg.

The degradation kinetics was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.

II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413161 in soils [redacted] 4a and [redacted]. Table 7.1.2.1.2-38 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 38: Kinetic parameters for the degradation of NOA 413161 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	89.6	1	2.54 x 10 ⁻⁹	o
[redacted] 4a	SFO	149.3	3.3	1.78 x 10 ⁻¹¹	+
[redacted]	SFO	85.0	2.9	1.52 x 10 ⁻¹⁵	+

¹ SFO: single first order
² visual assessment: + = good, o = moderate

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation product NOA 413161 in soil under aerobic conditions in the dark in the laboratory were between 85.0 and 149.3 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.2 /29; [redacted]; [redacted]; [redacted]; 2012; amended 2013-10-16
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite NOA 413161 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0729
Document No:	M-467681-02-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of major degradation product NOA 413161 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-068260-01-1 (Baseline Dossier, KCA 7.1.2.1.2 /09) was performed according to FOCUS kinetics (2006) ¹ to derive half-lives for NOA 413161, a degradation product of trifloxystrobin, which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413161 in soil [redacted] under aerobic conditions in the dark in the laboratory at 20 °C, 40% of the maximum water holding capacity and a test concentration of 100 µg/kg.

The half-life of NOA 413161 was 250.7 days.

1. METHODS

Soil residue data from the aerobic soil degradation study M-068260-01-1 (Baseline Dossier, KCA 7.1.2.1.2 /09) were used. In this study, the degradation of NOA 413161, a degradation product of trifloxystrobin, was studied in soil [redacted] (loamy sand) under aerobic conditions in the dark in the laboratory for 126 days at 20 °C, 40% of the maximum water holding capacity and a test concentration of 100 µg/kg.

The degradation kinetics was determined according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.

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II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413161 in soil [redacted]. Table 7.1.2.1.2- 39 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 39: Kinetic parameters for the degradation of NOA 413161 in soil under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	253.7	3.6	1.80 x 10 ⁻⁶	o

¹ SFO: single first order

² visual assessment: o = moderate

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of the major trifloxystrobin degradation product NOA 413161 in soil under aerobic conditions in the dark in the laboratory was 253.7 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 /30; [redacted]; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite CGA 357276 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2.1 Tool
Report No:	EP-Sa-13-0730
Document No:	M-467686-011
Guidelines:	- FOCUS Kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of major degradation product CGA 357276 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-465697-01-1 (Supplemental Dossier, KCA 7.1.2.1.2/14) was performed according to FOCUS kinetics (2006) ¹ to derive half-lives for CGA 357276, a degradation product of trifloxystrobin, which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Hockey stick was the most appropriate kinetic model for modelling purpose for the degradation of CGA 357276 in soil [redacted], double first order in parallel in soils [redacted] and [redacted] 4a, as well as first order multi compartment in soil [redacted] under aerobic conditions in the dark in the laboratory at 19.9 °C, 55.4% of the maximum water holding capacity and a test concentration of 25 µg/kg.

The half-life of CGA 357276 was 66.5 days in soil [redacted], 71.9 days in soil [redacted], 79.0 days in soil [redacted] 4a and 21.6 days in soil [redacted].



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I. METHODS

Soil residue data from the aerobic soil degradation study M-465697-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /14) were used. In this study, the degradation of CGA 357276, a degradation product of trifloxystrobin, was studied in soils [redacted] (sandy loam), [redacted] (loamy sand), [redacted] 4a (silt loam) and [redacted] (loam) under aerobic conditions in the dark in the laboratory for 120 days at 19.9 °C, 55.4% of the maximum water holding capacity and a test concentration of 25 µg/kg.

The degradation kinetics was determined according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameter.

II. RESULTS

Hockey stick (HS) was the most appropriate kinetic model for modelling purpose for the degradation of CGA 357276 in soil [redacted], double first order in parallel (DFOP) in soils [redacted] and [redacted] 4a, as well as first order multi compartment (FOMC) in soil [redacted]. Table 7.1.2.1.2- 40 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 40 Kinetic parameters for the degradation of CGA 357276 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test ³	Visual Assessment ⁴
[redacted]	HS	66.5	3.2	k ₂ : 7.46 x 10 ⁻⁷	+
[redacted]	DFOP	71.9	1.2	k ₂ : 6.17 x 10 ⁻⁷	+
[redacted] 4a	DFOP	79.0	2.8	k ₂ : 2.91 x 10 ⁻²	+
[redacted]	FOMC	21.6	1.8	2.24 x 10 ⁻⁶	+

¹ FOMC: first order multi compartment, DFOP: double first order in parallel, HS: hockey stick

² for FOMC: DT₅₀ was calculated as DT₉₀ 0.32

for DFOP, and HS: DT₅₀ was calculated from the slow k-rate

³ for FOMC: worst case value of rate parameters alpha and beta

⁴ visual assessment: + = good

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 357276 in soil under aerobic conditions in the dark in the laboratory were between 21.6 and 79.0 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.2 /31; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite CGA 381318 under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0731
Document No:	M-468502-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of major photodegradation product CGA 381318 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aerobic soil degradation study M-462102-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /11) was performed according to FOCUS kinetics (2006) to derive half-lives for CGA 381318, a photodegradation product of trifloxystrobin which are suitable for modelling purpose. The kinetic evaluation was performed with the software KinGUI 2.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of CGA 381318 in soils [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED] under aerobic conditions in the dark in the laboratory at 20.3 °C, 54.5% of the maximum water holding capacity and a test concentration of 36 µg/kg.

The half-life of CGA 381318 was 11.9 days in soil [REDACTED], 22.8 days in soil [REDACTED], 22.8 days in soil [REDACTED] 4a and 20.4 days in soil [REDACTED].

METHODS

Soil residue data from the aerobic soil degradation study M-462102-01-1 (Supplemental Dossier, KCA 7.1.2.1.2 /11) were used. In this study, the degradation of CGA 381318, a photodegradation product of trifloxystrobin, was studied in soils [REDACTED] (sandy loam), [REDACTED] (loamy sand), [REDACTED] 4a (silt loam) and [REDACTED] (loam) under aerobic conditions in the dark in the laboratory for 122 days at 20.3 °C, 54.5% of the maximum water holding capacity and a test concentration of 36 µg/kg.

The degradation kinetics was determined according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.

II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of CGA 381318 in soils [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED]. Table 7.1.2.1.2- 41 summarizes the results of the kinetic analysis.



Table 7.1.2.1.2- 41: Kinetic parameters for the degradation of CGA 381318 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-tot ³	Visual Assessment ²
	SFO	11.9	5.2	3.17 x 10 ⁻¹²	
	SFO	22.8	5.0	1.69 x 10 ⁻¹¹	
4a	SFO	22.8	4.1	2.76 x 10 ⁻¹³	o
	SFO	20.4	3.5	4.69 x 10 ⁻¹³	+

¹ SFO: single first order

² visual assessment: + = good, o = moderate

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin photodegradation product CGA 381318 in soil under aerobic conditions in the dark in the laboratory were between 11.9 and 22.8 days in the tested soils.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.2 /32; [redacted] 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Aerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa_13-0733
Document No:	M_468177-01-1
Guidelines:	FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data guideline requirement. Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the aged residues column leaching / aerobic soil degradation study M-033599-01-1 (Baseline Dossier, KCA 7.1.2.1.1 /06 and KCA 7.1.2.1.2 /06) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soils [redacted] and [redacted] under aerobic conditions in the dark in the laboratory at 20 °C and different soil moistures (75% of the field capacity at 1/3 bar for soil [redacted] and 40% of the maximum water holding capacity for soil [redacted]) and a test concentration of 1.0 mg/kg.

The half-life of CGA 321113 was 386.1 days in soil [redacted] and 115.3 days in soil [redacted].



The formation fraction of CGA 321113 was 0.935 in soil [redacted] and 0.913 in soil [redacted].

I. METHODS

Methods are summarized under KCA 7.1.2.1.1 /19 of the Supplemental Dossier.

II. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soils [redacted] and [redacted]. Table 7.1.2.1.2- 42 summarizes the results of the kinetic analysis.

Table 7.1.2.1.2- 42: Kinetic parameters for degradation of CGA 321113 in soils under aerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi Error [%]	t-test	Visual Assessment ²
[redacted]	0.935	SFO	386.1	1.3	2.57×10^{-8}	+
[redacted]	0.913	SFO	115.3	2.0	5.24×10^{-8}	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of the major trifloxystrobin degradation product CGA 321113 in soil under aerobic conditions in the dark in the laboratory were between 115.3 and 386.1 days in the tested soils. The formation fractions of CGA 321113 were between 0.913 and 0.935.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

CA 7.1.2.1.3 Anaerobic degradation of the active substance

The degradation rate of trifloxystrobin in soil under anaerobic conditions in the dark in the laboratory was evaluated during the Annex O inclusion using one radiolabel position, [¹⁴C-GP], and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.2.1.3 /01	[redacted]	1996	M-033427-01-1

An updated kinetic evaluation of the degradation behaviour of trifloxystrobin in soil under anaerobic conditions in the dark in the laboratory has been performed according to FOCUS kinetics (2006) ¹ to derive kinetic parameters suitable for modelling purpose and environmental risk assessment and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory is given in section CA 7.1.2.1.



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Report:	KCA 7.1.2.1.3 /02; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Anaerobic Soil Conditions in Laboratory According to FOCUS Kinetics using KinGUI 2 Tool
Report No:	EnSa-13-0732
Document No:	M-468176-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the anaerobic soil degradation study M-033427-01-1 (Baseline Dossier, KCA 7.1.2.1.3 /01 and KCA 7.1.2.1.4 /01) was performed, with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for trifloxystrobin are described here.

Hockey stick was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil North Carolina under anaerobic conditions in the dark in the laboratory at 25 °C and a test concentration of 159 µg/kg (based on soil/water combination).

The half-life of trifloxystrobin was 0.61 day.

1. METHODS

Soil residue data from the anaerobic soil degradation study M-033427-01-1 (Baseline Dossier, KCA 7.1.2.1.3 /01 and KCA 7.1.2.1.4 /01) were used. In this study, the degradation of trifloxystrobin was studied in soil North Carolina (loamy sand) under anaerobic conditions in the dark in the laboratory for 365 days at 25 °C and a test concentration of 159 µg/kg (based on soil/water combination).

The kinetic analysis was performed according to FOCUS kinetics (2006) ¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model.



II. RESULTS

Hockey stick (HS) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in soil North Carolina. Table 7.1.2.1.3- 1 summarizes the results of the kinetic analysis.

Table 7.1.2.1.3- 1: Kinetic parameters for the degradation of trifloxystrobin in soil under anaerobic conditions for modelling purpose according to FOCUS.

Soil	Kinetic Model ¹	DT _{50%} [days]	Chi ² Error [%]	t-test	Visual Assessment ²
North Carolina	HS	0.61	2.8	2.48 × 10 ⁻³	+

¹ HS: hockey stick

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of trifloxystrobin in soil under anaerobic conditions in the dark in the laboratory was 0.61 days in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

CA 7.1.2.1.4 Anaerobic degradation of metabolites, breakdown and reaction products

The degradation rate of the major degradation product CGA 321113 in soil under anaerobic conditions in the dark in the laboratory was evaluated during the Annex I inclusion using one radiolabel position, [¹⁴C-GP], and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.2.1.4 /01	[REDACTED]	1996	M-033427-01-1

Two additional studies have been performed for the major degradation products CGA 321113, NOA 413161 and NOA 413163, and are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using one radiolabel position, [¹⁴C-GP]. Furthermore, updated kinetic evaluations of the degradation behaviours of major degradation products in soil under anaerobic conditions in the dark in the laboratory have been performed according to FOCUS kinetics (2006)¹ to derive kinetic parameters suitable for modelling purpose and environmental risk assessment. A summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory is given in section CA 7.1.2.1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.4 /02; [REDACTED]; [REDACTED]; 2013
Title:	CGA 321113: Anaerobic Degradation / Metabolism in One Soil
Report No:	EnSa-13-0616
Document No:	M-467759-01-1
Guidelines:	- OECD Test Guideline No. 307 - DRAFT SANCO 11802/2010/rev 7 in accordance with Regulation (EC) No 1107/2009 - US EPA OCSP Test Guideline No. 835.4100 / 835.4200
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rate of major degradation product CGA 321113 according to OECD Test Guideline No. 307

Executive Summary

The route and rate of degradation of [¹⁴C-GP]CGA 321113, a degradation product of trifloxystrobin, were studied in one soil under anaerobic conditions following an aerobic incubation phase in the dark in the laboratory for 122 days at 20.1 °C:

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Burscheid, Germany	Clt loam	6.4	2.0

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

[¹⁴C-GP]trifloxystrobin was used as test item due to the limited availability of radiolabelled CGA 321113 and due to the rapid and nearly quantitative degradation of trifloxystrobin in soil under aerobic conditions in the dark to CGA 321113 with 80% of the applied amount being converted within 1 day. Therefore, a study application rate of 750 µg trifloxystrobin per kg soil dry weight was applied based on a single field application rate of trifloxystrobin of 187.5 g per hectare.

Mean material balance was 96.3% of applied radioactivity [% AR] (range from 93.4 to 98.8% AR).

The maximum amount of carbon dioxide was 10.7% AR at DAT-30 in the aerobic incubation phase and remained constant in the anaerobic incubation phase until study end (122 days after soil flooding (DASF)). Formation of volatile organic compounds was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals.

Extractable residues decreased from 98.4% AR at study start (DAT-0) to approximately 70% AR from DASF-62 onwards.

Non-extractable residues increased from DAT-0 to DASF-122 from 0.4 to 16.3% AR.

The amount of trifloxystrobin decreased rapidly in the aerobic incubation phase from DAT-0 to DAT-2 from 95.7 to 8.7% AR and decreased further to 0.9% AR at DAT-30. In parallel, the amount of CGA 321113 reached a maximum of 87.3% AR at DAT-2 and decreased to 67.1% AR at DAT-30. CGA 321113 decreased further in the anaerobic incubation phase to 55.4% AR at DASF-122.

Besides the formation of carbon dioxide, two additional degradation products were identified: NOA 413161 with a maximum amount of 4.7% AR at DASF-0, which slightly decreased in the anaerobic incubation phase to 4.2% AR at DASF-122, and CGA 357276 with a maximum amount of 2.2% AR at DASF-122. The total unidentified residues amounted to a maximum of 7.8% AR with no one component exceeding 4.7% AR at any sampling interval.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The experimental data could be well described by a single first order kinetic model. The half-life of CGA 321113 under anaerobic conditions was 356 days.

It is concluded that CGA 321113 will be slowly degraded under anaerobic conditions in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzeneacetic-phenyl-UL-¹⁴C]trifloxystrobin
Sample ID: KML 9481
Specific Activity: 3.01 MBq/mg (81.4 µCi/mg)
Radiochemical Purity: > 98%
Chemical Purity: > 99%

2. Test Soil

One soil was used (see [Table 7.1.2.1.4-4](#)). The soil was taken from an agricultural use area. No plant protection products were used for the previous 5 years. The soil was sampled freshly from the field (upper horizon of 0 to 20 cm) and sieved to a particle size of $\leq 2\text{ mm}$. Soil collection and handling were in accordance to ISO 10381-6.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2.1.4- 1: Physico-chemical properties of test soil

Parameter	Results / Units
Soil Designation	[REDACTED]
Geographic Location	
City	[REDACTED]
State	North-Rhine Westphalia
Country	Germany
GPS Coordinates	[REDACTED]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf
Soil Series	no information available
Textural Class (USDA)	silt loam
Sand [50 µm – 2 mm]	21%
Silt [2 µm – 50 µm]	65%
Clay [< 2 µm]	14%
pH (soil/CaCl ₂ 1/2)	6.1
pH (soil/water 1/1)	6.3
pH (saturated paste)	6.4
pH (soil/1 N KCl)	6.8
Organic Carbon (combustion)	2.0%
Organic Matter ¹	3.4%
Cation Exchange Capacity [meq/100 g]	11.1
Maximum Water Holding Capacity [g H ₂ O at 100 g soil DW]	59.0
maximum at 0.1 bar (pF 2.9)	23.7%
Bulk Density (Disturbed) [g/cm ³]	1.11
Microbial biomass (aerobic incubation phase) [mg microbial carbon per kg soil DW] ²	
DAT-0 (BIO-)	1034
DAT-30 (BIO- / BIO+)	1103 / 956
Microbial Viability (anaerobic incubation phase) [CFU/g soil DW] ²	
DASF-122 (BIO- / BIO+)	17000 / 13300

¹ % organic matter = % organic carbon x 1.724

² BIO- samples were left untreated, BIO+ samples were applied with solvent of application solution (200 µL methanol)

CFU: colony forming units

DAT: days after treatment

DASF: days after soil flooding

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture

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B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under anaerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). For the aerobic incubation phase, each flask was fitted with a trap attachment (permeable for oxygen) containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds (VOC). For the anaerobic incubation phase, the trap attachments were replaced by sealable two-valve glass stoppers connected with air-tight plastic gas sampling bags for the collection of volatiles.

For preparation of the test systems, 100 g dry weight equivalents of the sieved soil were weighed into each flask. Soil moisture was adjusted to $55 \pm 5\%$ of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The flasks were then fitted with trap attachments and equilibrated to study conditions for 5 days prior to application.

[^{14}C -GP]trifloxystrobin was used as test item due to the limited availability of radiolabelled CGA 321113 and due to the rapid and nearly quantitative degradation of trifloxystrobin in soil under aerobic conditions in the dark to CGA 321113 with $> 80\%$ of the applied amount being converted within 1 day. Therefore, the study application rate (SAR) was based on a single field application rate of trifloxystrobin of 187.5 g per hectare and a 1.5-fold application rate due to analytical reasons, resulting in a nominal SAR of $750 \mu\text{g } ^{14}\text{C-GP trifloxystrobin per kg soil dry weight}$.

The test item was applied dropwise onto the soil surface of the respective test systems in 200 μL methanol using a pipette. After application, the test vessels (except DAT-0 samples) were fitted with trap attachments.

The test systems were incubated in the dark for 30 days at 20.1°C and a soil moisture of $55 \pm 5\%$ MWHC in a walk-in climatic chamber.

30 days after treatment (DAT-30 corresponding to DASF-0), the soil was flooded with 140 mL oxygen-depleted water and set under an atmosphere of nitrogen. The trap attachments were replaced by air-tight plastic gas sampling bags. To ensure maintenance of oxygen-free conditions in the anaerobic incubation phase, the test systems were placed in a nitrogen-flooded box within the walk-in climatic chamber. The test systems were incubated in the dark under anaerobic conditions for 122 days at 20.1°C .

2. Sampling

Eleven sampling intervals were distributed over the entire incubation period of 152 days (30 days under aerobic conditions and 122 days under anaerobic conditions). Duplicate samples were processed and analysed 0, 2, 14 and 30 days after treatment (DAT) in the aerobic incubation phase and 0, 7, 14, 32, 62, 90 and 122 days after soil flooding (DASF) in the anaerobic incubation phase. Microbial soil biomass was determined in the aerobic incubation phase at study start (DAT-0) and DAT-30. The amounts of anaerobic bacteria were determined in the anaerobic incubation phase at study end (DASF-122).

3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped in a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The PU foam plugs of the trap attachments were extracted with ethyl acetate in an ultrasonic bath to desorb VOC. The radioactivity content was determined by LSC.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

Volatiles possibly present in anaerobic test systems were slowly purged through a soda lime trap for absorption of carbon dioxide, then through a catalytic oven for oxidative combustion of VOC (e.g. methane), and its combustion exhaust through a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by LSC and the soda lime was further processed as described before for carbon dioxide.

At each sampling interval of the anaerobic incubation phase, pH, oxygen content and redox potential in the water and the pH and redox potential in the soil were determined. Water and soil were separated by decantation. The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker and acetonitrile/water 4/1 (v/v). Furthermore, two accelerated extraction steps using a microwave with a magnetic stirrer were performed, first with acetonitrile/water 1/1 (v/v) at 70 °C and second with methanol/water 1/1 (v/v) at 50 °C. After each extraction step, extract and soil were separated by centrifugation (3480 x g) and decantation. The radioactivity content of the water, the combined ambient soil extracts and the microwave soil extract was determined by LSC. Aliquots of the soil extracts were combined. Water and combined soil extracts were concentrated and analysed by reversed phase HPLC/radiodetection. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC/radiodetection analysis of the water and combined soil extracts were 0.8 and 2.5% AR, respectively.

The exhaustive extracted soils were air-dried, homogenized and non-extractable residues were determined by combustion/LSC.

Test item and degradation products were identified by HPLC co-chromatography with reference items and by HPLC-MS(/MS) including accurate mass determination.

The degradation kinetics of GA 321113 was determined according to FOCUS kinetics (2006)¹ using the software KinGIM2 with two different kinetic models: single first order and first order multi compartment. Model input datasets were the residual amounts found in each replicate test system at each sampling interval of the anaerobic incubation phase (DASF-0 to DASF-122). The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi²-scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

4. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained in the aerobic and anaerobic incubation phase, and that the soil was microbially active over the duration of the laboratory study. Anaerobic bacteria plate count assays performed at study end confirmed the establishment of an anaerobic microflora in the test systems.

The pH values in water and soil of the anaerobic incubation phase ranged from 6.9 to 7.7 and from 6.6 to 7.4, respectively.

Oxygen contents in the water decreased from a maximum concentration of 3.7 mg/L at DASF-0 to ≤ 1.5 mg/L from DASF-9 onwards demonstrating the shift from aerobic to anaerobic conditions.

Redox potential measurements indicated reducing conditions in the water and soil from DASF-14 onwards.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

A. DATA

Table 7.1.2.1.4- 2: Degradation of CGA 321113 in soil [redacted] under anaerobic conditions (mean values and SD expressed as % AR)

Compound	DAT	0	2	14	30	30	37
	DASF	N/A					0
trifloxystrobin	Mean	95.7	87	1.4	0.9	1.0	LOD
	SD	± 0.8	± 0.1	± 0.0	± 0.1	± 0.0	
CGA 321113	Mean	n.d.	87.3	80.1	67.1	68.0	88.4
	SD		± 0.3	± 0.3	± 0.1	± 0.9	± 0.2
NOA 413161	Mean	n.d.	n.d.	2.8	4.4	4.7	4.3
	SD			± 0.0	± 0.0	± 0.0	± 0.0
CGA 357276	Mean	n.d.	n.d.	< LOD	< LOD	< LOD	< LOD
	SD						
Sum of Unid./Diff. Residues ¹	Mean	2.5	LOD	< LOD	1	1.0	0
	SD	± 0.0			± 0.0	± 0.1	± 0.0
Total Extractable Residues ²	Mean	98.4	96.0	84.3	73.5	74.9	73.5
	SD	± 0.8	± 0.2	± 0.2	± 0.4	± 0.9	± 0.2
Carbon Dioxide (sum aerobic and anaerobic) ³	Mean	n.a.	0.3	30	0.2	9.7	10.0
	SD		± 0.0	± 0.0	± 0.1	± 0.0	± 0.0
Volatile Organic Compounds (sum aerobic and anaerobic)	Mean	n.a.	0.1	0.1	< 0.1	0.1	< 0.1
	SD		± 0.1	± 0.0	± 0.0	± 0.0	± 0.0
Non-Extractable Residues ³	Mean	0.4	1.5	6.4	12.3	10.7	11.4
	SD	± 0.0	± 0.0	± 0.3	± 0.0	± 0.7	± 0.2
Total Recovered	Mean	98.2	97.9	94.3	95.9	95.3	94.9
	SD	± 0.8	± 0.2	± 0.6	± 0.3	± 1.6	± 0.0

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Table 7.1.2.1.4- 2 (continued)

Compound	DAT	44	62	92	120	152
	DASF	14	32	62	90	122
trifloxystrobin	Mean	< LOD	< LOD	< LOD	n.d.	n.d.
	SD					
CGA 321113	Mean	69.1	65.8	59.4	58.1	55.4
	SD	± 1.5	± 0.2	± 0.9	± 0.5	± 0.7
NOA 413161	Mean	4.4	4.5	4.3	4.2	4.2
	SD	± 0.0	± 0.2	± 0.2	± 0.1	± 0.0
CGA 357276	Mean	< LOD	1.1	1.2	1.8	2.2
	SD		± 0.1	± 0.0	± 0.0	± 0.1
Sum of Unid./Diff. Residues ¹	Mean	< LOD	< LOD	3.0	2.8	2.8
	SD			± 0.0	± 0.6	± 0.0
Total Extractable Residues ²	Mean	73.5	71.3	67.9	69.6	69.7
	SD	± 1.5	± 0.0	± 1.1	± 0.2	± 0.2
Carbon Dioxide (sum aerobic and anaerobic) ³	Mean	10.0	10.0	9.9	9.9	9.9
	SD	± 0.0	± 0.0	± 0.0	± 0.0	± 0.0
Volatile Organic Compounds (sum aerobic and anaerobic)	Mean	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
	SD	± 0.0	± 0.0	± 0.0	± 0.0	± 0.0
Non-Extractable Residues ³	Mean	10.7	13.1	14.6	15.9	16.3
	SD	± 0.1	± 0.0	± 0.1	± 0.1	± 0.4
Total Recovery	Mean	95.2	94.4	92.5	95.4	95.9
	SD	± 1.4	± 0.2	± 1.0	± 0.0	± 0.2

n.d.: not detected, n.a.: not analysed, N/A: not applicable, DAT: days after treatment, DASF: days after soil flooding

¹ Minor degradation products are summed up to sum of unidentified/diffuse residues, with no one component exceeding 4.7% AR.

² Difference to Material Balance values due to rounding errors as well as clean up and chromatographic losses.

³ Values taken from Material Balance.

B. MATERIAL BALANCE

Mean material balance was 96.3% of applied radioactivity [% AR] (range from 93.4 to 98.8% AR). The complete material balance found at all sampling intervals demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

C. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES

Extractable residues decreased from 98.4% AR at study start (DAT-0) to approximately 70% AR from DASF-62 onwards. Non-extractable residues increased from DAT-0 to study end (DASF-122) from 0.4 to 16.3% AR.

D. VOLATILES

The maximum amount of carbon dioxide was 10.2% AR at DAT-30 in the aerobic incubation phase and remained constant in the anaerobic incubation phase until 122 days after soil flooding (DASF). Formation of volatile organic compounds was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals.



E. DEGRADATION OF PARENT COMPOUND

The amount of trifloxystrobin rapidly decreased in the aerobic incubation phase from DAT-0 to DAT-2 from 95.7 to 8.7% AR and decreased further to 0.9% AR at DAT-30. In parallel, the amount of CGA 321113 reached a maximum of 87.3% AR at DAT-2 and decreased to 67.1% AR at DAT-30. CGA 321113 decreased further in the anaerobic incubation phase to 55.4% AR at DASF-122.

Besides the formation of carbon dioxide, two additional degradation products were identified: NOA 413161 with a maximum amount of 4.7% AR at DASF-0 which slightly decreased in the anaerobic incubation phase to 4.2% AR at DASF-122 and CGA 350276 with a maximum amount of 2.2% AR at DASF-122. The total unidentified residues amounted to a maximum of 7.8% AR with no one component exceeding 4.7% AR at any sampling interval.

The degradation of CGA 321113 in the anaerobic incubation phase followed single first order (SFO) kinetics according to the lowest chi² error values and visual assessments. Table 7.1.2.1.4-3 summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.

Table 7.1.2.1.4- 3: Degradation kinetics of CGA 321113 in soil [redacted] under anaerobic conditions according to FOCUS (best fit)

Best-Fit Kinetic Model	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	Visual Assessment
SFO	356	> 1000	1.4	+

¹ SFO: single first order
² visual assessment: + = good

III. CONCLUSIONS

CGA 321113, a major degradation product of trifloxystrobin, was slowly degraded in soil under anaerobic conditions in the dark in the laboratory. The calculated best-fit half-life was 356 days in the tested soil.

It is concluded that CGA 321113 will be slowly degraded under anaerobic conditions in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.1.4 /03; [REDACTED]; 2004
Title:	Anaerobic Soil Metabolism of NOA 413161 and NOA 413163
Report No:	MEF-04/254
Document No:	M-123509-01-1
Guidelines:	- OECD Test Guideline No. 307 - SETAC Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides - Commission Directive 95/36/EC amending Council Directive 91/414/EEC
GLP:	Yes
Justification:	New data / guideline requirement: Degradation rates of major degradation products NOA 413161 and NOA 413163

Executive Summary

The route and rate of degradation of [¹⁴C-GP]NOA 413161 and [¹⁴C-GP]NOA 413163, degradation products of trifloxystrobin, were studied in one soil under anaerobic conditions following an aerobic incubation phase in the dark in the laboratory for 364 days at 20.0 °C.

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Burscheid, Germany	Silt	6.7	2.1

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

A study application rate of 22.5 µg each of NOA 413161 and NOA 413163 per kg soil dry weight was applied (sum of 65 µg per kg soil dry weight) based on a single field application rate of trifloxystrobin of 250 g per hectare and a maximum formation of in sum 5.3% of NOA 413161 and NOA 413163 in a trifloxystrobin field dissipation study.

Mean material balance was 102.4% of applied radioactivity [% AR] (range from 94.1 to 109.1% AR).

The maximum amount of carbon dioxide was approximately 13% AR 30 days after treatment (DAT) in the aerobic incubation phase and remained constant in the anaerobic incubation phase until study end (364 days after soil flooding (DASF)). Formation of volatile organic compounds was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals.

Extractable residues decreased from 93.7% AR at study start (DAT-0) to approximately 40% AR from DASF-14 onwards.

Non-extractable residues increased from 7.4% AR at DAT-0 to a maximum of 35.8% AR at DAT-30 and decreased to approximately 20% AR from DASF-60 onwards.

The amounts of NOA 413161 and NOA 413163 decreased in the aerobic incubation phase from 46.1% AR each at DAT-0 to 22.0 and 27.9% AR at DAT-30, respectively. The amounts of NOA 413161 and NOA 413163 decreased further in the anaerobic incubation phase to 18.3 and 11.1% AR, respectively. The total unidentified residues amounted to a maximum of 36.5% AR with no one component exceeding 4.6% AR at any sampling interval. All components were < 5% AR if expressed as percentage of trifloxystrobin and considering the maximum formation of NOA 413161 and NOA 413163 in aerobic soil, and were therefore not identified.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The experimental DT₅₀ and DT₉₀ values for the anaerobic incubation phase were calculated using single first order kinetics. The half-lives of NOA 413161 and NOA 413163 under anaerobic conditions were 976 and 206 days, respectively.

It is concluded that NOA 413161 and NOA 413163 will be slowly degraded under anaerobic conditions in the environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Items

[(UL-¹⁴C-phenyl)-acetic acid]NOA 413161
Sample ID: BECH 0704
Specific Activity: 3.41 MBq/mg (92.1 µCi/mg)
Radiochemical Purity: 97.8%
Chemical Purity: > 98%

[(UL-¹⁴C-phenyl)-acetic acid]NOA 413163
Sample ID: BECH 0705
Specific Activity: 3.41 MBq/mg (92.1 µCi/mg)
Radiochemical Purity: 98%
Chemical Purity: > 99%

2. Test Soil

One soil was used (see Table 7.1.4.1). No plant protection products were used for the previous 5 years. The soil was sampled freshly from the field (upper horizon of 0 to 20 cm) and sieved to a particle size of 2 mm.

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Table 7.1.2.1.4- 4: Physico-chemical properties of test soil

Parameter	Results / Units
Soil Designation	██████████ 4a
Geographic Location	
City	██████████
State	North-Rhine Westphalia
Country	Germany
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf
Soil Series (SCS)	Argisol, Udalf
Textural Class (USDA)	silt
Sand [50 µm – 2 mm]	9%
Silt [2 µm – 50 µm]	82%
Clay [< 2 µm]	10%
pH (soil/CaCl ₂)	6.7
pH (soil/water)	7.6
pH (soil/1 N KCl)	7.0
Organic Carbon (combustion)	2.1%
Organic Matter ¹	3.0%
Cation Exchange Capacity [meq/100g]	15
Maximum Water Holding Capacity [g H ₂ O/g soil DW]	63
Bulk Density (disturbed) [g/cm ³]	1.0
Microbial biomass (aerobic incubation phase) [mg microbial carbon per kg soil DW]	
DAT-0	1473
Microbial Viability (anaerobic incubation phase) [CFU/g soil DW]	
DASF-122 (with / without test items)	807 / 1313
DASF-366 (with / without test items)	8000 / 7670

¹ % organic matter = % organic carbon × 1.724
 CFU: colony forming units
 DAT: days after treatment
 DASF: days after soil flooding
 DW: dry weight
 USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The static test system for degradation in soil under anaerobic conditions consisted of Erlenmeyer glass flasks (volume e.g. 300 mL). For the aerobic incubation phase, each flask was fitted with a trap attachment (permeable for oxygen) containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds (VOC). For the anaerobic incubation phase, the trap attachments were replaced by sealable two-valve glass stoppers connected with air-tight plastic gas sampling bags for the collection of volatiles.

The soil was equilibrated at approximately 23 °C in the laboratory for approximately one week.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

The study application rate (SAR) was based on a single field application rate of trifloxystrobin of 250 g per hectare and a maximum formation of in sum 5.3% of NOA 413161 and NOA 413163 in field dissipation study M-033523-02-1 (Baseline Dossier, KCA 7.1.1.1 /08), resulting in a nominal SAR of 33 µg each of NOA 413161 and NOA 413163 per kg soil dry weight (sum of 66 µg per kg soil dry weight).

The test items were simultaneously applied onto a air-dried soil aliquot and this soil aliquot was mixed with the bulk amount of the soil for 1 hour using a tumbling mixer.

For preparation of the test systems, 100 g dry weight equivalents of the applied soil were weighed into each test vessel. Soil moisture was adjusted to 50% of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The test vessels were then fitted with trap attachments and incubated under aerobic conditions for 30 days at 20 °C in a walk-in climatic chamber in the dark.

30 days after treatment (DAT-30 corresponding to DASF-0), the soil was flooded with 120 mL oxygen-depleted water (approx. 1 to 3 cm layer above soil level) and set under an atmosphere of nitrogen. The trap attachments were replaced by air-tight plastic gas sampling bags. To ensure maintenance of oxygen-free conditions in the anaerobic incubation phase, the test systems were placed in a nitrogen-flooded box within the walk-in climatic chamber. The test systems were incubated in the dark under anaerobic conditions for 364 days at 20 °C.

2. Sampling

Ten sampling intervals were distributed over the entire incubation period of 394 days (30 days under aerobic conditions and 364 days under anaerobic conditions). Duplicate samples were processed and analysed 0 and 30 days after treatment (DAT) in the aerobic incubation phase and 14, 31, 60, 90, 122, 180, 270 and 364 days after soil flooding (DASF) in the anaerobic incubation phase. Microbial soil biomass was determined in the aerobic incubation phase at study start (DAT-0). The amounts of anaerobic bacteria were determined in the anaerobic incubation phase during and at the end of the study (DASF-022 and DASF-364).

3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped in a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The PU foam plugs of the trap attachments were extracted with ethyl acetate in an ultrasonic bath to desorb VOC. The radioactivity content was determined by LSC.

Volatiles possibly present in anaerobic test systems were slowly purged through a soda lime trap for absorption of carbon dioxide, then through a catalytic oven for oxidative combustion of VOC (e.g. methane), and its combustion exhaust through a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by LSC and the soda lime was further processed as described before for carbon dioxide.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

At each sampling interval of the anaerobic incubation phase, pH, oxygen content and redox potential in the water and the pH and redox potential in the soil were determined. Water and soil were separated by decantation. The entire soil of each test system was extracted. The soil of DAT-0 sample was extracted six times at ambient temperature using a mechanical shaker, once using water, twice using acetonitrile and three times using acetonitrile/water 1/1 (v/v). The soil of DAT-30 and all anaerobic samples was extracted four times at ambient temperature using a mechanical shaker, once using water and three times using acetonitrile/water 1/1 (v/v). After each extraction step, extract and soil were separated by centrifugation and decantation. The radioactivity content of the water and the combined ambient soil extracts was determined by LSC. Aliquots of the water and the combined soil extracts were analysed by normal phase TLC/radiodetection. The limit of detection (LOD) and limit of quantitation (LOQ) for TLC/radiodetection analysis of the water and the combined soil extracts were 0.1% AR, respectively.

The exhaustive extracted soils were air-dried, homogenized and non-extractable residues were determined by combustion/LSC.

Test items were identified by TLC co-chromatography with reference items and by HPLC-MS(/MS).

The degradation kinetics of the test items was determined using the software Model Manager[®] with a single first order kinetic model. Model input datasets were the mean residual amounts found in the duplicate test systems at each sampling interval of the anaerobic incubation phase (DASF-14 to DASF-364). DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained in the aerobic and anaerobic incubation phase, and that the soil was microbially active over the duration of the laboratory study. Anaerobic bacteria plate count assays performed during and at the end of the study confirmed the establishment of an anaerobic microflora in the test systems.

The pH values in water and soil of the anaerobic incubation phase ranged from 7.4 to 7.7 and from 7.1 to 7.6, respectively.

Oxygen contents in the water were constant from DASF-14 onwards and ranged from 0.08 to 0.55 mg/L demonstrating anaerobic conditions.

Redox potential measurements indicated reducing conditions in the water and soil from DASF-14 onwards.



A. DATA

Table 7.1.2.1.4- 5: Degradation of NOA 413161 and NOA 413163 in soil [redacted] 4a under anaerobic conditions (mean values expressed as % AR)

Compound	DAT	0	30	44	61	90
	DASF	N/A		14	31	60
NOA 413161	Mean	46.1	22.6	26.4	22.8	22.4
NOA 413163	Mean	46.1	27.9	34.0	31.1	28.3
Sum of Unid./ Diff. Residues ¹	Mean	15	2.5	4.0	9.1	16.1
Total Extractable Residues ²	Mean	93.7	53.0	64.4	63.6	66.8
Carbon Dioxide (sum aerobic and anaerobic) ³	Mean	n.a.	12.7	13.3	13.1	13.2
Volatile Organic Compounds (sum aerobic and anaerobic) ³	Mean	n.a.	n.d.	< 0.1	0.1	< 0.1
Non-Extractable Residues ³	Mean	7.4	35.8	31.4	28.7	29.2
Total Recovery ²	Mean	101.0	101.5	109.1	105.4	103.2

Table 7.1.2.1.4- 5 (continued)

Compound	DAT	120	152	210	300	394
	DASF	90	122	180	270	364
NOA 413161	Mean	22.0	22.5	22.8	21.0	18.3
NOA 413163	Mean	25.8	23.1	18.9	14.3	11.1
Sum of Unid./ Diff. Residues ¹	Mean	18.4	24.2	31.3	36.5	29.6
Total Extractable Residues ²	Mean	66.5	69.9	72.5	71.8	59.0
Carbon Dioxide (sum aerobic and anaerobic) ³	Mean	12.8	13.1	12.9	13.7	14.4
Volatile Organic Compounds (sum aerobic and anaerobic) ³	Mean	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
Non-Extractable Residues ³	Mean	22.4	19.5	19.9	14.4	20.5
Total Recovery ²	Mean	101.7	102.5	105.3	99.9	93.9

n.d.: not detected, n.a.: not analysed, N/A: not applicable, DAT: days after treatment, DASF: days after soil flooding

¹ Minor degradation products are summed up to sum of unidentified / diffuse residues, with no one component exceeding 15.6% AR. All components were < 5% AR if expressed as percentage of trifloxystrobin and considering the maximum formation of NOA 413161 and NOA 413163, and were therefore not identified.

² Difference to Material Balance values due to rounding errors as well as clean up and chromatographic losses.

³ Values taken from Material Balance.

B. MATERIAL BALANCE

Mean material balance was 102.4% of applied radioactivity [% AR] (range from 94.1 to 109.1% AR). The complete material balances found at all sampling intervals demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

C. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES

Extractable residues decreased from 93.7% AR at study start (DAT-0) to approximately 40% AR from DASF-14 onwards. Non-extractable residues increased from 7.4% AR at DAT-0 to a maximum of 35.8% AR at DAT-30 and decreased to approximately 20% AR from DASF-60 onwards.



D. VOLATILES

The maximum amount of carbon dioxide was approximately 13% AR 30 days after treatment (DAT) in the aerobic incubation phase and remained constant in the anaerobic incubation phase until study end (364 days after soil flooding (DASF)). Formation of volatile organic compounds was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals.

E. DEGRADATION OF PARENT COMPOUND

The amounts of NOA 413161 and NOA 413163 decreased in the aerobic incubation phase from 46.1% AR each at DAT-0 to 22.6 and 27.9% AR at DAT-30, respectively. The amounts of NOA 413161 and NOA 413163 decreased further in the anaerobic incubation phase to 18.3 and 11.1% AR, respectively. The total unidentified residues amounted to a maximum of 36.5% AR with no one component exceeding 14.6% AR at any sampling interval. All components were $< 5\%$ AR if expressed as percentage of trifloxystrobin and considering the maximum formation of NOA 413161 and NOA 413163 in aerobic soil, and were therefore not identified.

The experimental DT₅₀ and DT₉₀ values for the anaerobic incubation phase were calculated using single first order (SFO) kinetics (see Table 7.1.2.1.4- 6).

Table 7.1.2.1.4- 6: Degradation kinetics of NOA 413161 and NOA 413163 in soil under anaerobic conditions

Compound	SFO ¹	
	DT ₅₀ (days)	DT ₉₀ (days)
NOA 413161	976	> 1000
NOA 413163	206	684

¹SFO: single first order

III. CONCLUSIONS

NOA 413161 and NOA 413163, major degradation products of trifloxystrobin, were slowly degraded in soil under anaerobic conditions in the dark in the laboratory. The calculated half-lives were 976 and 206 days in the tested soil.

It is concluded that NOA 413161 and NOA 413163 will be slowly degraded under anaerobic conditions in the environment.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.



Report:	KCA 7.1.2.1.4 /04; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolite under Anaerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using KinGUI 2 Tool
Report No:	EnSa-13-0732
Document No:	M-468176-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the anaerobic soil degradation study M-030427-01.1 (Baseline Dossier, KCA 7.1.2.1.3 /01 and KCA 7.1.2.1.4 /01) was performed, with the software KinGUI 2 according to FOCUS kinetics (2006) ¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113 as well as formation fractions for CGA 321113, which are suitable for modelling purpose. Only the results for CGA 321113 are described here.

The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil North Carolina under anaerobic conditions in the dark in the laboratory at 25 °C and a test concentration of 159 µg/kg (based on soil/water combination).

The half-life of CGA 321113 was > 1000 days.

The formation fraction of CGA 321113 was 1.000.

II. METHODS

Methods are summarized under KCA 7.1.2.1.3 /02 of the Supplemental Dossier.

III. RESULTS

The single first order (SFO) kinetic model was used for modelling purpose to describe the degradation of CGA 321113 in soil North Carolina. Table 7.1.2.1.4-7 summarizes the results of the kinetic analysis.

Table 7.1.2.1.4-7: Kinetic parameters for the degradation of CGA 321113 in soil under anaerobic conditions for modelling purpose according to FOCUS

Soil	FF	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
North Carolina	1.000	SFO	> 1000	1.2	4.60 x 10 ⁻³	+

FF: formation fraction

¹ SFO: single first order

² visual assessment: + good



III. CONCLUSIONS

The calculated half-life for modelling purpose for the degradation of CGA 321113 in soil under anaerobic conditions in the dark in the laboratory was > 100 days in the tested soil. The formation fraction of CGA 321113 was 1.000.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

Report:	KCA 7.1.2.1.4 /05; [REDACTED] ; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolites NOA 413161 and NOA 413163 under Anaerobic Soil Conditions in Laboratory According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0734
Document No:	M-468178-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of the major degradation products NOA 413161 and NOA 413163 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the anaerobic soil degradation study M-123509-01-1 (Supplemental Dossier, KCA 7.1.2.1.4 /03) was performed with the software KinGUI 2 according to FOCUS kinetics (2006)¹ to derive half-lives for the trifloxystrobin degradation products NOA 413161 and NOA 413163 which are suitable for modelling purpose.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413161 and NOA 413163 in soil [REDACTED] under anaerobic conditions in the dark in the laboratory at 20 °C and a test concentration of each 33 µg/kg.

The half-lives were 976.4 days for NOA 413161 and 206.1 days for NOA 413163.

METHODS

Soil residue data from the anaerobic soil degradation study M-123509-01-1 (Supplemental Dossier, KCA 7.1.2.1.4 /03) were used. In this study, the degradation of NOA 413161 and NOA 413163 was studied in soil [REDACTED] (silt) under anaerobic conditions in the dark in the laboratory for 364 days, following an aerobic incubation phase of 30 days, at 20 °C and a test concentration of each 33 µg/kg.

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DA70 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters.



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II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of NOA 413161 and NOA 413163 in soil [redacted] Table 7.1.2.1.4-8 and Table 7.1.2.1.4-9 are summarizing the results of the kinetic analysis.

Table 7.1.2.1.4- 8: Kinetic parameters for the degradation of NOA 413161 in soil under anaerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	976.4	4.0	4.88 x 10 ⁻³	o

¹ SFO: single first order

² visual assessment: + = good, o = moderate

Table 7.1.2.1.4- 9: Kinetic parameters for the degradation of NOA 413163 in soil under anaerobic conditions for modelling purpose according to FOCUS

Soil	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted]	SFO	206.1	1.6	2.45 x 10 ⁻⁵	+

¹ SFO: single first order

² visual assessment: + = good

III. CONCLUSIONS

The calculated half-lives for modelling purpose for the degradation of NOA 413161 and NOA 413163 in soil under anaerobic conditions in the dark in the laboratory were 976.4 days for NOA 413161 and 206.1 days for NOA 413163 in the tested soil.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil in the laboratory given in section CA 7.1.2.1.

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CA 7.1.2.2 Field studies

The dissipation and degradation of trifloxystrobin and its major photodegradation product CGA 357261 after soil incorporation under field conditions were studied at six sites in Germany, United Kingdom, France, Spain and Italy using unlabelled trifloxystrobin and CGA 357261 formulated as WG 50 to fulfil the EFSA requirements to obtain DegT₅₀ values in soil for modelling purpose (EFSA kinetics (2010)³). The kinetic models and DT₅₀ values used for modelling purpose (normalised to 20 °C and field capacity) and best-fit evaluation as well as formation fractions for major degradation products are summarized in Table 7.1.2.2- 2 to Table 7.1.2.2- 11. An overall summary for modelling purpose is given in Table 7.1.2.2- 1.

Table 7.1.2.2- 1: Overall summary of DegT₅₀ values and formation fractions for degradation of trifloxystrobin and its major degradation products in soils for modelling purpose (normalised to 20 °C and field capacity)

Compound	DegT ₅₀ ¹ [days]	Formation Fraction [days]
trifloxystrobin (EE)	1.69	N/A
CGA 357261 (ZE)	0.44	N/A
CGA 321403 (EE)	48.1	0.707
CGA 373466 (ZE)	22.4	0.853
NOA 413161 (ZE)	39.3	0.145
NOA 413163 (EE)	39.3	0.31
CGA 357276 (E)	51.7	0.068
NOA 409480 (Z)	51	0.028

N/A: not applicable
1 geometric mean
2 arithmetic mean

Table 7.1.2.2- 2: Overall summary of DegT₅₀ values for degradation of trifloxystrobin in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DegT ₅₀ ² [days]
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /18	DFOP	1.13
(United Kingdom)	sandy loam (0-75 cm), sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	SFO	1.66
(Northern France)	silt loam (0-100 cm)	KCA 7.1.2.2.1 /18	SFO	1.69
(Southern France)	silt loam (0-50 cm), silty clay loam (50-100 cm)	KCA 7.1.2.2.1 /18	SFO	2.73
(Spain)	loam (0-50 cm), sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /18	SFO	1.10
(Italy)	silty clay loam (0-50 cm), silty clay (50-75 cm), clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	SFO	2.49
geomean				1.69

¹ SFO: single first order, DFOP: double first order in parallel

² for DFOP: DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2.2- 3: Overall summary of DT₅₀ and DT₉₀ values for degradation of trifloxystrobin in soils (best-fit)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Kinetic Model	DT ₅₀ [days]	DT ₉₀ [days]
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /15	DFOP	2.4	35.5
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /15	SFO	6.0	22.1
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /15	SFO	6.0	22.5
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /15	SFO	6.0	22.3
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /15	FOMC	1.8	10.4
(Italy)	silty clay loam (0-50 cm) silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /15	FOMC	3.3	14.5

¹ SFO: single first order, FOMC: first order multi compartment, DFOP: double first order in parallel

Table 7.1.2.2- 4: Overall summary of DegT₅₀ values for degradation of CGA 357261 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Kinetic Model ¹	DegT ₅₀ ² [days]
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /19	DFOP	0.09
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	SFO	0.61
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /19	HS	0.12
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /19	SFO	1.35
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /19	SFO	0.95
(Italy)	silty clay loam (0-50 cm) silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	SFO	0.88
geomean				0.44

¹ SFO: single first order, DFOP: double first order in parallel, HS: hockey stick

² for DFOP and HS, DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve



Table 7.1.2.2- 5: Overall summary of DT₅₀ and DT₉₀ values for degradation of CGA 357261 in soils (best-fit)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Kinetic Model	DT ₅₀ [days]	DT ₉₀ [days]
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /16	DFOP	0.9	7.5
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /16	DFOP	2.2	9.0
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /16	FOMC	2.2	1.5
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /16	DFOP	0.7	13.0
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /16	FOMC	1.6	6.8
(Italy)	silty clay loam (0-50 cm), silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /16	FOMC	0.8	4.8

¹ FOMC: first order multi compartment, DFOP: double first order in parallel

Table 7.1.2.2- 6: Overall summary of DegT₅₀ values and formation fractions for degradation of CGA 321113 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DegT ₅₀ [days]
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /18	0.689	SFO	52.4
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	0.830	SFO	24.7
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /18	0.556	SFO	53.0
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /18	0.688	SFO	95.8
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /18	0.488	SFO	23.7
(Italy)	silty clay loam (0-50 cm), silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	1.000	SFO	79.8
arithmetic mean			0.707	geomean	48.1

¹ SFO: single first order



Table 7.1.2.2- 7: Overall summary of DegT₅₀ values and formation fractions for degradation of CGA 373466 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DegT ₅₀ [days]	
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /19	0.640	SFO	5.86	
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	1.000	SFO	8.5	
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /19	0.618	SFO	29.1	
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /19	1.000	SFO	9.6	
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /19	0.860	SFO	14.5	
(Italy)	silty clay loam (0-50 cm) silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	1.000	SFO	5.1	
			arithmetic mean	0.853	geomean	22.4

¹ SFO: single first order

Table 7.1.2.2- 8: Overall summary of DegT₅₀ values and formation fractions for degradation of NOA 43161 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DegT ₅₀ [days]	
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /18	0.071	SFO	66.1	
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	0.263	SFO	30.7	
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /18	- ²	SFO	- ²	
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /18	0.078	SFO	26.0	
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /18	0.259	SFO	34.9	
(Italy)	silty clay loam (0-50 cm) silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	0.055	SFO	50.8	
			arithmetic mean	0.145	geomean	39.3

¹ SFO: single first order

² value excluded from the calculation of arithmetic or geometric mean due to unreliable statistical parameters



Table 7.1.2.2- 9: Overall summary of DegT₅₀ values and formation fractions for degradation of NOA 413163 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DegT ₅₀ [days]	
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /19		SFO	35.0	
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	0.457	SFO	87.5	
(Northern France)	silt loam (0-100 cm)	KCA 7.1.2.2.1 /19	0.498	SFO	29.9	
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /19	0.185	SFO	3	
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /19	0.332	SFO	25.2	
(Italy)	silty clay loam (0-50 cm), silty clay (50-75 cm), clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	0.15	SFO	2	
			arithmetic mean	0.317	geomean	39.3

¹ SFO: single first order

² value excluded from the calculation of arithmetic mean due to unreliable statistical parameters

Table 7.1.2.2- 10: Overall summary of DegT₅₀ values and formation fractions for degradation of CGA 357276 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DegT ₅₀ [days]	
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /18	0.072	SFO	36.5	
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	0.098	SFO	80.2	
(Northern France)	silt loam (0-100 cm)	KCA 7.1.2.2.1 /18	0.062	SFO	36.1	
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /18	- ²	SFO	- ²	
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /18	0.077	SFO	45.5	
(Italy)	silty clay loam (0-50 cm), silty clay (50-75 cm), clay loam (75-100 cm)	KCA 7.1.2.2.1 /18	0.032	SFO	76.5	
			arithmetic mean	0.068	geomean	51.7

¹ SFO: single first order

² value excluded from the calculation of arithmetic or geometric mean due to unreliable statistical parameters



Table 7.1.2.2- 11: Overall summary of DegT₅₀ values and formation fractions for degradation of NOA 409480 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Annex Point / Reference No	Formation Fraction	Kinetic Model ¹	DegT ₅₀ [days]
(Germany)	loam (0-100 cm)	KCA 7.1.2.2.1 /19	0.006	SFO	17.3
(United Kingdom)	sandy loam (0-75 cm) sandy clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	0.041	SFO	95.7
(Northern France)	silt Loam (0-100 cm)	KCA 7.1.2.2.1 /19	0.025	SFO	34.7
(Southern France)	silt loam (0-30 cm) silty clay loam (30-100 cm)	KCA 7.1.2.2.1 /19	- ²	SFO	14.1
(Spain)	loam (0-50 cm) sandy clay loam (50-100 cm)	KCA 7.1.2.2.1 /19	0.035	SFO	18.1
(Italy)	silty clay loam (0-50 cm) silty clay (50-75 cm) clay loam (75-100 cm)	KCA 7.1.2.2.1 /19	0.035	SFO	10.7
arithmetic mean			0.028	geomean	51.7

¹ SFO: single first order

² value excluded from the calculation of arithmetic mean due to unreliable statistical parameters

CA 7.1.2.2.1 Soil dissipation studies

The dissipation and degradation of trifloxystrobin in soil under field conditions were evaluated during the Annex I inclusion using unlabelled trifloxystrobin formulated as WG 50 as well as [¹⁴C-TP]trifloxystrobin formulated as EC 250, and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.2.2.1 /01		1997	M-033482-01-1
KCA 7.1.2.2.1 /02		1997	M-033486-01-1
KCA 7.1.2.2.1 /03		1997	M-033490-01-1
KCA 7.1.2.2.1 /04		1997	M-033493-01-1
KCA 7.1.2.2.1 /05		1997	M-033496-01-1
KCA 7.1.2.2.1 /06		1997	M-033502-01-1
KCA 7.1.2.2.1 /07		1998	M-033504-01-1
KCA 7.1.2.2.1 /08		1998	M-033514-01-1
KCA 7.1.2.2.1 /09		1999	M-051252-01-1
KCA 7.1.2.2.1 /10		1999	M-051419-01-1
KCA 7.1.2.2.1 /11		1999	M-051248-01-1
KCA 7.1.2.2.1 /12		1997	M-033523-02-1
KCA 7.1.2.2.1 /13		1998	M-033520-01-1
KCA 7.1.2.2.1 /14		2001	M-064112-01-1



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Three additional studies have been performed for trifloxystrobin and its major photodegradation product CGA 357261 and are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval because the existing field dissipation studies do not fulfil the EFSA requirements to obtain DegT₅₀ values in soil for modelling purpose (EFSA (2010)³). Furthermore, updated kinetic evaluations of the degradation behaviours of trifloxystrobin and its major degradation products in soil under field conditions have been performed according to FOCUS kinetics (2006)¹ to derive kinetic parameters suitable for modelling purpose and environmental risk assessment. A summary of degradation rates of trifloxystrobin and its major degradation products in soil under field conditions is given in section CA 7.1.2.2.

Report:	KCA 7.1.2.2.1 /15; [REDACTED]; [REDACTED]; 2013, amended 2013-09-02
Title:	Amendment No. 1 to Determination of the Residues of Trifloxystrobin in/on Soil after Spraying of Trifloxystrobin WG 50 in the Field in Germany, the United Kingdom, France, Spain and Italy
Report No:	11-2710
Document No:	M-462061-02-1
Guidelines:	<ul style="list-style-type: none"> - EFSA Guidance for Evaluating Laboratory and Field Dissipation Studies to obtain DegT₅₀ Values of Plant Protection Products in Soil - Commission Directive 95/36/EC amending Council Directive 91/414/EEC - SETAC Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides - BBA guideline, part IV, 4.1 - ECPA Guidance Document on Field Soil Dissipation Studies
GLP:	Y
Justification:	New data / guideline requirement: Degradation of trifloxystrobin in soil under field conditions to fulfil the EFSA requirements to obtain DegT ₅₀ values in soil for modelling purpose (EFSA kinetics (2010) ³)

Executive Summary

Soil dissipation of trifloxystrobin was studied after pre-emergence application of trifloxystrobin WG 50 on bare soil plots under field conditions for up to 733 days at the six sites [REDACTED] (Germany), [REDACTED] (United Kingdom), [REDACTED] (Northern France), [REDACTED] (Southern France), [REDACTED] (Spain) and [REDACTED] (Italy). Additionally, kinetic data for a possible evaluation of the formation fractions of the trifloxystrobin degradation products CGA 321113, NOA 413161 and CGA 357261 were determined.

A nominal study application rate of 0.125 L per hectare, corresponding to nominal 187.5 g per hectare trifloxystrobin, was applied. Trifloxystrobin WG 50 was immediately incorporated into the soil after spraying.

Trifloxystrobin is rapidly degraded in soil to CGA 321113 by ester cleavage. Therefore, the total amounts of trifloxystrobin and CGA 321113 (expressed as trifloxystrobin equivalents) were calculated for total residues at study start (DAT-0). Significant amounts of NOA 413161 were detected at [REDACTED] at DAT-0 and were additionally included in the calculation of the total residues at DAT-0 (expressed as trifloxystrobin equivalents). The total residues detected at DAT-0 were 174 g/ha at [REDACTED], 140 g/ha at [REDACTED], 167 g/ha at [REDACTED], 114 g/ha at [REDACTED], 201 g/ha at [REDACTED] and 165 g/ha at [REDACTED], corresponding to 93, 75, 89, 61, 107 and 88% of the nominal application rate, respectively.

Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The amount of trifloxystrobin (total residues) decreased from DAT-0 to study end (DAT-733) from 174 to 0.49 g/ha at [REDACTED], from DAT-0 to DAT-708 from 140 to 0.39 g/ha at [REDACTED] and from DAT-0 to DAT-680 from 167 to 0.44 g/ha at [REDACTED], from DAT-0 to DAT-727 from 114 to 0.17 g/ha at [REDACTED], from DAT-0 to DAT-686 from 201 to 0.16 g/ha at [REDACTED] and from DAT-0 to DAT-661 from 165 to 0.33 g/ha at [REDACTED].

Residues of trifloxystrobin were primarily detected in the top 0-10 cm of soil, except for some very low residues detected down to a depth of 20-30 cm.

Dissipation and degradation of trifloxystrobin was accompanied by the formation of its degradation products CGA 321113, NOA 413161 and CGA 357276.

CGA 321113 amounted to maxima (trifloxystrobin equivalents) of 77.4 to 157 g/ha between DAT-8 and DAT-59 in the entire soil profiles. The major part of the residues was detected in the top 0-20 cm soil layer. Residues above the LOQ were detected down to a depth of 40-50 cm. At [REDACTED], residues between LOD and LOQ were detected down to a depth of 90-100 cm.

NOA 413161 amounted to maxima (trifloxystrobin equivalents) of 1.7 to 14.5 g/ha between DAT-90 and DAT-360 in the entire soil profiles. The major part of the residues was detected in the top 0-20 cm soil layer. Residues above the LOQ were detected down to a depth of 50-60 cm, except of [REDACTED] and [REDACTED], where low residues were detected down to a depth of 90-100 cm.

CGA 357276 amounted to maxima (trifloxystrobin equivalents) of 1.12 to 2.49 g/ha between DAT-28 and DAT-360 in the entire soil profiles. The major part of the residues was detected in the top 0-20 cm soil layer and no residues were detected below a depth of 30-40 cm.

The experimental data could be described by a single first order kinetic model for [REDACTED] and [REDACTED] and by a first order multi compartment kinetic model for [REDACTED] and [REDACTED] and by a double first order in parallel kinetic model for [REDACTED]. The half-life of trifloxystrobin under field conditions was 2.4, 6.7, 6.0, 6.7, 1.8 and 3.3 days at site [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [REDACTED], respectively. The corresponding DT₉₀ value was 35.6, 22.1, 20.0, 22.3, 10.4 and 14.7 days, respectively.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

trifloxystrobin formulated as WG 50 (wettable granulate, 50% w/w trifloxystrobin)

Certificate of Analysis: FAR 01568-00

Batch ID: SDFL011509

Specification No: 102000007798-02

2. Test sites

Six sites were selected (see [Table 7.1.2.2.1- 1](#)), which are typical for the ecoregions of Southern and Northern Europe. The sites were neither subjected to erosion, flooding nor run-off. The test plots had no significant slope and were largely free of stones. A field soil dissipation trial consisted of a treated and an untreated plot at each test site. The control plots were located at least 5 meters away from the treated plots. The selected sites have not been treated with chemicals which could influence the dissipation behaviour of trifloxystrobin or which could interfere with the analysis of the individual residues in soil.



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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.1.2.2.1- 1: Location, site description and climatic data of test sites

Site ID	(Germany)	(United Kingdom)	(Northern France)
Site Designation	Germany, [redacted]	United Kingdom, [redacted]	France, [redacted]
Geographic Location			
City	[redacted]	[redacted]	[redacted]
Country	Germany	United Kingdom	France
Ecoregion	Northern Europe	Northern Europe	Northern Europe
GPS Coordinates	[redacted]	[redacted]	[redacted]
Plot Size [m ²]	225	320	360
Distance from weather station used for climatic measurements	in 20 km distance from trial plot	at trial location (in 500 m distance)	in 5 km distance from trial plot
Meteorological conditions compared to long-term average within normal levels (Yes/No)	Overall: Yes	Overall: Yes, but 2011 was drier and 2012 was wetter	Overall: Yes, but winter and spring 2013 were drier
Textural Class (USDA)			
Soil 0-30 cm	loam	sandy loam	silt loam
Depth 30-50 cm	loam	sandy loam	silt loam
[cm] 50-75 cm	loam	sandy loam	silt loam
75-100 cm	loam	sandy clay loam	silt loam

Table 7.1.2.2.1- 1 (continued)

Site ID	(Southern France)	(Spain)	(Italy)
Site Designation	France, [redacted]	[redacted], Spain, Parcela 54	[redacted], Italy, [redacted]
Geographic Location			
City	[redacted]	[redacted]	[redacted]
Country	France	Spain	Italy
Ecoregion	Southern Europe	Southern Europe	Southern Europe
GPS Coordinates	[redacted]	[redacted]	[redacted]
Plot Size [m ²]	296	300	720
Distance from weather station used for climatic measurements	in 7 km distance from trial plot	at trial location (in < 500 m distance)	in 10 km distance from trial plot
Meteorological conditions compared to long-term average within normal levels (Yes/No)	Overall: Yes, but 2011 was drier	Overall: Yes	Overall: Yes, but winter and spring 2013 were very wet
Textural Class (USDA)			
Soil 0-30 cm	silt loam	loam	silty clay loam
Depth 30-50 cm	silty clay loam	loam	silty clay loam
50-75 cm	silty clay loam	sandy clay loam	silty clay
75-100 cm	silty clay loam	sandy clay loam	clay loam

GPS: global positioning system



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

USDA: United States Department of Agriculture

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B. STUDY DESIGN

1. Experimental Conditions

Trifloxystrobin WG 50 is a granule formulation containing 50% w/w trifloxystrobin. The test item was applied once on bare soil plots using Knapsack sprayers with a nominal application rate of 0.3750 kg/ha in 300 L water/ha, corresponding to 0.1875 kg trifloxystrobin/ha.

Prior to spraying the test item onto the soil, the plots were prepared to have a fine crumb structure and a fine seedbed. Grass was sown after spraying of the test item at [redacted] and [redacted] and before spraying of the test item at [redacted] and [redacted]. At [redacted] the incorporation of the test item into the soil and the sowing of grass were performed simultaneously. The test item was incorporated into the soil up to a depth of approximately 8 to 10 cm immediately after application using a curry comb at [redacted]° rotar harrow with roll at [redacted] and [redacted], a hay bob harrow at [redacted] and [redacted] and a hay bob harrow with roll at [redacted].

Air temperature, precipitation including irrigation, and sunshine data were recorded during the field soil dissipation trial at all sites.

Soil dissipation of trifloxystrobin was studied for up to 733 days

2. Sampling

Soil cores were taken to a depth of 10 cm using a soil piercer (Ø 50 mm) before application from the untreated control plots (10 to 20 soil cores) and immediately after application and incorporation of the test item into the soil from the treated plots (40 soil cores, DAT-0 samples). All subsequent samplings were performed using a "Wacker Hammer" (Ø 48 to 50 mm). At each sampling interval 20 soil cores from the treated plots were taken. The sampling spots were distributed randomly over the plots to obtain representative samples.

In all treated plots of the trials the soil cores were taken to a maximum depth of 100 cm on the following occasions: 0 (2 samplings post-incorporation, each 0-10 cm depth), 2-4, 6-8, 13-15, 28 (each 0-30 cm depth), 56-62, 83-90 (each 0-50 cm depth), and 118-130, 170-182, 356-371, 535-545 and 661-733 (each 0-100 cm depth) days after treatment (DAT). From the control plots, samples were taken on the following occasions: 0 days before application, 356-371 and 661-733 days after treatment.

In addition, samples for soil characterisation (10 to 20 soil cores, 0-100 cm depth) were taken before application from the treated plots, except of [redacted] for which the soil characterisation sample was taken at DAT-99 from the treated plot of a parallel study due to a time conflict.

The soil cores were stored dark immediately after sampling and were deep-frozen within 24 hours (DAT-0 samples within 6 hours). The frozen soil cores were cut into 10 cm segments and each horizon (laboratory samples) was milled separately in a hammer mill and carefully homogenized. An aliquot of each laboratory sample (analytical samples) was used for analysis. Soil cores and samples were stored in the dark at $\leq -15^{\circ}\text{C}$.



3. Analytical Procedures

The analytical method 01327/M001 (M-464872-01-1, Supplemental Dossier, KCA 4.1.2/24) was developed for the determination of trifloxystrobin and its degradation products CGA 352261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 in soil. Soil samples of 20 g were extracted three times at ambient temperature using a shaker and once by microwave-accelerated extraction at 70 °C using acetonitrile/water 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation (> 500 x g) and decantation. The soil extracts were combined, internal stable-labelled standards added and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in multiple reaction monitoring mode. The method was validated using three different soils. The limit of detection and limit of quantitation were 0.03 and 0.1 µg/kg for each analyte, respectively.

During analysis of the dissipation samples of the current study, concurrent recovery samples were prepared freshly by fortification of control samples with test item trifloxystrobin and reference items CGA 321113, NOA 413161 and CGA 357276 at levels of 0.1 and 1 µg/kg and processed in parallel to the dissipation samples. The mean recoveries were 105% (RSD 8.2%) for trifloxystrobin, 103% (RSD 9.9%) for CGA 321113, 89% (RSD 13.4%) for NOA 413161 and 93% (RSD 10.8%) for CGA 357276.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial total recovery at DAT-0 (2 samplings after incorporation) was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi² scaled-error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

A. DATA

Table 7.1.2.2.1- 2: Residues of trifloxystrobin in soil at [redacted] (Germany), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	2,3	3	6	14	28	56	91	124	182	368	543	733
trifloxystrobin	Mean	158	99.1	87.6	38.1	40.3	25.5	7.46	3.10	2.15	1.11	1.35	0.49	0.49
CGA 321113	Mean	70.3	45.1	49.6	71.9	79.7	84.7	98.5	78.2	45.1	27.3	21.2	7.51	7.24
NOA 413161	Mean	<LOD	<LOD	<LOD	<LOD	<LOD	0.04	0.66	2.09	4.23	3.55	1.00	1.01	0.27
CGA 357276	Mean	0.07	0.02	0.08	0.13	0.20	0.56	1.27	1.95	2.29	1.26	1.51	0.61	0.73

DAT: days after treatment, values in brackets are given as ½ LOD according to FOCUS kinetics (2006)¹

¹ trifloxystrobin equivalents sum of 0-100 cm

² DAT-0 single values (trifloxystrobin): 156, 160 g/ha (mean 158 g/ha); 116, 86.1, 95.3, 99.2 g/ha (mean 99.2 g/ha); overall mean 119 g/ha = 63% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (trifloxystrobin equivalents) = trifloxystrobin + CGA 321113): 224, 233 g/ha (mean 231 g/ha); 169, 127, 142, 146 g/ha (mean 146 g/ha); overall mean 174 g/ha = 93% of nominal application rate of 187.5 g/ha



Table 7.1.2.2.1- 3: Residues of trifloxystrobin in soil at [redacted] (United Kingdom), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	4	8	15	28	62	91	130	174	371	545	708
trifloxystrobin	Mean	99.4	108	87.6	76.4	15.9	9.6	3.71	3.40	2.12	1.63	1.11	0.45	0.39
CGA 321113	Mean	38.3	32.6	37.2	66.2	84.4	97.2	58.7	61.3	35.4	22.6	8.6	2.71	1.90
NOA 413161	Mean	<LOD	(0.02)	0.20	0.28	1.83	5.05	7.74	11.8	13.7	14.5	5.84	1.34	0.37
CGA 357276	Mean	(0.02)	0.06	0.09	0.20	0.98	1.81	2.12	2.49	2.08	1.98	1.36	0.61	0.57

DAT: days after treatment, values in (brackets) are given as 1/2 LOD according to FOCUS kinetics (2006)¹

¹ trifloxystrobin equivalents, sum of 0-100 cm

² DAT-0 single values (trifloxystrobin): 103, 69.1, 103, 122 g/ha (mean 99.3 g/ha); 98.9, 118 g/ha (mean 108 g/ha); overall mean 102 g/ha = 55% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (trifloxystrobin equivalents) = trifloxystrobin + CGA 321113): 140, 91.1, 153, 172 g/ha (mean 139 g/ha); 128, 156 g/ha (mean 142 g/ha); overall mean 140 g/ha = 75% of nominal application rate of 187.5 g/ha

Table 7.1.2.2.1- 4: Residues of trifloxystrobin in soil at [redacted] (Northern France), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	3	7	14	28	59	90	119	181	356	540	680
trifloxystrobin	Mean	125	178	89.0	90.6	31.4	5.36	1.15	1.83	1.12	0.74	0.64	0.32	0.44
CGA 321113	Mean	40.7	18.1	23.5	29.6	68.7	61.6	77.4	60.8	48.7	55.4	21.7	3.56	3.07
NOA 413161	Mean	(0.02)	<LOD	(0.03)	0.13	0.54	1.31	3.87	5.85	4.15	1.6	4.16	7.51	0.77
CGA 357276	Mean	<LOD	(0.02)	(0.03)	0.12	0.24	0.38	0.62	0.96	1.18	1.11	1.24	0.74	0.67

DAT: days after treatment, values in (brackets) are given as 1/2 LOD according to FOCUS kinetics (2006)¹

¹ trifloxystrobin equivalents, sum of 0-100 cm

² DAT-0 single values (trifloxystrobin): 120, 131 g/ha (mean 126 g/ha); 161, 196 g/ha (mean 179 g/ha); overall mean 152 g/ha = 81% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (trifloxystrobin equivalents) = trifloxystrobin + CGA 321113): 131, 142 g/ha (mean 137 g/ha); 178, 216 g/ha (mean 197 g/ha); overall mean 167 g/ha = 89% of nominal application rate of 187.5 g/ha

Table 7.1.2.2.1- 5: Residues of trifloxystrobin in soil at [redacted] (Southern France), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	3	7	14	28	62	83	118	180	361	543	727
trifloxystrobin	Mean	111	104	93.5	61.3	21.6	3.53	0.99	0.99	0.51	0.44	0.28	0.39	0.17
CGA 321113	Mean	61.0	60.8	29.5	46.0	78.5	56.5	51.7	67.2	45.5	35.7	15.6	11.3	7.28
NOA 413161	Mean	<LOD	(0.02)	0.08	0.13	0.34	0.54	0.77	0.88	1.17	0.91	0.95	0.28	0.29
CGA 357276	Mean	<LOD	(0.02)	0.15	0.23	0.66	1.12	0.74	0.96	0.55	0.64	0.61	0.53	0.47

DAT: days after treatment, values in (brackets) are given as 1/2 LOD according to FOCUS kinetics (2006)¹

¹ trifloxystrobin equivalents, sum of 0-100 cm

² DAT-0 single values (trifloxystrobin): 110, 112 g/ha (mean 111 g/ha); 98.0, 110 g/ha (mean 104 g/ha); overall mean 108 g/ha = 57% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (trifloxystrobin equivalents) = trifloxystrobin + CGA 321113): 117, 118 g/ha (mean 118 g/ha); 104, 116 g/ha (mean 110 g/ha); overall mean 114 g/ha = 61% of nominal application rate of 187.5 g/ha



Table 7.1.2.2.1- 6: Residues of trifloxystrobin in soil at [redacted] (Spain), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	2	8	14	28	62	90	119	170	366	540	686
trifloxystrobin	Mean	176	150	91.0	37.0	5.95	2.18	0.67	0.40	0.35	(0.03)	0.27	0.10	0.10
CGA 321113	Mean	35.3	38.0	46.7	106	57.7	64.3	32.8	7.48	4.97	2.71	1.6	1.08	0.42
NOA 413161	Mean	(0.02)	14.1	(0.03)	1.51	2.85	7.90	0.43	11.1	9.49	3.54	1.59	0.76	0.49
CGA 357276	Mean	(0.02)	0.05	(0.03)	0.47	0.61	1.31	0.09	0.53	0.42	(0.03)	0.24	0.21	0.18

DAT: days after treatment, values in (brackets) are given as 1/2 LOD according to FOCUS kinetics (2006)

¹ trifloxystrobin equivalents, sum of 0-100 cm

² DAT-0 single values (trifloxystrobin): 193, 159 g/ha (mean 176 g/ha); 150, 150 g/ha (mean 150 g/ha); overall mean 163 g/ha = 87% of nominal application rate of 187 g/ha

³ DAT-0 single values (total residues (trifloxystrobin equivalents) = trifloxystrobin + CGA 321113 + NOA 413161): 231, 194 g/ha (mean 213 g/ha); 191, 186 g/ha (mean 191 g/ha); overall mean 201 g/ha = 107% of nominal application rate of 187.5 g/ha

Table 7.1.2.2.1- 7: Residues of trifloxystrobin in soil at [redacted] (Italy), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	3	7	13	28	60	90	122	180	360	535	661
trifloxystrobin	Mean	163	136	83.0	52.2	15.2	3.83	1.04	0.82	1.04	0.54	0.75	0.39	0.33
CGA 321113	Mean	33.9	14.9	6.8	8.1	15.7	132	112	93.8	28	27	58.7	27.4	20.6
NOA 413161	Mean	<LOD	(0.02)	0.07	0.12	0.46	0.1	1.87	2.21	2.76	2.02	3.38	1.81	1.32
CGA 357276	Mean	0.05	0.04	0.12	0.19	0.56	0.83	0.82	0.54	1.27	0.99	1.94	1.22	1.03

DAT: days after treatment, values in (brackets) are given as 1/2 LOD according to FOCUS kinetics (2006)

¹ trifloxystrobin equivalents, sum of 0-100 cm

² DAT-0 single values (trifloxystrobin): 159, 168 g/ha (mean 164 g/ha); 138, 135 g/ha (mean 137 g/ha); overall mean 150 g/ha = 80% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (trifloxystrobin equivalents) = trifloxystrobin + CGA 321113): 175, 181 g/ha (mean 178 g/ha); 163, 151 g/ha (mean 152 g/ha); overall mean 165 g/ha = 88% of nominal application rate of 187.5 g/ha

B. RESIDUES

Trifloxystrobin is rapidly degraded in soil to CGA 321113 by ester cleavage. Therefore, the total amounts of trifloxystrobin and CGA 321113 (expressed as trifloxystrobin equivalents) were calculated for total residues at study start (DAT-0). Significant amounts of NOA 413161 were detected at [redacted] (Spain) at DAT-0, and were additionally included in the calculation of the total residues at DAT-0 (expressed as trifloxystrobin equivalents). The total residues detected at DAT-0 were 174 g/ha at [redacted] (Germany), 140 g/ha at [redacted] (United Kingdom), 167 g/ha at [redacted] (Northern France), 114 g/ha at [redacted] (Southern France), 201 g/ha at [redacted] (Spain) and 165 g/ha at [redacted] (Italy), corresponding to 93, 75, 89, 61, 107 and 88% of the nominal application rate, respectively.

The amount of trifloxystrobin (total residues) decreased from DAT-0 to study end (DAT-733) from 174 to 0.49 g/ha at [redacted], from DAT-0 to DAT-708 from 140 to 0.39 g/ha at [redacted], from DAT-0 to DAT-680 from 167 to 0.44 g/ha at [redacted], from DAT-0 to DAT-727 from 114 to 0.17 g/ha at [redacted], from DAT-0 to DAT-686 from 201 to 0.10 g/ha at [redacted] and from DAT-0 to DAT-661 from 165 to 0.33 g/ha at [redacted].



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Residues of trifloxystrobin were primarily detected in the top 0-10 cm of soil, except for some very low residues detected down to a depth of 20-30 cm.

Dissipation and degradation of trifloxystrobin was accompanied by the formation of its degradation products CGA 321113, NOA 413161 and CGA 357276.

CGA 321113 amounted to maxima (trifloxystrobin equivalents) of 77.4 to 157 g/ha between DAT-8 and DAT-59 in the entire soil profiles. The major part of the residues was detected in the top 0-20 cm soil layer. Residues above the limit of quantitation (LOQ) were detected down to a depth of 40-50 cm. At [redacted], residues between limit of detection (LOD) and LOQ were detected down to a depth of 90-100 cm.

NOA 413161 amounted to maxima (trifloxystrobin equivalents) of 1.7 to 14.5 g/ha between DAT-90 and DAT-360 in the entire soil profiles. The major part of the residues was detected in the top 0-20 cm soil layer. Residues above the LOQ were detected down to a depth of 50-60 cm, except of [redacted] and [redacted], where low residues were detected down to a depth of 90-100 cm.

CGA 357276 amounted to maxima (trifloxystrobin equivalents) of 1.12 to 2.49 g/ha between DAT-28 and DAT-360 in the entire soil profiles. The major part of the residues was detected in the top 0-20 cm soil layer and no residues were detected below a depth of 30-40 cm.

C. KINETIC ANALYSIS

The degradation of trifloxystrobin followed single first order (SFO) kinetics for [redacted] and [redacted], first order multi-compartment (FOMC) kinetics for [redacted] and [redacted], and double first order in parallel (DFOP) kinetics for [redacted] according to the lowest chi² error values and visual assessments. Table 7.1.2.2.1- 8 summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.

Table 7.1.2.2.1- 8: Best-fit degradation kinetics of trifloxystrobin in soils under field conditions according to FOCUS

Site	Best Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	Visual Assessment ²
[redacted] (Germany)	DFOP	2.0	35.6	12.6	+
[redacted] (United Kingdom)	SFO	6.7	22.1	17.9	+
[redacted] (Northern France)	SFO	6.0	20.0	22.6	+
[redacted] (Southern France)	SFO	6.7	22.3	12.9	+
[redacted] (Spain)	FOMC	1.8	10.4	11.2	+
[redacted] (Italy)	FOMC	3.3	14.7	9.3	+

¹ SFO: single first order, FOMC: first order multi-compartment, DFOP: double first order in parallel

² visual assessment: + = good

III. CONCLUSIONS

Trifloxystrobin was rapidly degraded in soil under field conditions in the ecoregions Northern and Southern Europe. The calculated best-fit half-lives were between 1.8 and 6.7 days at the tested sites. The major degradation products CGA 321113, NOA 413161 and CGA 357276 were formed and declined towards study end.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil under field conditions given in section CA 7.1.2.2.

Report:	KCA 7.1.2.2.1 /16; [REDACTED] O; [REDACTED]; 2013
Title:	Determination of the Residues of CGA 357261 in/on Soil after Spraying of CGA 357261 WG 50 in the Field in Germany, the United Kingdom, France, Spain and Italy
Report No:	11-2720
Document No:	M-465701-01-1
Guidelines:	<ul style="list-style-type: none"> - EFSA Guidance for Evaluating Laboratory and Field Dissipation Studies to obtain DegT₅₀ Values of Plant Protection Products in Soil - Commission Directive 95/36/EC amending Council Directive 91/414/EEC - SETAC Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides - BBA guideline, part IV, 4-1 - ECPA Guidance Document on Field Soil Dissipation Studies
GLP:	Yes
Justification:	<p>New data / guideline requirement</p> <p>Degradation of major photodegradation product CGA 357261 in soil under field conditions to fulfil the EFSA requirements to obtain DegT₅₀ values in soil for modelling purpose (EFSA kinetics (2010))</p>

Executive Summary

Soil dissipation of CGA 357261, a major photodegradation product of trifloxystrobin, was studied after pre-emergence application of CGA 357261 WG 50 on bare soil plots under field conditions for up to 733 days at the six sites [REDACTED] (Germany), [REDACTED] (United Kingdom), [REDACTED] (Northern France), [REDACTED] (Southern France), [REDACTED] (Spain) and [REDACTED] (Italy). Additionally, kinetic data for a possible evaluation of the formation fractions of the trifloxystrobin photodegradation products CGA 373466, NOA 413163 and NOA 409480, which are derived from CGA 357261, were determined.

A nominal study application rate of 0.125 L per hectare, corresponding to nominal 187.5 g per hectare CGA 357261, was applied. CGA 357261 WG 50 was immediately incorporated into the soil after spraying.

CGA 357261 is rapidly degraded in soil to CGA 373466 by ester cleavage as well as to a small extent further to NOA 413163 and NOA 409480. Therefore, the total amounts of CGA 357261 and its degradation products (expressed as CGA 357261 equivalents) were calculated for total residues at study start (DAT-0). The total residues detected at DAT-0 were 209 g/ha at [REDACTED], 114 g/ha at [REDACTED], 169 g/ha at [REDACTED], 122 g/ha at [REDACTED], 151 g/ha at [REDACTED] and 179 g/ha at [REDACTED], corresponding to 112, 61, 90, 65, 80 and 95% of the nominal application rate, respectively.

The amount of CGA 357261 (total residues) decreased from DAT-0 to study end (DAT-733) from 209 to 0.13 g/ha at [REDACTED], from DAT-0 to DAT-708 from 114 g/ha to < LOD at [REDACTED], from DAT-0 to DAT-680 from 169 to 0.14 g/ha at [REDACTED], from DAT-0 to DAT-727 from 122 to 0.16 g/ha at [REDACTED], from 151 g/ha at DAT-0 to < LOD from DAT-540 onwards at [REDACTED] and from DAT-0 to DAT-657 from 179 to 0.16 g/ha at [REDACTED].

Residues of CGA 357261 were primarily detected in the top 0-10 cm of soil, except for some very low residues detected down to a depth of 20-30 cm.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Dissipation and degradation of CGA 357261 was accompanied by the formation of its degradation products CGA 373466, NOA 413163 and NOA 409480.

CGA 373466 amounted to maxima (CGA 357261 equivalents) of 88.5 to 245 g/ha between DAT-20 and DAT-15 in the entire soil profiles. The major part of the residues was detected in the top 0-30 cm soil layer. Residues above the LOQ were detected down to a depth of 30-40 cm at [redacted] and [redacted], and down to a depth of 90-100 cm at [redacted] and [redacted].

NOA 413163 amounted to maxima (CGA 357261 equivalents) of 6.0 to 52.6 g/ha between DAT-20 and DAT-180 in the entire soil profiles. Residues above the LOQ were detected down to a depth of 50-60 cm, except of [redacted] and [redacted], where residues above the LOQ were detected down to a depth of 90-100 cm.

NOA 409480 amounted to maxima (CGA 357261 equivalents) of 0.51 to 161 g/ha between DAT-14 and DAT-119 in the entire soil profiles. The major part of the residues was detected in the top 0-10 cm soil layer and no residues were detected below a depth of 20-30 cm.

The experimental data could be described by a first order multi compartment kinetic model for [redacted] and [redacted], and by a double first order in parallel kinetic model for [redacted] and [redacted]. The half-life of CGA 357261 under field conditions was 0.9, 2.6, 2.2, 3.2, 1.6 and 0.8 days at site [redacted], [redacted], [redacted], [redacted], [redacted] and [redacted], respectively. The corresponding DT₅₀ value was 4.5, 9.0, 17.5, 13.0, 6.8 and 4.8 days, respectively.

MATERIALS AND METHODS

A. MATERIALS

1. Test Item

CGA 357261 formulated as WG 50 (wetable granulate, 51% w/w CGA 357261)
Certificate of Analysis: FAR 01571-00
Batch ID: 2021-002271
Specification No: 192000025869

2. Test Sites

Six sites were selected (see Table 7.1.2.2.1), which are typical for the ecoregions of Southern and Northern Europe. The sites were neither subjected to erosion, flooding nor run-off. The test plots had no significant slope and were largely free of stones. A field soil dissipation trial consisted of a treated and an untreated plot at each test site. The control plots were located at least 5 meters away from the treated plots. The selected sites have not been treated with chemicals which could influence the dissipation behaviour of trifloxystrobin or which could interfere with the analysis of the individual residues in soil.



Table 7.1.2.2.1- 9: Location, site description and climatic data of test sites

Site ID	(Germany)	(United Kingdom)	(Northern France)
Site Designation	Germany, [redacted]	United Kingdom, [redacted]	France, [redacted]
Geographic Location			
City	[redacted]	[redacted]	[redacted]
Country	Germany	United Kingdom	France
Ecoregion	Northern Europe	Northern Europe	Northern Europe
GPS Coordinates	[redacted]	[redacted]	[redacted]
Plot Size [m ²]	225	320	360
Distance from weather station used for climatic measurements	in 20 km distance from trial plot	at trial location (in 500 m distance)	in 5 km distance from trial plot
Meteorological conditions compared to long-term average within normal levels (Yes/No)	Overall: Yes	Overall: Yes, but 2011 was drier and 2012 wetter	Overall: Yes, but winter and spring 2013 were drier
Textural Class (USDA)			
Soil 0-30 cm	loam	sandy loam	silt loam
Depth 30-50 cm	loam	sandy loam	silt loam
[cm] 50-75 cm	loam	sandy loam	silt loam
75-100 cm	loam	sandy clay loam	silt loam

Table 7.1.2.2.1- 9 (continued)

Site ID	(Southern France)	(Spain)	(Italy)
Site Designation	France, [redacted]	[redacted], Spain, Parcela 54	[redacted], Italy, [redacted]
Geographic Location			
City	[redacted]	[redacted]	[redacted]
Country	France	Spain	Italy
Ecoregion	Southern Europe	Southern Europe	Southern Europe
GPS Coordinates	[redacted]	[redacted]	[redacted]
Plot Size [m ²]	296	300	720
Distance from weather station used for climatic measurements	in 7 km distance from trial plot	at trial location (in < 500 m distance)	in 10 km distance from trial plot
Meteorological conditions compared to long-term average within normal levels (Yes/No)	Overall: Yes, but 2011 was drier	Overall: Yes	Overall: Yes, but winter and spring 2013 were very wet
Textural Class (USDA)			
Soil 0-30 cm	silt loam	loam	silty clay loam
Depth 30-50 cm	silty clay loam	loam	silty clay loam
50-75 cm	silty clay loam	sandy clay loam	silty clay
75-100 cm	silty clay loam	sandy clay loam	clay loam

GPS: global positioning system



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

USDA: United States Department of Agriculture

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B. STUDY DESIGN

1. Experimental Conditions

CGA 357261 WG 50 is a granule formulation containing 51% w/w CGA 357261. The test item was applied once on bare soil plots using Knapsack sprayers with a nominal application rate of 0.3750 kg/ha in 300 L water/ha, corresponding to 0.1875 kg CGA 357261/ha.

Prior to spraying the test item onto the soil, the plots were prepared to have a fine crumb structure and a fine seedbed. Grass was sown after spraying of the test item at [redacted] and [redacted] and before spraying of the test item at [redacted] and [redacted]. At [redacted] the incorporation of the test item into the soil and the sowing of grass were performed simultaneously. The test item was incorporated into the soil up to a depth of approximately 8 to 10 cm immediately after application using a curry comb at [redacted], a rotary harrow with roll at [redacted] and [redacted], a hay bob harrow at [redacted] and [redacted], and a hay bob harrow with roll at [redacted].

Air temperature, precipitation including irrigation, and sunshine data were recorded during the field soil dissipation trial at all sites.

Soil dissipation of trifloxystrobin was studied for up to 733 days

2. Sampling

Soil cores were taken to a depth of 10 cm using a soil piercer (Ø 50 mm) before application from the untreated control plots (10 to 20 soil cores) and immediately after application and incorporation of the test item into the soil from the treated plots (40 soil cores, DAT-0 samples). All subsequent samplings were performed using a "Wacker Hammer" (Ø 45 to 50 mm). At each sampling interval 18 to 20 soil cores from the treated plots were taken. The sampling spots were distributed randomly over the plots to obtain representative samples.

In all treated plots of the trials the soil cores were taken to a maximum depth of 100 cm on the following occasions: 0 (2 samplings post-incorporation, each 0-10 cm depth), 2-4, 6-8, 13-15, 27-28 (each 0-50 cm depth), 56-62, 83-91, (each 0-50 cm depth), and 118-130, 173-182, 356-371, 532-546 and 657-733 (each 0-100 cm depth) days after treatment (DAT). From the control plots, samples were taken on the following occasions: 0 days before application, 356-371 and 661-733 days after treatment.

The soil cores were stored dark immediately after sampling and were deep-frozen within 24 hours (DAT-0 samples within 7 hours). The frozen soil cores were cut into 10 cm segments and each horizon (laboratory samples) was milled separately in a hammer mill and carefully homogenized. An aliquot of each laboratory sample (analytical samples) was used for analysis. Soil cores and samples were stored in the dark at $\leq -18^{\circ}\text{C}$.

3. Analytical Procedures

The analytical method 01927/M001 (M-464872-01-1, Supplemental Dossier, KCA 4.1.2/24) was developed for the determination of trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 in soil. Soil samples of 20 g were extracted three times at ambient temperature using a shaker and once by microwave-accelerated extraction at 70 °C using acetonitrile/water 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation ($> 500 \times g$) and decantation. The soil extracts were combined, internal stable-labelled standards added and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in multiple reaction monitoring mode. The method



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

was validated using three different soils. The limit of detection (LOD) and limit of quantitation (LOQ) were 0.03 and 0.1 µg/kg for each analyte, respectively.

During analysis of the dissipation samples of the current study, concurrent recovery samples were prepared freshly by fortification of control samples with test item CGA 357261 and reference items CGA 373466, NOA 413163 and NOA 409480 at levels of 0.1 and 1 µg/kg and processed in parallel to the dissipation samples. The mean recoveries were 102% (RSD 9.2%) for CGA 357261, 102% (RSD 11.0%) for CGA 373466, 79% (RSD 19.7%) for NOA 413163, and 98% (RSD 10.4%) for NOA 409480.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006) using the software KinGUI2 with three different kinetic models: single first order, first order multi compartment and double first order in parallel. Model input datasets were the Residual amounts found in each replicate test system at each sampling interval. The initial total recovery at DAT-0 (2 samplings after incorporation) was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The best fit kinetic model was selected on the basis of the chi²-scaled error criterion and on the basis of a visual assessment of the goodness of the fits. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

III. RESULTS AND DISCUSSION

A. DATA

Table 7.1.2.2.1- 10: Residues of CGA 357261 in soil at [redacted] (Germany), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	1 ^{2,3}	3	6	14	28	56	91	124	182	368	543	733
CGA 357261	Mean	58.0	47.1	42.6	25.8	8.23	3.37	0.66	0.43	0.33	0.22	0.27	0.15	0.13
CGA 373466	Mean	195	126	129	540	80.8	40.5	19.6	15.5	12.2	6.6	3.72	1.20	1.35
NOA 413163	Mean	0.05	0.06	0.35	0.34	1.03	1.05	2.15	4.41	8.97	6.96	1.79	0.73	0.47
NOA 409480	Mean	0.49	0.38	0.37	0.28	0.51	0.42	0.44	0.42	0.47	0.32	0.31	0.13	0.14

DAT: days after treatment

¹ CGA 357261 equivalents, sum of 0-100 cm

² DAT-0 single values (CGA 357261): 33.7, 60.2 g/ha (mean 48.0 g/ha); 44.8, 49.4 g/ha (mean 47.1 g/ha); overall mean 52.5 g/ha = 28% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (CGA 357261 equivalents) = CGA 357261 + degradation products): 233, 247 g/ha (mean 240 g/ha); 193, 165 g/ha (mean 179 g/ha); overall mean 209 g/ha = 112% of nominal application rate of 187.5 g/ha

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Table 7.1.2.2.1- 11: Residues of CGA 357261 in soil at [redacted] (United Kingdom), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	4	8	15	28	62	91	130	174	371	545	708
CGA 357261	Mean	37.5	41.0	39.0	15.4	2.87	1.23	0.53	0.42	0.28	0.28	0.31	0.12	(0.03)
CGA 373466	Mean	72.8	70.3	72.9	86.5	88.5	54.9	21.6	15.4	10.6	9.80	5.0	2.08	1.17
NOA 413163	Mean	0.23	0.19	0.83	2.95	14.8	52.6	28.7	32.3	37.6	31.5	48.0	8.56	4.5
NOA 409480	Mean	0.10	0.11	0.19	0.30	1.47	1.61	1.19	0.99	0.82	0.99	0.95	0.37	0.24

DAT: days after treatment, values in (brackets) are given at 1/2 LOD according to FOCUS kinetics (2006)

¹ CGA 357261 equivalents, sum of 0-100 cm

² DAT-0 single values (CGA 357261): 37.8, 37.2 g/ha (mean 37.5 g/ha); 42.0, 40.0 g/ha (mean 41.0 g/ha); overall mean 39.0 g/ha = 21% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (CGA 357261 equivalents) = CGA 357261 + degradation products): 109, 117 g/ha (mean 113 g/ha); 113, 115 g/ha (mean 114 g/ha); overall mean 114 g/ha = 61% of nominal application rate of 187.5 g/ha

Table 7.1.2.2.1- 12: Residues of CGA 357261 in soil at [redacted] (Northern France), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	3	7	14	28	59	90	119	181	356	540	680
CGA 357261	Mean	122	101	59	62	16.6	1.17	0.72	0.42	0.41	0.37	0.43	0.13	0.19
CGA 373466	Mean	37.7	32.5	40.1	40.7	96.4	37.4	89.4	51.7	31.5	19.5	6.23	1.54	1.38
NOA 413163	Mean	0.06	0.06	0.30	0.44	0.75	2.35	13.2	15.7	23.6	22.6	16.4	1.80	0.88
NOA 409480	Mean	0.0	0.06	0.03	0.13	0.51	0.33	0.47	0.64	0.84	0.83	0.70	0.22	0.23

DAT: days after treatment

¹ CGA 357261 equivalents, sum of 0-100 cm

² DAT-0 single values (CGA 357261): 121, 124 g/ha (mean 123 g/ha); 104, 98.5 g/ha (mean 101 g/ha); overall mean 112 g/ha = 60% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (CGA 357261 equivalents) = CGA 357261 + degradation products): 184, 181 g/ha (mean 183 g/ha); 158, 154 g/ha (mean 156 g/ha); overall mean 169 g/ha = 90% of nominal application rate of 187.5 g/ha

Table 7.1.2.2.1- 13: Residues of CGA 357261 in soil at [redacted] (Southern France), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	3	7	15	28	62	83	118	180	361	543	727
CGA 357261	Mean	102	86.3	62	31.3	12.0	1.50	0.38	0.48	0.24	0.20	0.28	0.10	0.11
CGA 373466	Mean	73.9	77.1	60.7	50	143	76.2	41.9	124	108	88.3	30.2	16.1	8.60
NOA 413163	Mean	0.06	0.06	0.82	0.84	1.82	2.14	3.47	3.28	5.21	6.00	3.97	1.66	1.24
NOA 409480	Mean	0.0	0.0	0.35	0.45	1.23	1.37	0.59	0.87	0.58	0.72	0.70	0.34	0.25

DAT: days after treatment

¹ CGA 357261 equivalents, sum of 0-100 cm

² DAT-0 single values (CGA 357261): 93.8, 111 g/ha (mean 102 g/ha); 88.6, 83.9 g/ha (mean 86.3 g/ha); overall mean 94.0 g/ha = 50% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (CGA 357261 equivalents) = CGA 357261 + degradation products): 122, 127 g/ha (mean 125 g/ha); 115, 114 g/ha (mean 115 g/ha); overall mean 122 g/ha = 65% of nominal application rate of 187.5 g/ha



Table 7.1.2.2.1- 14: Residues of CGA 357261 in soil at [redacted] (Spain), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	2	8	14	28	62	90	119	173	370	540	686
CGA 357261	Mean	55.8	69.4	65.5	12.4	1.37	0.99	0.41	0.17	0.14	0.12	(0.03)	<LOD	<LOD
CGA 373466	Mean	72.2	97.4	86.9	139	37.2	64.3	25.5	5.32	2.40	4.25	0.73	0.45	0.38
NOA 413163	Mean	0.13	0.13	0.90	7.07	6.62	18.3	24.7	12.7	9.27	10.4	3.80	1.73	1.03
NOA 409480	Mean	0.07	0.09	0.18	0.61	0.66	1.24	1.47	0.91	0.52	0.35	0.19	0.18	0.13

DAT: days after treatment, values in (brackets) are given at 1/2 LOD according to FOCUS kinetics (2006)

¹ CGA 357261 equivalents, sum of 0-100 cm

² DAT-0 single values (CGA 357261): 50.2, 61.4 g/ha (mean 55.8 g/ha); 69.3, 69.6 g/ha (mean 69.5 g/ha); overall mean 63.0 g/ha = 33% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (CGA 357261 equivalents) = CGA 357261 + degradation products): 118, 143 g/ha (mean 131 g/ha); 174, 167 g/ha (mean 171 g/ha); overall mean 151 g/ha = 80% of nominal application rate of 187.5 g/ha

Table 7.1.2.2.1- 15: Residues of CGA 357261 in soil at [redacted] (Italy), mean values (sum of 0-100 cm) expressed as g/ha

Compound	Mean ¹	DAT												
		0 ^{2,3}	0 ^{2,3}	3	7	14	27	59	90	118	176	360	532	657
CGA 357261	Mean	135	102	29.6	13.9	2.37	0.84	0.43	0.32	0.39	0.31	0.25	0.17	0.13
CGA 373466	Mean	64.0	51.5	120	21	194	109	118	88.2	124	56.7	32.6	17.2	9.80
NOA 413163	Mean	0.37	0.36	0.60	1.58	2.05	3.49	4.06	5.79	7.89	4.66	4.19	1.89	1.09
NOA 409480	Mean	0.13	0.07	0.26	0.45	0.65	0.98	1.32	1.83	1.29	1.24	1.07	0.74	0.41

DAT: days after treatment

¹ CGA 357261 equivalents, sum of 0-100 cm

² DAT-0 single values (CGA 357261): 138, 131 g/ha (mean 135 g/ha); 106, 97.9 g/ha (mean 102 g/ha); overall mean 118 g/ha = 63% of nominal application rate of 187.5 g/ha

³ DAT-0 single values (total residues (CGA 357261 equivalents) = CGA 357261 + degradation products): 211, 192 g/ha (mean 202 g/ha); 163, 148 g/ha (mean 156 g/ha); overall mean 179 g/ha = 95% of nominal application rate of 187.5 g/ha

B. RESIDUES

CGA 357261 is rapidly degraded in soil to CGA 373466 by ester cleavage as well as to a small extent further to NOA 413163 and NOA 409480. Therefore, the total amounts of CGA 357261 and its degradation products (expressed as CGA 357261 equivalents) were calculated for total residues at study start (DAT-0). The total residues detected at DAT-0 were 209 g/ha at [redacted] (Germany), 114 g/ha at [redacted] (United Kingdom), 169 g/ha at [redacted] (Northern France), 122 g/ha at [redacted] (Southern France), 151 g/ha at [redacted] (Spain) and 179 g/ha at [redacted] (Italy), corresponding to 112, 61, 90, 65, 80 and 95% of the nominal application rate, respectively.

The amount of CGA 357261 (total residues) decreased from DAT-0 to study end (DAT-733) from 209 to 0.13 g/ha at [redacted], from DAT-0 to DAT-708 from 114 g/ha to < LOD (limit of detection) at [redacted], from DAT-0 to DAT-680 from 169 to 0.14 g/ha at [redacted], from DAT-0 to DAT-727 from 122 to 0.06 g/ha at [redacted], from 151 g/ha at DAT-0 to < LOD from DAT-540 onwards at [redacted] and from DAT-0 to DAT-657 from 179 to 0.16 g/ha at [redacted].

Residues of CGA 357261 were primarily detected in the top 0-10 cm of soil, except for some very low residues detected down to a depth of 20-30 cm.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Dissipation and degradation of CGA 357261 was accompanied by the formation of its degradation products CGA 373466, NOA 413163 and NOA 409480.

CGA 373466 amounted to maxima (CGA 357261 equivalents) of 88.5 to 245 g/ha between DAT-10 and DAT-15 in the entire soil profiles. The major part of the residues was detected in the top 0-30 cm soil layer. Residues above the limit of quantitation (LOQ) were detected down to a depth of 30-40 cm at [redacted], [redacted] and [redacted], and down to a depth of 90-100 cm at [redacted] and [redacted].

NOA 413163 amounted to maxima (CGA 357261 equivalents) of 6.0 to 52.6 g/ha between DAT-28 and DAT-180 in the entire soil profiles. Residues above the LOQ were detected down to a depth of 50-60 cm, except of [redacted] and [redacted], where residues above the LOQ were detected down to a depth of 90-100 cm.

NOA 409480 amounted to maxima (CGA 357261 equivalents) of 0.51 to 1.01 g/ha between DAT-14 and DAT-119 in the entire soil profiles. The major part of the residues was detected in the top 0-10 cm soil layer and no residues were detected below a depth of 20-30 cm.

C. KINETIC ANALYSIS

The degradation of CGA 357261 followed first order multi compartment (FOMC) kinetics for [redacted], [redacted] and [redacted], and double first order in parallel kinetics for [redacted] and [redacted] according to the lowest chi² error values and visual assessments. Table 7.1.2.2.1-16 summarizes the best-fit results of the DT₅₀ and DT₉₀ calculations.

Table 7.1.2.2.1- 16. Best-fit degradation kinetics of CGA 357261 in soils under field conditions according to FOCUS

Site	Best Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	Visual Assessment ²
[redacted] (Germany)	DFOP	0.9	7.5	2.4	+
[redacted] (United Kingdom)	DFOP	2.6	9.0	2.2	+
[redacted] (Northern France)	FOMC	2.2	17.5	26.9	+
[redacted] (Southern France)	DFOP	0.2	13.0	1.1	+
[redacted] (Spain)	FOMC	1.6	6.8	3.0	+
[redacted] (Italy)	FOMC	0.8	4.8	4.7	+

¹ FOMC: first order multi compartment, DFOP: double first order in parallel

² visual assessment: + = good

III. CONCLUSIONS

CGA 357261, a major photodegradation product of trifloxystrobin, was rapidly degraded in soil under field conditions in the core regions Northern and Southern Europe. The calculated best-fit half-lives were between 0.6 and 3.2 days at the tested sites. The major trifloxystrobin photodegradation products CGA 373466, NOA 413163 and NOA 409480, which are derived from CGA 357261, were formed and declined towards study end.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil under field conditions given in section CA 7.1.2.2.



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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.2.2.1 /17; [REDACTED]; 2013; amended 2013-10-25
Title:	Amendment No. 01 to Report No. MR-13/108 – Determination of the storage stability of the trifloxystrobin and the metabolites CGA 279202 ZE- isomer, CGA 321113, CGA 373466, BCS-AB39385, BCS-CR74871, NOA 413161 and NOA 413163 in soil – Phase Report for an Interval of 0 to 18 and 21 Months
Report No:	MR-13/108
Document No:	M-467625-02-1
Guidelines:	- Regulation (EC) No 1107/2009 - European Commission DGA 7032/VI/95 rev. 5, Appendix H - US EPA OCSPP Test Guideline No. 860.1380.
GLP:	Yes
Justification:	New data / guideline requirement: Storage Stability of trifloxystrobin and its major degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 in soil

Executive Summary

The storage stabilities of trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 in soil were studied between -18 and -25 °C for up to 636 days using soils [REDACTED] (sandy loam), [REDACTED] (silt loam) and [REDACTED] (clay loam). Soils [REDACTED] and [REDACTED] were used for trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 357276 and NOA 409480, whereas soils [REDACTED] and [REDACTED] were used for NOA 413161 and NOA 413163.

Fortification concentrations of nominal 50 µg per kg soil were used for trifloxystrobin and each degradation product.

On average, more than 70% of the fortified amount of trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 were recovered from the stored samples at each sampling interval.

The mean recovered amounts after 636 days of storage were 98 and 95% for trifloxystrobin, 101 and 100% for CGA 357261, 91 and 99% for CGA 321113, 94 and 89% for CGA 373466, 95 and 96% for CGA 357276, and 101 and 99% for NOA 409480. After 557 days of storage the mean recovered amounts were 98 and 99% for NOA 413161 and 93 and 83% for NOA 413163.

The results demonstrate that residues of trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 357276 and NOA 409480 in soil are considered to be stable for at least 636 days and that residues of NOA 413161 and NOA 413163 in soil are considered to be stable for at least 557 days under frozen conditions.

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I. MATERIALS AND METHODS

A. MATERIALS

1. Test Items

unlabelled trifloxystrobin

Certificate of Analysis: AZ 17292
Batch Code: NLL5391-14
Chemical Purity: 99.6%

unlabelled CGA 357261

Certificate of Analysis: AZ 15228
Batch Code: SES10350-10-1
Chemical Purity: 95.7%

unlabelled CGA 321113

Certificate of Analysis: AZ 18276 (AZ 16887)
Batch Code: M20619
Chemical Purity: 98.7% (98.7%)

unlabelled CGA 373466

Certificate of Analysis: AZ 17621 (AZ 15111)
Batch Code: SES1648-63 (M18457)
Chemical Purity: 97.9% (96.3%)

unlabelled NOA 413161

Certificate of Analysis: AZ 17475
Batch Code: M19118
Chemical Purity: 91.8%

unlabelled NOA 413163

Certificate of Analysis: AZ 17463
Batch Code: M18477
Chemical Purity: 99.2%

unlabelled CGA 357266

Certificate of Analysis: AZ 18244 (AZ 16891)
Batch Code: BCSO6204-3-3
Chemical Purity: 97.8% (97.8%)

unlabelled NOA 409480

Certificate of Analysis: AZ 17488
Batch Code: BCSO6263-3-4
Chemical Purity: 98.6%

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2. Test Soils

Three soils were used (see Table 7.1.2.2.1- 17) representing different geographical origin and different soil properties. Two different soils were used for each test item. Soils [redacted] and [redacted] were used for trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 357276 and NOA 409480, whereas soils [redacted] and [redacted] were used for NOA 413161 and NOA 413163.

Table 7.1.2.2.1- 17: Physico-chemical properties of test soils

Parameter	Results / Units		
	[redacted]	[redacted]	[redacted]
Soil Designation	[redacted]	[redacted]	[redacted]
Geographic Location (Country)	Germany	Germany	Germany
Textural Class (USDA)	sandy loam	silt loam	clay loam
Sand [50 µm – 2 mm]	70.7%	4.3%	31%
Silt [2 µm – 50 µm]	18.3%	76.3%	38%
Clay [< 2 µm]	10.0%	19.4%	31%
pH (soil/CaCl ₂)	6.8	6.7	6.3
pH (soil/water)	7.4	7.4	7.4
Organic Carbon	1.0%	0.9%	5.0%
Organic Matter ¹	1.1%	1.6%	8.6%
Cation Exchange Capacity [meq/100 g]	9.8	12.4	20.6
Water Holding Capacity maximum [g H ₂ O/100 g soil DW]	7.9	39.5	79.1

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The test system for storage stability in soil under frozen conditions consisted of polypropylene Corning® centrifuge tubes (Volume 50 mL). For preparation of the test systems, 20 g of the soils were weighed into each tube.

Fortification concentrations of nominal 50 µg per kg soil were used for each test item. The test items were applied to the respective test systems in 200 µL acetonitrile.

After application, the test systems were stored at -18 °C in a deep-freezer for up to 636 days. This storage stability study is ongoing and will be continued for up to 28 months (820 days).

2. Sampling

Samples were processed and analysed 0, 84, 267 and 636 days after treatment (DAT) for trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 357276 and NOA 409480, as well as 0, 190, 286 and 557 days after treatment for NOA 413161 and NOA 413163.

At each sampling interval (except DAT-0), four fortified and six control samples were removed from the deep-freezer and allowed to reach ambient temperature. Four of the control samples were fortified with the test items at the same concentrations as the storage stability samples (50 µg per kg soil) to determine the concurrent recoveries. The samples were processed in parallel to the fortified and control samples of the respective sampling interval.



3. Analytical Procedures

The analytical method 01327/M001 (M-464872-01-1, Supplemental Dossier, KCA 4.1.2 /24) was developed for the determination of trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 in soil. Soil samples of 20 g were extracted three times at ambient temperature using a shaker and once by microwave-accelerated extraction at 70 °C using acetonitrile/water 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation (> 500 x g) and decantation. The soil extracts were combined, internal stable-labelled standards added and an aliquot of the combined soil extract was analysed by reversed phase HPLC-MS/MS in multiple reaction monitoring mode. The method was validated using three different soils. The limit of detection (LOD) and limit of quantitation (LOQ) were 0.03 and 0.1 µg/kg for each analyte, respectively.

Trifloxystrobin (*EE*) and its *E/Z* isomer CGA 357261 (*ZE*) are rapidly degraded in soil to CGA 321113 (*EE*) and its *E/Z* isomer CGA 373466 (*ZE*), respectively, by ester cleavage. The degradation observed from day 0 to day 84 is presumably caused by the time needed for the application procedure, deep-freezing and thawing of the samples prior to extraction. Therefore the total amounts of trifloxystrobin and its degradation product CGA 321113 (expressed as trifloxystrobin equivalents) as well as CGA 357261 and its degradation product CGA 373466 (expressed as CGA 357261 equivalents) were calculated for recoveries of trifloxystrobin and CGA 357261, respectively.

During analysis of the storage stability and control samples of the current study, concurrent recovery samples were prepared freshly by fortification of control samples with the test items trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 at a level of 50 µg per kg soil and processed in parallel to the storage stability and control samples. The mean recoveries were 103 and 100% (RSDs 6.3 and 7.0%) for trifloxystrobin, 96% (RSDs 10.0 and 14.4%) for CGA 357261, 100 and 95% (RSDs 7.1 and 6.0%) for CGA 321113, 99 and 95% (RSDs 7.6 and 7.1%) for CGA 373466, 96 and 78% (RSDs 11.8 and 14.3%) for NOA 413161, 92 and 78% (RSDs 11.8 and 12.7%) for NOA 413163, 99 and 97% (RSDs 9.4 and 10.4%) for CGA 357276, and 99 and 97% (RSDs 5.2 and 10.1%) for NOA 409480.

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II. RESULTS AND DISCUSSION

A. DATA

Table 7.1.2.2.1- 18: Recovered amounts of trifloxystrobin in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values [%]				Recoveries		Normalised to DAT-0 ¹ [%]
						Mean [%]	RSD [%]	
[Redacted]	0	88	94	90	88	90	3.2	100
	84	87	89	94	96	91	4.3	102
	267	104	112	111	98	106	6.0	118
	365	91	104	104	92	100	10.6	112
	636	104	106	101	107	104	2.3	106
	Overall Mean					98	8.8	-
[Redacted]	0	89	90	90	94	91	2.5	100
	84	94	89	90	94	92	2.7	101
	267	103	102	109	102	105	3.9	114
	365	94	87	81	99	91	8.8	100
	636	96	99	100	102	99	2.6	110
	Overall Mean					95	7.0	-

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT=0) x 100%

Table 7.1.2.2.1- 19: Recovered amounts of CGA 357261 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values [%]				Recoveries		Normalised to DAT-0 ¹ [%]
						Mean [%]	RSD [%]	
[Redacted]	0	93	97	95	94	95	1.7	100
	84	94	100	97	109	97	6.8	113
	267	103	84	96	105	97	9.7	102
	365	103	120	95	86	101	14.3	107
	636	104	104	100	106	104	2.4	109
	Overall Mean					101	8.8	-
[Redacted]	0	92	98	92	90	93	3.9	100
	84	112	103	106	95	104	7.0	112
	267	97	88	102	112	100	9.7	107
	365	117	85	105	96	102	11.9	109
	636	93	107	106	98	101	6.8	108
	Overall Mean					100	8.3	-

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT=0) x 100%



Table 7.1.2.2.1- 20: Recovered amounts of CGA 321113 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values				Recoveries		
		[%]				Mean	RSD	Normalised to DAT-0 ¹
						[%]	[%]	[%]
[Redacted]	0	95	95	99	100	97	2.7	100
	84	86	82	84	87	85	2.6	87
	267	88	92	87	88	89	2.5	91
	365	86	80	86	83	84	2.4	86
	636	91	90	98	99	95	4.9	97
	Overall Mean						91	5.8
[Redacted]	0	96	99	84	90	92	7.3	100
	84	79	77	88	81	81	6.1	88
	267	99	80	91	88	90	8.8	97
	365	92	93	85	93	91	4.3	98
	636	94	91	84	85	91	5.5	99
	Overall Mean						89	7.9

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT-0) x 100%

Table 7.1.2.2.1- 21: Recovered amounts of CGA 373466 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values				Recoveries		
		[%]				Mean	RSD	Normalised to DAT-0 ¹
						[%]	[%]	[%]
[Redacted]	0	106	106	106	108	106	0.9	100
	84	90	90	90	83	90	6.4	85
	267	85	102	96	98	90	11.9	85
	365	91	91	99	92	93	4.1	88
	636	89	89	89	94	90	3.3	84
	Overall Mean						94	8.8
[Redacted]	0	106	106	102	98	102	3.8	100
	84	88	88	88	84	88	6.6	86
	267	82	82	80	78	81	2.4	79
	365	93	88	86	91	90	3.5	88
	636	92	92	92	88	89	5.6	87
	Overall Mean						89	8.6

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT-0) x 100%



Table 7.1.2.2.1- 22: Recovered amounts of NOA 413161 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values				Recoveries		
		[%]				Mean	RSD	Normalised to DAT-0 ¹
						[%]	[%]	[%]
[Redacted]	0	111	107	106	111	109	2.6	95
	190	76	89	91	-	85	9.5	69
	286	79	80	79	94	83	8.9	89
	557	98	118	110	118	111	8.5	120
	Overall Mean					98	15.2	-
[Redacted]	0	95	95	84	93	92	5.3	100
	190	69	81	84	70	76	10.0	83
	286	59	89	79	96	81	19.9	88
	557	120	104	97	117	110	9.9	119
	Overall Mean					89	18.3	-

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT-0) x 100%

Table 7.1.2.2.1- 23: Recovered amounts of NOA 413163 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values				Recoveries		
		[%]				Mean	RSD	Normalised to DAT-0 ¹
						[%]	[%]	[%]
[Redacted]	0	105	90	106	95	99	7.7	100
	190	101	87	97	100	96	6.6	97
	286	59	71	104	90	81	24.0	82
	557	95	85	105	-	94	10.8	95
	Overall Mean					93	14.4	-
[Redacted]	0	79	75	81	99	83	12.6	100
	190	89	74	80	75	82	14.2	99
	286	80	66	91	86	81	13.4	97
	557	85	100	92	95	93	6.7	112
	Overall Mean					85	12.1	-

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT-0) x 100%

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Table 7.1.2.2.1- 24: Recovered amounts of CGA 357276 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values				Recoveries		
		[%]				Mean	RSD	Normalised to DAT-0 ¹
						[%]	[%]	[%]
[Redacted]	0	92	86	81	92	88	6.0	100
	84	81	90	107	93	93	11.5	100
	267	117	111	83	105	104	14.0	108
	365	92	96	107	82	94	11.0	107
	636	93	95	103	88	95	6.6	100
	Overall Mean					95	11.4	-
[Redacted]	0	84	92	87	93	88	6.2	100
	84	94	90	88	82	94	6.8	100
	267	86	116	108	92	101	13.5	114
	365	104	98	103	87	98	9.9	112
	636	106	101	99	94	100	5.0	100
	Overall Mean					96	9.2	-

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT-0) x 100%

Table 7.1.2.2.1- 25: Recovered amounts of NOA 409480 in soil expressed as percentage of nominal applied amount

Soil	DAT	Single Values				Recoveries		
		[%]				Mean	RSD	Normalised to DAT-0 ¹
						[%]	[%]	[%]
[Redacted]	0	104	104	91	99	100	6.2	100
	84	93	93	108	107	101	6.8	102
	267	105	100	100	119	106	8.5	107
	365	109	96	100	97	101	5.9	101
	636	92	103	95	91	96	5.4	96
	Overall Mean					101	6.8	-
[Redacted]	0	94	99	89	97	94	5.0	100
	84	106	94	100	97	99	5.3	106
	267	101	125	99	104	107	11.2	114
	365	90	119	105	98	103	11.9	110
	636	91	87	106	87	93	9.7	99
	Overall Mean					99	10.0	-

DAT: days after treatment

¹ Normalised recovery = (mean recovery / mean recovery at DAT-0) x 100%



B. RESIDUES

On average, more than 70% of the fortified amount of trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 were recovered from the stored samples at each sampling interval.

The mean recovered amounts after 636 days of storage were 98 and 95% for trifloxystrobin, 101 and 100% for CGA 357261, 91 and 89% for CGA 321113, 94 and 89% for CGA 373466, 96 and 95% for CGA 357276, and 101 and 99% for NOA 409480. After 557 days of storage the mean recovered amounts were 98 and 89% for NOA 413161 and 93 and 83% for NOA 413163.

The results demonstrate that residues of trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 357276 and NOA 409480 in soil are considered to be stable for at least 636 days and that residues of NOA 413161 and NOA 413163 in soil are considered to be stable for at least 557 days under frozen conditions.

III. CONCLUSIONS

Residues of trifloxystrobin and its degradation products CGA 357261, CGA 321113, CGA 373466, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 in soil are stable for at least 557 days under frozen conditions.

Report:	KCA 7.1.2.2.1 /18; [redacted]; [redacted] 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin and its Metabolites after Soil Incorporation under European Field Conditions according to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0722
Document No:	M-468499-01-1
Guidelines:	- FOCUS kinetics (2006)
GLP:	Yes
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of trifloxystrobin and its major degradation products CGA 321113, NOA 413161 and CGA 357276 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the field dissipation study M-462061-02-1 (Supplemental Dossier, KCA 7.1.2.2.1 /15) was performed with the software KinGUI 2 according to FOCUS kinetics (2006)¹ to derive normalised (20 °C and field capacity) half-lives for trifloxystrobin and its degradation products CGA 321113, NOA 413161 and CGA 357276 as well as normalised (20 °C and field capacity) formation fractions for CGA 321113, NOA 413161 and CGA 357276, which are suitable for modelling purpose.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin at the sites [redacted] (United Kingdom), [redacted] (Northern France), [redacted] (Southern France), [redacted] (Spain) and [redacted] (Italy), as well as double first order in parallel at site [redacted] (Germany) under field conditions with an application rate of 187.5 g/ha and normalised to 20 °C and field capacity. The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113, NOA 413161 and CGA 357276.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

The half-lives (geometric means) were 1.69 days for trifloxystrobin, 48.1 days for CGA 321113, 39.3 days for NOA 413163 and 51.7 days for CGA 357276.

The formation fractions (arithmetic means) were 0.707 for CGA 321113, 0.145 for NOA 413163 and 0.068 for CGA 357276.

I. METHODS

Soil residue data from the field dissipation study M-462061-02-1 (Supplemental Dossier, KCA 7.1.2.2.1/15) were used. In this study, the degradation of trifloxystrobin was studied at sites [redacted] (Germany), [redacted] (United Kingdom), [redacted] (Northern France), [redacted] (Southern France), [redacted] (Spain) and [redacted] (Italy) under field conditions for up to 733 days with an application rate of 187.5 g/ha and normalised to 20 °C and field capacity.

Soil temperature and moisture were simulated with the FOCUSPEARL 4.4.4 model based on daily weather data (precipitation and irrigation, maximum and minimum air temperature, humidity or vapour pressure, wind speed, global solar radiation). These values were used as input values for the time-step normalisation process implemented in a Microsoft Excel spreadsheet.

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi-compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi² scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ value from the double first order in parallel was not calculated from the slow k-rate as recommended by FOCUS. This procedure produces the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ value taken for modelling is based on the iteratively calculated values from KinGUI.

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II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin at the sites [redacted] (United Kingdom), [redacted] (Northern France), [redacted] (Southern France), [redacted] (Spain) and [redacted] (Italy), as well as double first order in parallel at site [redacted] (Germany). The SFO kinetic model was used for modelling purpose to describe the degradation of CGA 321113, NOA 413161 and CGA 357276. Table 7.1.2.2.1- 26 to Table 7.1.2.2.1- 29 are summarizing the results of the kinetic analysis.

Table 7.1.2.2.1- 26: Kinetic parameters for the degradation of trifloxystrobin in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	Kinetic Model ¹	Deg T ₅₀ ² [days]	Chi ² Error [%]	t-test	Visual Assessment ³
[redacted] (Germany)	DFOP	1.13	27.1	k ₁ : 2.4 x 10 ⁻² k ₂ : 1.6 x 10 ⁻²	+
[redacted] (United Kingdom)	SFO	1.66	16.3	< 2 x 10 ⁻¹⁶	o
[redacted] (Northern France)	SFO	1.69	28.8	7.5 x 10 ⁻⁷	+
[redacted] (Southern France)	SFO	2.33	9.0	2 x 10 ⁻¹⁰	+
[redacted] (Spain)	SFO	2.10	19.5	7.6 x 10 ⁻¹⁴	+
[redacted] (Italy)	SFO	2.49	13.5	6.7 x 10 ⁻¹⁵	+
	geomean	1.69			

¹ SFO: single first order, DFOP: double first order in parallel

² for DFOP: DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve

³ visual assessment: + = good, o = moderate

Table 7.1.2.2.1- 27: Kinetic parameters for degradation of CGA 321113 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	FF	Kinetic Model	Deg T ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
[redacted] (Germany)	0.680	SFO	52.4	8.9	3.8 x 10 ⁻¹⁰	+
[redacted] (United Kingdom)	0.820	SFO	24.7	9.5	5.8 x 10 ⁻¹⁴	+
[redacted] (Northern France)	0.556	SFO	59.0	16.8	1.2 x 10 ⁻⁶	o
[redacted] (Southern France)	0.668	SFO	95.8	19.1	3.6 x 10 ⁻⁸	o
[redacted] (Spain)	0.488	SFO	23.7	28.5	1.2 x 10 ⁻⁵	o
[redacted] (Italy)	0.000	SFO	79.8	15.2	5.1 x 10 ⁻⁷	+
	arithmetic mean	geomean	48.1			

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good, o = moderate



Table 7.1.2.2.1- 28: Kinetic parameters for degradation of NOA 413161 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	FF	Kinetic Model ¹	DegT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
(Germany)	0.071	SFO	66.1 ³	18.9	6.9 x 10 ⁻³	
(United Kingdom)	0.263	SFO	30.7	15.4	1.4 x 10 ⁻⁷	
(Northern France)	0.284 ⁴	SFO	32.6 ⁴	47.0	1.7 x 10 ⁻⁶	-
(Southern France)	0.078	SFO	26.0	14.3	5.9 x 10 ⁻⁵	
(Spain)	0.259	SFO	34.9	17.2	6.7 x 10 ⁻⁶	+
(Italy)	0.055	SFO	50.8	16.9	7.3 x 10 ⁻⁵	+
arithmetic mean	0.145	geomean	39.3			

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good, o = moderate, - = poor

³ estimate based on fit of the decline curve

⁴ value excluded from the calculation of arithmetic or geometric mean due to unreliable statistical parameters

Table 7.1.2.2.1- 29: Kinetic parameters for degradation of CGA 357276 on soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	FF	Kinetic Model ¹	DegT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
(Germany)	0.072	SFO	36.5	20.1	8.1 x 10 ⁻⁶	o
(United Kingdom)	0.098	SFO	80.2	2.8	1.0 x 10 ⁻⁶	+
(Northern France)	0.062	SFO	36.1	7.9	1.8 x 10 ⁻⁶	+
(Southern France)	0.22 ⁴	SFO	19.7 ⁴	24.5	4.3 x 10 ⁻²	-
(Spain)	0.07	SFO	45.5	19.7	1.9 x 10 ⁻³	o
(Italy)	0.032	SFO	76.5	23.2	1.9 x 10 ⁻³	o
arithmetic mean	0.068	geomean	51.7			

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good, o = moderate, - = poor

³ estimate based on fit of the decline curve

⁴ value excluded from the calculation of arithmetic or geometric mean due to unreliable statistical parameters

III. CONCLUSIONS

The calculated normalised (20 °C and field capacity) half-lives (geometric means) for modelling purpose for the degradation of trifloxystrobin and its major degradation products CGA 321113, NOA 413161 and NOA 409480 in soil under field conditions were 1.69 days for trifloxystrobin, 48.1 days for CGA 321113, 39.3 days for NOA 413161 and 51.7 days for CGA 357276 at the tested sites. The normalised (20 °C and field capacity) formation fractions (arithmetic means) were 0.707 for CGA 321113, 0.145 for NOA 413161 and 0.068 for CGA 357276.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil under field conditions given in sections [CA 7.1.2.2](#) and [CA 7.1.2](#)



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Report:	KCA 7.1.2.2.1 /19; [redacted]; [redacted]; [redacted]; 2013
Title:	Kinetic Evaluation of the Degradation of Trifloxystrobin Metabolite CGA 357261 and its Metabolites after Soil Incorporation under European Field Conditions according to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-13-0723
Document No:	M-468500-01-1
Guidelines:	- FOCUS kinetics (2006) ¹
GLP:	No
Justification:	New data / guideline requirement: Kinetic analysis of the degradation of the major trifloxystrobin photodegradation products CGA 357261, CGA 373466, NOA 413163 and NOA 409480 for modelling purpose

Executive Summary

A kinetic analysis of soil residue data from the field dissipation study M-468701-01-1 (Supplemental Dossier, KCA 7.1.2.2.1 /16) was performed with the software KinGUI 2 according to FOCUS kinetics (2006)¹ to derive normalised (20 °C and field capacity) half-lives for the trifloxystrobin photodegradation products CGA 357261, CGA 373466, NOA 413163 and NOA 409480 as well as normalised (20 °C and field capacity) formation fractions for CGA 373466, NOA 413163 and NOA 409480, which are suitable for modelling purpose.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of CGA 357261 at the sites [redacted] (United Kingdom), [redacted] (Southern France), [redacted] (Spain) and [redacted] (Italy), double first order in parallel at site [redacted] (Germany), as well as hockey stick at site [redacted] (Northern France) under field conditions with an application rate of 187.5 g/ha and normalised to 20 °C and field capacity. The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 373466, NOA 413163 and NOA 409480.

The half-lives (geometric means) were 0.44 days for CGA 357261, 22.4 days for CGA 373466, 39.3 days for NOA 413163 and 51.7 days for NOA 409480.

The formation fractions (arithmetic means) were 0.853 for CGA 373466, 0.317 for NOA 413163 and 0.028 for NOA 409480.

1. METHODS

Soil residue data from the field dissipation study M-468701-01-1 (Supplemental Dossier, KCA 7.1.2.2.1 /16) were used. In this study, the degradation of CGA 357261, a photodegradation product of trifloxystrobin, was studied at sites [redacted] (Germany), [redacted] (United Kingdom), [redacted] (Northern France), [redacted] (Southern France), [redacted] (Spain) and [redacted] (Italy) under field conditions for up to 733 days with an application rate of 187.5 g/ha and normalised to 20 °C and field capacity.

Soil temperature and moisture were simulated with the FOCUS PEARL 4.4.4 model based on daily weather data (precipitation and irrigation, maximum and minimum air temperature, humidity or vapour pressure, wind speed, global solar radiation). These values were used as input values for the time-step normalisation process implemented in a Microsoft Excel® spreadsheet.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The kinetic analysis was performed according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fit, chi-scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting DT₅₀ values from the double first order in parallel and hockey stick model were not calculated from the slow k-rates as recommended by FOCUS. These procedures produce the worst case DT₅₀ for the parent compound, which, however, does not describe the worst case scenario for the following degradation products. The DT₅₀ values taken for modelling are based on the iteratively calculated values from KinGUI 2.

II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of CGA 357261 at the sites [redacted] (United Kingdom), [redacted] (Southern France), [redacted] (Spain) and [redacted] (Italy), double first order in parallel (DFOP) at site [redacted] (Germany) as well as hockey stick (HS) at site [redacted] (Northern France). The SFO kinetic model was used for modelling purpose to describe the degradation of CGA 373466, NOA 413163 and NOA 409480. Table 7.1.2.2.1-30 to Table 7.1.2.2.1-33 are summarizing the results of the kinetic analysis.

Table 7.1.2.2.1- 30: Kinetic parameters for the degradation of CGA 357261 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	Kinetic Model	DegT ₅₀ ² [days]	Chi ² Error [%]	t-test	Visual Assessment ³
[redacted] (Germany)	DFOP	0.09	8	k ₁ : 0.281 k ₂ : 0.261	+
[redacted] (United Kingdom)	SFO	0.61	7.9	< 2 x 10 ⁻¹⁶	o
[redacted] (Northern France)	HS	0.12	17.5	k ₁ : 0.470 k ₂ : 3.44 x 10 ⁻³	o
[redacted] (Southern France)	SFO	1.35	8.5	< 2 x 10 ⁻¹⁶	o
[redacted] (Spain)	SFO	0.95	6.0	5.78 x 10 ⁻⁹	+
[redacted] (Italy)	SFO	0.88	24.9	1.95 x 10 ⁻⁷	+
	mean	0.44			

¹ SFO: single first order, DFOP: double first order in parallel, HS: hockey stick

² for DFOP and HS: DT₅₀ was not calculated from the slow k-rate, DT₅₀ is based on fit of the decline curve

³ visual assessment: + = good o = moderate



Table 7.1.2.2.1- 31: Kinetic parameters for degradation of CGA 373466 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	FF	Kinetic Model ¹	DegT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
(Germany)	0.640	SFO	6.86	36.5	2.09 x 10 ⁻³	
(United Kingdom)	1.000	SFO	8.67	12.7	5.94 x 10 ⁻²	o
(Northern France)	0.618	SFO	29.1	27.7	7.63 x 10 ⁻³	+
(Southern France)	1.000	SFO	91.0	36.5	6.69 x 10 ⁻⁵	
(Spain)	0.860	SFO	14.5 ³	9.4	4.80 x 10 ⁻³	+
(Italy)	1.000	SFO	56.1	20.4	1.84 x 10 ⁻⁷	+
arithmetic mean	0.853	geomean	22.4			

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good, o = moderate

³ estimate based on fit of the decline curve

Table 7.1.2.2.1- 32: Kinetic parameters for degradation of NOA 413163 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	FF	Kinetic Model ¹	DegT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
(Germany)	0.39 ⁴	SFO	52.0 ³	17.5	4.23 x 10 ⁻³	+
(United Kingdom)	0.457	SFO	37.4	40.5	2.59 x 10 ⁻²	+
(Northern France)	0.498	SFO	29.9	26.7	1.65 x 10 ⁻³	+
(Southern France)	0.485	SFO	36.5	20.6	1.18 x 10 ⁻³	+
(Spain)	0.332	SFO	25.2	21.0	3.47 x 10 ⁻³	+
(Italy)	0.55	SFO	28.5	20.3	9.47 x 10 ⁻⁴	+
arithmetic mean	0.317	geomean	39.3			

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

³ estimate based on fit of the decline curve

⁴ value excluded from the calculation of arithmetic mean due to unreliable statistical parameters



Table 7.1.2.2.1- 33: Kinetic parameters for degradation of NOA 409480 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)

Site	FF	Kinetic Model ¹	DegT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
(Germany)	0.006	SFO	97.3	33.7	4.71 x 10 ⁻³	
(United Kingdom)	0.041	SFO	95.5 ³	14.9	4.37 x 10 ⁻³	+
(Northern France)	0.025	SFO	34.7	23.0	1.87 x 10 ⁻³	+
(Southern France)	0.020 ⁴	SFO	11.1 ³	2.00	1.25 x 10 ⁻³	+
(Spain)	0.035	SFO	18.1	19.3	3.21 x 10 ⁻³	+
(Italy)	0.035	SFO	29.7	17.1	8.42 x 10 ⁻⁴	+
arithmetic mean	0.028	geomean	51.7			

FF: formation fraction

¹ SFO: single first order

² visual assessment: + = good

³ estimate based on fit of the decline curve

⁴ value excluded from the calculation of arithmetic mean due to unreliable statistical parameters

III. CONCLUSIONS

The calculated normalised (20 °C and field capacity) half-lives (geometric means) for modelling purpose for the degradation of the major trifloxystrobin photodegradation products CGA 357261, CGA 373466, NOA 413163 and NOA 409480 in soil under field conditions were 0.44 days for CGA 357261, 22.4 days for CGA 373466, 39.3 days for NOA 413163 and 51.7 days for NOA 409480 at the tested sites. The normalised (20 °C and field capacity) formation fractions (arithmetic means) were 0.853 for CGA 373466, 0.317 for NOA 413163 and 0.028 for NOA 409480.

The results are included in the summary of the degradation rates of trifloxystrobin and its major degradation products in soil under field conditions given in sections CA 7.1.2.2 and CA 7.1.2

CA 7.1.2.2.2 Soil accumulation studies

No field accumulation studies have been performed for trifloxystrobin. Accumulation of trifloxystrobin and its degradation products CGA 21113 and CGA 373466 was modelled from DT₅₀ values calculated in M-064112-01-1 (Baseline Dossier, KCA 7.1.2.2.1 /14), evaluated during the Annex I inclusion and accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No.	Author(s)	Year	Document No
KCA 7.1.2.2.2 /01		2001	M-065732-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval.



CA 7.1.3 Adsorption and desorption in soil

CA 7.1.3.1 Adsorption and desorption

The adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil were studied using two different radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP]. The studies have been performed in a number of soils in batch equilibrium experiments. Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation. The calculated adsorption constants and correlation coefficients are listed in Table 7.1.3.1- 2 to Table 7.1.3.1- 10, an overall summary is given Table 7.1.3.1- 1.

Table 7.1.3.1- 1: Overall summary of adsorption constants $K_{OC(ads)}$ in soils of trifloxystrobin and its major degradation products

Compound	$K_{OC(ads)}$ [mL/g]
trifloxystrobin (EE)	2377
CGA 357261 (ZE)	487
CGA 321413 (EE)	126
CGA 373466 (ZE)	876
CGA 381318 (ZZ)	6.5
NOA 413161 (ZE)	3.6
NOA 413163 (EE)	6
CGA 357276 (Z)	8170
NOA 409480 (Z)	2356

arithmetic mean

Table 7.1.3.1- 2: Overall summary of adsorption constants and correlation coefficients in soils of trifloxystrobin

Soil	Texture (USDA)	pH	Annex Point / Reference No	$K_F(ads)$ [mL/g]	1/n	$K_{OC(ads)}$ [mL/g]
	loamy sand	7.3	KCA 7.1.3.1.1 /01	14.7	0.925	1837
2.1	sand	6.8	KCA 7.1.3.1.1 /01	11.2	0.999	3745
	loam	7.1	KCA 7.1.3.1.1 /01	40.6	0.939	2031
	silt loam	7.2	KCA 7.1.3.1.1 /01	126	0.978	2683
	humic soil	6.7	KCA 7.1.3.1.1 /01	325	0.976	1642
	loamy sand	7.1	KCA 7.1.3.1.1 /02	23.3	0.942	2327
arithmetic mean				90.1	0.960	2377

¹ Soil [redacted] was tested with two different soil-to-solution ratios, the soil-to-solution ratio of 1/20 was excluded from the evaluation during the Annex I inclusion (SANCO/4339/2000-Final, 7 April 2003)

Table 7.1.3.1- 3: Overall summary of adsorption constants and correlation coefficients in soils of CGA 357261

Soil	Texture (USDA)	pH	Annex Point / Reference No	$K_F(ads)$ [mL/g]	1/n	$K_{OC(ads)}$ [mL/g]
174	sandy loam	7.0	KCA 7.1.3.1.2 /05	2.78	1.034	479
185	loam	6.9	KCA 7.1.3.1.2 /05	14.9	1.005	476
186	sandy loam	6.6	KCA 7.1.3.1.2 /05	3.17	0.962	389
187	sand	5.6	KCA 7.1.3.1.2 /05	4.61	0.980	567
188	clay loam	6.9	KCA 7.1.3.1.2 /05	12.8	0.990	526
arithmetic mean				7.65	0.994	487



Table 7.1.3.1- 4: Overall summary of adsorption constants and correlation coefficients in soils of CGA 321113

Soil	Texture (USDA)	pH	Annex Point / Reference No	K _{F(ads)} [mL/g]	1/n	K _{OC(ads)} [mL/g]
	loamy sand	7.3	KCA 7.1.3.1.2 /01	0.83	1.006	104
2.1	sand	6.8	KCA 7.1.3.1.2 /01	0.58	1.108	94
	loam	7.1	KCA 7.1.3.1.2 /01	2.33	0.993	117
	silt loam	7.2	KCA 7.1.3.1.2 /01	3.96	0.948	84
Illarsaz	humic soil	6.7	KCA 7.1.3.1.2 /01	18.6	0.972	94
	loamy sand	5.1	KCA 7.1.3.1.2 /02	1.3	0.984	132
arithmetic mean				4.60	0.901	121

Table 7.1.3.1- 5: Overall summary of adsorption constants and correlation coefficients in soils of CGA 373466

Soil	Texture (USDA)	pH	Annex Point / Reference No	K _{F(ads)} [mL/g]	1/n	K _{OC(ads)} [mL/g]
174	sandy loam	7.0	KCA 7.1.3.1.2 /03	0.75	0.909	30.1
185	loam	6.9	KCA 7.1.3.1.2 /03	3.07	0.877	97.7
186	sandy loam	6.6	KCA 7.1.3.1.2 /03	0.54	0.990	63.4
187	sand	5.6	KCA 7.1.3.1.2 /03	1.35	0.901	166
188	clay loam	6	KCA 7.1.3.1.2 /03	1.98	0.794	80.9
arithmetic mean				1.42	0.894	87.6

Table 7.1.3.1- 6: Overall summary of adsorption constants and correlation coefficients in soils of CGA 381318

Soil	Texture (USDA)	pH	Annex Point / Reference No	K _{F(ads)} [mL/g]	1/n	K _{OC(ads)} [mL/g]
	sandy loam	5.1	KCA 7.1.3.1.2 /06	1.41	0.866	78.2
	sandy loam	5.9	KCA 7.1.3.1.2 /06	1.13	0.892	75.5
	silt loam	6	KCA 7.1.3.1.2 /06	1.21	0.895	75.9
	clay loam	6.1	KCA 7.1.3.1.2 /06	3.68	0.896	76.6
arithmetic mean				1.86	0.887	76.5

Table 7.1.3.1- 7: Overall summary of adsorption constants and correlation coefficients in soils of NOA 413161

Soil	Texture (USDA)	pH	Annex Point / Reference No	K _{F(ads)} [mL/g]	1/n	K _{OC(ads)} [mL/g]
	loamy sand	5.1	KCA 7.1.3.1.2 /04	0.042 ¹	N/A ¹	4.2 ¹
	loam	5.3	KCA 7.1.3.1.2 /07	0.116	0.912	6.4
	sandy loam	6.2	KCA 7.1.3.1.2 /07	0.066	0.931	3.7
4a	silt loam	6.6	KCA 7.1.3.1.2 /07	0.049	0.885	2.0
	clay loam	7.3	KCA 7.1.3.1.2 /07	0.095	0.890	2.1
arithmetic mean				0.082	0.905	3.6

N/A: not applicable

¹ Study was terminated after preliminary tests, therefore the concentration dependency of the adsorption was not investigated and the K_{F(ads)} and K_{OC(ads)} values were not used for the calculation of the arithmetic mean.



Table 7.1.3.1- 8: Overall summary of adsorption constants and correlation coefficients in soils of NOA 413163

Soil	Texture (USDA)	pH	Annex Point / Reference No	$K_F^{(ads)}$ [mL/g]	1/n	$K_{OC}^{(ads)}$ [mL/g]
	loam	5.3	KCA 7.1.3.1.2 /08	0.172	0.887	976
	sandy loam	6.2	KCA 7.1.3.1.2 /08	0.115	0.920	674
4a	silt loam	6.6	KCA 7.1.3.1.2 /08	0.118	0.949	49
	clay loam	7.3	KCA 7.1.3.1.2 /08	0.201	0.893	44
arithmetic mean				0.151	0.912	63

Table 7.1.3.1- 9: Overall summary of adsorption constants and correlation coefficients in soils of CGA 357276

Soil	Texture (USDA)	pH	Annex Point / Reference No	$K_F^{(ads)}$ [mL/g]	1/n	$K_{OC}^{(ads)}$ [mL/g]
174	sandy loam	7.0	KCA 7.1.3.1.2 /09	48.5	0.952	8345
185	loam	6.9	KCA 7.1.3.1.2 /09	20	0.813	6587
186	sandy loam	6.6	KCA 7.1.3.1.2 /09	55.1	0.962	9228
187	sand	6.6	KCA 7.1.3.1.2 /09	79.4	0.847	9756
188	clay loam	6.9	KCA 7.1.3.1.2 /09	160	0.813	6934
arithmetic mean				616	0.877	8170

Table 7.1.3.1- 10: Overall summary of adsorption constants and correlation coefficients in soils of NOA 409480

Soil	Texture (USDA)	pH	Annex Point / Reference No	$K_F^{(ads)}$ [mL/g]	1/n	$K_{OC}^{(ads)}$ [mL/g]
	sandy loam	5.3	KCA 7.1.3.1.2 /10	41.7	0.847	2317
	sandy loam	5.9	KCA 7.1.3.1.2 /10	37.6	0.865	2507
	silt loam	6.2	KCA 7.1.3.1.2 /10	40.5	0.862	2530
	clay loam	7.1	KCA 7.1.3.1.2 /10	99.4	0.879	2070
arithmetic mean				54.8	0.863	2356

CA 7.1.3.1.1 Adsorption and desorption of the active substance

The adsorption and desorption behaviour of trifloxystrobin in soil in batch equilibrium experiments was evaluated during the Annex I inclusion using one radiolabel position, [¹⁴C-GP], and was accepted by the European Commission (SANCO 4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.3.1.1 /01		1995	M-033549-03-1
KCA 7.1.3.1.1 /02		2000	M-049477-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil is given in section CA 7.1.3.1.

CA 7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction



products

The adsorption and desorption behaviours of the major degradation products CGA 324113, CGA 373466 and NOA 413161 in soil in batch equilibrium experiments were evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.3.1.2 /01	[REDACTED]	1995	M-033369-02-1
KCA 7.1.3.1.2 /02	[REDACTED]	2000	M-051381-01-1
KCA 7.1.3.1.2 /03	[REDACTED]	1997	M-036332-01-1
KCA 7.1.3.1.2 /04	[REDACTED]	2000	M-046346-01-1

Six additional studies have been performed for the major degradation products CGA 357261, CGA 381318, NOA 413161, NOA 413163, CGA 357276 and NOA 409480 and are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP]. A summary of the adsorption and desorption behaviour of trifloxystrobin and its major degradation products in soil is given in section CA 7.1.3.1.

Report:	KCA 7.1.3.1.2 /05; [REDACTED]; [REDACTED]; 1997
Title:	Adsorption-Desorption of [p- ¹⁴ C]-(B)-U- ¹⁴ C]-CGA-357261 in Soil
Report No:	211-97
Document No:	M-036399-01-1
Guidelines:	- US EPA Pesticide Assessment Guidelines, Subdivision V, Section 163-1
GLP:	Yes
Justification:	New data / guideline requirement: Adsorption and desorption of major photodegradation product CGA 357261

Executive Summary

The adsorption / desorption behaviour of [¹⁴C-TP]CGA 357261, a photodegradation product of trifloxystrobin, was studied in five soils in batch equilibrium experiments in the dark at 25 ± 1 °C:

Soil	Source	Texture (USDA)	pH	OC [%]
174	Madera, USA	sandy loam	7.0	0.6
185	Northwood, USA	loam	6.9	3.1
186	Louisberg, USA	sandy loam	6.6	0.8
187	Raleigh, USA	sand	5.6	0.8
188	Northwood, USA	clay loam	6.9	2.4

The adsorption phase was carried out using sterilized soils with soil-to-solution ratios of 1/5 (soils 174, 186 and 187) and 1/10 (soils 185 and 188). CGA 357261 was applied at nominal concentrations of 0.5, 0.2, 0.07 and 0.025 mg/L in sterilized aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh sterilized aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 4 hours equilibration time each.

CGA 357261 was rapidly degraded to CGA 373466 by ester cleavage even in sterilized soil. Therefore, the mean parental mass balances after adsorption and desorption were only 82.7, 68.7, 71.4, 62.2 and 62.3% of applied radioactivity [% AR] for soil 174, 185, 186, 187 and 188, respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Mean material balances were 91.0, 94.3, 92.2, 93.3 and 93.5% AR for soil 174, 185, 186, 187 and 188, respectively.

Adsorption and desorption isotherms were calculated using the Freundlich equation. Since significant degradation (> 10%) was observed even in the sterilized soils, the sorption values were calculated based on both the applied radioactivity and on the measured [¹⁴C-TP]CGA 357261 concentration. Based on the measured [¹⁴C-TP]CGA 357261 concentration, the calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 2.78 to 14.9 mL/g (mean: 7.65 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 389 to 567 mL/g (mean: 487 mL/g). The Freundlich exponents $1/n$ were in the range of 0.962 to 1.034 (mean: 0.994) indicating that the concentration of CGA 357261 did not affect the adsorption behaviour in the examined concentration range. The desorption $K_{F(des)}$ (mean: 11.3 mL/g) and the normalised $K_{OC(des)}$ (mean: 781 mL/g) values were higher (1.6 times higher) than those obtained for the adsorption phase, indicating that CGA 357261 once adsorbed to soil is not readily desorbed.

CGA 357261 can be classified as low to medium mobile for adsorption and low mobile for desorption using the McCall⁹ classification for the estimation of the mobility in soil.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[phenyl (B)-U-¹⁴C]-CGA 357261
Reference No: CA XLL93
Specific Activity: 1.62 MBq/mg (43.8 µCi/mg)
Radiochemical Purity: 98.2%
Chemical Purity: 99.0%

2. Test Soils

Five soils were used (see Table 1.3.12- 1) representing different geographical origin and different soil properties as required by the guidelines. The soils were sieved to a particle size of ≤ 2 mm and sterilized by gamma radiation for the adsorption/desorption batch equilibrium experiments.

⁹ McCall P. J., Laskowski, B. A., Swarm, R. L., Bishburger, H. J.: "Measurement of Sorption Coefficients of Organic Chemicals and Their Use in Environmental Fate Analysis" in "Test Protocols for Environmental Fate and Movement of Toxicants"; A.O.A.C. Symposium proceedings, 94th annual meeting, Washington, BC, 1980.



Table 7.1.3.1.2- 1: Physico-chemical properties of test soils

Parameter	Results / Units				
Soil Designation	174	185	186	187	188
Geographic Location					
City	Madera	Northwood	Louisberg	Raleigh	Northwood
State	California	North Dakota	North Carolina	North Carolina	North Dakota
Country	USA	USA	USA	USA	USA
Soil Taxonomic Classification (USDA)	no information available				
Soil Series	hanford fine sandy loam	gardena	saw-awake wetlowe complex	Nichburg sandy loam	bearden-perella
Textural Class (USDA)	sandy loam	loam	sandy loam	sand	clay loam
Sand [50 µm – 2 mm]	69%	32%	78%	53%	28%
Silt [2 µm – 50 µm]	28%	44%	16%	30%	42%
Clay [< 2 µm]	3%	24%	12%	17%	30%
pH	5.0	5.9	6.6	5.6	6.9
Organic Carbon	0.6%	3.1%	0.6%	0.8%	2.4%
Organic Matter ¹	1.0%	5.4%	1.4%	1.4%	4.2%
Cation Exchange Capacity [meq/100 g]	15.2	24.0	5.5	4.9	28.6
Water Holding Capacity at 0.33 bar (pF 2.5)	8.5%	41.8%	9.8%	5.9%	40.4%
Bulk Density (disturbed) [g/cm ³]	1.36	0.96	1.19	1.38	1.03

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

USA: United States of America

USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of glass culture tubes (volume 15 mL) closed with Teflon® lined screw caps. Glassware and aqueous 0.01 M CaCl₂ solution were sterilized using an autoclave. The experiments were performed in duplicate.

In preliminary tests, the adsorption of the test item to the test system surface, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.

The adsorption phase was carried out using sterilized soils with soil-to-solution ratios of 1/5 (soils 174, 186 and 187) and 1/10 (soils 185 and 188). CGA 357261 was applied at nominal concentrations of 0.5, 0.2, 0.075 and 0.025 mg/L to sterilized aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh sterilized aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 4 hours equilibration time each (total of 8 hours).

The test systems were shaken by a platform shaker in the dark at 25 ± 1 °C in an environmental chamber.



2. Analytical Procedures

The suspensions were centrifuged and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC). After the adsorption and desorption step, the soil of 0.5 mg/L samples was additionally extracted three times at ambient temperature using a reciprocating shaker and acetonitrile/water_{pH 4} 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation and decantation. The radioactivity contents of the combined soil extracts after the adsorption and desorption step were determined by LSC. Aliquot of the combined soil extracts were concentrated. Aqueous 0.01 M CaCl₂ solutions and combined soil extracts were analysed by reversed phase HPLC/radiodetection. The extracted soil was dried and the radioactivity content determined by combustion/LSC to establish the material balance.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation. Since significant degradation of 10% was observed even in the sterilized soils, the sorption values were calculated based on both the applied radioactivity and on the measured [¹⁴C-TP]CGA 357261 concentration.

II. RESULTS AND DISCUSSION

A. MATERIAL BALANCE

Mean material balances were 91.0, 94.3, 92.2, 93.3 and 93.5% of applied radioactivity [% AR] for soil 174, 185, 186, 187 and 188, respectively. The complete material balances found for all soils and concentrations demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

B. DEGRADATION OF PARENT COMPOUND

CGA 357261 was rapidly degraded to CGA 373466 by ester cleavage even in sterilized soil. Therefore, the mean parental mass balances were 82.7, 68.7, 71.4, 62.2 and 62.3% AR after 8 hours for soil 174, 185, 186, 187 and 188, respectively.

C. FINDINGS

At the end of the adsorption phase, 28.9-32.8%, 47.7-49.3%, 53.5-36.0%, 36.1-38.1% and 42.0-43.8% were adsorbed based on the measured [¹⁴C-TP]CGA 357261 concentration in soil 174, 185, 186, 187 and 188, respectively (see [Table 7.1.3.1.2- 2](#)). Based on the measured [¹⁴C-TP]CGA 357261 concentration, the calculated adsorption coefficients, $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 2.78 to 14.9 mL/g (mean: 7.65 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 289 to 567 mL/g (mean: 487 mL/g). The Freundlich exponents $1/n$ were in the range of 0.9967 to 1.04 (mean: 1.01), indicating that the concentration of CGA 357261 did not affect the adsorption behaviour in the examined concentration range (see [Table 7.1.3.1.2- 3](#)).

At the end of the desorption phase, 45.4-52.0%, 24.0-26.1%, 35.3-39.2%, 28.3-31.5% and 25.5-28.0% of the initially adsorbed amount based on the measured [¹⁴C-TP]CGA 357261 concentration were desorbed in soil 174, 185, 186, 187 and 188, respectively (see [Table 7.1.3.1.2- 2](#)). Based on the measured [¹⁴C-TP]CGA 357261 concentration, the desorption $K_{F(des)}$ (mean: 11.3 mL/g) and the normalised $K_{OC(des)}$ (mean: 781 mL/g) values were higher (1.6 times higher) than those obtained for the adsorption phase, indicating that CGA 357261 once adsorbed to soil is not readily desorbed (see [Table 7.1.3.1.2- 3](#)).



Table 7.1.3.1.2- 2: Percentage of adsorbed and desorbed CGA 357261 in soils (mean values)

Soil	Test Concentration [mg/L]							
	Adsorption ¹				Desorption ¹			
	0.5	0.2	0.075	0.025	0.5	0.2	0.075	0.025
174	31.8	31.4	32.8	28.9	48.7	47.2	45.4	52.0
185	48.2	49.1	49.3	47.7	26.1	24.9	24.0	24.0
186	33.5	35.6	36.0	36.0	39.2	36.5	35.3	37.5
187	36.1	37.2	38.1	36.8	31.5	29.9	28.3	30.0
188	42.0	43.6	43.8	42.6	27.7	26.3	25.5	28.0

¹ end of adsorption phase, mean values expressed as percentage of the measured [¹⁴C-TP]CGA 357261 concentration

² end of desorption phase, mean values expressed as percentage of the initially adsorbed amount based on the measured [¹⁴C-TP]CGA 357261 concentration

Table 7.1.3.1.2- 3: Adsorption and desorption constants and correlation coefficients in soils of CGA 357261

Soil	Adsorption				Desorption			
	K _F [mL/g]	1/n ¹	r	K _{OC} [mL/g]	K _F [mL/g]	1/n ¹	r	K _{OC} [mL/g]
174	2.78	1.034	0.9970	479	2.79	1.036	0.9959	996
185	14.9	1.005	0.9987	476	18.4	0.943	0.9984	587
186	3.17	0.962	0.9989	389	5.23	0.962	0.9965	645
187	4.61	0.980	0.9989	567	7.03	0.962	0.9975	864
188	12.8	0.990	0.9992	526	19.8	1.001	0.9977	813
arithmetic mean	7.65	0.994	0.9985	487	11.3	0.981	0.9972	781

¹ n values were given in the report and converted to 1/n values

III. CONCLUSIONS

The adsorption constant K_{OC(ads)} (arithmetic mean) of CGA 357261 (a major photodegradation product of trifloxystrobin), was 487 mL/g. The Freundlich exponent 1/n (arithmetic mean) was 0.994.

The results are included in the summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil given in section 7.1.3.1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.3.1.2 /06; [REDACTED]; [REDACTED]; 2013
Title:	[Benzeneacetic-phenyl-UL- ¹⁴ C]BCS-CU98569 (Sodium Salt of CGA 381318): Adsorption / Desorption on Four European Soils
Report No:	EnSa-12-0384
Document No:	M-447879-01-1
Guidelines:	- OECD Test Guideline No. 106 - DRAFT SANCO 11802/2010/rev 1 in accordance with Regulation (EC) No 1107/2009 - US EPA OCSP Test Guideline No. 835.1230 - Canadian PMRA Guideline DACO 8.2.4.2
GLP:	Yes
Justification:	New data / guideline requirement: Adsorption and desorption of major photodegradation product CGA 381318

Executive Summary

The adsorption / desorption behaviour of [¹⁴C-GP]BCS-CU98569 (sodium salt of CGA 381318, a photodegradation product of trifloxystrobin) was studied in four soils in batch equilibrium experiments in the dark at 20.3 °C:

Soil	Source	Texture (USDA)	pH*	OC [%]
[REDACTED]	Monheim, Germany	sandy loam	5.1	1.8
[REDACTED]	Monheim, Germany	sandy loam	5.9	1.5
[REDACTED]	Burscheid, Germany	silt loam	6.2	1.6
[REDACTED]	Blankenheim, Germany	clay loam	7.1	4.8

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution with soil-to-solution ratios of 1/2 (soils [REDACTED] and [REDACTED]) and 1/4 (soil [REDACTED]). BCS-CU98569 was applied at concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution for one desorption cycle. For the highest concentration, two additional desorption cycles were performed. Adsorption and desorption cycles took place for 24 hours equilibration time each.

BCS-CU98569 was sufficient stable throughout the study. The mean parental mass balances were 96.1, 96.5, 99.0 and 98.6% of applied radioactivity [% AR] for soil [REDACTED], [REDACTED], [REDACTED] and [REDACTED], respectively.

Mean material balances were 94.3, 94.4, 95.9 and 92.6% AR for soil [REDACTED], [REDACTED], [REDACTED] and [REDACTED], respectively.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

Adsorption and desorption isotherms were calculated using the Freundlich equation. The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 1.13 to 3.68 mL/g (mean: 1.86 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 75.5 to 78.2 mL/g (mean: 76.5 mL/g). The Freundlich exponents $1/n$ were in the range of 0.866 to 0.896 (mean: 0.887), indicating that the concentration of BCS-CU98569 affected the adsorption behaviour in the examined concentration range. The desorption $K_{F(des)}$ (mean: 3.83 mL/g) and the normalised $K_{OC(des)}$ (mean: 165 mL/g) values were significantly higher (2 times higher) than those obtained for the adsorption phase, indicating that BCS-CU98569 once adsorbed to soil is not readily desorbed.

BCS-CU98569 can be classified as intermediate mobile for adsorption and low mobile for desorption using the Briggs¹⁰ classification for the estimation of the mobility in soil.

I. MATERIALS AND METHODS**A. MATERIALS****1. Test Item**

[benzenacetic-phenyl-UL-¹⁴C]BCS-CU98569
Sample ID: KMC9352
Specific Activity: 3.54 MBq/mg (97.7 µCi/mg)
Radiochemical Purity: >98%
Chemical Purity: >98%

2. Test Soils

Four soils were used (see [Table 1.3.1.2-4](#)). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous years. The soils were sampled from the fields (upper horizon of 0 to 20 cm), sieved to a particle size of <2 mm and air-dried.

¹⁰ Briggs, G. G.: A Simple Relationship Between Soil Adsorption of Organic Chemicals and their Octanol/Water Partition Coefficients; Proc. 7th British Insecticide and Fungicide Conference, Nottingham/UK, 1973.



Table 7.1.3.1.2- 4: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Geographic Location				
City	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambodoll	loamy, mixed, mesic, Typic Argudalf	fine-loamy, mixed, active, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USDA)	sandy loam	sandy loam	silt loam	clay loam
Sand [50 µm – 2 mm]	53%	25%	15%	41%
Silt [2 µm – 50 µm]	30%	16%	70%	26%
Clay [< 2 µm]	17%	9%	15%	33%
pH (soil/0.01 M CaCl ₂ 1/2)	5.3	5.9	6.2	7.1
pH (soil/water 1/1)	5.3	6.1	6.3	7.2
pH (saturated paste)	5.3	6.1	6.4	7.2
pH (soil/1 N KCl 1/2)	4.7	4.6	5.8	6.8
Organic Carbon	1.8%	1.5%	1.6%	4.8%
Organic Matter	3.1%	2.6%	2.8%	8.3%
Cation Exchange Capacity [meq/100 g]	10.9	8.7	11.7	20.7
Water Holding Capacity maximum [g H ₂ O added/100 g soil DW] at 0.1 bar (pF 2.0)	55.0 26.9%	42.6 14.7%	54.8 32.5%	81.6 36.1%
Bulk Density (disturbed) [g/cm ³]	1.26	1.26	1.09	0.97

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of Teflon[®] centrifuge tubes (volume 42 mL) closed with screw caps. The experiments were performed in duplicate.

In preliminary tests, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution for 4 days with soil-to-solution ratios of 1/2 (soils [REDACTED] and [REDACTED]) and 1/4 (soil [REDACTED]). The test item was applied at concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution for one desorption cycle. For the highest concentration, two additional desorption cycles were performed. Adsorption and desorption cycles took place for 24 hours equilibration time each (total of 96 hours).

The test systems were shaken by a mechanical overhead shaker in the dark at 20.3 °C in a walk-in climatic chamber.

2. Analytical Procedures

The suspensions were centrifuged (4500 x g) and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC).

In the preliminary parental mass balance test, the soil was additionally extracted three times using acetonitrile/water mixtures. The aqueous supernatant and the combined soil extracts were analysed by reversed phase HPLC/radiodetection to determine the stability of the test item and to establish the parental mass balance. The limit of detection (LOD) and limit of quantification (LOQ) for HPLC/radiodetection analysis were 0.4 and 1.5 % AR, respectively.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only due to the stability of the test item demonstrated by the parental mass balance. After the desorption steps, the soil was air-dried and the radioactivity content determined by combustion LSC to establish the material balance.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

II. RESULTS AND DISCUSSION**A. MATERIAL BALANCE**

Mean material balances were 94.3, 94.4, 95.9 and 92.6% of applied radioactivity [% AR] for soil [REDACTED] and [REDACTED], respectively. The complete material balances found for all soils and concentrations demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

B. DEGRADATION OF PARENT COMPOUND

BCS-CU98569 was sufficient stable throughout the study. The mean parental mass balances were 96.1, 96.5, 99.0 and 98.6% AR after 96 hours for soil [REDACTED] and [REDACTED], respectively.



C. FINDINGS

At the end of the adsorption phase, 43.4-59.3% AR, 36.5-49.8% AR, 38.7-50.5% AR and 48.9-61.2% AR were adsorbed in soil [redacted], [redacted], [redacted] and [redacted] II, respectively (see Table 7.1.3.1.2- 5). The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 1.13 to 3.68 mL/g (mean: 1.86 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 75.5 to 78.2 mL/g (mean: 76.5 mL/g). The Freundlich exponents $1/n$ were in the range of 0.866 to 0.896 (mean: 0.887), indicating that the concentration of BCS-CU98569 affected the adsorption behaviour in the examined concentration range (see Table 7.1.3.1.2- 6).

At the end of the first desorption phase, 24.8-35.7%, 33.6-41.5%, 30.6-37.8% and 27.0-33.8% of the initially adsorbed amount were desorbed in soil [redacted], [redacted], [redacted] and [redacted] II, respectively (see Table 7.1.3.1.2- 5). The desorption $K_{F(des)}$ (mean: 3.83 mL/g) and the normalised $K_{OC(des)}$ (mean: 165 mL/g) values were significantly higher (2 times higher) than those obtained for the adsorption phase, indicating that BCS-CU98569 once adsorbed to soil is not readily desorbed (see Table 7.1.3.1.2- 6).

Table 7.1.3.1.2- 5: Percentage of adsorbed and desorbed BCS-CU98569 (sodium salt of CGA 381318) in soils (mean values)

Soil	Test Concentration [mg/L]									
	Adsorption ¹					Desorption ²				
	1.0	0.3	0.1	0.03	0.01	1.0	0.3	0.1	0.03	0.01
[redacted]	43.4	47.2	51.4	56.4	59.3	35.7	31.5	29.8	27.0	24.8
[redacted]	36.5	41.6	44.2	46.7	49.8	41.5	37.5	36.6	35.3	33.6
[redacted]	38.7	42.3	45.5	50.0	50.5	37.8	25.6	33.4	31.0	30.6
[redacted]	48.9	53.6	56.7	60.0	61.2	33.8	32.0	29.9	28.5	27.0

¹ end of adsorption phase, mean values expressed as percentage of applied radioactivity

² end of first desorption phase, mean values expressed as percentage of the initially adsorbed amount

Table 7.1.3.1.2- 6: Adsorption and desorption constants and correlation coefficients in soils of BCS-CU98569 (sodium salt of CGA 381318)

Soil	K_F [mL/g]	Adsorption			K_{OC} [mL/g]	Desorption			
		$1/n$	R^2	K_{OC} [mL/g]		K_F [mL/g]	$1/n$	R^2	K_{OC} [mL/g]
[redacted]	1.41	0.866	0.9998	78.2	2.99	0.891	0.9996	166	
[redacted]	1.13	0.892	0.9994	75.5	2.58	0.932	0.9992	172	
[redacted]	1.2	0.895	0.9992	75.9	2.87	0.925	0.9997	179	
[redacted]	3.68	0.896	0.9995	76.6	6.90	0.929	0.9998	144	
arithmetic mean	1.86	0.887	0.9995	76.5	3.83	0.919	0.9996	165	

III. CONCLUSIONS

The adsorption constant $K_{OC(ads)}$ (arithmetic mean) of BCS-CU98569 (sodium salt of CGA 381318, a major photodegradation product of trifloxystrobin) was 76.5 mL/g. The Freundlich exponent $1/n$ (arithmetic mean) was 0.887.

The results are included in the summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil given in section CA 7.1.3.1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.3.1.2 /07; [REDACTED]; 2010
Title:	[Benzeneacetic-phenyl-UL- ¹⁴ C]NOA 413161: Adsorption / Desorption on four Soils
Report No:	MEF-09/479
Document No:	M-361829-01-1
Guidelines:	- OECD Test Guideline No. 106 - US EPA OCSP Test Guideline No. 835.1230
GLP:	Yes
Justification:	New data / guideline requirement: Adsorption and desorption of major degradation product NOA 413161

Executive Summary

The adsorption / desorption behaviour of [¹⁴C]GP]NOA 413161, a degradation product of trifloxystrobin, was studied in four soils in batch equilibrium experiments in the dark at 19.6 °C:

Soil	Source	Texture (USDA)	pH	OC [%]
[REDACTED]	Monheim, Germany	loam	6.3	1.8
[REDACTED]	Monheim, Germany	sandy loam	6.2	1.8
[REDACTED]	Burscheid, Germany	silt loam	6.0	2.4
[REDACTED]	Blankenheim, Germany	clay loam	7.3	4.6

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution with soil-to-solution ratios of 1/1 (soils [REDACTED] and [REDACTED] 4a) and 1/2 (soil [REDACTED]). NOA 413161 was applied at concentrations of 1.1, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 24 hours equilibration time each.

NOA 413161 was sufficient stable throughout the study. The mean parental mass balances were 94.7, 96.2, 98.4 and 91.3% of applied radioactivity (% AR) for soil [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

Mean material balances were 96.5, 96.9, 96.4 and 97.6% AR for soil [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

Adsorption and desorption isotherms were calculated using the Freundlich equation. The calculated adsorption coefficients K_{F(ads)} of the Freundlich adsorption isotherms ranged from 0.049 to 0.116 mL/g (mean: 0.082 mL/g) and the adsorption constants K_{OC(ads)} (normalised to organic carbon content) ranged from 2.0 to 6.4 mL/g (mean: 3.6 mL/g). The Freundlich exponents 1/n were in the range of 0.885 to 0.931 (mean: 0.905), indicating that the concentration of NOA 413161 affected the adsorption behaviour in the examined concentration range. The desorption K_{F(des)} (mean: 4.55 mL/g) and the normalised K_{OC(des)} (mean: 187 mL/g) values were significantly higher (50 times higher) than those obtained for the adsorption phase, indicating that NOA 413161 once adsorbed to soil is not readily desorbed. It must be considered, however, that due to the low adsorption the measured concentrations of desorbed NOA 413161 were also very low. Therefore, the desorption values should be interpreted with care.



NOA 413161 can be classified as very mobile for adsorption using the Briggs¹⁰ classification for the estimation of the mobility in soil.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzeneacetic-phenyl-UL-¹⁴C]NOA 413161
 Sample ID: KATH 6313
 Specific Activity: 3.41 MBq/mg (92.1 µCi/mg)
 Radiochemical Purity: > 99%
 Chemical Purity: > 99%

2. Test Soils

Four soils were used (see Table 7.1.3.1.2- 7). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled from the fields (upper horizon of 0 to 20 cm), sieved to a particle size of < 2 mm and air dried.

Table 7.1.3.1.2- 7: Physico-chemical properties of test soils

Parameter	Results/Units			
Soil Designation				4a
Geographic Location				
City				
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates				
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambudoll	loamy, mixed, mesic, Typic Argudalf	no information available
Soil Series	no information available			
Textural Class (USDA)	loam	sandy loam	silt loam	clay loam
Sand [50 µm - 2 mm]	51%	71%	27%	31%
Silt [2 µm - 50 µm]	28%	18%	54%	38%
Clay [< 2 µm]	20%	11%	19%	31%
pH (soil/0.01 M CaCl ₂)	5.3	6.2	6.6	7.3
pH (soil/water)	5.5	6.5	6.8	7.4
pH (soil/1 M KCl)	4.9	6.0	6.3	7.0
Organic Carbon	1.8%	1.8%	2.4%	4.6%
Organic Matter	3.1%	3.1%	4.1%	7.9%
Cation Exchange Capacity [meq/100 g]	10.8	9.0	13.9	21.9
Water Holding Capacity				
maximum [g H ₂ O ad 100 g soil DW]	53.9	45.9	63.2	78.4
at 0.33 bar (pF 2.5)	15.7%	11.2%	22.3%	31.9%
Bulk Density (disturbed) [g/cm ³]	1.19	1.24	1.05	1.00

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture

B. STUDY DESIGN**1. Experimental Conditions**

The test system for adsorption and desorption in batch equilibrium experiments consisted of Teflon centrifuge tubes (volume 42 mL) closed with screw caps. The experiments were performed in duplicate.

In preliminary tests, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution for 24 hours with soil-to-solution ratios of 10³ (soils [REDACTED] and [REDACTED] 4a and 1 [REDACTED]). The test item was applied at concentrations of 1.1, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 24 hours equilibration time each (total of 48 hours).

The test systems were shaken by a mechanical overhead shaker in the dark at 19.6 °C in a walk-in climatic chamber.

2. Analytical Procedures

The suspensions were centrifuged and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC).

In the preliminary parental mass balance test, the soil was additionally extracted three to five times using acetonitrile/water mixtures. The aqueous supernatant and the combined soil extracts were analysed by reversed phase HPLC/radiodetection to determine the stability of the test item and to establish the parental mass balance. The limit of quantitation (LOQ) for HPLC/radiodetection analysis was 1% AR.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only due to the stability of the test item demonstrated by the parental mass balance. After desorption, the soil was freeze-dried and the radioactivity content determined by combustion LSC to establish the material balance (one replicate per soil and concentration).

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

H. RESULTS AND DISCUSSION**A. MATERIAL BALANCE**

Mean material balances were 96.5, 96.9, 96.4 and 97.6% of applied radioactivity [% AR] for soil [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED], respectively. The complete material balances found for all soils and concentrations demonstrated that



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

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B. DEGRADATION OF PARENT COMPOUND

NOA 413161 was sufficient stable throughout the study. The mean parental mass balances were 94.7, 96.2, 98.4 and 91.3% AR after 96 hours for soil [redacted] and [redacted] 4a and [redacted], respectively.

C. FINDINGS

At the end of the adsorption phase, 10.1-15.6% AR, 6.3-8.9% AR, 4.7-9.3% AR and 4.0-7.3% AR were adsorbed in soil [redacted], [redacted] 4a and [redacted], respectively (see Table 7.1.3.1.2- 8). The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 0.049 to 0.116 mL/g (mean: 0.082 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 2.0 to 6.4 mL/g (mean: 3.6 mL/g). The Freundlich exponents $1/n$ were in the range of 0.885 to 0.931 (mean 0.905), indicating that the concentration of NOA 413161 affected the adsorption behaviour in the examined concentration range (see Table 7.1.3.1.2- 9).

At the end of the desorption phase, 25.1-40.5%, 26.6-32.3%, 15.0-38.9% and 22.2-36.4% of the initially adsorbed amount were desorbed in soil [redacted] and [redacted] 4a and [redacted], respectively (see Table 7.1.3.1.2- 8). The desorption $K_{F(des)}$ (mean: 4.55 mL/g) and the normalised $K_{OC(des)}$ (mean: 187 mL/g) values were significantly higher (50 times higher) than those obtained for the adsorption phase, indicating that NOA 413161 once adsorbed to soil is not readily desorbed (see Table 7.1.3.1.2- 9). It must be considered, however, that due to the low adsorption the measured concentrations of desorbed NOA 413161 were also very low. Therefore, the desorption values should be interpreted with care.

Table 7.1.3.1.2- 8: Percentage of adsorbed and desorbed NOA 413161 in soils (mean values)

Soil	Test Concentration [mg/L]									
	Adsorption ¹					Desorption ²				
	1.1	0.3	0.1	0.03	0.01	1.1	0.3	0.1	0.03	0.01
[redacted]	10.1	12.3	12.7	12.4	15.6	34.9	30.5	28.7	40.5	25.1
[redacted]	6.3	6.7	7.0	7.0	8.9	32.3	26.6	28.3	31.6	28.5
[redacted] 4a	4.7	5.9	5.8	5.5	9.3	19.9	15.0	18.4	38.9	26.7
[redacted]	4.0	6.2	5.7	6.2	7.3	22.2	23.7	36.4	35.2	25.4

¹ end of adsorption phase, mean values expressed as percentage of applied radioactivity

² end of desorption phase, mean values expressed as percentage of the initially adsorbed amount

Table 7.1.3.1.2- 9: Adsorption and desorption constants and correlation coefficients in soils of NOA 413161

Soil	Adsorption				Desorption			
	K_F [mL/g]	$1/n$	R^2	K_{OC} [mL/g]	K_F [mL/g]	$1/n$	R^2	K_{OC} [mL/g]
[redacted]	0.116	0.912	0.9964	6.4	1.57	0.942	0.9679	87.1
[redacted]	0.066	0.931	0.9924	3.7	2.03	0.971	0.9824	113
[redacted]	0.049	0.885	0.9673	2.0	11.64	1.184	0.8860	485
[redacted]	0.095	0.890	0.9877	2.1	2.95	0.907	0.8562	64.2
arithmetic mean	0.082	0.905	0.9860	3.6	4.55	1.001	0.9231	187



III. CONCLUSIONS

The adsorption constant $K_{OC(ads)}$ (arithmetic mean) of NOA 413161, a major degradation product of trifloxystrobin, was 3.6 mL/g. The Freundlich exponent $1/n$ (arithmetic mean) was 0.905.

The results are included in the summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil given in section CA 7.1.3.1.

Report:	KCA 7.1.3.1.2 /08; [redacted] 2010
Title:	[Benzeneacetic-phenyl-UL- ¹⁴ C]NOA 413163: Adsorption / Desorption on Four Soils
Report No:	MEF-09/518
Document No:	M-361835-01-1
Guidelines:	- OECD Test Guideline No. 106 - US EPA OCSP Test Guideline No. 835-1230
GLP:	Yes
Justification:	New data / guideline requirement Adsorption and desorption of major photodegradation product NOA 413163

Executive Summary

The adsorption / desorption behaviour of [¹⁴C-GP]NOA 413163, a photodegradation product of trifloxystrobin, was studied in four soils in batch equilibrium experiments in the dark at 19.6 °C:

Soil	Source	Texture (USDA)	pH *	OC [%]
[redacted]	Monheim, Germany	loam	5.3	1.8
[redacted]	Monheim, Germany	sandy loam	6.2	1.8
[redacted] 4a	Burscheid, Germany	silt loam	6.6	2.4
[redacted]	Blankenheim, Germany	clay loam	7.3	4.6

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution with soil-to-solution ratios of 1/1 (soils [redacted] and [redacted] 4a) and 1/2 (soil [redacted]). NOA 413163 was applied at concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 48 hours equilibration time each.

NOA 413163 was sufficient stable throughout the study. The mean parental mass balances were 92.8, 94.7, 93.9 and 94.7% of applied radioactivity [% AR] for soil [redacted], [redacted] 4a and [redacted], respectively.

Mean material balances were 95.8, 96.2, 96.4 and 97.9% AR for soil [redacted], [redacted] 4a and [redacted], respectively.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Adsorption and desorption isotherms were calculated using the Freundlich equation. The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 0.115 to 0.201 mL/g (mean: 0.151 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 4.4 to 9.6 mL/g (mean: 6.3 mL/g). The Freundlich exponents $1/n$ were in the range of 0.887 to 0.949 (mean: 0.912), indicating that the concentration of NOA 413163 affected the adsorption behaviour in the examined concentration range. The desorption $K_{F(des)}$ (mean: 2.95 mL/g) and the normalised $K_{OC(des)}$ (mean: 116 mL/g) values were significantly higher (18 times higher) than those obtained for the adsorption phase, indicating that NOA 413163 once adsorbed to soil is not readily desorbed. It must be considered, however, that due to the low adsorption the measured concentrations of desorbed NOA 413163 were also very low. Therefore, the desorption values should be interpreted with care.

NOA 413163 can be classified as mobile to very mobile for adsorption using the Briggs¹⁰ classification for the estimation of the mobility in soil.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzeneacetic-phenyl-UL-¹⁴C]NOA 413163
Sample ID: KATH 0756
Specific Activity: 3.41 MBq/mg (92.1 μ Ci/mg)
Radiochemical Purity: > 99%
Chemical Purity: > 98%

2. Test Soils

Four soils were used (see Table 7.1.3.1.2-10). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled from the fields (upper horizon of 0 to 20 cm), sieved to a particle size of ≤ 2 mm and air-dried.

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Table 7.1.3.1.2- 10: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation	[REDACTED]	[REDACTED]	[REDACTED] 4a	[REDACTED]
Geographic Location				
City	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambudoll	loamy, mixed, mesic, Typic Argudalf	no information available
Soil Series	no information available			
Textural Class (USDA)	loam	sandy loam	silt loam	clay loam
Sand [50 µm – 2 mm]	51%	71%	27%	31%
Silt [2 µm – 50 µm]	28%	18%	54%	38%
Clay [< 2 µm]	21%	11%	19%	31%
pH (soil/0.01 M CaCl ₂)	5.3	6.2	6.6	7.3
pH (soil/water)	5.5	6.5	6.8	7.4
pH (soil/1 N KCl)	4.9	6.0	6.3	7.0
Organic Carbon	1.8%	1.8%	2.4%	4.6%
Organic Matter ¹	3.1%	3.0%	4.1%	7.9%
Cation Exchange Capacity [meq/100 g]	10.8	9.0	13.9	21.9
Water Holding Capacity maximum [g H ₂ O at 100 g soil DW] at 0.33 bar (pF 2.5)	53.9 15.9%	45.9 14.2%	63.2 22.3%	78.4 31.9%
Bulk Density (disturbed) [g/cm ³]	1.19	1.24	1.05	1.00

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of Teflon® centrifuge tubes (volume 42 mL) closed with screw caps. The experiments were performed in duplicate.

In preliminary tests, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution for 3 days with soil-to-solution ratios of 1/1 (soils [REDACTED], [REDACTED] and [REDACTED] 4a) and 1/2 (soil [REDACTED]). The test item was applied at concentrations of 1.1, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 48 hours equilibration time each (total of 96 hours).

The test systems were shaken by a mechanical overhead shaker in the dark at 19.5 °C in a walk-in climatic chamber.

2. Analytical Procedures

The suspensions were centrifuged and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC).

In the preliminary parental mass balance test, the soil was additionally extracted three times using acetonitrile/water mixtures. The aqueous supernatant and the combined soil extracts were analysed by reversed phase HPLC/radiodetection to determine the stability of the test item and to establish the parental mass balance. The limit of quantitation (LOQ) for HPLC/radiodetection analysis was 1% AR.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only due to the stability of the test item demonstrated by the parental mass balance. After desorption, the soil was freeze-dried and the radioactivity content determined by combustion/LSC to establish the material balance (one replicate per soil and concentration).

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

II. RESULTS AND DISCUSSION**A. MATERIAL BALANCE**

Mean material balances were 95.8, 96.2, 96.4 and 97.9% of applied radioactivity [% AR] for soil [REDACTED], [REDACTED] 4a and [REDACTED], respectively. The complete material balances found for all soils and concentrations demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

B. DEGRADATION OF PARENT COMPOUND

NOA 413163 was sufficient stable throughout the study. The mean parental mass balances were 92.8, 94.7, 93.9 and 94.7% AR after 96 hours for soil [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED], respectively.



C. FINDINGS

At the end of the adsorption phase, 14.3-22.0% AR, 9.8-13.9% AR, 10.5-13.2% AR and 9.1-13.7% AR were adsorbed in soil [redacted], [redacted], [redacted] and [redacted] 4a and [redacted], respectively (see Table 7.1.3.1.2- 11). The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 0.115 to 0.201 mL/g (mean: 0.151 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 4.4 to 9.6 mL/g (mean: 6.3 mL/g). The Freundlich exponents $1/n$ were in the range of 0.887 to 0.949 (mean: 0.912), indicating that the concentration of NOA 413163 affected the adsorption behaviour in the examined concentration range (see Table 7.1.3.1.2- 12).

At the end of the desorption phase, 27.5-32.2%, 26.4-32.0%, 22.2-29.3% and 30.8-37.5% of the initially adsorbed amount were desorbed in soil [redacted], [redacted], [redacted] and [redacted] 4a and [redacted] respectively (see Table 7.1.3.1.2- 11). The desorption $K_{F(des)}$ (mean: 2.95 mL/g) and the normalised $K_{OC(des)}$ (mean: 0.16 mL/g) values were significantly higher (18 times higher) than those obtained for the adsorption phase, indicating that NOA 413163 once adsorbed to soil is not readily desorbed (see Table 7.1.3.1.2- 12). It must be considered, however, that due to the low adsorption the measured concentrations of desorbed NOA 413163 were also very low. Therefore, the desorption values should be interpreted with care.

Table 7.1.3.1.2- 11: Percentage of adsorbed and desorbed NOA 413163 in soils (mean values)

Soil	Test Concentration [mg/L]									
	Adsorption ¹					Desorption ²				
	1.0	0.3	0.1	0.03	0.01	1.0	0.3	0.1	0.03	0.01
[redacted]	14.3	16.6	19.0	22.0	21.5	31.0	28.2	27.6	27.5	32.2
[redacted]	9.8	11.3	13.3	13.9	13.3	27.2	30.1	32.0	26.4	30.9
[redacted] 4a	10.5	10.8	12.4	13.2	12.4	29.3	25.6	22.2	25.5	26.4
[redacted]	9.1	10.2	11.8	13.7	13.6	30.8	36.9	37.5	35.2	37.1

¹ end of adsorption phase, mean values expressed as percentage of applied radioactivity

² end of desorption phase, mean values expressed as percentage of the initially adsorbed amount

Table 7.1.3.1.2- 12: Adsorption and desorption constants and correlation coefficients in soils of NOA 413163

Soil	Adsorption				Desorption			
	K_F [mL/g]	$1/n$	R^2	K_{OC} [mL/g]	K_F [mL/g]	$1/n$	R^2	K_{OC} [mL/g]
[redacted]	0.172	0.887	0.9978	9.6	2.42	1.001	0.9940	134
[redacted]	0.113	0.920	0.9973	6.4	2.33	0.992	0.9788	129
[redacted] 4a	0.118	0.949	0.9981	4.9	2.37	0.965	0.9853	98.8
[redacted]	0.201	0.883	0.9968	4.4	4.70	1.046	0.9937	102
arithmetic mean	0.151	0.912	0.9975	6.3	2.95	1.001	0.9880	116

III. CONCLUSIONS

The adsorption constant $K_{OC(ads)}$ (arithmetic mean) of NOA 413163, a major photodegradation product of trifloxystrobin, was 6.3 mL/g. The Freundlich exponent $1/n$ (arithmetic mean) was 0.912.

The results are included in the summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil given in section CA 7.1.3.1.



Report:	KCA 7.1.3.1.2 /09; [REDACTED]; [REDACTED]; 1997
Title:	Adsorption-Desorption of [phenyl (B)-U- ¹⁴ C]-CGA-357276 in Soil
Report No:	210-97
Document No:	M-036507-01-1
Guidelines:	- US EPA Pesticide Assessment Guidelines, Subdivision N, Section 16-1
GLP:	Yes
Justification:	New data / guideline requirement: Adsorption and desorption of major degradation product CGA 357276

Executive Summary

The adsorption / desorption behaviour of [¹⁴C-TP]CGA 357276, a degradation product of trifloxystrobin, was studied in five soils in batch equilibrium experiments in the dark at 25 ± 1 °C:

Soil	Source	Texture (USDA)	pH	OC [%]
174	Madera, USA	sandy loam	7.0	0.6
185	Northwood, USA	loam	6.9	3.1
186	Louisberg, USA	sandy loam	6.6	0.8
187	Raleigh, USA	sand	5.6	0.8
188	Northwood, USA	clay loam	6.9	2.4

The adsorption phase was carried out using a soil-to-solution ratio of 1/50. CGA 357276 was applied at nominal concentrations of 0.25, 0.10, 0.025 and 0.010 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 48 hours equilibration time each.

CGA 357276 was sufficient stable throughout the study. The mean parental mass balances were 96.5, 89.5, 96.7, 95.7 and 91.6% of applied radioactivity [± AR] for soil 174, 185, 186, 187 and 188, respectively.

Mean material balances were 98.3, 102.4, 98.9, 98.3 and 100.9% AR for soil 174, 185, 186, 187 and 188, respectively.

Adsorption and desorption isotherms were calculated using the Freundlich equation. The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 48.5 to 207 mL/g (mean: 116 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 658 to 9756 mL/g (mean: 8170 mL/g). The Freundlich exponents $1/n$ were in the range of 0.813 to 0.962 (mean: 0.877), indicating that the concentration of CGA 357276 affected the adsorption behaviour in the examined concentration range. The desorption $K_{F(des)}$ (mean: 152 mL/g) and the normalised $K_{OC(des)}$ (mean: 11350 mL/g) values were slightly higher (1.4 times higher) than those obtained for the adsorption phase.

CGA 357276 can be classified as immobile for adsorption and desorption using the McCall⁹ classification for the estimation of the mobility in soil.



I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[phenyl (B)-U-¹⁴C]-CGA-357261
Reference No: JAK-XIII-84
Specific Activity: 1.47 MBq/mg (39.8 µCi/mg)
Radiochemical Purity: 99.3%
Chemical Purity: > 99.9%

2. Test Soils

Five soils were used (see Table 7.1.3.1.2- 13), representing different geographical origin and different soil properties as required by the guidelines. The soils were sieved to a particle size of < 2 mm.

Table 7.1.3.1.2- 13: Physico-chemical properties of test soils

Parameter	Results / Units				
Soil Designation	174	185	186	187	188
Geographic Location					
City	Madera	Northwood	Louisberg	Raleigh	Northwood
State	California	North Dakota	North Carolina	North Carolina	North Dakota
Country	USA	USA	USA	USA	USA
Soil Taxonomic Classification (USDA)	no information available				
Soil Series	hanford fine sandy loam	gardena	saw-toake wedowee complex	lynchburg sandy loam	bearden-perella
Textural Class (USDA)	sandy loam	loam	sandy loam	sand	clay loam
Sand [50 µm – 2 mm]	69%	52%	78%	53%	28%
Silt [2 µm – 50 µm]	28%	44%	10%	30%	42%
Clay [< 2 µm]	3%	24%	12%	17%	30%
pH	7.0	6.9	6.6	5.6	6.9
Organic Carbon	0.6%	3.1%	0.8%	0.8%	2.4%
Organic Matter ¹	1.0%	5.4%	1.4%	1.4%	4.2%
Cation Exchange Capacity [meq/100 g]	15.2	24.0	5.5	4.9	28.6
Water Holding Capacity at 0.33 bar (pF 2.5)	8.5%	41.8%	9.8%	5.2%	40.4%
Bulk Density (disturbed) [g/cm ³]	1.46	0.96	1.19	1.38	1.03

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

USA: United States of America

USDA: United States Department of Agriculture



B. STUDY DESIGN

1. Experimental Conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of glass culture tubes (volume 50 mL) closed with Teflon® lined screw caps. The experiments were performed in duplicate.

In preliminary tests, the adsorption of the test item to the test system surface, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.

The adsorption phase was carried out using a soil-to-solution ratio of 1/50 for all soils. CGA 357276 was applied at nominal concentrations of 0.25, 0.10, 0.025 and 0.010 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh sterilized aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 48 hours equilibration time each (total of 96 hours).

The test systems were shaken by a platform shaker in the dark at 25 ± 1 °C in an environmental chamber.

2. Analytical Procedures

The suspensions were centrifuged and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC). After the adsorption and desorption step, the soil of 0.25 mg/L samples was additionally extracted three times at ambient temperature using a reciprocating shaker and acetonitrile/water_{pH 4} 1/1 (v/v). After each extraction step, extract and soil were separated by centrifugation and decantation. The radioactivity contents of the combined soil extracts after the adsorption and desorption step were determined by LSC. Aliquot of the combined soil extracts were concentrated. Aqueous 0.01 M CaCl₂ solutions and combined soil extracts were analysed by reversed phase HPLC/radiodetection. The extracted soil was dried and the radioactivity content determined by combustion/LSC to establish the material balance.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only due to the stability of the test item demonstrated by the parental mass balance.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

H. RESULTS AND DISCUSSION

A. MATERIAL BALANCE

Mean material balances were 98.3, 102.4, 98.9, 98.3 and 100.9% of applied radioactivity [% AR] for soil 174, 185, 186, 187 and 188, respectively. The complete material balances found for all soils and concentrations demonstrate that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

B. DEGRADATION OF PARENT COMPOUND

CGA 357276 was sufficient stable throughout the study. The mean parental mass balances were 96.5, 89.5, 96.0, 95.7 and 91.6% AR after 96 hours for soil 174, 185, 186, 187 and 188, respectively.



C. FINDINGS

At the end of the adsorption phase, 49.7-55.6% AR, 89.0-94.0% AR, 61.7-65.4% AR, 70.1-80.3% AR and 86.5-92.5% AR were adsorbed in soil 174, 185, 186, 187 and 188, respectively (see Table 7.1.3.1.2- 14). The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 48.5 to 207 mL/g (mean: 116 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 6587 to 9756 mL/g (mean: 8170 mL/g). The Freundlich exponents $1/n$ were in the range of 0.813 to 0.962 (mean: 0.877), indicating that the concentration of CGA 357276 affected the adsorption behaviour in the examined concentration range (see Table 7.1.3.1.2- 15).

At the end of the desorption phase, 38.7-43.0%, 36-7.6%, 27.8-30.4%, 15.5-22.5% and 5.2-10.0% of the initially adsorbed amount were desorbed in soil 174, 185, 186, 187 and 188, respectively (see Table 7.1.3.1.2- 14). The desorption $K_{F(des)}$ (mean: 152 mL/g) and the normalised $K_{OC(des)}$ (mean: 11350 mL/g) values were slightly higher (1.4 times higher) than those obtained for the adsorption phase (see Table 7.1.3.1.2- 15).

Table 7.1.3.1.2- 14: Percentage of adsorbed and desorbed CGA 357276 in soils (mean values)

Soil	Test Concentration [mg/L]							
	Adsorption				Desorption ¹			
	0.25	0.10	0.025	0.010	0.25	0.10	0.025	0.010
174	49.7	55.1	55.6	52.8	38.7	40.9	41.1	43.0
185	89.0	90.8	92.8	94.0	7.6	5.6	4.3	3.6
186	61.7	64.9	64.9	65.4	30.4	31.3	29.4	27.8
187	70.1	74.3	77.3	80.3	25.5	19.8	17.6	15.5
188	86.5	88.5	91.3	92.5	10.0	8.5	6.1	5.2

¹ end of adsorption phase, mean values expressed as percentage of applied radioactivity

² end of desorption phase, mean values expressed as percentage of the initially adsorbed amount.

Table 7.1.3.1.2- 15: Adsorption and desorption constants and correlation coefficients in soils of CGA 357276

Soil	Adsorption				Desorption			
	K_F [mL/g]	$1/n$	r	K_{oc} [mL/g]	K_F [mL/g]	$1/n$	r	K_{oc} [mL/g]
174	48.5	0.952	0.9966	8345	88.2	1.042	0.9996	15169
185	207	0.865	0.9993	6587	263	0.787	0.9989	8386
186	75.5	0.962	0.9984	9228	91.2	0.943	0.9973	11206
187	79.4	0.847	0.9994	9756	110	0.862	0.9994	13575
188	169	0.813	0.9997	6934	206	0.800	0.9992	8434
arithmetic mean	116	0.877	0.9986	8170	152	0.887	0.9989	11350

¹ n values were given in the report and converted to 1/n values

III. CONCLUSIONS

The adsorption constant $K_{OC(ads)}$ (arithmetic mean) of CGA 357276, a major degradation product of trifloxystrobin, was 8170 mL/g. The Freundlich exponent $1/n$ (arithmetic mean) was 0.877.

The results are included in the summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil given in section CA 7.1.3.1.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.1.3.1.2 /10; [REDACTED]; [REDACTED]; 2012
Title:	[Benzonitrile-ring-UL- ¹⁴ C]NOA 409480: Adsorption / Desorption on Four European Soils
Report No:	EnSa-12-0383
Document No:	M-442865-01-1
Guidelines:	- OECD Test Guideline No. 106 - DRAFT SANCO 11802/2010/rev 1 in accordance with Regulation (EC) No 1107/2009 - US EPA OCSP Test Guideline No. 835.1230 - Canadian PMRA Guideline DAG 8.2.4.2
GLP:	Yes
Justification:	New data / guideline requirement: Adsorption and desorption of major photodegradation product NOA 409480

Executive Summary

The adsorption / desorption behaviour of ¹⁴C-GP-NOA 409480, a photodegradation product of trifloxystrobin, was studied in four soils in batch equilibrium experiments in the dark at 20.3 °C:

Soil	Source	Texture (USDA)	pH *	OC [%]
[REDACTED]	Monheim, Germany	sandy loam	5.7	1.8
[REDACTED]	Monheim, Germany	sandy loam	5.9	1.5
[REDACTED] 4a	Burscheid, Germany	silt loam	6.2	1.6
[REDACTED]	Blankenheim, Germany	clay loam	7.1	4.8

* pH value was derived from aqueous 0.01 M CaCl₂ suspension

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution with a soil-to-solution ratio of 1/20. NOA 409480 was applied at concentrations of 1.1, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 15 and 5 hours equilibration time, respectively.

NOA 409480 was sufficient stable throughout the study. The mean parental mass balances were 97.0, 96.1, 93.7 and 94.8% of applied radioactivity [% AR] for soil [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

Mean material balances were 95.8, 95.6, 97.1 and 94.7% AR for soil [REDACTED], [REDACTED], [REDACTED] 4a and [REDACTED], respectively.

Adsorption and desorption isotherms were calculated using the Freundlich equation. The calculated adsorption coefficients K_{F(ads)} of the Freundlich adsorption isotherms ranged from 37.6 to 99.4 mL/g (mean: 54.8 mL/g) and the adsorption constants K_{OC(ads)} (normalised to organic carbon content) ranged from 2070 to 2530 mL/g (mean: 2356 mL/g). The Freundlich exponents 1/n were in the range of 0.847 to 0.879 (mean: 0.863), indicating that the concentration of NOA 409480 affected the adsorption behaviour in the examined concentration range. The desorption K_{F(des)} (mean: 66.9 mL/g) and the normalised K_{OC(des)} (mean: 2889 mL/g) values were slightly higher (1.2 times higher) than those obtained for the adsorption phase.

NOA 409480 can be classified as immobile for adsorption and desorption using the Briggs¹⁰ classification for the estimation of the mobility in soil.



I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzotrifluoride-¹⁴C]NOA 409480
Sample ID: KML 9333
Specific Activity: 4.09 MBq/mg (110.54 µCi/mg)
Radiochemical Purity: > 98%
Chemical Purity: 97.3%

2. Test Soils

Four soils were used (see [Table 7.1.3.1.2- 16](#)). The soils were taken from agricultural use areas representing different geographical origin and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled from the fields (upper horizon of 0 to 20 cm), sieved to a particle size of $\leq 2\text{ mm}$ and air-dried.

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Table 7.1.3.1.2- 16: Physico-chemical properties of test soils

Parameter	Results / Units			
Soil Designation			4a	
Geographic Location				
City				
State	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia	North-Rhine Westphalia
Country	Germany	Germany	Germany	Germany
GPS Coordinates				
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf	sandy, mixed, mesic, Typic Cambudoll	loamy, mixed, mesic, Typic Argudalf	fine loamy, mixed, active, frigid Typic Eutrudept
Soil Series	no information available			
Textural Class (USDA)	sandy loam	sandy loam	silt loam	clay loam
Sand [50 µm – 2 mm]	53%	55%	15%	41%
Silt [2 µm – 50 µm]	30%	16%	70%	26%
Clay [< 2 µm]	17%	9%	15%	33%
pH (soil/0.01 M CaCl ₂ 1/2)	5.1	5.9	6.2	7.1
pH (soil/water 1/1)	5.3	6.1	6.3	7.2
pH (saturated paste)	5.3	6.1	6.4	7.2
pH (soil/1 N KCl 1/1)	4	5.6	5.8	6.8
Organic Carbon	1.8%	1.5%	1.6%	4.8%
Organic Matter ¹	3.1%	2.6%	2.8%	8.3%
Cation Exchange Capacity [meq/100 g]	10.9	8.7	11.7	20.7
Water Holding Capacity maximum [g H ₂ O/g soil DW] at 0.1 bar (pF 2.0)	55.0 26.0%	42.6 14.7%	54.8 32.5%	81.6 36.1%
Bulk Density (disturbed) [g/cm ³]	1.16	1.26	1.09	0.97

¹ % organic matter = % organic carbon x 1.724

DW: dry weight

GPS: global positioning system

USDA: United States Department of Agriculture

B. STUDY DESIGN

1. Experimental Conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of Teflon[®] centrifuge tubes (volume 42 mL) closed with screw caps. The experiments were performed in duplicate.

In preliminary tests, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

The adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl₂ solution for 3 days with a soil-to-solution ratio of 1/20. The test item was applied at concentrations of 1.1, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl₂ solution. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl₂ solution. Adsorption and desorption took place for 15 and 5 hours equilibration time (total of 20 hours), respectively.

The test systems were shaken by a mechanical overhead shaker in the dark at 20.3°C in a walk-in climatic chamber.

2. Analytical Procedures

The suspensions were centrifuged (4550 x g) and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC).

In the preliminary parental mass balance test, the soil was additionally extracted three times using acetonitrile/water mixtures. The aqueous supernatant and the combined soil extracts were analysed by reversed phase HPLC/radiodetection to determine the stability of the test item and to establish the parental mass balance. The limit of detection (LOD) and limit of quantitation (LOQ) for HPLC/radiodetection analysis were 0.3 and 0.9% AR, respectively.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only, due to the stability of the test item demonstrated by the parental mass balance. After desorption the soil was air-dried and the radioactivity content determined by combustion LSC to establish the material balance.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

II. RESULTS AND DISCUSSION

A. MATERIAL BALANCE

Mean material balances were 95.8, 95.6, 97.1, and 94.7% of applied radioactivity [% AR] for soil [redacted], [redacted], [redacted] 4a and [redacted], respectively. The complete material balances found for all soils and concentrations demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

B. DEGRADATION OF PARENT COMPOUND

NOA 409480 was sufficient stable throughout the study. The mean parental mass balances were 97.0, 96.1, 93.7 and 94.8% AR after 20 hours for soil [redacted], [redacted], [redacted] 4a and [redacted], respectively.



C. FINDINGS

At the end of the adsorption phase, 70.9-84.6% AR, 68.9-80.8% AR, 71.0-82.4% AR and 85.8-91.8% AR were adsorbed in soil [redacted], [redacted], [redacted] 4a and [redacted] II, respectively (see Table 7.1.3.1.2- 17). The calculated adsorption coefficients $K_{F(ads)}$ of the Freundlich adsorption isotherms ranged from 37.6 to 99.4 mL/g (mean: 54.8 mL/g) and the adsorption constants $K_{OC(ads)}$ (normalised to organic carbon content) ranged from 2070 to 2530 mL/g (mean: 2356 mL/g). The Freundlich exponents $1/n$ were in the range of 0.847 to 0.879 (mean: 0.863), indicating that the concentration of NOA 409480 affected the adsorption behaviour in the examined concentration range (see Table 7.1.3.1.2- 18).

At the end of the first desorption phase, 11.9-23.9%, 14.2-24.6%, 12.6-23.5% and 6.5-10.8% of the initially adsorbed amount were desorbed in soil [redacted], [redacted], [redacted] 4a and [redacted] I, respectively (see Table 7.1.3.1.2- 17). The desorption $K_{F(des)}$ (mean: 66.9 mL/g) and the normalised $K_{OC(des)}$ (mean: 2889 mL/g) values were slightly higher (1.2 times higher) than those obtained for the adsorption phase (see Table 7.1.3.1.2- 18).

Table 7.1.3.1.2- 17: Percentage of adsorbed and desorbed NOA 409480 in soils (mean values)

Soil	Test Concentration [µg/L]									
	Adsorption					Desorption ²				
	1.1	0.3	0.1	0.03	0.01	1.1	0.3	0.1	0.03	0.01
[redacted]	70.9	75.9	79.4	82.0	84.6	23.9	18.9	16.4	13.7	11.9
[redacted]	68.9	71.2	76.0	79.4	80.8	24.6	22.1	18.4	15.8	14.2
[redacted] 4a	71.0	73.0	77.2	81.2	82.4	23.5	20.5	17.2	14.0	12.6
[redacted]	85.8	88.6	90.9	91.7	91.8	10.8	9.9	7.4	6.2	5.5

¹ end of adsorption phase, mean values expressed as percentage of applied radioactivity

² end of desorption phase, mean values expressed as percentage of the initially adsorbed amount

Table 7.1.3.1.2- 18: Adsorption and desorption constants and correlation coefficients in soils of NOA 409480

Soil	Adsorption				Desorption			
	K_F [mL/g]	$1/n$	R^2	K_{oc} [mL/g]	K_F [mL/g]	$1/n$	R^2	K_{oc} [mL/g]
[redacted]	41.7	0.847	0.9995	2317	50.0	0.837	0.9996	2776
[redacted]	37.6	0.865	0.9997	2507	47.6	0.857	0.9995	3171
[redacted] 4a	40.5	0.862	0.9994	2530	49.5	0.845	0.9997	3094
[redacted]	99.4	0.879	0.9995	2070	120.7	0.858	0.9996	2514
arithmetic mean	54.8	0.863	0.9995	2356	66.9	0.849	0.9996	2889

III. CONCLUSIONS

The adsorption constant $K_{OC(ads)}$ (arithmetic mean) of NOA 409480, a major photodegradation product of trifloxystrobin, was 2356 mL/g. The Freundlich exponent $1/n$ (arithmetic mean) was 0.863.

The results are included in the summary of the adsorption and desorption behaviours of trifloxystrobin and its major degradation products in soil given in section CA 7.1.3.1.



CA 7.1.3.2 Aged sorption

Studies are not required under Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 1107/2009.

CA 7.1.4 Mobility in soil

A study for the determination of the plant uptake factor has been performed for the major degradation products CGA 321113, CGA 373466, NOA 413161 and NOA 413163, and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using one radiolabel position [¹⁴C-GP].

Report:	KCA 7.1.4 /01; [REDACTED]; [REDACTED] 2012
Title:	Determination of the Plant Uptake Factor of Metabolites of Trifloxystrobin in Tomatoes (CGA 321113, CGA 373466, NOA 413161 and NOA 413163)
Report No:	EnSa-12-0333
Document No:	M-433176-01-1
Guidelines:	- US EPA OCSPP not applicable
GLP:	Yes
Justification:	Experimental data for refinement of exposure

Executive Summary

The plant uptake factors (PUFs) of [¹⁴C-GP]CGA 321113, [¹⁴C-GP]CGA 373466, [¹⁴C-GP]NOA 413161 and [¹⁴C-GP]NOA 413163, degradation products of trifloxystrobin, were studied in tomato plants for 8 days in a greenhouse under controlled temperature (approx. 20 °C), light and humidity (60 to 80%) conditions similar to the natural conditions of Central Europe.

The volumes taken up by the tomato plants ranged from 275 mL to 425 mL per test. The mean initial concentration in the test solutions amounted to 19.4 µg/L for CGA 321113, 18.1 µg/L for CGA 373466, 18.3 µg/L for NOA 413161 and 18.9 µg/L for NOA 413163. Overall, the concentrations of CGA 321113 and CGA 373466 in the solutions decreased slightly during the tests, while the concentrations of NOA 413161 and NOA 413163 increased slightly towards the end of the tests.

PUFs were calculated from the amounts of the test items in the solutions and the volumes of the solutions at day 0 and day 8. The mean PUFs were 1.41, 1.13, 0.84 and 0.80 for CGA 321113, CGA 373466, NOA 413161 and NOA 413163 respectively.

The uptake of NOA 413161 and NOA 413163 was slightly restricted compared with the good plant uptake behaviour of CGA 321113 and CGA 373466, likely due to the lower permeability of the cell wall for more polar compounds.

**I. MATERIALS AND METHODS****A. MATERIALS****1. Test Items**[benzeneacetic-phenyl-UL-¹⁴C]CGA 321113

Sample ID: KML 9188

Specific Activity: 1.98 MBq/mg (53.5 µCi/mg)

Radiochemical Purity: > 98%

Chemical Purity: > 98%

[benzeneacetic-phenyl-UL-¹⁴C]CGA 373466

Sample ID: KML 9351

Specific Activity: 3.71 MBq/mg (100.27 µCi/mg)

Radiochemical Purity: > 98%

Chemical Purity: > 98%

[benzeneacetic-phenyl-UL-¹⁴C]NOA 413164

Sample ID: KML 9344

Specific Activity: 3.41 MBq/mg (92.08 µCi/mg)

Radiochemical Purity: > 98%

Chemical Purity: > 98%

[benzeneacetic-phenyl-UL-¹⁴C]NOA 413163

Sample ID: KML 9343

Specific Activity: 3.41 MBq/mg (92.08 µCi/mg)

Radiochemical Purity: 95.7%

Chemical Purity: 95.8%

2. Test Crop

Tomato plants were acquired from a commercial supplier and were grown on soil till the start of the test. At growth stage BBCH 45 to 16 the pre-grown tomato plants were removed from the soil, their root system was cleaned with water and they were transferred to the test vessels and to the greenhouse.

3. Test Solutions

A stock solution of each test item was prepared in acetonitrile/water 5/2. An aliquot of the respective stock solution was mixed with buffer solution (0.01 M 2-morpholino-ethanesulfonic acid (MES), 0.01 M CaCl₂; adjusted with sodium hydroxide solution to pH 6.5) to obtain nominal test item concentrations of 20 µg/L.

B. STUDY DESIGN**1. Experimental Conditions**

The test system for determination of plant uptake factors (PUFs) consisted of one pre-grown tomato plant (BBCH code 15 to 16) in a brown glass bottle (volume 1 L) filled with 800 mL test solution. The tomato plant was fixed with elastomer foam in the bottle and the bottle was sealed with aluminium foil to avoid test solution losses due to evaporation. The tests were performed in quadruplicates. The water uptake behaviour of the tomato plants was tested with two additional controls without test items.

During the experimental phase, the plants were cultivated in a greenhouse. Temperature (approx. 20 °C), humidity (60 to 80%) and light (at least 35 klx between 6 am and 8 pm) were kept similar to the natural conditions of Central Europe.



2. Analytical Procedures

Triplicate aliquots taken from the solutions of each test system were analysed 0, 0.17, 1, 4 and 8 days after treatment. The radioactivity content of the aliquots was determined by LSC. The volumes of the solutions were determined at day 0 and day 8. The solutions were analysed at day 8 by reversed phase HPLC/radiodetection for determination of the stability of the test items. Test items were identified by HPLC-MS(/MS) including accurate mass determination.

II. RESULTS AND DISCUSSION

A. DEGRADATION OF PARENT COMPOUNDS

CGA 321113, CGA 373466, NOA 413161 and NOA 413163 were sufficient stable throughout the study with purities of $\geq 96.5\%$.

C. FINDINGS

The volumes taken up by the tomato plants ranged from 275 mL to 425 mL per test. The mean initial concentration in the test solutions amounted to 19.4 $\mu\text{g/L}$ for CGA 321113, 18.1 $\mu\text{g/L}$ for CGA 373466, 18.3 $\mu\text{g/L}$ for NOA 413161 and 18.9 $\mu\text{g/L}$ for NOA 413163. Overall, the concentrations of CGA 321113 and CGA 373466 in the solutions decreased slightly during the tests, while the concentrations of NOA 413161 and NOA 413163 increased slightly towards the end of the tests.

PUFs were calculated from the amounts of the test items in the solutions and the volumes of the solutions at day 0 and day 8. The mean PUFs were 1.41, 1.13, 0.84 and 0.80 for CGA 321113, CGA 373466, NOA 413161 and NOA 413163, respectively.

The uptake of NOA 413161 and NOA 413163 was slightly restricted compared with the good plant uptake behaviour of CGA 321113 and CGA 373466, likely due to the lower permeability of the cell wall for more polar compounds.

III. CONCLUSIONS

The plant uptake factors in tomato plants for CGA 321113, CGA 373466, NOA 413161 and NOA 413163, major degradation products of trifloxystrobin, were 1.41, 1.13, 0.84 and 0.80, respectively.

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CA 7.1.4.1 Column leaching studies

CA 7.1.4.1.1 Column leaching of the active substance

The leaching behaviour of trifloxystrobin in soil in the laboratory was evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.4.1.1 /01	[REDACTED]	1996	M-033582-01-1
KCA 7.1.4.1.1 /02	[REDACTED]	1997	M-033599-01-1
KCA 7.1.4.1.1 /03	[REDACTED]	1997	M-033617-01-1
KCA 7.1.4.1.1 /04	[REDACTED]	1997	M-033629-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval.

CA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products

The leaching behaviours of trifloxystrobin degradation products in soil in the laboratory were evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.4.1.2 /01	[REDACTED]	1997	M-033599-01-1
KCA 7.1.4.1.2 /02	[REDACTED]	1997	M-033617-01-1
KCA 7.1.4.1.2 /03	[REDACTED]	1997	M-033629-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval.

CA 7.1.4.2 Lysimeter studies

The leaching behaviours of trifloxystrobin and its degradation products in soil in lysimeters were evaluated during the Annex I inclusion using one radiolabel positions, [¹⁴C-GP], and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.4.2 /01	[REDACTED]	1997	M-033705-01-1
KCA 7.1.4.2 /02	[REDACTED]	1998	M-051722-04-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval.

**CA 7.1.4.3 Field leaching studies**

The leaching behaviours of trifloxystrobin and its degradation products in soil under field conditions were evaluated during the Annex I inclusion using unlabelled trifloxystrobin formulated as WG 50 as well as [¹⁴C-TP]trifloxystrobin formulated as EC 250, and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.1.4.3 /01		1997	M-033482-01-1
KCA 7.1.4.3 /02		1997	M-033486-01-1
KCA 7.1.4.3 /03		1997	M-033490-01-1
KCA 7.1.4.3 /04		1997	M-033493-01-1
KCA 7.1.4.3 /05		1997	M-033496-01-1
KCA 7.1.4.3 /06		1997	M-033502-01-1
KCA 7.1.4.3 /07		1998	M-033504-01-1
KCA 7.1.4.3 /08		1998	M-033514-01-1
KCA 7.1.4.3 /09		1997	M-033523-02-1
KCA 7.1.4.3 /10		2002	M-059343-01-1
KCA 7.1.4.3 /11		2000	M-049606-01-1
KCA 7.1.4.3 /12		1999	M-033716-01-1
KCA 7.1.4.3 /13		2001	M-072939-01-1
KCA 7.1.4.3 /14		2001	M-065772-01-1
KCA 7.1.4.3 /15		2002	M-059402-01-1
KCA 7.1.4.3 /16		2002	M-059473-01-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval.

CA 7.2 Fate and behaviour in water and sediment

Trifloxystrobin (*EE*) is rapidly degraded in water and sediment to the major degradation products carbon dioxide and CGA 321473 (*EE*), and non-extractable residues. In presence of light, the major *E/Z* isomers CGA 357261 (*Z*), CGA 357062 (*Z*) and CGA 373466 (*Z*) of trifloxystrobin (*EE*) and its major degradation product CGA 321113 (*ZE*) are observed, as well as the major degradation product 2-hydroxymethylbenzotrile and the major volatile degradation product CGA 107170. However, the degradation of trifloxystrobin in water and sediment is driven by microbial degradation under typical conditions in the environment but photodegradation could play a role in the overall fate of trifloxystrobin.

The route and rate of degradation of trifloxystrobin in water and sediment were studied using two different radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP]. The studies have been performed in buffers, natural waters and water-sediment systems in the laboratory at different temperatures, and under semi-field conditions (microcosms). The maximum occurrences of degradation products in percentage of applied radioactivity (% AR) are given as means of duplicates. The DT₅₀ values were taken from study reports. These values may slightly differ from the List of Endpoints (SANCO/4339/2000-Final, 7 April 2003).

Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Hydrolytic degradation of trifloxystrobin (*EE*) in sterile aqueous buffer solutions in the dark in the laboratory is strongly dependent on the temperature and the pH value. Trifloxystrobin (*EE*) is stable at pH 5 ($DT_{50} > 1000$ days), relatively stable at pH 7 (DT_{50} approx. 40 days at 25 °C) and rapidly degraded at pH 9 ($DT_{50} = 15.0$ hours). The single major degradation product at 25 °C was CGA 321113 (*EE*) with maximum amounts of 57.9 and 102.3% AR at pH 7 and pH 9, respectively. CGA 321113 (*EE*) is stable to hydrolysis at 25 °C. The major volatile degradation product CGA 107170 was only observed as major at pH 5 and elevated temperatures (≥ 40 °C) with a maximum amount of 39.5% AR at pH 5 and 60 °C by cleavage of the bridge between the aromatic ring systems. The major degradation product CGA 357266 (*E*) with a maximum amount of 10.4% AR at pH 7 and 60 °C was assessed as a thermal decomposition product of CGA 321113 (*EE*).

Under photolytic conditions in the laboratory in sterile buffers at pH 5 and pH 7 and in sterile natural water, trifloxystrobin (*EE*) was rapidly degraded ($DT_{50} \leq 17$ days) by *E/Z* isomerization (in this summary referred to as "photodegradation products"). Trifloxystrobin (*EE*) isomerized to its major *E/Z* isomers CGA 357261 (*ZE*) with max. 51.5% AR (natural water) and CGA 357262 (*ZZ*) with max. 10.1% AR (buffer pH 7). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to the major degradation product CGA 321113 (*EE*) with max. 57.4% AR (natural water) and its major *E/Z* isomer CGA 373466 (*ZE*) with max. 21.1% AR (natural water) by hydrolytic ester cleavage and *E/Z* isomerization. Furthermore, the major volatile degradation product CGA 107170 was formed with a maximum amount of 53.8% AR (buffer pH 5) by cleavage of the bridge between the aromatic ring systems. Formation of carbon dioxide was very low with a maximum amount of 0.5% AR. A similar process was observed for CGA 321113 (*EE*) in sterile buffer at pH 5. CGA 321113 (*EE*) was rapidly degraded ($DT_{50} \leq 1.7$ days) by *E/Z* isomerization to its major *E/Z* isomer CGA 373466 (*ZE*) with max. 60.5% AR. Furthermore, the major degradation product 2-hydroxymethylbenzotrile was formed with a maximum amount of 20.1% AR by cleavage of the bridge between the aromatic ring systems.

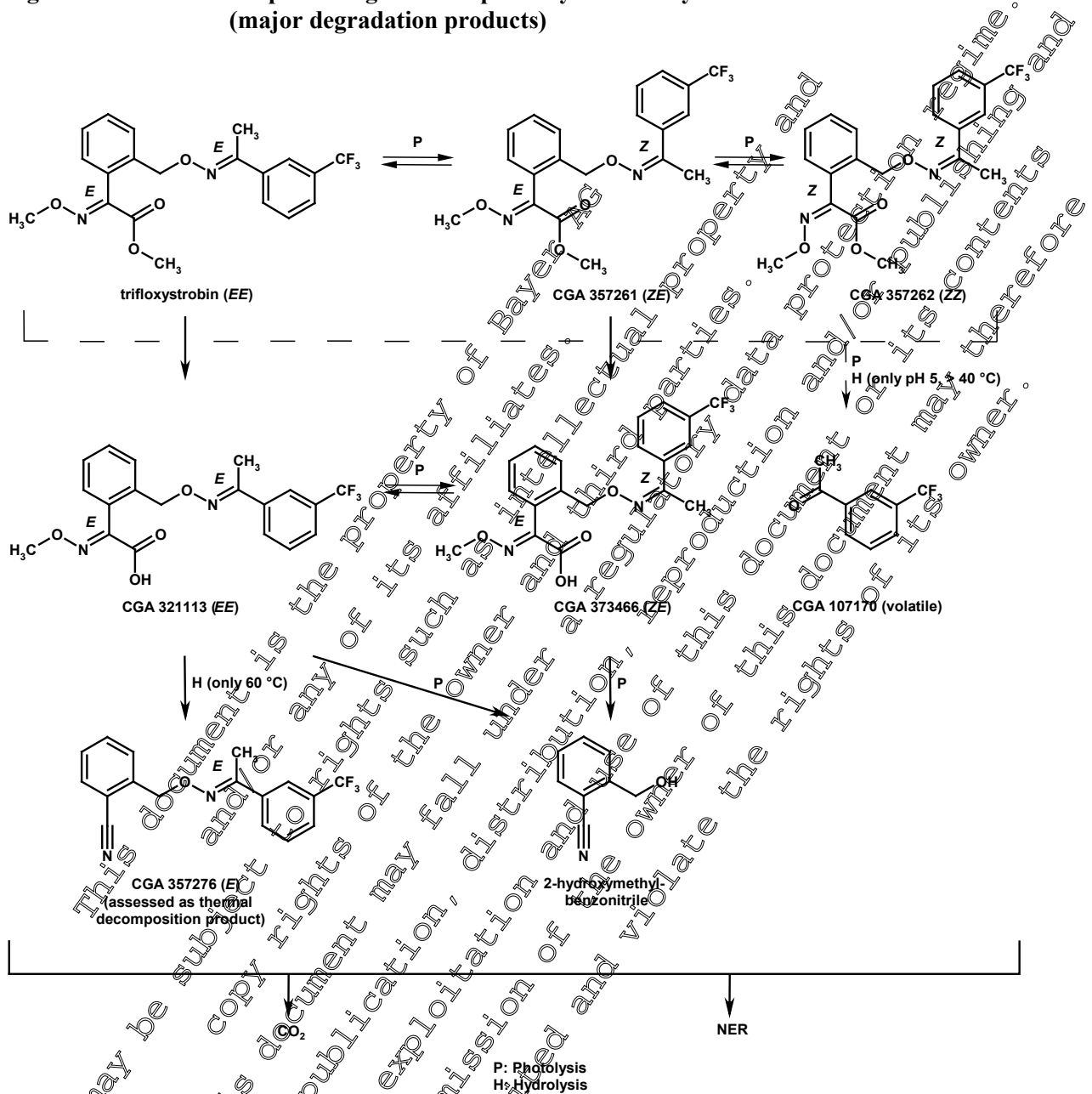
In surface water under aerobic conditions in the dark in the laboratory, trifloxystrobin (*EE*) was rapidly and quantitatively hydrolysed ($DT_{50} = 1.4$ days, see [Table 7.2-1](#)) to the single major degradation product CGA 321113 (*EE*). Formation of carbon dioxide was very low with a maximum amount of 0.3% AR.

In water/sediment systems under aerobic conditions in the dark in the laboratory, trifloxystrobin (*EE*) was rapidly degraded in the water ($DT_{50} \leq 0.9$ days), the sediment ($DT_{50} \leq 4.1$ days) and the total system ($DT_{50} \leq 2.6$ days) to the single major degradation product CGA 321113 (*EE*). The maximum amount of trifloxystrobin (*EE*) in the sediment was 42.3% AR. CGA 321113 (*EE*) had maximum amounts of 76.9 and 4.1% AR in the water and sediment, respectively. Further degradation led to carbon dioxide with a range of 5.9 to 9.5% AR for the [14 C-GP]-label and 5.1 to 8.8% AR for the [14 C-TP]-label. Non-extractable residues ranged from 11.8 to 13.5% AR for the [14 C-GP]-label and from 12.4 to 13.2% AR for the [14 C-TP]-label. The half-life of the major degradation product CGA 321113 (*EE*) was between 79.6 and 320 days in the water, between 442 and 571 days in the sediment and between 341 and 433 days in the total system. The degradation rates of trifloxystrobin (*EE*) and its major degradation product CGA 321113 (*EE*) in water and sediment for modelling purpose and trigger evaluation are summarized in [Table 7.2-2](#) to [Table 7.2-3](#).

Under semi-field conditions in presence of light, trifloxystrobin (*EE*) was rapidly degraded in the water ($DT_{50} \leq 0.4$ days) and the total system ($DT_{50} = 6.9$ days). The degradation product CGA 321113 (*EE*) was identified as the most important one. The half-life of the degradation product CGA 321113 (*EE*) was 99 days for the water and the total system.

The proposed degradation pathway of trifloxystrobin in water and sediment is shown in [Figure 7.2-1](#).

Figure 7.2- 1: Proposed degradation pathway of trifloxystrobin in water and sediment (major degradation products)





Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.2- 1: Summary of DT₅₀ and DT₉₀ values for degradation of trifloxystrobin in aerobic surface water for trigger evaluation

Temp. [°C]	Surface Water	Concentration [µg/L]	Annex Point / Reference No	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
20	Pond	6.1	KCA 7.2.2.2 /01	SFO	1.4	4.1
	Pond	53.7	KCA 7.2.2.2 /01	SFO	1.0	4.5

¹ SFO: single first order

Table 7.2- 2: Summary of DT₅₀ and DT₉₀ values for degradation of trifloxystrobin in aerobic water/sediment systems for modelling purpose (non-normalised) and trigger evaluation

Temp. [°C]	Water/Sediment System	Annex Point / Reference No.	Modelling Purpose		Trigger Evaluation		
			Kinetic Model	DT ₅₀ [days]	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
Total System							
20	Rhine	KCA 7.2.2.3 /05	SFO	2.18	SFO	2.08	7.25
	Rhine	KCA 7.2.2.3 /05	SFO	2.63	SFO	2.63	8.73
	Pond	KCA 7.2.2.3 /05	SFO	1.25	SFO	1.25	4.16
	Pond	KCA 7.2.2.3 /05	SFO	1.14	SFO	1.14	3.79
			geomean	1.69			
Water							
20	Rhine	KCA 7.2.2.3 /05	SFO	0.77	DFOP	0.66	3.23
	Rhine	KCA 7.2.2.3 /05	SFO	0.57	HS	0.56	3.18
	Pond	KCA 7.2.2.3 /05	SFO	0.90	FOMC	0.86	3.33
	Pond	KCA 7.2.2.3 /05	SFO	0.86	FOMC	0.83	3.12
			geomean	0.76			
Sediment							
20	Rhine	KCA 7.2.2.3 /05	SFO	3.57	SFO	3.57	11.85
	Rhine	KCA 7.2.2.3 /05	SFO	4.08	SFO	4.08	13.55
	Pond	KCA 7.2.2.3 /05	SFO	1.48	HS	1.45	4.82
	Pond	KCA 7.2.2.3 /05	SFO	1.67	FOMC	1.37	6.59
			geomean	2.45			

¹ SFO: single first order, FOMC: first order multi-compartment, DFOP: double first order in parallel, HS: hockey stick

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Table 7.2- 3: Summary of DT₅₀ and DT₉₀ values for degradation of CGA 321113 in aerobic water/sediment systems for modelling purpose (non-normalized) and trigger evaluation

Temp. [°C]	Water/Sediment System	Annex Point / Reference No	Modelling Purpose		Trigger Evaluation		
			Kinetic Model ¹	DT ₅₀ [days]	Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]
Total System							
20	Rhine	KCA 7.2.2.3 /05	SFO	423.1	SFO	423.1	> 1000
	Rhine	KCA 7.2.2.3 /05	SFO	362.9	SFO	362.9	> 1000
	Pond	KCA 7.2.2.3 /05	SFO	341.7	SFO	341.1	1000
	Pond	KCA 7.2.2.3 /05	SFO	432.7	SFO	432.7	> 1000
			geomean	388.0			
Water							
20	Rhine	KCA 7.2.2.3 /05	SFO	285.1	DFOP	281.0	> 1000
	Rhine	KCA 7.2.2.3 /05	SFO	319.9	SFO	319.9	> 1000
	Pond	KCA 7.2.2.3 /05	SFO	154.6	DFOP	156.7	633.4
	Pond	KCA 7.2.2.3 /05	SFO	137.1	FOMC	79.6	- ²
			geomean	209.7			
Sediment							
20	Rhine	KCA 7.2.2.3 /05	SFO	570.9	SFO	570.9	> 1000
	Rhine	KCA 7.2.2.3 /05	SFO	441.8	SFO	441.8	> 1000
	Pond	KCA 7.2.2.3 /05	- ³	- ³	- ³	- ³	- ³
	Pond	KCA 7.2.2.3 /05	- ⁴	- ⁴	- ⁴	- ⁴	- ⁴
			geomean	502.2			

¹ SFO: single first order, FOMC: first order multi compartment, DFOP: double first order in parallel, HS: hockey stick

² could not be calculated by the kinetic model

³ no clear dissipation observed, therefore no appropriate kinetic model could be selected

⁴ could not be calculated due to a too low number of data

CA 7.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

CA 7.2.1.1 Hydrolytic degradation

The hydrolytic route and rate of degradation of trifloxystrobin in buffers under sterile conditions in the dark in the laboratory were evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.2.1.1 /01	[REDACTED]	1996	M-033720-01-1
KCA 7.2.1.1 /02	[REDACTED]	1997	M-033737-01-1
KCA 7.2.1.1 /03	[REDACTED]	1997	M-033746-01-1

No additional studies were submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the route and rate of degradation of trifloxystrobin in water and sediment is given in section CA 7.2 and Figure 7.2- 1.



CA 7.2.1.2 Direct photochemical degradation

The photolytic routes and rates of degradation of trifloxystrobin and its major degradation product CGA 321113 in buffers in the laboratory were evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], as well as unlabelled trifloxystrobin and CGA 321113, and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.2.1.2 /01	[REDACTED]	1996	M-033754-02-1
KCA 7.2.1.2 /02	[REDACTED]	1997	M-033788-01-1
KCA 7.2.1.2 /03	[REDACTED]	1997	M-033842-01-1
KCA 7.2.1.2 /04	[REDACTED]	1997	M-033847-02-1
KCA 7.2.1.2 /05	[REDACTED]	1997	M-033856-02-1

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the route and rate of degradation of trifloxystrobin in water and sediment is given in section CA 7.2 and Figure 72- 1.

CA 7.2.1.3 Indirect photochemical degradation

A study for the determination of the photolytic route and rate of degradation of trifloxystrobin in natural water has been performed and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using one radiolabel position, [¹⁴C-GP].

Report:	KCA 7.2.1.3 /01; [REDACTED]; 2003
Title:	Photolysis of Trifloxystrobin in Natural Water
Report No:	MEF-24703
Document No:	M-106330-01
Guidelines:	- SETAC Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides - Commission Directive 95/36/EC amending Council Directive 91/414/EEC - US EPA Pesticide Assessment Guidelines, Subdivision N, Section 161-2 - Japanese MAFF New Test Guidelines 12 Nohsan 8147
GLP:	Yes
Justification:	New data / guideline requirement: Indirect photochemical degradation of trifloxystrobin in natural water

Executive Summary

The photolytic route and rate of degradation of [¹⁴C-GP]trifloxystrobin were studied in sterile natural water from the river Rhine under exposure to simulated sunlight in the laboratory for 8 days at 24.6 °C.

A study application rate of 1.35 µg per test system (0.27 mg/L) was applied.

8 days of incubation under exposure to simulated sunlight were equivalent to 30 and 62 solar summer days in Phoenix (Arizona, USA) and Tokyo (Japan), respectively. For comparison, additional samples were incubated in the dark.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

Mean material balances ranged from 93.0 to 106.2% of applied radioactivity [% AR] for irradiated and dark samples.

The maximum amount of carbon dioxide was 0.4% AR at study end (DAT-8) in irradiated samples. Formation of volatile organic compounds was insignificant as demonstrated by values of 0.1% AR at all sampling intervals for both irradiated and dark samples.

The amount of trifloxystrobin in water decreased from 88.4% AR at study start (DAT-0) to 2.1 and 18.7% AR at DAT-8 in irradiated and dark samples, respectively.

In irradiated samples, trifloxystrobin (*EE*) isomerized to its *E/Z* isomers CGA 357261 (*ZE*) (max. 51.5% AR at DAT-0.29), CGA 357262 (*ZZ*) (max. 5.1% AR at DAT-0.13) and CGA 331409 (*EZ*) (max. 3.3% AR at DAT-13). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to CGA 321113 (*EE*) (max. 11.1% AR at DAT-4) and its *E/Z* isomers CGA 373468 (*ZE*) (max. 21.1% AR at DAT-4) and CGA 373465 (*EZ*) (max. 0.8% AR at DAT-0) by hydrolytic ester cleavage and *E/Z* isomerization. Unidentified residues were observed with no one component exceeding 10% AR at any sampling interval.

In dark samples, trifloxystrobin (*EE*) was degraded to CGA 321193 (*EE*) (max. 86% AR at DAT-8) by hydrolytic ester cleavage. The total unidentified residues amounted to a maximum of 1.5% AR.

The DT_{50} and DT_{90} values were calculated using hockey stick kinetics, resulting in an experimental half-life for trifloxystrobin of 0.1 days in the irradiated samples. Based on the experimental DT_{50} value of 0.1 days for irradiated samples, the DT_{50} value of trifloxystrobin under environmental conditions is calculated to be e.g. 0.4 and 0.9 solar summer days at Phoenix and Tokyo, respectively.

It is concluded that photodegradation contributes significantly to the degradation of trifloxystrobin under typical conditions in the aquatic environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzene acetic- ^{14}C] trifloxystrobin
Sample ID: BECH0538
Specific Activity: 3.01 MBq/mg (81.4 μ Ci/mg)
Radiochemical Purity: > 99%



2. Test Water

Natural water from the river Rhine was used (see Table 7.2.1.3- 1). The water was sampled freshly from the river (depth of 0 to 30 cm) and sterilized by steam pressure sterilization prior to use.

Table 7.2.1.3- 1: Physico-chemical properties of test water

Parameter	Results / Units
Water Designation	Rhine
Geographic Location	
City	██████████
State	North-Rhine Westphalia
Country	Germany
pH ¹	7
Suspended Solid [mg/L] ¹	51
Total Evaporation Residues [mg/L] ¹	46
Oxygen Content [mg/L] ¹	12.8
Conductivity [μ S/cm] ¹	520
DOC [mg C/L]	2
TOC [mg C/L]	2
Hardness [°dH]	12.2
Total Nitrate [mg N/L]	3.2
Total Phosphorous [mg/L]	0.07

¹ measured after fresh sampling

DOC: dissolved organic carbon

TOC: total organic carbon

3. Test Solution

A stock solution of the test item was prepared in acetonitrile. An aliquot of the stock solution was mixed with sterile natural water to obtain a test item concentration of 0.27 μ g/L.

B. STUDY DESIGN

1. Experimental Conditions

The static test system for photolytic degradation in natural water consisted of a flat quartz glass vessel (volume approx. 23 mL). Each vessel was equipped with a trap attachment (permeable for oxygen), containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds (VOC). All glassware was sterilized by steam pressure sterilization before use.

For preparation of the test systems 5 mL of the test solution were transferred into each vessel, resulting in a study application rate of 1.35 μ g per test system. The test vessels (except DAT-0 samples) were equipped with trap attachments.

**Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin**

The irradiated test systems were continuously irradiated for 8 days at 24.6 °C in a Suntest® unit containing a Xenon lamp simulating natural sunlight. The light emission was filtered with a 290 nm cut-off UV-filter, which eliminated all wavelengths < 290 nm. The intensity of the Xenon lamp was determined at the beginning and the end of the overall test period using an irradiance monitor and was calculated as 1344 W/m² for 300 to 3000 nm. The radiation intensity and exposure time under experimental conditions can be related to natural solar radiation at e.g. Phoenix (Arizona, USA), representing extraordinary conditions, or Tokyo (Japan). At this light intensity, it takes 0.4 and 3.1 hours in the Suntest® unit to equal one solar summer day at Phoenix and Tokyo, respectively. Therefore, the equivalent of 30 solar days is achieved by this design using continuous irradiation for approximately 8.0 and 3.9 days for Phoenix and Tokyo, respectively.

The dark test systems were incubated in the dark for 8 days at 25.1 °C in a climatic cabinet.

2. Sampling

Nine sampling intervals were distributed over the entire incubation period of 8 days. Duplicate samples were processed and analysed 0, 0.13, 0.29, 1, 2.3, 4, 7 and 8 days after treatment (DAT) for irradiated samples and at DAT-8 for dark samples.

3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped in a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The PU foam plugs were extracted with ethyl acetate to desorb VOC. The radioactivity content was determined by LSC.

At each sampling interval, pH and sterility were determined. The oxygen content was determined at DAT-0 and DAT-8.

The radioactivity content of the water was determined by LSC. The test vessel was rinsed additionally with acetonitrile and the radioactivity content was determined by LSC. Aliquots of water and acetonitrile rinse were analysed by 2D-TLC/radiodetection. The limit of quantitation (LOQ) for 2D-TLC/radiodetection analysis of the solutions and acetonitrile rinses was 0.1% AR.

Test item and degradation products were identified by 2D-TLC co-chromatography with reference items.

The degradation kinetics of the test item was determined using the software ModelManager® with a hockey stick kinetic model. Model input datasets were the mean residual amounts found at each sampling interval. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that anticipated standardized conditions were maintained and that the test systems were sterile over the duration of the laboratory study.

The pH in the water ranged from 7.7 to 9.0 and the oxygen content (dissolved oxygen) from 4.8 to 6.8 mg/L in irradiated and dark samples.



A. DATA

Table 7.2.1.3- 2: Photodegradation of trifloxystrobin in natural water (mean values expressed as % AR)

Compound	Mean	DAT				
		0	0.13	0.29	1	2
trifloxystrobin (EE)	Mean	88.4	39.4	29.5	17.0	12.3
CGA 331409 (EZ)	Mean	n.d.	3.3	1.2	1.0	0.5
CGA 357261 (ZE)	Mean	n.d.	43.4	51.5	49.4	38.9
CGA 357262 (ZZ)	Mean	n.d.	5.1	4.4	4.7	4.3
CGA 321113 (EE)	Mean	0.3	4.9	5.0	7.8	9.6
CGA 373465 (EZ)	Mean	n.d.	n.d.	n.d.	0.2	0.5
CGA 373466 (ZE)	Mean	n.d.	2.3	3.5	11.1	16.7
Sum of Unid./Diff. Residues ¹	Mean	0.2	0.2	1.4	11.6	20.2
Carbon Dioxide ²	Mean	n.a.	< 0.1	< 0.1	< 0.1	< 0.1
Volatile Organic Compounds ²	Mean	n.a.	< 0.1	< 0.1	< 0.1	< 0.1
Total Recovery ³	Mean	93.6	98.6	99.3	102.6	102.8

Table 7.2.1.3- 2 (continued)

Compound	Mean	DAT				
		3	4	7	8	8 (dark)
trifloxystrobin (EE)	Mean	10.7	5.4	2.6	2.1	18.7
CGA 331409 (EZ)	Mean	n.d.	0.3	0.1	n.d.	n.d.
CGA 357261 (ZE)	Mean	11.1	15.0	17.1	7.2	n.d.
CGA 357262 (ZZ)	Mean	3.5	2.7	2.0	1.3	n.d.
CGA 321113 (EE)	Mean	9.6	11.1	9.9	9.0	86.0
CGA 373465 (EZ)	Mean	0.3	0.6	0.8	0.3	n.d.
CGA 373466 (ZE)	Mean	15.9	21.1	19.5	18.7	n.d.
Sum of Unid./Diff. Residues ¹	Mean	27.3	45.6	62.9	65.3	1.5
Carbon Dioxide	Mean	0.1	0.2	0.3	0.4	< 0.1
Volatile Organic Compounds	Mean	0.1	< 0.1	< 0.1	< 0.1	< 0.1
Total Recovery ³	Mean	104.3	102.3	104.6	104.4	106.2

n.d.: not detected, n.a.: not analysed, DAT: days after treatment

¹ Minor degradation products are summed up to sum of unidentified / diffuse residues, with no one component exceeding 10% AR.² Values taken from Material Balance.³ Difference to Material Balance values due to rounding errors as well as clean up and chromatographic losses.

B. MATERIAL BALANCE

Mean material balances ranged from 93.0 to 106.2% of applied radioactivity [% AR] for irradiated and dark samples. The complete material balances found at all sampling intervals for both irradiated and dark samples demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

D. VOLATILES

The maximum amount of carbon dioxide was 0.4% AR at study end (DAT-8) in irradiated samples. Formation of volatile organic compounds was insignificant as demonstrated by values of $\leq 0.1\%$ AR at all sampling intervals for both irradiated and dark samples.



E. DEGRADATION OF PARENT COMPOUND

The amount of trifloxystrobin in water decreased from 88.4% AR at study start (DAT-0) to 2.2% and 18.7% AR at DAT-8 in irradiated and dark samples, respectively.

In irradiated samples, trifloxystrobin (*EE*) isomerized to its *E/Z* isomers CGA 357261 (*ZE*) (max. 51.5% AR at DAT-0.29), CGA 357262 (*ZZ*) (max. 5.1% AR at DAT-0.13) and CGA 331469 (*EZ*) (max. 3.3% AR at DAT-13). Trifloxystrobin (*EE*) and its *E/Z* isomers were degraded to CGA 321113 (*EE*) (max. 11.1% AR at DAT-4) and its *E/Z* isomers CGA 373466 (*ZE*) (max. 21.1% AR at DAT-4) and CGA 373465 (*EZ*) (max. 0.8% AR at DAT-7) by hydrolytic ester cleavage and *E/Z* isomerization. Unidentified residues were observed with no one component exceeding 10% AR at any sampling interval.

In dark samples, trifloxystrobin (*EE*) was degraded to CGA 321113 (*EE*) (max. 86% AR at DAT-8) by hydrolytic ester cleavage. The total unidentified residues amounted to a maximum of 15% AR.

The experimental DT₅₀ and DT₉₀ values of trifloxystrobin in irradiated samples were calculated using hockey stick (HS) kinetics (see Table 7.2.1.3.3).

Table 7.2.1.3- 3: Photodegradation kinetics of trifloxystrobin in sterile natural water

Test System	DT ₅₀ (exp.) [days]	DT ₉₀ (exp.) [days]	HS ¹ Rate Constant [day ⁻¹]	DT ₅₀ under natural conditions [days]
Irradiated	0.1	2.9	k ₁ = 6.46 k ₂ = 0.43	0.4 (Phoenix, USA) 0.9 (Tokyo, Japan)

¹ HS: hockey stick

III. CONCLUSIONS

Trifloxystrobin (*EE*) was rapidly degraded by *E/Z* isomerization in sterile natural water (experimental half-life of 0.1 days) when being exposed to simulated sunlight in the laboratory.

In irradiated samples, trifloxystrobin (*EE*) isomerized to its major *E/Z* isomer CGA 357261 (*ZE*). Trifloxystrobin (*EE*) and its *E/Z* isomer were degraded to the major degradation product CGA 321113 (*EE*) and its major *E/Z* isomer CGA 373466 (*ZE*) by hydrolytic ester cleavage and *E/Z* isomerization. CGA 321113 (*EE*) was observed as the single major degradation product in dark samples. Formation of carbon dioxide was very low.

It is concluded that photodegradation contributes significantly to the degradation of trifloxystrobin under typical conditions in the aquatic environment.

The results are in good agreement with the proposed degradation pathway of trifloxystrobin in water and sediment known from studies included in the Baseline Dossier.

The results are included in the proposed degradation pathway of trifloxystrobin in water and sediment shown in Figure 7.1 and in the summary of the route and rate of degradation of trifloxystrobin in water and sediment given in section CA 7.2.



CA 7.2.2 Route and rate of biological degradation in aquatic systems

CA 7.2.2.1 "Ready biodegradability"

The "ready biodegradability" of trifloxystrobin was evaluated during the Annex I inclusion using unlabelled trifloxystrobin, and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.2.2.1 /01	[REDACTED]	1994	M-0339/4-01

No additional studies are submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the route and rate of degradation of trifloxystrobin in water and sediment is given in section CA 7.2 and Figure 7.2- 1.

CA 7.2.2.2 Aerobic mineralisation in surface water

A study for the determination of the route and rate of degradation of trifloxystrobin in surface water under aerobic conditions conditions in the dark in the laboratory has been performed and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval using one radiolabel position, [¹⁴C-GP].

Report:	KCA.7.2.2.2 /01; [REDACTED]; 2013
Title:	[Benzenecetic-phenyl-UL- ¹⁴ C] trifloxystrobin: Aerobic Mineralization in Surface Water
Report No:	D60632
Document No:	M-449602-01
Guidelines:	- OECD Test Guideline No. 309
GLP:	Yes
Justification:	New data / guideline requirement: Route and rate of degradation of trifloxystrobin in aerobic surface water

Executive Summary

The route and rate of degradation of [¹⁴C-GP]trifloxystrobin were studied in surface water under aerobic conditions in the dark in the laboratory for 62 days at 22.9 °C.

Study application rates of 1.83 µg (6.0 µg/L) and 16.1 µg (53.7 µg/L) per test system were applied for the low and the high concentration, respectively.

Mean material balances were 98.1% of applied radioactivity [% AR] (range from 96.1 to 102.1% AR) for the low concentration and 96.9% AR (range from 95.5 to 98.8% AR) for the high concentration.

The maximum amount of carbon dioxide was 0.3 and 0.2% AR after 62 days of incubation for the low and high concentrations, respectively. Formation of volatile organic compounds was insignificant as demonstrated by values of 0.1% AR at all sampling intervals for both concentrations.



Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Trifloxystrobin was rapidly and quantitatively hydrolysed to CGA 321113 with its amount decreasing from 95.1% AR and 94.8% AR at study start (DAT-0) to < LOD (limit of detection) from DAT-28 onwards in the low and high concentration, respectively. In parallel, the amount of the single degradation product CGA 321113 reached a maximum of 99.4 and 97.0% AR at study end (DAT-62) in the low and high concentration, respectively. The same was observed in sterile controls (max. amount of 98.3% AR at DAT-62 for CGA 321113). The total unidentified residues amounted to a maximum of 4.5% AR.

The experimental DT₅₀ and DT₉₀ values were calculated using single first order kinetics. The half-lives for trifloxystrobin were 1.4 days for both concentrations.

It is concluded that hydrolysis will be the major process in the degradation of trifloxystrobin under typical conditions in the aquatic environment.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[benzeneacetic-phenyl-UL-¹⁴C]trifloxystrobin
Sample ID: KML 9414
Specific Activity: 2.01 MBq/mg (81.4 µCi/mg)
Radiochemical Purity: > 99%
Chemical Purity: 99%

2. Test Water

Natural water from a pond system not receiving effluent discharges was used (see [Table 7.2.2.2- 1](#)). The water was sampled freshly from the pond (depth of approx. 30 cm) and sieved through a 0.2 mm sieve prior to use.

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Table 7.2.2- 1: Physico-chemical properties of test water

Parameter	Results / Units
Water Designation	██████████ Pond
Origin	██████████ AG, Switzerland
GPS Coordinates	██████████ ██████████
pH ¹	8.2
Redox Potential E _H [mV] ¹	466
Oxygen Content [mg/L] ¹	10.6
Hardness [°dH] ¹	14.6
BOD [mg/L]	< 5.0
DOC [mg C/L]	21.3
TOC [mg C/L]	22.8
Total Nitrogen [mg/L]	2.22
Total Phosphorous [mg/L]	0.45
Total Nitrate [mg/L]	1.2
Total Nitrite [mg/L]	1.23
Total Ammonium [mg/L]	1.98
Dissolved Orthophosphate [mg/L]	0.04
Microbial Activity	DT ₅₀ < 3 days

¹ measured at sampling site
BOD: biological oxygen demand
DOC: dissolved organic carbon
GPS: global positioning system
TOC: total organic carbon

B. STUDY DESIGN

1. Experimental Conditions

The flow through test system for degradation in surface water under aerobic conditions consisted of glass metabolism flasks (inner diameter approx. 5.3 cm, volume approx. 500 mL). Each flask was equipped with a gas inlet and outlet, and a flow of humidified air was maintained. The outlet was connected to a series of trapping solutions (ethylene glycol and 2 N sodium hydroxide) for adsorption of carbon dioxide and volatile organic compounds.

For preparation of the test systems, 300 mL of the natural water were transferred into each flask. The flasks were then connected to the traps and equilibrated to study conditions for 7 days prior to application. The water was continuously agitated using a magnetic stirrer.

Study application rates of 1.83 µg (6.9 µg/L) and 16.1 µg (53.7 µg/L) per test system were applied for the low and the high concentration, respectively.

The test item was applied dropwise onto the water surface of the respective test systems in 300 µL methanol using a pipette. After application, the test vessels were connected to the traps (except of DAT samples).

The test systems were incubated in the dark for 62 days at 22.9 °C in an air-conditioned room.



2. Sampling

Eight sampling intervals were distributed over the entire incubation period of 62 days. Duplicate samples were processed and analysed 0, 1, 2, 4, 7, 14, 28 and 62 days after treatment (DAT) for both low and high concentration. Sterile controls were processed and analysed at DAT-62 for the high concentration, microbial activity samples at DAT-0, DAT-3 and DAT-14.

3. Analytical Procedures

The radioactivity content of the ethylene glycol and 2 N sodium hydroxide trapping solutions was determined by liquid scintillation counting (LSC). In addition, sodium hydroxide traps were exchanged at DAT-21.

At each sampling interval, pH, oxygen content and redox potential in the water were determined. The water was acidified to pH 5 and the test vessel was rinsed additionally with methanol. From DAT-0 to DAT-7, the rinsing solutions were pooled with the water, from DAT-14 onwards the rinsing solutions were treated separately due to biofilm formation. The radioactivity content of the (pooled) water and the methanol rinses was determined by LSC. Due to the low amounts of radioactivity in the methanol rinses ($\leq 1.8\%$ AR), the rinsing solutions were not analysed by HPLC/radiodetection. The acidified water was submitted to one to three liquid-liquid extraction steps using ethyl acetate. The ethyl acetate extracts were combined, concentrated to dryness, dissolved in methanol/water 2/3 (v/v) and analysed by reversed phase HPLC/radiodetection. The limits of quantitation for HPLC/radiodetection analysis of the water were 0.8 and 0.4% AR for the low and high concentration, respectively.

Test item and CGA 321113 were identified by HPLC and TLC co-chromatography with reference items.

The degradation kinetics of the test item was determined according to FOCUS kinetics (2006)¹ using the software KinGUI 2 with a single first-order kinetic model. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. DT₅₀ and DT₉₀ values were calculated from the resulting kinetic parameters.

II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained and that the water was microbially active over the duration of the laboratory study.

The pH in the water ranged from 8.2 to 8.5 for both low and high concentration.

Oxygen contents (range from 8.1 to 9.4 mg/L) and redox potential measurement (E_H, range from 336 to 410 mV) indicated aerobic conditions in the water for both concentrations.



A. DATA

Table 7.2.2.2- 2: Degradation of trifloxystrobin in natural pond water under aerobic conditions (low concentration, mean values and SD expressed as % AR)

Compound	Mean SD	DAT								
		0	1	2	4	7	14	28	62	
trifloxystrobin	Mean SD	95.1 ± 0.3	55.1 ± 3.3	36.2 ± 2.4	14.3 ± 1.1	3.6 ± 0.2	0.8 ± 0.2	0.6 ± 0.8	n.d.	
CGA 321113	Mean SD	n.d.	42.8 ± 5.2	61.6 ± 0.4	77.1 ± 1.9	97.3 ± 1.3	95.7 ± 1.4	97.0 ± 2.9	99.4 ± 2.7	
Sum of Unid./Diff. Residues ¹	Mean SD	0.9 ± 0.0	n.d.	1.0 ± 0.0	4.5 ± 1.1	n.d.	1.4 ± 0.6	4.0 ± 2.0	0.6	
Total Residues in Water ²	Mean	96.0	97.9	98.8	96.0	95.9	97.7	101.8	100.0	
Carbon Dioxide ²	Mean	n.a.	< 0.1	< 0.1	0.1	0.2	0.2	0.3	0.6	
Volatile Organic Compounds ²	Mean	n.a.	< 0.1	0.1	< 0.1	< 0.1	0.1	< 0.1	0.1	

n.d.: not detected, n.a.: not analysed, DAT: days after treatment, SD: standard deviation

¹ Minor degradation products are summed up to sum of unidentified / diffuse residues.

² Values taken from Material Balance.

Table 7.2.2.2- 3: Degradation of trifloxystrobin in natural pond water under aerobic conditions (high concentration, mean values and SD expressed as % AR)

Compound	Mean SD	DAT									
		0	1	2	4	7	10	28	62	62 (sterile)	
trifloxystrobin	Mean SD	94.8 ± 6.2	54.8 ± 1.1	33.2 ± 2.8	14.5 ± 0.1	4.1 ± 1.3	1.2 ± 0.9	0.3	n.d.	n.d.	
CGA 321113	Mean SD	n.d.	40.7 ± 2.3	63.0 ± 2.6	82.3 ± 0.0	91.0 ± 2.2	93.7 ± 3.1	93.1 ± 3.0	97.0 ± 2.1	98.3 ± 2.1	
Sum of Unid./Diff. Residues ¹	Mean SD	1.0 ± 0.0	n.d.	0.9 ± 0.0	n.d.	0.3 ± 0.5	1.4 ± 0.6	4.4 ± 0.4	1.0	0.9	
Total Residues in Water ²	Mean	97.8	95.5	96.5	96.8	95.4	96.3	97.8	98.0	98.8	
Carbon Dioxide	Mean	n.a.	< 0.1	0.1	0.1	< 0.1	< 0.1	0.2	0.2	< 0.1	
Volatile Organic Compounds	Mean	n.a.	< 0.1	0.1	> 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	

n.d.: not detected, n.a.: not analysed, DAT: days after treatment, SD: standard deviation

¹ Minor degradation products are summed up to sum of unidentified / diffuse residues.

² Values taken from Material Balance.

B. MATERIAL BALANCE

Mean material balances were 98.1% of applied radioactivity [% AR] (range from 96.1 to 102.1% AR) for the low concentration and 96.9% AR (range from 95.5 to 98.8% AR) for the high concentration. The complete material balances found at all sampling intervals demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.



C. VOLATILES

The maximum amount of carbon dioxide was 0.3 and 0.2% AR after 62 days of incubation for the low and high concentrations, respectively. Formation of volatile organic compounds was insignificant as demonstrated by values of < 0.1% AR at all sampling intervals for both concentrations.

E. DEGRADATION OF PARENT COMPOUND

Trifloxystrobin was rapidly and quantitatively hydrolysed to CGA 321113 with its amount decreasing from 95.1% AR and 94.8% AR at study start (DAT-0) to < LOD (Limit of detection) from DAT-28 onwards in the low and high concentration, respectively. In parallel, the amount of the single degradation product CGA 321113 reached a maximum of 99.4 and 97.0% AR at study end (DAT-62) in the low and high concentration, respectively. The same was observed in sterile controls (max. amount of 98.3% AR at DAT-62 for CGA 321113). Low amounts of characterisable by chromatography residues were observed (max. 4.5% AR in total).

The experimental DT₅₀ values of trifloxystrobin were calculated using single first order (SFO) kinetics (see Table 7.2.2.2- 4).

Table 7.2.2.2- 4: Degradation kinetics of trifloxystrobin in natural pond water under aerobic conditions according to FOCUS

Test System	DT ₅₀ [days]	DT ₉₅ [days]	SFO Chi ² Error [%]
Low concentration (6.1 µg/L)	1.4	4.7	3.6
High concentration (53.7 µg/L)	1.4	4.5	3.9

SFO: single first order

III. CONCLUSIONS

Trifloxystrobin was rapidly and quantitatively hydrolysed to the single major degradation product CGA 321113 in natural water under aerobic conditions in the dark in the laboratory. The calculated half-lives were 1.4 days for both low and high concentration. Formation of carbon dioxide was very low.

It is concluded that hydrolysis will be the major process in the degradation of trifloxystrobin under typical conditions in the aquatic environment.

The results are in good agreement with the proposed degradation pathway of trifloxystrobin in water and sediment known from studies included in the Baseline Dossier.

The results are included in the proposed degradation pathway of trifloxystrobin in water and sediment shown in Figure 72.1 and in the summary of the route and rate of degradation of trifloxystrobin in water and sediment given in section CA 7.2.



CA 7.2.2.3 Water/sediment study

The route and rate of degradation of trifloxystrobin in water/sediment systems under aerobic conditions were evaluated during the Annex I inclusion using two radiolabel positions, [¹⁴C-GP] and [¹⁴C-TP], as well as unlabelled trifloxystrobin, and were accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following studies are included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.2.2.3 /01	[REDACTED]	1997	M-033922-01-1
KCA 7.2.2.3 /02	[REDACTED]	1997	M-033933-01-1
KCA 7.2.2.3 /03	[REDACTED]	1997	M-049272-01-1
KCA 7.2.2.3 /04	[REDACTED]	2002	M-062201-01-1

An updated kinetic evaluation of the degradation behaviours of trifloxystrobin and its major degradation product CGA 321113 in water and sediment under aerobic conditions in the dark in the laboratory has been performed according to FOCUS kinetics (2006)¹ to derive kinetic parameters suitable for modelling purpose and environmental risk assessment and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval. A summary of the route and rate of degradation of trifloxystrobin in water and sediment is given in section CA 7.2 and Figure 7.2- 1.

Report:	KCA 7.2.2.3 /05; [REDACTED]; [REDACTED]; [REDACTED]; 2013
Title:	Kinetic Evaluation of Degradation and Dissipation Behaviour of Trifloxystrobin and its Metabolite CGA 321113 in Water/Sediment Systems According to FOCUS Kinetics Using the KinGUI 2 Tool
Report No:	EnSa-P3-0736
Document No:	M-468895-01-1
Guidelines:	FOCUS kinetics (2006)¹
GLP:	No
Justification:	New data guideline requirement Kinetic analysis of the degradation of trifloxystrobin and its major degradation product CGA 321113 for modelling purpose

Executive Summary

A kinetic analysis of residue data from the two aerobic water/sediment degradation studies M-033922-01-1 and M-033933-01-1 (Baseline Dossier, KCA 7.2.2.3 /01 and KCA 7.2.2.3 /02) was performed with the software KinGUI 2 according to FOCUS kinetics (2006)¹ to derive half-lives for trifloxystrobin and its degradation product CGA 321113, which are suitable for modelling purpose and trigger evaluation.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in water/sediment systems Rhine and Pond under aerobic conditions in the dark in the laboratory at 20 °C and test concentrations of 0.3 mg/L water. The single first order kinetic model was used for modelling purpose to describe the degradation of CGA 321113.

The half-life of trifloxystrobin for modelling purpose (geometric means) was 0.76 days in the water, 2.45 days in the sediment and 1.69 days in the total system. The half-life of CGA 321113 for modelling purpose (geometric means) was 209.7 days in the water, 502.2 days in the sediment and 388.0 days in the total system.



The half-lives of trifloxystrobin for trigger evaluation were between 0.6 and 0.9 days in the water, between 1.4 and 4.1 days in the sediment and between 1.1 and 2.6 days in the total system. The half-lives of CGA 321113 for trigger evaluation were between 79.6 and 320 days in the water, between 442 and 571 days in the sediment and between 341 and 433 days in the total system.

I. METHODS

Residue data from the two aerobic water/sediment degradation studies M-033922-01-1 and M-033933-01-1 (Baseline Dossier, KCA 7.2.2.3 /01 and KCA 7.2.2.3 /02) were used. In these studies, the degradation of trifloxystrobin was studied in water/sediment systems Rhine and Pond under aerobic conditions in the dark in the laboratory for up to 214 days at 20 °C and test concentrations of 0.3 mg/L water.

The kinetic analysis was performed according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the model. The most appropriate kinetic model for modelling purpose and trigger evaluation was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, χ^2 scaled error criterion, t-test significance, correlation analysis and standard deviation. The DT₅₀ value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model for modelling purpose.

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II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of trifloxystrobin in water/sediment systems Rhine and Pond. The SFO kinetic model was used for modelling purpose to describe the degradation of CGA 32111. Table 7.2.2.3- 1 to Table 7.2.2.3- 4 are summarizing the results of the kinetic analysis for modelling purpose and trigger evaluation.

Table 7.2.2.3- 1: Kinetic parameters for the degradation of trifloxystrobin in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
Total System					
Rhine	SFO	2.18	4.2	2.93×10^{-13}	+
Rhine	SFO	2.63	6.1	1.39×10^{-5}	+
Pond	SFO	1.25	1.9	4.28×10^{-13}	+
Pond	SFO	1.14	1.0	9.17×10^{-10}	+
	geomean	1.69			
Water					
Rhine	SFO	0.77	9.7	6.07×10^{-9}	o
Rhine	SFO	0.57	8.9	2.33×10^{-7}	o
Pond	SFO	0.90	4.8	6.51×10^{-10}	o
Pond	SFO	0.86	2.8	7.27×10^{-5}	o
	geomean	0.76			
Sediment					
Rhine	SFO	3.57	9.2	4.8×10^{-9}	o
Rhine	SFO	4.08	12.3	2.22×10^{-7}	o
Pond	SFO	1.48	6.0	2.28×10^{-6}	o
Pond	SFO	1.67	6.3	4.05×10^{-5}	o
	geomean	2.45			

¹ SFO: single first order

² visual assessment: + = good, o = moderate

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Table 7.2.2.3- 2: Kinetic parameters for the degradation of trifloxystrobin in water/sediment system under aerobic conditions for trigger evaluation according to FOCUS

Water/Sediment System	Best-Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ³
Total System						
Rhine	SFO	2.18	7.25	4.2	9.92×10^{-13}	
Rhine	SFO	2.63	8.73	6.1	1.39×10^{-10}	+
Pond	SFO	1.25	4.16	1.9	4.28×10^{-12}	+
Pond	SFO	1.14	3.79	1.0	9.17×10^{-10}	
Water						
Rhine	DFOP	0.66	3.23	0.7	$k_1: 4.42 \times 10^{-5}$ $k_2: 2.41 \times 10^{-7}$	+
Rhine	HS	0.56	3.18	1.3	$k_1: 7.39 \times 10^{-5}$ $k_2: 8.95 \times 10^{-7}$	+
Pond	FOMC	0.86	3.33	1.4	$k_1: 1.44 \times 10^{-2}$	
Pond	FOMC	0.83	3.12	0.7	$k_1: 1.06 \times 10^{-2}$	+
Sediment						
Rhine	SFO	3.57	11.85	9.2	4.85×10^{-9}	o
Rhine	SFO	4.08	13.55	12.3	2.22×10^{-7}	o
Pond	HS	1.45	4.32	2.2	$k_1: 9.68 \times 10^{-3}$ $k_2: 1.59 \times 10^{-2}$	+
Pond	FOMC	1.37	6.59	2.4	$k_1: 7.16 \times 10^{-3}$ $k_2: 1.87 \times 10^{-2}$	+

¹ SFO: single first order, FOMC: first order multi compartment, DFOP: double first order in parallel, HS: hockey stick

² for FOMC: worst case value of rate parameters alpha and beta

³ visual assessment: + = good, o = moderate

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Table 7.2.2.3- 3: Kinetic parameters for the degradation of CGA 321113 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model ¹	DT ₅₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ²
Total System					
Rhine	SFO	423.1	2.3	5.59 x 10 ⁻¹²	
Rhine	SFO	362.9	2.1	2.64 x 10 ⁻¹¹	+
Pond	SFO	341.1	1.5	1.76 x 10 ⁻¹⁵	+
Pond	SFO	432.7	2.6	2.05 x 10 ⁻⁷	+
	geomean	388.0			
Water					
Rhine	SFO	285.1	6	1.30 x 10 ⁻⁴	o
Rhine	SFO	319.9	2	4.55 x 10 ⁻³	o
Pond	SFO	154.6	7.1	3.74 x 10 ⁻³	o
Pond	SFO	137.1	11	1.23 x 10 ⁻³	o
	geomean	209.7			
Sediment					
Rhine	SFO	530.9	2.7	4.00 x 10 ⁻⁴	o
Rhine	SFO	441.8	3.4	1.27 x 10 ⁻³	o
Pond	SFO	- ³	- ³	- ³	- ³
Pond	SFO	- ³	- ⁴	- ⁴	- ⁴
	geomean	502.2			

¹ SFO: single first order

² visual assessment + = good, o = moderate

³ no clear dissipation observed, therefore, no appropriate kinetic model could be selected

⁴ could not be calculated due to a too low number of data

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Table 7.2.2.3- 4: Kinetic parameters for the degradation of CGA 321113 in water/sediment system under aerobic conditions for trigger evaluation according to FOCUS

Water/Sediment System	Best Fit Kinetic Model ¹	DT ₅₀ [days]	DT ₉₀ [days]	Chi ² Error [%]	t-test	Visual Assessment ³
Total System						
Rhine	SFO	423.1	> 1000	2.2	5.59×10^{-12}	
Rhine	SFO	362.9	> 1000	2.1	2.64×10^{-11}	+
Pond	SFO	341.1	> 1000	1.5	1.76×10^{-11}	+
Pond	SFO	432.7	> 1000	2.6	2.05×10^{-11}	
Water						
Rhine	DFOP	281.0	- ⁴	4	$k_1: 1.19 \times 10^{-3}$ $k_2: 1.99 \times 10^{-4}$	+
Rhine	SFO	319.9	> 1000	5.2	4.55×10^{-3}	o
Pond	DFOP	126.7	33.4	2.8	$k_1: 4.64 \times 10^{-3}$ $k_2: 1.73 \times 10^{-5}$	+
Pond	FOMC	79.6	- ⁵	5.2	4.42×10^{-2}	+
Sediment						
Rhine	SFO	570.9	> 1000	2.1	4.00×10^{-4}	o
Rhine	SFO	441.8	> 1000	3.4	1.26×10^{-3}	o
Pond		- ⁶	- ⁶	- ⁵	- ⁵	- ⁵
Pond		- ⁶	- ⁶	- ⁶	- ⁶	- ⁶

¹ SFO: single first order, FOMC: first order multi compartment, DFOP: double first order in parallel, HS: hockey stick
² for FOMC: worst case value of rate parameters alpha and beta
³ visual assessment: + = good, o = moderate
⁴ could not be calculated by the kinetic model
⁵ no clear dissipation observed, therefore no appropriate kinetic model could be selected
⁶ could not be calculated due to a too low number of data

III CONCLUSIONS

The calculated half-life for modelling purpose (geometric mean) for the degradation of trifloxystrobin in water/sediment systems under aerobic conditions in the dark in the laboratory was 0.76 days in the water, 2.45 days in the sediment and 1.69 days in the total system. The half-life of CGA 321113 for modelling purpose (geometric mean) was 209.7 days in the water, 502.2 days in the sediment and 388.0 days in the total system.

The calculated half-lives for trigger evaluation for the degradation of trifloxystrobin in water/sediment systems under aerobic conditions in the dark in the laboratory were between 0.6 and 0.9 days in the water, between 1.4 and 4.1 days in the sediment and between 1.1 and 2.6 days in the total system. The half-lives of CGA 321113 for trigger evaluation were between 79.6 and 320 days in the water, between 442 and 251 days in the sediment and between 341 and 433 days in the total system.

The results are included in the summary of the route and rate of degradation of trifloxystrobin and its major degradation products in water and sediment given in section CA 7.2.



CA 7.2.2.4 Irradiated water/sediment study

The route and rate of degradation of trifloxystrobin in water and sediment (including photolytic conditions) were comprehensively studied in sections CA 7.2.1.1 to CA 7.2.1.3 and CA 7.2.2.1 to CA 7.2.2.3. Therefore, the route and rate of degradation of trifloxystrobin in irradiated water/sediment systems were not studied. A summary of the route and rate of degradation of trifloxystrobin in water and sediment is given in section CA 7.2 and Figure 7.2- 1.

CA 7.2.3 Degradation in the saturated zone

The degradation of trifloxystrobin in the saturated zone was not studied since trifloxystrobin is not expected to reach the saturated zone after its use according to good agricultural practices. A summary of the route and rate of degradation of trifloxystrobin in water and sediment is given in section CA 7.2 and Figure 7.2- 1.

CA 7.3 Fate and behaviour in air

The volatilization of trifloxystrobin from bean leaves under indoor conditions was evaluated during the Annex I inclusion using one radiolabel position, [¹⁴C-GP] and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.3 /01	[REDACTED]	1997	M-033956-01-1

CA 7.3.1 Route and rate of degradation in air

The degradation rate of trifloxystrobin in air was evaluated during the Annex I inclusion using the Atkinson method, and was accepted by the European Commission (SANCO/4339/2000-Final, 7 April 2003). The following study is included in the Baseline Dossier:

Annex Point / Reference No	Author(s)	Year	Document No
KCA 7.3.1 /01	[REDACTED]	1997	M-033960-01-1

An additional Atkinson calculation has been performed for the major volatile degradation product CGA 107170 and is submitted within this Supplemental Dossier for the trifloxystrobin renewal of approval.

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Report:	KCA 7.3.1 /02; [REDACTED]; 2013
Title:	CGA 107170: Calculation of the Chemical Half-Life in the Troposphere
Report No:	EnSa-13-0667
Document No:	M-465896-01-1
Guidelines:	- Commission Regulation (EU) No 283/2013 in accordance with Regulation (EU) No 1107/2009 - US EPA OCSP Test Guideline: not applicable
GLP:	No
Justification:	New data / guideline requirement: Degradation rate of CGA 107170 in Air

Executive Summary

The half-life in air of CGA 107170, a volatile degradation product of trifloxystrobin, was estimated according to structure-activity relationship (SAR) methods developed by Atkinson *et al.*

The half-life in air was estimated with 34.9 days (long-term scenario) assuming the typical OH radical concentration averaged over 24 hours (0.5×10^6 radicals/cm³).

It is concluded that CGA 107170 will be degraded in air.

II. METHODS

The half-life of CGA 107170 in air was estimated according to structure-activity relationship (SAR) methods developed by Atkinson *et al.* The approach of Atkinson *et al.* was based on a comprehensive set of experimental data to result in a quantitative structure-activity relationship (QSAR) mathematic model that allows for estimation by calculation, starting from the molecular structure of a compound. The calculation procedure has been transferred into the personal computer program "Atmospheric Oxidation Program" (AOP) by Meylan & Howard. The current version AOPWIN™ 1.92a (U.S. EPA, 2008) was used for the calculations being part of the EPI Suite™ set of programs.

Considering the chemical structure of CGA 107170, it can be concluded that reactions with photochemically produced hydroxyl radicals will mainly determine its degradation rate in air. The typical OH radical concentration of 0.5×10^6 radicals/cm³ per day (24 hours) was taken for the long-term estimation.

III. RESULTS AND DISCUSSION

The overall reaction rate of CGA 107170 with hydroxyl radicals is estimated to be 0.4593×10^{-12} cm³ x molecule⁻¹ x s⁻¹. This rate is derived mainly from incremental reactions like hydrogen abstraction (0.1020×10^{-12} cm³ x molecule⁻¹ x s⁻¹) and an addition reaction to the aromatic ring (0.3573×10^{-12} cm³ x molecule⁻¹ x s⁻¹).

Based on the overall hydroxyl radical reaction rate constant in combination with the long-term concentration of these radicals in the atmosphere, i.e. 0.5×10^6 radicals/cm³, the half-life of CGA 107170 in air was estimated with 34.9 days. This estimate should be regarded as worst-case assumption as the approach does not consider the contribution of any other reactive species to the overall atmospheric degradation of CGA 107170 in air.

III. CONCLUSIONS

CGA 107170, a major volatile degradation product of trifloxystrobin, will be degraded in air with an estimated half-life of 34.9 days.



CA 7.3.2 Transport via air

The transport via air of trifloxystrobin was not studied since its vapour pressure is below the trigger value of 10^{-5} Pa.

CA 7.3.3 Local and global effects

Local and global effects of trifloxystrobin were not considered since its half-life in air is ≤ 2 days (See M-033960-01-1, Baseline Dossier, KCA 7.3.1 /01).

CA 7.4 Definition of the residue

CA 7.4.1 Definition of the residue for risk assessment

The proposed residue definitions relevant for risk assessment for each compartment are the following:

Compartment	Residue Definition
Soil	trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 381118, NOA 413161, NOA 413163, CGA 357276, NOA 409480
Groundwater	same as soil
Surface water	same as soil plus CGA 357262, CGA 107170, 2-hydroxymethylbenzotrile
Sediment	trifloxystrobin, CGA 321113
Air	trifloxystrobin, CGA 107170

CA 7.4.2 Definition of the residue for monitoring

The proposed residue definition for monitoring is trifloxystrobin only for all compartments since none of the major degradation products is of toxicological or ecotoxicological relevance.

CA 7.5 Monitoring data

Monitoring data from the literature review have been evaluated and are submitted within this Supplemental Dossier for the trifloxystrobin General of approval. Data were available for trifloxystrobin in air and for the major trifloxystrobin degradation products CGA 321113, NOA 413161 and NOA 413163 in groundwater and surface water and are summarized below:

The detected concentrations of the major trifloxystrobin degradation products CGA 321113, NOA 413161 and NOA 413163 in groundwater and surface water were always below the European Union drinking water and groundwater limit of 0.1 µg/L.

The detected concentrations of trifloxystrobin in air were very low and therefore of no toxicological or ecotoxicological relevance.

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Document MCA: Section 7 Fate and behaviour in the environment
Trifloxystrobin

Report:	KCA 7.5 /01; [REDACTED], T.; [REDACTED], L.; [REDACTED], U.; 2013
Title:	Emerging pesticide metabolites in groundwater and surface water as determined by the application of a multimethod for 150 pesticide metabolites
Report No:	M-462781-01-1
Document No:	M-462781-01-1
Guidelines:	None
GLP:	No, published study
Justification:	New data / guideline requirement: Literature review
Classification:	b) supplementary information (EFSA Journal 2011, 9(2):2092)

Executive Summary

The trifloxystrobin degradation products CGA 321113, NOA 413161 and NOA 413163 were determined in 58 groundwater and surface water samples by a multimethod comprising 150 pesticide degradation products in total.

The detected concentrations of CGA 321113, NOA 413161 and NOA 413163 were always below the European Union drinking water and groundwater limit of 0.1 µg/L whereas NOA 413161 was the most frequently detected trifloxystrobin degradation product compared to CGA 321113 and NOA 413163.

All detected pesticide degradation products were ranked separately in groundwater and surface water according to their concentration and frequency of detection. NOA 413161 was on rank 7 in groundwater but NOA 413161 is assessed as non-relevant for drinking water.

I. MATERIALS AND METHODS

A. MATERIALS

1. Standards

CGA 321113, NOA 413161 and NOA 413163 were provided by Bayer and were of certified quality.

2. Test Waters

58 water samples in total were used, 42 groundwater and 16 surface water samples. Samples of groundwater and surface water were received from the State Institute for Environment, Measurements and Nature Conservation Baden-Wuerttemberg (Karlsruhe, Germany) and the State Institute for Nature, Environment and Consumer Protection North Rhine Westfalia (Duesseldorf, Germany) in October 2009. A part of the groundwater wells were selected based on the previous determination of pesticide degradation products. Additionally samples of surface runoff from impervious urban areas were received from Berliner Wasser-Betriebe (Berlin, Germany).



B. STUDY DESIGN

1. Sampling

All samples were transported and kept cooled (approx. 7 °C).

2. Analytical Procedures

A multimethod was developed for the determination of 150 pesticide degradation products in groundwater and surface water by HPLC-MS/MS, including the trifloxystrobin degradation products CGA 321113, NOA 413161 and NOA 413163. Water samples were filtered and directly analysed by reversed phase HPLC-MS/MS in multiple reaction monitoring mode using standard addition at two concentration levels and matrix-matched three-point calibration curves. The method was validated using ultrapure water and drinking water as surrogate matrix. The lower limits of calibration in drinking water were 0.01 µg/L for CGA 321113 and 0.025 µg/L for NOA 413161 and NOA 413163. The limits of quantitation in ultrapure water were 0.01 µg/L for CGA 321113, NOA 413161 and NOA 413163.

II. RESULTS AND DISCUSSION

A. DATA

Table 7.5- 1: Summary of the concentration data obtained from 58 samples of groundwater and surface water (expressed in µg/L)

Compound	No of Detections	25 th Percentile	50 th Percentile	75 th Percentile
CGA 321113	2	0.000	0.001	-
NOA 413161	3	0.001	0.003	0.045
NOA 413163		0.002	0.008	0.012

B. FINDINGS

The detected concentrations of CGA 321113, NOA 413161 and NOA 413163 were always below the European Union drinking water and groundwater limit of 0.1 µg/L, whereas NOA 413161 was the most frequently detected trifloxystrobin degradation product compared to CGA 321113 and NOA 413163.

All detected pesticide degradation products were ranked separately in groundwater and surface water according to their concentration and frequency of detection. NOA 413161 was on rank 7 in groundwater but NOA 413161 is assessed as non-relevant for drinking water.

III. CONCLUSIONS

The detected concentrations of the major trifloxystrobin degradation products CGA 321113, NOA 413161 and NOA 413163 in groundwater and surface water were always below the European Union drinking water and groundwater limit of 0.1 µg/L.



Report:	KCA 7.5 /02; [REDACTED], C.; [REDACTED], E.; [REDACTED], B.; [REDACTED], A.; [REDACTED], R.; [REDACTED], M.; 2010
Title:	Temporal variations of concentrations of currently used pesticides in the atmosphere of Strasbourg, France
Report No:	M-457521-01-1
Document No:	M-457521-01-1
Guidelines:	None
GLP:	No, published study
Justification:	New data / guideline requirement: Literature review
Classification:	b) supplementary information (EFSA Journal 2011;9(2):2092)

Executive Summary

Trifloxystrobin was determined in atmospheric samples collected in Strasbourg, France, between April 17th and May 29th, 2007, by a multimethod comprising 70 pesticides in total.

The detected concentrations of trifloxystrobin ranged from 0.49 to 4.58 ng/m³ with an average of 2.62 ng/m³. Trifloxystrobin was mostly present in the gas phase with a gas/particle distribution of approximately 60:40.

Trifloxystrobin showed a statistically significant increase of its concentration in air with rising temperature ($r = 0.69$) and its high average concentrations suggest that it was applied during or just before the sampling period. This correlation indicates that trifloxystrobin volatilises from surfaces and that this volatilisation is strongly influenced by temperature.

I. MATERIALS AND METHODS

A. MATERIALS

1. Standards

Trifloxystrobin and teconazem, which was used as internal standard, were of certified quality (purity > 98%).

2. Test Site

Air samples were collected in Strasbourg with a high volume sampler, which was placed in the botanical garden of Strasbourg University, approximately 0.5 km from the town centre, 2 km from industrial zones and about 5 km from the first exploitation of high maize and cereal crops. Trifloxystrobin was not used in the botanical garden.

B. STUDY DESIGN

1. Experimental Conditions

A high volume sampler collected simultaneously particulate and gaseous samples on 30 cm (diameter) glass fibre filters and 20g XAD-2 resin, a copolymer of styrene/divinylbenzene and macroporous acrylic ester, at a flow rate of 9.96 L/min.

2. Sampling

Air samples were collected at 10 sampling intervals for 48 hour periods on average between April 17th and May 29th, 2007. After sampling, filters and resins were stored in the dark at -20 °C for a maximum of 4 days until extraction.



3. Analytical Procedures

Prior to sampling, the glass fibre filters and the XAD-2 resin were Soxhlet-cleaned for 24 hours with n-hexane/CH₂Cl₂ 1/1 and dried. After drying, they were individually wrapped in clean plastic bags or aluminium foil, and stored in the dark at -20 °C.

The extraction of the pesticides from the filters and the resin was done separately by Soxhlet extraction for 20 hours with n-hexane/CH₂Cl₂ 1/1. After extraction, the solvents were concentrated to approximately 1 mL in a rotary evaporator at 40 °C, and spiked with tecnazen, which was used as internal standard.

A multimethod was developed for the determination of 71 pesticides in air by GC-MS/MS or GC-ECD, including trifloxystrobin. Intraday and interday accuracies and variabilities were determined by spiking blank filters and resin samples with two different concentrations. The analysis has been performed on samples of particulate and gaseous phases, respectively. The results of both phases were combined to obtain the concentration found in the total atmosphere. The limit of detection in air was approximately 100 pg/m³ for trifloxystrobin.

II. RESULTS AND DISCUSSION

A. DATA

Table 7.5- 2: Summary of the concentration data obtained in 10 air samples (expressed in ng/m³)

Compound	No of Detections	Range	Average ± 95% CI ¹
trifloxystrobin	10	0.49 to 4.58	2.62 ± 1.44

CI: confidence interval

¹ Average and CI were calculated from the arithmetic mean and standard deviation of samples with concentration superior to the LOD.

B. FINDINGS

The detected concentrations of trifloxystrobin ranged from 0.49 to 4.58 ng/m³ with an average of 2.62 ng/m³. Trifloxystrobin was mostly present in the gas phase with a gas-particle distribution of approximately 60:40.

Trifloxystrobin showed a statistically significant increase of its concentration in air with rising temperature (r = 0.69) and its high average concentrations suggest that it was applied during or just before the sampling period. This correlation indicates that trifloxystrobin volatilises from surfaces and that this volatilisation is strongly influenced by temperature.

III. CONCLUSIONS

The detected concentrations of trifloxystrobin in air were very low and therefore of no toxicological or ecotoxicological relevance.

The distribution between gas and particle phase and therefore the suggested volatilisation of trifloxystrobin from surfaces is questionable due to the study design, which is overestimating the gas phase concentrations (e.g. sampling of aerosols from spraying as false-positive indication for volatilisation or artificial extraction of particles during the sampling period of 48 hours due to the high volume sampler), and because the vapour pressure of trifloxystrobin is < 10⁻⁵ Pa (see section CA 7.3.2).