European Commission

Draft Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

BAS 750F
(Mefentrifluconazole)

Volume 3 – B.8 (AS)

Rapporteur Member State: United Kingdom
Co-Rapporteur Member State: France & Austria

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Table of contents

B.8. ENVIRONMENTAL FATE AND BEHAVIOUR 4

B.8.1. FATE AND BEHAVIOUR IN SOIL 6

B.8.1.1. Route and rate of degradation in soil 6
B.8.1.2. Adsorption and desorption in soil 185
B.8.1.3. Mobility in soil 195
B.8.1.4. Summary of fate and behaviour in soil 203
B.8.1.5. Assessment of Persistence in soil 205

B.8.2. FATE AND BEHAVIOUR IN WATER AND SEDIMENT 206

B.8.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation) 206
B.8.2.2. Route and rate of biological degradation in aquatic systems 226
B.8.2.3. Degradation in the saturated zone 264
B.8.2.4. Potential effects of water treatment processes 265
B.8.2.5. Summary of fate and behaviour in water 267
B.8.2.6. Assessment of persistence in water and sediment 269

B.8.3. FATE AND BEHAVIOUR IN AIR 270

B.8.3.1. Route and rate of degradation in air 270
B.8.3.2. Transport via air 271
B.8.3.3. Local and global effects 271
B.8.3.4. Summary of fate and behaviour in air 271

B.8.4. MONITORING DATA CONCERNING FATE AND BEHAVIOUR OF THE ACTIVE SUBSTANCE, METABOLITES, DEGRADATION AND REACTION PRODUCTS 271

B.8.5. REFERENCES RELIED ON 272

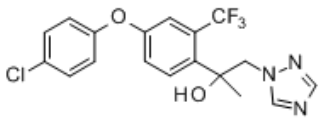
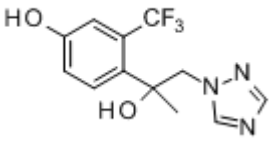
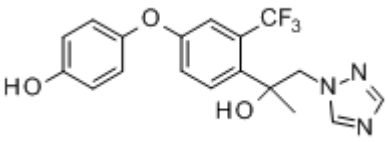
B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

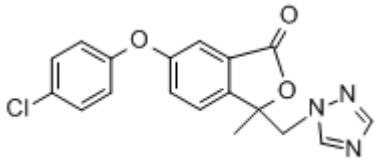
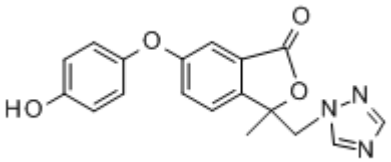
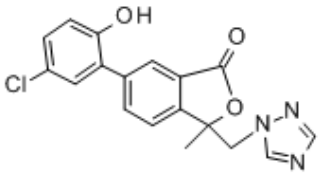
Unless stated otherwise, all studies were conducted in accordance with requirements contained within Regulation (EC) 1107/2009 and are considered to be acceptable by the RMS. Studies were performed to investigate the environmentally relevant properties of BAS 750 F using one of three different C-14 labeled compounds representing each ring system of BAS 750 F: chlorophenyl, triazole and trifluoromethylphenyl. However, the RMS notes that the trifluoromethylphenyl ring was only radio-labelled in two studies (a laboratory aerobic degradation study and a water/sediment study); the chlorophenyl and triazole rings were labelled in all the other studies (with the exception of the ready biodegrability study where non-radiolabelled BAS 750 F was used). In order to fully and confidently assess the degradation behaviour of BAS 750 F, the RMS is of the opinion that the Applicant should have radio-labelled the trifluoromethylphenyl ring in each of the studies. However, because generally high material balances could be recovered for the studies where the trifluoromethylphenyl ring had not been radio-labelled, the RMS is of the opinion that all relevant degradation pathways have been identified. Therefore, the RMS accepts the Applicant's labelling approach; however, in future studies, the RMS recommends the Applicant labels all ring structures.

A literature review was performed on the parent molecule and the soil and aquatic metabolites. No reference in the literature was found for BAS 750 F, this is not unexpected as it is a new active substance. References were found for 1,2,4-triazole, a common metabolite in azole fungicides, fertilisers and a natrurally occurring molecule. However, none were found to be relevant for this dossier submission or add to the overall risk assessment (see section B.8.5).

An overview of the metabolites discussed in this section are presented within Table 8.1.

Table 8.1: Active substance and metabolites from environemtnal fate and behaviour studies

Metabolite Code	Reg number	Compartments assessed	Structure
BAS 750 F	5834378	Soil Surface Water Ground Water Air	
M759F001 (1,2,4-triazole)	87084	Soil Surface Water Ground Water	
M750F003	5924326	Surface Water	
M750F005	6003433	Surface Water	

M750F006	5863469	Surface Water	
M750F007	6003432	Surface Water	
M750F008	6010286	Surface Water	

B.8.1. FATE AND BEHAVIOUR IN SOIL

B.8.1.1. Route and rate of degradation in soil

B.8.1.1.1. Aerobic degradation

Report:	**KCA 7.1.1.1/001, Staudenmaier, H. and Dalkmann, P., (2015a)**
Title:	Aerobic soil metabolism of BAS 750 F
Report No &	430697
Document No	2014/1275177
Guidelines:	- OECD: Guideline 307, Aerobic and Anaerobic Transformation in Soil, 2002 - EPA 835.4100
GLP	Yes

Introduction

An aerobic soil route and rate of degradation study was conducted according to OECD guidelines (OECD 307: Aerobic and Anaerobic Transformation in Soil). This was conducted under aerobic conditions at 20 °C in two soils by incubation in the dark for 120 days (New Jersey soil) and 121 days (LUFA 5M soil). The study was conducted to GLP and according to OECD 307 guidelines. Deviations from the guidelines did occur (see 'Results and discussion' section for further information), however, these were not deemed significant enough to affect the outcomes of the study.

Test procedure

The soil was collected from the field according to OECD 307 and kept at room temperature until sieving. The soil was passed through a 2 mm sieve, remoistened to approximately 7 - 15 % soil moisture and stored at approximately 4 °C in the dark for no longer than 3 months before use. Table 8.1.1.1-1 gives details of the soil and site characteristics.

Table 8.1.1.1-1 Characterisation of test soils

Soil name	**LUFA 5M** **BASF soil No. 13/1651/02**	**New Jersey** **BASF soil No. 13/1720/01**
Date of collection	23/04/2013	27/03/2013
Sampling location	Germany (Origin LUFA Speyer)	Unites States (Frenchtown, New Jersey)
GPS coordinates	49°16'19.33" N 8°24'15.77" E	Latitude: 40.54487 Longitude: -74.99286
Previous pesticide use	None in last 5 years	None in last 5 years
Sampling depth	0 – 20 cm	15 cm
DIN 4220 Particle size distribution *[%]* sand 0.063 – 2 mm silt 0.002 – 0.063 mm clay < 0.002 mm textural class	 80.0 13.9 6.1 loamy sand (Sl2)	 n.d. n.d. n.d. n.d.
USDA Particle size distribution *[%]* sand 0.050 – 2 mm silt 0.002 – 0.050 mm clay < 0.002 mm textural class	 82.8 11.1 6.1 loamy sand	 29 49 22 loam
Organic C *[%]*	2.03	1.33
Organic matter [%][a]	3.50	2.29
pH [H_2O] pH [$CaCl_2$]	7.9 7.2	6.9 n.d.
cation exchange capacity *[$cmol^+ kg^{-1}$]*	11.4	9.1
Max. water holding capacity *[g /100 g dry weight]*	25.2	37.0
Moisture at field capacity (pF2) *[g /100 g dry weight]*	21.4	n.d.[c]
microbial biomass (from certificate) *[mg C/100 g dry soil]*	26.5	51.7
microbial biomass (after 60/62 days of incubation) *[mg C/100 g dry soil]* [b]	23.6	40.4
microbial biomass (after 120/123 days of incubation) *[mg C/100 g dry soil]* [b]	19.8	34.6

n.d. = Not determined
[a] Organic matter = organic C * 1.724
[b] Determined at BASF test facility Limburgerhof
[c] Only moisture at 1/3 bar (pF2.5) was provided – 23.5 *g /100 g dry weight*

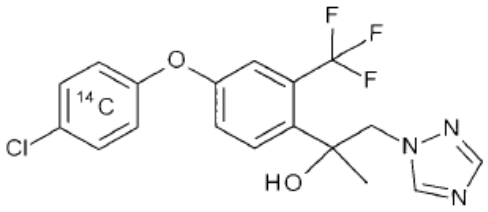
The test item BAS 750 F was used in two ^{14}C-labelled forms.

Internal code:	BAS 750 F
Reg. No.:	5834378
CAS No.:	1417782-03-6
Chemical name (IUPAC):	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molecular mass:	397.78 g mol^{-1}
Molecular formula:	$C_{18}H_{15}ClF_3N_3O_2$

1. Chlorophenyl-U-^{14}C-label (in the following referred to as "chlorophenyl"-label)

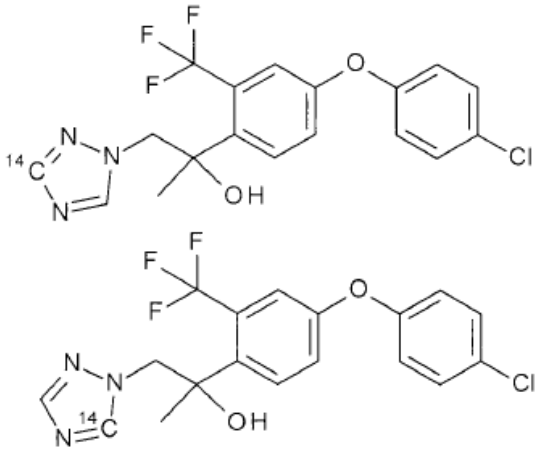
Batch No.:	CFQ41561
Specific radioactivity of a.s.:	7.878 MBq mg^{-1}

Radiochemical purity: 98.9 %
Purity: 99.1 %
Chemical structure:



2. Triazole-3(5)-^{14}C-label (in the following referred to as "triazole"-label)

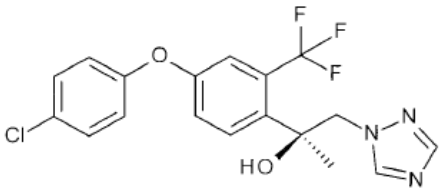
Batch No.: 1062-2001
Specific radioactivity of a.s.: 5.46 MBq mg^{-1}
Radiochemical purity: 98.8 %
Purity: 98.9 %
Chemical structure:



Both of these radiolabelled substances were applied as a racemic mixture (50:50) of enantiomers (S- and R-enantiomer) in the test:

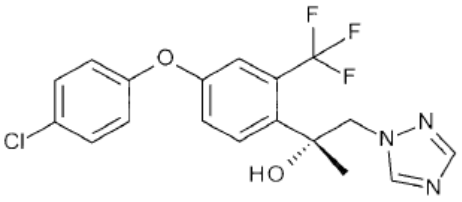
1. (2S)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol (in the following referred to as "S-enantiomer")

Reg. No.: 5934588
Batch No.: L84-256
Chemical purity: 99.5 %
Ratio of isomers: S-enantiomer : R-enantiomer = 100 : 0
Chemical structure:



2. (2S)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol (in the following referred to as "R-enantiomer")

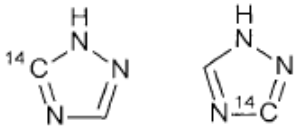
Reg. No.:	5934591
Batch No.:	L84-254
Chemical purity:	98.9 %
Ratio of isomers:	R-enantiomer : S-enantiomer = 99.7 : 0.3
Chemical structure:	



Other reference items used in the study:

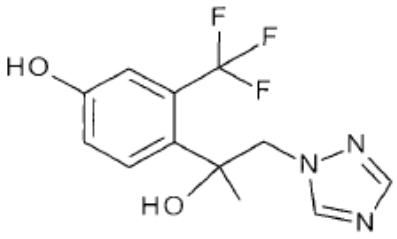
1. [triazole-3(5)-^{14}C]-1,2,4-(1H)-triazole (M750F001)

Reg. No.:	87084
CAS-No.:	288-88-0
Batch No.:	QBC146_B12140-12111
Position of radiolabel	triazole-3(5)-^{14}C
Specific radioactivity:	29.7 MBq/mg (1782000 dpm/µg)
Radiochemical purity:	> 99.9 %
Chemical structure:	



2. M750F003

Reg. No.:	5924326
Batch No.:	L84-250
Chemical name (IUPAC):	4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenol
Molecular weight:	287.2 g/mol
Chemical purity:	99.6 %
Chemical structure:	



The test item (both labels) was applied at a nominal concentration of 0.4 mg ^{14}C-BAS 750 per kg dry soil which corresponds to a field application rate of 150 g a.s. ha^{-1} (calculated on the basis of an equal distribution in the top 2.5 cm soil layer and a soil density of 1.5 g cm^{-3}). This application rate is considered acceptable by the UK RMS. Additional samples were dosed at the higher rate of approximately 4 mg a.s./kg dry soil to aid in the identification of unknown metabolites. Data from these incubations are not presented in the study report, so they have not be discussed further in this evaluation. Portions of 100 g soil (dry weight basis) were then filled into test vessels.

The chlorophenyl-label treatment solution was prepared by dissolving 3.7 mg of [chlorophenyl-U-^{14}C]-BAS 750 F in acetonitrile. This was transferred to a 5 mL volumetric flask and made up to the volume with acetonitrile. The exact concentration was determined by liquid scintillation counting (LSC) (5 repeats). The radiochemical purity of the treatment solution was determined to be 98.8 % and 99.3 % (measured before the treatment of New Jersey and LUFA 5M soils, respectively).

The triazole-label treatment solution was prepared by dissolving 4.0 mg of [triazole-3(5)-^{14}C]-BAS 750 F in acetonitrile. This was transferred to a 5 mL volumetric flask and made up to the volume with acetonitrile. The exact concentration was determined by liquid scintillation counting (LSC) (5 repeats). The radiochemical purity of the treatment solution was determined to be 100.0 % (measured before the treatment of New Jersey and LUFA 5M soils).

The test vessels were connected in line with aeration tubes and the samples were continuously aerated with a slight stream of moistened synthetic air. The air was passed through a bottle containing NaOH to remove carbon dioxide before it reached the test vessels. Three gas washing flasks containing ethylene glycol, 0.5 M H_2SO_4, and 0.5 M NaOH were used to trap volatiles. The treated soils were incubated at 40 % of the maximum water holding capacity and 20 ± 2 °C in the dark.

To determine the microbial biomass at 0, 60/62 and 120/123 days after treatment (DAT), an additional soil portion was treated with acetonitrile (without test item) and incubated under the same conditions as the treated soils. The microbial biomass declined over the incubation phase (see Table 8.1.1.1-1). However, the results demonstrate that the soil was still viable and microbially active at days 60/62 and 120/123 (end) of the study.

For New Jersey soil (both labels) and LUFA 5M soil (triazole label), duplicate samples of each soil type were taken for analysis immediately after application, and after 1, 3, 7, 14, 30, 58, 90 and 121 DAT. These sample timings were also followed for LUFA 5M soil (chlorophenyl label) except that the 58 DAT samples were replaced by sampling at 62 DAT.

For the determination of the extractable radioactive residues (ERR), soil samples were consecutively extracted twice with acetonitrile (ACN), twice with ACN/water (80/20; v/v), and twice with ACN/water (50/50; v/v). After each extraction step, the sample was centrifuged at 10,000 rpm for 15 minutes. Each extract was analysed for radioactivity by liquid scintillation counting (LSC). The ACN-extracts as well as the ACN/water-extracts were pooled and each solution was concentrated. The residues were then re-dissolved in a well-defined volume of solvent and analysed by radio HPLC.

For chlorophenol-^{14}C-BAS 750 F, the limit of detection (LOD) and limit of quantification (LOQ) of the LSC instrument was 0.015 % total applied radioactivity (TAR) and 0.023 % TAR, respectively (background 0.08 % TAR). For the HPLC instrument, the LOQ was 0.025 % TAR and the LOD was not given.

For triazole-^{14}C-BAS 750 F, the limit of detection (LOD) and limit of quantification (LOQ) of the LSC instrument was 0.022 % total applied radioactivity (TAR) and 0.033 % TAR, respectively (background 0.011 % TAR). For the HPLC instrument, the LOQ was 0.031 % TAR and the LOD was not given.

Results and discussion

The overall mean recoveries of total applied radioactivity (TAR) were in the range 94.9 – 101.7 %, which falls within the guideline values stated in OECD 307 (tables 8.1.1.1-2 - 8.1.1.1-5).

Table 8.1.1.1-2 **Recovery and distribution of radioactivity in LUFA 5M soil after treatment with chlorophenyl-^{14}C-labelled BAS 750 F [% TAR]**

Days after treatment	Extractable residues				NER	Volatiles [a]			Material balance
	ACN	ACN/H_2O (80/20)	ACN/H_2O (50/50)	Total		CO_2	Others [b]	Total	
0	89.8	8.7	0.8	99.3	1.0	n.a.	n.a.	n.a.	100.3
0	88.5	9.4	0.9	98.7	1.0	n.a.	n.a.	n.a.	99.7
0 (mean)	**89.1**	**9.0**	**0.8**	**99.0**	**1.0**	**-**	**-**	**-**	**100.0**
3	87.0	9.5	1.3	97.8	2.6	0.2	0.0	0.2	100.6
3	86.6	9.6	1.3	97.5	2.7	0.2	0.0	0.2	100.3
3 (mean)	**86.8**	**9.5**	**1.3**	**97.6**	**2.7**	**0.2**	**0.0**	**0.2**	**100.4**
7	84.6	10.0	1.6	96.2	3.6	0.4	0.0	0.4	100.2
7	84.9	10.1	1.6	96.6	3.7	0.4	0.0	0.4	100.7
7 (mean)	**84.8**	**10.0**	**1.6**	**96.4**	**3.6**	**0.4**	**0.0**	**0.4**	**100.5**
14	83.7	9.1	1.8	94.6	4.9	0.8	0.0	0.8	100.3
14	82.9	9.2	1.9	94.0	5.0	0.8	0.0	0.8	99.8
14 (mean)	**83.3**	**9.2**	**1.8**	**94.3**	**4.9**	**0.8**	**0.0**	**0.8**	**100.0**
30	79.0	9.4	2.0	90.4	6.9	1.5	0.0	1.5	98.8
30	79.3	10.1	2.1	91.5	7.1	1.5	0.0	1.5	100.0
30 (mean)	**79.2**	**9.7**	**2.0**	**90.9**	**7.0**	**1.5**	**0.0**	**1.5**	**99.4**
62	74.4	9.9	2.4	86.7	9.9	2.6	0.0	2.6	99.3
62	74.5	10.2	2.4	87.1	10.1	2.6	0.0	2.6	99.8
62 (mean)	**74.5**	**10.1**	**2.4**	**86.9**	**10.0**	**2.6**	**0.0**	**2.6**	**99.5**
90	71.8	9.9	2.5	84.2	11.3	3.6	0.0	3.6	99.1
90	71.9	10.1	2.6	84.6	11.6	3.6	0.0	3.6	99.8
90 (mean)	**71.9**	**10.0**	**2.6**	**84.4**	**11.4**	**3.6**	**0.0**	**3.6**	**99.4**
121	69.0	10.3	2.7	82.0	12.8	4.7	0.0	4.7	99.4
121	69.5	10.6	2.8	82.8	12.6	4.7	0.0	4.7	100.0
121 (mean)	**69.2**	**10.4**	**2.8**	**82.4**	**12.7**	**4.7**	**0.0**	**4.7**	**99.7**

TAR = Total applied radioactivity (100 % = 0.418 mg kg^{-1})

n.a. = Not available

[a] Cumulative values

[b] Sum of H_2SO_4 and ethylene glycol trap

Table 8.1.1.1-3 **Recovery and distribution of radioactivity in LUFA 5M soil after treatment with triazole-^{14}C-labelled BAS 750 F [% TAR]**

Days after treatment	Extractable residues				NER	Volatiles [a]			Material balance
	ACN	ACN/H_2O (80/20)	ACN/H_2O (50/50)	Total		CO_2	Others [b]	Total	
0	88.2	10.0	0.9	99.1	0.9	n.a.	n.a.	n.a.	100.0
0	89.7	8.6	0.8	99.1	0.9	n.a.	n.a.	n.a.	100.0
0 (mean)	**88.9**	**9.3**	**0.8**	**99.1**	**0.9**	**-**	**-**	**-**	**100.0**
3	87.2	9.4	1.3	97.9	2.8	0.0	0.0	0.0	100.7
3	85.4	9.6	1.3	96.4	2.8	0.0	0.0	0.0	99.2
3 (mean)	**86.3**	**9.5**	**1.3**	**97.2**	**2.8**	**0.0**	**0.0**	**0.0**	**100.0**
7	84.8	10.1	1.6	96.4	3.8	0.1	0.0	0.1	100.3
7	84.4	10.1	1.6	96.1	3.8	0.1	0.0	0.1	100.0
7 (mean)	**84.6**	**10.1**	**1.6**	**96.3**	**3.8**	**0.1**	**0.0**	**0.1**	**100.2**
14	82.7	9.1	1.9	93.8	5.5	0.1	0.0	0.1	99.3
14	82.5	9.2	1.9	93.6	5.5	0.1	0.0	0.1	99.2
14 (mean)	**82.6**	**9.2**	**1.9**	**93.7**	**5.5**	**0.1**	**0.0**	**0.1**	**99.3**
30	78.9	9.9	2.1	91.0	8.1	0.1	0.0	0.1	99.2
30	79.7	10.0	2.2	91.9	8.3	0.1	0.0	0.1	100.3
30 (mean)	**79.3**	**10.0**	**2.1**	**91.5**	**8.2**	**0.1**	**0.0**	**0.1**	**99.8**
58	76.3	9.9	2.4	88.5	12.4	0.1	0.0	0.1	101.0
58	74.4	10.1	2.4	86.9	12.5	0.1	0.0	0.1	99.5
58 (mean)	**75.3**	**10.0**	**2.4**	**87.7**	**12.4**	**0.1**	**0.0**	**0.1**	**100.3**
90	71.6	10.0	2.8	84.4	14.9	0.2	0.0	0.2	99.4
90	72.3	10.1	2.8	85.2	15.0	0.2	0.0	0.2	100.4
90 (mean)	**71.9**	**10.1**	**2.8**	**84.8**	**14.9**	**0.2**	**0.0**	**0.2**	**99.9**
121	68.7	10.4	3.0	82.1	17.5	0.2	0.0	0.2	99.8
121	68.2	10.5	3.0	81.7	18.2	0.2	0.0	0.2	100.2
121 (mean)	**68.4**	**10.5**	**3.0**	**81.9**	**17.9**	**0.2**	**0.0**	**0.2**	**100.0**

TAR = Total applied radioactivity (100 % = 0.420 mg kg^{-1})

n.m. = Not available

[a] Cumulative values

[b] Sum of H_2SO_4 and ethylene glycol trap

Table 8.1.1.1-4 **Recovery and distribution of radioactivity in New Jersey soil after treatment with chlorophenyl-^{14}C-labelled BAS 750 F [% TAR]**

Days after treatment	Extractable residues				NER	Volatiles [a]			Material balance
	ACN	ACN/H_2O (80/20)	ACN/H_2O (50/50)	Total		CO_2	Others [b]	Total	
0	90.8	7.3	0.7	98.9	0.8	n.a.	n.a.	n.a.	99.7
0	91.3	7.5	0.7	99.5	0.8	n.a.	n.a.	n.a.	100.3
0 (mean)	**91.0**	**7.4**	**0.7**	**99.2**	**0.8**	**-**	**-**	**-**	**100.0**
3	83.9	9.5	1.5	94.8	3.4	0.3	0.0	0.3	98.6
3	86.4	8.9	1.8	97.1	3.5	0.3	0.0	0.3	100.9
3 (mean)	**85.1**	**9.2**	**1.7**	**96.0**	**3.5**	**0.3**	**0.0**	**0.3**	**99.7**
7	81.3	8.5	1.7	91.5	5.0	0.9	0.0	0.9	97.4
7	80.3	8.7	1.7	90.7	5.1	0.9	0.0	0.9	96.6
7 (mean)	**80.8**	**8.6**	**1.7**	**91.1**	**5.0**	**0.9**	**0.0**	**0.9**	**97.0**
14	77.2	10.2	2.3	89.6	6.9	1.7	0.0	1.7	98.2
14	77.2	10.0	1.7	88.9	6.7	1.7	0.0	1.7	97.3
14 (mean)	**77.2**	**10.1**	**2.0**	**89.2**	**6.8**	**1.7**	**0.0**	**1.7**	**97.7**
30	70.7	9.6	2.8	83.1	10.8	3.3	0.0	3.3	97.2
30	71.6	9.1	2.7	83.4	10.7	3.3	0.0	3.3	97.4
30 (mean)	**71.1**	**9.4**	**2.8**	**83.2**	**10.7**	**3.3**	**0.0**	**3.3**	**97.3**
58	64.2	8.6	2.5	75.3	14.6	5.5	0.0	5.5	95.4
58	66.3	8.9	2.4	77.7	14.8	5.5	0.0	5.5	98.0
58 (mean)	**65.3**	**8.8**	**2.4**	**76.5**	**14.7**	**5.5**	**0.0**	**5.5**	**96.7**
90	59.6	9.5	3.3	72.4	17.1	7.6	0.0	7.6	97.1
90	58.5	9.1	3.1	70.8	16.9	7.6	0.0	7.6	95.3
90 (mean)	**59.1**	**9.3**	**3.2**	**71.6**	**17.0**	**7.6**	**0.0**	**7.6**	**96.2**
120	55.3	8.5	3.0	66.8	19.7	9.7	0.0	9.7	96.2
120	53.0	8.5	3.0	64.5	19.3	9.7	0.0	9.7	93.5
120 (mean)	**54.1**	**8.5**	**3.0**	**65.7**	**19.5**	**9.7**	**0.0**	**9.7**	**94.9**

TAR = Total applied radioactivity (100 % = 0.421 mg kg^{-1})

n.m. = Not available

[a] Cumulative values

[b] Sum of H_2SO_4 and ethylene glycol trap

Table 8.1.1.1-5 **Recovery and distribution of radioactivity in New Jersey soil after treatment with triazole-^{14}C-labelled BAS 750 F [% TAR]**

Days after treatment	Extractable residues				NER	Volatiles [a]			Material balance
	ACN	ACN/H_2O (80/20)	ACN/H_2O (50/50)	Total		CO_2	Others [b]	Total	
0	92.1	7.6	0.8	100.5	0.6	n.a.	n.a.	n.a.	101.0
0	90.2	7.5	0.8	98.5	0.5	n.a.	n.a.	n.a.	99.0
0 (mean)	**91.2**	**7.5**	**0.8**	**99.5**	**0.5**	**-**	**-**	**-**	**100.0**
3	85.9	9.9	1.7	97.5	3.3	0.0	0.0	0.0	100.8
3	86.3	10.0	1.9	98.2	3.4	0.0	0.0	0.0	101.6
3 (mean)	**86.1**	**10.0**	**1.8**	**97.8**	**3.3**	**0.0**	**0.0**	**0.0**	**101.2**
7	84.8	9.8	2.1	96.7	5.2	0.1	0.0	0.1	102.0
7	83.2	9.4	1.9	94.5	4.9	0.1	0.0	0.1	99.5
7 (mean)	**84.0**	**9.6**	**2.0**	**95.6**	**5.0**	**0.1**	**0.0**	**0.1**	**100.7**
14	79.5	11.5	2.1	93.1	6.9	0.1	0.0	0.1	100.1
14	82.3	11.4	2.3	96.0	7.1	0.1	0.0	0.1	103.2
14 (mean)	**80.9**	**11.4**	**2.2**	**94.6**	**7.0**	**0.1**	**0.0**	**0.1**	**101.7**
30	72.4	11.0	3.4	86.7	12.6	0.2	0.0	0.2	99.5
30	73.0	10.5	3.5	87.0	12.5	0.2	0.0	0.2	99.7
30 (mean)	**72.7**	**10.7**	**3.4**	**86.9**	**12.6**	**0.2**	**0.0**	**0.2**	**99.6**
58	67.1	10.9	3.5	81.6	19.1	0.3	0.0	0.3	100.9
58	64.9	10.9	3.3	79.1	18.3	0.3	0.0	0.3	97.6
58 (mean)	**66.0**	**10.9**	**3.4**	**80.3**	**18.7**	**0.3**	**0.0**	**0.3**	**99.3**
90	60.6	11.2	4.1	75.8	24.1	0.4	0.0	0.4	100.3
90	58.5	11.4	4.1	74.0	23.3	0.4	0.0	0.4	97.7
90 (mean)	**59.5**	**11.3**	**4.1**	**74.9**	**23.7**	**0.4**	**0.0**	**0.4**	**99.0**
120	58.4	11.2	4.2	73.8	26.6	0.5	0.0	0.5	101.0
120	57.5	11.1	4.2	72.8	26.7	0.5	0.0	0.5	100.0
120 (mean)	**57.9**	**11.2**	**4.2**	**73.3**	**26.7**	**0.5**	**0.0**	**0.5**	**100.5**

TAR = Total applied radioactivity (100 % = 0.416 mg kg^{-1})

n.m. = Not available

[a] Cumulative values

[b] Sum of H_2SO_4 and ethylene glycol trap

In LUFA 5M soil, amounts of BAS 750 F declined from an average of 98.2 % TAR (day 0) to an average of 80.8 % TAR after 120 days for the chlorophenyl-label and from 98.9 % to 81.2 % TAR for the triazole-label (table 8.1.1.1-6). Several metabolites were detected, none of them exceeding 0.8 % TAR at any sampling time for soil samples treated with the chlorophenyl-labelled test item (sum of metabolites ≤ 1.6 % TAR). Metabolites detected in extracts of soil samples treated with the triazole-labelled test item were formed in low amounts as well. Metabolites M750F001 and M750F003 were detected in maximum amounts of 0.5 % TAR (121 DAT) and 0.6 % TAR (14 DAT). None of the other metabolites exceeded 0.2 % TAR with the triazole-label (mean of two replicates; sum of metabolites ≤ 0.6 % TAR).

In New Jersey soil, amounts of BAS 750 F declined from an average of 98.3 % TAR (day 0) to an average of 63.3 % TAR after 120 days for the chlorophenyl-label and from 99.2 % to 67.4 % TAR for the triazole-label (table 8.1.1.1-7). Metabolites M750F001 and M750F003 were exclusively detected in soil samples treated with the triazole-labelled test item, reaching maximum amounts of 5.1 % (90 DAT) and 1.4 % TAR (14 DAT). A number of other metabolites were detected in the soil extracts, none of them exceeding 1.2 % TAR (both labels) at any sampling time. The sum of other metabolites never exceeded 2.2 % TAR (chlorophenyl-label) and 0.5 % TAR (triazole-label).

Table 8.1.1.1-6 **Radio-HPLC analysis of soil extracts: after treatment of LUFA 5M soil with ^{14}C-labelled BAS 750 F (sum of ACN and ACN/water extracts [% TAR], LC188, gradient 02).**

chlorophenyl-^{14}C-label				triazole-^{14}C-label					
DAT	**ERR (total)**	**42.3 min BAS 750 F**	**sum others [a]**	**DAT**	**ERR (total)**	**7.2 min M750F001**	**29.9 min M750F003**	**42.3 min BAS 750 F**	**sum others [b]**
0	99.3	98.4	0.9	0	99.1	0.1	-	98.9	0.1
0	98.7	97.9	0.8	0	99.1	0.2	-	98.9	0.0
0 (mean)	**99.0**	**98.2**	**0.9**	**0 (mean)**	**99.1**	**0.1**	**-**	**98.9**	**0.0**
3	97.8	96.1	1.6	3	97.9	0.1	0.1	97.8	0.0
3	97.5	96.9	0.5	3	96.4	0.1	0.1	96.1	0.0
3 (mean)	**97.6**	**96.5**	**1.1**	**3 (mean)**	**97.2**	**0.1**	**0.1**	**96.9**	**0.0**
7	96.2	94.7	1.5	7	96.4	0.1	0.6	95.7	0.0
7	96.6	95.0	1.6	7	96.1	0.1	0.5	95.4	0.0
7 (mean)	**96.4**	**94.9**	**1.5**	**7 (mean)**	**96.3**	**0.1**	**0.6**	**95.6**	**0.0**
14	94.6	93.5	1.1	14	93.8	0.1	0.5	93.1	0.0
14	94.0	93.2	0.8	14	93.6	0.1	0.6	92.9	0.0
14 (mean)	**94.3**	**93.4**	**0.9**	**14 (mean)**	**93.7**	**0.1**	**0.6**	**93.0**	**0.0**
30	90.4	89.4	1.0	30	91.0	0.2	0.6	89.6	0.6
30	91.5	90.6	0.9	30	91.9	0.2	0.5	91.0	0.2
30 (mean)	**90.9**	**90.0**	**0.9**	**30 (mean)**	**91.5**	**0.2**	**0.5**	**90.3**	**0.4**
62	86.7	85.9	0.9	58	88.5	0.3	0.2	87.9	0.2
62	87.1	86.3	0.8	58	86.9	0.3	0.2	86.2	0.2
62 (mean)	**86.9**	**86.1**	**0.8**	**58 (mean)**	**87.7**	**0.3**	**0.2**	**87.0**	**0.2**
90	84.2	82.9	1.2	90	84.4	0.4	0.2	83.6	0.2
90	84.6	83.4	1.2	90	85.2	0.4	0.1	84.5	0.2
90 (mean)	**84.4**	**83.2**	**1.2**	**90 (mean)**	**84.8**	**0.4**	**0.2**	**84.0**	**0.2**
121	82.0	80.4	1.6	121	82.1	0.5	-	81.4	0.2
121	82.8	81.2	1.6	121	81.7	0.6	-	81.0	0.1
121 (mean)	**82.4**	**80.8**	**1.6**	**121 (mean)**	**81.9**	**0.5**	**-**	**81.2**	**0.2**

DAT = Days after treatment

TAR = Total applied radioactivity (100 % = 0.418 mg kg^{-1} (chlorophenyl-label), 0.420 mg kg^{-1} (triazole-label)

ERR = Extractable radioactive residues

[a] ≤ 0.8 % TAR each for single metabolite (mean of two replicates)

[b] ≤ 0.2 % TAR each for single metabolite (mean of two replicates)

Table 8.1.1.1-7 **Radio-HPLC analysis of soil extracts: after treatment of New Jersey soil with ^{14}C-labelled BAS 750 F (sum of ACN and ACN/water extracts [% TAR], LC188, gradient 02).**

chlorophenyl-^{14}C-label				triazole-^{14}C-label					
DAT	**ERR (total)**	**42.3 min BAS 750 F**	**sum others [a]**	**DAT**	**ERR (total)**	**7.2 min M750F001**	**29.9 min M750F003**	**42.3 min BAS 750 F**	**sum others [b]**
0	98.9	98.3	0.6	0	100.5	0.2	-	100.2	0.0
0	99.5	98.3	1.2	0	98.5	0.3	-	98.2	0.0
0 (mean)	**99.2**	**98.3**	**0.9**	**0 (mean)**	**99.5**	**0.2**	**-**	**99.2**	**0.0**
3	94.8	93.7	1.1	3	97.5	0.4	0.5	96.5	0.0
3	97.1	96.1	1.0	3	98.2	0.5	0.7	97.0	0.1
3 (mean)	**96.0**	**94.9**	**1.1**	**3 (mean)**	**97.8**	**0.4**	**0.6**	**96.7**	**0.1**
7	91.5	90.6	0.9	7	96.7	1.3	1.2	93.4	0.9
7	90.7	89.6	1.1	7	94.5	1.1	1.1	92.2	0.1
7 (mean)	**91.1**	**90.1**	**1.0**	**7 (mean)**	**95.6**	**1.2**	**1.1**	**92.8**	**0.5**
14	89.6	88.1	1.4	14	93.1	2.0	1.3	89.7	0.1
14	88.9	87.8	1.1	14	96.0	1.7	1.5	92.8	0.1
14 (mean)	**89.2**	**88.0**	**1.3**	**14 (mean)**	**94.6**	**1.8**	**1.4**	**91.3**	**0.1**
30	83.1	81.7	1.3	30	86.7	2.7	1.1	82.9	0.1
30	83.4	82.1	1.3	30	87.0	2.4	1.2	83.3	0.1
30 (mean)	**83.2**	**81.9**	**1.3**	**30 (mean)**	**86.9**	**2.6**	**1.2**	**83.1**	**0.1**
58	75.3	73.1	2.3	58	81.6	4.3	0.9	76.1	0.3
58	77.7	75.6	2.1	58	79.1	4.5	1.0	73.5	0.1
58 (mean)	**76.5**	**74.3**	**2.2**	**58 (mean)**	**80.3**	**4.4**	**1.0**	**74.8**	**0.2**
90	72.4	70.8	1.6	90	75.8	5.2	0.9	69.5	0.2
90	70.8	68.4	2.4	90	74.0	4.9	0.9	67.7	0.4
90 (mean)	**71.6**	**69.6**	**2.0**	**90 (mean)**	**74.9**	**5.1**	**0.9**	**68.6**	**0.3**
120	66.8	64.5	2.3	120	73.8	4.8	0.8	67.8	0.4
120	64.5	62.0	2.5	120	72.8	4.9	0.8	66.9	0.1
120 (mean)	**65.7**	**63.3**	**2.4**	**120 (mean)**	**73.3**	**4.9**	**0.8**	**67.4**	**0.3**

DAT = Days after treatment

TAR = Total applied radioactivity (100 % = 0.421 mg kg^{-1} (chlorophenyl-label), 0.416 mg kg^{-1} (triazole-label)

ERR = Extractable radioactive residues

[a] ≤ 1.2 % TAR each for single metabolite (mean of two replicates)

[b] ≤ 0.4 % TAR each for single metabolite (mean of two replicates)

The soil residues remaining after extraction were dried, homogenised using a small mill, and aliquots were combusted in a biological oxidiser. The evolved $^{14}CO_2$ from each combusted aliquot was trapped and measured by LSC to determine the amount of the non-extractable residues (NER). From 7 DAT (New Jersey soil) and 14 DAT (LUFA 5M soil) onwards, the non-extractable residues were further characterised by NaOH extraction. The samples were consecutively extracted with NaOH (three times) and water (once). Finally, all extracts were pooled and acidified with concentrated hydrochloric acid to pH 1.5 to precipitate the humic acid fraction. After centrifugation, the supernatant (fulvic acids) was separated from the precipitate. The precipitate (humic acid fraction) was dissolved in NaOH. The humic and fulvic acid fractions were measured for radioactivity. The remaining soil samples after NaOH and water extraction were dried at room temperature. Afterwards, aliquots were combusted. The released $^{14}CO_2$ was trapped and analysed by LSC to determine the ^{14}C-residues in the humin fraction. The fulvic acid fraction was partitioned with ethyl acetate. The organic phase was further analysed by LSC and radio HPLC. Results are displayed in tables 8.1.1.1-8 - 8.1.1.1-11.

Table 8.1.1.1-8 **Characterisation of the non-extractable residues (NER) in LUFA 5M soil after treatment with chlorophenyl-^{14}C-BAS 750 F (% TAR).**

DAT	NER	NaOH extract (sum)	Fulvic acids			Humic acids	Humins
			Total	Aqueous phase	Ethyl acetate		
14	5.0	2.0	0.8	0.4	0.4	1.0	3.0
30	7.1	2.7	1.1	0.5	0.6	1.5	4.2
62	10.1	3.8	1.5	0.8	0.7	2.2	5.6
90	11.6	4.5	1.8	0.9	0.9	2.5	6.6
121	12.8	5.0	2.1	1.1	1.1	2.5	7.4

TAR = total applied radioactivity (100 % = 0.418 mg/kg)
DAT = days after treatment
NER = non-extractable radioactive residues
Ethyl acetate = organic phase after liquid-liquid extraction of fulvic acids

Table 8.1.1.1-9 **Characterisation of the non-extractable residues (NER) in LUFA 5M soil after treatment with triazole-^{14}C-BAS 750 F (% TAR).**

DAT	NER	NaOH extract (sum)	Fulvic acids			Humic acids	Humins
			Total	Aqueous phase	Ethyl acetate		
14	5.5	3.1	2.2	1.4	0.6	0.9	2.7
30	8.1	4.7	3.1	2.4	0.9	1.2	3.7
58	12.4	7.1	4.9	3.9	1.3	1.8	5.1
90	15.0	9.3	6.6	5.3	1.5	2.5	6.0
121	18.2	10.9	8.7	6.6	1.8	2.2	6.7

TAR = total applied radioactivity (100 % = 0.420 mg/kg)
DAT = days after treatment
NER = non-extractable radioactive residues
Ethyl acetate = organic phase after liquid-liquid extraction of fulvic acids

Table 8.1.1.1-10 **Characterisation of the non-extractable residues (NER) in New Jersey soil after treatment with chlorophenyl-^{14}C-BAS 750 F (% TAR).**

DAT	NER	NaOH extract (sum)	Fulvic acids			Humic acids	Humins
			Total	Aqueous phase	Ethyl acetate		
7	5.1	2.3	1.0	0.6	0.4	1.5	2.8
14	6.9	2.9	1.4	0.9	0.5	1.5	3.8
30	10.8	4.5	2.0	1.2	0.8	2.3	6.2
58	14.8	5.8	2.5	1.6	1.0	3.0	8.6
90	17.1	7.1	3.0	2.0	1.1	3.8	10.7
120	19.7	8.5	3.7	2.4	1.3	4.1	12.2

TAR = total applied radioactivity (100 % = 0.421 mg/kg)
DAT = days after treatment
NER = non-extractable radioactive residues
Ethyl acetate = organic phase after liquid-liquid extraction of fulvic acids

Table 8.1.1.1-11 **Characterisation of the non-extractable residues (NER) in New Jersey soil after treatment with triazole-^{14}C-BAS 750 F (% TAR).**

DAT	NER	NaOH extract (sum)	Fulvic acids			Humic acids	Humins
			Total	Aqueous phase	Ethyl acetate		
7	5.2	2.3	1.0	0.8	0.7	0.9	2.8
14	6.9	3.2	2.2	1.3	1.0	1.1	3.7
30	12.6	6.0	3.7	2.5	1.6	2.0	6.7
58	19.1	9.8	6.4	4.3	2.3	3.1	9.9
90	24.1	12.6	8.5	6.2	2.5	3.7	11.4
120	26.7	14.2	9.4	6.8	2.9	4.2	13.1

TAR = total applied radioactivity (100 % = 0.416 mg/kg)
DAT = days after treatment
NER = non-extractable radioactive residues
Ethyl acetate = organic phase after liquid-liquid extraction of fulvic acids

In order to determine the ratio of BAS 750 F enantiomers, all pooled soil extracts were analysed by chiral HPLC. *S*- and *R*-enantiomers of BAS 750 F were almost equally present in the pooled acetonitrile as well as acetonitrile/water extracts of LUFA 5M soil. In pooled extracts of New Jersey soil, the ratio changed from an equal distribution of both enantiomers to a higher ratio (~ 55:45) of the *S*-enantiomer of BAS 750 F at the end of the study. The Applicant states that this is not deemed a significant change due to the inherent variation of the methodology. The UK RMS agrees with this assessment (see section B.8.1.4 for further information). Results are presented in tables 8.1.1.1-12 - 8.1.1.1-15.

Table 8.1.1.1-12 **Chiral radio-HPLC analysis (LC188, gradient 03) of solvent extracts after treatment of LUFA 5M soil with chlorophenyl-^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	51.0	49.0	49.2	50.8
0	50.6	49.4	49.9	50.1
0 (mean)	**50.8**	**49.2**	**49.5**	**50.5**
3	50.4	49.6	50.1	49.9
3	49.5	50.5	49.5	50.5
3 (mean)	**49.9**	**50.1**	**49.8**	**50.2**
7	49.2	50.8	49.9	50.1
7	49.8	50.2	50.4	49.6
7 (mean)	**49.5**	**50.5**	**50.1**	**49.9**
14	49.4	50.6	50.5	49.5
14	49.9	50.1	50.4	49.6
14 (mean)	**49.7**	**50.3**	**50.5**	**49.5**
30	50.3	49.7	49.6	50.4
30	49.0	51.0	49.2	50.8
30 (mean)	**49.6**	**50.4**	**49.4**	**50.6**
62	49.0	51.0	49.8	50.2
62	49.4	50.6	49.5	50.5
62 (mean)	**49.2**	**50.8**	**49.7**	**50.3**
90	49.5	50.5	48.6	51.4
90	49.5	50.5	49.4	50.6
90 (mean)	**49.5**	**50.5**	**49.0**	**51.0**
121	49.1	50.9	48.8	51.2
121	49.9	50.1	49.8	50.2
121 (mean)	**49.5**	**50.5**	**49.3**	**50.7**

% ROI = portion of the region of interest with regard to the total integrated peak area
ERR = extractable radioactive residues

Table 8.1.1.1-13 **Chiral radio-HPLC analysis (LC188, gradient 03) of solvent extracts after treatment of LUFA 5M soil with triazole-^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	49.8	50.2	49.9	50.1
0	49.8	50.2	50.1	49.9
0 (mean)	**49.8**	**50.2**	**50.0**	**50.0**
3	49.7	50.3	49.9	50.1
3	50.4	49.6	49.8	50.2
3 (mean)	**50.0**	**50.0**	**49.9**	**50.1**
7	49.6	50.4	49.9	50.1
7	49.8	50.2	49.3	50.7
7 (mean)	**49.7**	**50.3**	**49.6**	**50.4**
14	49.6	50.4	49.1	50.9
14	49.6	50.4	49.4	50.6
14 (mean)	**49.6**	**50.4**	**49.3**	**50.7**
30	49.6	50.4	49.7	50.3
30	50.3	49.7	49.4	50.6
30 (mean)	**50.0**	**50.0**	**49.6**	**50.4**
58	49.6	50.4	48.9	51.1
58	49.1	50.9	48.6	51.4
58 (mean)	**49.4**	**50.6**	**48.7**	**51.3**
90	49.5	50.5	49.0	51.0
90	47.8	52.2	49.1	50.9
90 (mean)	**48.6**	**51.4**	**49.1**	**50.9**
121	48.6	51.4	49.2	50.8
121	48.3	51.7	48.1	51.9
121 (mean)	**48.5**	**51.5**	**48.7**	**51.3**

% ROI = portion of the region of interest with regard to the total integrated peak area
ERR = extractable radioactive residues

Table 8.1.1.1-14 **Chiral radio-HPLC analysis (LC188, gradient 03) of solvent extracts after treatment of New Jersey soil with chlorophenyl-^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	50.1	49.9	49.5	50.5
0	51.0	49.0	49.9	50.1
0 (mean)	**50.6**	**49.4**	**49.7**	**50.3**
3	49.5	50.5	49.8	50.2
3	50.0	50.0	49.4	50.6
3 (mean)	**49.7**	**50.3**	**49.6**	**50.4**
7	49.8	50.2	49.4	50.6
7	50.6	49.4	49.8	50.2
7 (mean)	**50.2**	**49.8**	**49.6**	**50.4**
14	49.1	50.9	49.7	50.3
14	49.2	50.8	48.9	51.1
14 (mean)	**49.1**	**50.9**	**49.3**	**50.7**
30	47.6	52.4	47.7	52.3
30	48.8	51.2	47.9	52.1
30 (mean)	**48.2**	**51.8**	**47.8**	**52.2**
58	46.7	53.3	47.9	52.1
58	47.4	52.6	48.0	52.0
58 (mean)	**47.1**	**52.9**	**48.0**	**52.0**
90	46.0	54.0	46.5	53.5
90	46.0	54.0	46.6	53.4
90 (mean)	**46.0**	**54.0**	**46.6**	**53.5**
120	44.5	55.5	45.8	54.2
120	44.6	55.4	44.8	55.2
120 (mean)	**44.5**	**55.5**	**45.3**	**54.7**

% ROI = portion of the region of interest with regard to the total integrated peak area
ERR = extractable radioactive residues

Table 8.1.1.1-15 **Chiral radio-HPLC analysis (LC188, gradient 03) of solvent extracts after treatment of New Jersey soil with triazole-^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	50.1	49.9	50.6	49.4
0	50.3	49.7	50.1	49.9
0 (mean)	**50.2**	**49.8**	**50.4**	**49.6**
3	49.6	50.4	49.7	50.3
3	49.6	50.4	49.9	50.1
3 (mean)	**49.6**	**50.4**	**49.8**	**50.2**
7	49.6	50.4	49.0	51.0
7	49.9	50.1	50.2	49.8
7 (mean)	**49.7**	**50.3**	**49.6**	**50.4**
14	48.8	51.2	49.1	50.9
14	49.1	50.9	49.7	50.3
14 (mean)	**48.9**	**51.1**	**49.4**	**50.6**
30	48.3	51.7	48.7	51.3
30	48.5	51.5	48.9	51.1
30 (mean)	**48.4**	**51.6**	**48.8**	**51.2**
58	47.9	52.1	47.9	52.1
58	47.3	52.7	47.5	52.5
58 (mean)	**47.6**	**52.4**	**47.7**	**52.3**
90	46.6	53.4	46.9	53.1
90	45.7	54.3	47.0	53.0
90 (mean)	**46.1**	**53.9**	**47.0**	**53.0**
120	46.0	54.0	47.4	52.6
120	44.3	55.7	46.6	53.4
120 (mean)	**45.1**	**54.9**	**47.0**	**53.0**

The kinetic fits provided by the Applicant are evaluated in section B.8.1.1.2.

The following minor deviations from OECD 307 were noted by the UK RMS. These deviations are judged not to have significantly altered the results of the study:

- Substance properties are not stated in the study (e.g. solubility in water, solubility in organic solvents, n-octanol/water partition coefficient, chemical stability in the dark, vapour pressure and Henry's law constant).
- No samples were sterilised before treatment with ^{14}C-labelled BAS 750 F in this study. This precludes the possibility of characterising the relevance of abiotic transformation in the test substance.
- OECD 307 states that a pre-incubation period of between 2 and 28 days is generally adequate. The Applicant states that the soil samples were pre-incubated, but no timings are given.

Conclusion

Two minor metabolites of BAS 750 F were characterised (M750F001 and M750F003). No major metabolites were detected in this study. Even though it is not a legislative requirement, the Applicant proposed to consider metabolite M750F001 (1,2,4-(1H)-triazole) in the environmental risk assessment because of its widespread occurrence in the environment. The UK RMS has accepted this approach. Several other minor metabolites were detected in the soil extracts, none of them individually exceeding 1.2 % TAR at any sampling time and the sum of which never exceeded 2.2 % TAR.

Report:	**KCA 7.1.1.1/002, Staudenmaier, H. and Dalkmann, P., (2015b)**
Title:	Aerobic soil metabolism of Trifluoromethylphenyl-labeled BAS 750 F
Report No &	430690
Document No	2015/1003306
Guidelines:	- OECD: Guideline 307, Aerobic and Anaerobic Transformation in Soil, 2002 - EPA 835.4100
GLP	Yes

Introduction

An aerobic soil route and rate of degradation study was conducted according to OECD guidelines (OECD 307: Aerobic and Anaerobic Transformation in Soil). This was conducted under aerobic conditions at 20 °C in New Jersey soil by incubation in the dark for 121 days. The study was conducted to GLP and according to OECD 307 guidelines. Deviations from the guidelines did occur (see 'Results and discussion' section for further information), however, these were not deemed significant enough to affect the outcomes of the study.

Test procedure

The soil was collected from the field according to OECD 307 and kept at room temperature until sieving. The soil was passed through a 2 mm sieve and stored at approximately 4 °C and 19 % of the maximum water holding capacity in the dark for no longer than 3 months before use. Table 8.1.1.1-16 gives details of the soil characteristics.

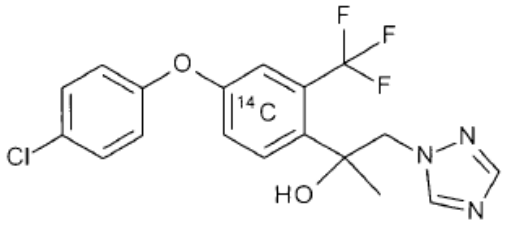
Table 8.1.1.1-16 Characterisation of test soils

Soil designation	**New Jersey** **BASF soil No. 14/1720/01**
Date of collection	20/06/2014
Sampling location	United States (Frenchtown, New Jersey/United States)
GPS coordinates	Not given
Previous pesticide use	None in last 5 years
Sampling depth	15 cm
DIN 4220 Particle size distribution *[%]* sand 0.063 – 2 mm silt 0.002 – 0.063 mm clay < 0.002 mm textural class	 31 48 21 sandy silt loam
USDA Particle size distribution *[%]* sand 0.050 – 2 mm silt 0.002 – 0.050 mm clay < 0.002 mm textural class	 33 46 21 loam
Organic C *[%]*	1.3
Organic matter [%][a]	2.24
pH [H_2O] pH [$CaCl_2$]	6.8 6.4
cation exchange capacity *[$cmol^+ kg^{-1}$]*	8.5
Max. water holding capacity *[g /100 g dry weight]*	33.3
Moisture at field capacity (pF2) *[g /100 g dry weight]*	32.2
microbial biomass (from certificate) *[mg C/100 g dry soil]*	65.0
microbial biomass (after 63 days of incubation) *[mg C/100 g dry soil]* [b]	42.0
microbial biomass (after 123 days of incubation) *[mg C/100 g dry soil]* [b]	38.8

n.d. = Not determined
[a] Organic matter = organic C * 1.724
[b] Determined at BASF test facility Limburgerhof

The test item BAS 750 F was used in the following ^{14}C-labelled form.

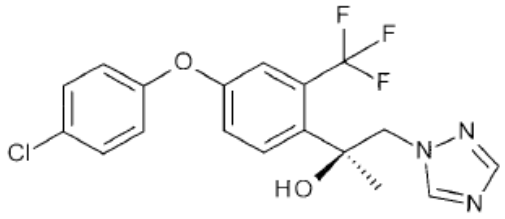
Internal code:	BAS 750 F
Reg. No.:	5834378
CAS No.:	1417782-03-6
Chemical name (IUPAC):	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molecular mass:	397.78 g mol^{-1}
Molecular formula:	$C_{18}H_{15}ClF_3N_3O_2$
Position of radiolabel:	trifluoromethylphenyl-ring-U-^{14}C
Batch No.:	CFQ42039
Specific radioactivity of a.s.:	8.288 MBq mg^{-1}
Radiochemical purity:	98.3 %
Purity:	96.3 %
Chemical structure:	



Both of these radiolabelled substances were applied as a racemic mixture (50:50) of enantiomers (S- and R-enantiomer) in the test:

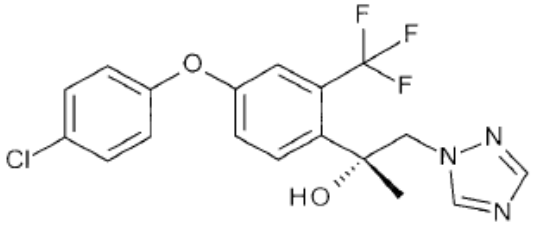
1. (2S)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol (in the following referred to as "S-enantiomer")

Reg. No.:	5934588
Batch No.:	L84-256
Chemical purity:	99.5 %
Ratio of isomers:	S-enantiomer : R-enantiomer = 100 : 0
Chemical structure:	



2. (2R)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol (in the following referred to as "R-enantiomer")

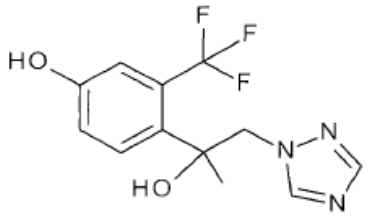
Reg. No.:	5934591
Batch No.:	L84-254
Chemical purity:	98.8 %
Ratio of isomers:	R-enantiomer : S-enantiomer = 99.7 : 0.3
Chemical structure:	



Other reference item used in the study:

1. M750F003

Reg. No.:	5924326
Batch No.:	L84-250
Chemical name (IUPAC):	4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenol
Molecular weight:	287.2 g/mol
Chemical purity:	99.6 %
Chemical structure:	



The test item was applied at a nominal concentration of 0.4 mg ^{14}C-BAS 750 per kg dry soil which corresponds to a field application rate of 150 g a.s. ha^{-1} (calculated on the basis of an equal distribution in the top 2.5 cm soil layer and a soil density of 1.5 g cm^{-3}). This application rate is considered acceptable by the UK RMS. Additional samples were dosed at the higher rate of approximately 4 mg a.s./kg dry soil to aid in the identification of unknown metabolites. Data from these incubations are not presented in the study report, so they have not be discussed further in this evaluation. Portions of 100 g soil (dry weight basis) were then filled into test vessels.

The trifluoromethylphenyl-label treatment solution was prepared by dissolving 5.5 mg of [trifluoromethylphenyl-ring-U-^{14}C]-BAS 750 F in acetonitrile. This was transferred to a 10 mL volumetric flask and made up to the volume with acetonitrile. The exact concentration was determined by liquid scintillation counting (LSC) (3 repeats). The radiochemical purity of the treatment solution was determined to be 98.4 % (measured before the treatment of New Jersey soil).

The test vessels were connected in line with aeration tubes and the samples were continuously aerated with a slight stream of moistened synthetic air. The air was passed through a bottle containing NaOH to remove carbon dioxide before it reached the test vessels. Three gas washing flasks containing 50 mL ethylene glycol, 0.5 M H_2SO_4, and 0.5 M NaOH were used to trap volatiles. The treated soils were incubated at 40 % of the maximum water holding capacity and 20 ± 2 °C in the dark.

To determine the microbial biomass at 0, 63 and 123 days after treatment (DAT), an additional soil portion was treated with acetonitrile (without test item) and incubated under the same conditions as the treated soils. The microbial biomass declined over the incubation phase (see Table 8.1.1.1-16). However, the results demonstrate that the soil was still viable and microbially active at days 63 and 123 (end) of the study.

Duplicate samples were taken for analysis immediately after application, and after 1, 3, 7, 14, 30, 59, 90 and 121 DAT.

For the determination of the extractable radioactive residues (ERR), soil samples were consecutively extracted twice with acetonitrile (ACN), twice with ACN/water (80/20; v/v), and twice with ACN/water (50/50; v/v). After each extraction step, the sample was centrifuged at 10,000 rpm for 15 minutes. Each extract was analysed for radioactivity by liquid scintillation counting (LSC). The ACN-extracts as well as the ACN/water-extracts were pooled and each solution was concentrated. The residues were then re-dissolved in a well-defined volume of solvent and analysed by radio HPLC.

The limit of detection (LOD) and limit of quantification (LOQ) of the LSC instrument was 0.015 % total applied radioactivity (TAR) and 0.022 % TAR, respectively (background 0.07 % TAR). For the HPLC instrument, the LOQ was 0.024 % TAR and the LOD was not given.

Results and discussion

The overall mean recoveries of total applied radioactivity (TAR) were in the range 99.7 % - 102.6 %, which falls within the guideline values stated in OECD 307 (table 8.1.1.1-17).

Table 8.1.1.1-17 **Recovery and distribution of radioactivity in New Jersey soil after treatment with trifluoromethylphenyl-^{14}C-labelled BAS 750 F [% TAR]**

Days after treatment	Extractable residues				NER	Volatiles [a]			Material balance
	ACN	ACN/H_2O (80/20)	ACN/H_2O (50/50)	Total		CO_2	Others [b]	Total	
0	90.0	7.7	0.6	98.3	0.5	n.a.	n.a.	n.a.	98.8
0	92.2	7.9	0.6	100.7	0.5	n.a.	n.a.	n.a.	101.2
0 (mean)	**91.1**	**7.8**	**0.6**	**99.5**	**0.5**	**-**	**-**	**-**	**100.0**
3	85.4	9.0	1.5	96.0	3.9	0.1	0.0	0.1	99.9
3	85.1	9.1	1.5	95.6	3.8	0.1	0.0	0.1	99.5
3 (mean)	**85.3**	**9.1**	**1.5**	**95.8**	**3.8**	**0.1**	**0.0**	**0.1**	**99.7**
7	84.7	9.9	2.4	97.1	5.9	0.2	0.0	0.2	103.1
7	83.8	9.8	2.4	96.0	5.7	0.2	0.0	0.2	102.0
7 (mean)	**84.2**	**9.9**	**2.4**	**96.5**	**5.8**	**0.2**	**0.0**	**0.2**	**102.6**
14	78.8	10.2	2.4	91.4	8.3	0.6	0.0	0.6	100.3
14	80.8	10.5	2.4	93.8	8.1	0.6	0.0	0.6	102.4
14 (mean)	**79.8**	**10.4**	**2.4**	**92.6**	**8.2**	**0.6**	**0.0**	**0.6**	**101.3**
30	73.3	10.3	3.6	87.2	12.6	1.4	0.0	1.4	101.2
30	73.7	10.5	3.6	87.7	12.4	1.4	0.0	1.4	101.5
30 (mean)	**73.5**	**10.4**	**3.6**	**87.5**	**12.5**	**1.4**	**0.0**	**1.4**	**101.4**
59	66.3	11.0	3.5	80.8	19.1	3.0	0.0	3.0	102.8
59	63.5	10.5	3.5	77.5	18.9	3.0	0.0	3.0	99.4
59 (mean)	**64.9**	**10.7**	**3.5**	**79.2**	**19.0**	**3.0**	**0.0**	**3.0**	**101.1**
90	60.4	9.8	4.6	74.8	21.1	4.5	0.0	4.5	100.4
90	59.1	9.7	4.5	73.3	21.3	4.5	0.0	4.5	99.1
90 (mean)	**59.8**	**9.8**	**4.5**	**74.1**	**21.2**	**4.5**	**0.0**	**4.5**	**99.7**
121	55.5	10.1	4.9	70.5	24.0	5.7	0.0	5.7	100.2
121	54.8	10.1	4.9	69.8	23.9	5.7	0.0	5.7	99.5
121 (mean)	**55.1**	**10.1**	**4.9**	**70.1**	**24.0**	**5.7**	**0.0**	**5.7**	**99.9**

TAR = Total applied radioactivity (100 % = 0.407 mg kg^{-1})

n.a. = Not available

[a] Cumulative values

[b] Sum of H_2SO_4 and ethylene glycol trap

The amounts of trifluoromethylphenyl-^{14}C-labelled-BAS 750 F in New Jersey soil extracts decreased from an average of 97.7 % TAR at day 0 to 64.9 % TAR after 121 days of incubation.

Several minor metabolites were detected in the soil extracts, none of them exceeding 1.8 % TAR at any sampling time (table 8.1.1.1-18). The sum of metabolites (mean of two replicates) never exceeded 5.5 % TAR. The metabolite M750F003 was identified by means of mass spectrometry (LC-MS/MS). M750F003 was detected at a maximum amount of 1.6 % TAR at 30 DAT (mean of two replicates).

Table 8.1.1.1-18 **Radio-HPLC analysis of soil extracts: after treatment of New Jersey soil with trifluoromethylphenyl-^{14}C-labelled BAS 750 F (sum of ACN and ACN/water extracts [% TAR].**

Days after treatment	ERR (total)	4.2 min	28.2 min M750F003	40.1 min BAS 750 F	Sum others [a]
0	98.3	-	-	96.5	1.8
0	100.7	-	-	99.0	1.7
0 (mean)	**99.5**	**-**	**-**	**97.7**	**1.8**
3	96.0	-	0.6	93.4	2.0
3	95.6	-	0.5	93.1	2.1
3 (mean)	**95.8**	**-**	**0.5**	**93.2**	**2.0**
7	97.1	-	0.9	93.8	2.3
7	96.0	-	1.0	92.5	2.5
7 (mean)	**96.5**	**-**	**1.0**	**93.2**	**2.4**
14	91.4	-	1.4	87.3	2.6
14	93.8	-	1.3	89.8	2.7
14 (mean)	**92.6**	**-**	**1.4**	**88.6**	**2.6**
30	87.2	0.1	1.6	82.6	2.9
30	87.7	0.1	1.7	83.3	2.6
30 (mean)	**87.5**	**0.1**	**1.6**	**83.0**	**2.8**
59	80.8	0.2	1.3	75.8	3.5
59	77.5	0.1	1.1	73.2	3.1
59 (mean)	**79.2**	**0.2**	**1.2**	**74.5**	**3.3**
90	74.8	0.2	1.4	69.1	4.2
90	73.3	0.2	1.2	68.0	3.8
90 (mean)	**74.1**	**0.2**	**1.3**	**68.6**	**4.0**
121	70.5	0.2	1.1	65.1	4.1
121	69.8	0.3	1.2	64.6	3.7
121 (mean)	**70.1**	**0.2**	**1.2**	**64.9**	**3.9**

TAR = Total applied radioactivity (100 % = 0.407 mg kg^{-1})

ERR = Extractable radioactive residues

[a] ≤ 1.7 % TAR for single metabolite (mean of two replicates)

The soil residues remaining after extraction were dried at 60 °C, homogenised using a small mill, and aliquots were combusted in a biological oxidiser. The evolved $^{14}CO_2$ from each combusted aliquot was trapped and measured by LSC to determine the amount of the non-extractable residues (NER). From 7 DAT onwards, the non-extractable residues were further characterised by NaOH extraction. The samples were consecutively extracted with NaOH (three times) and water (once). Finally, all extracts were pooled and acidified with concentrated hydrochloric acid to pH 1.5 to precipitate the humic acid fraction. After centrifugation, the supernatant (fulvic acids) was separated from the precipitate. The precipitate (humic acid fraction) was dissolved in NaOH. The humic and fulvic acid fractions were measured for radioactivity. The remaining soil samples after NaOH and water extraction were dried at room temperature. Afterwards, aliquots were combusted. The released $^{14}CO_2$ was trapped and analysed by LSC to determine the ^{14}C-residues in the humin fraction. The fulvic acid fraction was partitioned with ethyl acetate. The organic phase was further analysed by LSC and radio HPLC. Results are displayed in table 8.1.1.1-19.

Table 8.1.1.1-19 **Characterisation of the non-extractable residues (NER) in New Jersey soil after treatment with trifluoromethylphenyl-^{14}C-BAS 750 F (% TAR).**

DAT	NER	NaOH extract (sum)	Fulvic acids			Humic acids	Humins
			Total	Aqueous phase	Ethyl acetate		
7	5.9	2.0	1.0	0.3	0.7	1.1	3.9
14	8.3	3.2	1.6	0.5	1.1	1.6	5.4
30	12.6	4.9	2.5	0.9	1.7	2.4	7.7
59	19.1	7.5	3.8	1.5	2.4	3.5	11.7
90	21.3	9.1	4.6	2.0	2.8	4.2	12.0
121	24.0	10.7	5.1	2.3	2.8	5.3	13.6

TAR = Total applied radioactivity (100 % = 0.407 mg kg^{-1})
DAT = Days after treatment
NER = Non-extractable radioactive residues
Ethyl acetate = Organic phase after liquid-liquid extraction of fulvic acids

In order to determine the ratio of BAS 750 F enantiomers, the Applicant states that all pooled soil extracts were analysed by chiral HPLC. However, only one value is provided per sampling time point, rather than from both replicates. This is not explained by the Applicant. The ratio changed from an equal distribution of both enantiomers to a higher ratio (~ 55:45) of the *S*-enantiomer of BAS 750 F at the end of the study. The UK RMS does not consider this a significant change (see section B.8.1.4 for further information). Results are presented in table 8.1.1.1-20.

Table 8.1.1.1-20 **Chiral radio-HPLC analysis (LC188, gradient 03) of solvent extracts after treatment of New Jersey soil with ^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	50.1	49.9	50.4	49.6
3	50.4	49.6	49.7	50.3
7	50.5	49.5	49.4	50.6
14	49.4	50.6	50.1	49.9
30	48.6	51.4	49.0	51.0
59	47.8	52.2	47.9	52.1
90	47.3	52.7	47.1	52.9
121	46.1	53.9	45.3	54.7

% ROI = Portion of the region of interest with regard to the total integrated peak area
ERR = Extractable Radioactive Residues

The kinetic fits provided by the Applicant are evaluated in section B.8.1.1.2.

The following minor deviations from OECD 307 were noted by the UK RMS. These deviations are judged not to have significantly altered the results of the study:

- Substance properties are not stated in the study (e.g. solubility in water, solubility in organic solvents, n-octanol/water partition coefficient, chemical stability in the dark, vapour pressure and Henry's law constant).
- No samples were sterilised before treatment with ^{14}C-labelled BAS 750 F in this study. This precludes the possibility of characterising the relevance of abiotic transformation in the test substance.
- OECD 307 states that a pre-incubation period of between 2 and 28 days is generally adequate. The Applicant states that the soil samples were pre-incubated, but no timings are given.

Conclusion

One minor metabolite of BAS 750 F was identified (M750F003). Several other minor metabolites were detected in the soil extracts, none of them individually exceeding 1.8 % TAR at any sampling time and the sum of which never exceeded 5.5 % TAR.

Report:	**KCA 7.1.2.1./001, Staudenmaier, H. and Dalkmann, P., (2015c)**
Title:	Degradation of BAS 750 F in soil under aerobic conditions
Report No &	433558
Document No	2014/1275178
Guidelines:	- OECD: Guideline 307, Aerobic and Anaerobic Transformation in Soil, 2002 - EPA 835.4100
GLP	Yes

Introduction

An aerobic soil route and rate of degradation study was conducted according to OECD guidelines (OECD 307: Aerobic and Anaerobic Transformation in Soil). This was conducted under aerobic conditions at 20 °C in two soils from Germany (Li10) and USA (Indiana) by incubation in the dark for 120 days. The study was conducted to GLP and according to OECD 307 guidelines. Deviations from the guidelines did occur (see 'Results and discussion' section for further information), however, these were not deemed significant enough to affect the outcomes of the study.

Test procedure

The soil was collected from the field according to OECD 307 and kept at room temperature until sieving. The soil was passed through a 2 mm sieve, remoistened to approximately 7 – 15 % soil moisture and stored at approximately 4 °C in the dark for no longer than 3 months before use. Table 8.1.1.1-21 gives details of the soil characteristics. As can be seen, for soil Indianna, pesticides had been applied at the site in the preceding 5 years. In response to the RMS querying this with the Applicant, the Applicant states that "*all of the products are herbicides and their active substances (Roundup - Glyphosate, Anthem – Pyroxasulfone and Fluthiacet-methyl, Balance - Isoxaflutole, Harness – Acetochlor, Surpass - Acetochlor, Lumax - S-Metolachlor, Atrazine and Mesotrione, and Distinct – Diflufenzopyr and Dicamba) belong to other chemical classes than the fungicidal active substance BAS 750 F. Neither the test item itself nor any other compound of the same chemical class have been used on the Indiana soil in the previous years. The requirement of the OECD guideline 307 is fulfilled, that soils should not be used for transformation studies if they have been treated with the test substance or its structural analogues within the previous four years. Therefore, the previous pesticide use on the Indiana soil is not expected to impact the study*". Given that none of the active substances are structurally similar to BAS 750 F, the RMS accepts the Applicant's justification and deems the Indianna soil acceptable.

Table 8.1.1.1-21 **Characterisation of test soils**

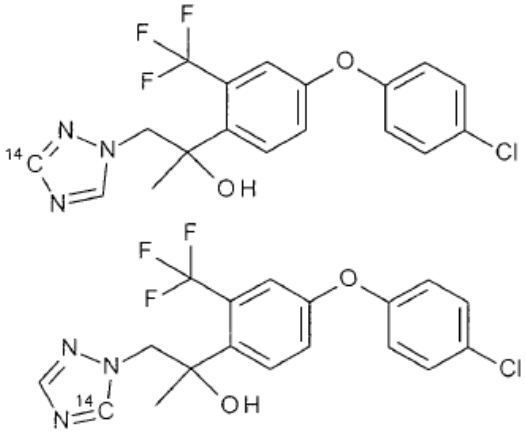
Soil designation	**Li10** **BASF soil No. 13/1680/04**	**Indiana** **BASF soil No. 13/1806/01**
Date of collection	17/09/2013	11/09/2013
Sampling location	Germany (Limburgerhof)	Unites States (Indiana)
GPS coordinates	49°24'30.17" N 08°23'04.09" E	39°59'096.4 N 85°56'43.80 W
Previous pesticide use	None in last 5 years	Roundup, Anthem, Balance, Harness, Surpass, Lumax and Distinct (in last 5 years)
Sampling depth	0 – 20 cm	0 – 15 cm
DIN 4220 Particle size distribution *[%]* sand 0.063 – 2 mm silt 0.002 – 0.063 mm clay < 0.002 mm textural class	 81.8 13.3 5.0 loamy sand (Sl2)	 n.d. n.d. n.d. n.d.
USDA Particle size distribution *[%]* sand 0.050 – 2 mm silt 0.002 – 0.050 mm clay < 0.002 mm textural class	 84.0 11.0 5.0 loamy sand	 35 46 19 loam
Organic C *[%]* Organic matter *[%]* [a]	0.93 1.60	n.d. 2.0
pH [H_2O] pH [$CaCl_2$]	6.6 6.1	6.3 5.8
cation exchange capacity *[$cmol^+ kg^{-1}$]*	3.7	10.3
Max. water holding capacity *[g /100 g dry weight]*	26.9	33.3
Moisture at field capacity (pF2) *[g /100 g dry weight]*	10.5	n.d.[c]
microbial biomass (after 0 days of incubation) *[mg C/100 g dry soil]*	25.2	42.3
microbial biomass (after 58 days of incubation) *[mg C/100 g dry soil]* [b]	18.9	29.5
microbial biomass (after 122 days of incubation) *[mg C/100 g dry soil]* [b]	10.5	24.0

n.d. = Not determined
[a] Organic matter = organic carbon x 1.724
[b] Determined at BASF test facility Limburgerhof
[c] Only moisture at 1/3 bar (pF2.5) was provided – 21.3 *g /100 g dry weight*

The test item BAS 750 F was used in the following ^{14}C-labelled form.

Internal code:	BAS 750 F
Reg. No.:	5834378
CAS No.:	1417782-03-6
Chemical name (IUPAC):	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molecular mass:	397.78 g mol^{-1}
Molecular formula:	$C_{18}H_{15}ClF_3N_3O_2$
Position of radiolabel:	triazole-3(5)-^{14}C
Batch No.:	1062-2001
Specific radioactivity of a.s.:	5.46 MBq mg^{-1}
Radiochemical purity:	98.8 %, see certificate of analysis in the final report
Purity:	98.9 %

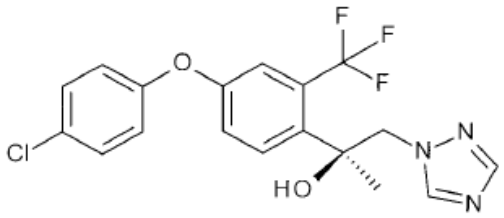
Chemical structure:



This radiolabelled substance was applied as a racemic mixture (50:50) of enantiomers (S- and R-enantiomer) in the test:

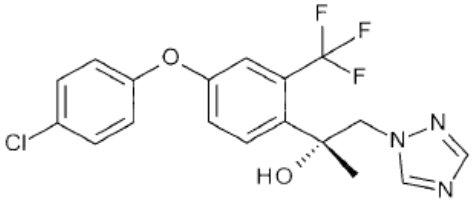
1. (2S)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol (in the following referred to as "S-enantiomer")

Reg. No.:	5934588
Batch No.:	L84-256
Chemical purity:	99.5 %
Ratio of isomers:	S-enantiomer : R-enantiomer = 100 : 0
Chemical structure:	



2. (2R)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol (in the following referred to as "R-enantiomer")

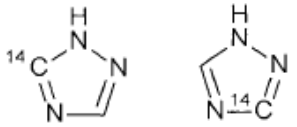
Reg. No.:	5934591
Batch No.:	L84-254
Chemical purity:	98.9 %
Ratio of isomers:	R-enantiomer : S-enantiomer = 99.7 : 0.3
Chemical structure:	



Other reference items used in the study:

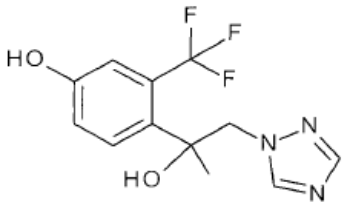
1. [triazole-3(5)-^{14}C]-1,2,4-(1H)-triazole (M750F001)

Reg. No.:	87084
CAS-No.:	288-88-0
Batch No.:	QBC146_B12140-12111
Position of radiolabel	triazole-3(5)-^{14}C
Specific radioactivity:	29.7 MBq/mg (1782000 dpm/µg)
Radiochemical purity:	> 99.9 %
Chemical structure:	



2. M750F003

Reg. No.:	5924326
Batch No.:	L84-250
Chemical name (IUPAC):	4-[2-hydroxy-1-(1H-1,2,4-triazol-1-yl)propan-2-yl]-3-(trifluoromethyl)phenol
Molecular weight:	287.2 g/mol
Chemical purity:	99.6 %
Chemical structure:	



The test item was applied at a nominal concentration of 0.4 mg ^{14}C-BAS 750 per kg dry soil which corresponds to a field application rate of 150 g a.s. ha^{-1} (calculated on the basis of an equal distribution in the top 2.5 cm soil layer and a soil density of 1.5 g cm^{-3}). This application rate is considered acceptable by the UK RMS. Additional samples were dosed at the higher rate of approximately 1 mg a.s./kg dry soil to aid in the identification of unknown metabolites. Data from these incubations are not presented in the study report, so they have not be discussed further in this evaluation. Portions of 100 g soil (dry weight basis) were then filled into test vessels.

The ^{14}C-label treatment solution was prepared by dissolving 4.9 mg of ^{14}C-BAS 750 F in 5 mL of acetonitrile. Three 50 µL aliquots of this solution were pipetted into three 5 mL volumetric flasks, which were subsequently made up to volume with acetonitrile. The exact concentration was determined by liquid scintillation counting (LSC) (5 repeats from each). The radiochemical purity of the treatment solution was determined to be 99.3 % (measured one day before treatment).

The test vessels were connected in line with aeration tubes and the samples were continuously aerated with a slight stream of moistened synthetic air. The air was passed through a bottle containing NaOH to remove carbon dioxide before it reached the test vessels. Three gas washing flasks containing ethylene glycol, 0.5 M H_2SO_4, and 0.5 M NaOH were used to trap volatiles. The treated soils were incubated at 40 % of the maximum water holding capacity and 20 ± 2 °C in the dark.

To determine the microbial biomass at 0, 58 and 122 days after treatment (DAT), an additional soil portion was treated with acetonitrile (without test item) and incubated under the same conditions as the treated soils. The microbial biomass declined over the incubation phase. However, the results demonstrate that the soil was still viable and microbially active at days 58 and 122 (end) of the study.

Duplicate samples were taken for analysis immediately after application, and after 1, 3, 7, 14, 30, 58, 91 and 120 DAT.

For the determination of the extractable radioactive residues (ERR), soil samples were consecutively extracted twice with acetonitrile (ACN), twice with ACN/water (80/20; v/v), and twice with ACN/water (50/50; v/v). After each extraction step, the sample was centrifuged at 10,000 rpm for 15 minutes. Each extract was analysed for radioactivity by liquid scintillation counting (LSC). The ACN-extracts as well as the ACN/water-extracts were pooled and each solution was concentrated. The residues were then re-dissolved in a well-defined volume of solvent and analysed by radio HPLC.

The limit of detection (LOD) and limit of quantification (LOQ) of the LSC instrument was 0.022 % total applied radioactivity (TAR) and 0.032 % TAR, respectively (background 0.011 % TAR). For the HPLC instrument, the LOQ was 0.017 % TAR and the LOD was not given.

Results and discussion

The overall mean recoveries of total applied radioactivity (TAR) were in the range 98.5 % - 105.4 %, which falls within the guideline values stated in OECD 307 (tables 8.1.1.1-22 and 8.1.1.1-23).

Table 8.1.1.1-22 **Recovery and distribution of radioactivity in Li10 soil after treatment with triazole-3(5)-^{14}C-labelled BAS 750 F (% TAR).**

Days after treatment	Extractable residues						Total	NER	Volatiles [a]		Material balance
	Acetonitrile		ACN/H_2O (80/20)		ACN/H_2O (50/50)				NaOH (CO_2)	Others [b]	
	1	2	1	2	1	2					
0	74.5	17.2	5.4	1.4	0.4	0.1	99.0	0.5	n.a.	n.a.	99.5
0	74.9	17.8	5.4	1.4	0.4	0.1	100.0	0.5	n.a.	n.a.	100.5
0 (mean)	**74.7**	**17.5**	**5.4**	**1.4**	**0.4**	**0.1**	**99.5**	**0.5**	**-**	**-**	**100.0**
3	71.9	17.8	5.8	1.6	0.7	0.3	98.0	1.7	0.1	0.0	99.8
3	72.6	17.8	5.8	1.6	0.7	0.3	98.8	1.7	0.1	0.0	100.6
3 (mean)	**72.3**	**17.8**	**5.8**	**1.6**	**0.7**	**0.3**	**98.4**	**1.7**	**0.1**	**0.0**	**100.2**
7	71.3	17.2	6.0	1.7	0.8	0.3	97.2	2.6	0.1	0.0	100.0
7	70.7	17.7	6.0	1.7	0.8	0.4	97.3	2.6	0.1	0.0	100.0
7 (mean)	**71.0**	**17.5**	**6.0**	**1.7**	**0.8**	**0.3**	**97.3**	**2.6**	**0.1**	**0.0**	**100.0**
14	68.6	17.9	6.3	1.8	0.8	0.5	95.9	3.7	0.1	0.0	99.7
14	68.7	18.3	6.3	1.9	0.8	0.5	96.5	3.8	0.1	0.0	100.4
14 (mean)	**68.7**	**18.1**	**6.3**	**1.9**	**0.8**	**0.5**	**96.2**	**3.8**	**0.1**	**0.0**	**100.1**
30	65.4	17.3	6.6	2.1	1.1	0.5	93.0	6.1	0.2	0.0	99.3
30	65.9	17.1	6.7	2.2	1.1	0.5	93.5	5.9	0.2	0.0	99.6
30 (mean)	**65.6**	**17.2**	**6.7**	**2.2**	**1.1**	**0.5**	**93.3**	**6.0**	**0.2**	**0.0**	**99.5**
58	62.8	16.6	6.6	2.3	1.3	0.7	90.2	8.6	0.3	0.0	99.1
58	63.1	16.7	6.7	2.3	1.3	0.6	90.7	8.6	0.3	0.0	99.6
58 (mean)	**63.0**	**16.7**	**6.6**	**2.3**	**1.3**	**0.6**	**90.5**	**8.6**	**0.3**	**0.0**	**99.4**
91	60.3	16.5	6.7	2.4	1.6	0.7	88.1	10.5	0.4	0.0	99.0
91	59.7	16.5	6.7	2.3	1.6	0.7	87.5	10.6	0.4	0.0	98.5
91 (mean)	**60.0**	**16.5**	**6.7**	**2.3**	**1.6**	**0.7**	**87.8**	**10.6**	**0.4**	**0.0**	**98.8**
120	58.9	15.7	6.6	2.5	1.6	0.8	86.0	12.6	0.5	0.0	99.1
120	58.3	16.2	6.8	2.5	1.6	0.7	86.1	12.5	0.5	0.0	99.1
120 (mean)	**58.6**	**16.0**	**6.7**	**2.5**	**1.6**	**0.8**	**86.0**	**12.6**	**0.5**	**0.0**	**99.1**

TAR = Total applied radioactivity (100 % = 0.425 mg kg^{-1})

ACN = Acetonitrile

NER = Non-extractable residues

n.a. = Not analyzed

[a] Values for volatile radioactive residues were calculated cumulatively

[b] Sum of volatile radioactive residues in H_2SO_4 and ethylene glycol traps

Table 8.1.1.1-23 **Recovery and distribution of radioactivity in Indiana soil after treatment with triazole-3(5)-^{14}C-labelled BAS 750 F (% TAR).**

Days after treatment	Extractable residues						Total	NER	Volatiles [a]		Material balance
	Acetonitrile		ACN/H_2O (80/20)		ACN/H_2O (50/50)				NaOH (CO_2)	Others [b]	
	1	2	1	2	1	2					
0	79.0	13.7	4.9	1.1	0.4	0.2	99.3	0.5	n.a.	n.a.	99.9
0	79.1	13.7	5.0	1.2	0.4	0.2	99.6	0.5	n.a.	n.a.	100.1
0 (mean)	**79.0**	**13.7**	**5.0**	**1.2**	**0.4**	**0.2**	**99.5**	**0.5**	**-**	**-**	**100.0**
3	77.0	14.8	5.6	1.8	0.9	0.4	100.3	2.2	0.0	0.0	102.6
3	78.9	14.8	5.8	1.9	0.9	0.4	102.6	2.2	0.0	0.0	104.9
3 (mean)	**77.9**	**14.8**	**5.7**	**1.8**	**0.9**	**0.4**	**101.5**	**2.2**	**0.0**	**0.0**	**103.7**
7	73.9	14.6	6.4	2.0	1.2	0.5	98.7	3.3	0.1	0.0	102.1
7	73.5	14.5	6.3	2.0	1.2	0.5	98.1	3.2	0.1	0.0	101.4
7 (mean)	**73.7**	**14.6**	**6.4**	**2.0**	**1.2**	**0.5**	**98.4**	**3.3**	**0.1**	**0.0**	**101.7**
14	72.2	14.5	6.3	2.3	1.1	0.8	97.0	4.8	0.1	0.0	101.9
14	72.8	14.7	6.1	2.2	1.1	0.8	97.6	4.9	0.1	0.0	102.7
14 (mean)	**72.5**	**14.6**	**6.2**	**2.2**	**1.1**	**0.8**	**97.3**	**4.9**	**0.1**	**0.0**	**102.3**
30	71.9	14.7	6.9	2.7	1.6	0.7	98.5	6.8	0.1	0.0	105.4
30	67.7	14.6	6.9	2.7	1.6	0.7	94.3	6.5	0.1	0.0	101.0
30 (mean)	**69.8**	**14.7**	**6.9**	**2.7**	**1.6**	**0.7**	**96.4**	**6.6**	**0.1**	**0.0**	**103.2**
58	67.9	15.1	7.3	2.9	2.0	0.9	96.0	9.2	0.2	0.0	105.4
58	64.1	14.0	6.9	2.7	1.9	0.9	90.6	8.8	0.2	0.0	99.6
58 (mean)	**66.0**	**14.5**	**7.1**	**2.8**	**2.0**	**0.9**	**93.3**	**9.0**	**0.2**	**0.0**	**102.5**
91	61.7	14.1	7.1	2.9	2.3	0.9	89.1	10.8	0.2	0.0	100.1
91	62.4	14.4	7.3	3.0	2.4	1.0	90.5	10.7	0.2	0.0	101.5
91 (mean)	**62.1**	**14.3**	**7.2**	**3.0**	**2.3**	**1.0**	**89.8**	**10.8**	**0.2**	**0.0**	**100.8**
120	61.6	14.1	7.2	3.2	2.3	1.0	89.4	12.7	0.3	0.0	102.4
120	62.0	13.9	7.2	3.3	2.3	1.1	89.7	12.7	0.3	0.0	102.7
120 (mean)	**61.8**	**14.0**	**7.2**	**3.2**	**2.3**	**1.0**	**89.6**	**12.7**	**0.3**	**0.0**	**102.6**

TAR = Total applied radioactivity (100 % = 0.417 mg kg^{-1})

ACN = Acetonitrile

NER = Non-extractable residues

n.a. = Not analyzed

[a] values for volatile radioactive residues were calculated cumulatively

[b] sum of volatile radioactive residues in H_2SO_4 and ethylene glycol traps

Amounts of BAS 750 F declined from an average of 98.9 % TAR (day 0) to an average of 83.5 % TAR after 120 days for Li10 soil and from 98.6 % TAR (day 0) to 87.1 % TAR after 120 days for Indiana soil (tables 8.1.1.1-24 and 8.1.1.1-25). The test item ^{14}C-BAS 750 F represented the only major radioactive fraction in the extracts of Li10 and Indiana soils. Metabolite M750F001 was detected, reaching a maximum of 1.5% TAR (Li10 soil) and 1.3% TAR (Indiana soil) in single replicates. Metabolite M750F003 was detected, reaching a maximum of 1.8 % TAR (Li10 soil) and 0.6 % TAR (Indiana soil) in the respective soils. Up to seven other metabolites were detected, none of which exceeded 0.7 % TAR (Li10 soil) and 0.6 % TAR (Indiana soil). The sum of all other metabolites never exceeded 1.2 % TAR.

Table 8.1.1.1-24 **Radio-HPLC analysis of soil extracts: after treatment of Li10 soil with triazole-3(5)-^{14}C-labelled BAS 750 F (sum of ACN and ACN/water extracts (% TAR).**

Days after treatment	ERR (total)	7.2 min M750F001	28.4 min M750F003	42.3 min BAS 750 F	sum others [a]
0	99.0	0.4	-	98.6	0.0
0	100.0	0.8	-	99.2	0.0
0 (mean)	**99.5**	**0.6**	**-**	**98.9**	**0.0**
3	98.0	0.4	0.4	97.0	0.2
3	98.8	0.8	0.3	97.6	0.1
3 (mean)	**98.4**	**0.6**	**0.4**	**97.3**	**0.1**
7	97.2	0.5	0.6	96.0	0.2
7	97.3	0.5	0.8	95.9	0.1
7 (mean)	**97.3**	**0.5**	**0.7**	**95.9**	**0.1**
14	95.9	0.7	0.9	93.7	0.6
14	96.5	0.8	0.9	94.1	0.7
14 (mean)	**96.2**	**0.8**	**0.9**	**93.9**	**0.6**
30	93.0	0.6	1.7	90.3	0.4
30	93.5	1.0	1.8	89.8	1.0
30 (mean)	**93.3**	**0.8**	**1.8**	**90.0**	**0.7**
58	90.2	0.8	1.7	87.2	0.5
58	90.7	1.3	1.2	87.8	0.4
58 (mean)	**90.5**	**1.1**	**1.4**	**87.5**	**0.5**
90	88.1	1.4	1.1	84.7	0.8
90	87.5	1.5	0.9	84.3	0.7
91 (mean)	**87.8**	**1.5**	**1.0**	**84.5**	**0.8**
120	86.0	1.4	0.8	83.4	0.4
120	86.1	1.1	0.9	83.7	0.4
120 (mean)	**86.0**	**1.3**	**0.9**	**83.5**	**0.4**

TAR = total applied radioactivity (100 % = 0.425 mg kg^{-1})

ERR = extractable radioactive residues

[a] ≤ 0.4% TAR each

Table 8.1.1.1-25 **Radio-HPLC analysis of soil extracts: after treatment of Indiana soil with triazole-3(5)-^{14}C-labelled BAS 750 F (sum of ACN and ACN/water extracts (% TAR).**

Days after treatment	ERR (total)	7.2 min M750F001	28.4 min M750F003	42.3 min BAS 750 F	sum others [a]
0	99.3	0.7	-	98.5	0.1
0	99.6	0.9	-	98.8	0.0
0 (mean)	**99.5**	**0.8**	**-**	**98.6**	**0.1**
3	100.3	0.8	-	99.0	0.5
3	102.6	0.6	-	101.9	0.2
3 (mean)	**101.5**	**0.7**	**-**	**100.5**	**0.3**
7	98.7	0.5	0.0	97.9	0.2
7	98.1	0.6	-	97.3	0.2
7 (mean)	**98.4**	**0.6**	**0.0**	**97.6**	**0.2**
14	97.0	0.8	0.3	94.7	1.3
14	97.6	0.8	0.3	95.4	1.1
14 (mean)	**97.3**	**0.8**	**0.3**	**95.0**	**1.2**
30	98.5	0.6	0.5	97.2	0.3
30	94.3	0.8	0.4	92.8	0.3
30 (mean)	**96.4**	**0.7**	**0.4**	**95.0**	**0.3**
58	96.0	1.0	0.7	93.9	0.4
58	90.6	0.9	0.6	88.2	0.9
58 (mean)	**93.3**	**0.9**	**0.6**	**91.1**	**0.6**
90	89.1	0.9	0.6	86.8	0.8
90	90.5	1.1	0.4	88.0	1.1
91 (mean)	**89.8**	**1.0**	**0.5**	**87.4**	**0.9**
120	89.4	1.1	0.5	86.9	1.0
120	89.7	1.3	0.5	87.3	0.7
120 (mean)	**89.6**	**1.2**	**0.5**	**87.1**	**0.8**

TAR = total applied radioactivity (100 % = 0.417 mg kg^{-1})

ERR = extractable radioactive residues

[a] ≤ 0.6% TAR each

The soil residues remaining after extraction were dried, homogenised using a small mill, and aliquots were combusted in a biological oxidiser. The evolved $^{14}CO_2$ from each combusted aliquot was trapped and measured by LSC to determine the amount of the non-extractable residues (NER). The NER fraction was not further characterised within this study.

In order to determine the ratio of BAS 750 F enantiomers, the Applicant states that all pooled soil extracts were analysed by chiral HPLC. However, only one value is provided per sampling time point, rather than from both replicates. This is not explained by the Applicant. The ratio changed from an equal distribution of both enantiomers to a higher ratio (~ 53:47) of the *S*-enantiomer of BAS 750 F at the end of the study. The UK RMS does not consider this a significant change (see section B.8.1.4 for further information). Results are presented in tables 8.1.1.1-26 and 8.1.1.1-27.

Table 8.1.1.1-26 **Chiral radio-HPLC analysis of solvent extracts after treatment of Li10 soil with ^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	49.7	50.3	49.6	50.4
3	49.8	50.2	50.1	49.9
7	49.3	50.7	49.2	50.8
14	49.4	50.6	48.4	51.6
30	48.3	51.7	48.8	51.2
58	48.6	51.4	47.8	52.2
91	46.8	53.2	48.2	51.8
120	47.1	52.9	48.0	52.0

TAR = Total Applied Radioactivity (100% = 0.425 mg/kg)
% ROI = portion of the region of interest with regard to the total integrated peak area, ROI is the two enantiomer peaks of BAS 750 F

Table 8.1.1.1-27 **Chiral radio-HPLC analysis of solvent extracts after treatment of Indiana soil with ^{14}C-labelled BAS 750 F (% ROI).**

Days after treatment	Acetonitrile extracts		Acetonitrile : Water extracts	
	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer	18.8 min Reg. No. 5934591 R-enantiomer	20.1 min Reg. No. 5934588 S-enantiomer
0	49.7	50.3	49.7	50.3
3	50.5	49.5	49.8	50.2
7	50.0	50.0	50.1	49.9
14	49.8	50.2	48.8	51.2
30	49.3	50.7	49.2	50.8
58	48.7	51.3	49.7	50.3
91	49.5	50.5	49.0	51.0
120	49.1	50.9	49.8	50.2

TAR = Total Applied Radioactivity (100% = 0.425 mg/kg)
% ROI = portion of the region of interest with regard to the total integrated peak area, ROI is the two enantiomer peaks of BAS 750 F

The kinetic fits provided by the Applicant are evaluated in section B.8.1.1.2.

The following minor deviations from OECD 307 were noted by the UK RMS. These deviations are judged not to have significantly altered the results of the study:

- Substance properties are not stated in the study (e.g. solubility in water, solubility in organic solvents, n-octanol/water partition coefficient, chemical stability in the dark, vapour pressure and Henry's law constant).
- No samples were sterilised before treatment with ^{14}C-labelled BAS 750 F in this study. This precludes the possibility of characterising the relevance of abiotic transformation in the test substance.
- OECD 307 states that a pre-incubation period of between 2 and 28 days is generally adequate. The Applicant does not state whether the samples were pre-incubated.
- Several pesticides were applied at the Indiana site in the 5 years prior to sampling (see Table 8.1.1.1-21). However, because none of the active ingredients present in the products used are structurally similar to BAS 750 F, the RMS is of the opinion that microbial resistance to BAS 750 F as a result of their use is unlikely. Therefore, the results from the soil are still valid.

Conclusion

Two minor metabolites of BAS 750 F were characterised (M750F001 and M750F003). No major metabolites were detected in this study. Even though it is not a legislative requirement, the Applicant proposed to consider

metabolite M750F001 (1,2,4-(1H)-triazole) in the environmental risk assessment because of its widespread occurrence in the environment. The UK RMS has accepted this approach. Several other minor metabolites were detected in the soil extracts, none of them individually exceeding 0.7 % TAR at any sampling time and the sum of which never exceeded 1.2 % TAR.

B.8.1.1.2. Aerobic rate of degradation in soil

B.8.1.1.2.1. Kinetic analysis of degradation behaviour of BAS 750 F from laboratory degradation studies

Report:	**KCA 7.1.2.1.1/002, Platz, K., (2015)**
Title:	Normalized modelling DegT50 endpoints of BAS 750 F derived from laboratory soil degradation experiments
Report No & Document No	CALC-2005 2015/1239053
Guidelines:	- FOCUS kinetics guidance (2006)
GLP	N/A

Introduction

The Applicant has provided the calculation of trigger endpoints in three studies (Staudenmaier and Dalkmann, 2015a, b and c) and the modelling endpoints are calculated in a single study (KCA 7.1.2.1.1/002 Platz, 2015) following FOCUS kinetic guidance (version 1.1, December 2014). Table 8.1.1.2.1-1 provides a summary of the kinetic reports evaluated in section B.8.1.1.1. The UK RMS notes that field studies have been provided by the Applicant (see section B.8.1.1.4); the kinetic evaluation of these are presented after section. Therefore, the kinetics evaluation presented below addresses parent degradation only from the laboratory soil degradation studies. The minor metabolite 1,2,4-triazole is addressed in a following section.

Table 8.1.1.2.1-1 **Summary of the kinetic reports evaluated in section B.8.1.1.1.**

Kinetic study	Laboratory degradation study	Soil	Compound Applied	Compound calculated	Modelling or trigger endpoints?
Included in lab study	Staudenmaier and Dalkmann (2015a) [KCA 7.1.1.1/001]	LUFA 5M	BAS 750 F	BAS 750 F	Trigger
	Staudenmaier and Dalkmann (2015a and b) [KCA 7.1.1.1/001 and KCA 7.1.1.1/002]	New Jersey			Trigger
	Staudenmaier and Dalkmann (2015c) [KCA 7.1.2.1.1/001]	Li10			Trigger
		Indiana			
Platz (2015) [KCA 7.1.2.1.1/002]	Staudenmaier and Dalkmann (2015a, b and c)	LUFA 5M			Modelling
		New Jersey			
		Li10			
		Indiana			

The UK RMS has independently validated all of the fits using alternative software in each case. Where the UK RMS agrees with the Applicant's proposals, only the Applicant's results are included. Significant differences between fits produced by the UK RMS and the Applicant are highlighted and full visual and statistical results are provided.

For both LUFA 5M and New Jersey soils, the Applicant elected to consider the different radiolabel positions of the test substance as separate soils. Therefore, LUFA 5M soil was treated as 2 soils (each with 2 replicates) and New Jersey soil was treated as 3 soils (each with 2 replicates). The FOCUS Guidance on kinetics suggests that these soils should each be considered as single soils (4 replicates of LUFA 5M soil and 6 replicates of New Jersey soil). The UK RMS undertook a kinetic assessment for both interpretations of the FOCUS guidance (see below for further information).

Test procedure

The initial concentration of the applied substance was set to the material balance recovered at day 0. The Applicant fitted Single First Order (SFO), Gustafson & Holden (FOMC) and bi-phasic bi-exponential (DFOP) kinetics to each data set using KinGUI (version 2). The acceptability of these fits was assessed visually and based on the χ^2 error % and the t-test probablility. A χ^2 error % of < 15 % was preferred and a parameter was considered acceptable if it had a significance level > 95 % as well as a good visual fit. The Applicant used IRLS optimisation whilst the UK RMS used OLS, both are considered acceptable. The UK RMS used CAKE (version 3.2) to evaluate the Applicant's kinetic fits.

Results and discussion

Figures 8.1.1.2.1-1 - 8.1.1.2.1-7 show the fitted curves and residual plots for all soils in the three laboratory studies and tables 8.1.1.2.1-2 - 8.1.1.2.1-5 present the associated kinetic data from the Applicant. The DT_{50} and DT_{90} values are reported as calculated by the modelling program; i.e. no back-calculated DT_{50}s are presented at this stage.

Table 8.1.1.2.1-2 **Applicant's summary of kinetic data for BAS 750 F in LUFA 5M soil using KinGUI (version 2).**

Flowchart step	Model	Visual assessment	χ^2 error %	M0	Parameters	Prob > t (St. Dev for FOMC)	DT_{50} [days]	DT_{90} [days]
LUFA 5M soil (chlorophenyl-label)								
Run SFO & FOMC	SFO	Poor	1.4	96.7	k: 1.6E-03	1.0E-9	420.8	> 1000
	FOMC	Good	0.6	99.1	α: 0.0844 β: 12.9	0.00952 3.71	> 1000	> 1000
Run DFOP	DFOP	Good	0.4	99.7	k1: 1.4E-01 k2: 1.2E-03 g: 6.3E-02	0.000749 1.47E-9 N/A	505.0	> 1000
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. FOMC and DFOP statistically similar. Visual inspection reveals that the last data point is met better by FOMC than DFOP. **FOMC appropriate**. **UK RMS agrees.** **Applicant's modelling endpoint proposal**: SFO visually unacceptable, DFOP acceptable. **DFOP appropriate**. **UK RMS disagrees.** SFO statistically acceptable and the systematic overestimation of degradation at final timepoints is within acceptable limits – **SFO appropriate**.								
LUFA 5M soil (triazole-label)								
Run SFO & FOMC	SFO	Poor	1.4	96.9	k: 1.6E-03	2.09E-9	434.5	> 1000
	FOMC	Good	0.5	99.4	α: 0.0797 β: 11.9	0.00972 3.79	> 1000	> 1000
Run DFOP	DFOP	Good	0.2	99.8	k1: 1.2E-01 k2: 1.2E-03 g: 6.6E-02	0.000881 1.15E-8 N/A	543.5	> 1000
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. DFOP better fit than FOMC. **DFOP appropriate**. **UK RMS agrees.** **Applicant's modelling endpoint proposal**: SFO visually unacceptable, DFOP acceptable. **DFOP appropriate**. **UK RMS disagrees.** SFO statistically acceptable and the systematic overestimation of degradation at final timepoints is within acceptable limits –**SFO appropriate**.								

Figure 8.1.1.2.1-1 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in LUFA 5M soil (chlorophenol-label) using KinGUI (2006). SFO: DT_{50} = 420.8 days, DT_{90} = > 1000 days and Chi^2 = 1.4 %, FOMC: DT_{50} = > 1000 days, DT_{90} = > 1000 days and Chi^2 = 0.6 % and DFOP: DT_{50} = 505.0 days, DT_{90} = > 1000 days and Chi^2 = 0.4 %.**

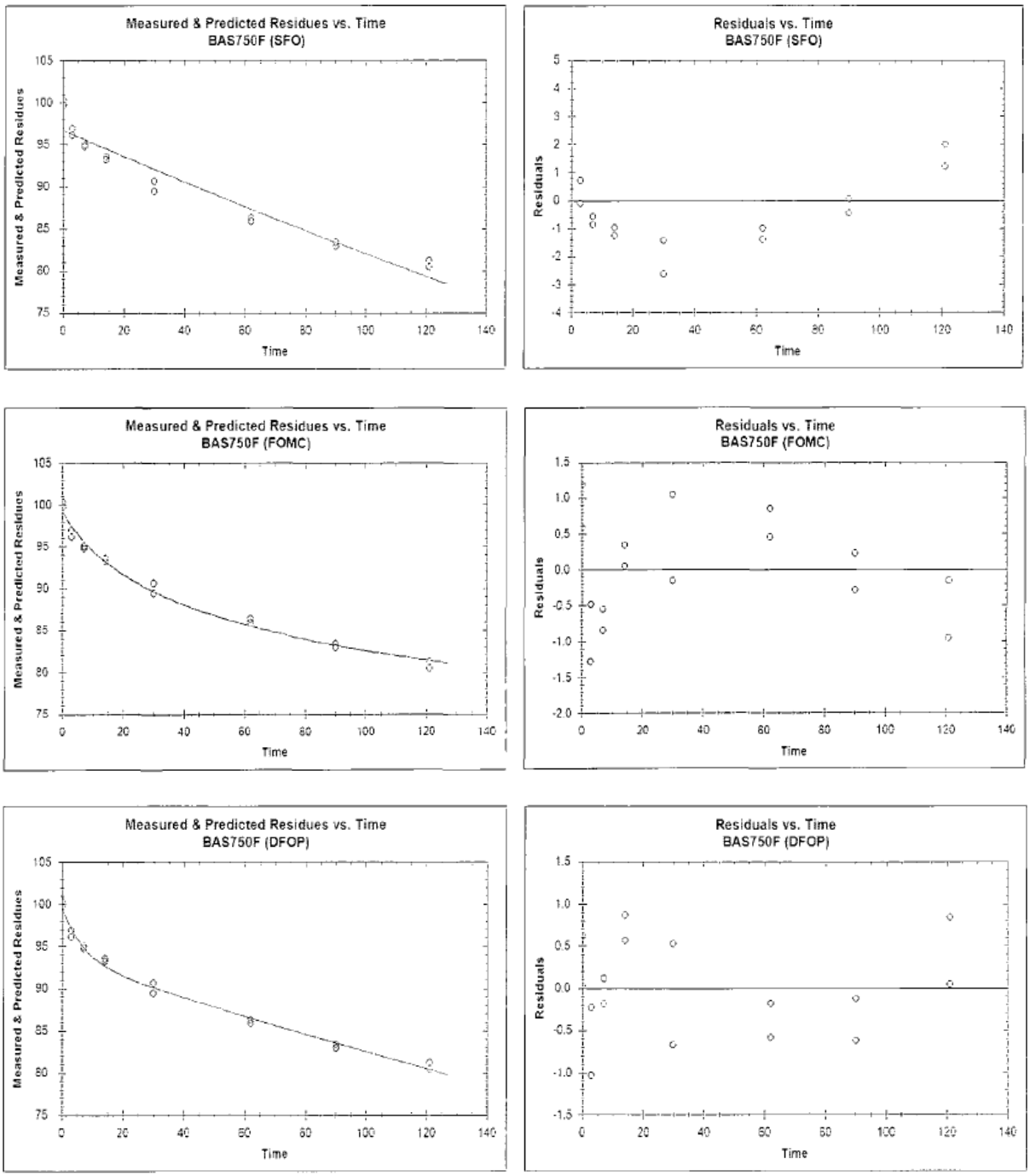


Figure 8.1.1.2.1-2 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in LUFA 5M soil (triazole-label) using KinGUI (2006). SFO: DT_{50} = 434.5 days, DT_{90} = > 1000 days and Chi^2 = 1.4 %, FOMC: DT_{50} = > 1000 days, DT_{90} = > 1000 days and Chi^2 = 0.5 % and DFOP: DT_{50} = 543.5 days, DT_{90} = > 1000 days and Chi^2 = 0.2 %.**

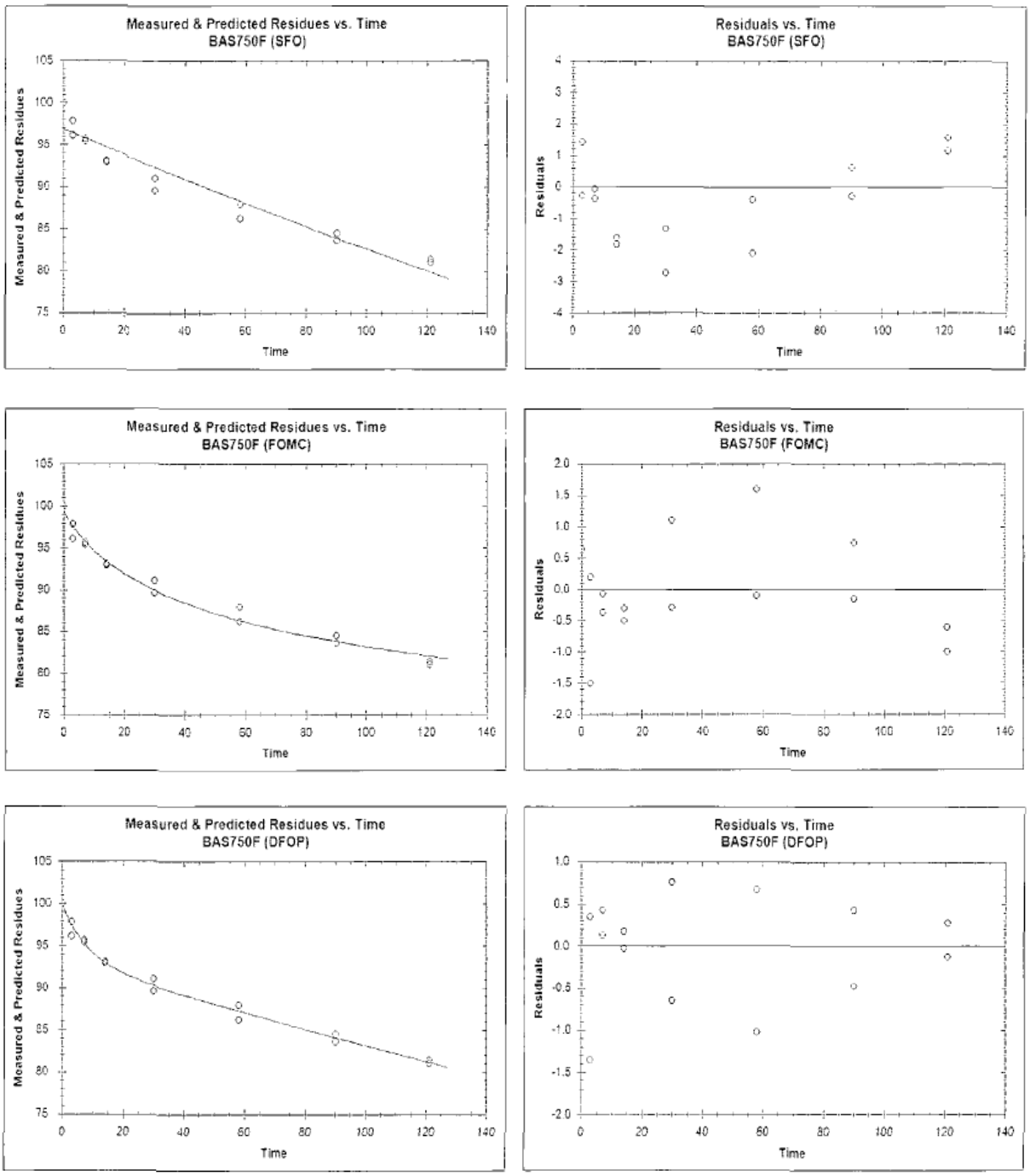
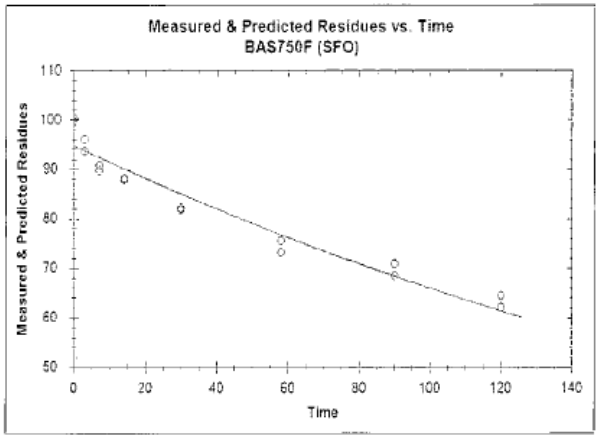


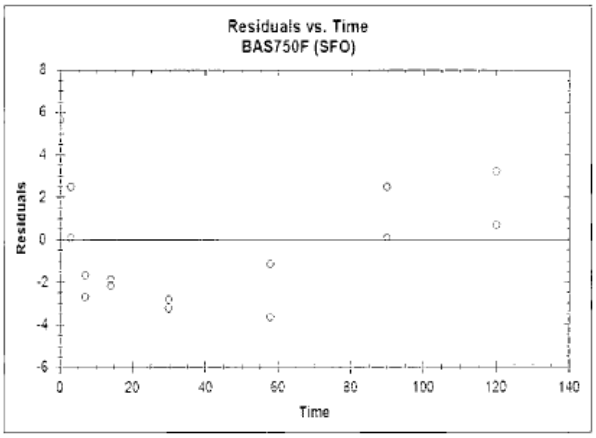
Table 8.1.1.2.1-3 **Applicant's summary of kinetic data for BAS 750 F in New Jersey soil using KinGUI (version 2).**

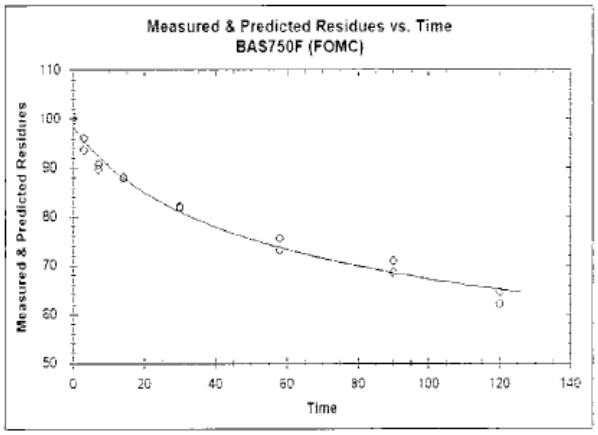
Flowchart step	Model	Visual assessment	χ^2 error %	M0	Parameters	Prob > t (St. Dev for FOMC)	DT_{50} [days]	DT_{90} [days]
New Jersey soil (chlorophenyl-label)								
Run SFO & FOMC	SFO	Poor	2.6	94.7	k: 3.6E-03	<0.001	191.5	636.1
	FOMC	Good	1.3	98.4	α: 0.213 β: 19.8	0.0346 6.96	497.3	> 1000
Run DFOP	DFOP	Good	0.8	99.9	k1: 1.7E-01 k2: 2.9E-03 g: 1.1E-01	0.00269 <0.001 N/A	201.9	761.3
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. DFOP better fit than FOMC. **DFOP appropriate**. **UK RMS agrees.** **Applicant's modelling endpoint proposal**: SFO visually unacceptable, DFOP acceptable. **DFOP appropriate**. **UK RMS disagrees.** SFO statistically and visually acceptable; the overestimation of degradation at final timepoints is within acceptable limits – **SFO appropriate**.								
New Jersey soil (triazole-label)								
Run SFO & FOMC	SFO	Poor	2.7	96.2	k: 3.5E-03	<0.001	195.4	649.0
	FOMC	Good	0.9	99.7	α: 0.229 β: 24.2	0.0336 7.215	474.5	> 1000
Run DFOP	DFOP	Good	0.9	99.1	k1: 2.1E-02 k2: 2.3E-14 g: 3.6E-01	0.0469 0.500 N/A	> 1000	> 1000
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. DFOP statistically unacceptable. FOMC acceptable. **FOMC appropriate**. **UK RMS agrees;** the DFOP k2 value fails the t-test. **Applicant's modelling endpoint proposal**: SFO visually unacceptable, DFOP acceptable. **DFOP appropriate**. **UK RMS disagrees.** SFO statistically and visually acceptable; the overestimation of degradation at final timepoints is within acceptable limits –**SFO appropriate**.								

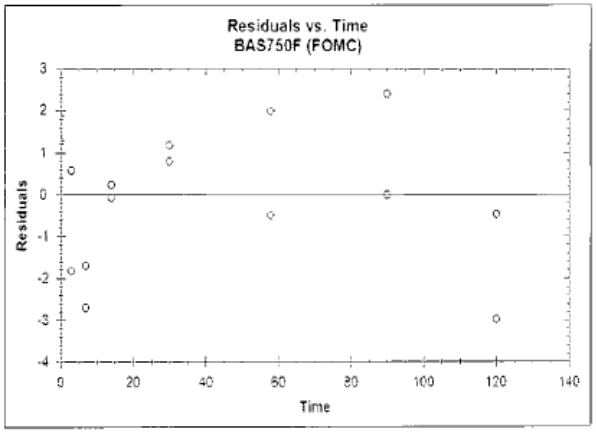
Flowchart step	Model	Visual assessment	χ^2 error %	M0	Parameters	Prob > t (St. Dev for FOMC)	DT_{50} [days]	DT_{90} [days]
New Jersey soil (trifluoromethylphenyl-label)								
Run SFO & FOMC	SFO	Poor	2.4	95.1	k: 3.6E-03	<0.001	194.3	645.3
	FOMC	Good	1.2	98.1	α: 0.249 β: 28.5	0.0434 9.65	433.7	> 1000
Run DFOP	DFOP	Good	1.3	98.4	k1: 5.9E-02 k2: 2.4E-03 g: 1.3E-01	0.0309 <0.001 N/A	232.9	906.5
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. FOMC statistically slightly better than DFOP. **FOMC appropriate**. **UK RMS agrees.** **Applicant's modelling endpoint proposal**: SFO visually unacceptable, DFOP acceptable. **DFOP appropriate**. **UK RMS disagrees.** SFO statistically and visually acceptable; the overestimation of degradation at final timepoints is within acceptable limits – **SFO appropriate**.								

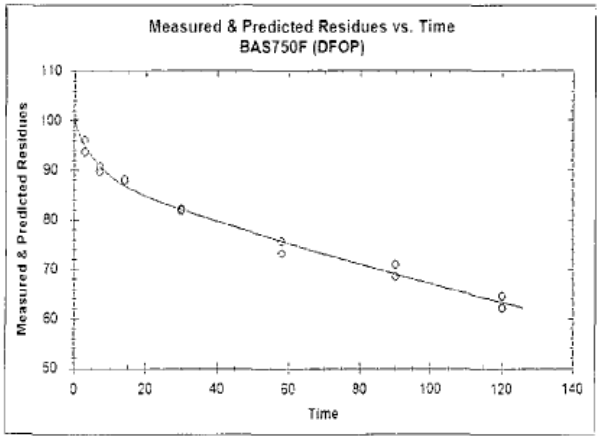
Figure 8.1.1.2.1-3 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in New Jersey soil (chlorophenol-label) using KinGUI (2006). SFO: DT_{50} = 191.5 days, DT_{90} = 636.1 days and Chi^2 = 2.6 %, FOMC: DT_{50} = 497.3 days, DT_{90} = > 1000 days and Chi^2 = 1.3 % and DFOP: DT_{50} = 201.9 days, DT_{90} = 761.3 days and Chi^2 = 0.8 %.**











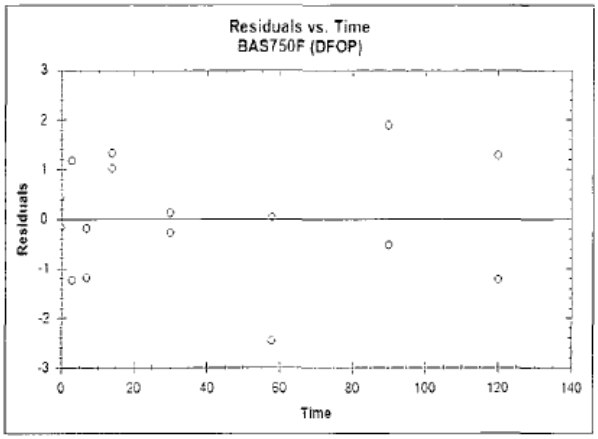


Figure 8.1.1.2.1-4 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in New Jersey soil (triazole-label) using KinGUI (2006). SFO: DT_{50} = 195.4 days, DT_{90} = 649.0 days and Chi^2 = 2.7 %, FOMC: DT_{50} = 474.5 days, DT_{90} = > 1000 days and Chi^2 = 0.9 % and DFOP: DT_{50} = > 1000 days, DT_{90} = > 1000 days and Chi^2 = 0.9 %.**

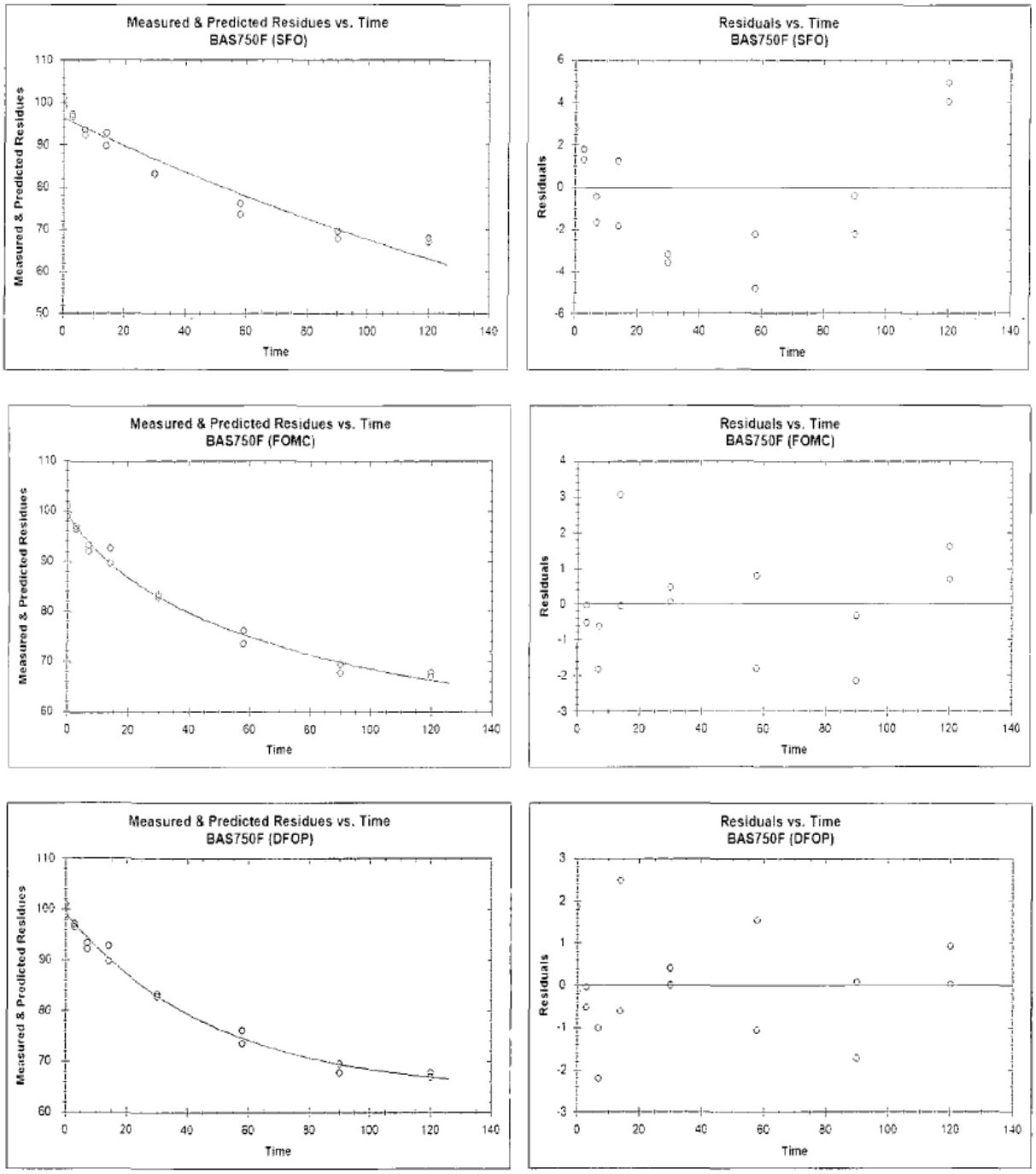


Figure 8.1.1.1-5 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in New Jersey soil (trifluoromethylphenyl-label) using KinGUI (2006). SFO: DT_{50} = 194.3 days, DT_{90} = 645.3 days and Chi^2 = 2.4 %, FOMC: DT_{50} = 433.7 days, DT_{90} = > 1000 days and Chi^2 = 1.2 % and DFOP: DT_{50} = 232.9 days, DT_{90} = 906.5 days and Chi^2 = 1.3 %.**

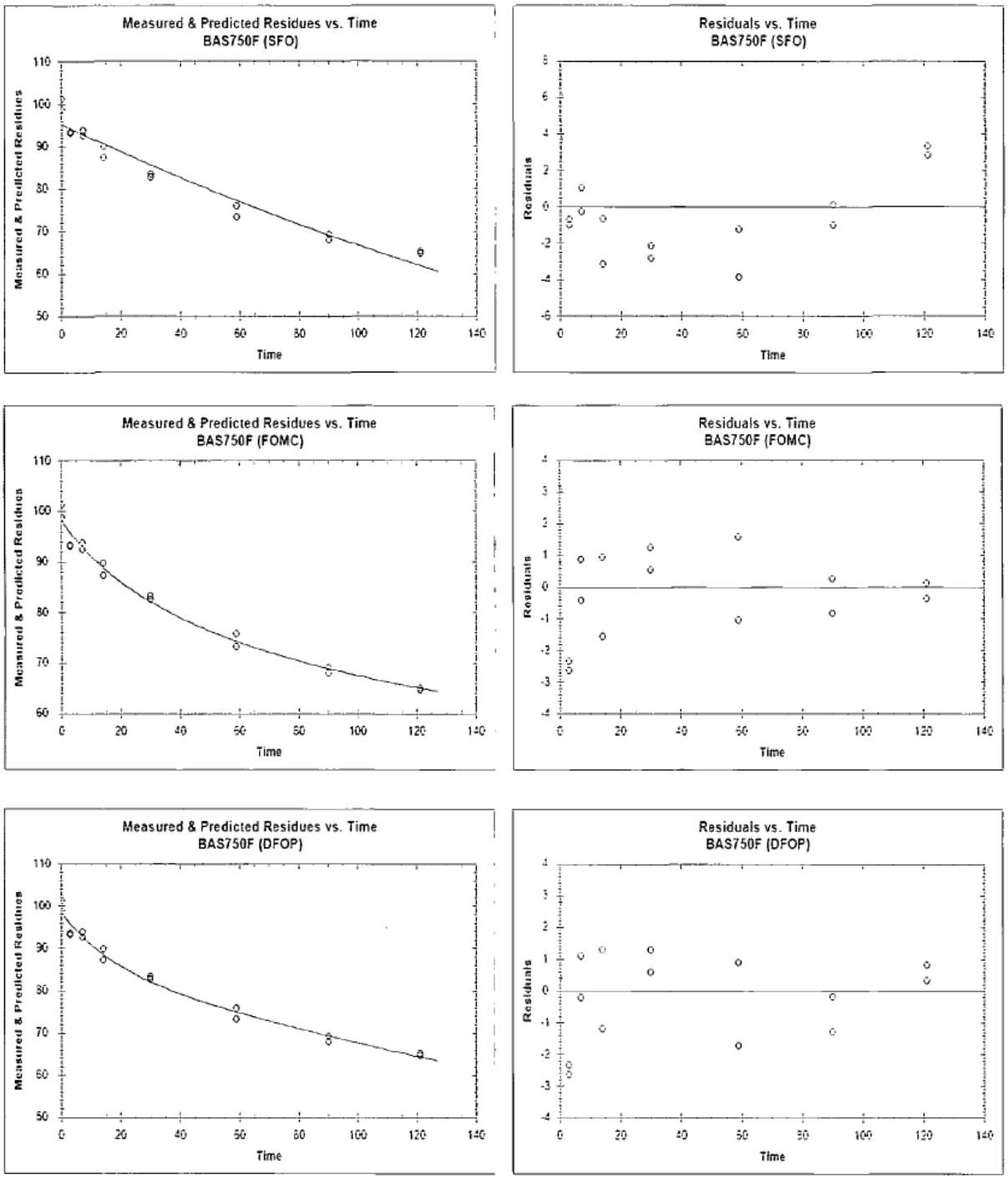
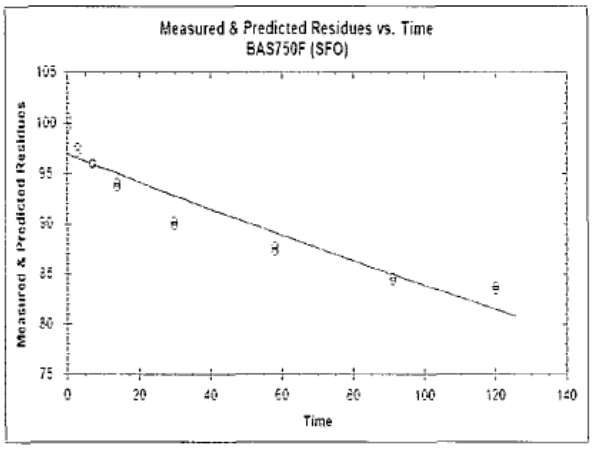
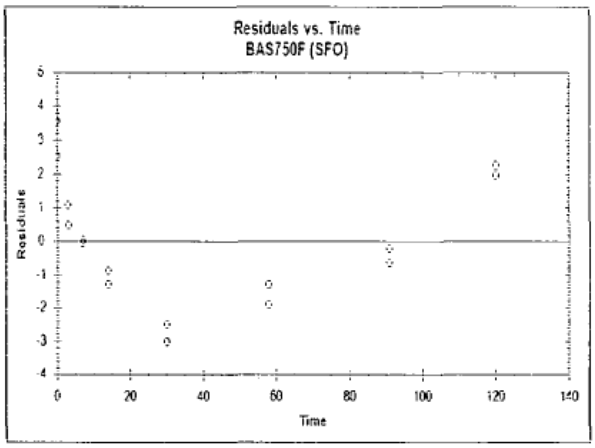


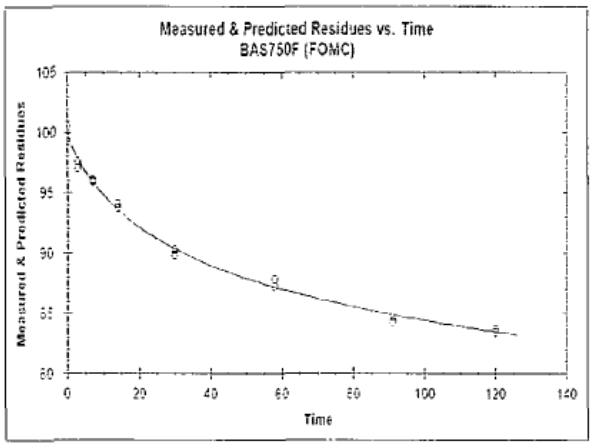
Table 8.1.1.2.1-4 **Applicant's summary of kinetic data for BAS 750 F in Li10 soil using KinGUI (version 2).**

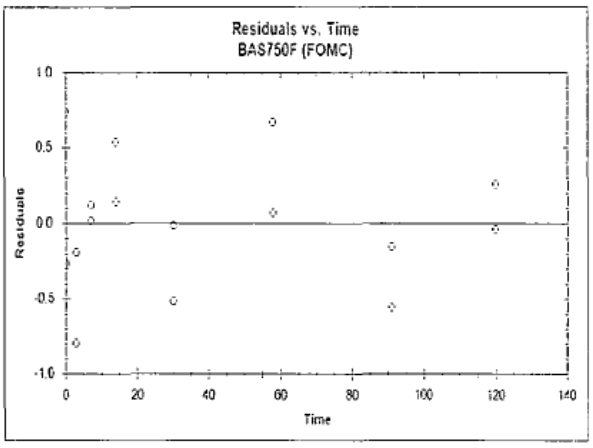
Flowchart step	Model	Visual assessment	χ^2 error %	M0	Parameters	Prob > t (St. Dev for FOMC)	DT_{50} [days]	DT_{90} [days]
Li10 soil								
Run SFO & FOMC	SFO	Poor	1.6	97.0	k: 1.5E-03	<0.001	477.1	> 1000
	FOMC	Good	0.3	99.8	α: 0.0656 β: 8.43	0.004033 1.502	> 1000	> 1000
Run DFOP	DFOP	Good	0.4	99.6	k1: 6.0E-02 k2: 7.0E-04 g: 9.1E-02	<0.001 <0.001 N/A	857.8	> 1000
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. FOMC slightly better fit than DFOP. **FOMC chosen**. **UK RMS agrees.** **Applicant's modelling endpoint proposal**: SFO visually unacceptable, DFOP acceptable. **DFOP chosen**. **UK RMS disagrees.** SFO statistically and visually acceptable; the overestimation of degradation at final timepoints is within acceptable limits – **use SFO**.								

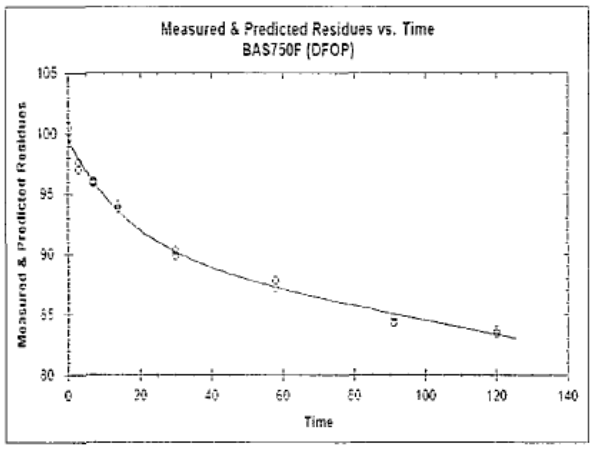
Figure 8.1.1.2.1-6 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in Li10 soil using KinGUI (2006). SFO: DT_{50} = 477.1 days, DT_{90} = > 1000 days and Chi^2 = 1.6 %, FOMC: DT_{50} = > 1000 days, DT_{90} = > 1000 days and Chi^2 = 0.3 % and DFOP: DT_{50} = 857.8 days, DT_{90} = > 1000 days and Chi^2 = 0.4 %.**











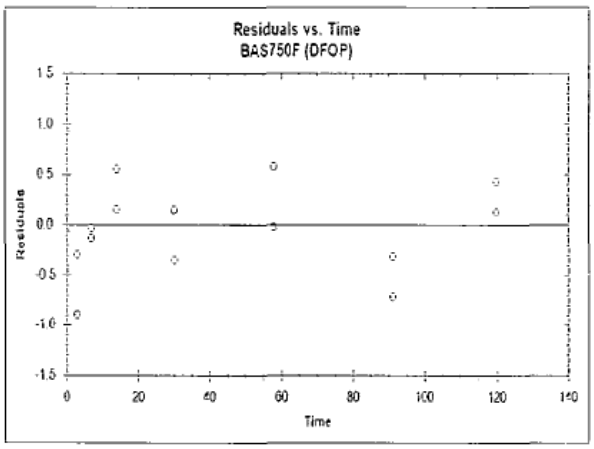
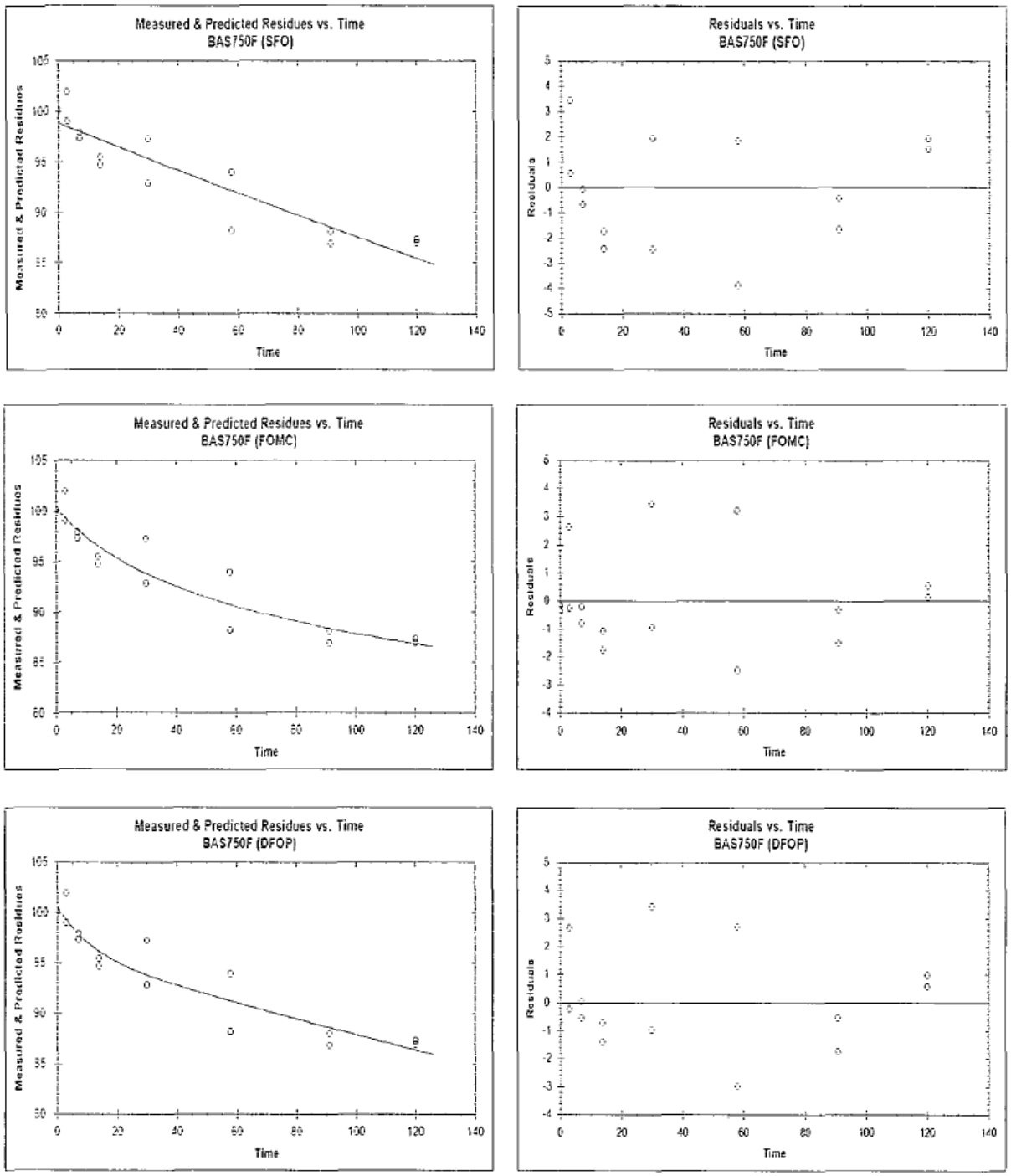


Table 8.1.1.2.1-5 **Applicant's summary of kinetic data for BAS 750 F in Indiana soil using KinGUI (version 2).**

Flowchart step	Model	Visual assessment	χ^2 error %	M0	Parameters	Prob > t (St. Dev for FOMC)	DT_{50} [days]	DT_{90} [days]
Indiana soil								
Run SFO & FOMC	SFO	Acceptable	1.2	98.8	k: 1.2E-03	<0.001	569.8	> 1000
	FOMC	Good	0.8	100.3	α: 0.0762 β: 21.13	0.03255 19.77	> 1000	> 1000
Run DFOP	DFOP	Good	0.9	100.6	k1: 8.8E-02 k2: 8.8E-04 g: 4.6E-02	0.20168 0.00678 N/A	733.6	> 1000
Applicant's trigger endpoint proposal: FOMC better fit than SFO, run DFOP. DFOP statistically unacceptable. FOMC acceptable. **FOMC chosen**. **UK RMS agrees; DFOP k1 value fails the t-test.** **Applicant's modelling endpoint proposal**: SFO acceptable. **SFO chosen**. **UK RMS agrees**.								

Figure 8.1.1.2.1-7 **Applicant's fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in Indiana soil using KinGUI (2006). SFO: DT_{50} = 569.8 days, DT_{90} = > 1000 days and Chi^2 = 1.2 %, FOMC: DT_{50} = > 1000 days, DT_{90} = > 1000 days and Chi^2 = 0.8 % and DFOP: DT_{50} = 733.6 days, DT_{90} = > 1000 days and Chi^2 = 0.9 %.**



An independent evaluation of the degradation data was performed by the UK RMS for all soils using CAKE (version 3.2) as an alternative model to that used by the Applicant.

For Li10 and Indiana soils, negligible differences between endpoints were calculated independently and by the Applicant, which can be put down to variability within the models. The endpoints calculated by the Applicant have been accepted without alteration.

For both LUFA 5M and New Jersey soils, the Applicant elected to consider the different radiolabel positions of the test substance as separate soils. Therefore, LUFA 5M soil was treated as 2 soils (each with 2 replicates) and New Jersey soil was treated as 3 soils (each with 2 replicates). The FOCUS Guidance on kinetics suggests that these soils should each be considered as single soils (4 replicates of LUFA 5M soil and 6 replicates of New Jersey soil). However, the trifluoromethylphenyl-labelled New Jersey soil was at a different moisture content to the chlorophenyl- and triazole-labelled test soils. This difference means that the trifluoromethyphenyl results cannot be combined as replicates with the chlorophenyl and triazole-labelled results until after the endpoints have been normalised (table 8.1.1.2.1-8).

Therefore, the UK RMS undertook a kinetic assessment using the approach highlighted in the FOCUS guidance (i.e. combining the LUFA 5M results and combining the New Jersey triazole and chlorophenyl results) as well as repeating the Applicant's approach. The UK RMS found no significant differences between endpoints calculated independently and by the Applicant. However, as the UK RMSs approach is deemed more in line with the guidance, the RMSs modelling results are considered appropriate to derive endpoints for soils LUFA 5M and New Jersey. Independently fitted curves and residual plots are shown in figures 8.1.1.2.1-8 - 8.1.1.2.1-10 and table 8.1.1.2.1-6 presents the associated kinetic data.

Table 8.1.1.2.1-6 **Summary of the independently produced kinetic data for BAS 750 F in LUFA 5M and New Jersey soils using CAKE (version 3.2).**

Soil	Kinetic Model	$DegT_{50}$ [d]	$DegT_{90}$ [d]	Visual assessment	Chi^2 error %	M_0	Parameters	Prob > t (St. Dev for FOMC)	Lower 95 %	Upper 95 %
LUFA 5M (chlorophenyl- and triazole labels)	SFO	427	1420	Acceptable	1.4	96.8	k = 0.001622	<0.001	0.001448	0.002
	FOMC	> 10,000	> 10,000	Good	0.56	99.2	α = 0.0821 β = 12.45	0.006701 2.614	0.06839 7.102	0.096 17.79
	DFOP	525	1870	Good	0.33	99.7	k_1 = 0.1302 k_2 = 0.001194 g = 0.06439	<0.001 <0.001 N/A	0.08419 0.001071 0.0541	0.176 0.001 0.075
UK RMS decision for trigger endpoint: FOMC better fit than SFO, run DFOP. DFOP better fit than FOMC. **DFOP chosen**. **UK RMS decision for modelling endpoint**: SFO visually and statistically acceptable. **SFO chosen**.										
New Jersey (chlorophenyl- and triazole labels)	SFO	194	646	Acceptable	2.56	95.42	k = 0.003565	<0.001	0.003194	0.004
	FOMC	488	> 10,000	Good	0.814	99.02	α = 0.2205 β = 21.99	0.02613 5.463	0.167 10.81	0.274 33.16
	DFOP	245	987	Good	0.919	99.08	k_1 = 0.05572 k_2 = 0.002172 g = 0.148	0.002666 <0.001 N/A	0.01794 0.001381 0.08289	0.094 0.003 0.213
UK RMS decision for trigger endpoint: FOMC better fit than SFO, run DFOP. FOMC better fit than DFOP. **FOMC chosen.** **UK RMS decision for modelling endpoint:** SFO visually and statistically acceptable. **SFO chosen.**										
New Jersey (trifluoromethylphenyl label)	SFO	194	645	Acceptable	2.42	95.1	k = 0.003568	<0.001	0.00307	0.004
	FOMC	434	>10,000	Good	1.18	98.15	α = 0.2487 β = 28.48	0.04338 9.654	0.155 7.627	0.342 49.34
	DFOP	233	907	Good	1.29	98.39	k_1 = 0.05919 k_2 = 0.002389 g = 0.1278	0.03095 <0.001 N/A	-0.00345 0.001348 0.0421	0.122 0.003 0.213
UK RMS decision for trigger endpoint: FOMC better fit than SFO, run DFOP. FOMC better fit than DFOP. **FOMC chosen.** **UK RMS decision for modelling endpoint:** SFO visually and statistically acceptable. **SFO chosen.**										

Figure 8.1.1.2.1-8 **Independently fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in LUFA 5M soil (both radiolabel positions) using CAKE (version 3.2). SFO: DT_{50} = 427 days, DT_{90} = 1420 days and Chi^2 = 1.39 %, FOMC: DT_{50} = > 10,000 days, DT_{90} = > 10,000 days and Chi^2 = 0.556 % and DFOP: DT_{50} = 525 days, DT_{90} = 1870 days and Chi^2 = 0.328 %.**

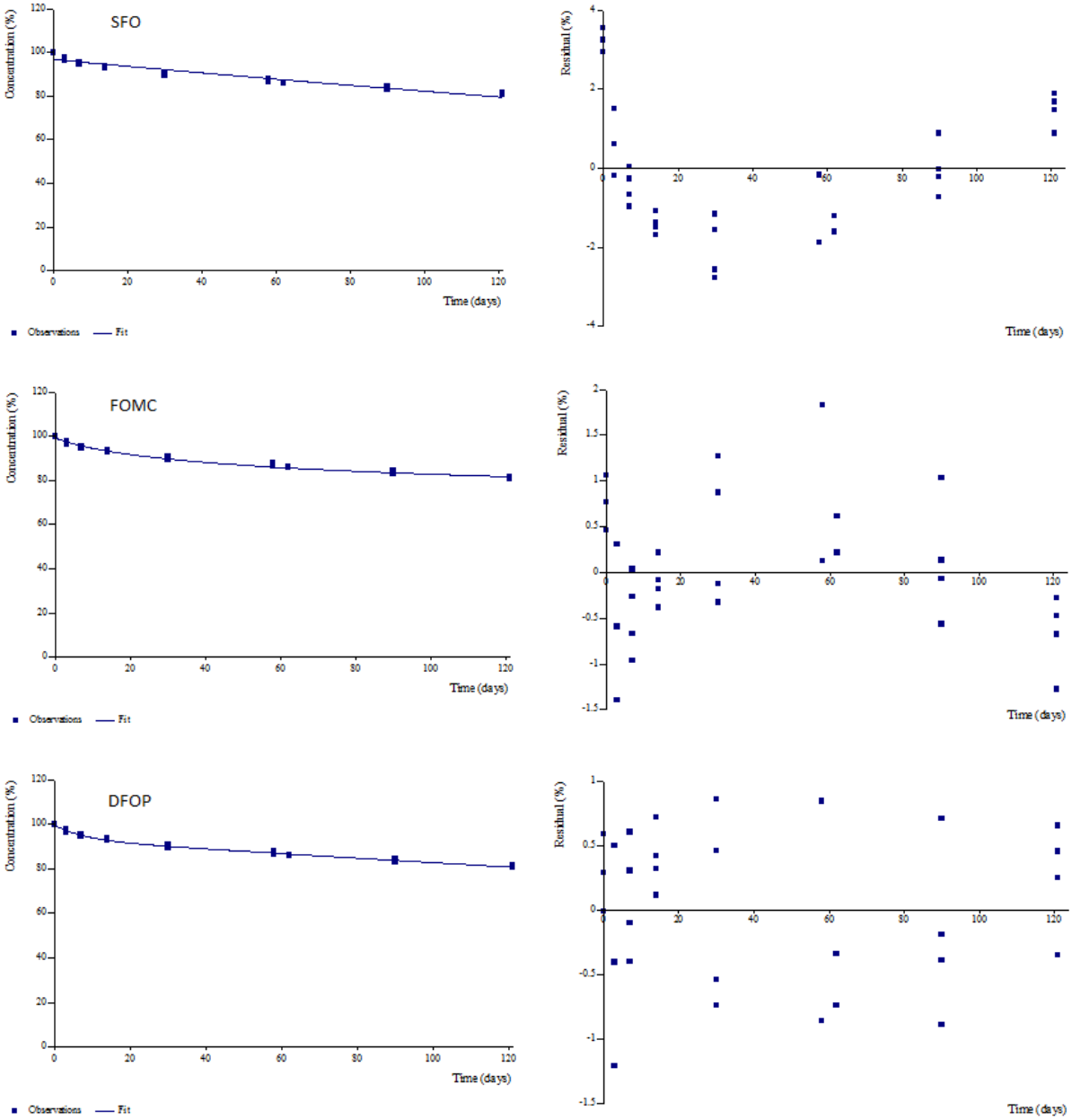


Figure 8.1.1.2.1-9 **Independently fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in New Jersey soil (chlorophenyl and triazole radiolabel positions) using CAKE (version 3.2). SFO: DT_{50} = 194 days, DT_{90} = 646 days and Chi^2 = 2.42 %, FOMC: DT_{50} = 488 days, DT_{90} = > 10,000 days and Chi^2 = 0.814 % and DFOP: DT_{50} = 245 days, DT_{90} = 987 days and Chi^2 = 0.919 %.**

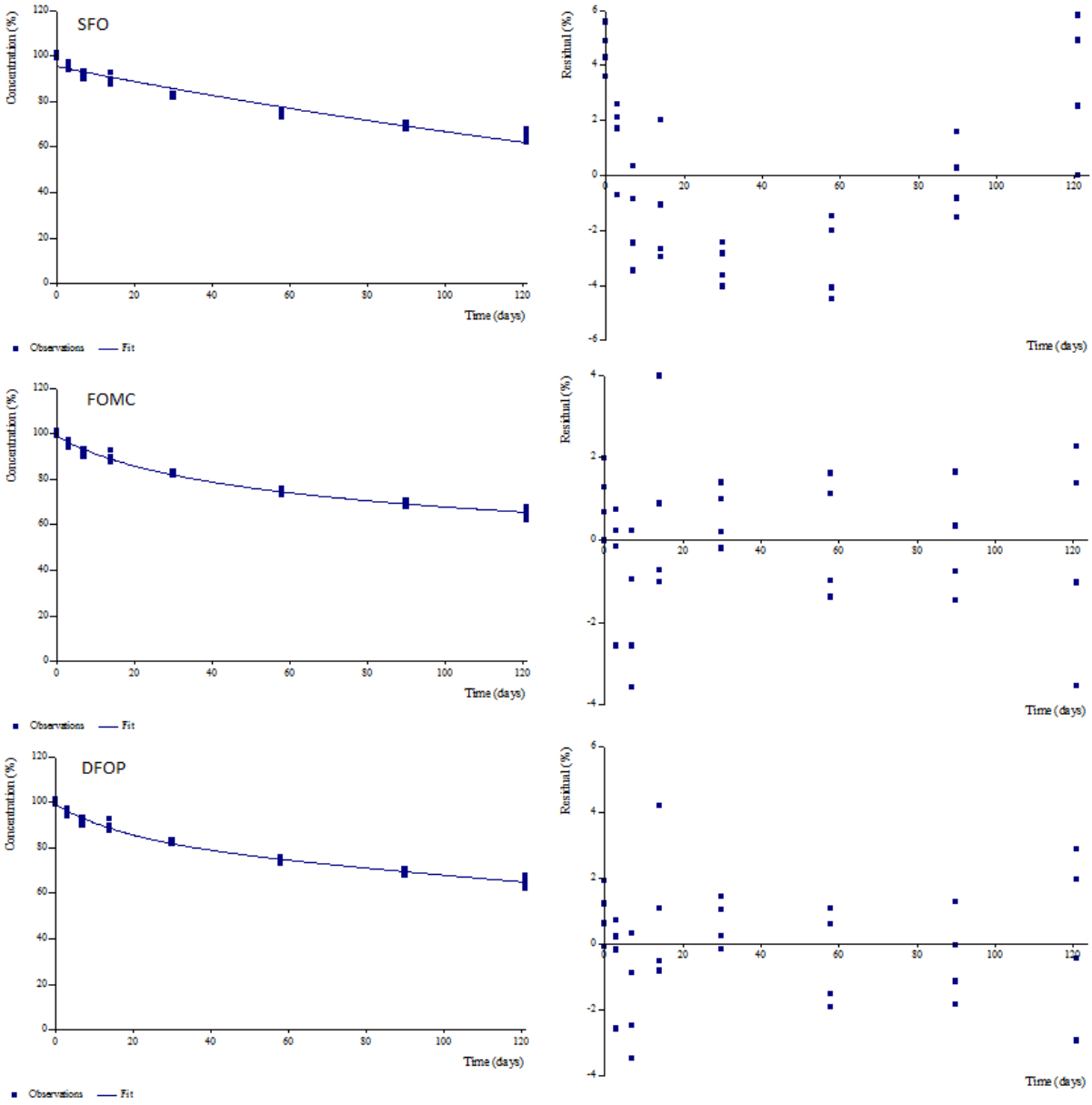
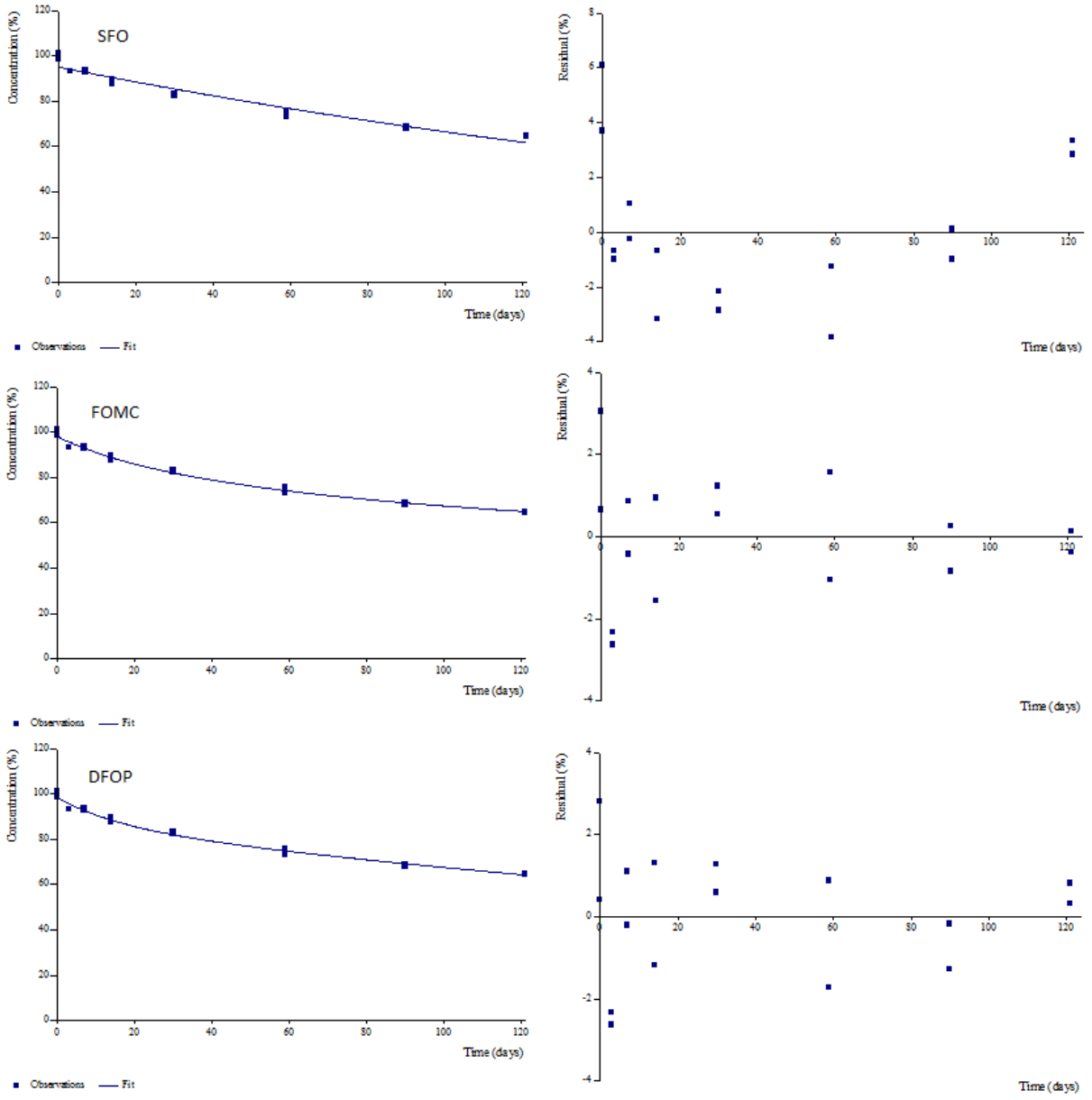


Figure 8.1.1.2.1-10 **Independently fitted SFO, FOMC and DFOP curves and residual plots for BAS 750 F in New Jersey soil (trifluoromethylphenyl radiolabel position) using CAKE (version 3.2). SFO: DT_{50} = 194 days, DT_{90} = 645 days and Chi^2 = 2.42 %, FOMC: DT_{50} = 434 days, DT_{90} = > 10,000 days and Chi^2 = 1.18 % and DFOP: DT_{50} = 233 days, DT_{90} = 907 days and Chi^2 = 1.29 %.**



Data values used in the moisture normalisation step (using the Walker Equation) are presented in table 8.1.1.2.1-7. Table 8.1.1.2.1-8 presents the normalisation of New Jersey soil, as well as details of how values from different radiolabel positions were combined.

Tables 8.1.1.2.1-9 and 8.1.1.2.1-10 present the final list of endpoints for the aerobic rate of degradation of BAS 750 F in soil.

Table 8.1.1.2.1-7 **Input values for moisture normalisation**

Laboratory study	Soil	Soil type (USDA)	MWHC (g/100 g)	Lab moisture content (% MWHC)	Lab moisture content (g/100 g)	Moisture at field capacity (g/100 g)
Staudenmaier and Dalkmann (2015a)	LUFA 5M	Loamy sand	25.2	40	10.1	21.4
	New Jersey (chlorophenyl and triazole labels)	Loam	37.0	40	14.8	25.0*
Staudenmaier and Dalkmann (2015b)	New Jersey (trifluoromethylphenyl label)	Loam	33.3	40	13.3	32.2
Staudenmaier and Dalkmann (2015c)	Li10	Loamy sand	26.9	40	10.8	10.5
	Indiana	Loam	33.3	40	13.3	25.0*

* For these soils, only the moisture at 1/3 bar (pF 2.5) was provided. In these instances, the FOCUS Ground Water Assessments Guidance (version 2.2, 2014) states to use the default gravimetric values presented in Table 2.2 of the FOCUS Ground Water Assessments Guidance; for loam soils, this is 25.0 g/100 g.

Table 8.1.1.2.1-8 **Normalisation of values from New Jersey soil. For modelling and trigger endpoints, the geomean of normalised values are taken as the final endpoints.**

Soil	Radiolabel position	BAS 750 F				
		Kinetic model	DT_{50} (days)	DT_{90} (days)	DT_{50} at 20 °C and pF2 (days)[a]	DT_{90} at 20 °C and pF2 (days)
Trigger values						
New Jersey	Combined chlorophenyl and triazole labels	FOMC	488	> 10,000	338	1000*
	Trifluoromethylphenyl label	FOMC	434	> 10,000	234	1000*
Geomean					**281**	**1000***
Modelling values						
New Jersey	Combined chlorophenyl and triazole labels	SFO	194	646	134	448
	Trifluoromethylphenyl label	SFO	194	645	104	347
Geomean					**118**	**394**

* Model output states > 1000 days, conservative default of 1000 days used.

Table 8.1.1.2.1-9 Summary of independently validated and normalised modelling endpoints for BAS 750 F.

Soil	Radiolabel position	Soil texture (USDA)	Soil pH ($CaCl_2$)	Soil pH (water)	BAS 750 F				
					Kinetic model	DT_{50} (days)	DT_{90} (days)	DT_{50} at 20 °C and pF2 (days)	DT_{90} at 20 °C and pF2 (days)
LUFA 5M	Chlorophenyl	Loamy sand	7.2	7.9	SFO	427	1420	252	840
	Triazole								
New Jersey	Chlorophenyl	Loam	Not determined	6.9	SFO	See table 8.1.1.2.1-8	See table 8.1.1.2.1-8	118	394
	Triazole								
	Trifluoromethylphenyl		6.4	6.8					
Li10	Triazole	Loamy sand	6.1	6.6	SFO	477.1	> 1000	477.1	> 1000
Indiana	Triazole	Loam	5.8	6.3	SFO	569.8	> 1000	366	1000*
Geomean								**268**	**-**

* Model output states > 1000 days, conservative default of 1000 days used.

Table 8.1.1.2.1-10 Summary of independently validated and normalised trigger endpoints for BAS 750 F.

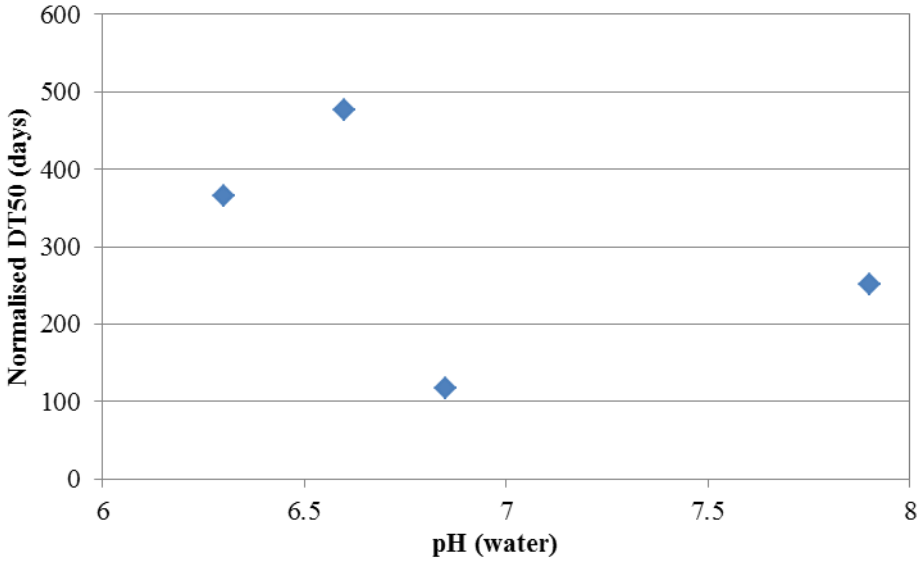
Soil	Radiolabel position	Soil texture (USDA)	Soil pH ($CaCl_2$)	Soil pH (water)	BAS 750 F				
					Kinetic model	DT_{50} (days)	DT_{90} (days)	DT_{50} at 20 °C and pF2 (days)	DT_{90} at 20 °C and pF2 (days)
LUFA 5M	Chlorophenyl	Loamy sand	7.2	7.9	DFOP	525	1870	310	1106
	Triazole								
New Jersey	Chlorophenyl	Loam	Not determined	6.9	FOMC	See table 8.1.1.1-15	See table 8.1.1.1-15	281	1000*
	Triazole								
	Trifluoromethylphenyl		6.4	6.8					
Li10	Triazole	Loamy sand	6.1	6.6	FOMC	> 1000	> 1000	1000*	1000*
Indiana	Triazole	Loam	5.8	6.3	FOMC	> 1000	> 1000	1000*	1000*
Maximum								**1000***	**-**

* Model output states > 1000 days, conservative default of 1000 days used.

To determine whether BAS 750 F should be considered as 'Persistent', the normalised trigger DT_{90} values should be divided by 3.32 (according to FOCUS guidance and SANCO working document Brussels, 25.09.2012 – rev. 3). However, these calculations have not been performed in this case because the DT_{90}s are all > 1000 days, therefore, any back-calculated DT_{50}s will be greater than the 'Persistent' trigger of 120 days and the 'very Persistent' trigger of 180 days.

The UK RMS has assessed whether BAS 750 F exhibits any pH dependent behaviour by comparing the pH of the test soils (using the soil water pH value as this was reported for all test soils) and the modelling DT_{50} values (derived from SFO fits). As figure 8.1.1.2.1-11 shows, there is no significant correlation between pH and modelling DT_{50} values.

Figure 8.1.1.1-11 Plot of normalised modelling DT_{50} values against pH (measured in water).



Conclusions

A parent only kinetics assessment of BAS 750 F was performed on four soils using KinGUI (version 2) and CAKE (version 3.2). BAS 750 F can be classed as a very persistent substance and field dissipation studies have been triggered (submitted as part of this dossier).

B.8.1.1.2.2. Estimation of the formation fraction of 1,2,4-triazole

Report: **KCA 7.1.2.1.2/2, Szegedi K., 2016 a**
Estimation of the formation fraction of 1,2,4-triazole from BAS 750 F using modelling enpoints
2016/1234478
Guidelines: none
GLP No

The aim of the study is to estimate the formation fraction of 1,2,4- triazole from BAS 750 F in a conservative manner. The evaluation is based on the finding of aerobic soil degradation studies with BAS 750 F, where 1,2,4-triazole was detected (0.6- 5.2 % TAR). Please see above for full study details.

Degradation parameters for BAS 750 F were taken from the modelling obtained in the kinetic evaluation of the relevant soil studies. The derived parameters are presented within table 8.1.1.2.2-1. The RMS is of the opinion that fittings which consider the modelling enpoints (rather thn best-fit) are more appropriate as the subsequent fitting will better reflect the 1,2,4-triazole estimation which will occur within the subsequent modelling.

Table 8.1.1.2.2-1: Modelling parameters for BAS 750 F

Soil	Kinetic Model	Visual Assessment	χ^2	Parameters
LUFA 5M (loamy sand)	SFO	Acceptable	1.4	M0 = 96.8, k = 0.001622
New Jersey (Loam)	SFO	Acceptable	2.6	M0 = 95.42, k = 0.003565
Li 10 (Loam sand)	SFO	Acceptable	1.6	M0 = 97.0, k = 1.5E-03
Indiana (Loam)	SFO	Accpetable	1.2	M0 = 98.8, k = 1.2E-03

For 1,2,4- triazole, EU agreed endpoints recommended for use in environmental fate models were considered as degradation parameters[1], and are shown below within table 8.1.1.2.2-2.

Table 8.1.1.2.2-2: EU agreed 1,2,4- triazole DT_{50}/DT_{90} values normalised to 20°C/pF2 for environmental modelling purposes

Soil type	Location	pH	Depth (cm)	Overall degradation		g	Fast phase	Slow phase	St. (χ^2)	Method of Calculation
				DT_{50} (d)	DT_{90} (d)		DT_{50} (d)	DT_{50} (d)		
Silt Loam	Germany	6.4	0-30	4.8	126.3	0.655	2.5	70.7	18.8	DFOP
Silty clay loam	Italy	7.6	0-40	20.8	159.6	0.364	1.4	59.8	10.6	DFOP
Sandy loam	UK	7.4	0-40	3.3	61.2	0.458	0.5	25.1	18.1	DFOP
Loam	Spain	5.8	0-30	17.4	296.5	0.477	4.6	126.0	12.7	DFOP
Geometric mean				8.7	138.3		**1.68**[a]	**60.6**[b]		
Arithmetic mean						**0.489**				

[a] $K_1 = 0.2075$
[b] $K_2 = 0.00747$

A compartmental model including both BAS 750 F and 1,2,4- triazole was implemented in the programme package ModelMaker 3.0.3. The compartmental model is shown within Figure 8.1.1.2.2-1.

[1] *CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT_{50} Summary, Scientific Evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting)*

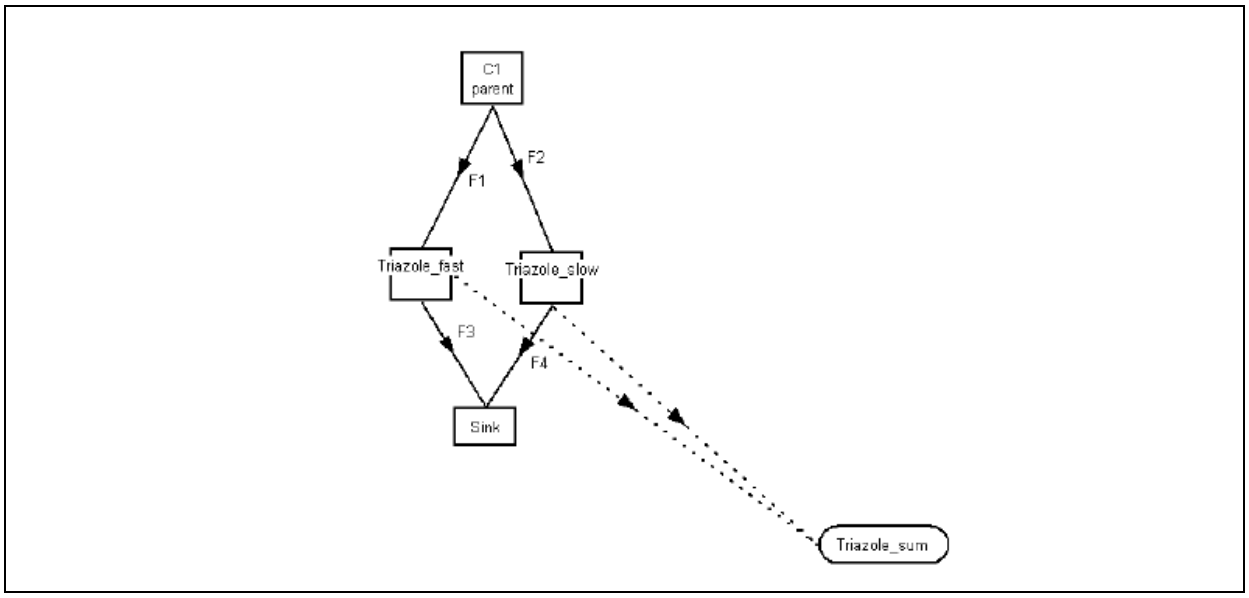


Figure 8.1.1.2.2-1: Compartment model to predict the environmental concentration of 1,2,4-triazole in soils with SFO kinetic from parent: Applicant screenshot from ModelMaker main window

During the analysis the decline kinetics of BAS 750 F and 1,2,4-triazole are fixed and the formation fraction is manually adjusted so that the simulated residue curve covers, in a conservative manner, all measured residues in the soils.

The RMS notes that the conceptual model does not include a sink from the parent. However as all parameters (except the formation fraction) are fixed, and the formation fraction is manually optimised this is this is not considered to have an impact on the suitability of the resulting formation fraction.

Results

The RMS agrees with the Applicants values, except for LUFA 5M, as the RMS could not attain the visual fit produced by the applicant; for this data set the results presented are those calculated by the RMS. The resulting graphs from the fitting procedure are shown within figure 8.1.1.2.2-1, and the estimated formfation fraction presented within 8.1.1.2.2-3.

Table 8.1.1.2.2-3: Estimated formation of 1,2,4-triazole

Soil	Formation fraction of 1,2,4-triazole
LUFA 5M (loamy sand)	0.12
New Jersey (Loam)	0.65
Li 10 (Loam sand)	0.42
Indiana (Loam)	0.42
Arithemetic mean	0.40

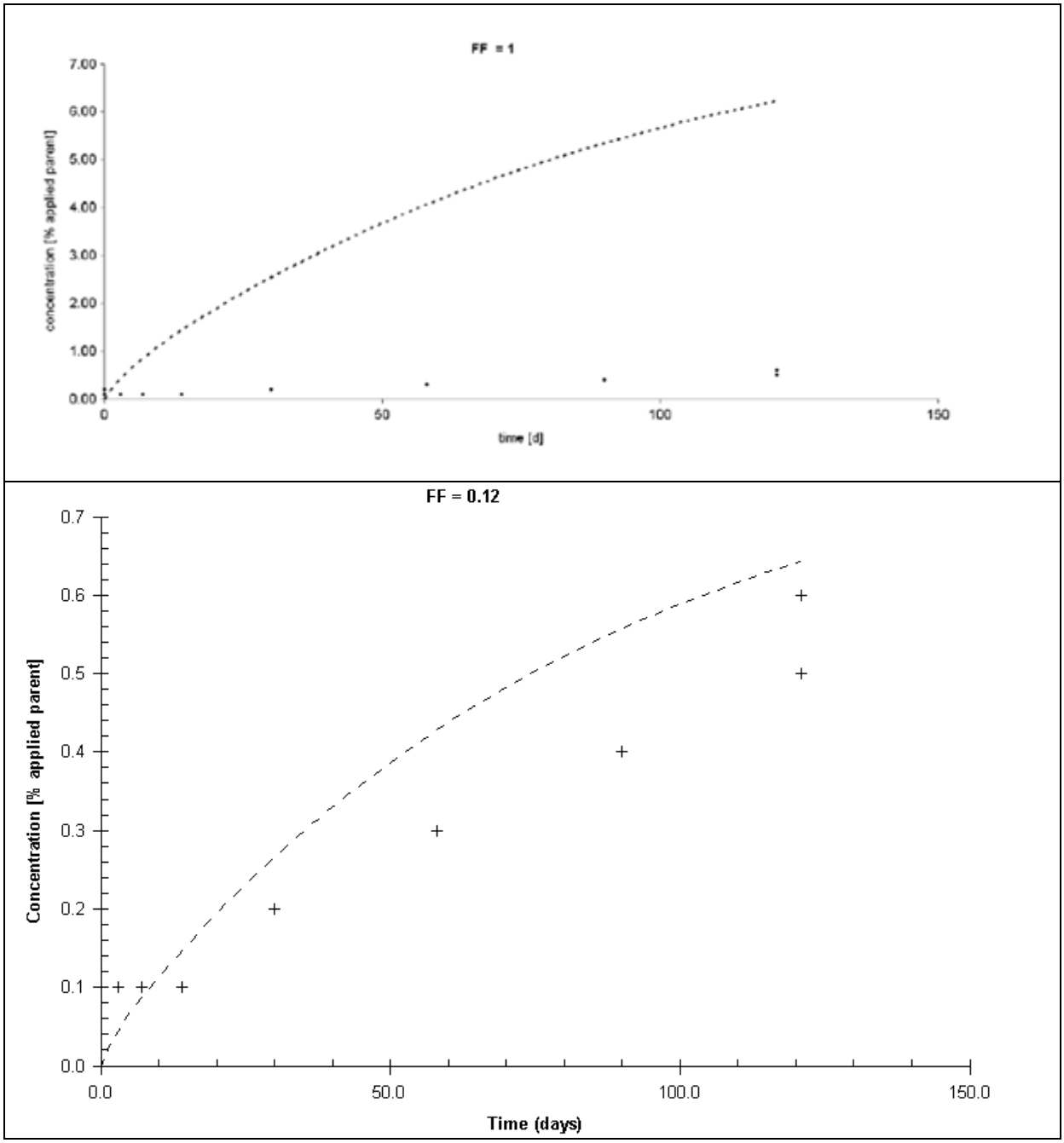


Figure 8.1.1.2.2-2: Predicted concentration of 1,2,4-triazole, compared to measured concentration of 1,2,4-triazole in soil LUFA 5M using formation fraction FF=1 (Applicant) and FF=0.12 (RMS) respectively.

Dashed line: Predicted values' dots measured values, note different scale on the Y axis.

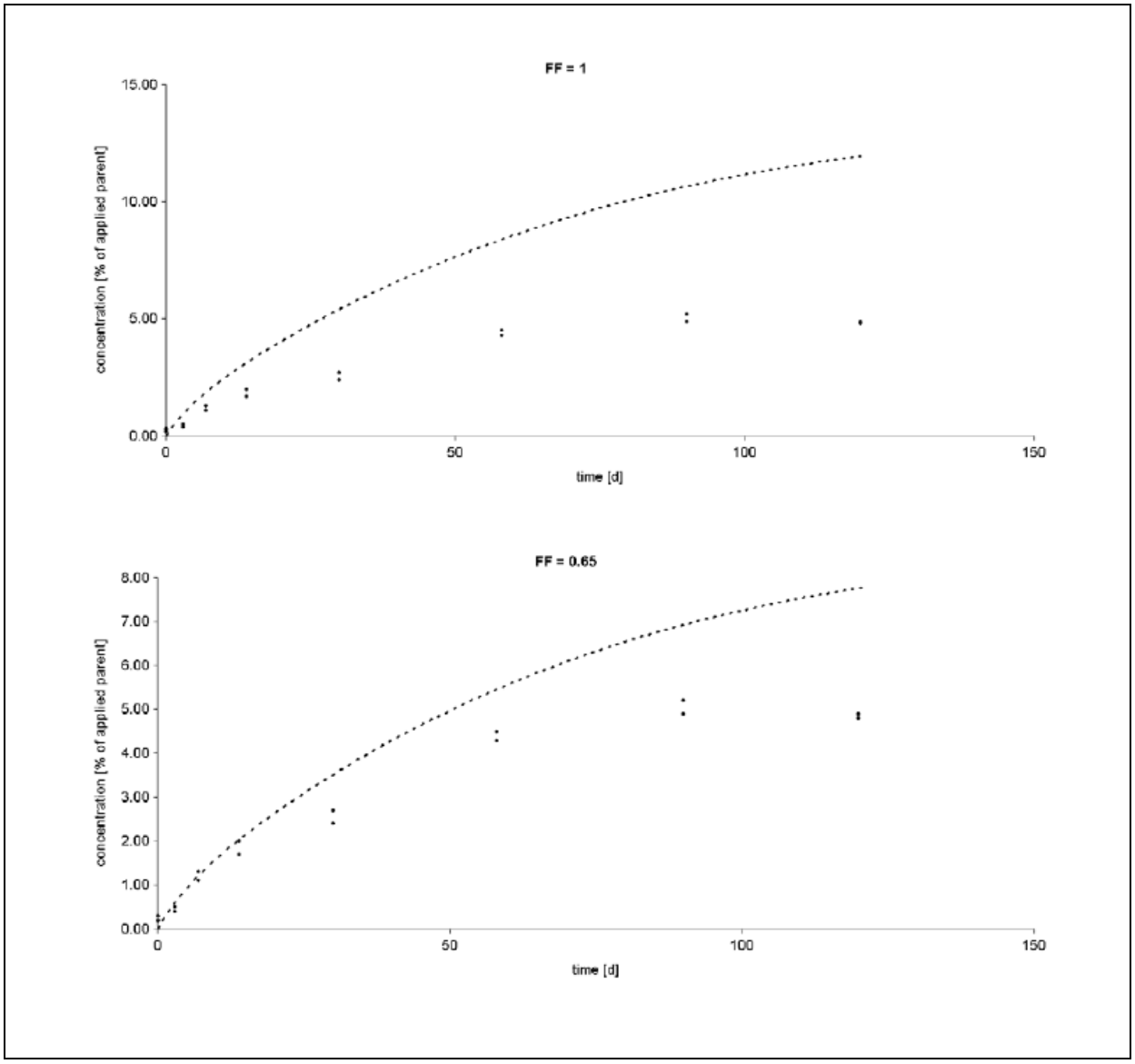


Figure 8.1.1.2.2-3: Predicted concentration of 1,2,4-triazole, compared to measured concentration of 1,2,4-triazole in soil New Jersey using formation fraction FF=1 and FF=0.65 respectively.

Dashed line: Predicted values' dots measured values, note different scale on the Y axis.

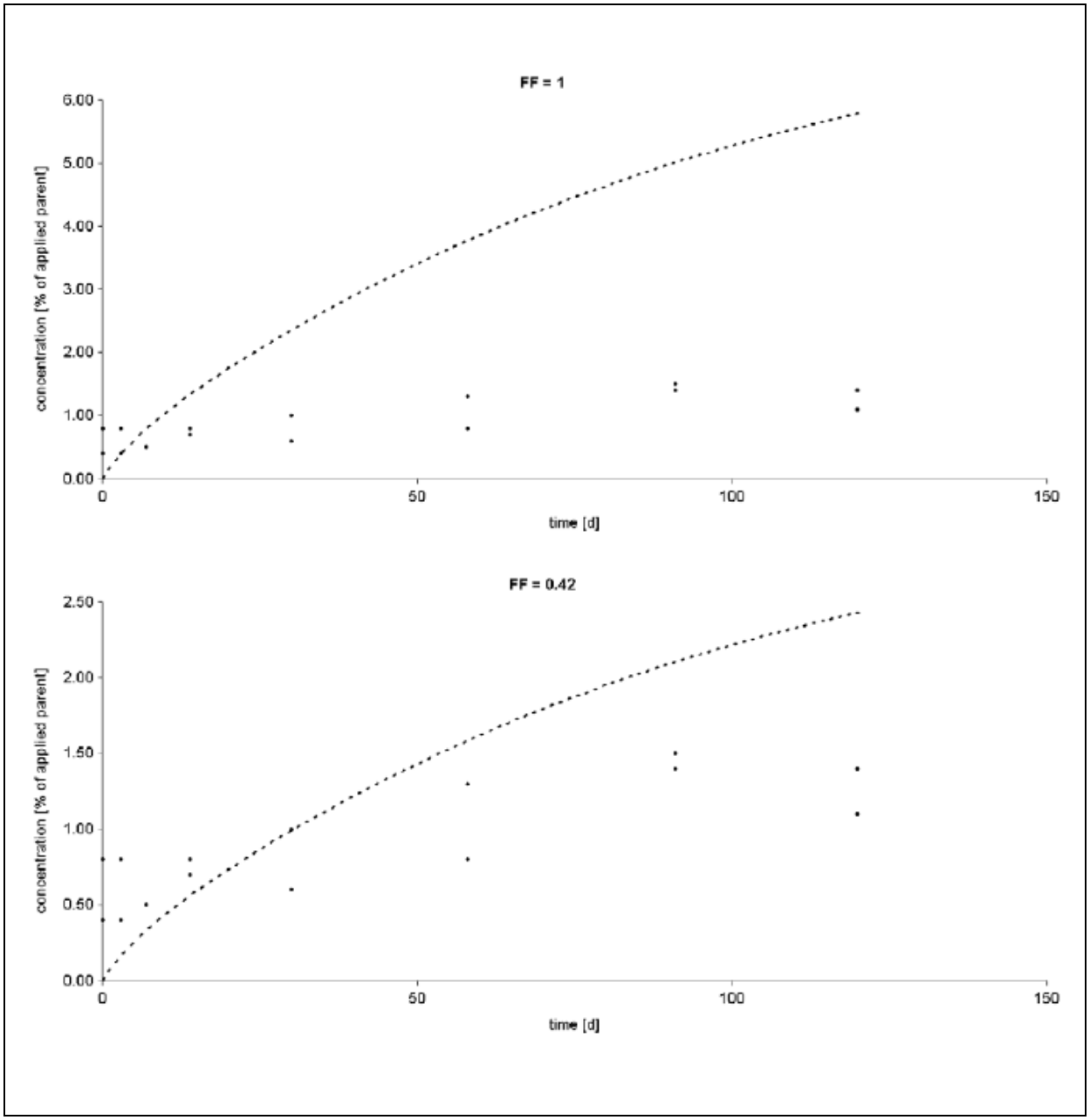


Figure 8.1.1.2.2-4: Predicted concentration of 1,2,4-triazole, compared to measured concentration of 1,2,4-triazole in soil Li 10 using formation fraction FF=1 and FF=0.42 respectively.

Dashed line: Predicted values' dots measured values, note different scale on the Y axis.

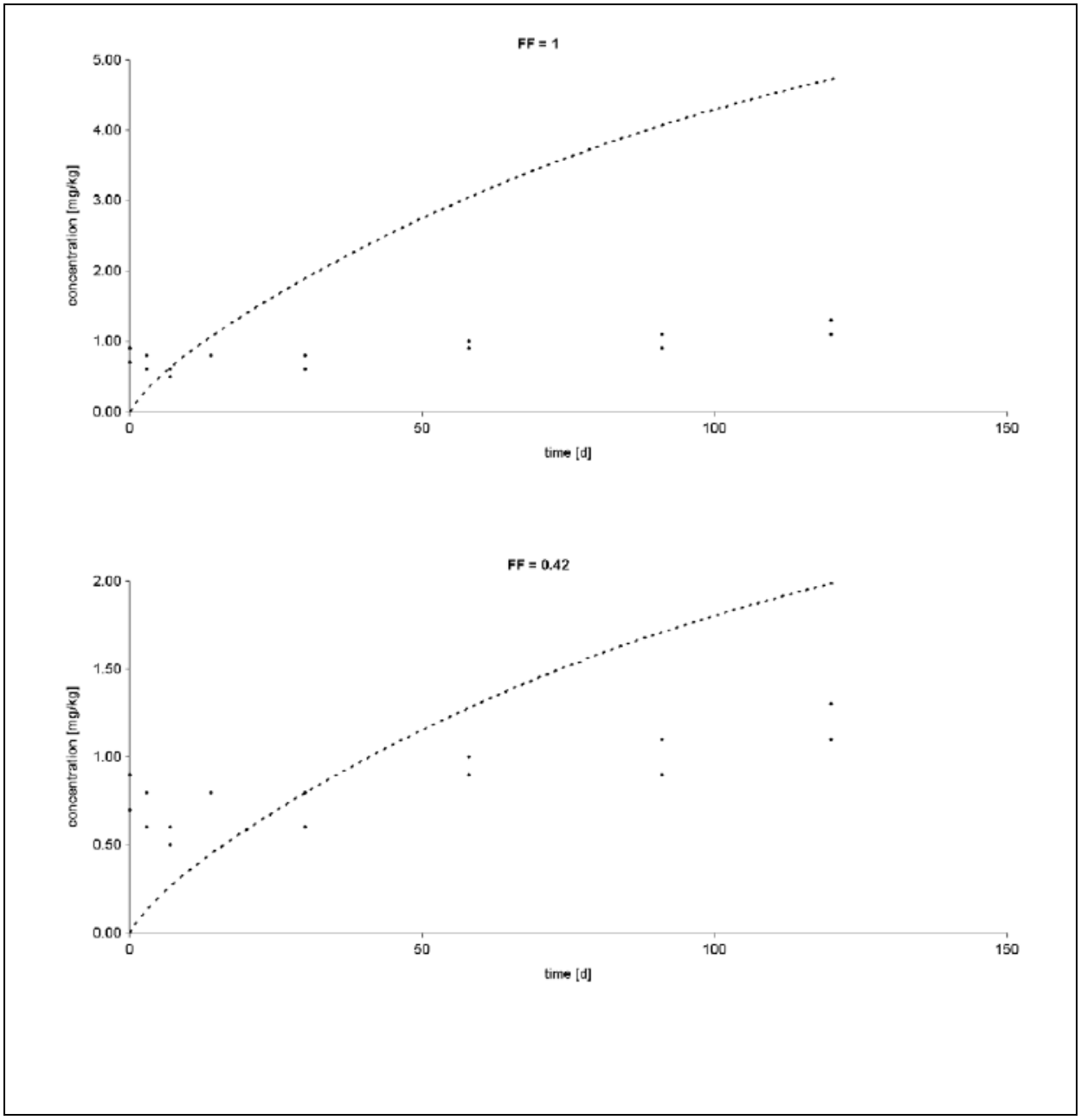


Figure 8.1.1.2.2-5: Predicted concentration of 1,2,4-triazole, compared to measured concentration of 1,2,4-triazole in soil Indiana using formation fraction FF=1 and FF=0.42 respectively.

Dashed line: Predicted values' dots measured values, note different scale on the Y axis.

The Applicant initially submitted formation fraction calculations based upon the best-fit endpoints. As indicated within the above report the RMS considers that it is more appropriate to consider the BAS 750 F modelling endpoints (rather than best-fit) as the subsequent modelling will better describe how the subsequent modelling will predict 1,2,4-triazole formation and a such requested the applicant to submit relevant modelling.

However it must be noted, that ultimately, the study below could not be considered as the best fit parameters for BAS 750 F were not in line with that concluded within the previous sections. As such the study cannot be relied upon. It is also for this reason that the RMS did not validate the applicants modelling in the following study.

For transparency, and to aid discussion, the setting on the formation fraction the RMS has included the estimation of the formation fraction based upon the best fit-endpoints. However, the values presented have not been considered within the subsequent risk assessment.

Report: CA 7.1.2.1.2/1, Szegedi K., 2015 a
Estimation of the formation fraction of 1,2,4-triazole from BAS 750 F
2015/1260802
Guidelines: none
GLP: no

The aim of the study is to estimation the formation fraction of 1,2,4-triazole from BAS 750 F in a conservative manner. The evaluation is based on the findings of aerobic soil degradation studies with BAS 750 F, where 1,2,4-triazole was detected (0.6 – 5.2 % TAR). Please see above for full study details.

Degradation parameters for BAS 750 F were taken from the modelling obtained in the kinetic evaluation of the relevant soil studies. The derived parameters considered by the Applicant are presented within table 8.1.1.2.2-4. The RMS notes that the values presented are not in line with that concluded previously. As such the subsequent analysis cannot be relied upon. Therefore the RMS has not verified the subsequent fitting and the following text is for information only.

Table 8.1.1.2.2-4: Best fit parameters for BAS 750 F

Soil	Kinetic Model	Visual Assessment	χ^2	Parameters
LUFA 5M	DFOP	Good	0.2	$k_{1\ parent}$ = 0.1225 $k_{2\ parent}$ = 0.001151 g_{parent} = 0.06558
New Jersey	FOMC	Good	0.9	□ = 0.22908 □ = 24.1983
Li 10	FOMC	Good	0.3	□ = 0.0656 □ = 8.4325
Indiana	FOMC	Good	0.8	□ = 0.0762 □ = 21.1284

For 1,2,4-triazole, EU agreed endpoints recommended for use in environmental fate models were considered as degradation parameters[2], and are shown below within table 8.1.1.2.2-5

Table 8.1.1.2.2-5: EU agreed 1,2,4- triazole DT_{50}/DT_{90} values normalised to 20°C/pF2 for environmental modelling purposes

Soil type	Location	pH	Depth (cm)	Overall degradation		g	Fast phase	Slow phase	St. (χ^2)	Method of Calculation
				DT_{50} (d)	DT_{90} (d)		DT_{50} (d)	DT_{50} (d)		
Silt Loam	Germany	6.4	0-30	4.8	126.3	0.655	2.5	70.7	18.8	DFOP
Silty clay	Italy	7.6	0-40	20.8	159.6	0.364	1.4	59.8	10.6	DFOP

[2] *CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT_{50} Summary, Scientific Evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting)*

loam										
Sandy loam	UK	7.4	0-40	3.3	61.2	0.458	0.5	25.1	18.1	DFOP
Loam	Spain	5.8	0-30	17.4	296.5	0.477	4.6	126.0	12.7	DFOP
Geometric mean				8.7	138.3		**1.68**[a]	**60.6**[b]		
Arithmetic mean						**0.489**				

[a] $K_1 = 0.2075$
[b] $K_2 = 0.00747$

A compartmental model including both BAS 750 F and 1,2,4- triazole was implemented in the programme package ModelMaker 3.0.3. the compartmental model is shown within figures 8.1.1.2.2-6 and 8.1.1.2.2-7.

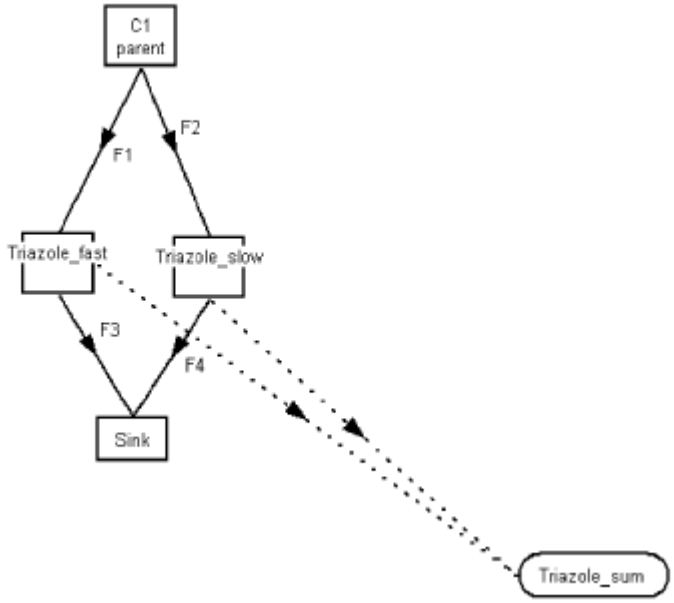


Figure 8.1.1.2.2-8: Compartmental model to predict the environmental concentration of 1,2,4-triazole in soils with FOMC kinetics for parent. Applicant screenshot from ModelMaker Main window

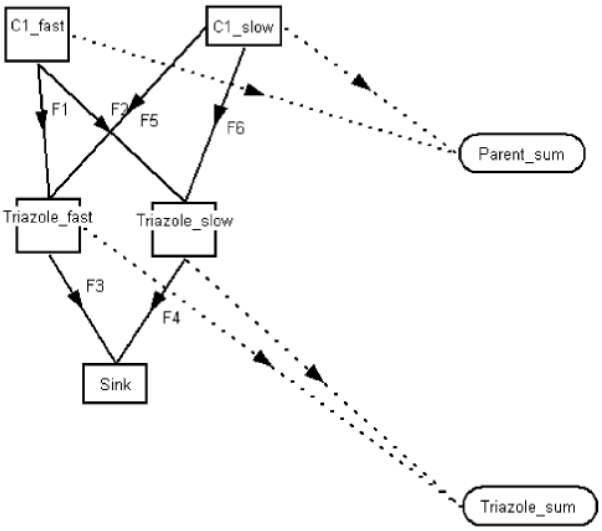


Figure 8.1.1.2.2-7: Compartmental model to predict the environmental concentration of 1,2,4-triazole in soil with DFOP kinetics for parent- Screenshot from ModelMaker Main window

During the analysis the decline kinetics of BAS 750 F and 1,2,4-triazole are fixed and the formation fraction , starting from 1.0, was successively reduced to fit the predicted maximum occurrence of the metabolite to its observed maximum occurrence.

Results

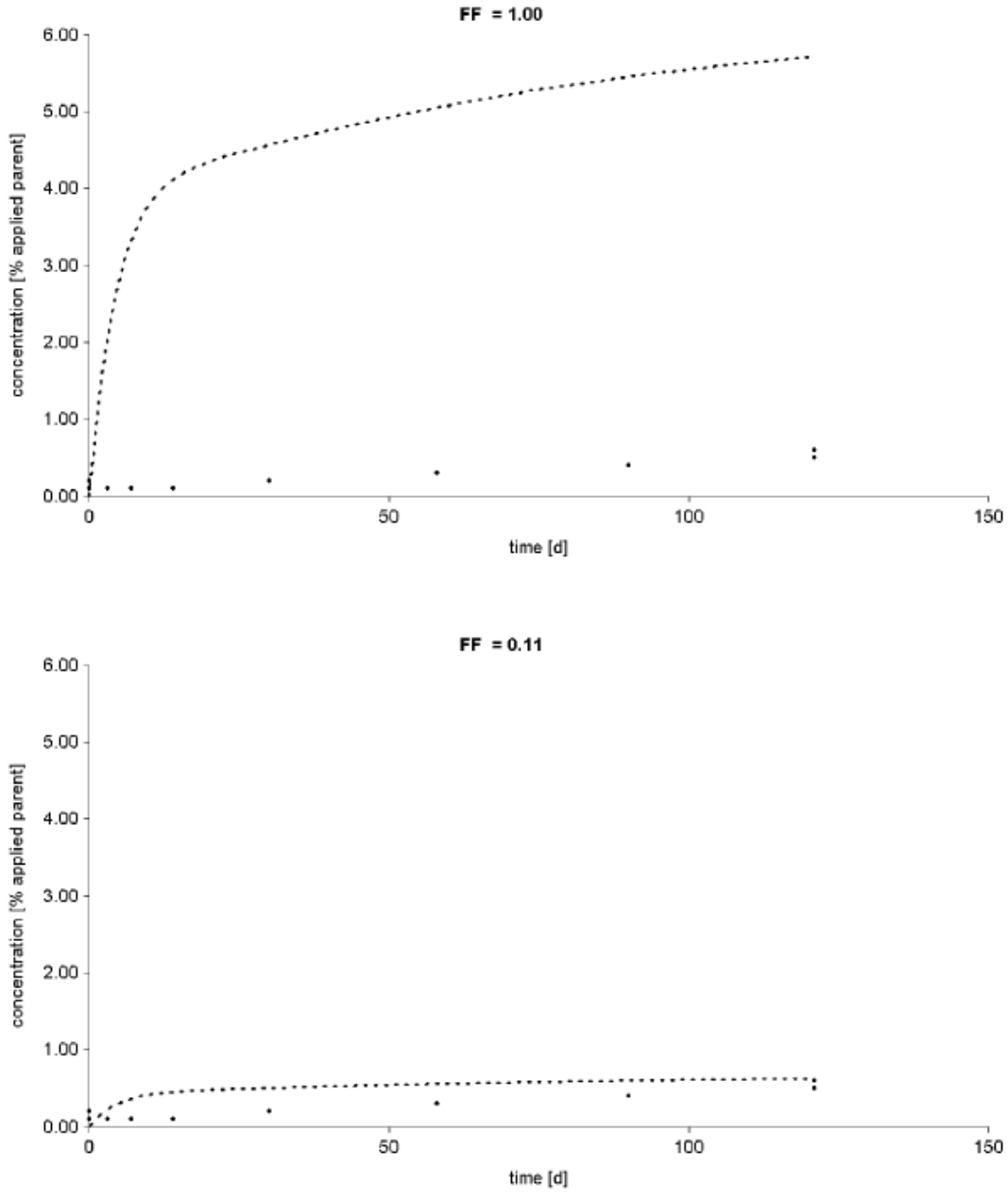
The resulting graphs from the fitting procedure are shown within figures Figure 8.1.1.2.2-8 to 8.1.1.2.2-11, and the estimated formation fraction presented within 8.1.1.2.2-6.

Table 7.1.2.1.2-6: Estimated formation fractions of 1,2,4-triazole

Soil	Formation fraction of 1,2,4-triazole
LUFA 5M	0.11
New Jersey	0.50
Li 10	0.32
Indiana	0.35
Arithmetic mean	**0.32**

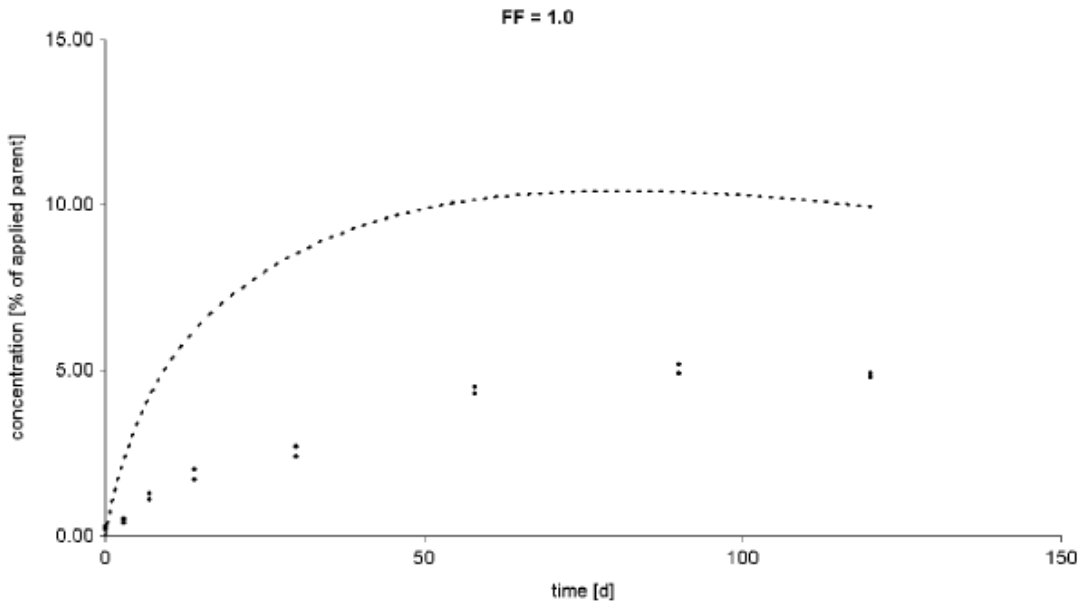
III. CONCLUSION

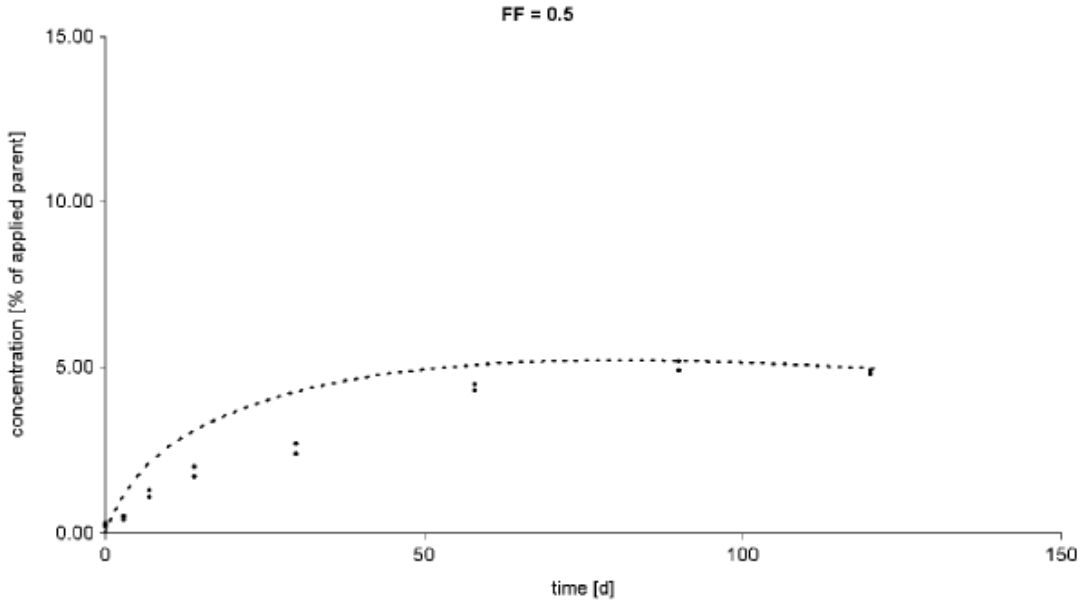
Formation fractions for 1,2,4-triazole from BAS 750 F for use in environmental fate models were estimated for four different soils with a shell approach. The estimated formation fractions of 1-2-4-triazole ranged from 0.11 to 0.50, with an arithmetic mean value of 0.32.



Dashed line: predicted values; dots: measured values

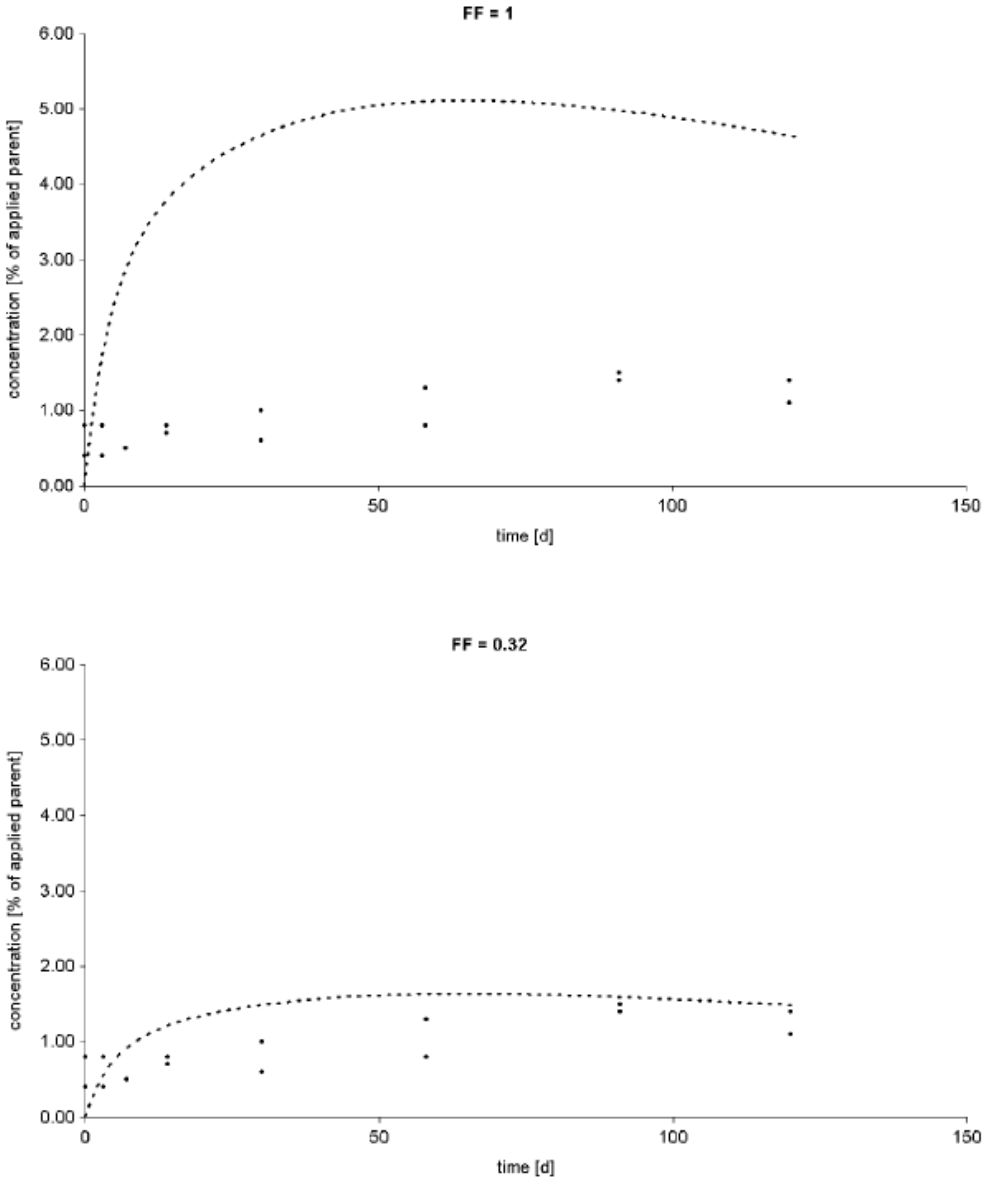
Figure 8.1.1.2.2-8: Predicted compared to measured concentration of 1,2,4-triazole in soil LUFA 5M using the estimated formation fraction





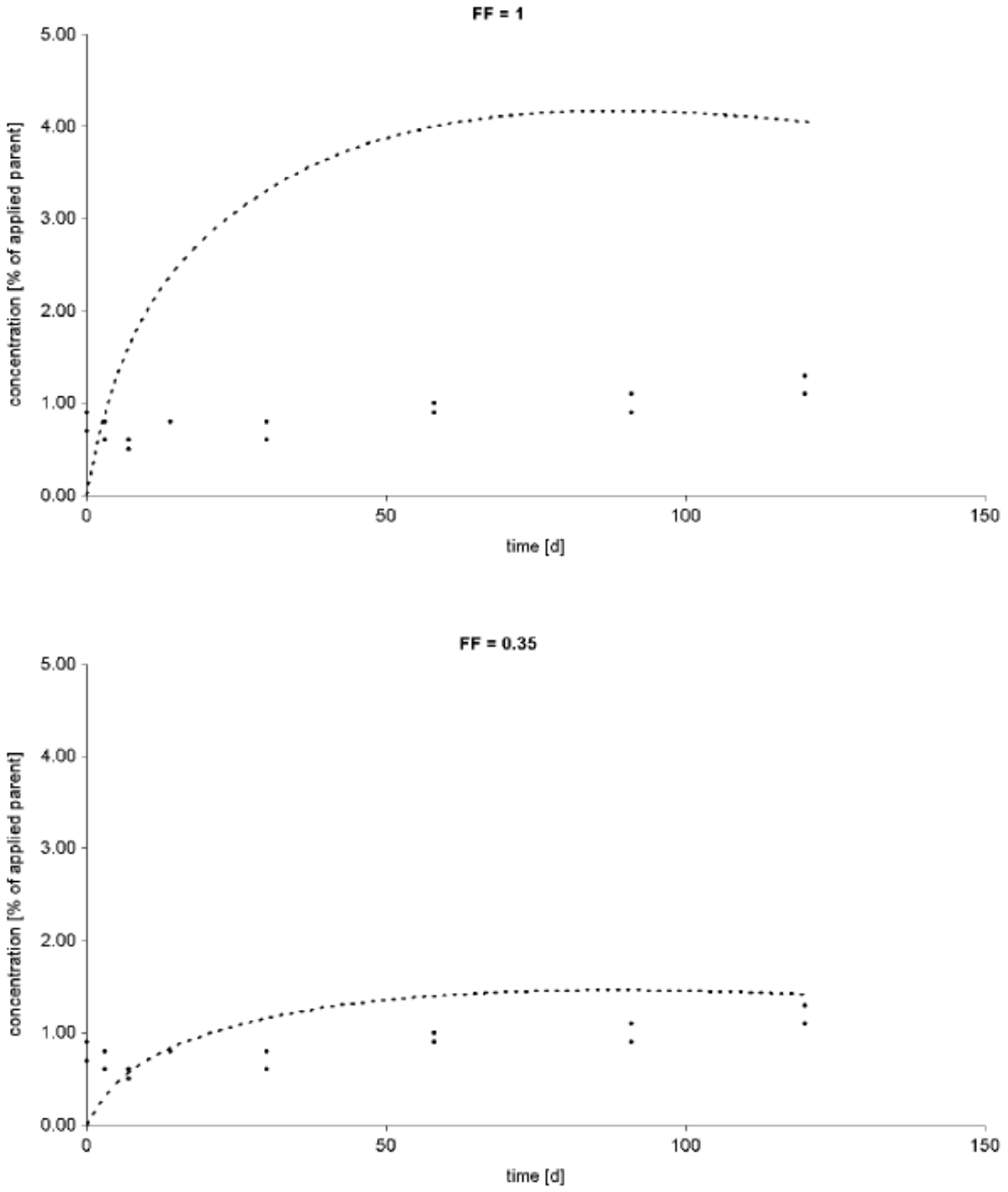
Dashed line: predicted values; dots: measured values

Figure 8.1.1.2.2-9: Predicted compared to measured concentration of 1,2,4-triazole in soil New Jersey using the estimated formation fraction



Dashed line: predicted values; dots: measured values

Figure 8.1.1.2.2-10:Predicted compared to measured concentration of 1,2,4-triazole in soil Li 10 using the estimated formation fraction



Dashed line: predicted values; dots: measured values

Figure 8.1.1.2.2-11: Predicted compared to measured concentration of 1,2,4-triazole in soil Indiana using the estimated formation fraction

B.8.1.1.3. Anaerobic degradation

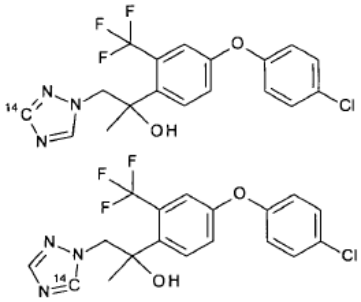
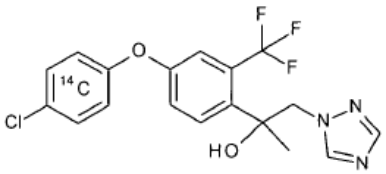
Report:	CA 7.1.1.2/1 Leed M.G., 2015 a Anaerobic soil metabolism of 14C-BAS 750 F 2014/7003496
Guidelines:	EPA 835.4200, OECD 307 (2002), SETAC Procedures for assessing the environmental fate and ecotoxicity for pesticides (March 1995)
GLP:	yes (certified by United States Environmental Protection Agency)

Introduction

This study was designed to determine the route and rate of degradation of BAS 750 F in soil under anaerobic conditions. This study was conducted to GLP and according to OECD 307 test guidelines; there were no significant deviations that would affect the validity of the study.

Information on the ^{14}C-labeled test materials used in the study is presented in Table 8.1.1.3-1.

Table 8.1.1.3-1: Test materials

Substance code	BAS 750 F	
Reg number	5834378	
CAS number	1417782-03-6	
Chemical name (IUPAC)	(2*RS*)-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	
Molecular mass	397.78 g mol^{-1}	
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$	
Label	Triazole-3(5)-^{14}C	Chlorophenyl-U-^{14}C
Batch number	1062-2001	CFQ41561
Specific radioactivity of a.s. (MBq mg^{-1})	5.46	7.878
Radiochemical purity (%)	98.8	98.9
Purity (%)	98.9	99.1
Position of label		

In addition to these test materials, unlabelled BAS 750 F and 1,2,4-Triazole were used as reference compounds.

Test soils and experimental setup

Four test soils were used in this study; Li10 (loamy fine sand), LUFA 5M (sandy loam), IN (loam) and NJ (loam). After sampling from the field, the soil was allowed to dry at room temperature, then sieved through a 2 mm sieve before use and then stored in the refrigerator for up to 30 days. Prior to dosing, the moisture of the soil was adjusted to approximately 50% of the MWHC by adding the appropriate amount of deionised water. The soil moisture was determined as the difference between the weights of fresh soil and dried soil (after drying in an oven at ~110°C). The soil characteristics and pesticide use history are summarised in Table 8.1.1.3-2. As stated in section B.1.1.1, the use of the pesticides at the Indianna site is not expected to impact on the results of the study due the active substances of the products not being structurally similar to BAS 750 F.

Table 8.1.1.3-2: Physicochemical characteristics and pesticide use history of test soils

Soil ID	**Li10**	**LUFA 5M**	**IN**	**NJ**
Location	Limburgerhof	In der Speyerer Hohl	Indianna	New Jersey
GPS coordinates	49 24 30.17 N 08 23 04.09 E	49 16 19.33 N 08 24 15.77 E	39 59 09.64 N 85 56 43.80 W	40 54 48.20 N 74 99 18.40 W
USDA Texture Class	loamy fine sand	sandy loam	loam	loam
Sand (%)	83.7	62.6	41	35
Silt (%)	11.3	27.3	40	42
Clay (%)	5.0	10.2	19	23
pH (water)	6.9	8.0	5.6	6.9
pH ($CaCl_2$)	6.1	7.2	5.6	6.6
Total Organic Matter (%) [a)]	1.64	1.55	2.1	2.0
Total Organic Carbon (%)	0.95	0.90	1.2	1.1
Soil Biomass-0 DAT [µg g^{-1} dry soil]	244	408	190.8	246.3
Soil Biomass- 30 DAT (µg g^{-1} dry soil)	381.3	475.3	462.8	479.4
Cation Exchange Capacity [$cmol^+$ kg^{-1}] or meq/100g]	5.7	10.9	11.4	9.3
Maximum Water Holding Capacity [g 100 g^{-1} dry soil]	25.8	28.9	42.3	37.0
Bulk Density [g L^{-1}]	1353	1235	1120	1060
Pesticide use history				
2014	None	None	None	None
2013	None	None	Lumax	None
2012	None	None	Round-up	None
2011	None	None	Round-up Anthem	None
2010	None	None	Balance Harness Surpass	None

a) Total organic matter = Total organic carbon * 1.724

All four soils were treated with the triazole-labelled BAS 750 F; only soil NJ was additionally treated with the chlorophenyl-labelled BAS 750 F. The RMS notes that OECD guidelines indicate that all three of BAS 750 F's rings (including the trifluoromethylphenyl ring) should have been radio-labelled and added to each of the test soils. However, given the relatively slow anaerobic degradation rate observed in this study and that no anaerobic specific metabolites were formed (see 'Results and discussion' section below), the RMS is of the opinion that this deviation from the guidelines has not significantly impacted upon the outcomes of the study.

The proposed maximum single application rate for ^{14}C-BAS 750 F is 150 g a.s. ha^{-1}. Assuming that the applied ^{14}C-BAS 750 F distributes evenly into a soil depth of 0-2.5 cm and the bulk density of the soil is 1 g cm^{-3}, the concentration of BAS 750 F in soil will be 0.6 ppm. The RMS accepts this application rate of 150 g a.s. ha^{-1} as it is in line with the proposed product application rate. The RMS does note, however, that PEC_{soil} calculations are based on a soil depth of 5 cm and a bulk density of 1.5 g/cm^3. Therefore, an application rate of 150 g a.s. ha^{-1} equates to a soil concentration of 0.2 ppm.

The test vessels used in the study were 250 mL Teflon centrifuge tubes. 50 g (dry weight) of soil was added to the test vessels which were then placed in a climatic chamber to acclimatise in the dark at 20 ± 2°C. The test vessels were connected to a flow-through system. Before air was allowed to enter the test vessels, it was passed through an aqueous solution of sodium hydroxide (1N) which removed CO_2 from the air, as well as moistening it. Ethylene glycol traps were used at the end of the air-flow system to capture volatiles that formed during the incubation period. After the ethylene glycol traps, the air was passed through two sodium hydroxide traps to capture any CO_2 formed during the incubation period.

The application solutions were prepared as follows: 9.13 mg of triazole labelled BAS 750 F was diluted to a volume of 10 mL with acetonitrile, resulting in an application solution of 0.91 mg/mL (App0001). 1.78 mg of chlorophenyl labelled BAS 750 F was diluted with 4.2 mL of acetonitrile, resulting in an application solution of 0.42 mg/mL (App0002). A higher dosed application solution was also prepared by mixing 2.9 mL of the triazole labelled BAS 750 F with 1.91 mL of unlabelled BAS 750 F, resulting in a total volume of 4 mL and a concentration of 0.95 mg/mL (App0003).

33 µL of App0001 or 72 µL of App0002 were added to each test vessel using an automatic pipette. After dosing, each test vessel was gently shaken by hand to incorporate the test substance into the soil and was replaced in the flow-through system. The final concentration of BAS 750 F was approximately 0.6 ppm. High dosed vessels were treated at a higher rate (5-fold application rate). High dose vessels were treated with 157 µL of App0003 or 360 µL of App002 by drop-wise addition with an automatic pipette.

The aerobic samples were sampled in duplicate on 0, 7, 11, and 30 DAT (Days After Treatment). At the initiation of the anaerobic phase of the study (after 30 days), nitrogen-purged water (100 mL) was added to all the samples. The samples were put back into the incubator and the flow-through lines were switched from air to nitrogen. The anaerobic samples were sampled on 2, 7, 14, 30, 61, and 90 DAF (Days After Flooding). Ten control samples (soil without test substance) were also used in the study for biomass determination.

Analytical methods

Immediately after removal from the incubator system, the soil samples were extracted twice with 100 mL of each of the following solvents: acetonitrile (ACN), ACN:water (8:2), and ACN:water (1:1) by shaking for 30 minutes at 300 rpm followed by centrifugation for 15 minutes at 3000 rpm. The supernatant was decanted into a graduated cylinder, the volume was recorded and an aliquot was assayed by LSC. All of the extracts were combined and an aliquot (~15 mL) was concentrated to ~1 mL. The pooled extracts were analysed by LSC and by HPLC. The Applicant states that, for LSC, the analysis was undertaken on the day of sampling. For the HPLC analysis, the samples were stored for a period ranging from 1 – 41 days. The Applicant states that the samples were stored in a refrigerator at 4°C and that no degradation or instability was observed under these conditions. The RMS is of the opinion that, preferably, the the storage time between sampling and analysis ought to be kept to a minimum. However, because most soils and labels recorded acceptable mass balances (see section below) the RMS is of the opinion that, on this occasion, the storage times and conditions were acceptable.

For the anaerobic phase of the study (post-flooding), the soil samples were first centrifuged for 15 minutes at 3000 rpm, then the water was decanted into a graduated cylinder and the volume recorded before an aliquot was analysed by LSC. Samples were then treated to the same extraction procedure outlined above. The water layer was pooled with the rest of the extracts.

The aqueous sodium hydroxide and ethylene glycol traps were assayed at all sampling times (except for 0 DAT) by LSC. The traps were replaced with fresh aqueous sodium hydroxide (1N) and ethylene glycol, as appropriate, at each sampling time.

After the extractions were completed, the soils were air-dried and the amount of non-extractable residues (NER) was determined by oxidative combustion analysis. For selected samples (30 DAT and 90 DAF), the extracted soil samples were further extracted with 0.5N NaOH solution to characterise the bound residues. A soil sample (~25 g aliquots) was transferred to a centrifuge bottle and 50 mL of 0.5N NaOH was added. The mixture was shaken for 7 hours. After centrifugation (30 minutes at ~4000 rpm), the supernatant was decanted into a graduated cylinder and the volume was recorded. An aliquot was analysed by LSC (3×0.5 mL).

A second extraction was performed by adding 50 mL of 0.5N NaOH to each sample followed by shaking on a mechanical shaker overnight. Samples were centrifuged (30 minutes at ~4000 rpm) and the supernatant was decanted into a graduated cylinder and the volume was recorded. An aliquot was analysed by LSC (3×0.5 mL).

A third extraction was performed by adding 50 mL of 0.5N NaOH to each sample followed by shaking on a mechanical shaker for ~6 hours. After centrifugation (30 minutes at ~4000 rpm), the supernatant was decanted into a graduated cylinder and the volume was recorded. An aliquot was analysed by LSC (3×1 mL).

A fourth and final extraction (water wash) was performed by adding 25 mL of HPLC grade water to each sample followed by shaking on a mechanical shaker for 30 minutes. After centrifugation (30 minutes at 4000 rpm), the supernatant was decanted into a graduated cylinder and the volume was recorded. An aliquot was analysed by LSC (3×1 mL). The NaOH and water extracts were pooled together and fractionated into fulvic and humic components by adjusting the pH to 1-2 by the addition of concentrated HCl and allowing for precipitation in a refrigerator overnight. The supernatant (fulvic acid) was separated from the humic acid (precipitate) by centrifugation at ~4000 rpm for 30 minutes. The supernatant was decanted into a graduated cylinder, the volume was recorded, and aliquots were analysed by LSC (3×0.5 mL). The supernatant was extracted with ethyl acetate (3×75 mL) in a separatory funnel and aliquots of each extract were analysed by LSC (3×1.0 mL). The ethyl acetate extracts were pooled and concentrated. The volume of the aqueous phase was recorded and an aliquot was analysed by LSC (3×1.0 mL). The dried humic acids remaining in the centrifuge bottle were dissolved in 0.5N NaOH (50 mL) and analysed by LSC. The humin solids were milled and an aliquot from each sample were analysed by LSC (combustion).

The LOQ and LOD values of the LSC measurement were 0.062% TAR and 0.041% TAR respectively. The LOQ and LOD values of the HPLC measurement were 0.589% TAR and 0.294% TAR respectively.

Results and discussion

On each sampling day after flooding (DAF), the pH, redox and dissolved oxygen values were measured (Table 8.1.1.3-3). The Applicant indicates that slight variations in pH readings were detected, but no clear trends were evident. The concentration of dissolved oxygen in the water layer over all soils was less than 1 mg L^{-1} by 7 DAF, and continued to decrease, indicating that the system was anaerobic for the majority of the study. The redox potential was negative for all soils after 30 day of flooding, and by the next sampling point (61 DAF) the water layer also had a negative redox potential.

Table 8.1.1.3-3: Water/soil redox, oxygen content and pH during experimental period

	2 DAF	7 DAF	14 DAF	30 DAF	61 DAF	90 DAF
Li10 soil						
Water						
pH	8.33	7.46	7.51	7.14	7.14	7.19
O_2 conc. (mg/L)	0.48	0.39	0.29	0.18	0.12	0.00
Redox (mV)	124.0	197.0	174.6	42	-158.8	-197.5
Soil						
pH	7.12	7.18	7.16	6.71	7.23	7.12
Redox (mV)	209.7	163.3	129.9	-83.6	-255.9	-289.4
LUFA 5M soil						
Water						
pH	6.98	6.87	7.52	7.50	7.88	7.68
O_2 conc. (mg/L)	2.10	0.76	0.52	0.05	0.17	0.13
Redox (mV)	206.8	176.1	95.8	-65.5	-47.3	-50
Soil						
pH	6.88	7.14	7.66	7.58	7.78	7.63
Redox (mV)	170.4	50.9	10.2	-211.5	-201.4	-180.1
IN soil						
Water						
pH	7.29	6.88	7.83	6.46	7.75	7.55
O_2 conc. (mg/L)	0.60	0.39	0.31	0.11	0.31	0.40
Redox (mV)	237.1	202.7	134.0	145.0	-64.2	-119.4
Soil						
pH	6.24	6.38	6.95	6.64	7.52	7.17

Redox (mV)	178.1	120.1	72.4	-80.2	-57	-231.8
NJ soil						
Water						
pH	8.30	7.07	7.40	7.26	7.19	7.37
O_2 conc. (mg/L)	0.54	0.29	0.20	0.02	0.08	0.00
Redox (mV)	168.1	147.9	127.6	-174.7	-152.2	-164.8
Soil						
pH	7.45	7.24	7.35	6.78	7.02	7.46
Redox (mV)	186.9	81.9	34.0	-262.7	-227.9	-244.3

The Applicant states that, at the end of the experimental period, the dilution solutions Dil001 and Dil002 (prepared by diluting 10 µL aliquots of App001 and App002 to 10 mL with acetonitrile respectively) were analysed by HPLC to determine the storage stability. And that the results indicate the test samples were stable throughout the experimental period, with >95% purity of the parent peak. The RMS notes that these HPLC results were not supplied with the study report and so the RMS cannot verify this claim. However, given the generally high mass balances observed (see section below), the RMS accepts the Applicant's statement.

Mass balance

For soil Li10 (triazole label), mean material balance ranged from 82.20% TAR at 11 DAT to 101.72% TAR at 32 DAT, displaying no clear trends between length of time after dosing and total recovery (Table 8.1.1.3-4). In total, four replicate samples recorded a material balance <90% TAR (the minimum acceptable value according to OECD 307 guidelines). The Applicant states that these are not indicative of an overall trend or deficiency of the method, but only reflect small, isolated instances in the analytical procedure for the individual time points. Furthermore, that this is not expected to have any impact on the overall study.

The RMS notes that two of the samples <90% TAR occurred at 11 DAT and, therefore, are not included in the anaerobic degradation kinetic analysis. The other two samples <90% TAR occurred at 7 DAF and 90 DAF respectively. With these data points included in the kinetic evaluation of the soil (see 'Kinetic analysis' section below), a reliable visual and statistical fit could be obtained. Therefore, the RMS accepts the Applicant's argument that this deviation from the guidelines will not have significantly impacted on the outcomes of the study.

For soil LUFA 5M (triazole label), the mean material balance ranged from 92.97 to 109.68% of the TAR (Table 8.1.1.3-5). The RMS notes that two replicate samples were <90% TAR, however, given that on each occasion the other replicate sample recorded a value within the acceptable OECD range, the RMS is of the opinion that this will not have significantly impacted on the outcomes of the study.

For soil IN (triazole label), the mean material balance ranged from 90.32 at 120 DAT to 108.19% at 7 DAT (Table 8.1.1.3-6). The RMS notes that two replicate samples were <90% TAR, however, again, given that on each occasion the other replicate sample recorded a value within the acceptable OECD range, the RMS is of the opinion that this will not have significantly impacted on the outcomes of the study.

For soil NJ (triazole label), the mean material balance ranged from 83.86 to 107.49% of the TAR (Table 8.1.1.3-7). Both 60 DAT replicates (30 DAF) recorded material balances <90%, with one of the replicates recording a mass balance of 79.57%. The Applicant states that these are not indicative of an overall trend, but only reflect small, isolated mistakes in the analytical procedure for the individual time points. Furthermore, that this is not expected to have any impact on the overall study.

The RMS notes that with these data points included in the kinetic evaluation of the soil (see 'Kinetic analysis' section below), a reliable visual and statistical fit could be obtained. Therefore, the RMS accepts the Applicant's argument that this deviation from the guidelines will not have significantly impacted on the outcomes of the study.

For soil NJ (chlorophenyl label), the mean material balance ranged from 96.48 to 102.82% of the TAR (Table 8.1.1.3-8). No samples recorded values outside of the OECD acceptable range.

Table 8.1.1.3-4: Material Balance of [Triazole-3(5)-^{14}C]-BAS 750 F in Li10 Soil [%TAR]

DAT	DAF	Extracts							ERR	NER	Volatiles			Material Balance
		Water	1	2	3	4	5	6			NaOH	EG	Total	
0 rep1	NA	NA	84.23	10.05	4.16	0.69	0.22	0.07	99.42	0.31	NA	NA	NA	99.73
0 rep2	NA	NA	85.10	9.62	4.24	0.75	0.24	0.09	100.04	0.24	NA	NA	NA	100.27
0 mean	**NA**	**NA**	**84.66**	**9.84**	**4.20**	**0.72**	**0.23**	**0.08**	**99.73**	**0.27**	**NA**	**NA**	**NA**	**100.00**
7 rep1	NA	NA	76.23	10.47	4.61	1.05	0.63	0.24	93.23	1.76	0.26	<LOQ	0.26	95.26
7 rep2	NA	NA	76.03	11.47	5.47	1.29	0.68	0.25	95.19	1.98	0.26	<LOQ	0.26	97.43
7 mean	**NA**	**NA**	**76.13**	**10.97**	**5.04**	**1.17**	**0.66**	**0.25**	**94.21**	**1.87**	**0.26**	**<LOQ**	**0.26**	**96.35**
11 rep1	NA	NA	63.07	10.81	4.25	0.96	0.37	0.24	79.71	2.25	0.30	<LOQ	0.30	82.26
11 rep2	NA	NA	65.13	9.02	4.16	0.94	0.38	0.22	79.84	2.00	0.30	<LOQ	0.30	82.15
11 mean	**NA**	**NA**	**64.10**	**9.92**	**4.20**	**0.95**	**0.38**	**0.23**	**79.78**	**2.13**	**0.30**	**<LOQ**	**0.30**	**82.20**
30 rep1	NA	NA	23.46	10.51	55.77	10.31	1.62	0.44	102.10	3.39	0.35	<LOQ	0.35	105.84
30 rep2	NA	NA	51.52	8.21	26.64	4.40	0.88	0.31	91.96	2.76	0.35	<LOQ	0.35	95.08
30 mean	**NA**	**NA**	**37.49**	**9.36**	**41.20**	**7.35**	**1.25**	**0.38**	**97.03**	**3.08**	**0.35**	**<LOQ**	**0.35**	**100.46**
32 rep1	2 rep1	3.01	79.72	10.85	2.58	0.67	0.33	0.22	97.38	3.22	0.37	<LOQ	0.37	100.96
32 rep2	2 rep2	10.85	72.59	10.91	2.55	0.71	0.35	0.26	98.21	3.90	0.37	<LOQ	0.37	102.48
32 mean	**2 mean**	**6.93**	**76.15**	**10.88**	**2.57**	**0.69**	**0.34**	**0.24**	**97.80**	**3.56**	**0.37**	**<LOQ**	**0.37**	**101.72**
37 rep1	7 rep1	4.39	75.77	10.65	2.82	0.93	0.49	0.33	95.37	4.67	0.38	<LOQ	0.38	100.42
37 rep2	7 rep2	8.06	58.56	8.82	2.36	0.74	0.43	0.28	79.24	4.38	0.38	<LOQ	0.38	84.00
37 mean	**7 mean**	**6.22**	**67.16**	**9.73**	**2.59**	**0.84**	**0.46**	**0.30**	**87.31**	**4.53**	**0.38**	**<LOQ**	**0.38**	**92.21**
44 rep1	14 rep1	5.63	73.77	11.67	3.38	1.08	0.51	0.35	96.39	5.94	0.38	<LOQ	0.38	102.71
44 rep2	14 rep2	12.01	64.35	10.60	3.14	0.95	0.53	0.34	91.91	4.46	0.38	<LOQ	0.38	96.75
44 mean	**14 mean**	**8.82**	**69.06**	**11.13**	**3.26**	**1.02**	**0.52**	**0.34**	**94.15**	**5.20**	**0.38**	**<LOQ**	**0.38**	**99.73**
60 rep1	30 rep1	6.26	64.32	11.16	3.39	1.07	0.56	0.38	87.14	7.05	0.39	<LOQ	0.39	94.59
60 rep2	30 rep2	10.35	65.42	11.43	3.22	0.92	0.51	0.33	92.19	4.06	0.39	<LOQ	0.39	96.64
60 mean	**30 mean**	**8.30**	**64.87**	**11.30**	**3.31**	**1.00**	**0.54**	**0.36**	**89.67**	**5.56**	**0.39**	**<LOQ**	**0.39**	**95.62**
91 rep1	61 rep1	3.22	64.37	11.31	3.70	1.27	0.67	0.55	85.09	9.87	0.40	<LOQ	0.40	95.37
91 rep2	61 rep2	6.00	66.04	11.55	3.98	1.30	0.76	0.56	90.19	9.38	0.40	<LOQ	0.40	99.97
91 mean	**61 mean**	**4.61**	**65.21**	**11.43**	**3.84**	**1.29**	**0.71**	**0.55**	**87.64**	**9.62**	**0.40**	**<LOQ**	**0.40**	**97.67**
120 rep1	90 rep1	2.82	64.16	11.34	3.61	1.13	0.67	0.45	84.18	8.81	0.41	<LOQ	0.41	93.40
120 rep2	90 rep2	4.17	52.41	9.84	3.29	1.10	0.64	0.42	71.87	7.97	0.41	<LOQ	0.41	80.25
120 mean	**90 mean**	**3.49**	**58.29**	**10.59**	**3.45**	**1.11**	**0.65**	**0.44**	**78.02**	**8.39**	**0.41**	**<LOQ**	**0.41**	**86.83**

Extract 1 = ACN
Extract 2 = ACN
Extract 3 = ACN:water (8:2)
Extract 4 = ACN:water (8:2)
Extract 5 = ACN:water (1:1)
Extract 6 = ACN:water (1:1)
EG = Ethylene glycol
ERR= Extractable Radioactive Residues
NER = Un Extractable Residues (by combustion)
NA = Not Applicable (no sample analysed)
LOQ = 0.06% TAR

Table 8.1.1.3-5: Material Balance of [Triazole-3(5)-^{14}C]-BAS 750 F in LUFA 5M Soil [%TAR]

DAT	DAF	Extracts							ERR	NER	Volatiles			Material Balance
		Water	1	2	3	4	5	6			NaOH	EG	Total	
0 rep1	NA	NA	85.10	13.71	6.20	1.28	0.55	0.29	107.15	1.15	NA	NA	NA	108.30
0 rep2	NA	NA	70.51	12.66	5.58	1.23	0.51	0.22	90.70	0.99	NA	NA	NA	91.70
0 mean	**NA**	**NA**	**77.81**	**13.19**	**5.89**	**1.26**	**0.53**	**0.26**	**98.93**	**1.07**	**NA**	**NA**	**NA**	**100.00**
7 rep1	NA	NA	79.42	12.34	7.10	1.85	1.14	0.52	102.37	4.00	0.27	<LOQ	0.27	106.64
7 rep2	NA	NA	80.94	12.20	7.23	1.81	1.04	0.50	103.71	4.09	0.27	<LOQ	0.27	108.07
7 mean	**NA**	**NA**	**80.18**	**12.27**	**7.17**	**1.83**	**1.09**	**0.51**	**103.04**	**4.04**	**0.27**	**<LOQ**	**0.27**	**107.36**
11 rep1	NA	NA	73.20	11.07	6.59	1.69	0.72	0.48	93.75	4.27	0.30	<LOQ	0.30	98.33
11 rep2	NA	NA	65.50	10.15	6.11	1.77	0.72	0.47	84.72	4.41	0.30	<LOQ	0.30	89.43
11 mean	**NA**	**NA**	**69.35**	**10.61**	**6.35**	**1.73**	**0.72**	**0.47**	**89.23**	**4.34**	**0.30**	**<LOQ**	**0.30**	**93.88**
30 rep1	NA	NA	81.04	12.93	7.16	2.23	0.83	0.47	104.66	5.49	0.33	<LOQ	0.33	110.48
30 rep2	NA	NA	76.02	14.67	7.87	2.49	0.80	0.48	102.34	6.04	0.33	<LOQ	0.33	108.71
30 mean	**NA**	**NA**	**78.53**	**13.80**	**7.52**	**2.36**	**0.81**	**0.47**	**103.50**	**5.77**	**0.33**	**<LOQ**	**0.33**	**109.60**
32 rep1	2 rep1	4.52	78.80	13.21	4.29	1.45	0.84	0.58	103.67	6.84	0.33	<LOQ	0.33	110.85
32 rep2	2 rep2	4.80	70.48	11.80	3.87	1.27	0.71	0.47	93.40	5.89	0.33	<LOQ	0.33	99.62
32 mean	**2 mean**	**4.66**	**74.64**	**12.50**	**4.08**	**1.36**	**0.77**	**0.52**	**98.54**	**6.37**	**0.33**	**<LOQ**	**0.33**	**105.24**
37 rep1	7 rep1	5.91	73.00	11.98	3.69	1.33	0.87	0.59	97.36	7.11	0.34	<LOQ	0.34	104.81
37 rep2	7 rep2	4.79	59.94	9.95	3.22	1.16	0.72	0.52	80.30	6.07	0.34	<LOQ	0.34	86.71
37 mean	**7 mean**	**5.35**	**66.47**	**10.97**	**3.46**	**1.25**	**0.79**	**0.56**	**88.83**	**6.58**	**0.34**	**<LOQ**	**0.34**	**95.75**
44 rep1	14 rep1	4.23	60.86	11.47	3.97	1.42	0.76	0.52	83.23	6.87	0.34	<LOQ	0.34	90.44
44 rep2	14 rep2	3.80	65.12	11.92	4.28	1.51	0.82	0.59	88.04	7.13	0.34	<LOQ	0.34	95.51
44 mean	**14 mean**	**4.01**	**62.99**	**11.69**	**4.13**	**1.46**	**0.79**	**0.55**	**85.63**	**7.00**	**0.34**	**<LOQ**	**0.34**	**92.97**
60 rep1	30 rep1	4.19	68.90	14.54	5.08	1.81	1.07	0.77	96.36	9.78	0.35	<LOQ	0.35	106.49
60 rep2	30 rep2	5.37	65.92	15.65	5.02	1.71	1.05	0.78	95.50	9.55	0.35	<LOQ	0.35	105.40
60 mean	**30 mean**	**4.78**	**67.41**	**15.10**	**5.05**	**1.76**	**1.06**	**0.77**	**95.93**	**9.66**	**0.35**	**<LOQ**	**0.35**	**105.95**
91 rep1	61 rep1	3.18	69.27	14.51	5.33	1.93	1.15	0.90	96.26	13.51	0.37	<LOQ	0.37	110.15
91 rep2	61 rep2	3.49	67.14	14.63	5.34	1.99	1.20	0.94	94.73	14.11	0.37	<LOQ	0.37	109.21
91 mean	**61 mean**	**3.34**	**68.20**	**14.57**	**5.33**	**1.96**	**1.18**	**0.92**	**95.50**	**13.81**	**0.37**	**<LOQ**	**0.37**	**109.68**
120 rep1	90 rep1	4.49	66.52	13.03	5.01	1.99	1.13	0.85	93.03	13.81	0.38	<LOQ	0.38	107.22
120 rep2	90 rep2	4.73	63.78	14.48	5.87	2.22	1.45	0.98	93.50	14.15	0.38	<LOQ	0.38	108.03
120 mean	**90 mean**	**4.61**	**65.15**	**13.75**	**5.44**	**2.11**	**1.29**	**0.92**	**93.26**	**13.98**	**0.38**	**<LOQ**	**0.38**	**107.63**

Extract 1 = ACN
Extract 2 = ACN
Extract 3 = ACN:water (8:2)
Extract 4 = ACN:water (8:2)
Extract 5 = ACN:water (1:1)
Extract 6 = ACN:water (1:1)

EG = Ethylene glycol
ERR= Extractable Radioactive Residues
NER = Un Extractable Residues (by combustion)
NA = Not Applicable (no sample analysed)
LOQ = 0.06% TAR

Table 8.1.1.3-6: Material Balance of [Triazole-3(5)-^{14}C]-BAS 750 F in IN Soil [%TAR]

DAT	DAF	Extracts							ERR	NER	Volatiles			Material Balance
		Water	1	2	3	4	5	6			NaOH	EG	Total	
0 rep1	**NA**	**NA**	81.70	11.74	3.51	0.66	0.21	0.09	97.92	0.23	NA	NA	NA	98.15
0 rep2	NA	NA	86.27	10.81	3.47	0.70	0.23	0.09	101.57	0.28	NA	NA	NA	101.85
0 mean	**NA**	**NA**	**83.99**	**11.28**	**3.49**	**0.68**	**0.22**	**0.09**	**99.75**	**0.25**	**NA**	**NA**	**NA**	**100.00**
7 rep1	NA	NA	84.84	14.48	4.86	1.52	1.27	0.54	107.51	2.78	0.23	<LOQ	0.23	110.52
7 rep2	NA	NA	80.55	13.58	5.07	1.68	1.39	0.50	102.77	2.85	0.23	<LOQ	0.23	105.86
7 mean	**NA**	**NA**	**82.69**	**14.03**	**4.97**	**1.60**	**1.33**	**0.52**	**105.14**	**2.82**	**0.23**	**<LOQ**	**0.23**	**108.19**
11 rep1	NA	NA	76.30	13.25	5.05	1.84	0.83	0.52	97.79	1.83	0.26	<LOQ	0.26	99.88
11 rep2	NA	NA	66.00	11.51	4.23	1.41	0.72	0.47	84.36	3.64	0.26	<LOQ	0.26	88.25
11 mean	**NA**	**NA**	**71.15**	**12.38**	**4.64**	**1.63**	**0.78**	**0.50**	**91.07**	**2.73**	**0.26**	**<LOQ**	**0.26**	**94.06**
30 rep1	NA	NA	75.03	12.95	4.86	2.28	0.88	0.52	96.52	5.81	0.30	<LOQ	0.30	102.63
30 rep2	NA	NA	68.13	11.44	4.34	1.99	0.76	0.47	87.12	4.86	0.30	<LOQ	0.30	92.28
30 mean	**NA**	**NA**	**71.58**	**12.19**	**4.60**	**2.13**	**0.82**	**0.49**	**91.82**	**5.33**	**0.30**	**<LOQ**	**0.30**	**97.45**
32 rep1	2 rep1	6.11	73.51	13.39	4.44	1.59	0.94	0.64	100.63	6.84	0.30	<LOQ	0.30	107.77
32 rep2	2 rep2	6.34	69.49	12.19	4.07	1.52	0.86	0.62	95.09	6.50	0.30	<LOQ	0.30	101.89
32 mean	**2 mean**	**6.23**	**71.50**	**12.79**	**4.26**	**1.56**	**0.90**	**0.63**	**97.86**	**6.67**	**0.30**	**<LOQ**	**0.30**	**104.83**
37 rep1	7 rep1	5.99	68.31	11.71	3.84	1.49	0.84	0.57	92.75	6.09	0.30	<LOQ	0.30	99.14
37 rep2	7 rep2	8.31	71.41	13.20	4.14	1.50	0.91	0.61	100.09	7.15	0.30	<LOQ	0.30	107.54
37 mean	**7 mean**	**7.15**	**69.86**	**12.46**	**3.99**	**1.49**	**0.88**	**0.59**	**96.42**	**6.62**	**0.30**	**<LOQ**	**0.30**	**103.34**
44 rep1	14 rep1	9.05	65.90	13.04	4.77	1.80	0.96	0.71	96.22	7.63	0.31	<LOQ	0.31	104.16
44 rep2	14 rep2	11.83	65.82	12.95	4.55	1.76	1.01	0.72	98.63	7.96	0.31	<LOQ	0.31	106.90
44	**14 mean**	**10.44**	**65.86**	**12.99**	**4.66**	**1.78**	**0.98**	**0.72**	**97.42**	**7.79**	**0.31**	**<LOQ**	**0.31**	**105.53**

mean														
60 rep1	30 rep1	7.23	64.19	13.23	5.13	1.82	1.02	0.73	93.34	8.36	0.32	<LOQ	0.32	102.02
60 rep2	30 rep2	6.90	47.97	20.19	5.41	1.60	0.88	0.63	83.58	7.33	0.32	<LOQ	0.32	91.22
60 mean	**30 mean**	**7.06**	**56.08**	**16.71**	**5.27**	**1.71**	**0.95**	**0.68**	**88.46**	**7.84**	**0.32**	**<LOQ**	**0.32**	**96.62**
91 rep1	61 rep1	5.63	62.10	13.42	5.42	2.10	1.27	0.96	90.90	11.43	0.34	<LOQ	0.34	102.67
91 rep2	61 rep2	6.60	59.24	12.98	4.87	1.84	1.11	0.82	87.46	9.84	0.34	<LOQ	0.34	97.63
91 mean	**61 mean**	**6.11**	**60.67**	**13.20**	**5.14**	**1.97**	**1.19**	**0.89**	**89.18**	**10.64**	**0.34**	**<LOQ**	**0.34**	**100.15**
120 rep1	90 rep1	4.12	59.18	11.55	4.27	1.82	1.06	0.81	82.81	9.86	0.35	<LOQ	0.35	93.03
120 rep2	90 rep2	5.35	53.01	11.93	4.29	1.74	1.07	0.75	78.13	9.12	0.35	<LOQ	0.35	87.60
120 mean	**90 mean**	**4.74**	**56.09**	**11.74**	**4.28**	**1.78**	**1.07**	**0.78**	**80.47**	**9.49**	**0.35**	**<LOQ**	**0.35**	**90.32**

Extract 1 = ACN
Extract 2 = ACN
Extract 3 = ACN:water (8:2)
Extract 4 = ACN:water (8:2)
Extract 5 = ACN:water (1:1)
NA = Not Applicable (no sample analysed)
Extract 6 = ACN:water (1:1)
EG = Ethylene glycol
ERR= Extractable Radioactive Residues
NER = Un Extractable Residues (by combustion)
LOQ = 0.06% TAR

Table 8.1.1.3-7: Material Balance of [Triazole-3(5)-^{14}C]-BAS 750 F in NJ Soil [%TAR]

DAT	DAF	Extracts							ERR	NER	Volatiles			Material Balance
		Water	1	2	3	4	5	6			NaOH	EG	Total	
0 rep1	NA	NA	88.12	13.84	3.98	0.80	0.33	0.13	107.20	0.39	NA	NA	NA	107.59
0 rep2	NA	NA	74.30	12.83	3.72	0.78	0.30	0.14	92.08	0.33	NA	NA	NA	92.41
0 mean	**NA**	**NA**	**81.21**	**13.33**	**3.85**	**0.79**	**0.32**	**0.14**	**99.64**	**0.36**	**NA**	**NA**	**NA**	**100.00**
7 rep1	NA	NA	82.57	14.60	5.13	1.55	1.51	0.52	105.89	3.60	0.13	<LOQ	0.13	109.62
7 rep2	NA	NA	69.92	12.31	4.31	1.44	1.32	0.59	89.90	3.60	0.13	<LOQ	0.13	93.63
7 mean	**NA**	**NA**	**76.25**	**13.46**	**4.72**	**1.50**	**1.42**	**0.55**	**97.90**	**3.60**	**0.13**	**<LOQ**	**0.13**	**101.63**
11 rep1	NA	NA	75.20	13.93	5.06	1.59	0.85	0.59	97.21	5.36	0.16	<LOQ	0.16	102.74
11 rep2	NA	NA	77.50	14.29	5.21	1.80	0.78	0.58	100.17	5.32	0.16	<LOQ	0.16	105.65
11 mean	**NA**	**NA**	**76.35**	**14.11**	**5.14**	**1.69**	**0.82**	**0.58**	**98.69**	**5.34**	**0.16**	**<LOQ**	**0.16**	**104.19**
30 rep1	NA	NA	69.43	13.53	5.20	2.38	0.97	0.58	92.09	7.23	0.22	<LOQ	0.22	99.55
30 rep2	NA	NA	70.11	12.96	4.61	2.20	0.88	0.57	91.31	7.30	0.22	<LOQ	0.22	98.83
30 mean	**NA**	**NA**	**69.77**	**13.24**	**4.90**	**2.29**	**0.93**	**0.57**	**91.70**	**7.27**	**0.22**	**<LOQ**	**0.22**	**99.19**
32 rep1	2 rep1	8.04	63.68	11.66	3.40	1.40	0.83	0.57	89.57	8.46	0.23	<LOQ	0.23	98.26
32 rep2	2 rep2	10.19	70.59	12.63	3.68	1.55	0.94	0.67	100.25	9.37	0.23	<LOQ	0.23	109.84
32 mean	**2 mean**	**9.11**	**67.13**	**12.14**	**3.54**	**1.48**	**0.89**	**0.62**	**94.91**	**8.91**	**0.23**	**<LOQ**	**0.23**	**104.05**
37 rep1	7 rep1	10.94	69.45	13.27	3.81	1.47	1.01	0.72	100.66	8.40	0.23	<LOQ	0.23	109.29
37 rep2	7 rep2	7.36	55.40	10.10	3.20	1.35	0.83	0.59	78.84	11.21	0.23	<LOQ	0.23	90.28
37 mean	**7 mean**	**9.15**	**62.42**	**11.68**	**3.51**	**1.41**	**0.92**	**0.65**	**89.75**	**9.81**	**0.23**	**<LOQ**	**0.23**	**99.79**
44 rep1	14 rep1	12.70	58.62	12.84	4.28	1.78	1.09	0.80	92.10	10.55	0.23	<LOQ	0.23	102.88
44 rep2	14 rep2	11.15	64.23	13.78	4.57	2.01	1.09	0.80	97.63	10.11	0.23	<LOQ	0.23	107.97
44 mean	**14 mean**	**11.92**	**61.42**	**13.31**	**4.42**	**1.90**	**1.09**	**0.80**	**94.86**	**10.33**	**0.23**	**<LOQ**	**0.23**	**105.43**
60 rep1	30 rep1	6.92	53.00	11.40	3.83	1.57	1.03	0.76	78.52	9.38	0.24	<LOQ	0.24	88.14
60 rep2	30 rep2	6.97	46.38	10.35	3.68	1.56	0.96	0.69	70.59	8.74	0.24	<LOQ	0.24	79.57
60 mean	**30 mean**	**6.94**	**49.69**	**10.87**	**3.76**	**1.57**	**0.99**	**0.73**	**74.56**	**9.06**	**0.24**	**<LOQ**	**0.24**	**83.86**
91 rep1	61 rep1	5.57	60.16	13.57	5.28	2.50	1.51	1.19	89.78	16.65	0.26	<LOQ	0.26	106.69
91 rep2	61 rep2	5.58	52.69	11.85	4.64	2.15	1.38	1.05	79.35	14.51	0.26	<LOQ	0.26	94.13
91 mean	**61 mean**	**5.58**	**56.42**	**12.71**	**4.96**	**2.32**	**1.45**	**1.12**	**84.57**	**15.58**	**0.26**	**<LOQ**	**0.26**	**100.41**
120 rep1	90 rep1	6.42	61.42	13.77	5.05	2.39	1.56	1.09	91.70	15.21	0.27	<LOQ	0.27	107.17
120 rep2	90 rep2	7.41	59.53	14.22	5.44	2.44	1.60	1.09	91.74	15.81	0.27	<LOQ	0.27	107.82
120 mean	**90 mean**	**6.91**	**60.48**	**14.00**	**5.25**	**2.42**	**1.58**	**1.09**	**91.72**	**15.51**	**0.27**	**<LOQ**	**0.27**	**107.49**

Extract 1 = ACN
Extract 2 = ACN
Extract 3 = ACN:water (8:2)
Extract 4 = ACN:water (8:2)
Extract 5 = ACN:water (1:1)
Extract 6 = ACN:water (1:1)
EG = Ethylene glycol
ERR= Extractable Radioactive Residues
NER = Un Extractable Residues (by combustion)
LOQ = 0.06% TAR
NA = Not Applicable (no sample analysed)

Table 8.1.1.3-8: Material Balance of [Chlorophenyl-U-^{14}C]-BAS 750 F in NJ Soil [%TAR]

DAT	DAF	Extracts							ERR	NER	Volatiles			Material Balance
		Water	1	2	3	4	5	6			NaOH	EG	Total	
0 rep1	NA	NA	80.31	14.38	3.95	0.85	0.42	0.21	100.12	0.74	NA	NA	NA	100.86
0 rep2	NA	NA	79.59	13.31	3.88	0.85	0.41	0.26	98.30	0.84	NA	NA	NA	99.14
0 mean	**NA**	**NA**	**79.95**	**13.84**	**3.91**	**0.85**	**0.41**	**0.24**	**99.21**	**0.79**	**NA**	**NA**	**NA**	**100.00**
7 rep1	NA	NA	74.89	13.84	4.89	1.56	1.65	0.62	97.45	4.91	0.80	<LOQ	0.80	103.16
7 rep2	NA	NA	69.90	12.68	4.43	1.47	1.55	0.60	90.63	4.77	0.80	<LOQ	0.80	96.20
7 mean	**NA**	**NA**	**72.39**	**13.26**	**4.66**	**1.52**	**1.60**	**0.61**	**94.04**	**4.84**	**0.80**	**<LOQ**	**0.80**	**99.68**
11 rep1	NA	NA	71.55	13.37	4.86	1.77	0.78	0.60	92.93	6.18	0.97	<LOQ	0.97	100.08
11 rep2	NA	NA	69.23	13.27	4.58	1.62	0.70	0.56	89.95	5.84	0.97	<LOQ	0.97	96.77
11 mean	**NA**	**NA**	**70.39**	**13.32**	**4.72**	**1.69**	**0.74**	**0.58**	**91.44**	**6.01**	**0.97**	**<LOQ**	**0.97**	**98.42**
30 rep1	NA	NA	72.88	12.51	5.09	2.43	0.97	0.60	94.48	8.39	1.59	<LOQ	1.59	104.46
30 rep2	NA	NA	70.33	12.29	4.85	2.31	0.99	0.55	91.32	8.27	1.59	<LOQ	1.59	101.18
30 mean	**NA**	**NA**	**71.60**	**12.40**	**4.97**	**2.37**	**0.98**	**0.57**	**92.90**	**8.33**	**1.59**	**<LOQ**	**1.59**	**102.82**
32 rep1	2 rep1	7.36	59.84	10.89	3.18	1.36	0.82	0.56	84.01	9.08	1.62	<LOQ	1.62	94.71
32 rep2	2 rep2	6.67	63.97	11.04	3.33	1.41	0.84	0.58	87.83	9.27	1.62	<LOQ	1.62	98.72
32 mean	**2 mean**	**7.02**	**61.91**	**10.97**	**3.25**	**1.38**	**0.83**	**0.57**	**85.92**	**9.17**	**1.62**	**<LOQ**	**1.62**	**96.72**
37 rep1	7 rep1	9.97	55.50	10.45	3.29	1.38	0.88	0.61	82.08	8.37	1.64	<LOQ	1.64	92.09
37 rep2	7 rep2	6.98	64.96	11.66	3.45	1.41	0.89	0.63	89.97	9.26	1.64	<LOQ	1.64	100.87
37 mean	**7 mean**	**8.47**	**60.23**	**11.05**	**3.37**	**1.40**	**0.88**	**0.62**	**86.03**	**8.81**	**1.64**	**<LOQ**	**1.64**	**96.48**
44 rep1	14 rep1	9.24	57.82	11.84	4.02	1.63	0.99	0.72	86.25	9.97	1.69	<LOQ	1.69	97.91
44 rep2	14 rep2	8.45	59.79	11.93	4.16	1.77	1.07	0.78	87.96	10.60	1.69	<LOQ	1.69	100.25
44 mean	**14 mean**	**8.85**	**58.81**	**11.89**	**4.09**	**1.70**	**1.03**	**0.75**	**87.10**	**10.29**	**1.69**	**<LOQ**	**1.69**	**99.08**
60 rep1	30 rep1	6.82	59.90	13.24	4.72	1.92	1.18	0.83	88.62	11.66	1.83	<LOQ	1.83	102.11
60 rep2	30 rep2	6.72	58.82	12.94	4.58	1.98	1.25	0.85	87.14	11.63	1.83	<LOQ	1.83	100.60
60 mean	**30 mean**	**6.77**	**59.36**	**13.09**	**4.65**	**1.95**	**1.22**	**0.84**	**87.88**	**11.65**	**1.83**	**<LOQ**	**1.83**	**101.36**
91 rep1	61 rep1	4.73	53.45	12.40	4.69	2.01	1.27	0.98	79.54	14.98	1.98	<LOQ	1.98	96.51
91 rep2	61 rep2	5.24	56.81	12.51	4.97	2.25	1.40	1.09	84.28	15.34	1.98	<LOQ	1.98	101.61
91 mean	**61 mean**	**4.99**	**55.13**	**12.45**	**4.83**	**2.13**	**1.34**	**1.04**	**81.91**	**15.16**	**1.98**	**<LOQ**	**1.98**	**99.06**
120 rep1	90 rep1	4.18	57.17	12.46	4.70	2.16	1.37	1.05	83.08	16.67	2.16	<LOQ	2.16	101.91
120 rep2	90 rep2	3.47	55.96	13.43	5.09	2.38	1.43	1.08	82.83	16.07	2.16	<LOQ	2.16	101.06
120 mean	**90 mean**	**3.82**	**56.56**	**12.94**	**4.89**	**2.27**	**1.40**	**1.06**	**82.95**	**16.37**	**2.16**	**<LOQ**	**2.16**	**101.49**

Extract 1 = ACN
Extract 2 = ACN
Extract 3 = ACN:water (8:2)
Extract 4 = ACN:water (8:2)
Extract 5 = ACN:water (1:1)
Extract 6 = ACN:water (1:1)
EG = Ethylene glycol
ERR= Extractable Radioactive Residues
NER = Un Extractable Residues (by combustion)
LOQ = 0.06% TAR
NA = Not Applicable (no sample analysed)

Transformation of parent compound

The pooled extract for each sampling point was analysed by HPLC. The amounts of BAS 750 F and its metabolites recovered at each time point for each soil are shown in the following tables as percentages of the total applied radioactivity.

For soil Li10, the mean amount of triazole-BAS 750 F decreased from 97.18% TAR at 0 DAT to 75.96% TAR at 120 DAT (see Table 8.1.1.3-9). Two minor transformation products were observed and neither of them exceeded an average of 5% TAR at any time point.

For soil LUFA 5M, the mean amount of triazole-BAS 750 F decreased from 97.79% TAR at 0 DAT to 92.62% TAR at 120 DAT (see Table 8.1.1.3-10). Two minor transformation products were observed and neither of them exceeded an average of 5% TAR at any time point.

For soil IN, the mean amount of triazole-BAS 750 F decreased from 97.15% TAR at 0 DAT to 78.72% TAR at 120 DAT (see Table 8.1.1.3-11). Two minor transformation products were observed and neither of them exceeded an average of 5% TAR at any time point.

For soil NJ (triazole-label), the mean amount of triazole-BAS 750 F decreased from 97.56% TAR at 0 DAT to 88.95% TAR at 120 DAT (see Table 8.1.1.3-12). Two minor transformation products were observed and neither of them exceeded an average of 5% TAR at any time point. The RMS notes that one replicate sample (at 30 DAT), for a metabolite with a retention time of 3.7-4 minutes, was >5% TAR but this does not meet the criteria of two consecutive time points >5% TAR.

For soil NJ (chlorophenyl-label), the mean amount of chlorophenyl-BAS 750 F decreased from 97.74% TAR at 0 DAT to 81.69% TAR at 120 DAT (see Table 8.1.1.3-13). Three minor transformation products were observed and none of them exceeded an average of 5% TAR at any time point.

Table 8.1.1.3-9: HPLC Quantitation of [Triazole-3(5)-^{14}C]-BAS 750 F Residues in Li10 Extract [% TAR]

				BAS 750 F
	t_R (min)	**3.7-4.0**	**4.3-4.7**	**36.6-38.1**
DAT	**DAF**			
0 rep1	NA	1.81	0.69	96.91
0 rep2	NA	1.81	0.77	97.45
0 mean	**NA**	**1.81**	**0.73**	**97.18**
7 rep1	NA	1.09	< LOQ	92.14
7 rep2	NA	1.57	< LOQ	93.62
7 mean	**NA**	**1.33**	**< LOQ**	**92.88**
11 rep1	NA	2.77	< LOQ	76.95
11 rep2	NA	1.19	< LOQ	78.65
11 mean	**NA**	**1.98**	**< LOQ**	**77.80**
30 rep1	NA	2.28	< LOQ	99.40
30 rep2	NA	0.97	< LOQ	91.00
30 mean	**NA**	**1.63**	**< LOQ**	**95.20**
32 rep1	2 rep1	1.08	< LOQ	96.30
32 rep2	2 rep2	1.57	< LOQ	96.64
32 mean	**2 mean**	**1.33**	**< LOQ**	**96.47**
37 rep1	7 rep1	1.36	< LOQ	94.01
37 rep2	7 rep2	5.63	< LOQ	73.61
37 mean	**7 mean**	**3.50**	**< LOQ**	**83.81**
44 rep1	14 rep1	1.02	< LOQ	95.37
44 rep2	14 rep2	1.10	< LOQ	90.40
44 mean	**14 mean**	**1.06**	**< LOQ**	**92.89**
60 rep1	30 rep1	1.97	< LOQ	84.85
60 rep2	30 rep2	1.25	< LOQ	90.69
60 mean	**30 mean**	**1.61**	**< LOQ**	**87.77**
91 rep1	61 rep1	0.55	< LOQ	84.27
91 rep2	61 rep2	1.14	< LOQ	88.60
91 mean	**61 mean**	**0.85**	**< LOQ**	**86.44**
120 rep1	90 rep1	1.47	< LOQ	82.70
120 rep2	90 rep2	2.03	0.64	69.21
120 mean	**90 mean**	**1.75**	**0.32**	**75.96**

NA = Not Applicable
LOQ = 0.59% TAR
Arithmetic mean values may be reported as a value less than the stated LOQ value. Individual replicates reported as <LOQ have been treated as a zero value in the calculation of arithmetic mean values.

Table 8.1.1.3-10: HPLC Quantitation of [Triazole-3(5)-^{14}C]-BAS 750 F Residues in LUFA 5M Extract [% TAR]

				BAS 750 F
	t_R (min)	**3.1-4.3**	**4.3-4.7**	**36.7-38.1**
DAT	**DAF**			
0 rep1	NA	< LOQ	< LOQ	106.44
0 rep2	NA	< LOQ	1.25	89.14
0 mean	**NA**	**< LOQ**	**0.63**	**97.79**
7 rep1	NA	0.64	< LOQ	101.72
7 rep2	NA	0.60	< LOQ	103.11
7 mean	**NA**	**0.62**	**< LOQ**	**102.42**
11 rep1	NA	< LOQ	< LOQ	93.27
11 rep2	NA	< LOQ	< LOQ	84.27
11 mean	**NA**	**< LOQ**	**< LOQ**	**88.77**
30 rep1	NA	0.68	< LOQ	103.77
30 rep2	NA	< LOQ	< LOQ	101.84
30 mean	**NA**	**0.34**	**< LOQ**	**102.81**
32 rep1	2 rep1	0.66	< LOQ	103.01
32 rep2	2 rep2	< LOQ	< LOQ	93.23
32 mean	**2 mean**	**0.33**	**< LOQ**	**98.12**
37 rep1	7 rep1	0.61	< LOQ	96.75
37 rep2	7 rep2	< LOQ	< LOQ	80.05
37 mean	**7 mean**	**0.31**	**< LOQ**	**88.40**
44 rep1	14 rep1	< LOQ	< LOQ	82.71
44 rep2	14 rep2	< LOQ	< LOQ	87.56
44 mean	**14 mean**	**< LOQ**	**< LOQ**	**85.14**
60 rep1	30 rep1	< LOQ	< LOQ	96.18
60 rep2	30 rep2	< LOQ	< LOQ	94.99
60 mean	**30 mean**	**< LOQ**	**< LOQ**	**95.59**
91 rep1	61 rep1	< LOQ	< LOQ	95.89
91 rep2	61 rep2	< LOQ	< LOQ	94.46
91 mean	**61 mean**	**< LOQ**	**< LOQ**	**95.18**
120 rep1	90 rep1	< LOQ	< LOQ	92.69
120 rep2	90 rep2	0.95	< LOQ	92.54
120 mean	**90 mean**	**0.48**	**< LOQ**	**92.62**

NA = Not Applicable
LOQ = 0.59% TAR
Arithmetic mean values may be reported as a value less than the stated LOQ value. Individual replicates reported as <LOQ have been treated as a zero value in the calculation of arithmetic mean values.

Table 8.1.1.3-11: HPLC Quantitation of [Triazole-3(5)-^{14}C]-BAS 750 F Residues in IN Extract [% TAR]

				BAS 750 F
	t_R (min)	**3.7-4.3**	**4.3-4.7**	**36.7-38.1**
DAT	**DAF**			
0 rep1	NA	1.49	1.47	94.97
0 rep2	NA	1.36	0.89	99.32
0 mean	**NA**	**1.43**	**1.18**	**97.15**
7 rep1	NA	1.54	< LOQ	108.47
7 rep2	NA	0.97	< LOQ	101.81
7 mean	**NA**	**1.26**	**< LOQ**	105.14
11 rep1	NA	2.94	< LOQ	94.84
11 rep2	NA	1.25	< LOQ	82.61
11 mean	**NA**	**2.10**	**< LOQ**	**88.73**
30 rep1	NA	4.88	< LOQ	91.63
30 rep2	NA	1.32	< LOQ	85.80
30 mean	**NA**	**3.10**	**< LOQ**	**88.72**
32 rep1	2 rep1	1.90	< LOQ	98.72
32 rep2	2 rep2	2.02	< LOQ	92.90
32 mean	**2 mean**	**1.96**	**< LOQ**	**95.81**
37 rep1	7 rep1	1.29	< LOQ	91.46
37 rep2	7 rep2	2.25	< LOQ	97.38
37 mean	**7 mean**	**1.77**	**< LOQ**	**94.42**
44 rep1	14 rep1	1.03	< LOQ	95.19
44 rep2	14 rep2	1.82	< LOQ	96.43
44 mean	**14 mean**	**1.43**	**< LOQ**	**95.81**
60 rep1	30 rep1	1.64	< LOQ	91.47
60 rep2	30 rep2	2.65	< LOQ	80.62
60 mean	**30 mean**	**2.15**	**< LOQ**	**86.05**
91 rep1	61 rep1	2.14	< LOQ	88.76
91 rep2	61 rep2	2.17	< LOQ	84.92
91 mean	**61 mean**	**2.16**	**< LOQ**	**86.84**
120 rep1	90 rep1	1.54	< LOQ	81.27
120 rep2	90 rep2	1.27	0.70	76.16
120 mean	**90 mean**	**1.41**	**0.35**	**78.72**

NA = Not Applicable
LOQ = 0.59% TAR
Arithmetic mean values may be reported as a value less than the stated LOQ value. Individual replicates reported as <LOQ have been treated as a zero value in the calculation of arithmetic mean values.

Table 8.1.1.3-12: HPLC Quantitation of [Triazole-3(5)-^{14}C]-BAS 750 F Residues in NJ Extract [% TAR]

				BAS 750 F
	t_R (min)	**3.7-4.0**	**4.2-4.7**	**36.7-38.1**
DAT	**DAF**			
0 rep1	NA	1.28	1.16	104.78
0 rep2	NA	1.08	0.66	90.33
0 mean	**NA**	**1.18**	**0.91**	**97.56**
7 rep1	NA	1.39	< LOQ	104.51
7 rep2	NA	1.58	< LOQ	88.32
7 mean	**NA**	**1.49**	**< LOQ**	**96.42**
11 rep1	NA	4.32	< LOQ	92.90
11 rep2	NA	1.79	< LOQ	98.38
11 mean	**NA**	**3.06**	**< LOQ**	**95.64**
30 rep1	NA	5.78	< LOQ	86.31
30 rep2	NA	2.36	< LOQ	88.96
30 mean	**NA**	**4.07**	**< LOQ**	**87.64**
32 rep1	2 rep1	1.46	< LOQ	88.11
32 rep2	2 rep2	2.03	< LOQ	98.23
32 mean	**2 mean**	**1.75**	**< LOQ**	**93.17**
37 rep1	7 rep1	2.49	1.01	97.17
37 rep2	7 rep2	< LOQ	< LOQ	78.84
37 mean	**7 mean**	**1.25**	**0.51**	**88.01**
44 rep1	14 rep1	1.91	< LOQ	90.19
44 rep2	14 rep2	2.62	< LOQ	94.50
44 mean	**14 mean**	**2.27**	**< LOQ**	**92.35**
60 rep1	30 rep1	1.40	< LOQ	76.82
60 rep2	30 rep2	1.96	< LOQ	68.44
60 mean	**30 mean**	**1.68**	**< LOQ**	**72.63**
91 rep1	61 rep1	2.33	< LOQ	87.45
91 rep2	61 rep2	1.74	< LOQ	77.15
91 mean	**61 mean**	**2.04**	**< LOQ**	**82.30**
120 rep1	90 rep1	2.94	< LOQ	88.55
120 rep2	90 rep2	2.23	< LOQ	89.35
120 mean	**90 mean**	**2.59**	**< LOQ**	**88.95**

NA = Not Applicable
LOQ = 0.59% TAR
Arithmetic mean values may be reported as a value less than the stated LOQ value. Individual replicates reported as <LOQ have been treated as a zero value in the calculation of arithmetic mean values.

Table 8.1.1.3-13: HPLC Quantitation of [Chlorophenyl-U-^{14}C]-BAS 750 F Residues in NJ Extract [% TAR]

			BAS 750 F		
	t_R (min)	33.92	36.7-38.1	40.0-41.7	42.4-42.6
DAT	**DAF**				
0 rep1	NA	< LOQ	98.46	< LOQ	1.66
0 rep2	NA	< LOQ	97.01	< LOQ	1.29
0 mean	**NA**	**< LOQ**	**97.74**	**< LOQ**	**1.48**
7 rep1	NA	< LOQ	95.10	1.10	1.25
7 rep2	NA	< LOQ	87.84	1.64	1.15
7 mean	**NA**	**< LOQ**	**91.47**	**1.37**	**1.20**
11 rep1	NA	< LOQ	92.63	< LOQ	< LOQ
11 rep2	NA	< LOQ	89.08	0.87	< LOQ
11 mean	**NA**	**< LOQ**	**90.86**	**0.44**	**< LOQ**
30 rep1	NA	< LOQ	93.83	0.64	< LOQ
30 rep2	NA	< LOQ	90.69	0.63	< LOQ
30 mean	**NA**	**< LOQ**	**92.26**	**0.64**	**< LOQ**
32 rep1	2 rep1	< LOQ	83.54	< LOQ	< LOQ
32 rep2	2 rep2	< LOQ	87.15	0.68	< LOQ
32 mean	**2 mean**	**< LOQ**	**85.35**	**0.34**	**< LOQ**
37 rep1	7 rep1	0.70	80.34	1.04	< LOQ
37 rep2	7 rep2	< LOQ	89.42	< LOQ	< LOQ
37 mean	**7 mean**	**0.35**	**84.88**	**0.52**	**< LOQ**
44 rep1	14 rep1	< LOQ	85.28	0.97	< LOQ
44 rep2	14 rep2	< LOQ	86.31	1.64	< LOQ
44 mean	**14 mean**	**< LOQ**	**85.80**	**1.31**	**< LOQ**
60 rep1	30 rep1	< LOQ	88.18	< LOQ	< LOQ
60 rep2	30 rep2	< LOQ	86.35	0.79	< LOQ
60 mean	**30 mean**	**< LOQ**	**87.27**	**0.40**	**< LOQ**
91 rep1	61 rep1	< LOQ	78.28	1.26	< LOQ
91 rep2	61 rep2	< LOQ	83.01	1.27	< LOQ
91 mean	**61 mean**	**< LOQ**	**80.65**	**1.27**	**< LOQ**
120 rep1	90 rep1	< LOQ	82.06	1.01	< LOQ
120 rep2	90 rep2	< LOQ	81.32	1.51	< LOQ
120 mean	**90 mean**	**< LOQ**	**81.69**	**1.26**	**< LOQ**

NA = Not Applicable
LOQ = 0.59% TAR
Arithmetic mean values may be reported as a value less than the stated LOQ value. Individual replicates reported as <LOQ have been treated as a zero value in the calculation of arithmetic mean values.

Characterisation of non-extractable residues (NER)

The non-extractable residues in all soils were further characterised by repetitive extractions with aqueous sodium hydroxide to evaluate the activity in each fraction of the soil. Two time points (30 DAT and 120 DAT) were examined. Results for each soil are listed below and in Tables 8.1.1.3-14 to -18. No further HPLC characterisation was performed on the soil fractions due to low levels of detected activity.

As the Tables show, the NER increased for all soils throughout the study period. As the characterisation shows, the majority of the NER can be attributed to humins.

Table 8.1.1.3-14: Characterisation of Bound Residues in [Triazole-3(5)-^{14}C]-BAS 750 F Treated Li10 Soil (Expressed as % TAR)

DAT	Rep	NER	Fulvic Acid	Humic Acid	Humins	% Recovery
30	1	3.39	1.19	0.67	1.33	94.26
	2	2.76	1.01	0.64	1.09	98.99
	mean	**3.08**	**1.10**	**0.65**	**1.21**	**96.62**
120 (90 DAF)	1	8.81	1.69	1.32	5.54	97.01
	2	7.97	1.31	1.23	5.07	95.54
	mean	**8.39**	**1.50**	**1.27**	**5.31**	**96.27**

NER: Non-Extractable Residues (by combustion)
% Recovery = 100 × (Fulvic Acids + Humic Acids + Humins) / NER
Values have been rounded to two decimal places. All calculations were performed using the full precision data reported in ALADIN. Calculations based on the rounded values in the tables may vary slightly from those shown above.

Table 8.1.1.3-15: Characterisation of Bound Residues in [Triazole-3(5)-^{14}C]-BAS 750 F Treated LUFA 5M Soil (Expressed as % TAR)

DAT	Rep	NER	Fulvic Acid	Humic Acid	Humins	% Recovery
30	1	5.49	2.69	0.74	1.93	97.63
	2	6.04	2.96	0.88	2.10	98.29
	mean	**5.77**	**2.82**	**0.81**	**2.01**	**97.96**
120 (90 DAF)	1	13.81	3.70	1.69	8.11	97.75
	2	14.15	3.83	1.84	8.34	98.94
	mean	**13.98**	**3.76**	**1.76**	**8.22**	**98.35**

NER: Non-Extractable Residues (by combustion)
% Recovery = 100 × (Fulvic Acids + Humic Acids + Humins) / NER
Values have been rounded to two decimal places. All calculations were performed using the full precision data reported in ALADIN. Calculations based on the rounded values in the tables may vary slightly from those shown above.

Table 8.1.1.3-16: Characterisation of Bound Residues in [Triazole-3(5)-^{14}C]-BAS 750 F Treated IN Soil (Expressed as % TAR)

DAT	Rep	NER	Fulvic Acid	Humic Acid	Humins	% Recovery
30	1	5.81	1.94	0.78	3.04	99.21
	2	4.86	1.56	0.63	2.58	98.21
	mean	**5.33**	**1.75**	**0.71**	**2.81**	**98.71**
120 (90 DAF)	1	9.86	2.26	1.07	6.66	101.33
	2	9.12	1.97	1.02	5.96	98.19
	mean	**9.49**	**2.11**	**1.05**	**6.31**	**99.76**

NER: Non-Extractable Residues (by combustion)
% Recovery = 100 × (Fulvic Acids + Humic Acids + Humins) / NER
Values have been rounded to two decimal places. All calculations were performed using the full precision data reported in ALADIN. Calculations based on the rounded values in the tables may vary slightly from those shown above.

Table 8.1.1.3-17: Characterisation of Bound Residues in [Triazole-3(5)-^{14}C]-BAS 750 F Treated NJ Soil (Expressed as % TAR)

DAT	Rep	NER	Fulvic Acid	Humic Acid	Humins	% Recovery
30	1	7.23	2.47	0.87	3.87	99.68
	2	7.3	2.35	1.04	3.90	99.92
	mean	**7.27**	**2.41**	**0.95**	**3.89**	**99.80**
120 (90 DAF)	1	15.21	2.92	1.69	10.61	100.05
	2	15.81	3.16	1.66	10.98	99.90
	mean	**15.51**	**3.04**	**1.67**	**10.80**	**99.97**

NER: Non-Extractable Residues (by combustion)
% Recovery = 100 × (Fulvic Acids + Humic Acids + Humins) / NER
Values have been rounded to two decimal places. All calculations were performed using the full precision data reported in ALADIN. Calculations based on the rounded values in the tables may vary slightly from those shown above.

Table 8.1.1.3-18: Characterisation of Bound Residues in [Chlorophenyl-U-^{14}C]-BAS 750 F Treated NJ Soil (Expressed as % TAR)

DAT	Rep	NER	Fulvic Acid	Humic Acid	Humins	% Recovery
30	1	8.39	1.97	1.70	4.63	98.94
	2	8.27	1.94	1.59	4.52	97.39
	mean	**8.33**	**1.96**	**1.65**	**4.58**	**98.17**
120 (90 DAF)	1	16.67	3.06	2.01	11.15	97.30
	2	16.07	2.72	2.21	11.42	101.68
	mean	**16.37**	**2.89**	**2.11**	**11.29**	**99.49**

NER: Non-Extractable Residues (by combustion)
% Recovery = 100 × (Fulvic Acids + Humic Acids + Humins) / NER
Values have been rounded to two decimal places. All calculations were performed using the full precision data reported in ALADIN. Calculations based on the rounded values in the tables may vary slightly from those shown above.

Chiral analysis

Chiral analysis was performed on representative samples from the beginning, middle and end of the study. The Applicant states that the ratios showed no relevant shift throughout the study (~ 52:48) (see Table 8.1.1.3-19); the RMS agrees with the Applicant's statement (see section B.8.1.4 for further information).

Table 8.1.1.3-19: Chirality analysis

Label		**Triazole (%ROI)**								**Chlorophenyl (%ROI)**	
Soil		**Li10**		**Lufa 5M**		**IN**		**NJ**		**NJ**	
DAT	DAF	*R*	*S*	*R*	*S*	*R*	*S*	*R*	*S*	*R*	*S*
0	NA	47.5	52.5	49.0	51.0	50.0	50.0	51.2	48.8	48.2	51.8
11	NA	49.5	50.5	50.9	49.1	50.6	49.5	48.3	51.7	50.0	50.0
30	NA	48.5	51.5	50.2	49.8	52.2	47.8	49.0	51.0	51.1	48.9
32	2	50.0	50.0	50.0	50.0	49.6	50.4	49.1	51.0	51.1	48.9
60	30	50.7	49.3	50.4	49.6	51.4	48.6	50.3	49.7	49.2	50.8
120	90	52.4	47.7	47.6	52.4	51.1	48.9	52.1	47.9	51.9	48.1

Kinetic analysis

The Applicant undertook kinetic analysis on the anaerobic results of this study (i.e. from 30 DAT onwards) in accordance with FOCUS Kinetic Guidance, 2006, and using KinGUII v2 software. For soil LUFA 5M, no

discernible decline phase was observed in the results (as can be seen in Table 8.1.1.3-9), therefore, kinetic analysis has not been undertaken on this soil.

For soil NJ, both sets of replicate samples (from the triazole-label and the chlorophenyl-label) were combined, therefore, for each time point there were 4 individual results. For the other soils, there were 2 individual results for each time point.

The Applicant followed the 'trigger endpoints' flow chart (Figure 7-4, page 113 in the FOCUS kinetic guidance). In line with the guidance, SFO and FOMC models were initially run and compared for each soil; in all instances, the FOMC model did not provide a better statistical and/or visual fit than the SFO model. Therefore, the SFO model was used to derive triggering endpoints. A comparison of the visual and statistical fits of the SFO and FOMC models are given in Figures 8.1.1.3-1 to -3 and in Table 8.1.1.3-20.

Figure 8.1.1.3-1: SFO (left) and FOMC (right) graphs for soil Li10

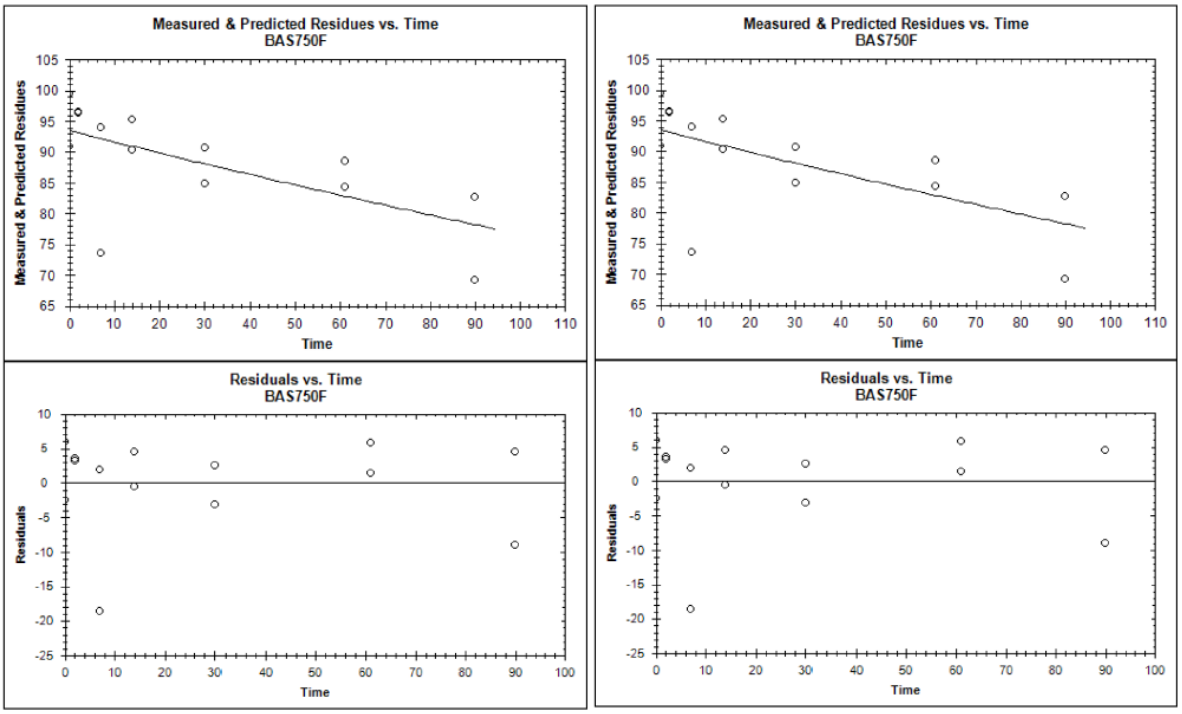


Figure 8.1.1.3-2: SFO (left) and FOMC (right) graphs for soil IN

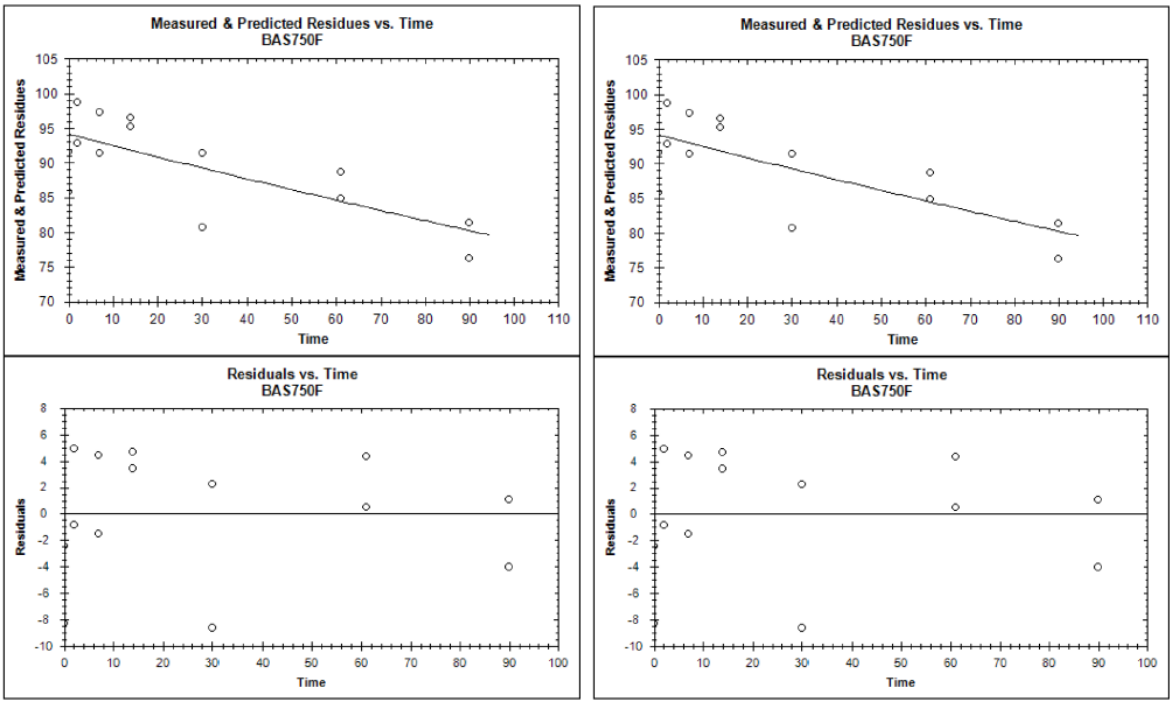


Figure 8.1.1.3-3: SFO (left) and FOMC (right) graphs for soil NJ

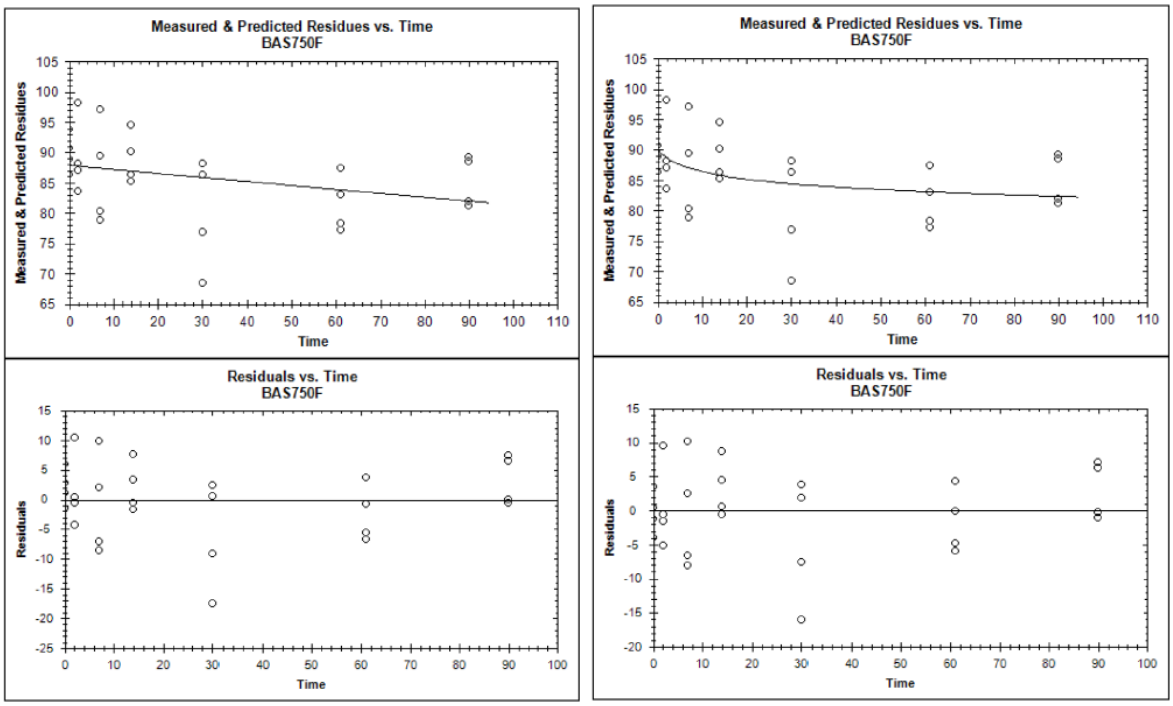


Table 8.1.1.3-20: Kinetic Analysis of BAS 750 F Degradation in Soil Under Anaerobic Conditions

	Li10		**IN**		**NJ**	
	SFO	FOMC	SFO	FOMC	SFO	FOMC
M_0	93.44	93.44	94.09	94.09	87.85	90.24
k	0.0020	n/a	0.0018	n/a	0.0008	n/a
χ^2	3.51	3.79	2.80	3.03	2.80	2.47
t-test	<0.01	Acceptable[a)]	<0.01	Acceptable[a)]	0.05	Unacceptable[a)]
DT_{50}	349	349	390	390	899	>1000
DT_{90}	>1000	>1000	>1000	>1000	>1000	>1000

a) For FOMC, instead of a t-test, the alpha and beta error values are compared to the estimated parameters; if the error values are lower, the FOMC model is considered acceptable

The RMS has repeated the Applicant's modelling using CAKE v3.2 and can replicate all of the Applicant's SFO and FOMC results. Therefore, the RMS considers the Applicant's endpoints to be appropriate. Based on visual assessment and χ^2 values, the SFO model is considered to be the best fit model for all soils.

The RMS notes that, given the SFO models provided the best-fit for each of the soils, then the 'trigger endpoints' calculated by the Applicant are also the appropriate 'modelling endpoints'.

Conclusion

BAS 750 F degrades slowly under anaerobic soil conditions, as demonstrated in this laboratory study. At all sampling points, the parent compound was the major residue detected by HPLC analysis, for all soil types and labels tested. DT_{50} values for BAS 750 F were in excess of 349 days. Formation of NER was the major end product during incubation. No new or novel metabolites were discovered under anaerobic conditions that were not seen under aerobic conditions and no metabolites were present at >10 % AR or >5 % AR at 2 consecutive time points. There is no discernible isomerisation of the enantiomers, or preferred degradation of either enantiomer.

B.8.1.1.4. Field dissipation Studies

B.8.1.1.4.1. EU Field Dissipation

Report:	**KCA 7.1.2.2.1/1, Schaeufele M., 2015d** Field dissparion study of Reg No 5834378 in the formulation EXP 5834378 F-AV on bare soil at six sites in Europe, 2013 2015/1046920
Guidelines:	NAFTA Guidance Document for conducting Terrestrial Field dissipation Studies Regulatory Directive DIR2006-01 (March 2006), EPA 835.6100, SETAC procedures for assessing the environmental fate and behaviour and ecotoxicology of pesticides (March, 1995), EFSA Guidance to obtain DegT50 values in soil (2014), SANCO/3029/99 rev. 4 (11 July 2000), EEC 91/414 Annex II (Part A Section 4), EEC 91/414 Annex III (Part A Section 5)
GLP	Yes Certified by Department of Health of the Government of the United Kingdom, United Kingdom

Report:	**KCA 7.1.2.2.1/2, Schaeufele M., 2015e** Final report amendment No. 1: Field dissparion study of Reg No 5834378 in the formulation EXP 5834378 F-AV on bare soil at six sites in Europe, 2013 2015/1242234
Guidelines:	NAFTA Guidance Document for conducting Terrestrial Field dissipation Studies Regulatory Directive DIR2006-01 (March 2006), EPA 835.6100, SETAC procedures for assessing the environmental fate and behaviour and ecotoxicology of pesticides (March, 1995), EFSA Guidance to obtain DegT50 values in soil (2014), SANCO/3029/99 rev. 4 (11 July 2000), EEC 91/414 Annex II (Part A Section 4), EEC 91/414 Annex III (Part A Section 5)
GLP	Yes Certified by Department of Health of the Government of the United Kingdom, United Kingdom

Test Sites

The dissipation of BAS 750 F and its metabolites M750F003 and M750F001(1,2,4-triazole) under field conditions was investigated at six sites in Europe representative of Northern, Central and Southern EU conditions. The study design followed EFSA DegT50 guidance on study design for generation of DegT50 values in the fiels, as such this study is not considered to be a standard field dissipation study designed to elucidate persistence under more realistic field condition. Two trials were performed in Germany (one is western and on in eastern Germany), and one trial each was performed in Denmark, Northern France, Italy and Spain. The site characteristics are presented in Table 8.1.1.4.1-1. Soil parameters were determined from soil samples taken before application from the boundaries of the treated plot following segmentation according to the soil horizons. The RMS notes that the soil taxonomy (WRB or FAO classification) was identified through the use of regional soil maps, rather than by through soil profiles at each trial site (as required by NAFTA, 2006). The RMS is of the opinion that this is an acceptable deviation, from the guideline, as soil maps are considered to be a reliable data source, plus ultimately the soil taxonomy has only been considered when concluding on the agricultural relevance of the selected sites and will have no impact upon the resulting degradation rates. The RMS is of the opinion that the taxonomy indicated that the trial sites are in locations of agricultural relevance.

Table 8.1.1.4.1-1: Soil characteristics of the trial sites L130556, L130557, L130558 used to investigate the field dissipation of BAS 750 F

Trial	**L130556**		**L130557**		**L130558**	
Location	**Bogense, Denmark**		**Lentzke, Germany (East)**		**Goch-Nierswalde, Germany (West)**	
GPS coordinates[d]	**55° 32' 10" N 10° 02' 41" E**		**52° 47' 06" N 12° 13' 16" E**		**51° 43' 27" N 06° 07' 16'' E**	
Geographical area[e]	**Northern/ Central Europe**		**Northern/ Central Europe**		**Northern/ Central Europe**	
Soil properties	0 – 30 cm	30 – 50 cm	0 – 35 cm	35 – 50 cm	0 – 30 cm	30 – 50 cm
Soil class (DIN 4220)	Sandy loam (Sl3)	Sandy loam (Sl3)	Strong loamy sand (Sl2)	Strong loamy sand (Su3)	Loamy silt (Ut2)	Loamy silt (Uls)
sand ([%]	61.1	58.6			16.1	34.0
silt [%]	29.7	30.6	68.2	66.9	75.3	56.3
clay [%]	9.2	10.8	24.6	25.7	8.5	9.8
			7.1	7.3		
Soil class (USDA)	Sandy loam	Sandy loam	Loamy sand	Sandy loam	Silt loam	Loam
sand [%]	73.3	71.5	80.0	76.3	39.0	49.5
silt [%]	15.3	16.0	12.0	12.3	51.5	41.2
clay [%]	11.4	12.5	7.9	11.5	9.6	9.3
Total organic C [%]	1.1	0.5	0.7	0.2	1.6	0.3
Organic matter [%] [a]	1.8	0.9	1.2	0.4	2.8	0.5
pH [$CaCl_2$]	6.4	7.4	5.4	4.5	6.5	6.0
pH [H_2O]	6.9	7.9	5.9	5.4	7.1	6.7
CEC [$cmol^+ kg^{-1}$]	7.2	7.0	3.8	2.6	10.2	3.8
MWHC [$g\ 100g^{-1}$ dry weight]	32.8	28.8	22.6	19.7	39.0	26.2
pF 2.0 [$g\ 100g^{-1}$ dry weight] [b]	18.3	16.9	15.9	14.5	34.6	23.2
pF 2.5 [$g\ 100g^{-1}$ dry weight] [b]	11.3	11.7	10.4	9.9	21.0	16.6
Dry bulk density [$g\ cm^{-3}$] [c]	1.39 (10-20 cm)	-	1.55 (10-20 cm)	-	1.29 (10-20 cm)	-
Soil taxonomy	Haplic Luvisols		Podzoluvisols- Luvisols		Gleyic Cambisols and Stagnic Luvisols	
Classification Scheme	WRB		FAO		WRB	
Source	European Soil database Scale 1:1000000		(Bodenübersichtskarte CC 3942 Berlin, M 1 : 200000)		regional soil map (digital soil map of NRW) of the geological Survey of North Rhine-Westphalia	

CEC = Cation exchange capacity
MWHC = Maximum water holding capacity
[a] Organic matter = Organic carbon x 1.724
[b] Water retention characteristics, soil moisture at 0.1 or 0.33 bar
[c] Mean of three replicates
[d] GPS determined by Google Earth, except trial L130558 where a GPS receiver was used
[e] Climatic zone according to SANCO 7525/VI/95, rev. 9, March 2011

Table 8.1.1.4.1-2: Soil characteristics of the trial sites L130559, L130560, L130571 used to investigate the field dissipation of BAS 750 F

Trial	**L130559**		**L130560**		**L130561**		
Location	**Stotzheim, France**		**Poggio Renatico, Italy**		**Utrera, Spain**		
GPS coordinates[d]	**48.368179 N 07.498884E**		**44° 44' 42'' N 11° 31 ' 07 E ''**		**37° 10' 55.96'' N 5° 51' 17.35'' W**		
Geographical area[e]	**Northern Europe**		**Southern Europe**		**Southern Europe**		
Soil properties	0 – 30 cm	30 – 50 cm	0 – 30 cm	30 – 50 cm	0 – 20 cm	20 – 40 cm	40 – 50 cm
Soil class (DIN 4220)	Silt loam (Ut4)	Silt loam (Tu4)	Silt loam (Ut4)	Silt loam (Ut4)	Weak loamy sand (St2)	Strong loamy sand (Sl3)	Sandy clay (Ts4)
sand [%]	8.1	6.7	7.8	6.3	82.9	78.2	52.5
silt [%]	70.3	67.6	67.9	68.8	8.8	11.3	13.0
clay [%]	21.6	25.5	24.3	24.8	8.3	10.4	34.5
Soil class (USDA)	Silty clay loam	Silty clay loam	Silty clay loam	Silty clay loam	Loamy sand	Loamy sand	Sandy clay
sand [%]	13.3	13.2	15.6	14.5	87.9	83.1	58.5
silt [%]	57.6	51.5	49.8	49.2	3.8	4.9	5.0
clay [%]	29.2	35.2	34.6	36.2	8.3	12.1	36.5
Total organic C [%]	0.8	0.7	1.1	1.1	0.4	0.2	0.4
Organic matter [%] [a]	1.4	1.2	1.8	1.9	0.7	0.4	0.6
pH [$CaCl_2$]	7.4	7.6	7.6	7.6	7.4	7.0	6.7
pH [H_2O]	8.0	8.3	8.3	8.2	7.9	7.6	7.1
CEC [$cmol^+ kg^{-1}$]	14.4	16.4	17.0	17.3	3.5	4.0	21.0
MWHC [g $100g^{-1}$ dry weight]	41.7	41.0	44.4	47.3	28.8	34.3	46.2
pF 2.0 [g $100g^{-1}$ dry weight] [b]	31.9	31.5	35.7	37.2	19.1	17.6	32.7
pF 2.5 [g $100g^{-1}$ dry weight] [b]	25.9	26.0	28.4	30.9	7.4	8.5	25.0
Dry bulk density [g cm^{-3}] [c]	1.43 (10-20 cm)	-	1.17 (10-20 cm)	-	1.62 (10-20 cm)	-	-
Soil taxonomy	Haplic Calcisols		Calcaric Endostagnic Fluvisols		Eutric Planosol, Gleyic Luvisols, and Plinthic Luvisols		
Classification Scheme	WRB		WRB		FAO		
Source	map (Scala 1 :2 500 000) from tha Soil Atlas of Europa, European Soil Bureau Network, European Commission, 2005		regional Emilia Romagna soil map, from the geological Survey of Soils from Ferrara Province		regional soil map FAO Soil Taxonomy of Consejerfa de Medio Ambiente de la Junta de Andalucfa		

CEC = Cation exchange capacity
MWHC = Maximum water holding capacity
[a] Organic matter = Organic carbon x 1.724
[b] Water retention characteristics, soil moisture at 0.1 or 0.33 bar
[c] Mean of three replicates
[d] GPS determined by Google Earth, except trial L130558 where a GPS receiver was used
[e] Climatic zone according to SANCO 7525/VI/95, rev. 9, March 2011

The sites were all flat without significant slope. Before commencement of the study, the soil at each trial site was prepared as for sowing and was rolled if considered necessary, but then was left to fallow. No product containing the test item (BAS 750F) or azole fungicides has been used on the test plot in the last three years. A summary of the pesticide history is provided within table 8.1.1.4.1-3. While all locations have previous pesticide applications, the structures of these pesticides are not considered to be of a similar nature to BAS 750F, therefore it is not expected that the application shall significantly influence the degradation of BAS 750F.

Furthermore it is not unexpected that agricultural soil will have a number of pesticides previously applied; as such the RMS accepts the use of these trial sites which have previous pesticide use.

Table 8.1.1.4.1-3 : Management history of the trial sites in previous years (non-GLP)

Trial	Location	Year	Crops Grown	Pesticide Used	Fertilizer used
L130566	Bogenese, Denmark	2013*	White clover	No pesticide applied	No fertilizer applied
		2012	White clover	No pesticide applied	No fertilizer applied
		2011	White clover	No pesticide applied	No fertilizer applied
		2010	Spring barley + White clover undersown	propyzamide	24-0-0-6 (N-P-K-S)
L130557	Lentzke, German (East)	2013*	Winter rye	No pesticide applied	No Information available
		2012	Winter rye	Isoproturon, bifenox and tribenuron	
		2011	Winter rye	Metsulfuron and thifensulfuron	
		2010	Winter rye	Metsulfuron, thifensulfuron and florasulam	
L130558	Goch-Nierswalde, German (West)	2013*	Grass	No pesticide applied	None
		2012	Winter wheat	Diflufenican , flufenacet, beta-cyfluthrin	Data Not available
		2011	Winter wheat	Diflufenican , flufenacet and beta-cyfluthrin	
		2010	Caraway	Pendimethalin and propaquizafop	
L130559	Stotzheim, France	2013*	Maize	Cypermethrine	Data Not available
		2012	Maize	Cypermethrin, nicosulfuron, mesotrione, fluroxypyr and florasulam	
		2011	Maize	Tefluthrin, nicosulfuron, mesotrione, fluroxypyr and florasulam	
		2010	Maize	Nicosulfuron, mesotrione, fluroxypyr, florasulam and dicamba	
L130560	Poggio Renatico, Italy	2013*	None	No pesticide applied	None
		2012	Soybean	Imazamox and tifensulfuron-methyl	None
		2011	Winter wheat	Fluroxypir, clodinafop-propargyl, cloquintocet-mexyl and primicarb	Urea- N46% Nitrato ammonico-N27%
		2010	Soybean	Imazamox and tifensulfuron-methyl	None
L130561	Utera, Spain	2013*	Fallow field	No pesticide applied	None
		2012	Fallow field	Glyphosate and glufosinate ammonium	None
		2011	Fallow field	Glyphosate and pendimethalin	None
		2010	Fallow field	Pendimethalin	N-P-K 15-15-15

*Until start of trial

Experimental treatments

The trial area at each site was divided into two plots, one untreated control plot (size: 30 - 96 m^2) and one treated plot (size: 288 – 364.5 m^2). The treated plot consisted of three equal sized subplots A, B, and C that were assigned for replicates.

The product (EXP 5834378 F-AV), formulated as emulsifiable concentrate (EC), was broadcast applied to bare soil in a single application at a nominal rate of 150 g a.s. ha^{-1} using a target water volume of 300 L ha^{-1}. While this is less that the total annual application rate presented within the GAP table (300g a.s./ha), considering crop interception for cereals at BBCH 30 (80%), the annual soil loading is calculated to be 60g a.s./ha. As such the RMS is of the opinion that the application dose used within the study is acceptable. Applications were conducted between early May and mid-June 2013 using calibrated boom sprayers. Treated subplots were three-fold replicated with subplot sizes ranging from 96 to 121.5 m^2. For each treated replicate, a separate spray mixture was prepared and the test item was applied to each subplot individually. Each spray mixture was visually checked for homogeneity and small aliquots of the spray mixture were taken before and after application of each individual subplot for analysis. Details on the conditions at time of application are provided within table 8.1.1.4.1-4.

Table 8.1.1.4.1-4 : Application details and conditions during application

Site	**L130556**	**L130557**	**L130558**	**L130559**	**L130560**	**L130561**
Location	**Bogense, Denmark**	**Lentzke, Germany**	**Goch-Nierswalde, Germany**	**Stotzheim, France**	**Poggio Renatico, Italy**	**Utrera, Spain**
Nominal application rate of a.s.	150 g a.s./ha					
Water rate	300 l/ha					
Date of application	6th June 2013	5th June 2013	14th June 2013	11th June 2013	5th June 2013	7th May 2013
Air temperature at application (°C)	12.1- 12.2	10.8- 12.1	14-18	19.5	20.5- 20.8	17.3- 19.0
Windspeed (m/s) and direction	1.3-1.8 South	0.0-0.7 North	0-1 West	0 n.a.	0 n.a.	0- 1.0 North-East
Rainfall (mm) on day 0 after application	0	0	0	0	2.54*	0

n.a.- Not Applicable
*The precipitation started 10 hours after the end of treatment

The actual application rates determined by quantifying the amount of spray discharged ranged from 152 to 166 g a.s. ha^{-1} averaged over the three replicates of each treated plot. In addition, the dose was verified by means of sampling Petri dishes filled with untreated soil from the trial site (approximately 40 g per dish, sieved to 2 mm). The Petri dishes with an inner diameter of nominal 9.0 cm were placed on the treated plot (ten in each subplot) before application. On completion of the application, the Petri dishes were closed with a lid, sealed with adhesive tape, stored chilled after collection, and placed on dry ice or frozen within a maximum of 62 minutes. Further details on the application are presented in Table 8.1.1.4.1-5.

Table 8.1.1.4.1-5 : Application rates of field trial sites treated with EXP 5834378 F-AV (EC)

Trial Country	**Application Method**	**No. of applications**	**Subplot (m^2)**	**Application rate per treatment**				**Application date**
				nominal [g a.s. ha^{-1}]	**actual [a] [g a.s. ha^{-1}]**	**dose verification [b]**		
						[g a.s ha^{-1}]	**% of nominal**	
L130556 Denmark	broadcast spray to bare soil	1	A (96)	150	168	176	117	06 June 2013
			B (96)	150	167	164	110	
			C (96)	150	155	161 [c]	107 [c]	
			Average	**150**	**164**	**167 [d]**	**112 [d]**	

Table 8.1.1.4.1-5 : Application rates of field trial sites treated with EXP 5834378 F-AV (EC)

Trial Country	Application Method	No. of applications	Subplot (m^2)	Application rate per treatment				Application date
				nominal [g a.s. ha^{-1}]	actual [a] [g a.s. ha^{-1}]	dose verification [b] [g a.s ha^{-1}]	dose verification [b] % of nominal	
L130557 Germany (East)	broadcast spray to bare soil	1	A (108)	150	153	151	101	05 June 2013
			B (108)	150	151	149	100	
			C (108)	150	152	143	96	
			Average	**150**	**152**	**148**	**99**	
L130558 Germany (West)	broadcast spray to bare soil	1	A (96)	150	162	137	91	14 June 2013
			B (96)	150	156	129	86	
			C (96)	150	160	138	92	
			Average	**150**	**159**	**134**	**90**	
L130559 France (North)	broadcast spray to bare soil	1	A (121.5)	150	170	162	108	11 June 2013
			B (121.5)	150	160	145	97	
			C (121.5)	150	168	168	112	
			Average	**150**	**166**	**158**	**106**	
L130560 Italy	broadcast spray to bare soil	1	A (96)	150	158	152	102	05 June 2013
			B (96)	150	156	145	96	
			C (96)	150	157	164	109	
			Average	**150**	**157**	**154**	**102**	
L130561 Spain	broadcast spray to bare soil	1	A (96)	150	159	157	105	07 May 2013
			B (96)	150	162	174	116	
			C (96)	150	163	164	109	
			Average	**150**	**161**	**165**	**110**	

[a] Determined by calculation of spray liquid applied
[b] Determined by means of petri dishes filled with soil (recovery corrected)
[c] This values is based on the results from 9 petrid-dishes instead of 10. One petri dish within this replicate was identified as an outlier (result of this petri dish (recovery corrected): 578 g/ha – Dixon Test gave a 95% certainty for being an outlier). Taking this outlier into consideration (all 10 petri dishes) dose verification is 203 g a.s./ha and 135% nominal.
[d] This value is based on the results of exclusion the outlier. Taking the outlier in consideration (all 10 petri dishes) dose verification is 181 g a.s./ha and 121% of nominal.

Immediately after application of the test item and before subsequent soil sampling, the control plot and the treated replicates were covered with a thin layer of sand (maximum particle size of 4mm) to protect the applied product from surface processes like photolysis or volatilization, and to exclude any potential impact on the degradation of the test item caused by any of these processes. The application of sand was conducted manually or using a fertilizer spreader, a box- or drop-spreader until complete coverage of the soil surface. The thickness of the sand layer necessary for complete coverage of the soil was between 3 and 8 mm (EFSA DegT50 guidance indicates at least a 3mm depth is required). As BAS 750F has a vapour pressure of 3.2×10^{-6} Pa (20 °C) application of a sand layer is an effective means to reduce volatilisation

The layer of sand was monitored and controlled for up to around 30 days after application and was renewed when needed, ensuring that the sand cover remained intact until at least 30 days after application. Within this time period of 30 days, the individual fields received a total precipitation (rain and irrigation) of 86 mm (Denmark), 120 mm (Germany East), 94 mm (Germany West), 65 mm (France North), 63 mm (Italy), and 39 mm (Spain), respectively.

No tillage or fertilisation was performed during the course of the study from first to last sampling and no crops were grown throughout any of the trials. The plots were kept free of vegetation via the application of glyphosate, 2,4-D, MCPA, dicamba, glufosinate ammonium, quinoclamin, or flumioxazin. In the opinion of the RMS, the structures of these are not considered to be of a similar nature to BAS 750F, therefore it is not expected that the application shall significantly influence the degradation of BAS 750F.

Rainfall was supplemented with irrigation at sites in Denmark (217 mm), Eastern Germany (188 mm), Western Germany (565 mm), Northern France (273 mm), Italy (178 mm), and Spain (506 mm). Historical (long-term) weather data on precipitation and average air temperature from at least 10 years were sourced from official weather stations located nearby (1-25Km distance to trial site).

The sites were irrigated to adjust the precipitation to historical values in case of dryer than normal conditions. To this end, the actual precipitation at the trial site was checked three times per month (about every 10 days) and compared to the historical rainfall in the region, on an at least 10-year basis. If actual values for each 10-day period were lower than 110% of historical incremental values, the missing amount of water was applied to the field. It should be noted that the actual soil conditions at each moment were taken into consideration' therefore in some cases less than the calculated irrigation amount was applied. The EFSA DegT50[3] guidance indicates that irrigation can be applied, if required. As there is no evidence of significant leaching out of the top 30cm, the RMS considers irrigation at the specified sites to be acceptable.

The test plot L130561 (Spain), was irrigated to compensate for the evaporation at the bare soil plots. The actual precipitation at the trial site was checked three times per month (about every 10 days) and compared to the actual evaporation at the plots derived from daily reference evapotranspiration (ETo). If actual precipitation were lower than 55% of ETo values, the missing amount of water was applied to the field. Again actual soil conditions were taken into consideration.

This historical and actual data, each averaged over the complete duration of the individual trials are presented within table 8.1.1.4.1-6 Due to additional irrigation, the total water input at the test sites during the study was at least 102% of the historical average rainfall, which is considered sufficient to allow the cultivation of cereal crops

Table 8.1.1.4.1-6 Summary of historic and actual weather data at field trial sites averaged over entire trial duration- from the application day until the last sampling day

Trial County	Tmean Air [°C] (average over tial period		Precipitation [mm] (sum over trial peiod)		Irrigation [mm]	Sum of actual precipitation and irrigation [mm]	% of historic precipitation
	Historic	Actual	Historic	Actual			
L130556 Denmark	8.1	10.0	1276	1599	217	1817	142
L130557 Germany (East)	8.5	10.1	1024	1293	188	1481	145
L130558 Germany (west)	9.7	10.9	1515	985	565	1550	102
L130559 France (North)	10.9	11.9	1185	1415	273	1689	142
L130560 Italy	13.0	14.2	1223.6	1321	178	1499	122
L130561 Spain	17.5	19.4	1097.4	983.6	505.7	1489.3	136

Actual weather data are based on records of appropriate weather stations located on-site. Monthly summary results on temperature, precipitation, and irrigation are presented in Table 8.1.1.4.1-7 and Table 8.1.1.4.1-8 where daily data is available within the original study report.

[3] European food Safety Authority, 2914. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37pp., doi:10.2903/j.efsa.2014.3662

Table 8.1.1.4.1-7 : Summary of climatic conditions at field trial sites used to investigate the dissipation of BAS 750 F (trial sites L130556, L130557 and L130558)

Trial	**L130556** [ab]			**L130557** [ac]			**L130558** [a]		
Location	**Bogense**			**Lentzke**			**Goch-Nierswalde**		
	Denmark			**Germany (East)**			**Germany (West)**		
Climatic conditions	T_{mean} Air [°C]	Prec. [mm]	Irrigation [mm]	T_{mean} Air [°C]	Prec. [mm]	Irrigation [mm]	T_{mean} Air [°C]	Prec. [mm]	Irrigation [mm]
Month		∑	∑		∑	∑		∑	∑
May 13	-	-	-	-	-	-	-	-	-
Jun 13	14.5	83.3	0.0	16.7	99.2	0.0	16.1	60.4	15.0
Jul 13	18.3	12.9	49.5	20.0	47.4	31.0	19.3	66.2	40.0
Aug 13	17.5	49.4	18.5	18.7	58.6	30.6	18.1	18.6	60.0
Sep 13	13.5	108.9	24.2	13.0	74.8	0.0	14.2	59.4	45.0
Oct 13	11.2	112.6	33.3	11.0	95.8	0.0	12.0	39.6	35.0
Nov 13	6.3	80.9	0.0	5.2	75.8	0.0	6.3	39.8	10.0
Dec 13	5.5	125.8	0.0	4.0	50.6	0.0	5.6	22.6	10.0
Jan 14	2.1	76.3	0.0	0.3	35.0	0.0	5.2	47.6	0.0
Feb 14	4.7	44.6	0.0	4.6	26.2	0.0	6.3	46.2	0.0
Mar 14	6.1	30.1	14.0	6.7	18.8	21.5	8.5	26.6	45.0
Apr 14	9.0	36.5	8.2	10.8	41.0	6.2	12.2	16.6	30.0
May 14	12.1	68.8	0.0	12.8	90.8	0.0	13.0	65.6	10.0
Jun 14	15.4	62.5	11.0	16.0	109.4	10.3	16.2	33.4	55.0
Jul 14	19.5	33.3	21.9	20.7	69.2	13.2	19.5	25.6	40.0
Aug 14	15.9	132.0	24.5	16.8	50.2	8.1	15.9	100.8	0.0
Sep 14	15.0	49.4	12.3	15.7	27.4	29.0	15.7	23.4	50.0
Oct 14	12.5	77.6	0.0	12.1	47.8	5.3	13.1	39.4	15.0
Nov 14	7.8	30.4	0.0	6.4	11.4	0.0	8.1	19.0	10.0
Dec 14	3.8	116.0	0.0	2.3	57.4	0.0	4.1	44.4	0.0
Jan 15	3.3	91.2	0.0	2.7	71.4	0.0	3.4	88.6	0.0
Feb 15	2.3	26.2	0.0	1.2	18.8	0.0	2.8	38.4	0.0
Mar 15	4.9	57.4	0.0	5.3	67.4	12.3	5.7	28.8	25.0
Apr 15	7.6	29.2	0.0	8.3	31.4	13.5	8.5	12.6	40.0
May 15	10.0	64.0	0.0	11.8	16.8	7.2	13.0	21.2	30.0

[a] Actual weather data refer to time period from start of trial (day of application) until end of trial (day of last sampling)

[b] Bogense, Denamark- 29 July -21 Aug 2014: Weather data were obtained from the nearest Agrolab weather station, which is about 20Km away from the trial site

[c] Lentzke, Germany (East)- Weather data from 03.06.2013 07:00 to 10.06.2013 15:00 are taken from agro-check weather station 6FA, less than 1Km away from the trial site.

Table 8.1.1.4.1-8 : Summary of climatic conditions at field trial sites used to investigate the dissipation of BAS 750 F (trial sites L130559, L130560 and L130561)

Trial	**L130559** [a]			**L130560** [a]			**L130561** [a]		
Location	**Stotzheim**			**Poggio Renatico**			**Utrera**		
	France (North)			**Italy**			**Spain**		
Distance from weather station									
Climatic conditions	T_{mean} Air [°C]	Prec. [mm]	Irrigation [mm]	T_{mean} Air [°C]	Prec. [mm]	Irrigation [mm]	T_{mean} Air [°C]	Prec. [mm]	Irrigation [mm]
Month		∑	∑		∑	∑		∑	∑
May 13	-	-	-	-	-	-	20.3	8.0	18.9
Jun 13	18.8	38.0	6.6	22.0	29.0	33.8	25.0	0.0	41.0
Jul 13	22.2	21.0	44.4	25.0	4.6	22.3	28.2	0.0	58.6
Aug 13	19.3	57.6	25.6	23.8	63.2	19.3	28.7	0.0	74.0
Sep 13	15.7	86.6	0.0	19.7	29.7	24.7	25.5	21.5	30.0
Oct 13	12.1	140.8	9.3	14.9	98.0	0.0	21.5	88.5	0.0
Nov 13	5.6	85.8	0.0	9.4	69.2	0.0	14.2	3.0	9.3
Dec 13	3.5	35.6	0.0	3.7	10.8	0.0	12.0	59.0	24.7
Jan 14	4.6	33.8	0.0	5.8	94.4	0.0	12.9	85.0	0.0
Feb 14	5.7	47.6	0.0	7.7	87.6	0.0	13.0	85.3	0.0
Mar 14	8.9	8.0	22.2	10.4	52.0	0.0	15.1	32.8	21.3
Apr 14	12.5	25.8	35.6	13.9	68.8	10.2	19.5	93.0	0.0
May 14	14.8	55.4	13.5	17.1	48.8	19.5	22.6	10.0	23.0
Jun 14	19.8	24.4	64.0	22.3	25.1	21.0	24.8	8.0	38.9
Jul 14	19.8	210.8	0.0	22.6	67.6	15.6	26.3	0.0	55.7
Aug 14	17.6	81.4	0.0	22.4	84.9	0.0	27.0	0.0	59.7
Sept 14	16.3	12.4	33.8	18.8	64.5	0.0	24.5	61.0	28.6
Oct 14	13.2	85.2	0.0	15.8	36.8	0.0	22.7	58.0	0.0
Nov 14	7.5	61.8	0.0	11.4	53.2	0.0	16.8	212.0	0.0
Dec 14	4.4	32.0	0.0	5.6	47.6	0.0	10.9	29.5	0.0
Jan 15	3.3	75.8	0.0	3.6	13.9	0.0	10.5	56.0	0.0
Feb 15	1.9	20.8	0.0	5.1	111.7	0.0	11.6	11.0	0.0
Mar 15	7.3	26.2	18.4	9.0	71.3	0.0	14.5	55.5	10.3
Apr 15	11.2	59.4	0.0	13.0	59.1	11.4	18.4	6.5	11.7
May 15	15.4	89.0	0.0	19.1	29.2	0.0	-	-	-
Jun 15	16.3	0.0	0.0	-	-	-	-	-	-

[a] Actual weather data refer to time period from start of trial (day of application) until end of trial (day of last sampling)

Analytical

Replicate soil specimens (8 per treated subplot and 10 or 15 per control plot) were taken at intervals up to 720 days after treatment (DAT) and down to a maximum soil depth of 50 cm. At day 0, immediately after application, the treated plots were sampled down to 10 cm only. The detailed sampling intervals are presented in Table 8.1.1.4.1-9.

Table 8.1.1.4.1-9 : Summary of sampling intervals of residue soil samples at each trial site

Trial	Country	Sampling intervals [days after treatment]
L130556	Denmark	-1, 0, 6, 13, 29, 61, 92, 124, 174, 245, 363, 487, 615, 713
L130557	Germany (East)	-2, 0, 6, 14, 33, 56, 85, 118, 176, 272, 355, 476, 590, 715
L130558	Germany (West)	-3, 0, 7, 13, 27, 59, 95, 125, 185, 248, 361, 474, 613, 710
L130559	France (North)	-1, 0, 7, 14, 30, 62, 91, 120, 175, 238, 366, 471, 591, 720
L130560	Italy	-1, 0, 7, 13, 29, 56, 90, 120, 183, 285, 351, 475, 600, (712 [a]), 714 [a]
L130561	Spain	-1, 0, 6, 13, 29, 58, 92, 127, 183, 230, 353, 478, 591, 713

[a] Untreated soil samples (Sampling No. 16) were collected at 712 DAT, and the treated soil samples (Sampling No. 17) were collected at 714 DAT.

Untreated soil specimens were collected from the control plot on three occasions, between one and three days before application down to a depth of 50 cm, and after about one year and again after about two years to a depth of 10 cm. The specimens were taken randomly from the untreated plot each time and pooled according to soil depth. The 15 cores collected at the first sampling interval were taken using a common soil probe equipped with a plastic liner of 4.4 to 5.0 cm diameter. As an exception in trial L130560 (Italy), soil cores taken from 30-50 cm depth were done with plastic liner of diameter 2.5 cm. The 10 cores taken after about one and two years were collected with a metal tube of minimum 7.2 and maximum 9.8 cm diameter.

Treated soil specimens were taken randomly from eight points of each of the three treated subplots A – C and pooled according to subplot and depth. All soil specimens from 0-10 cm depth collected from the treated plots were taken separately using a metal tube of minimum 7.2 and to maximum 9.8 cm diameter which left a hole contained by a guard collar. Alternatively, samples were taken by pressing the metal tube described above into the ground and collecting the soil with a spoon or similar device. Soil specimens deeper than 10 cm were collected through the centre of the excavation hole contained by the guard collar, using a common soil corer fitted with a plastic liner of diameter 4.4 to 5.0 cm. Sampling of these cores was conducted in one run or in up to two consecutive steps. As an exception in trial L130560 (Italy), soil cores taken from 30-50 cm depth at all sampling events were done with plastic liner of diameter 2.5 cm.

All main soil cores collected with the soil probe were sectioned into 10 cm segments and pooled by depth. The segmentation was done before freezing or in frozen stage. If soil cores were segmented in frozen stage, the specimens did not defrost during the segmentation process.

In addition to the main sampling described above, a second complete sampling (double sampling) was carried out. The reserve samples were not sectioned into 10 cm segments but directly put into freezers at the field test sites.

All soil specimens intended for residue analysis were stored at about -18°C within a maximum of 5.75 h after sampling and remained frozen through storage, shipment, and processing until final analysis except for short term temperature rise in trial L130559, where temperature raised to -12°C for 15 hours. Since samples were always deep-frozen, any negative impact can be excluded.

Shipment verification specimens were prepared to demonstrate stability of the residues in soil during storage and through any shipment processes. The samples were prepared at three occasions by fortification of soil with 0.1 mg kg^{-1} BAS 750 F and were subsequently handled in the same manner as the actual residue samples. The analytical results demonstrated no significant losses from the shipment verification samples. The recovery of BAS 750 F was in the range of 80 - 99% (mean of each trial and fortification level).

Analytical Procedure

Field soil specimens, were analysed for BAS 750 F, M750F003, and 1,2,4-triazole (M750F001) according to the analytical method L0214/01 validated in a separate study [see *KCA 4.1.2/1 2015/1039006]* provided by BASF. Petri dish and shipment verification specimens were analysed for BAS 750 F according to the same method with minor adaptations to account for the larger quantity of soil to be extracted (the amounts of soil and extraction solutions were increased proportionally for the larger quantity of soil to be extracted).

The soil samples (5g) were extracted twice with an acetronitrile: water solution (70:30, v:v, 40mL) by mechanical shaking. The samples were centrifuged, and combined aliquots of the supernatant were analysed for BAS 750 F and M750F003 using LC-MS/Ms. For analysis of 1,2,4-Triazole, an aliquot of the supernatant was concentrated by a factor of 5, by evaporation under nitrogen at approximately 40°C, prior to analysis by LC-MS/MS.

For the analyses of larger samples (application verification and shipping verification samples) the entire sample was taken for analysis and the volume of extraction solution increased proportionally to maintain the soil: extract solution ratio.

The limit of quantification (LOQ) was 0.002 mg kg^{-1} for each individual analyte. The limit of detection (LOD) was set at 0.0004 mg kg^{-1} (20% of LOQ).

Analysis of field soil specimens originating from the treated plots was conducted down to a depth until at least one soil layer was free of detectable residues (< LOD of 0.0004 mg kg^{-1}). Analysis was performed up to a maximum of 720 DAT.

A number of changes were made to method L0214/01 to adapt it the available equipment in the analytical laboratory. These changes are considered minor and are as follows:

1. The preparation of the analytical standards is slightly different to those presented in the supplied method, but the same final concentrations are achieved.
2. Equivalent laboratory equipment (flasks, tubes, vials) were used, as available.
3. Equivalent laboratory shakers were used, with slightly different speed setting to those used in the supplied method (set at 200 rpm)
4. Different LC-MS conditions were used

The validity of the analytical method wasdemonstrated within the present study by analysis of untreated control and fortified samples within each analytical sample set.

4. Storage stability experiments

Storage stability of BAS 750 F and its metabolite M750F003 in frozen soil was investigated in a separate study *[see KCA 7.1.2.2.1/6 2015/1050221]* which is on-going. The storage stability of 1,2,4-triazole (M750F001) was

investigated in a report supporting another triazole containing a.s. in representative field sites [*see KCA 7.1.2.2.1/8 2015/1204922*]. The storage stability of M750F003 was initiated in support of this field study before the final results from the Aerobic Soil Metabolism were collected. Once the results of the metabolism study were seen in their final form, it was realized that M750F003 never reached the official trigger values to initiate a storage stability study (never observed > 2.2% TAR).

RESULTS AND DISCUSSION

Spray broth concentration and application verification

Analysed concentrations of BAS 750 F averaged for the individual trial sites were in the range of 479.6 to 512.2 mg L^{-1} corresponding to 92 - 98% of the target concentration of 523.5 mg L^{-1}. The analytical results confirm the integrity of the test item used in the trials.

Application verification was conducted by means of petri dishes filled with fine untreated soil from the trial site. As a result, the obtained application rates for the individual trials (overall mean) ranged from 134 to 167 g a.s. ha^{-1} representing 90 - 112% of the target application rate. The applied amount determined via the application monitors in these trials is in agreement with the nominal value of 150 g ha^{-1}, and the results from spray broth analysis.

Shipment verification specimens

Shipment verification specimens were prepared to demonstrate stability of the residues in soil during storage and through any shipping process. The samples were prepared at nominal 0, 30 and 90 DAT by fortification of soil aliquots with 0.1 mg kg^{-1} BAS 750 F and were subsequently handled in the same manner as the actual residue samples. Concentrations of BAS 750 F analysed were corrected for the mean recovery of the respective analytical set. The analysed concentrations averaged across the individual trial sites were in the range of 0.123 to 0.136 mg kg^{-1} corresponding to 123 to 136% of the target concentration of 0.100 mg kg^{-1}.

Table 8.1.1.4.1-10 : Shipment verification concentrations

Trial	Country	Actual sampling time (DAT)	BAS 750 F analysed (mg/kg)*	BAS 750 F (% of nominal)
L130556	Bogense, Denmark	**0**	**0.120**	**120**
		29	**0.116**	**116**
		92	**0.140**	**140**
		Average (n=9)	**0.125**	**125**
L130557	Lentzke, Germany (East)	**0**	**0.106**	**106**
		33	**0.128**	**127**
		85	**0.135**	**135**
		Average (n=9)	**0.123**	**123**
L130558	Goch-Nierswalde, Germany (West)	**0**	**0.124**	**124**
		27	**0.139**	**139**
		95	**0.144**	**144**
		Average (n=9)	**0.136**	**136**
L130559	Stotzheim, France (North)	**0**	**0.134**	**134**
		30	**0.134**	**134**
		91	**0.137**	**137**
		Average (n=9)	**0.135**	**135**
L130560	Poggio Renatico, Italy	**0**	**0.155**	**155**
		29	**0.125**	**125**
		90	**0.126**	**126**
		Average (n=9)	**0.135**	**135**
L130561	Utrera, Spain	**0**	**0.123**	**123**
		29	**0.131**	**131**
		92	**0.133**	**133**
		Average (n=9)	**0.129**	**129**

* mean of 3 values; corrected for the mean recovery of the respective analytical set

The analytical results demonstrated no losses from the shipping verification samples. The average amount of BAS 750 F from the spiked field samples was 130% (recovery corrected) across all trials. It is concluded that BAS 750 F is stable in all soils under the storage and shipping conditions used.

Time of storage

The predominant part of the samples was analysed within less than 11 months. Some individual samples typically foreseen for re-analysis or double sample analysis were stored for a longer time period prior to analysis. The maximum period any soil sample from the present field soil dissipation study was stored from the time of sampling to extraction was 646 days. To confirm residue stability over the maximal storage period, a storage stability study was set up and it is still running [*see KCA 7.1.2.2.1/6 2015/1050221*]. In addition, the storage stability of metabolite 1,2,4-triazole (M750F001) was confirmed for over 2 years in a separate study [*see KCA 7.1.2.2.1/8 2015/1204922*] conducted as part of the EU renewal of BAS 555 F (metconazole).

Residues in field soil samples

Untreated soil specimens (control samples) of the respective soil depths from each trial were analyzed for residues of BAS 750 F, M750F001 (1,2,4-triazole), and M750F003.

No residues above the LOD of any analytes were detected in any of the control samples, except in trial L130557 (Eastern Germany). The soil obtained from this trial before the application showed a substantial background contamination with 1,2,4- triazole (M750F001); it should be noted that no information on fertiliser application was contained within the original study report. Residues of 1,2,4-triazole (M750F001) in these samples were detected in a range between <LOQ (1.4 µg kg^{-1}) and 12.0 µg kg^{-1} (70 to 600% LOQ, respectively). Procedural recovery values were corrected for any corresponding control amounts for this analyte in fortified soil samples from this trial.

Except the soil from trial L130557 regarding 1,2,4-triazole (M750F001), no interferences of the untreated soil material with the analytical procedures occurred. This is discussed later in this report.

Procedural recovery experiments performed with untreated field soil specimens spiked with all three analytes at concentration levels of 0.002 and 0.02 mg kg^{-1} yielded overall mean recovery rates for field soil samples of the individual trials between 90-97% (BAS 750 F), 80-90% (1,2,4-triazole (M750F001)), and 96-100% (M750F003), confirming the validity of the analytical method used in this study. Detailed results are summarized in Table 8.1.1.4.1-11.

Table 8.1.1.4.1-11 : Procedural recoveries of soil residue method

Analyte	Fortification level [mg kg^{-1}]	n [a]	Mean recovery ± RSD [a] [%]
BAS 750 F	0.002	7 - 15	85 - 93 ± 8.2 – 13.8
	0.02	11 - 20	93 - 102 ± 3.8 – 7.5
	All fortification levels	**18 - 35**	**90 - 97 ± 7.5 – 11.0**
M750F001 (1,2,4-triazole)	0.002	7 - 15	77 - 85 ± 6.4 – 13.3
	0.02	11 - 19	82 - 93 ± 12.7 – 20.2
	All fortification levels	**18 - 33**	**80 - 90 ± 11.4– 16.9**
M750F003	0.002	7 - 15	91 - 100 ± 3.5 – 8.9
	0.02	11 - 18	99 - 100 ± 2.5 – 5.6
	All fortification levels	**18 - 33**	**96 - 100 ± 3.2 – 7.2**

RSD = Relative standard deviation
[a] Range given for the six individual field trial sites.

These data demonstrate that the analytical method applied was able to determine residues of BAS 750 F and its metabolites 1,2,4-triazole (M750F001) and M750F003 in soil samples accurately down to a concentration of 0.002 mg kg^{-1} for each analyte.

Field soil specimens from the treated plots were analysed down to a depth until one soil layer was free of detectable residues (< LOD of 0.0004 mg kg^{-1}) except for soil obtained from trial L130557, as the soil showed a background contamination with 1,2,4-triazole (M750F001), hence, all available soil layers from this trial were analysed for 1,2,4-triazole (M750F001) (0-50 cm depth). Obtained residue values were related to moist soil were then converted to soil dry weight values. If samples were analysed in duplicate, the individual numbers (related to dry weight) were averaged to produce a mean for the respective soil sample. For all trials, the 0 DAT double samples of the 0-10 cm soil layer were analysed as well, in order to account for the importance of the day 0 value, and the final data were obtained by averaging the mean values of the respective main and double samples.

Residue values for BAS 750 F, 1,2,4-triazole (M750F001) and M750F003 are presented in Table 8.1.1.4.1-13 to 8.1.1.4.1-21. All residue values presented in these tables are related to the dry weight of the soil and are not corrected for procedural recoveries. Residue levels of the analytes in µg kg^{-1} dry soil were converted to residue rates in g ha^{-1} taking into account the actual dry soil density of the field samples, and were summed up for all depths between 0 and 50 cm analysed. It should be noted that Residue values < LOQ (limit of quantification) or < LOD (limit of quantification) were reported and treated as zero. The conversion was performed using the following equation:

Dry soil residue [g a.s./ha] = Depth increment [cm] * dry soil residue [mg/kg] * dry soil density [g/cm^{3*}] * 100^{**}

* Dry soil density of undisturbed soil
** Conversion factor from 10^6 mg/Kg and 10^8 cm^2/ha

BAS 750F

Analytical data shows that BAS 750 F degraded at all six European field sites. The total amount of BAS 750 F residues detected in the soil profiles decreased from an average of 122 g ha^{-1} at day 0 to an average of 30 g ha^{-1} (range 8 to 75 g ha^{-1}) after 24 months.

Considering the distribution of BAS 750 F residues in the soil profiles, residues were exclusively found in the top 0-20 cm layer of the soils. No residues above the LOQ were detected below 20 cm in any sample at any site. Altogether, it can be concluded that BAS 750 F does not show any significant tendency to move into deeper soil layers indicating low potential to leach to groundwater.

Metabolite M750F001 (1,2,4- triazole)

Metabolite M750F001 (1,2,4-triazole) was also monitored during the study. No residues of 1,2,4-triazole (M750F001) above the LOQ were detected in any sample at sites in Denmark, Germany (West), France (North), Italy and Spain, except in one sample of trial L130559 in France (North), where 0.003 mg kg^{-1} (equivalent to 3.3 g ha^{-1}) were measured in one 0-10 cm sample at 7 DAT sampling.

A different picture was seen at the trial in Germany (East), where residues of 1,2,4-triazole (M750F001) were detected in significant amounts in all replicates, all soil depths and all time points. These findings, however, are considered the result of a substantial background contamination of the trial site with 1,2,4-triazole (M750F001), as high amounts of 1,2,4-triazole (M750F001) were also detected in the untreated control samples (table 8.1.1.4.1-12) taken two days before the application at a depth of 0-50 cm. Therefore, the analytical results for 1,2,4-triazole (M750F001) from the trial in Germany (East) are considered meaningless and not to be useful for further exposure assessments. The observed background concentration of the soil in Germany (East) might be explained by the potential application of 1,2,4-triazole (M750F001) containing nitrogen fertilizers since no triazole containing fungicides had been applied in the past three years. The resulting kinetics for this trial did not show shorter $DegT_{50}$ values compared other trials, as such the RMS is of the opinion that this contamination has not significantly influenced the degradation of BAS 750F.

Table 8.1.1.4.1-12 : Field Soil Samples (Trial L130557- Germany (East)

Sample No.	DAT nominal	Sub plot	Soil depth (cm)	Soil moisture (%)*	1,2,4- triazole (µg/Kg dry soil)
L1305570001	-3/-1	Control	0-10	9.76	< LOQ (1.4)
L1305570002	-3/-1	Control	10-20	10.16	2.4
L1305570003	-3/-1	Control	20-30	10.68	12.0
L1305570004	-3/-1	Control	30-40	9.64	8.4
L1305570005	-3/-1	Control	40-50	10.20	< LOQ (1.6)
L1305570006	360 (±10)	Control	0-10	9.32	< LOQ (1.5)
L1305570007	720 (± 10)	Control	0-10	n.c.	< LOD

*related to wet weight
n.c. = not calculated (no residues detected for correction)
Soil moisture and analytical data are mean values in case of multiple measurements

Metabolite M750F003

Metabolite M750F003 was also monitored during the study. No residues of M750F003 above the LOQ were detected in any sample.

Conclusion

BAS 750 F residues degraded under field conditions in soil at all six European field sites; $DegT_{50}$ values are presented below as part of study report CA 7.1.2.2.1/4.

Quantifiable residues of BAS 750 F residues were detected only in the first 20 cm of the soils. No residues above the LOQ were detected below 20 cm in any sample at any site. Altogether, it can be concluded that BAS 750 F does not show any significant tendency to move into deeper soil layers indicating low potential to leach to groundwater.

Table 8.1.1.4.1-13 : Total residue of BAS 750 F under field conditions in soil calculated to g/ha and summed up for all depths analysed

Trial Country	L130556 Bogense, Denmark			L130557 Lentzke, Germany (East)			
DAT	Subplot A [g ha^{-1}]	Subplot B [g ha^{-1}]	Subplot C [g ha^{-1}]	DAT	Subplot A [g ha^{-1}]	Subplot B [g ha^{-1}]	Subplot C [g ha^{-1}]
0	109	123	91	**0**	140	101	121
6	136	135	100	**6**	118	138	137
13	161	98	107	**14**	126	113	105
29	117	125	124	**33**	118	98	105
61	94	56	92	**56**	119	120	85
92	90	89	80	**85**	113	87	75
124 [a]	69	69	74	**118** [a]	102	107	70
174	68	65	73	**176**	92	80	86
245	53	59	39	**272**	84	87	85
363 [a]	42	21	42	**355** [a]	42	42	33
487	16	14	8.7	**476**	45	43	37
615	17	18	7.8	**590**	33	57	54
713	10	7.5	5.4	**715**	42	36	25
Trial Country	**L130558 Goch-Nierswalde, Germany (West)**			**L130559 Stotzheim, France (North)**			
DAT	**Subplot A [g ha^{-1}]**	**Subplot B [g ha^{-1}]**	**Subplot C [g ha^{-1}]**	**DAT**	**Subplot A [g ha^{-1}]**	**Subplot B [g ha^{-1}]**	**Subplot C [g ha^{-1}]**
0	97	140	125	**0**	127	136	135
7	165	154	92	**7**	130	112	103
13	108	133	122	**14**	126	116	125
27	146	77	23	**30**	119	110	113
59	132	107	121	**62**	122	71	85
95	132	94	78	**91**	75	57	75
125 [a]	89	84	101	**120** [a]	61	69	60
185	106	112	63	**175**	67	59	61
248	106	104	68	**238**	61	51	58
361 [a]	37	33	24	**366** [a]	53	55	52
474	22	18	14	**471**	23	21	31
613	14	5.3	30	**591**	26	20	12
710	31	23	29	**720**	15	12	21
Trial Country	**L130560 Poggio Renatico, Italy**			**L130561 Utrera, Spain**			
DAT	**Subplot A [g ha^{-1}]**	**Subplot B [g ha^{-1}]**	**Subplot C [g ha^{-1}]**	**DAT**	**Subplot A [g ha^{-1}]**	**Subplot B [g ha^{-1}]**	**Subplot C [g ha^{-1}]**
0	112	130	107	0	141	123	133
7	124	139	149	6	116	110	126
13	108	111	96	13	120	90	112
29	118	119	127	29	101	96	96
56	126	117	99	58	69	73	95
90	111	104	92	92	94	106	84
120 [a]	87	96	102	127 [a]	78	73	72
183	95	106	90	183	78	64	54
285	131	118	111	230	72	73	52
351 [a]	94	83	63	353 [a]	46	50	59
475	70	78	68	478	40	47	40
600	82	58	63	591	20	24	21
714	63	80	80	713	21	22	18

DAT = Days after treatment
Residue values < LOQ (limit of quantification) or < LOD (limit of quantification) were reported and treated as zero.
[a] Samples analysed in duplicate.

Table 8.1.1.4.1-14 : Total residue of 1,2,4-triazole (M750F001) under field conditions in soil calculated to µg/kg and summed up for all depths analysed

Trial Country	L130556 Bogense, Denmark			L130557 Lentzke, Germany (East)			
DAT	Subplot A [µg kg^{-1}]	Subplot B [µg kg^{-1}]	Subplot C [µg kg^{-1}]	DAT	Subplot A [µg kg^{-1}]	Subplot B [µg kg^{-1}]	Subplot C [µg kg^{-1}]
0	< LOD	< LOD	< LOD	**0**	2.7	2.7	2.1
6	< LOD	< LOD	< LOD	**6**	32	37	37
13	< LOD	< LOD	< LOD	**14**	38	47	41
29	< LOD	< LOD	< LOD	**33**	38	39	26
61	< LOD	< LOD	< LOQ	**56**	31	27	29
92	< LOD	< LOD	< LOQ	**85**	19	27	21
124 [a]	< LOQ	< LOD	< LOD	**118** [a]	26	22	16
174	< LOD	< LOD	< LOQ	**176**	7.6	14	13
245	< LOD	< LOD	< LOD	**272**	6.1	3.0	2.5
363 [a]	< LOD	< LOQ	< LOD	**355** [a]	15	6.6	6.6
487	< LOD	< LOD	< LOD	**476**	< LOQ	2.2	2.1
615	< LOD	< LOD	< LOD	**590**	< LOQ	< LOQ	< LOQ
713	< LOD	< LOD	< LOD	**715**	< LOQ	< LOQ	< LOQ
Trial Country	**L130558 Goch-Nierswalde, Germany (West)**			**L130559 Stotzheim, France (North)**			
DAT	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**	**DAT**	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**
0	< LOD	< LOD	< LOD	**0**	< LOD	< LOD	< LOD
7	< LOD	< LOD	< LOD	**7**	< LOQ	3.1 [b]	< LOQ
13	< LOD	< LOD	< LOD	**14**	< LOQ	< LOQ	< LOQ
27	< LOD	< LOD	< LOD	**30**	< LOQ	< LOD	< LOQ
59	< LOD	< LOD	< LOD	**62**	< LOQ	< LOD	< LOQ
95	< LOD	< LOD	< LOD	**91**	< LOD	< LOD	< LOD
125 [a]	< LOD	< LOD	< LOD	**120** [a]	< LOD	< LOD	< LOD
185	< LOD	< LOD	< LOD	**175**	< LOD	< LOD	< LOD
248	< LOD	< LOD	< LOD	**238**	< LOD	< LOD	< LOD
361 [a]	< LOD	< LOD	< LOD	**366** [a]	< LOD	< LOD	< LOD
474	< LOD	< LOD	< LOD	**471**	< LOD	< LOD	< LOD
613	< LOD	< LOD	< LOD	**591**	< LOD	< LOD	< LOD
710	< LOQ	< LOD	< LOD	**720**	< LOD	< LOD	< LOD
Trial Country	**L130560 Poggio Renatico, Italy**			**L130561 Utrera, Spain**			
DAT	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**	**DAT**	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**
0	< LOQ	< LOQ	< LOQ	0	< LOD	< LOD	< LOD
7	< LOQ	< LOQ	< LOD	6	< LOD	< LOD	< LOD
13	< LOQ	< LOQ	< LOQ	13	< LOD	< LOD	< LOD
29	< LOQ	< LOQ	< LOQ	29	< LOQ	< LOQ	< LOD
56	< LOQ	< LOD	< LOQ	58	< LOD	< LOD	< LOD
90	< LOQ	< LOQ	< LOQ	92	< LOD	< LOD	< LOD
120 [a]	< LOQ	< LOQ	< LOQ	127 [a]	< LOD	< LOD	< LOD
183	< LOQ	< LOQ	< LOQ	183	< LOD	< LOD	< LOD
285	< LOQ	< LOD	< LOD	230	< LOD	< LOD	< LOD
351 [a]	< LOQ	< LOQ	< LOQ	353 [a]	< LOD	< LOD	< LOD
475	< LOD	< LOD	< LOD	478	< LOD	< LOD	< LOD
600	< LOD	< LOD	< LOD	591	< LOD	< LOD	< LOD
714	< LOD	< LOD	< LOD	713	< LOD	< LOD	< LOD

DAT = Days after treatment

LOQ (limit of quantification): 2 µg kg^{-1}; LOD (limit of detection): 0.4 µg kg^{-1}

[a] Samples analyzed in duplicate.

[b] Converting this value to g ha^{-1} = 3.3 g ha^{-1} (based on actual dry soil density)

Table 8.1.1.4.1-15 : Total residue of M750F003 under field conditions in soil calculated to µg/kg and summed up for all depths analysed

Trial Country	L130556 Bogense, Denmark			L130557 Lentzke, Germany (East)			
DAT	Subplot A [µg kg^{-1}]	Subplot B [µg kg^{-1}]	Subplot C [µg kg^{-1}]	DAT	Subplot A [µg kg^{-1}]	Subplot B [µg kg^{-1}]	Subplot C [µg kg^{-1}]
0	< LOD	< LOD	< LOD	**0**	< LOD	< LOD	< LOD
6	< LOQ	< LOQ	< LOQ	**6**	< LOD	< LOD	< LOD
13	< LOQ	< LOQ	< LOQ	**14**	< LOD	< LOD	< LOD
29	< LOQ	< LOQ	< LOQ	**33**	< LOD	< LOD	< LOD
61	< LOQ	< LOQ	< LOQ	**56**	< LOD	< LOD	< LOD
92	< LOD	< LOQ	< LOD	**85**	< LOD	< LOD	< LOD
124 [a]	< LOQ	< LOQ	< LOQ	**118** [a]	< LOD	< LOD	< LOD
174	< LOQ	< LOQ	< LOQ	**176**	< LOD	< LOD	< LOD
245	< LOQ	< LOD	< LOQ	**272**	< LOD	< LOD	< LOD
363 [a]	< LOD	< LOD	< LOD	**355** [a]	< LOD	< LOD	< LOD
487	< LOD	< LOD	< LOD	**476**	< LOD	< LOD	< LOD
615	< LOD	< LOD	< LOD	**590**	< LOD	< LOD	< LOD
713	< LOD	< LOD	< LOD	**715**	< LOD	< LOD	< LOD
Trial Country	**L130558 Goch-Nierswalde, Germany (West)**			**L130559 Stotzheim, France (North)**			
DAT	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**	**DAT**	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**
0	< LOD	< LOD	< LOD	**0**	< LOD	< LOD	< LOD
7	< LOD	< LOD	< LOD	**7**	< LOD	< LOD	< LOD
13	< LOD	< LOD	< LOD	**14**	< LOD	< LOD	< LOD
27	< LOD	< LOD	< LOD	**30**	< LOD	< LOD	< LOD
59	< LOQ	< LOD	< LOD	**62**	< LOD	< LOD	< LOD
95	< LOQ	< LOD	< LOD	**91**	< LOD	< LOD	< LOD
125 [a]	< LOQ	< LOD	< LOQ	**120** [a]	< LOD	< LOD	< LOD
185	< LOQ	< LOQ	< LOD	**175**	< LOD	< LOD	< LOD
248	< LOQ	< LOQ	< LOD	**238**	< LOD	< LOD	< LOD
361 [a]	< LOQ	< LOD	< LOD	**366** [a]	< LOD	< LOD	< LOD
474	< LOQ	< LOD	< LOD	**471**	< LOD	< LOD	< LOD
613	< LOD	< LOD	< LOQ	**591**	< LOD	< LOD	< LOD
710	< LOQ	< LOQ	< LOQ	**720**	< LOD	< LOD	< LOD
Trial Country	**L130560 Poggio Renatico, Italy**			**L130561 Utrera, Spain**			
DAT	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**	**DAT**	**Subplot A [µg kg^{-1}]**	**Subplot B [µg kg^{-1}]**	**Subplot C [µg kg^{-1}]**
0	< LOD	< LOD	< LOD	0	< LOQ	< LOQ	< LOQ
7	< LOQ	< LOD	< LOQ	6	< LOQ	< LOQ	< LOQ
13	< LOQ	< LOD	< LOD	13	< LOQ	< LOQ	< LOQ
29	< LOD	< LOD	< LOD	29	< LOQ	< LOQ	< LOQ
56	< LOQ	< LOD	< LOQ	58	< LOD	< LOQ	< LOQ
90	< LOQ	< LOD	< LOQ	92	< LOQ	< LOQ	< LOD
120 [a]	< LOD	< LOD	< LOD	127 [a]	< LOQ	< LOQ	< LOD
183	< LOD	< LOD	< LOQ	183	< LOD	< LOD	< LOD
285	< LOD	< LOD	< LOQ	230	< LOD	< LOD	< LOD
351 [a]	< LOD	< LOD	< LOD	353 [a]	< LOD	< LOD	< LOD
475	< LOD	< LOD	< LOD	478	< LOD	< LOD	< LOD
600	< LOD	< LOD	< LOD	591	< LOD	< LOD	< LOD
714	< LOQ	< LOD	< LOD	713	< LOD	< LOD	< LOD

DAT = Days after treatment
LOQ (limit of quantification): 2 µg kg^{-1}; LOD (limit of detection): 0.4 µg kg^{-1}
[a] Samples analyzed in duplicate.

Table 8.1.1.4.1-16 : BAS 750 F residues in treated soil specimens of trial L130556 (Bogense, Denmark) measured in µg/kg (replicate A, B, C)

Sampling No	3	4	5	6	7	8	9	10	11	13	14	15	17
DAT	0	6	13	29	61	92	124**	174	245	363**	487	615	713
Replicate A (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	88*	118#	143#	92#	85	81	50	47	37	30	13	11	8.4
10-20	-	<LOQ	2.1	2.8	<LOQ	<LOQ	3.3	<LOD	<LOD	<LOQ	<LOQ	<LOQ	<LOQ
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	<LOD	--	--	<LOD	--	--		--	--	--
40-50	-	--	--	--	--	--	--	--	--		--	--	--
Replicate B (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	102*	122	81	99	48	70	56	46	43	19	10	13	5.9
20-30	-	<LOQ	<LOQ	<LOQ	<LOQ	2.5	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOD	<LOD
30-40	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	--	--	--	--	--	<LOD	--	--	--	--	--	--	--
40-50		--	--	--	--	--	--	--	--	--	--	--	--
Replicate C (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	79*	93#	96#	99#	77	57	55	57	29	33	6.1	5.2	3.8
10-20	-	<LOQ	<LOQ	<LOQ	<LOQ	2.7	2.1	<LOQ	<LOQ	<LOQ	<LOQ	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	>LOD	<LOQ	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	<LOD	<LOD	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--

- No sample taken
-- sample not analysed
*mean value of double determinations of each, mean and double samples (in total from 4 values)
mean of duplicate analysis and single double sample analysis (in total from 3 values)
** 124 and 363 DAT samples were all analysed in duplicate
LOQ= 0.002 mg/Kg = 2ug/Kg
LOD= 0.0004mg/Kg= 0.4ug/kg
DAT days after treatment

Table 8.1.1.4.1-17: BAS 750 F residues in treated soil specimens of trial L139557 (Lentzke, Germany-East) measured in µg/kg (replicate A, B, C)

Sampling No	3	4	5	6	7	8	9	10	11	13	14	15	17
DAT	0	6	14	33	56	85	118**	176	272	355**	476	590	715
Replicate A (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	107*	80	80#	77	74	76#	66	62	56	28	28	22	26
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--
Replicate B (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	69*	94	69	69	81	58	68	53	58	26	27	39##	24
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50-	-	--	--	--	--	--	--	--	--	--	--	--	--
Replicate C (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	85*	87	63	67	56	51	44	58	53	22	24	36	16
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40 -50	-	--	--	--	--	--	--	--	--	--	--	--	--

- no sample taken
-- sample not analysed
* mean value of double determinations of each, mean and double samples (in total from 4 values)
# Mean of duplicate analysis and single double sample analysis (in total from 3 values)
mean of single analysis of main and double samples (in total from 2 values)
LOQ= 0.002 mg/Kg = 2ug/Kg
LOD= 0.0004mg/Kg= 0.4ug/kg
DAT days after treatment

Table 8.1.1.4.1-18 : BAS 750 F residues in treated soil specimens of trial L139558 (Goch-Nierswalde, Germany-West) measured in µg/kg (replicate A, B, C)

Sampling No	3	4	5	6	7	8	9	10	11	13	14	15	17
DAT	0	7	13	27	59	95	125**	185	248	361**	474	613	710
Replicate A (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	73*	125	89	122	103	117	72	65	75	32	16	11	24##
10-20	-	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	--	--	--	--	--	--	--	--	--	--	--	--	--
Replicate B (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	106*	116	105#	66#	89	78	61	74#	75	29	12	4.5	21##
10-20	-	<LOD	<LOD	<LOD	<LOQ	<LOQ	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	--	--	--	--	--	--	--	--	--	--	--	--	--
Replicate C (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	94*	69	99	19#	96	70	85	43	45	24	9.6	24	26
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOQ	<LOD	3.4	<LOQ	<LOQ	<LOD	<LOQ
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOQ	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	<LOD	<LOD	<LOD	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--

- no sample taken
-- sample not analysed
* mean value of double determinations of each, mean and double samples (in total 4 values)
# mean of duplicate analysis and single double sample analysis (in total from3 values)
mean of single analysis of main and double sample (in totoal from 2 values)
**125 and 361 DAT samples were all analysed in duplicate
LOQ= 0.002 mg/Kg = 2ug/Kg
LOD= 0.0004mg/Kg= 0.4ug/kg
DAT days after treatment

Table 8.1.1.4.1-19 : BAS 750 F residues in treated soil specimens of trial L139559 (Stotzheim, France-North) measured in µg/kg (replicate A, B, C)

Sampling No	3	4	5	6	7	8	9	10	11	13	14	15	17
DAT	0	7	14	30	62	91	120**	175	238	366**	471	591	720
Replicate A (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	105*	122	102	107	101	52	46	75	48	42	20	20	16
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOQ	3.6	<LOQ	<LOQ	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	<LOD	<LOD	--	--	--	--
40-50		--	--	--	--	--	--	--	--	--	--	--	--
Replicate B (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	117*	106	90	108	62	42	56	60	36	50	18	16	14
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	2.1	<LOQ	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	<LOD	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--
Replicate C (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	112*	96	92	91	64	48	51	52	44	52	25	9.8	20
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--

- No sample taken
-- sample not analysed
* mean value of double determinations of each, mean and double samples (in total from 4 samples)
** 120 and 366 DAT samples were analysed in duplicate
LOQ= 0.002 mg/Kg = 2ug/Kg
LOD= 0.0004mg/Kg= 0.4ug/kg
DAT days after treatment

Table 8.1.1.4.1-20 : BAS 750 F residues in treated soil specimens of trial L139560 (Poggio Renatico, Italy) measured in µg/kg (replicate A, B, C)

Sampling No	3	4	5	6	7	8	9	10	11	13	14	15	17
DAT	0	7	13	29	56	90	120**	183	285	351**	475	600	714
Replicate A (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	94*	113#	83#	103#	104#	106#	75#	105#	133#	60#	56#	87	46
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOD	8.0
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--
Replicate B (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	106*	122#	87#	102#	95#	90#	82#	119#	114#	67	79	74	71
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOQ
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	<LOD	--	--	--	--	--	--
40-50	-	--	--	--	--	--	<LOD	--	--	--	--	--	--
Replicate C (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	88*	120	75	106	77	80	86	102	108#	44	69	64	69
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOQ	<LOD	<LOD	<LOD	<LOQ
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	<LOD	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--

- No sample taken
-- sample not analysed
*mean of double determinations of each, mean and double samples (in total from 4 values)n value
mean of single analysis of main and double sample (in total from 2 values)
** 120 and 351 DAT samples were analysed in duplicates
LOQ= 0.002 mg/Kg = 2ug/Kg
LOD= 0.0004mg/Kg= 0.4ug/kg
DAT days after treatment

Table 8.1.1.4.1-21 : BAS 750 F residues in treated soil specimens of trial L139561 (, Spain) measured in µg/kg (replicate A, B, C)

Sampling No	3	4	5	6	7	8	9	10	11	13	14	15	17
DAT	0	6	13	29	58	92	127**	183	230	353**	478	581	713
Replicate A (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	96*	83	87	72	47	67	57	56	48	32	27	13	14
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--
Replicate B (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	81	74	62	66	51	72#	52	44	48#	34	30	15	15
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--
Replicate C (Residue of BAS 750 F ug/Kg)													
Depth [cm]													
0-10	89	88	78	68	67	59	52	38	34	39#	26	14	12
10-20	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
20-30	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
30-40	-	--	--	--	--	--	--	--	--	--	--	--	--
40-50	-	--	--	--	--	--	--	--	--	--	--	--	--

- No sample taken
-- sample not analysed
*mean of double determinations of each, mean and double samples (in total from 4 values)n value
mean of single analysis of main and double sample (in total from 2 values)
** 127 and 353 DAT samples were analysed in duplicate
LOQ= 0.002 mg/Kg = 2ug/Kg
LOD= 0.0004mg/Kg= 0.4ug/kg
DAT days after treatment

Report:	**KCA 7.1.2.2.1/4, Studenroth S., Pape L., 2015a** Kinetic Evaluation of a field dissipation study with BAS 750 F conducted in 2013 to 2015: Determination of best-fit and modelling endpoints according to FOCUS 2015/1249176
Guidelines:	FOCUS Degradation Kinetics (2006) SANCO/10058/2005 version1.1 of December 2013, EFSA Guidance to obtain DegT50 calues in soil (2014)
GLP	No

The kinetic evaluation was conducted for six field trials with BAS 750 F from the data of one field dissipation study, which can be found in section.8.1.1.3.1. The trials were situated in different regions of Europe (Denmark, Germany (two trials), France, Italy and Spain) considering a range of different soils and climatic conditions. Detailed soil characteristics in each trial are reported in the cited study. Applications were made to bare soil using a calibrated boom sprayer. Immediately after application and before subsequent soil sampling all plots were covered with a thin layer of sand to protect the applied product from surface processes like photolysis or volatilization, and to exclude any potential impact on the degradation of the test item caused by any of these processes. Soil samples were taken at day 0, immediately after application down to 10 cm soil depth and at 12

consecutive sampling dates after application down to a maximum soil depth of 50 cm from three individual subplots, for full details see section 8.1.1.4.1.

The field study complies with the criteria within section 9.1 of the FOCUS guidance document for estimating persistence and degradation kinetics from environmental fate studies on Pesticides in EU registration[4]; as such the data can be reliably utilised to calculate dissipation rates.

Kinetic modeling strategy

The appropriate kinetic model was identified considering the procedures and kinetic models proposed by the FOCUS workgroup on degradation kinetics [*FOCUS (2006)*]. In a first step, a kinetic evaluation was performed on the original data (non-normalised) set in order to derive best-fit field dissipation parameters for BAS 750 F (trigger endpoints). Within the original report, modelling endpoints for the non-normalised data was not considered; non-normalised degradation rates are required for PEC soil calculation. Sufficient information was presented to allow the RMS to conclude on the model choice for the determination of modelling endpoints.

In a second step, a kinetic evaluation was performed on a time-step normalized data set to derive degradation parameters that can be used as modelling endpoints.

Normalization procedure

The normalization procedure was carried out based on the recommendations of FOCUS [*FOCUS (2006)*] for all field trials by reducing or increasing day lengths depending on soil temperature and moisture by means of correction factors (f_{temp} and f_{moist}).

The daily soil temperature and moisture used for the temperature and moisture correction were estimated for each day of the study period from the respective day of application until the last sampling day.

The calculations were conducted within FOCUS-PEARL 4.4.4 using actual soil characteristics; weather data (maximum and minimum air temperature, precipitation, reference evapotranspiration) and irrigation. It should be noted that for all trials except L130557 (DE-E) and L130449 (FR), all required data was available from an on-site weather station. For these trials the actual evapotranspiration was estimated using the Penman approach.

Temperature correction factors (f_{temp}) were determined to account for differences between actual daily soil temperatures as calculated by FOCUS-PEARL 4.4.4 and a reference temperature of 20°C using a Q_{10} value of 2.58.

Moisture correction factors (f_{moist}) were determined to account for differences between actual daily moisture as calculated by FOCUS PEARL and the reference soil moisture as field capacity (pF2).

For DAT 0, no normalization was considered and application was assumed to occur at the time point zero.

Normalized sampling days after application (DAT_{norm}) were calculated by cumulatively summing up normalized day lengths.

Table 7.1.2.2.1-25 shows the field sampling dates for the trial locations and the normalized (20°C, pF2) day lengths based on soil moisture and soil temperature data as simulated by FOCUS-PEARL 4.4.4.

[4] FOCUS (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

Table 8.1.1.4.1-21 : Time-step normalised (temperature and moisture) sampling days

Bogense, Denmark (L130556)		**Lentzke, Germany (L130557)**	
DAT	**D_{norm}**	**DAT**	**D_{norm}**
0	0	0	0
6	3.3	6	3.8
13	7.3	14	10.4
29	17.0	33	26.0
61	45.7	56	50.0
92	68.3	85	78.1
124	85.2	118	97.1
174	103.2	176	117.8
245	118.0	272	137.2
363	159.5	355	171.5
487	250.6	476	272.3
615	286.9	590	308.9
713	315.0	715	342.0
Goch-Nierswalde, Germany (L130558)		**Stotzheim, France North (L130559)**	
DAT	**D_{norm}**	**DAT**	**D_{norm}**
0	0	0	0
7	5.9	7	6.9
13	9.6	14	14.7
27	19.9	30	28.7
59	51.6	62	69.1
95	78.5	91	94.0
125	92.8	120	111.4
185	113.0	175	131.5
248	129.6	238	145.5
361	180.7	366	208.4
474	267.3	471	301.6
613	310.7	591	344.6
710	343.7	720	393.1
Poggio Renatico, Italy (L130560)		**Utrera, Spain (L130561)**	
DAT	**D_{norm}**	**DAT**	**D_{norm}**
0	0	0	0
7	7.0	6	8.9
13	14.9	13	15.5
29	34.8	29	32.8
56	77.2	58	83.3
90	126.8	92	163.3
120	156.4	127	246.3
183	188.2	183	328.8
285	217.7	230	357.3
351	257.0	353	441.7
475	405.1	478	661.1
600	463.4	591	807.6
714	515.9	713	880.7

DAT = Days after treatment

Kinetic models included in the evaluations

For each data set, the kinetic models proposed by the FOCUS Kinetics guidance [*FOCUS (2006)*] were tested.

The goodness-of-fit of the kinetic models was assessed by visual inspection and statistical measures, as recommended by the FOCUS Kinetics guidance. A kinetic model was considered appropriate if the residuals were randomly distributed around zero, the χ^2 error value was ideally <15% and the estimated degradation parameters differed significantly from zero.

Data handling and software for kinetic evaluation

As surface processes had been excluded by covering the soil with sand in the field study, all data points were considered in this evaluation regardless of the 10 mm rain criterion described in the EFSA guidance document [*EFSA (2014): Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 38 pp.*].

For the evaluation, the residue data in g ha^{-1} cumulated over the whole sampling depth were taken from the study report. Values below LOQ (0.002 mg kg^{-1}) were set to 0.5 × LOQ according to FOCUS [*FOCUS (2006)*].

The software package KinGUI version 2 was used for parameter fitting. The error tolerance and the number of iterations of the optimization tool (IRLS) were set to 10^{-6} and 100, respectively. The RMS validated the modelling using the software package CAKE version 3.2 for parameter fitting where Ordinary Least Squares (OLS) was the selected optimisation tool.

Results and discussion

As an initial step, to determine the triggering endpoints, the study author ran Single First Order (SFO) and First Order Multiple Compartment (FOMC) kinetics with the non-normalised data for parent only performing a visual assessment and calculating the error percentage at which the Chi^2 test was passed, where FOMC modelling resulted in an improved fit Double First Order Parallel (DFOP) modelling was undertaken. In regards to the determination of modelling endpoints the suitability of the SFO model was determined; only where SFO was rejected were bi-phasic models investigated.

The applicants calculated values are presented below in table 8.1.1.4.1-22 to 8.1.1.4.1-24 (non- normalised) and table 8.1.1.4.1-25 (normalised) .The RMS has verified these values, fitted curves and residual plots and agrees with the applicants results. To avoid confusion, where a parameter is not relevant to the kinetic model the cells of the table have been greyed out

Non-Normalised Kinetics

Table 8.1.1.4.1-22 : Statistical and visual assessment of kinetic models for derivation of endpoints for BAS 750 F in field trial L130556 and L130557 (non-normalised data)

Trial, Country		**L130556, Bognese, Denmark**		**L130557. Lentzke, Germany (East)**	
Kinetic Model		**SFO**	**FOMC**	**SFO**	**FOMC**
Parameters	**Pini (g/ha)**	120.7	120.7	119.8	122.671
	K/K1	3.737E-03		1.977E-03	
	Alpha (error value)		1.951E+04 (1.928E+03)		1.713 (1.617)
	Beta (error value)		5.219E+06 (7.204)		645.156 (787.124)
Statistics	**χ^2 (%)**	9.2	9.6	8.9	8.8
	t-test (P value) (K/K1;K2)	<0.01		<0.01	
	Visual Fit	Good (Figure 8.1.1.3.1.1)	Good (Figure 8.1.1.3.1.2)	Good (Figure 8.1.1.3.1.3)	Good (Figure 8.1.1.3.1.4)
	$DegT_{50}$ (days)	185.5	185.5	350.6	321.9
	$DegT_{90}$ (days)	616.1	616.1	>1000[#]	>1000[#]
Modelling Endpoint conclusion		SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.		SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.	
Triggering Endpoint conclusion		The FOMC model does not improve the visual and statistical fit (compared to SFO). SFO is appropriate for derivation of triggering endpoint.		The FOMC model does not improve the visual and statistical fit (compared to SFO). SFO is appropriate for derivation of triggering endpoint.	

[#] extrapolated beyond study duration

Table 8.1.1.4.1-23 : Statistical and visual assessment of kinetic models for derivation of endpoints for BAS 750 F in field trial L130558 and L130559 (non-normalised data)

Trial, Country		**L130558 Goch-Nierswalde, Germany (West)**		**L130559 Stotzheim, France**		
Kinetic Model		**SFO**	**FOMC**	**SFO**	**FOMC**	**DFOP**
Parameters	**Pini (g/ha)**	125.5	125.5	120.0	129.549	131.5
	K/K1	2.590E-03		3.391E-03		2.027E-02
	K2					2.17E-03
	G/Tb					0.3389
	Alpha (error value)		7.039E+03 (1.218E+03)		1.0104 (0.3017)	
	Beta (error value)		2.718E+06 (3.154)		147.8750 (73.1739)	
Statistics	**χ^2 (%)**	16.2	16.8	11.4	8.9	8.4
	t-test (P value) (K/K1;K2)	<0.01		<0.01		<0.05: <0.01
	Visual Fit	Acceptable (Figure 8.1.1.3.1.5)	Acceptable (Figure 8.1.1.3.1.6)	Acceptable (Figure 8.1.1.3.1.7)	Acceptable (Figure 8.1.1.3.1.8)	Good (Figure 8.1.1.3.1.9)
	$DegT_{50}$ (days)	267.6	267.6	204.4	145.8	145.4[a]/ 262.1[b]
	$DegT_{90}$ (days)	889.1[#]	889.1[#]	679.0	>1000[#]	870.2[a#]
Modelling Endpoint conclusion		SFO visual fit is acceptable, the χ^2 is greater than 15% but this is due to the scattering of the data rather than the kinetic fitting; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.		SFO visual fit is acceptable the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.		
Triggering Endpoint conclusion		The FOMC model does not improve the visual and statistical fit (compared to SFO). SFO is appropriate for derivation of triggering endpoint.		The FOMC model improves the visual fit (compared to SFO) and provides a lower χ^2, the associated error for alpha and beta are less than the parameter estimate. Further biphasic (DFOP) modelling investigated. The DFOP model further improves the visual fit and provides a lower χ^2, all parameters are significantly different from zero. DFOP is appropriate for the derivation of triggering endpoint.		

[a] Overall Value
[b] Calculated value: Overall DegT90 / 3.32 (conducted by the RMS)
[#] extrapolated beyond study duration

Table 8.1.1.4.1-24 : Statistical and visual assessment of kinetic models for derivation of endpoints for BAS 750 F in field trial L130560 and L130561 (non-normalised data)

Trial, Country		**L130560, Poggio Renatico, Italy**		**L130561, Utrera, Spain***		
Kinetic Model		**SFO**	**FOMC**	**SFO**	**FOMC**	**DFOP**
Parameters	**Pini (g/ha)**	118.4	120.1396	132.33	132.33	132.4 (not fixed)
	K/K1	8.188E-04		3.3702E-03		9.477E-02
	K2					2.087E-03
	G/Tb					0.2401
	Alpha (error value)		0.7355 (1.1187)		0.5525 (0.1172)	
	Beta (error value)		636.1104 (1303.6029)		59.5381 (24.1128)	
Statistics	**χ^2 (%)**	9.4	9.6	14.9	10.4	6.3
	t-test (P value) (K/K1;K2)	<0.01		<0.01		<0.05: <0.01
	Visual Fit	Acceptable (Figure 8.1.1.3.1.10)	Acceptable (Figure 8.1.1.3.1.11)	Acceptable (Figure 8.1.1.3.1.12)	Acceptable (Figure 8.1.1.3.1.13)	Good (Figure 8.1.1.3.1.14)
	$DegT_{50}$ (days)	846.6[#]	996.2[#]	205.7	149.2	200.5[a]/ 292.6[b]
	$DegT_{90}$ (days)	>1000[#]	>1000[#]	683.2	>1000[#]	971.6[a#]
Modelling Endpoint conclusion		SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero.		SFO visual fit is acceptable the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.		
Triggering Endpoint conclusion		The FOMC model does not improve the visual and statistical fit (compared to SFO). SFO is appropriate for derivation of triggering endpoint.		The FOMC model improves the visual fit (compared to SFO) and provides a lower χ^2, the associated error for alpha and beta are less than the parameter estimate. Further biphasic (DFOP) modelling investigated. The DFOP model further improves the visual fit and provides a lower χ^2, all parameters are significantly different from zero. DFOP is appropriate for the derivation of triggering endpoint.		

*Initial concentration was fixed to the mean of the measured values. Initial investigation indicated parametrisation led to the initial concentration being significantly underestimated. The RMS also experiences this issue and agrees with fixing the initial concentration parameter.

[a] Overall Value

[b] Calculated value: Overall $DegT_{90}$ / 3.32 (conducted by the RMS)

[#] extrapolated beyond study duration

Figure 8.1.1.4.1-1 : Kingui fit for BAS 750 F in trial L130556 (DK), time-step (non-normalised) data sets, SFO kinetics

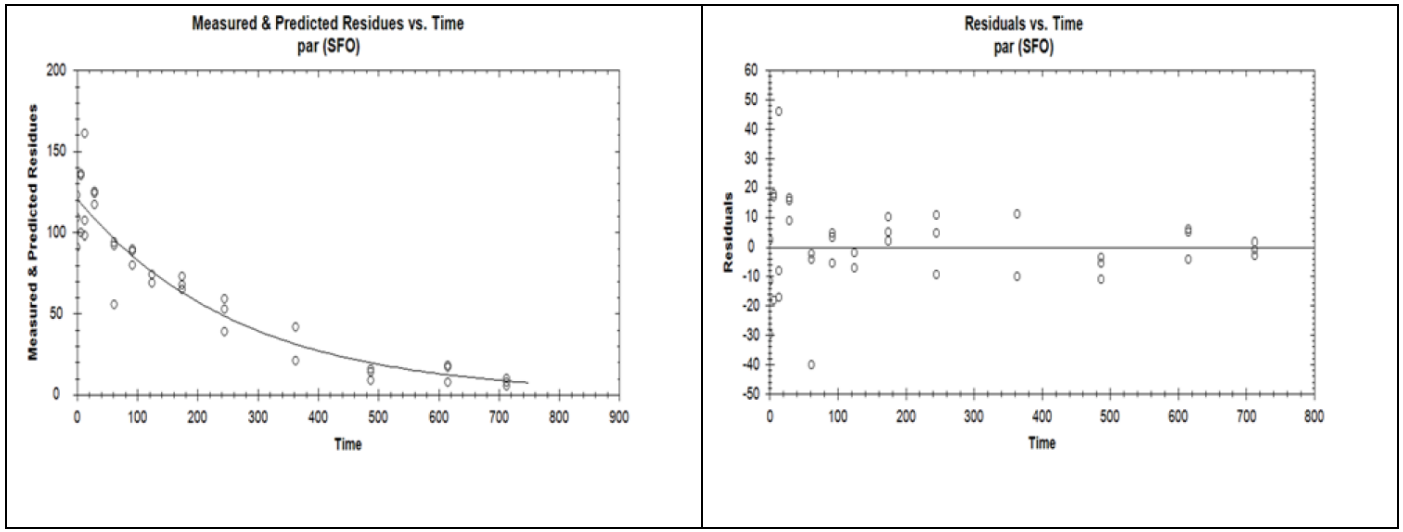


Figure 8.1.1.4.1-2: Kingui fit for BAS 750 F in trial L130556 (DK), time-step normalizes data sets, FOMC kinetics

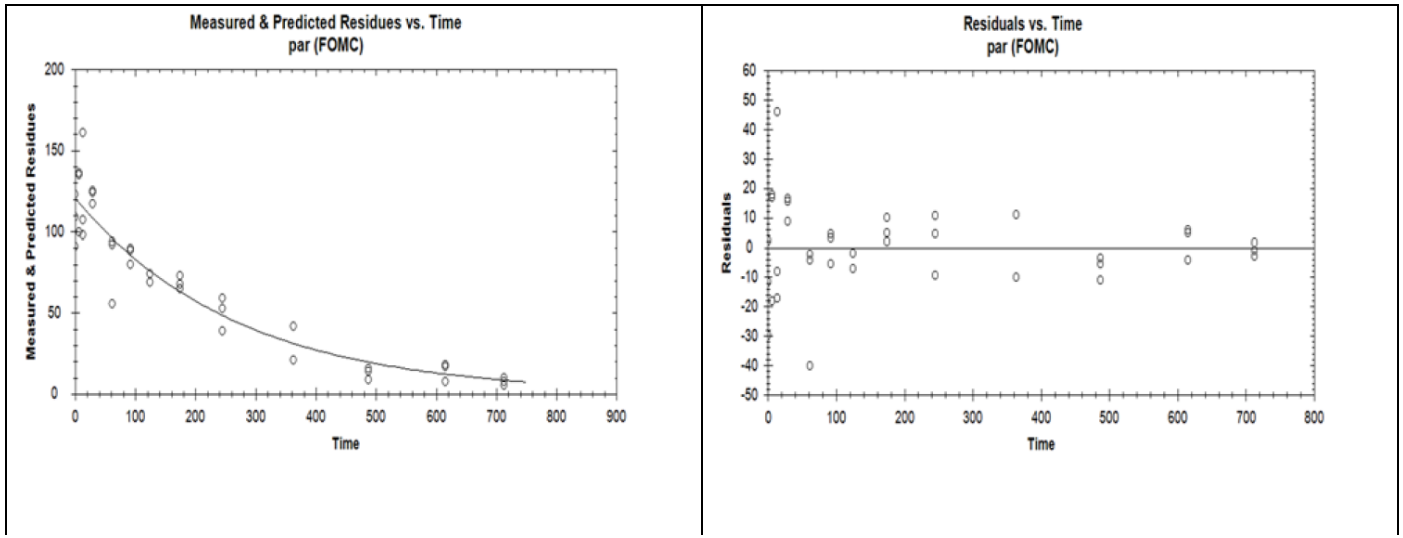


Figure 8.1.1.4.1-3: Kingui fit for BAS 750 F in trial L130557 (DE-E), time-step (non-normalised) data sets, SFO kinetics

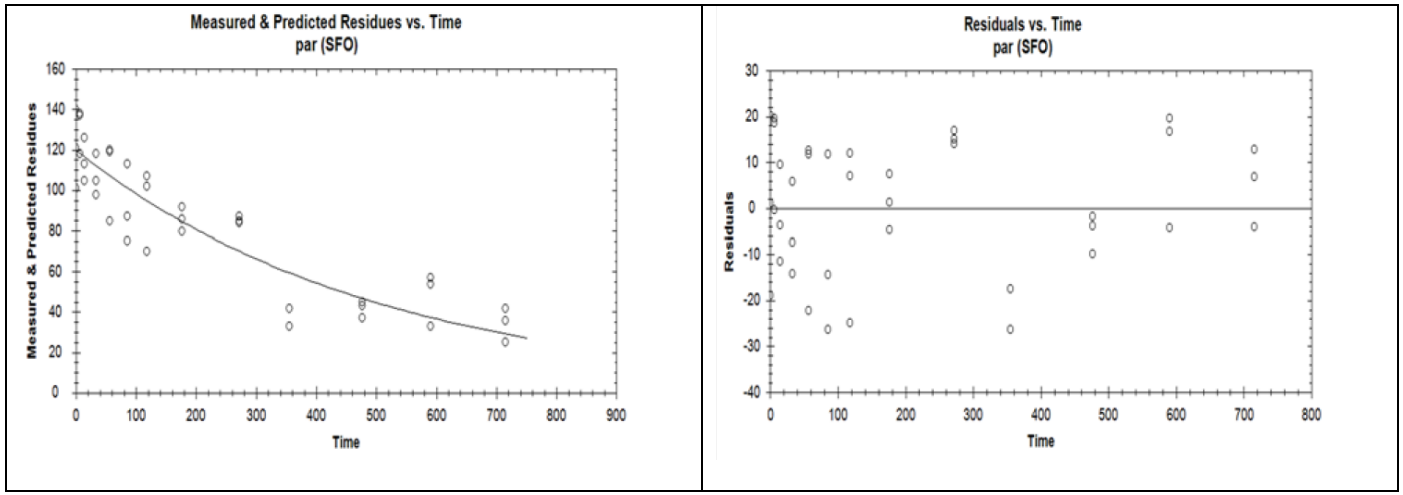


Figure 8.1.1.4.1-4: Kingui fit for BAS 750 F in trial L130557 (DE-E), time-step normalizes data sets, FOMC kinetics

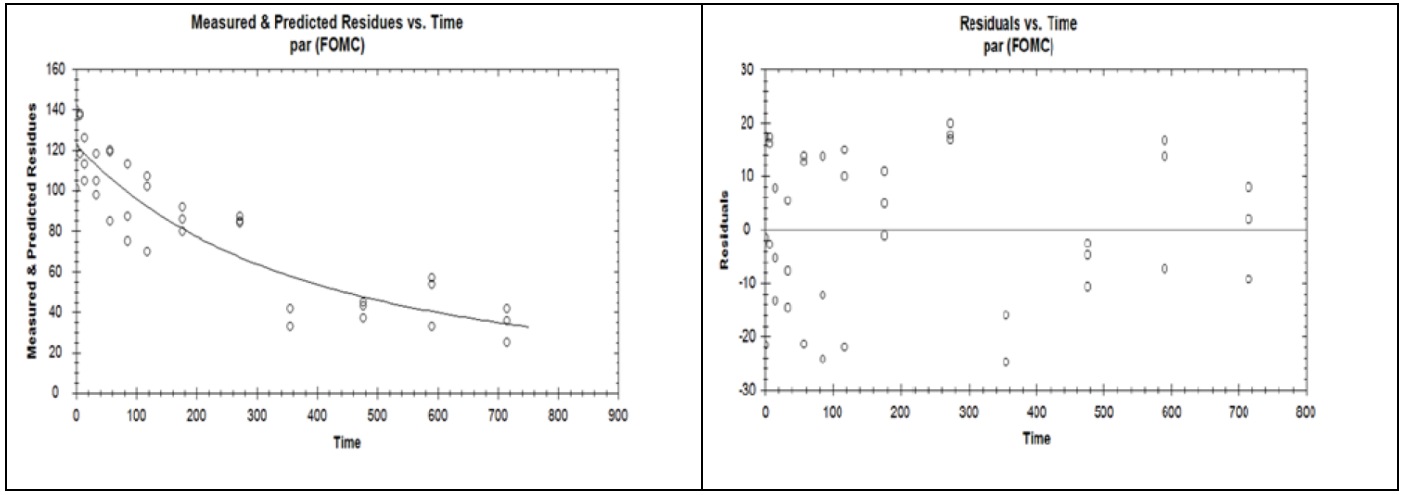


Figure 8.1.1.4.1-5: Kingui fit for BAS 750 F in trial L130558 (DE-W), time-step (non-normalised) data sets, SFO kinetics

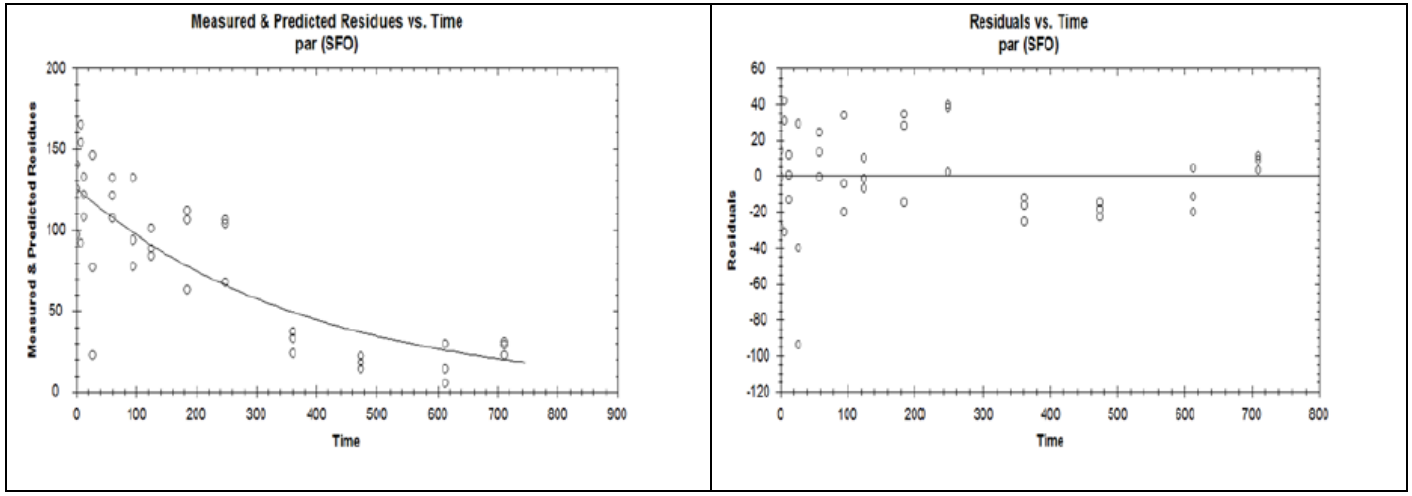


Figure 8.1.1.4.1-6: Kingui fit for BAS 750 F in trial L130558 (DE-W), time-step normalizes data sets, FOMC kinetics

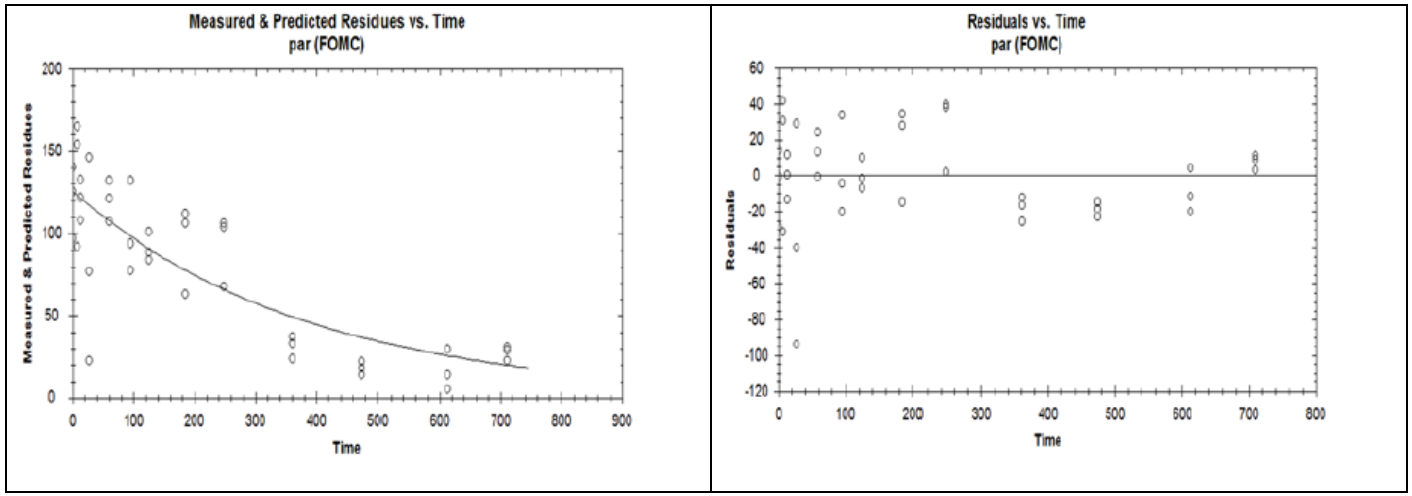


Figure 8.1.1.4.1-7: Kingui fit for BAS 750 F in trial L130559 (FR), time-step (non-normalised) data sets, SFO kinetics

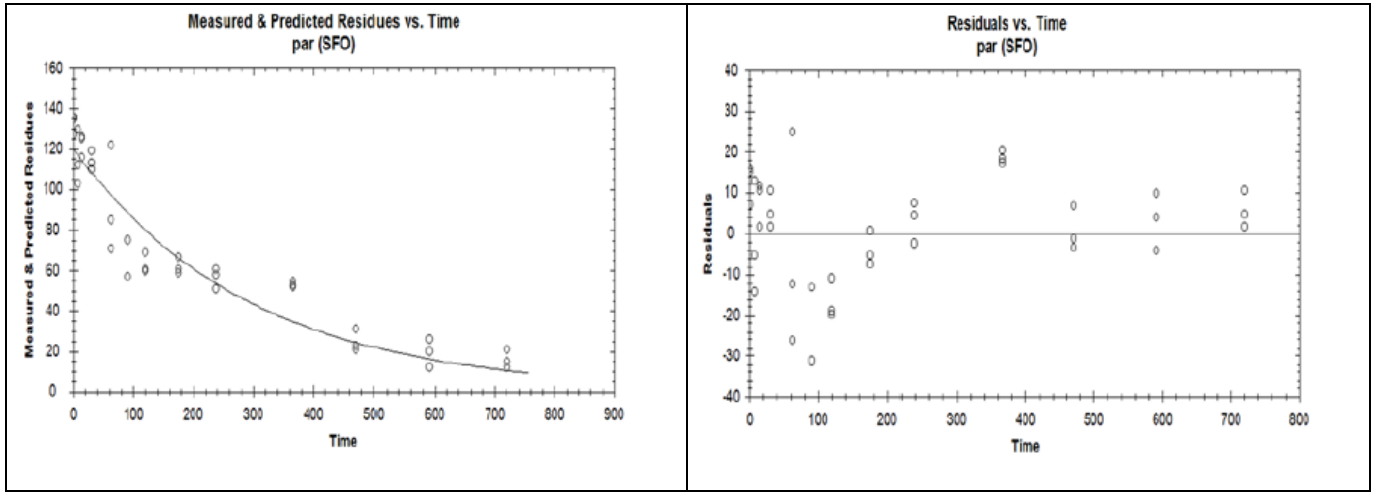


Figure 8.1.1.4.1-8: Kingui fit for BAS 750 F in trial L130559 (FR), time-step normalizes data sets, FOMC kinetics

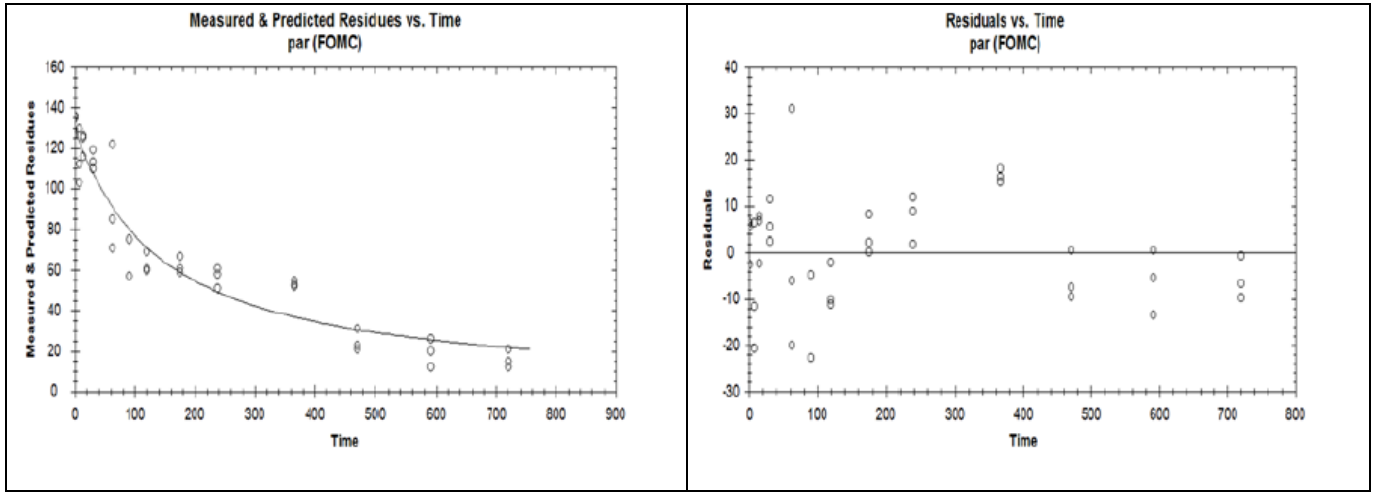


Figure 8.1.1.4.1-9: Kingui fit for BAS 750 F in trial L130559 (FR), time-step (non-normalised) data sets, DFOP kinetics

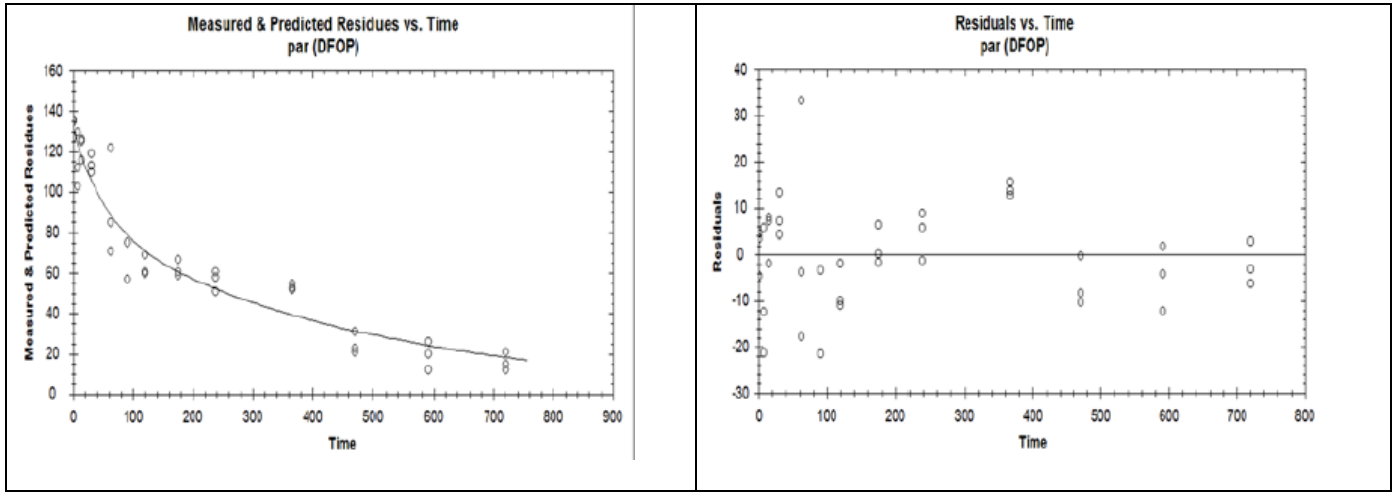


Figure 8.1.1.4.1-10: Kingui fit for BAS 750 F in trial L130560 (IT), time-step normalizes data sets, SFO kinetics

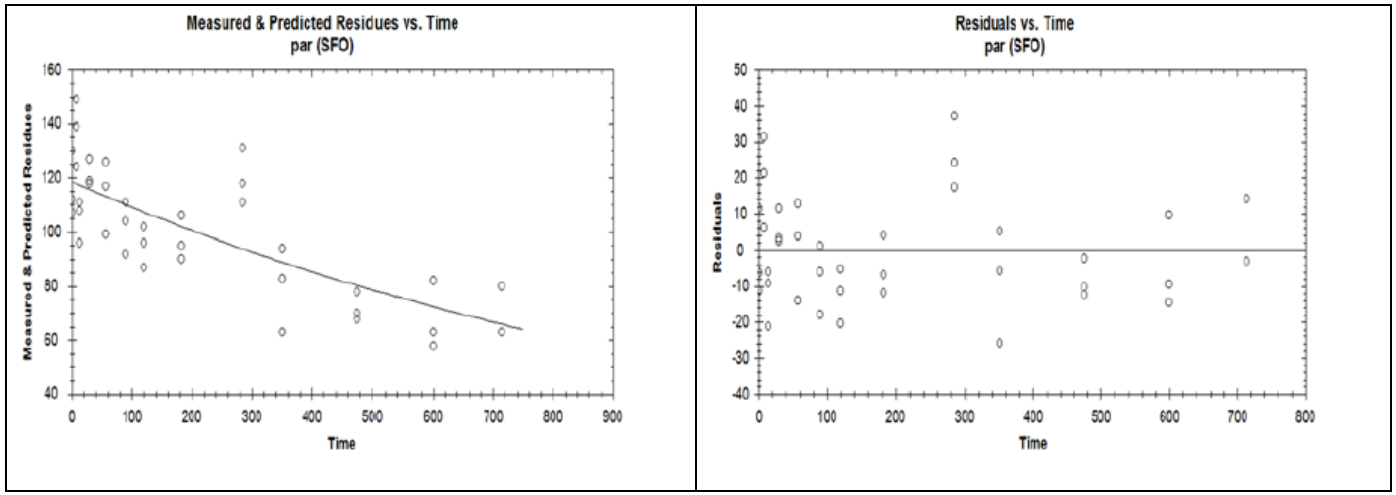


Figure 8.1.1.4.1-11: Kingui fit for BAS 750 F in trial L130560 (IT), time-step normalizes data sets, FOMC kinetics

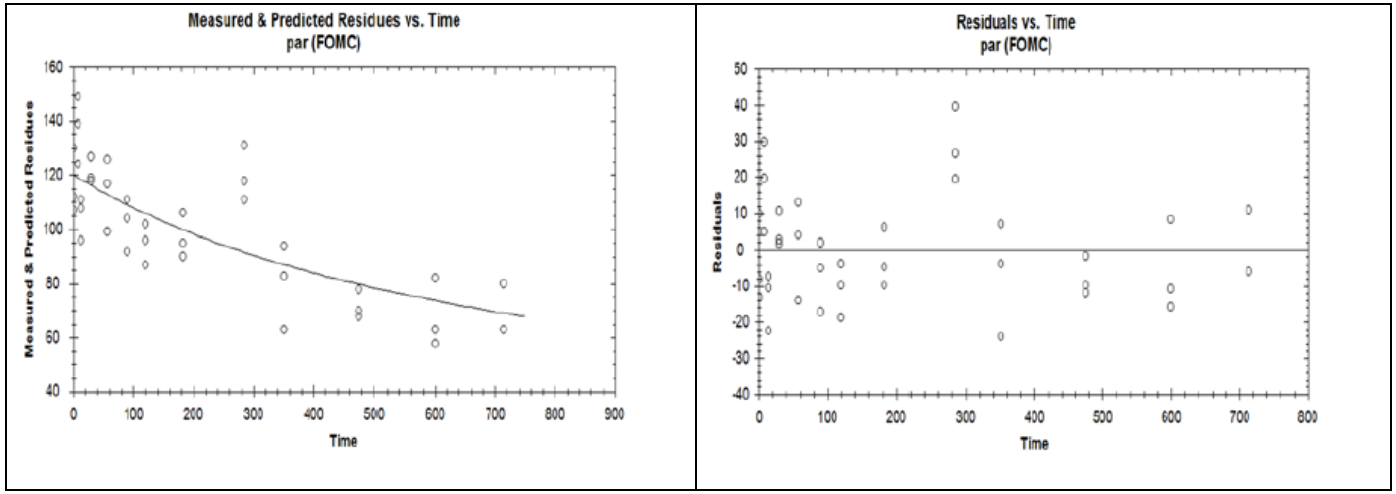


Figure 8.1.1.4.1-12: Kingui fit for BAS 750 F in trial L130561 (ES) time-step normalizes data sets, SFO kinetics

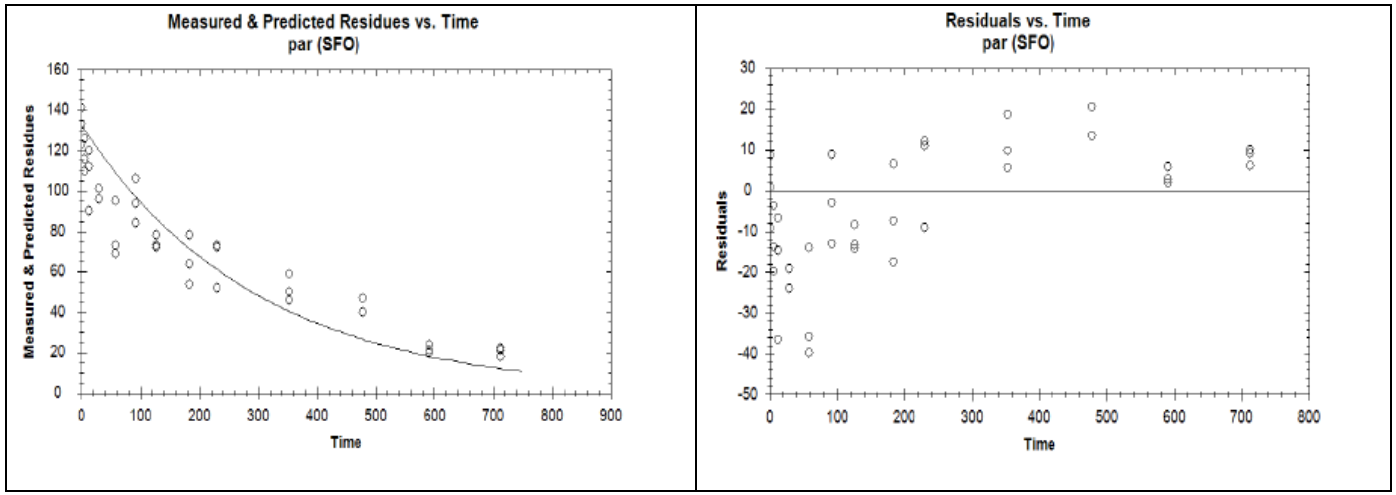


Figure 8.1.1.4.1-13: Kingui fit for BAS 750 F in trial L130561 (ES), time-step normalizes data sets, FOMC kinetics

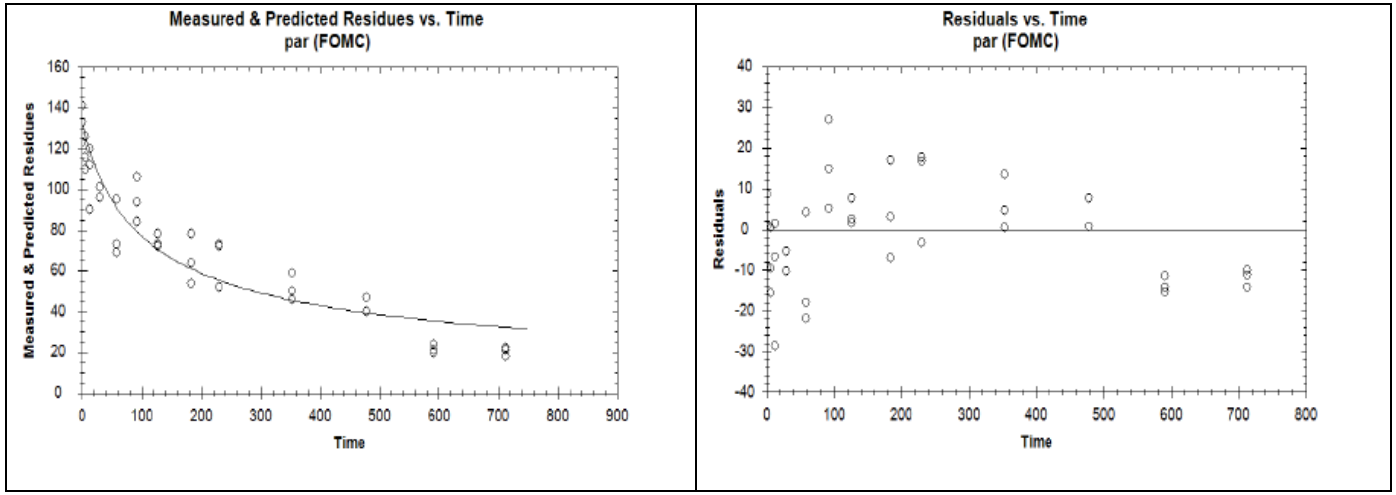
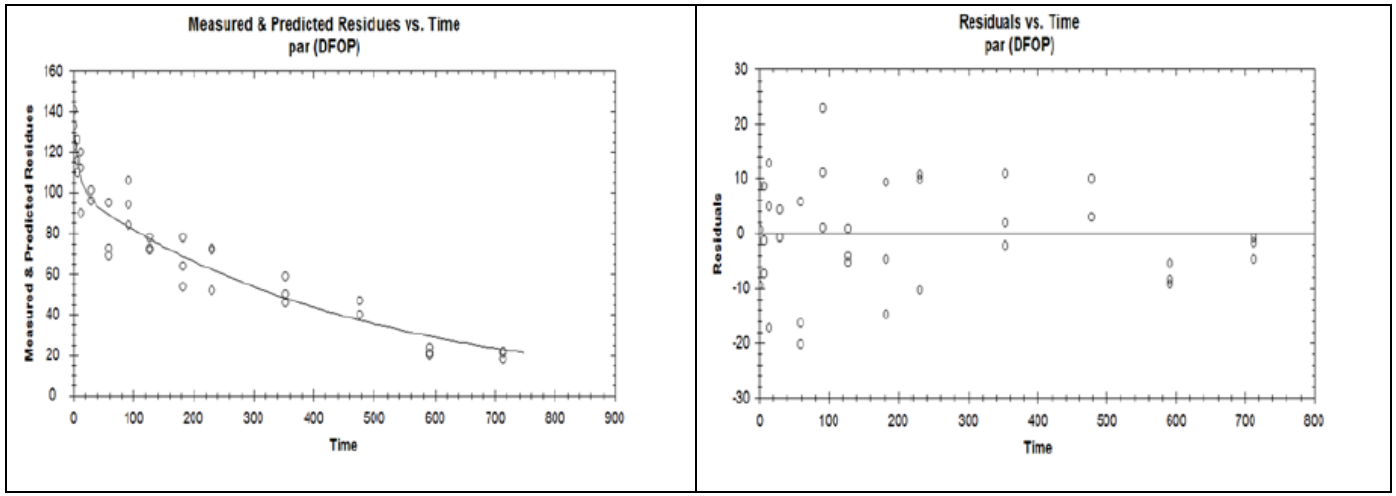


Figure 8.1.1.4.1-14: Kingui fit for BAS 750 F in trial L130561 (ES), time-step normalizes data sets, DFOP kinetics



Normalised kinetics

Table 8.1.1.4.1-25 : Statistical and visual assessment of kinetic models for derivation of endpoints for BAS 750 F in field trial L130546 - L130561 (normalised data)							
Trial, Country		**L130556 Bognese, Denmark**	**L130557 Lentzke, Germany (East)**	**L130558 Goch-Nierswalde, Germany (West)**	**L130559 Stotzheim, France**	**L130560 Poggio Renatico, Italy**	**L130561 Utrera, Spain***
Kinetic Model		**SFO**	**SFO**	**SFO**	**SFO**	**SFO**	**SFO[5]**
Parameters	**Pini (g/ha)**	124.6	124.6	129.3	128.2	122.0	114.8
	K	7.187E-3	3.768E-3	4.724E-3	5.390E-3	1.135E-3	1.77E-3
Statistics	**χ^2 (%)**	9.4	9.0	17.5	6.2	8.5	14.2
	t-test (P value) (K/K1;K2)	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01
	Visual Fit	Good (Figure 8.1.1.3.1.15)	Good (Figure 8.1.1.3.1.16)	Acceptable (Figure 8.1.1.3.1.17)	Good (Figure 8.1.1.3.1.18)	Good (Figure 8.1.1.3.1.19)	Good (Figure 8.1.1.3.1.20)
	$DegT_{50}$ (days)	96.5	184.0	146.6	128.6	610.8#	313.0
	$DegT_{90}$ (days)	320.4#	611.1#	487.4#	427.2#	>1000#	>1000#
Modelling Endpoint conclusion:		SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.	SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero . SFO is appropriate for derivation of modelling endpoints.	SFO visual fit is good, the χ^2 is greater than 15% but this is due to the scattering of the data rather than the kinetic fitting; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.	SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero . SFO is appropriate for derivation of modelling endpoints.	SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.	SFO visual fit is good, the χ^2 is less than 15%; K is significantly different from zero. SFO is appropriate for derivation of modelling endpoints.

* Initial concentration was fixed to the mean of the measured values. Initial investigation indicated parametrisation led to the initial concentration being significantly underestimated. The RMS also experienced this issue and agrees with fixing the initial concentration parameter.
# extrapolated beyond study duration (considering D_{norm} values)

Figure 8.1.1.4.1-15: Kingui fit for BAS 750 F in trial L130556 (DK), time-step normalizes data sets, SFO kinetics

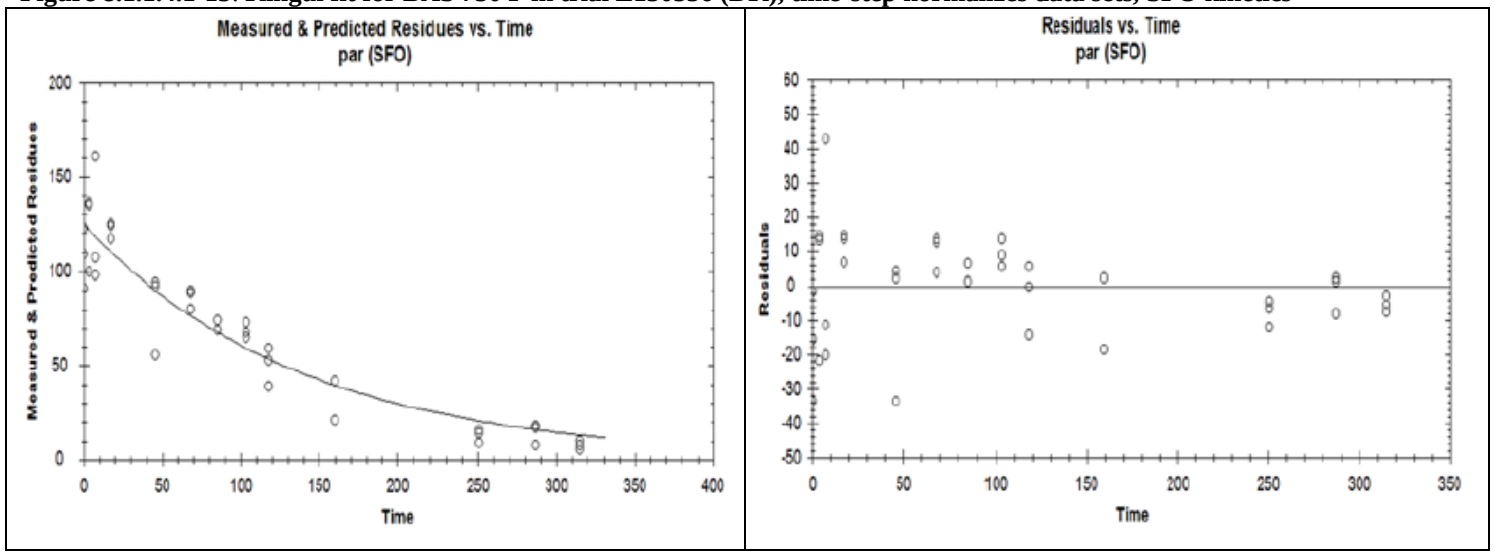


Figure 8.1.1.4.1-16: Kingui fit for BAS 750 F in trial L130557 (DE-E), time-step normalizes data sets, SFO kinetics

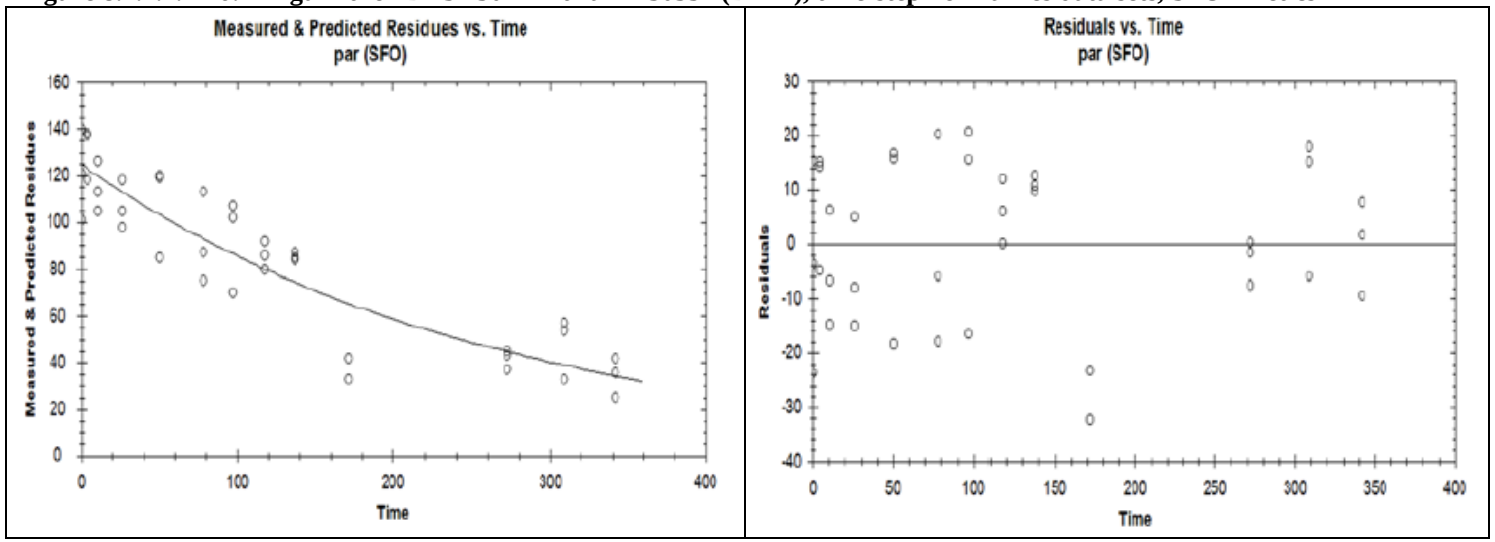


Figure 8.1.1.4.1-17: Kingui fit for BAS 750 F in trial L130558 (DE-W), time-step normalizes data sets, SFO kinetics

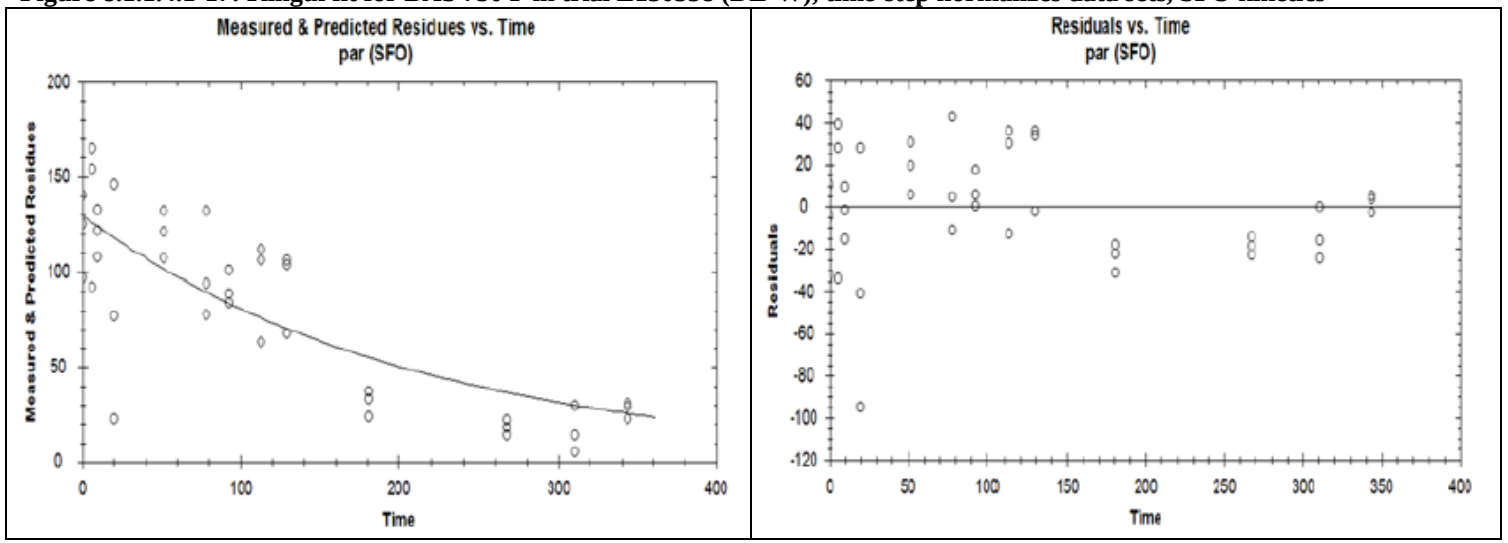


Figure 8.1.1.4.1-18: Kingui fit for BAS 750 F in trial L130559 (FR), time-step normalizes data sets, SFO kinetics

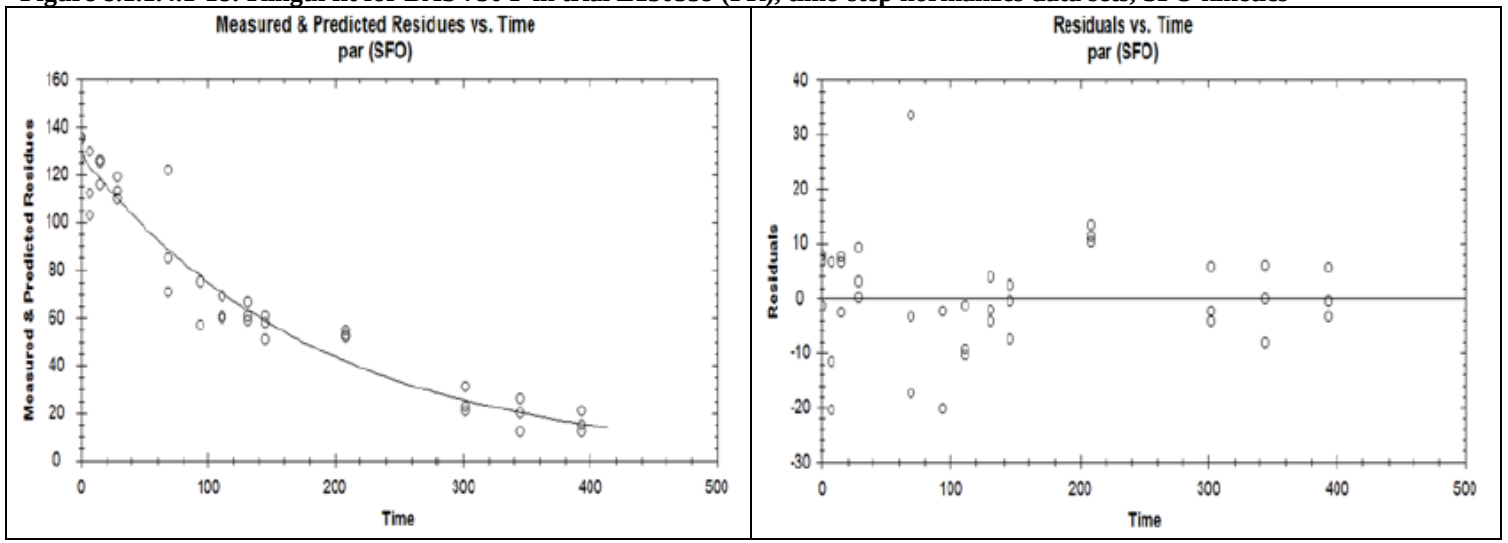


Figure 8.1.1.4.1-19: Kingui fit for BAS 750 F in trial L130560 (IT), time-step normalizes data sets, SFO kinetics

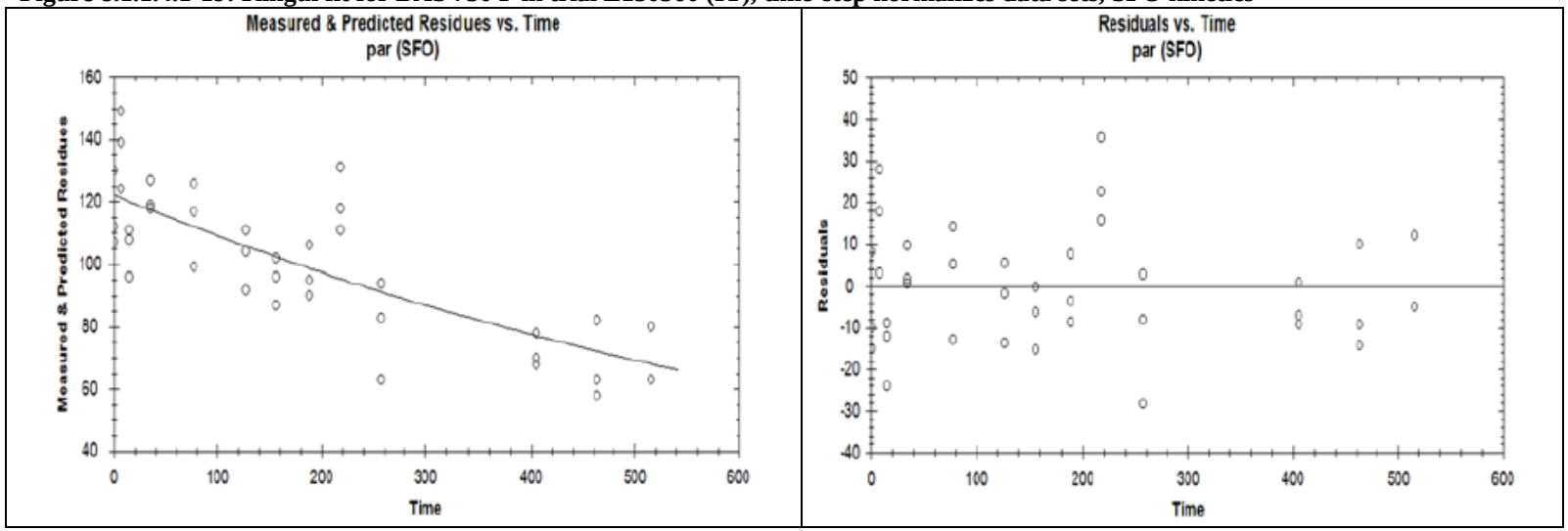
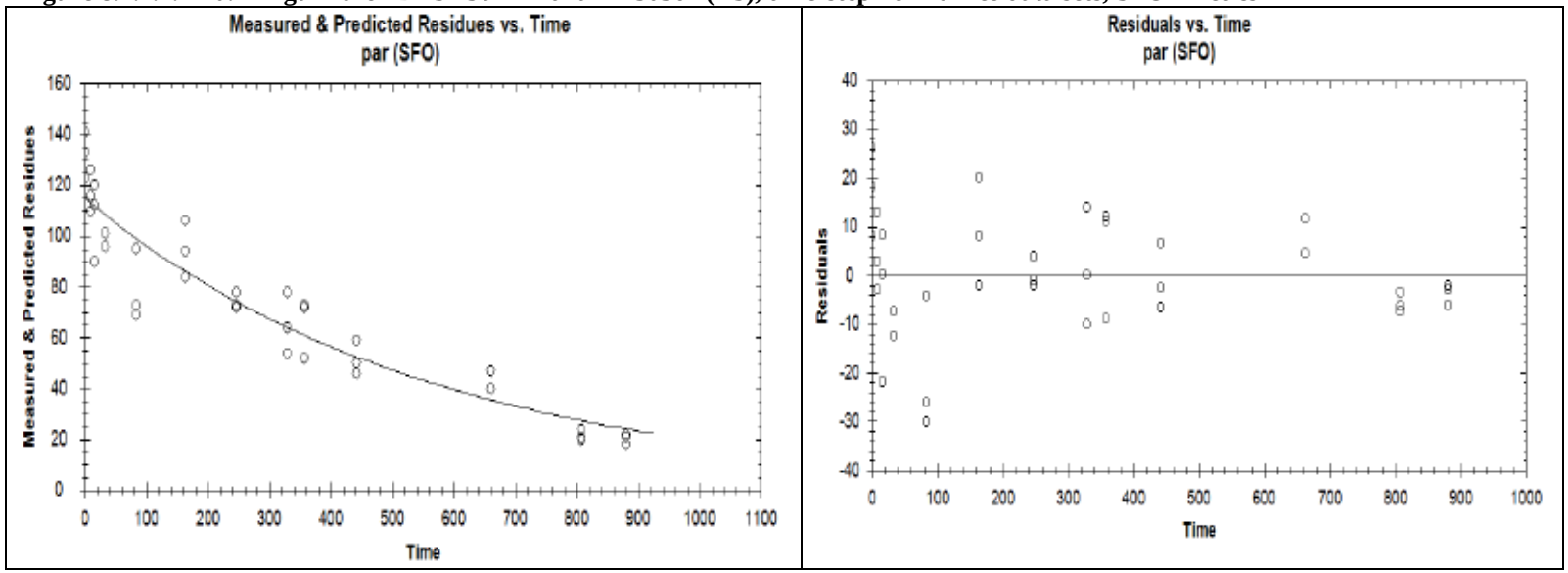


Figure 8.1.1.4.1-20: Kingui fit for BAS 750 F in trial L130561 (ES), time-step normalizes data sets, SFO kinetics



Conclusion

Best-fit models and corresponding endpoints ($DegT_{50}$ and $DegT_{90}$) and the appropriate modelling endpoints of BAS 750 F are summarized in table 8.1.1.4.1-26.

Table 8.1.1.4.1-26: Summary of modelling field degradation endpoints for BAS 750 F

Field trial	Soil type (USDA)	Modelling endpoints Non-Normalised				Modelling endpoints Normalised			
		Kinetic model	χ^2 [%]	$DegT_{50}$ [d]	$DegT_{90}$ [d]	Kinetic model	χ^2 [%]	Normalized $DegT_{50}$ [d]	Normalised $DegT_{90}$ [d]
L130556 (Denmark)	Sandy loam	SFO	9.2	185.5	616.1	SFO	9.4	96.5	320.4
L130557 (Germany-East)	Loamy sand	SFO	8.9	350.6	>1000	SFO	9.0	184.0	611.1
L130558 (Germany-West)	Silt loam	SFO	16.2	267.6	889.1	SFO	17.5	146.7	487.4
L130559 (France)	Silty clay loam	SFO	1.4	204.4	679.0	SFO	6.2	128.6	427.2
L130560 (Italy)	Silty clay loam	SFO	9.4	846.6	>1000	SFO	8.5	610.8	>1000
L130561 (Spain)*	Loamy sand	SFO	6.3	205.7	638.2	SFO [a]	14.2	313.0	>1000

* Endpoint was derived with the initial concentration fixed to the mean of the measured values.

Table 8.1.1.4.1-27: Summary of triggering field degradation endpoints for BAS 750F

Field trial	Soil type (USDA)	Triggering endpoints			
		Kinetic model	χ^2 [%]	$DegT_{50}$ [d]	$DegT_{90}$ [d]
L130556 (Denmark)	Sandy loam	SFO	9.2	185.5	616.1
L130557 (Germany-East)	Loamy sand	SFO	8.9	350.6	>1000
L130558 (Germany-West)	Silt loam	SFO	16.2	267.6	889.1
L130559 (France)	Silty clay loam	DFOP	8.4	145.4[a]/ 262.1[b]	870.2[a]
L130560 (Italy)	Silty clay loam	SFO	9.4	846.6	>1000
L130561 (Spain)	Loamy sand	DFOP	6.3	200.5[a]/ 292.6[b]	971.6[a]

* Endpoint was derived with the initial concentration fixed to the mean of the measured values.

[a] Overall Value

[b] Calculated value: Overall DegT90 / 3.32

Kinetic evaluation of six field trials with BAS 750 F, originating from one field dissipation study, was conducted in order to derive reliable best-fit and normalized modelling endpoints according to the current guidance of the FOCUS workgroup on degradation kinetics.

The non-normalized trigger half-lives ($DegT_{50}$) for BAS 750 F ranged from 145.4 to 846.6 days. The corresponding $DegT_{90}$ values ranged from 616.1 to >1000 days.

Modelling endpoints (non-normalised) for BAS 750 F could be derived from SFO kinetics for all field trials. Kinetic evaluation of the data resulted in non-normalized field half-lives ($DegT_{50}$) between 185.5 and 846.6 days.

Modelling endpoints (normalised) for BAS 750 F could be derived from SFO kinetics for all field trials. Kinetic evaluation of the time-step normalized data set (20°C, pF2) resulted in normalized field half-lives ($DegT_{50}$) between 96.5 and 610.8 days.

B.8.1.1.4.2. US field dissipation studies

Report:	CA 7.1.2.2.1/3 Jacobson B. et al., 2016 a Terrestrial field dissipation of the fungicide BAS 750 F following broadcast applications of BAS 750 01 F (EC) or BAS 750 UA F (SC) 2015/7006396
Guidelines:	EPA 835.6100
GLP:	yes (certified by United States Environmental Protection Agency)

Introduction

This study investigates the dissipation of BAS 750 F and its metabolites 1,2,4-triazole (M750F001) and M750F003 when BAS 750 F is applied as an EC or SC formulation to a bare soil plot. At the time of writing of the DAR (summer 2016), the report was an interim report with the study still in progress. Testing was conducted at six sites in the USA. Sampling and analysis are presented for time points up to 390 days post treatment. Sampling is still ongoing and interim results are reported, therefore no final conclusions may be drawn on the overall DT50 until the completed final report is submitted and reviewed. This study was conducted to GLP and according to EPA Fate, Transport and Transformation Test Guideline, OPPTS 835.6100 test guidelines; there were no significant deviations that would affect the validity of the study.

Information on the test materials used in the study are presented below.

Test item (formulation):	BAS 750 01 F
Active ingredient:	BAS 750 F (Reg. No. 5834378)
Chemical name (IUPAC):	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molar mass:	397.8 g mol^{-1}
Batch No.:	FD-140113-0006 (containing 98.9 g BAS 750 F L^{-1})
Type of formulation:	EC

Test item (formulation):	BAS 750 UA F
Active ingredient:	BAS 750 F (Reg. No. 5834378)
Chemical name (IUPAC):	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molar mass:	397.8 g mol^{-1}
Batch No.:	FD-140121-0040 (containing 403.5 g BAS 750 F L^{-1})
Type of formulation:	SC

Test sites

The dissipation of BAS 750 F and its metabolites 1,2,4-triazole and M750F003 was investigated at six sites in the USA. The selected fields represented typical regions of agricultural practice in the USA. and had been under cultivation for many years. The sampling sites were flat without any significant slope (<2% slope) and were fallow prior to the study. The cropping and chemical histories for the sites have been provided. The applicant has provided details of pesticide use history and no product containing the test item active substance or azole fungicides had been used on the test plots in the previous three years, a summary of the products applied is detailed in Table 8.1.1.4.2-1. The site characteristics including the basic soil parameters of the corresponding soil horizons are presented in Table 8.1.1.4.2-2and 8.1.1.4.2-3.

Table 8.1.1.4.2-1: Characteristics of the trial sites used in the field dissipation study (New York and North Dakota sites)

Trial	R140591							
Location	New York (NY), USA							
Soil properties	Depth [inches] ([cm])							
	0-6 (0-15)	6-12 (15-30)	12-18 (30-46)	18-24 (46-61)	24-30 (61-76)	30-36 (76-91)	36-42 (91-107)	42-48 (107-123)
Soil class (USDA)	Silt Loam	Silt Loam	Silt Loam	Silt Loam	Silt Loam	Silt Loam	Silt Loam	Silt Loam
sand [%]	27	23	23	21	17	13	17	21
silt [%]	58	62	68	72	72	76	72	62
clay [%]	15	15	9	7	11	11	11	17
Organic matter [%]	4.3	2.7	1.09	0.31	0.31	0.22	0.17	0.22
Total organic C [%]	2.5	1.6	0.63	0.18	0.18	0.13	0.10	0.13
pH a	5.0	4.9	5.0	5.1	5.1	4.9	5.0	5.7
CEC [meq 100g-1]	8.4	7.4	5.2	4.2	5.3	6	5.6	7.3
Moisture (gravimetric) at 1/3 bar [%]	32.1	35.7	32.4	27.1	27.5	28.9	23.7	23.9
Taxonomic classification	Niagra - Fine-silty, mixed, active, mesic Aeric Endoaqualfs							
Trial	R140592							
Location	North Dakota (ND), USA							
Soil properties	Depth [inches] ([cm])							
	0-6 (0-15)	6-12 (15-30)	12-18 (30-46)	18-24 (46-61)	24-30 (61-76)	30-36 (76-91)	36-42 (91-107)	42-48 (107-123)
Soil class (USDA)	Clay	Clay	Clay	Clay	Sandy Clay Loam	Clay	Clay	Clay
sand [%]	30	34	42	40	56	38	32	44
silt [%]	29	19	17	13	9	15	17	9
clay [%]	41	47	41	47	35	47	51	47
Organic matter [%]	3.2	1.9	1.6	1.4	1.4	1.2	0.95	0.95
Total organic C [%]	1.9	1.1	0.90	0.83	0.80	0.68	0.55	0.55
pH a	7.5	7.6	7.7	7.8	7.8	8.0	7.9	8.0
CEC [meq 100g-1]	33.9	36.5	34.9	33.3	33.0	31.1	30.2	34.1
Moisture (gravimetric) at 1/3 bar [%]	41.3	45.3	43.1	46.4	43.8	44.2	43.7	41.4
Taxonomic classification	Hegne - Fine, smectitic, frigid Typic Calciaquerts Fargo - Fine, smectitic, frigid Typic Epiaquerts							

CEC = Cation exchange capacity
a Measured in saturated paste

Table 8.1.1.4.2-2: Characteristics of the trial sites used in the field dissipation study (Washington and California sites)

Trial	R140593							
Location	Washington (WA), USA							
Soil properties	Depth [inches] ([cm])							
	0-6 (0-15)	6-12 (15-30)	12-18 (30-46)	18-24 (46-61)	24-30 (61-76)	30-36 (76-91)	36-42 (91-107)	42-48 (107-123)
Soil class (USDA)	Loamy Sand	Sand	Sand	Loamy Sand	Loamy Sand	Sandy Loam	Sandy Loam	Sandy Loam
sand [%]	86	88	90	84	76	70	64	68
silt [%]	11	11	9	15	21	29	33	29
clay [%]	3	1	1	1	3	1	3	3
Organic matter [%]	0.39	0.22	0.22	0.18	0.18	0.13	0.18	0.09
Total organic C [%]	0.23	0.13	0.13	0.10	0.10	0.08	0.10	0.05
pH a	8.3	8.2	8.2	8.2	8.1	8.1	8.4	8.4
CEC [meq 100g-1]	7.6	8.0	8.1	8.9	9.3	10.7	13.7	14.6
Moisture (gravimetric) at 1/3 bar [%]	8.1	7.4	7.0	9.4	12.0	15.3	19.3	20.1
Taxonomic classification	Quincy- Mixed, mesic Xeric Torripsamments							
Trial	R140594							
Location	California (CA), USA							
Soil properties	Depth [inches] ([cm])							
	0-6 (0-15)	6-12 (15-30)	12-18 (30-46)	18-24 (46-61)	24-30 (61-76)	30-36 (76-91)	36-42 (91-107)	42-48 (107-123)
Soil class (USDA)	Loamy Sand	Loamy Sand	Loamy Sand	Loamy Sand	Loamy Sand	Loamy Sand	Loamy Sand	Loamy Sand
sand [%]	74	76	76	74	76	80	80	82
silt [%]	22	20	20	22	22	18	18	16
clay [%]	4	4	4	4	2	2	2	2
Organic matter [%]	0.70	0.48	0.31	0.13	0.13	0.09	0.26	0.31
Total organic C [%]	0.41	0.28	0.18	0.08	0.08	0.05	0.15	0.18
pH a	7.6	8.0	8.3	8.3	8.3	8.3	8.5	8.4
CEC [meq 100g-1]	9.5	10.0	9.9	10.1	10.1	10.3	10.0	9.9
Moisture (gravimetric) at 1/3 bar [%]	11.2	10.6	11.7	11.9	11.1	11.3	9.4	10.0
Taxonomic classification	Nord – Coarse-loamy, mixed, superactive, thermic Cumulic Haploxerolls							

CEC = Cation exchange capacity
a Measured in saturated paste

Table 8.1.1.4.2-3: Characteristics of the trial sites used in the field dissipation study (Oklahoma and Illinois sites)

Trial	R140595							
Location	Oklahoma (OK), USA							
Soil properties	Depth [inches] ([cm])							
	0-6 (0-15)	6-12 (15-30)	12-18 (30-46)	18-24 (46-61)	24-30 (61-76)	30-36 (76-91)	36-42 (91-107)	42-48 (107-123)
Soil class (USDA)	Sandy Loam	Sandy Loam	Sandy Loam	Loam	Loam	Loam	Loam	Sandy Clay Loam
sand [%]	59	59	53	47	43	39	47	55
silt [%]	26	24	28	32	34	34	30	24
clay [%]	15	17	19	21	23	27	23	21
Organic matter [%]	0.67	0.97	0.76	0.71	0.63	0.63	0.50	0.42
Total organic C [%]	0.39	0.56	0.44	0.42	0.37	0.37	0.29	0.24
pH a	7.1	5.8	5.8	6.3	6.4	6.7	6.8	7.0
CEC [meq 100g-1]	7.8	8.2	9.2	9.6	11.0	13.2	12.1	11.8
Moisture (gravimetric) at 1/3 bar [%]	10.8	12.8	14.7	17.0	20.4	23.1	20.0	18.9
Taxonomic classification	Pond Creek - Fine-silty, mixed, superactive, thermic Pachic Argiustolls							
Trial	R140596							
Location	Illinois (IL), USA							
Soil properties	Depth [inches] ([cm])							
	0-6 (0-15)	6-12 (15-30)	12-18 (30-46)	18-24 (46-61)	24-30 (61-76)	30-36 (76-91)	36-42 (91-107)	42-48 (107-123)
Soil class (USDA)	Silty Clay Loam	Silty Clay Loam	Silty Clay Loam	Silty Clay	Silty Clay Loam	Silty Clay Loam	Silty Clay Loam	Clay Loam
sand [%]	15	9	9	11	15	7	13	23
silt [%]	52	52	56	46	48	54	52	46
clay [%]	33	39	35	43	37	39	35	31
Organic matter [%]	4.3	3.3	1.8	0.82	0.56	0.56	0.47	0.34
Total organic C [%]	2.5	1.9	1.0	0.47	0.32	0.32	0.27	0.20
pH a	6.0	6.0	6.3	6.6	6.8	7.0	7.2	7.4
CEC [meq 100g-1]	18.9	21.0	23.0	23.8	22.6	21.6	19.0	16.6
Moisture (gravimetric) at 1/3 bar [%]	33.9	34.9	36.8	39.8	37.9	35.9	33.5	29.6
Taxonomic classification	Drummer - Fine-silty, mixed, superactive, mesic Typic Endoaquolls							

CEC = Cation exchange capacity
a Measured in saturated paste

Experimental conditions

At each test site there were two test plots; a control bare soil plot of a minimum 3m x 15m (Plot 1) and a treated bare soil plot (Plot 2). The treated plot was divided into three replicate areas, ranging in size from 825 to 1100 m^2, to provide three replicate samples (Subplot 1, 2, and 3). The control plot was not subdivided, but was separated from the treated plot by a buffer zone of at least 15 m width.

The formulated product was broadcast applied to bare soil in two (IL test site) or three applications (NY, ND, OK, WA and CA test sites) at target application rates of 150 g a.s. ha-1 (NY, IL, ND, WA, and CA test sites) or 200 g a.s. ha-1 (OK test site), which resulted in the maximum proposed label use rate for the crop represented at each test site. Three methods were used to verify the application of BAS 750 F at each trial site:

- The pass time of the calibrated sprayer in the treated plot at each site was used to calculate the delivery of BAS 750 F.
- Treated application verification samples were generated in the field to confirm the amount of test compound applied to a given area.

- The total mass of BAS 750 F in the soil profile just before and after each application was used to directly determine the actual application rates applied to soil.

Treated application verification (AV) samples (three samples per plot) were generated in the field to confirm the amount of test compound applied to a given area. Upon analysis the filters did not perform as expected and are under further assessment. The results of the application verification experiment have not therefore been presented and they will be detailed at finalisation of the study report. The actual application rates have therefore been determined from the analytical dry weight residue concentrations just after each application and soil bulk density values in the core segments. Based upon this calculation, and supporting calculations determined from the sprayer calibration and pass times, the RMS considers that the soil residue levels determined are as expected from the indicated application rates of 150g or 200g a.s./ha.

The initial application at each test site was timed to occur at the approximate typical timing of fungicide applications for use in the representative crop(s) for that location/region. Details of the application are presented in 8.1.1.4.2-4.

Table 8.1.1.4.2-4: Application parameters of field trial sites treated with BAS 750 F

Trial, location	Formulated product	No. of applications (interval)	Application rate per treatment		Application date
			Nominal [g a.s. ha-1]	Actual [g a.s. ha-1]	
R140591, New York	BAS 750 UA F (SC)	3 (7 days)	150	150 152 147	17-Jun-14 24-Jun-14 01-Jul-14
R140592, North Dakota	BAS 750 01 F (EC)	3 (7 days)	150	141 150 148	19-Jul-14 26-Jul-14 02-Aug-14
R140593, Washington	BAS 750 UA F (SC)	3 (7 days)	150	149 149 148	17-Jun-14 24-Jun-14 01-Jul-14
R140594, California	BAS 750 UA F (SC)	3 (7 days)	150	148 149 148	15-Aug-14 22-Aug-14 29-Aug-14
R140595, Oklahoma	BAS 750 01 F (EC)	3 (14 days)	200	196 197 199	12-Aug-14 26-Aug-14 09-Sep-14
R140596, Illinois	BAS 750 01 F (EC)	2 (7 days)	150	157 152	13-Aug-14 20-Aug-14

After application of the test substance, the test plots were maintained in ways that minimized the disturbance of the plots. The bare soil plots, treated and control, were kept weed free for the study duration by the use of glyphosate and paraquat so that the maximum amount of test substance could reach the soil surface.

At all test sites daily precipitation data were collected on site for the duration of the study period. With the exception of the ND and OK sites other climatic measurements such as air temperature, wind speed, solar radiation and humidity were collected daily throughout the study period either on site or within 20 km of the test site. For the ND and OK sites the weather station reported daily weather conditions at 15 and 20 miles (24 and 32 km) from the test site respectively. The climate data presented can be considered acceptable as the precipitation data have been determined at the test site. With regard to the other climatic measurements at the ND and OK sites it is not considered that there are any climatological barriers that would affect the measurements taken for air temperature, wind speed, solar radiation and humidity. In addition, historical weather data (average monthly minimum, maximum, and average air temperatures and monthly precipitation totals) were submitted for at least a thirty-year period from a reliable source located no more than approximately 20 miles (32 km) from the test site.

Sprinkler irrigation was provided to ensure that the entire area could be irrigated with even water distribution. Irrigation was applied to supplement normal precipitation so that the plots would receive 110% of historical average rainfall for the study period.

A summary of already available monthly weather data (temperature and precipitation, as well as volumes of the supplementary irrigation) is presented in Table 8.1.1.4.2-5.

Table 8.1.1.4.2-5: Summary of monthly air temperature, precipitation, and irrigation at each field trial site – interim data

Trial	R140591			R140592		
Location	New York			North Dakota		
Month/ Year	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]
Jun-14	20.0	37.3	38.4	n.d.	n.d.	n.d.
Jul-14	19.8	181.6	0.0	21.4	19.6	9.9
Aug-14	19.5	100.3	19.1	20.9	114.0	0.0
Sep-14	16.3	26.9	94.5	15.9	36.8	0.0
Oct-14	11.9	55.6	76.2	8.8	13.7	0.0
Nov-14	3.5	49.5	0.0	-5.4	43.4	0.0
Dec-14	1.0	7.9	0.0	-6.4	6.4	0.0
Jan-15	-6.6	43.7	0.0	-9.1	1.0	0.0
Feb-15	-10.1	8.6	0.0	-13.9	0.5	0.0
Mar-15	-1.6	35.6	0.0	0.8	7.6	0.0
Apr-15	7.6	98.6	0.0	8.2	26.9	0.0
May-15	17.1	95.3	0.0	12.7	187.5	0.0
Jun-15	18.2	137.9	0.0	19.6	76.7	0.0
Jul-15	21.1	62.7	38.1	22.3	73.2	0.0
Aug-15	n.d.	n.d.	n.d.	20.3	37.1	0.0
Trial	R140593			R140594		
Location	Washington			California		
Month/ Year	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]
Jun-14	18.4	1.3	59.4	n.d.	n.d.	n.d.
Jul-14	24.5	0.5	297.2	n.d.	n.d.	n.d.
Aug-14	23.1	9.7	219.5	25.6	0.0	50.8
Sep-14	17.8	9.4	114.3	24.2	0.0	184.2
Oct-14	12.4	19.3	11.4	19.2	0.0	88.9
Nov-14	2.1	23.1	0.0	11.6	29.7	12.7
Dec-14	1.0	25.4	0.0	8.0	74.4	0.0
Jan-15	0.0	21.6	0.0	5.0	4.8	76.2
Feb-15	5.3	15.0	0.0	9.6	26.2	38.1
Mar-15	9.0	26.9	0.0	14.8	1.5	69.9
Apr-15	10.6	9.7	0.0	16.4	13.2	101.6
May-15	17.7	17.0	106.4	19.4	9.4	88.9
Jun-15	23.3	0.3	182.9	25.9	0.3	152.4
Jul-15	25.8	0.0	197.9	27.0	3.3	241.3
Aug-15	n.d.	n.d.	n.d.	26.3	0.0	171.5
Trial	R140595			R140596		
Location	Oklahoma			Illinois		
Month/ Year	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]
Aug-14	28.5	0.3	89.4	23.6	49.3	0.0
Sep-14	23.1	1.5	53.3	18.4	93.0	0.0
Oct-14	18.3	13.2	17.8	12.3	91.9	0.0
Nov-14	6.7	6.6	0.0	1.8	47.5	0.0
Dec-14	4.7	6.6	0.0	0.9	44.2	0.0
Jan-15	3.1	48.3	0.0	-3.4	8.4	0.0
Feb-15	2.5	17.8	19.8	-6.7	9.1	0.0
Mar-15	10.7	76.2	25.4	3.2	42.4	0.0
Apr-15	15.8	127.0	0.0	12.8	67.8	0.0
May-15	18.1	439.4	0.0	19.4	124.2	0.0
Jun-15	26.1	53.3	22.1	22.7	178.8	0.0
Jul-15	27.6	129.5	0.0	23.4	82.8	16.3
Aug-15	26.4	55.9	0.0	22.3	58.4	17.3

Table 8.1.1.4.2-5: Summary of monthly air temperature, precipitation, and irrigation at each field trial site – interim data

Trial	R140591			R140592		
Location	New York			North Dakota		
Month/ Year	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]	Tmean Air [°C]	Precipitation [mm]	Irrigation [mm]

Weather data refer to time period from start of trial (day of application) until end of trial (day of last sampling)
n.d. = Not determined

Relevance of the USA test sites to the EU authorisation.

The applicant has conducted an ecoregion comparison of the US test sites using the OECD Europe – North America Soil Geographic Information for Pesticide Studies (ENASGIPS) v2.3.2 application. This software tool compares regions based on five parameters: mean annual temperature, mean annual precipitation, mean soil pH, mean soil organic carbon, and soil texture. The applicant did not include pH in the comparison as they consider that dissipation or degradation of BAS 750 F is known not be influenced by soil pH. The analysis concluded that five of the sites could be considered comparable to the EU, with North Dakota not being considered comparable.

The UK RMS has considered the comparability of the climate data presented with that in the EU and also the comparability of the soil characteristics of pH, organic matter and clay content as reported at the US test sites, with that likely found in EU agricultural conditions. Based upon climatic information and characteristics of the soil presented it is considered that the conditions in the study at all US test sites can be deemed comparable to those in the EU agricultural conditions to enable them to be considered in support of the proposed EU use of BAS 750F.

Sampling

There were 16 (IL test site) or 18 (NY, ND, OK, WA and CA test sites) scheduled sampling intervals in the treated plots: Prior to and immediately after each test substance application and then 3, 7, 15, 30, 60, 90, 180, 270, 390, 510, 630, and 750 days after last application (DALA). The sampling events available for the interim report (≤390 days) are summarized in Table 8.1.1.4.2-6. In the control plots, six sampling intervals were scheduled: Prior to the first test substance application (-T1) and then 3, 15, 60, 90, and 390 days after last application.

Table 8.1.1.4.2-6: Sampling intervals of the treated plots following first application at each field trial site – interim data

R140591, New York

Event	Date	DA1A	DALA
T1	17-Jun-14	0	--
-T2	23-Jun-14	6	--
T2	24-Jun-14	7	--
-T3	30-Jun-14	13	--
T3	01-Jul-14	14	0
3	04-Jul-14	17	3
7	08-Jul-14	21	7
15	16-Jul-14	29	15
30	31-Jul-14	44	30
60	30-Aug-14	74	60
90	29-Sep-14	104	90
180	29-Dec-14	195	181
270	24-Mar-15	280	266
390	27-Jul-15	405	391

R140592, North Dakota

Event	Date	DA1A	DALA
T1	19-Jul-14	0	--
-T2	25-Jul-14	6	--
T2	26-Jul-14	7	--
-T3	01-Aug-14	13	--
T3	02-Aug-14	14	0
3	05-Aug-14	17	3
7	09-Aug-14	21	7
15	20-Aug-14	32	18
30	03-Sep-14	46	32
60	02-Oct-14	75	61
90	31-Oct-14	104	90
270	26-May-15	311	297
390	26-Aug-15	403	389

R140593, Washington

Event	Date	DA1A	DALA
T1	17-Jun-14	0	--
-T2	23-Jun-14	6	--
T2	24-Jun-14	7	--
-T3	30-Jun-14	13	--
T3	01-Jul-14	14	0
3	04-Jul-14	17	3
7	08-Jul-14	21	7
15	16-Jul-14	29	15
30	31-Jul-14	44	30
60	29-Aug-14	73	59
90	29-Sep-14	104	90
180	10-Dec-14	176	162
270	27-Mar-15	283	269
390	21-Jul-15	399	385

R140594, California	R140595, Oklahoma	R140596, Illinois

Event	Date	DA1A	DALA
T1	15-Aug-14	0	--
-T2	22-Aug-14	7	--
T2	22-Aug-14	7	--
-T3	28-Aug-14	13	--
T3	29-Aug-14	14	0
3	01-Sep-14	17	3
7	05-Sep-14	21	7
15	13-Sep-14	29	15
30	28-Sep-14	44	30
60	28-Oct-14	74	60
90	19-Nov-14	96	82
180	25-Feb-15	194	180
270	26-May-15	284	270
390	24-Aug-15	374	360

Event	Date	DA1A	DALA
T1	12-Aug-14	0	--
-T2	25-Aug-14	13	--
T2	26-Aug-14	14	--
-T3	08-Sep-14	27	--
T3	09-Sep-14	28	0
3	11-Sep-14	30	2
7	16-Sep-14	35	7
15	24-Sep-14	43	15
30	09-Oct-14	58	30
60	06-Nov-14	86	58
90	08-Dec-14	118	90
180	11-Mar-15	211	183
270	10-Jun-15	302	274
390	21-Aug-15	374	346

Event	Date	DA1A	DALA
T1	13-Aug-14	0	--
-T2	19-Aug-14	6	--
T2	20-Aug-14	7	0
3	23-Aug-14	10	3
7	27-Aug-14	14	7
15	04-Sep-14	22	15
30	19-Sep-14	37	30
60	20-Oct-14	68	61
90	14-Nov-14	93	86
180	17-Mar-15	216	209
270	18-May-15	278	271
390	25-Aug-15	377	370

T = Day of application (immediately after treatment)
-T = Day before the first application
DA1A = days after first application
DALA = days after last application

At each sampling event in the treated plots, five cores were taken to a depth of 48 inches (~122 cm) in each subplot. Immediately after sampling and before freezing, all soil cores were sectioned into segments of three inches (7.6 cm) for the top two soil horizons or six inches (15.2 cm) for the deeper horizons. Cores were then pooled into composite samples by depth and subplot, resulting in 3 composite samples of five cores from each subplot. This resulted in 15 cores being collected in the treated plot during a sampling event (except on days of application T1, T2, and T3 events when three additional composite samples, one from each treated subplot, were also collected for analysis).

All soil specimens stored under freezer conditions at about -18°C and remained frozen until processing and/or analysis of the samples. Field spikes were prepared at both test locations at 3 and 15 DALA. For each interval, four field spikes were prepared by fortifying untreated soil (approx 20 g aliquots of control plot soil) with 1 mL each of a 10 µg BAS 750 F /mL solution. The field spikes were transported and stored under the same conditions as the soil test samples from the field to the laboratory. Data to address the freezer storage stability of BAS750F when stored in soil under frozen conditions for up to 650 days is ongoing. Interim results indicating stability in soil for up to 240 days have been presented. The study is due to be completed in Sep 2016. Freezer stability data to support the stability of metabolite 1,2,4-triazole in frozen storage for up to 720 days have been provided (see Volume 3CA, Section B.5 of the DAR for details of the evaluation).

Analytical method

Analysis of soil core samples was conducted using BASF Analytical Method L0214/01 (Version October 29, 2013). Soil samples were extracted twice with acetonitrile:water 70:30 and the extracts were combined. The extracts were analysed for parent BAS 750 F and the metabolites 1,2,4-triazole and M750F003. Analysis was performed using LC-MS/MS. The limit of quantitation (LOQ) and limit of detection (LOD) for residues of BAS 750 F and its metabolites were 0.002 mg/kg (ppm) and 0.0004 mg/kg (ppm), respectively. Full details of the validation of the analytical method L0124/01 are presented in Volume 3CA, Section B.5 of the DAR. Results of soil analysis were reported on a "dry weight" basis for residue determination. Acceptable procedural recoveries, with mean recoveries within 70 -120%, were determined in support of the soil sample analysis.

Results and discussion

Residues in field soil samples

The mean residue data for the samples from the treated plots up to 390 days post treatment are shown in Tables 8.1.1.4.2-7 to 8.1.1.4.2-12. All residue values presented in these tables are related to the dry weight of the soil and were not corrected for procedural recoveries.

Acceptable procedural recoveries from control soil samples fortified with BAS 750 F and its metabolites at LOQ and 100 × LOQ were presented, with the mean values of recoveries between 70-110%. A summary of the individual procedural recovery results was provided.

Table 8.1.1.4.2-7: Residues of BAS 750 F and metabolites [mg kg-1 dry weight] in treated soil samples (mean of three replicates) – New York site (R140591) – interim results

Compound	Soil depth [inch]	Targeted days after last application														
		-T1	T1	-T2	T2	-T3	T3	3	7	15	30	60	90	181	266	391
BAS 750 F	0-3	<LOD	0.16	0.063	0.16	0.064	0.18	0.077	0.14	0.12	0.087	0.12	0.11	0.14	0.459	0.064
	3-6	<LOD	0.00067	<LOD	0.0036	0.0065	0.0014	0.11	0.0016	0.0018	0.00088	0.0034	0.003	0.016	0.067	0.0039
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.012	0.0021
1,2,4-triazole	0-3	0.0024	0.0015	0.0022	0.0023	0.0021	0.0022	0.0018	0.0023	0.0022	0.002	0.0021	0.0022	0.0023	0.0023	0.0024
	3-6	0.0024	0.0014	0.0017	0.0015	0.0016	0.0017	0.0019	0.0016	0.0014	0.0018	0.0018	0.0023	0.0021	0.0031	0.0015
	6-12	0.00094		0.001	0.001	0.0012	0.0016	0.00068	0.0007	0.0011	0.001	0.00071	0.0013	0.001	0.0013	0.0008
M750F003	0-3	<LOD	<LOD	0.0021	0.0023	0.0013	0.0019	0.0012	0.0023	0.0025	0.0018	0.0022	0.0024	0.0047	0.0076	0.0022
	3-6	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.0011	<LOD	<LOD	<LOD	<LOD	<LOD	0.00069	0.00178	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

T = Application dates
LOQ = 0.002 mg kg-1
LOD = 0.0004 mg kg-1
T1 = first application, 14 days prior to T3
T2 = second application, 7d prior to T3

Table 8.1.1.4.2-8: Residues of BAS 750 F and metabolites [mg kg-1 dry weight] in treated soil samples (mean of three replicates) – North Dakota site (R140592) – interim results

Compound	Soil depth [inch]	Targeted days after last application													
		-T1	T1	-T2	T2	-T3	T3	3	7	18	32	61	90	294	390
BAS 750 F	0-3	<LOD	0.08	0.1	0.16	0.14	0.3	0.19	0.33	0.24	0.22	0.19	0.15	0.17	0.09
	3-6	<LOD	<LOD	<LOD	0.00062	0.000849	0.0068	0.00083	0.0023	0.0011	<LOD	0.00081	0.00085	0.004	0.011
	6-12	<LOD		<LOD	<LOD	<LOD	0.0017	0.0033	0.0013	0.0015	0.0082	0.0014	0.0027	<LOD	0.0005
	12-18	<LOD		<LOD	<LOD	<LOD	0.0018	<LOD	0.005	0.001	<LOD	<LOD	<LOD	<LOD	-
1,2,4-triazole	0-3	0.0033	0.0041	0.0049	0.0046	0.0047	0.0051	0.0056	0.0051	0.0048	0.0056	0.0053	0.0046	0.0054	0.0054
	3-6	0.0028	0.003	0.0036	0.0032	0.0036	0.0041	0.0041	0.004	0.004	0.0033	0.004	0.0027	0.0035	0.0022
	6-12	0.0054		0.0018	0.0016	0.0013	0.0018	0.0016	0.0016	0.0021	0.0020	0.0026	0.0021	0.0019	0.0009
	12-18	0.0013		0.0013	0.00089	0.00093	0.0012	0.00079	0.0015	0.00085	0.0014	0.0013	0.0013	0.00076	
M750F003	0-3	<LOD	<LOD	0.0021	0.0017	0.0035	0.0045	0.0038	0.0064	0.0054	0.0045	0.0038	0.0035	0.0048	0.0015
	3-6	<LOD	<LOD	<LOD	<LOD	0.00021	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	-

T = Application dates
LOQ = 0.002 mg kg-1
LOD = 0.0004 mg kg-1
T1 = first application, 14 days prior to T3
T2 = second application, 7d prior to T3

Table 8.1.1.4.2-9: Residues of BAS 750 F and metabolites [mg kg-1 dry weight] in treated soil samples (mean of three replicates) – Washington site (R140593) – interim results

Compound	Soil depth [inch]	Targeted days after last application														
		-T1	T1	-T2	T2	-T3	T3	3	7	15	30	59	90	162	269	385
BAS 750 F	0-3	<LOD	0.11	0.065	0.15	0.13	0.24	0.19	0.2	0.2	0.21	0.17	0.15	0.14	0.15	0.052
	3-6	<LOD	0.00025	0.00031	0.00061	0.00031	0.00076	0.0016	0.0016	0.00079	0.0011	0.0016	0.0035	0.00043	<LOD	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.0016	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.00052	<LOD	0.002	<LOD	
1,2,4-triazole	0-3	<LOD	<LOD	0.00042	<LOD	0.00069	0.00049	0.00088	0.00075	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	3-6	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.0007	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	
M750F003	0-3	<LOD	<LOD	0.0005	0.00047	<LOD	0.00052	0.001	0.0013	<LOD	<LOD	<LOD	<LOD	0.00065	0.00068	<LOD
	3-6	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.00036	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	

T = Application dates
LOQ = 0.002 mg kg-1
LOD = 0.0004 mg kg-1
T1 = first application, 14 days prior to T3
T2 = second application, 7d prior to T3

Table 8.1.1.4.2-10: Residues of BAS 750 F and metabolites [mg kg-1 dry weight] in treated soil samples (mean of three replicates) – California site (R140594) – interim results

Compound	Soil depth [inch]	Targeted days after last application														
		-T1	T1	-T2	T2	-T3	T3	3	7	15	30	60	82	180	270	360
BAS 750 F	0-3	<LOD	0.17	0.033	0.25	0.095	0.17	0.12	0.12	0.1	0.14	0.089	0.12	0.13	0.07	0.04
	3-6	<LOD	0.0052	0.0038	0.0053	0.0038	0.0024	0.0047	0.0059	0.00046	0.0027	0.0028	0.0017	0.0023	0.001	0.0003
	6-12	<LOD	-	0.014	0.0042	0.016	0.044	0.01	0.011	0.0092	0.015	0.0091	0.0021	0.011	0.007	0.0027
	12-18	<LOD	-	0.001	<LOD	<LOD	0.00055	<LOD	0.00089	<LOD	0.00058	<LOD	<LOD	<LOD	<LOD	
1,2,4-triazole	0-3	<LOD	0.0007	0.00083	0.0018	0.00086	0.00093	0.0018	0.0017	0.0012	0.0014	<LOD	<LOD	0.00067	0.0064	0.0021
	3-6	<LOD	<LOD	<LOD	<LOD	0.00066	0.00095	<LOD	0.00058	0.00041	0.00046	<LOD	<LOD	<LOD	0.000442	<LOD
	6-12	<LOD	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.0012	<LOD
	12-18	<LOD	-	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	
M750F003	0-3	<LOD	<LOD	0.0013	0.0023	0.0016	0.0015	0.0022	0.0014	0.0011	0.00068	0.00034	0.00074	0.0015	0.0006	0.00048
	3-6	<LOD	<LOD	<LOD	<LOD	0.00053	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	

T = Application dates
LOQ = 0.002 mg kg-1
LOD = 0.0004 mg kg-1
T1 = first application, 14 days prior to T3
T2 = second application, 7d prior to T3

Table 8.1.1.4.2-11: Residues of BAS 750 F and metabolites [mg kg-1 dry weight] in treated soil samples (mean of three replicates) – Oklahoma site (R140595) – interim results

Compound		Targeted days after last application														
	Soil depth [inch]	-T1	T1	-T2	T2	-T3	T3	2	7	15	30	58	90	183	274	346
BAS 750 F	0-3	<LOD	0.11	0.093	0.25	0.17	0.25	0.28	0.28	0.3	0.24	0.27	0.31	0.2	0.15	0.08
	3-6	<LOD	0.00084	<LOD	0.0037	0.0039	<LOD	<LOD	0.00054	0.006	0.0024	<LOD	0.0045	0.0068	<LOD	<LOD
	6-12	<LOD		<LOD	0.00063	0.00074	0.0028	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	0.00042	0.0012	0.0025	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	
1,2,4-triazole	0-3	<LOD	<LOD	<LOD	<LOD	0.00041	<LOD	0.0014	0.001	0.0014	0.0016	0.001	0.0012	0.0014	0.0102	0.0011
	3-6	<LOD	<LOD	<LOD	<LOD	0.00056	0.00041	<LOD	<LOD	0.00074	0.00089	0.0012	0.00075	0.001	0.0133	<LOD
	6-12	0.001		0.00092	0.0013	0.0014	0.0013	0.0017	0.00096	0.00099	0.00097	0.0012	0.00084	0.0011	0.0262	0.0011
	12-18	0.00031		<LOD	0.00067	0.0007	<LOD	0.00053	<LOD	<LOD	0.0006	0.00069	<LOD	0.00088	0.0107	
M750F003	0-3	<LOD	<LOD	0.00053	0.00085	0.00078	0.0008	0.0008	0.0017	0.0016	0.0014	0.001	0.0022	0.0018	0.0008	<LOD
	3-6	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.00042	<LOD	<LOD
	6-12	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	

T = Application dates
LOQ = 0.002 mg kg-1
LOD = 0.0004 mg kg-1
T1 = first application, 28 days prior to T3
T2 = second application, 14d prior to T3

Table 8.1.1.4.2-12: Residues of BAS 750 F and metabolites [mg kg-1 dry weight] in treated soil samples (mean of three replicates) – Illinois site (R140596) – interim results

Compound		Targeted days after last application												
	Soil depth [inch]	-T1	T1	-T2	T2	3	7	15	30	61	86	209	271	370
BAS 750 F	0-3	<LOD	0.13	0.16	0.24	0.25	0.24	0.20	0.19	0.20	0.055	0.055	0.06	0.03
	3-6	<LOD		0.028	0.036	0.017	0.025	0.015	0.015	0.087	0.022	0.0017	0.0012	0.0023
	6-12	<LOD		0.0035	0.04	0.0033	0.0024	0.016	0.00077	0.005	0.0022	0.0005	<LOD	0.00075
	12-18	<LOD		<LOD	<LOD	0.0006	0.00062	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	
1,2,4-triazole	0-3	0.00076	0.00087	0.0012	0.0012	0.0015	0.0016	0.0019	0.0015	0.0014	0.0014	0.00047	0.00093	0.00184
	3-6	0.00083		0.00086	0.00074	0.00079	0.00092	0.0010	0.0010	0.0013	0.0013	0.00088	0.00070	0.0015
	6-12	0.00085		0.00053	0.00073	0.00072	0.0010	0.00095	0.00061	0.0012	0.0014	0.00082	0.00072	0.0008
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	0.00043	<LOD	0.0006	0.00058
M750F003	0-3	<LOD	<LOD	0.0026	0.0024	0.0034	0.0050	0.0058	0.0047	0.0055	0.0038	0.0026	0.0019	0.0010
	3-6	<LOD		0.00044	<LOD	<LOD	<LOD	0.00054	<LOD	0.0025	0.002	<LOD	<LOD	<LOD
	6-12	<LOD		<LOD	0.00062	0.00022	<LOD	0.00045	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD
	12-18	<LOD		<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	

T = Application dates
LOQ = 0.002 mg kg-1
LOD = 0.0004 mg kg-1
T1 = first application, 7 days prior to T2

Prior to the first application (-T1), residue concentrations of BAS 750 F were below LOD in all samples taken at all sites. With the exception of the NY site, BAS 750 F dissipated slowly in all trials. At the NY site a peak of BAS 750 F was determined at the 266 DALA timepoint; the applicant claims this could be due to handling error and this will be confirmed in the final report. The interim analytical data shows that about 10 to 40% of the applied amount remained as parent after 390 DALA. At all sites, BAS 750 F was detected in all soil horizons analysed so far.

The metabolite 1,2,4-triazole was detected at all trial sites, with quantifiable amounts (>0.002 mg kg-1) being determined at the NY (R140591), ND (R140592), CA (R140594) and OK (R140595) sites. In some trial sites quantifiable levels of 1,2,4-triazole were determined prior to the study commencing NY (R140591), ND (R140592), and OK (R140595). No explanation has been given for the low levels of 1,2,4-triazole being present prior to application and no information on fertiliser application prior to the study commencing was contained within the original study report. It is also noted that total levels may not have not been fully determined as detectable residues have been determined at the lowest soil horizon analysed up to this time.

Prior to the first application (-T1), residue concentrations of M750F003 were below LOD in all samples taken at all sites. Following application the metabolite M750F003 was detected at all trial sites. Quantifiable amounts (>0.002 mg kg-1) of M750F003 were found at the trial sites NY (R140591), ND (R140592), CA (R140594) and IL (R140596). With the exception of the NY site, the residues of M750F003 determined were at <5% of the applied dose and indicate that the metabolite is not occurring at significant levels up to 390 DALA. At the NY site a peak of BAS 750 F and metabolite M750F003 was determined at the 266 DALA timepoint, in this sample the levels of metabolite M750F003 were at 5% of the applied does of parent BAS750F. The applicant has indicated that this result appears erroneous and could be due to handling error; this will be confirmed in the final report.

Kinetic evaluation

The applicant has presented a preliminary kinetic analysis of the interim field data for the parent BAS750F. Dissipation kinetics were assessed using KinGUI and the guidance of FOCUS kinetics. BAS 750 F dissipation was assessed from the time of the last application onwards. The values are based on the total mass in the sampled soil profile (0-48 inches) over time. The SFO kinetic model was selected as the most appropriate to describe the dissipation of BAS 750 F at all six sites. The preliminary kinetic endpoints for field dissipation (DisT50 and DisT90) are summarized in Table 8.1.1.4.2-13. The applicant has indicated that these should be viewed with caution as the results in the final report may differ.

Table 8.1.1.4.2-13: Applicants summary of preliminary kinetic endpoints for BAS 750 F

Trial, location	Soil type (USDA)	pH (H2O)	Kinetic model	χ^2 [%]	DisT50 [d]	DisT90 [d]
R140591, New York	silt loam	5.0	SFO	15.1	281	933
R140592, North Dakota	clay	7.5	SFO	16.9	286	951
R140593, Washington	loamy sand	8.3	SFO	10.1	286	951
R140594, California	loamy sand	7.6	SFO	23.7	266	884
R140595, Oklahoma	sandy loam	7.1	SFO	11.6	292	969
R140596, Illinois	silty clay loam	6.0	SFO	20.4	101	335

In addition the RMS has done a preliminary validation of the dissipation kinetic assessment of the field data presented for BAS750F using CAKE 3.2. The values are based on the total mass in the currently sampled soil profile over time. Using the applicant's data and the SFO kinetic model the RMS would agree with the proposed DisT50 and DisT90 values presented. It is noted that the data are scattered and in addition to the data values from the NY site at the 266 d sampling the applicant has excluded one replicate from each of the 181d NY site, 209d OK site and 209s IL site.

Kinetic analysis of the metabolite data was not presented due to the low and variable levels of metabolites being determined also, in the case of 1,2,4-triazole, the presence of the metabolite in some plots prior to the study commencing.

Conclusion

The dissipation of BAS 750 F in soil under field conditions was investigated at six sites in the U.S. As sampling and analysis are still ongoing, interim results were reported. Based upon climatic information and characteristics of the soil presented it is considered that the conditions in the study at US test sites can be deemed comparable to those in the EU agricultural conditions to enable them to be considered in support of the proposed EU use of BAS 750F, once the final report is made available.

BAS 750 F dissipated slowly with preliminary DisT50 values from 101 to 292 days. The 101 day result is unusually short as compared to the other 5 sites with preliminary DT50 values ranging from 266 – 292 days

The metabolites 1,2,4-triazole and M750F003 were detected at all trial sites. 1,2,4-triazole was observed in some sites prior to or at application and at NY (R140591), ND (R140592) these initial values were at quantifiable levels. The metabolite M750F003 was detected at quantifiable amounts (>0.002 mg kg-1) at four of the six trial sites. With the exception of the 266 DALA time point at the NY (R140591) site, the residues of M750F003 determined were at <5% of the applied dose and indicate that the metabolite is not occurring at significant levels up to 390 DALA. The applicant is to provide further clarification on the data for the 266 DALA time point for the NY site.

The interim data presented are acceptable as presented thus far to give an indication of the likely rate of dissipation of BAS750F in field conditions and further supports the EU data in the consideration of the lack of significance of the M750F003 metabolite in field conditions at the proposed GAP of 2 x 150 g a.s./ha. However, it should be noted that if interpretation of metabolite data and the calculation of any kinetic parameters is required for M750F003 this could prove difficult due to the multiple applications used within the field trials. Due to the interim nature of the data study and areas that require clarification and further investigation no further consideration of these data has been made in this evaluation.

B.8.1.1.4.3. Soil Accumulaton Studies

B.8.1.1.4.3.1. Accumulation under field conditions in the United Kingdom

Report:	**KCA 7.1.2.2.2/1, Schäufele M., 2015b**
Title:	Accumulation behaviour of BAS 750 F in soil under field conditions in the United Kingdom following repeated application onto winter wheat over several years 2015/1076325
Guidelines:	NAFTA Guidance Document for Conducting Terrestrial Field Dissipation Studies, Regulatory Directive DIR2006-01, March 2006 EPA (Environmental Protection Agency) US: Fate, Transport and Transformation Test Guidelines, OPPTS 835.6100, Terrestrial Field Dissipation, October 2008 SETAC – Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, March 1995 SANCO/3029/99 rev. 4 (11/07/00): Guidance document for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, Official Journal of the European Union L 93, Volume 56, 03 April 2013
GLP	Yes Certified by the The Department of Health of the Government of the United Kingdom

Test Sites

The accumulation of BAS 750 F and its metabolite 1,2,4-triazole under field conditions was investigated at one site in the United Kingdom. The site characteristics are presented within table 8.1.1.4.3.1-1. Soil parameters were determined from soil samples taken before application from the boundaries of the treated plot following segmentation according to soil horizons. The site represents a typical region of agricultural practice representative for growing cereals.

Table 8.1.1.4.3.1-1: Soil characteristics of trial site used to investigate the accumulation of BAS 750 F

Trial	**L140318**	
Location	**Statton Audley, United Kingdom**	
GPS coordinates[d]	51° 55’ 21’’ N -1° 6 ‘ 47 W ‘’	
Geographical area[e]	**Northern/ Central Europe**	
Soil properties	0 – 55 cm	55-75 cm
Soil class (DIN 4220) sand ([%] silt [%] clay [%]	Silty Clay (Lt3) 18.8 40.1 41.1	Sandy Loam (Slu) 41.2 45.1 13.7
Soil class (USDA) sand [%] silt [%] clay [%]	Clay 25.4 24.3 50.2	Sandy Loam 55.4 26.8 17.8
Total organic C [%]	2.4	0.6
Organic matter [%] [a]	4.1	1.0
pH [$CaCl_2$]	7.0	7.6
pH [H_2O]	7.4	8.3
CEC [$cmol^+ kg^{-1}$]	32.8	9.8
MWHC [% w/w disturbed soil]	65.4	36.8
pF 2.0 [% w/w disturbed soil] [b]	46.4	24.3
pF 2.5 [% w/w disturbed soil] [b]	39.3	20.1
Dry bulk density [g cm^{-3}] [c]	0.94	-
Soil taxonomy	Stagnosols	
Classification Scheme	NSRI World Reference Base	
Source	Soil map: Cranfield National Soil Resources Institute (NSRI), Cranfield University	

CEC = Cation exchange capacity
MWHC = Maximum water holding capacity
[a] Organic matter = Organic carbon x 1.724
[b] Water retention characteristics, soil moisture at 0.1 or 0.33 bar
[c] Mean of three replicates- samples taken at approximately 10 cm depth
[d] GPS determined via Google Earth
[e] Climatic zone according to SANCO 7525/VI/95, rev. 9, March 2011

The site was flat without significant slope; it was not subject to flooding and erosion and was not prone to run-off. Before commencement of sampling the site was cropped with spring wheat following local agricultural practices (ploughing, harrowing and drilling).

No product containing the test item (BAS 750 F), any triazole fungicide or soil disinfectant has been used on the test plot in the last three years. It is also noted that no ammonium fertiliser containing 1,2,4-triazole was used (table 8.1.1.4.3.1-2).

Table 8.1.1.4.3.1-2: Management history of the trial sites in previous years (non-GLP)

Trial	Location	Year	Crops Grown	Pesticide Used	Fertilizer used
L140318	Statton Audley, United Kingdom	2014 (until sowing of wheat crop)	Grass	No pesticide applied	No fertilizer applied
		2013	Grass	No pesticide applied	No fertilizer applied
		2012	Grass	No pesticide applied	No fertilizer applied
		2011	Grass	No pesticide applied	No fertilizer applied

Weather data

Historical (long-term) weather data on precipitation and average air temperature for at least 10 years were taken from UK weather stations located at Brize Norton (48.6 km from trial site), Begbroke (21.5 km), London Heathrow (89.5 km) and Molcombe (21.9 km). Actual weather data are based on records of weather stations located on-site (16.75 m from test plot).

Monthly summary results on temperature and precipitation are presented within table 8.1.1.4.3.1-3

Table 8.1.1.4.3.1-3: Summary of climatic conditions at field trial site

Actual data from trial L140318[a]			Historic data (2005-2014)		
Month	T_{mean} Air (°C)	Prec. (mm) Σ	Month	T_{mean} Air (°C)	Prec. (mm) Σ
Mar 14	7.7	26.9	Mar	6.5	27.6
Apr 14	10.4	39.4	Apr	9.4	30.8
May 14[b]	12.3	86.2	May	12.1	55.5
Jun 14[b]	15.2	35.9	Jun	15.3	35.7
Jul 14	18.0	31.4	Jul	17.4	47.7
Aug 14	14.9	91.2	Aug	16.3	44.6
Sep 14	14.8	10.2	Sep	14.5	19.3
Oct 14	12.2	47.0	Oct	11.6	30.3
Nov 14	7.9	55.0	Nov	7.3	43.0
Dec 14	4.7	34.1	Dec	4.7	38.5
Average	11.9	-	Average	11.5	-
Σ	-	457	Σ	-	373

[a] Weather data refer to time period from 01 March until 31 December 2014

[b] The on site weather station was not working from 01 May to 03 Jun 2014. Data were used predominately from weather station 3 (9.57 Km from site). Other weather stations used to give a full set of data included weather stations at Turweston aerodrome (13.3 km) weather station 4 Fringefors (3.42 Km). Rothamsted (56.6 km) was used to determine soil temperature.

prec. = precipitation

Plot Layout

The trial area was divided into two plots; one untreated control plot (465m^2) and one treated plot (1395m^2). The treated plot consisted of three equal sized subplots A, B and C that were assigned for replicates.

The untreated control plot and each subplot were subdivided into 31 subplots of equal size. The treated plot contained one reserve area (60m^2) and a buffer strips at each end (each 20m^2). The width of the treated subplots was 10m and adapted to the size of the spraying boom used. The buffer strips, as well as the reserve area were treated with the test item but were not sampled.

The three treated subplots form together a contiguous acreage. The distance between treated and untreated plot is 20m.

Test Item application

The product, formulated as an emulsifiable concentrate (EC), was broadcast sprayed to wheat using a calibrated mounted boom sprayer. The test item was applied at a nominal rate of 150g a.s./ha per application, which is in line with the proposed GAP.

The target application timings were BBCH 25-29 (1st application) and BBCH 37-39 (2nd application), it is noted that the first target is prior to the first application presented within the GAP (BBCH 30), however as this will likely increase soil exposure this difference is considered to be acceptable by the RMS. Application details are presented within table 8.1.1.4.3.1-4; for both applications application was delayed due to adverse weather conditions.

The treated subplots and the reserve and buffer area were applied together in one run; as such only one spray mixture was prepared. The spray mixture was visually checked for homogeneity and small aliquots (~10-~30 mL) of the spray mixture were taken before and after application for later analysis (this data is not available within the interim report).

At each application the dose rate was additionally verified by means of sampling petri dishes (inner diameter of 10.8 cm) filled with untreated soil from the field (approximately 50 g per dish, sieved to 2 mm). The petri dishes were placed on the subplot borders within the treated plot (5 in each subplot) before application and were set up in a way that they were not affected by the crop. It should be noted that the data is not available within the interim report.

Table 8.1.1.4.3.1-4: Application parameters of field trial site treated with BAS 750 01 F (EC)

Trial Crop	Application Method	Year and number of applications and crop growth stage	Subplot	Application rate per treatment				Application date
				Nominal (g a.s./ha)	Actual[a] (g a.s./ha)	Dose verification (g a.s./ha)	Dose verification % of nominal	
L140318 Spring Wheat	Broadcast spray	2014- 1 BBCH 33	A	150	153			03/06/2014
			B	150	153			
			C	150	153			
			Average	150	153			
L140318 Spring Wheat	Broadcast spray	2014- 2 BBCH 39-51	A	150	152			20/06/2014
			B	150	152			
			C	150	152			
			Average	150	153			

[a] determined by calculation of spray liquid applied. Determined only once: treated plot including reserve area were applied in one run.
[b]determined by means of petri dishes filled with soil (recovery corrected)- Data not available

Crop and sowing information

The crop and sowing information is presented in table 8.1.1.4.3.1-5 below. The variety used and drilling rate is considered to be representative for the region and followed local agricultural practice.

The harvest was performed with a Sampo 2010 combine harvester. The trial site remained fallow between harvest in summer 2014 and sowing in autumn 2014.

Table 8.1.1.4.3.1-5: 2014 Crop and sowing information

Crop	Variety	Date of sowing	Date of crop flowering (start-end)	Date of crop harvest	Date of crop destruction[c]	Sowing depth (cm)	Row distance (cm)	Drilling Rate (kg/ ha)	Thousand grain weight (g)
Spring Wheat[a]	Tybalt	04/04/14	01/07-18/07/14	24/08/14	24/08/14	~ 5	12	200	unknown
Winter Wheat[b]	KWS Santiago	20/10/14	n/a	n/a	n/a	~ 5	10.15	200	48.42[d]

[a] Spring wheat sown in Spring 2014
[b] Winter wheat sown in autumn 2014
[c] The grain was removed from the trial site area and disposed of. Plant residues (straw) remained at the trial site. The straw was chopped with the harvester and spread on the soil surface on the respective plots
[d] determined on 10/08/15 using stroed grain from the same batch as drilled; this equates to approx.. 425 seeds/ m^2.
n/a Not applicable to this report; will be reported with subsequent data.

Trial maintenance

During the study both pesticide and fertiliser applications were made to both the treated and untreated plots; full details are presented within table 8.1.1.4.3.1-6 and 8.1.1.4.3.1-7. No azole pesticides were applied during the trial, as such it is not expected that the application shall significantly influence the degradation of BAS 750 F. Furthermore it is not expected that agricultural soil will have a number of pesticides applied during cropping. No mechanical maintenance was performed within 2014. Irrigation was not performed during the trial period.

Table 8.1.1.4.3.1-6: Pesticide maintenance after sowing in spring 2014

Year	Crop	Application date	Product applied	Active substance	Rate applied
2014	Spring Wheat	01/04/14	Atlantis	Iodsulfuron-methy sodium Mesosulfuron-methyl	0.4 Kg/ ha
		01/04/14	Biopower	Adjuvant	1 L/ ha
		11/06/14	Bravo	Chlorothalonil	1 L/ ha
		11/06/14	Verone	2-chloroethylphosphonic acid	0.5 L/ ha
		16/10/14	Clinic Ace	Glyphosate	2 L/ ha
	Winter Wheat	06/11/14	Defy	Produlfocarb	4 L/ ha
		06/11/14	Liberator	Diflufenican and flufenacet	0.6 L/ ha
		07/11/14	Gusto	Metaldehyde	11 kg/ ha

Table 8.1.1.4.3.1-7: Fertiliser applications after sowing in spring 2014

Year	Date of application	Fertiliser applied	Type of fertiliser	Rate applied (Kg/ ha)	Rate applied (Kg N/ ha)
2014	08/04/14	Nitram	0:25:25 (N:P:K)	200	70

Sampling

Replicate soil specimens (10 per treated subplot and control plot) were taken before the first application (-1 days after the first treatment DAFT), after the second application (20 DAFT) and after crop harvest, but before ploughing (121 DAFT). Soil cores were collected to a depth of 60 cm. The specimens were taken randomly at each sampling occasion from the control and from each treaded subplot. Soil cores were taken in one run (0-60 cm) using a tractor mounted hydraulic soil corer, fitted with plastic tubes of 125 cm length and an inner diameter of 4.5cm.

After freezing, all main soil cores collected were cut into 10 cm segments and pooled by depth, plot and sampling event. Soil cores did not defrost during the segmentation process.

Analytical procedure
Residue analysis in ongoing, no information on the analytical procedure are contained within the interim report.

Results and Conclusion
The study is ongoing; no residue data is presented within the interim report. While this interim reports presents the study design no assessment of the accumulation of BAS 750 F can be made.

B.8.1.1.4.3.2. Accumulation under field conditions in Germany

Report:	**KCA 7.1.2.2.2/2, Schäufele M., 2015c**
Title:	Accumulation behaviour of BAS 750 F in soil under field conditions in Germany following repeated application onto winter barley over several years 2015/1076326
Guidelines:	NAFTA Guidance Document for Conducting Terrestrial Field Dissipation Studies, Regulatory Directive DIR2006-01, March 2006 EPA (Environmental Protection Agency) US: Fate, Transport and Transformation Test Guidelines, OPPTS 835.6100, Terrestrial Field Dissipation, October 2008 SETAC – Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, March 1995 SANCO/3029/99 rev. 4 (11/07/00): Guidance document for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, Official Journal of the European Union L 93, Volume 56, 03 April 2013
GLP	Yes Certified by the The Department of Health of the Government of the United Kingdom

Test Sites

The accumulation of BAS 750 F under field conditions was investigated at one site in Germany. The site characteristics are presented within table 8.1.1.4.3.2-1. Soil parameters were determined from soil samples taken before application from the boundaries of the treated plot following segmentation according to soil horizons. The RMS notes that the soil taxonomy (FAO classification) was identified through the use of regional soil maps, rather than by through soil profiles at each trial site (as required by NAFTA, 2006). The RMS is of the opinion that this is an acceptable deviation, from the guideline, as soil maps are considered to be a reliable data source. The site represents a typical region of agricultural relevance.

Table 8.1.1.4.3.2-1: Soil characteristics of trial site used to investigate the accumulation of BAS 750 F

Trial	**L140319**		
Location	**Lentzke, Germany**		
GPS coordinates[d]	52° 47’ 27” N 12° 42’ 44” E		
Geographical area[e]	Northern/ Central Europe		
Soil properties	0 - 35 cm	45 – 65 cm	65 – 90 cm
Soil class (DIN 4220)	Weak Loam Sand (SI2)	Weak Loamy Sand/ Strong Loamy Sandy (SU3)	Sandy Loam (SI3)
sand ([%]	69.9	66.3	59.1
silt [%]	24.8	28.0	30.4
clay [%]	5.3	5.7	10.5
Soil class (USDA)	Loamy Sand	Loamy Sand	Sandy Loam
sand [%]	78.8	79.2	70.1
silt [%]	13.1	12.9	17.4
clay [%]	8.1	7.8	12.5
Total organic C [%]	0.8	0.3	0.1
Organic matter [%] [a]	1.3	0.5	0.2
pH [$CaCl_2$]	6.2	6.5	6.2
pH [H_2O]	6.8	7.3	7.0
CEC [meq/ 100g dry weigt]	4.6	2.9	5.5
MWHC [% w/w disturbed soil]	29.9	25.1	27.2
pF 2.0 [% w/w disturbed soil] [b]	15.9	12.8	15.3
pF 2.5 [% w/w disturbed soil] [b]	8.4	8.2	11.7
Dry bulk density [g cm^{-3}] [c]	1.61	-	-
Soil taxonomy	Podzoluvisol-Luvisol		
Classification Scheme	FAO		
Source	Soil Map: Bodenübersichtskarte CC 3942 Berlin, M 1L200000		

CEC = Cation exchange capacity
MWHC = Maximum water holding capacity
[a] Organic matter = Organic carbon x 1.724
[b] Water retention characteristics, soil moisture at 0.1 or 0.33 bar
[c] Mean of three replicates- samples taken at approximately 10 cm depth
[d] GPS determined via Google Earth
[e] Climatic zone according to SANCO 7525/VI/95, rev. 9, March 2011

The site was flat without significant slope; it was not subject to flooding and erosion and was not prone to run-off. Before commencement of sampling the site was cropped with spring barley following good agricultural practices (harrowing and seedbed preparation).

No product containing the test item (BAS 750 F), any triazole fungicide or soil disinfectant has been used on the test plot in the last three years. Several pesticides were applied to the site since 2011 (table 8.1.1.4.3.2-2), however no azole pesticides were applied. As such it is not expected that the previous application shall not significantly influence the degradation of BAS 750 F. Furthermore it is not expected that agricultural soil will have a number of pesticides applied during cropping, as such the RMS considers the previous pesticide application to be acceptable. It is also reported that no ammonium fertiliser containing 1,2,4-triazole was used.

Table 8.1.1.4.3.2-2: Management history of the trial sites in previous years (non-GLP)

Trial	Location	Year	Crops Grown	Pesticide Used	Fertilizer used
L140319	Lentzke, Germany	2014 (until sowing of spring barely)	Winter Wheat	Glyphosate	n/a
		2013	Oilseed Rape	Chlortoluron, pendimethalin, diflufenican and tribenuron-methyl	n/a
		2012	Winter Barley	Pethoxamid and Metazachlor	n/a
		2011	Winter Wheat	Diflufenican, flufenacet, alpha cypermethrin and tribenuron-methyl	n/a

Weather data

Actual Weather data are based on record of a weather station located on-site. Historical (long-term) weather data on precipitation and average air temperature from 1981-2010 were taken from the official German weather station location at 16816 Neuruppin, about 15Km away from the trial site. This historical and actual data, each averaged over the complete duration, are presented within table 8.1.1.4.3.2-3.

Table 8.1.1.4.3.2-3: Summary of climatic conditions at field trial site

Actual data from trial L140319[a]			Historic data (1981-2010)		
Month	T_{mean} Air (°C)	Prec. (mm) Σ	Month	T_{mean} Air (°C)	Prec. (mm) Σ
Mar 14	6.5	15.4	Mar	4.1	40
Apr 14	10.6	40.6	Apr	8.7	31
May 14	12.6	79.4	May	13.7	51
Jun 14	15.8	98.9	Jun	16.3	59
Jul 14	20.4	60.4	Jul	18.7	52
Aug 14	16.5	48.4	Aug	18.2	52
Sep 14	15.4	27.4	Sep	14.1	44
Oct 14	11.9	42.8	Oct	9.5	39
Nov 14	6.2	10.2	Nov	4.7	42
Dec 14	2.1	51.8	Dec	1.3	46
Average	11.8	-	Average	10.9	-
Σ	-	475.2	Σ	-	456

[a] Weather data refer to time period from 01 March (> 1 months before 1st sampling) until 31 December 2014

Plot Layout

The trial area was divided into two plots; one untreated control plot (408m^2) and one treated plot (1224m^2). The treated plot consisted of three equal sized subplots A, B and C that were assigned for replicates.

The untreated control plot and each suplot were subdivided into 31 subplots of equal size. The treated plot contained one reserve area (24m^2) and two buffer strips (each 1m^2), at each end. The width of the treated subplots was 6m and adapted to the size of the spraying boom used. The buffer strips, as well as the reserve area were treated with the test item but were not sampled.

Each treated subplot form an individual area. The distance between treated and untreated plot is 20m.

Test Item application

The product, formulated as an emulsifiable concentrate (EC), was broadcast sprayed to barley using a calibrated mounted boom sprayer, while barley is not the crop stated within the GAP, it is considered crop exposure is comparable to that expected for wheat cultivation. The test item was applied at a nominal rate of 150g a.s./ha per application, which is in line with the proposed GAP.

The target application timings were BBCH 25-29 (1st application) and BBCH 37-39 (2nd application), it is noted that the first target is prior to the first application presented within the GAP (BBCH 30), however as this will likely increase soil exposure this difference is considered to be acceptable by the RMS. Application details are presented within table 8.1.1.4.3.2-4.

The treated subplots and the reserve and buffer area were applied individually. For each treated replicate a separate spray mixture was prepared. Each spray mixture was visually checked for homogeneity and small aliquots (~10mL) of the spray mixture were taken before and after application for later analysis (this data is not available within the interim report).

At each application the dose rate was additionally verified by means of sampling petri dishes (inner diameter of 10.8 cm) filled with untreated soil from the field (approximately 50 g per dish, sieved to 2 mm). The petri dishes were placed on the subplot borders within the treated plot (5 in each subplot) before application and were set up in a way that they were not affected by the crop. It should be noted that the data is not available within the interim report.

Table 8.1.1.4.3.2-4: Application parameters of field trial site treated with BAS 750 01 F (EC)

Trial Crop	Application Method	Year and number of applications and crop growth stage	Subplot	Application rate per treatment				Application date
				Nominal (g a.s./ha)	Actual[a] (g a.s./ha)	Dose verification (g a.s./ha)	Dose verification % of nominal	
L140319 Spring Barley	Broadcast spray	2014- 1 BBCH 23-29[c]	A	150	144			30/04/14
			B	150	141			
			C	150	147			
			Average	150	144			
L140319 Spring Barley	Broadcast spray	2014- 2 BBCH 35-49[d]	A	150	144			29/05/14
			B	150	139			
			C	150	146			
			Average	150	143			

[a] determined by calculation of spray liquid applied
[b]determined by means of petri dishes filled with soil (recovery corrected)- Data not available
[c] Application conducted early due to ideal weather conditions
[d] Delayed due to unstable weather conditions

Crop and sowing information

The crop and sowing information is presented in table 8.1.1.4.3.2-5below. The variety used and drilling rate is considered to be representative for the region and followed local agricultural practice.

The harvest was performed with a plot harvester Hege C 165. The trial site remained fallow between harvest in autumn 2014 and sowing in autumn 2014.

Table 8.1.1.4.3.2-5: 2014 Crop and sowing information

Crop	Variety	Date of sowing	Date of crop flowering (start-end)	Date of crop harvest	Date of crop destruction[a]	Sowing depth (cm)	Row distance (cm)	Drilling Rate (kg/ ha)
Spring Barley	Simba	24/03/14	11/06 – 26/06/14	05/08/14	08/08/14	2-3	13	280
Winter Barley	Anisette	24/09/14	n/a	n/a	n/a	2-3	12.5	250

[a] The grain was removed from the trial area. Plant residues (straw) remained on the trial site. The straw was chopped with the harvester and spread on the soil surface of the respective plots.
n/a Not applicable to this report; will be reported with subsequent data.

Trial maintenance

During the study both pesticides and fertiliser applications were made to both the treated and untreated plots; full details are presented within tables 8.1.1.4.3.2-6 to -7; no azole pesticides were applied during the trial, as such it is not expected that the application shall significantly influence the degradation of BAS 750 F. Furthermore it is not expected that agricultural soil will have a number of pesticides applied during cropping. No mechanical maintenance was performed within 2014. Irrigation was not performed during the trial period.

Table 8.1.1.4.3.2-6: Pesticide maintenance after sowing in spring 2014

Year	Crop	Application date	Product applied	Active substance	Rate applied
2014	Spring Barely	14/03/14	Ariane C	Fluroxypyr, Flurosulam and Clopyralid	1.5 L/ha
		28/08/14	Roundup Powerflex	Glyphosate	3.75 L/ha
	Winter Barley	13/10/14	Picona	Pendimethalin and Picolinafen	2.0 L/ha
			IPU	Isoproturon	2.0 L/ha
			Pointer SX	Tribenuron	20 g/ha
			Sumicidin Alpha EC	Esfenvalerat	0.2 L/ha

Table 8.1.1.4.3.2-7: Fertiliser applications after sowing in spring 2014

Year	Date of application	Fertiliser applied	Type of fertiliser	Rate applied (Kg/ ha)	Rate applied
2014	17/04/14	KAS	N (27%)	300 Kg/ha	81 Kg N/ha
	11/11/14	Triple Super Phosphat	P (46% P_2O_5)	75 Kg/ha	15.2 Kg P/ha
		Kornkali	K (40% K_2O)	100 Kg/ha	33.2 Kg K/ha

Sampling

Replicate soil specimens (10 per treated subplot and control plot) were taken before the first application (-5 and -1 days after the first treatment DAFT), after the second application (30 DAFT) and after crop harvest, but before ploughing (113 DAFT). The specimens were taken randomly at each sampling occasion. Further specimens were collected from the control and from each treated subplot. Soil cores were taken using a tractor mounted hydraulic soil corer, fitted with plastic tubes of 30 cm length and an inner diameter of 5.0cm. Sampling of these cores was conducted in two runs.

After freezing, all main soil cores collected were cut into 10 cm segments and pooled by depth, plot and sampling event. Soil cores did not defrost during the segmentation process.

In addition to the main sampling described above, a second complete sampling (double sampling) was carried out. The reserve samples were not sectioned but directly placed and kept into freezers at the field test site.

Analytical procedure
Residue analysis in ongoing, no information on the analytical procedure are contained within the interim report.

Results and Conclusion
The study is ongoing; no residue data is presented within the interim report. While this interim reports presents the study design no assessment of the accumulation of BAS 750 F can be made.

B.8.1.1.5. Soil photolysis

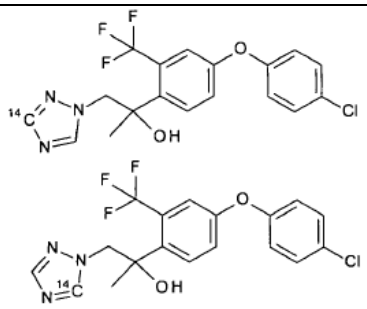
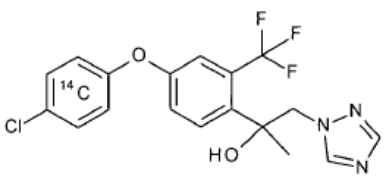
Report:	CA 7.1.1.3/1 Hassink J., Delgado M., 2014 a Soil photolysis of (triazole-3(5)-C14 and chlorophenyl-U-C14) BAS 750 F 2014/1181666
Guidelines:	EPA Subdivision N, §161-3 Photodegradation Studies on Soil EPA: OPPTS 835.2410 – Photodegradation on Soil SETAC Europe: Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides Draft OECD Guideline "Phototransformation of Chemicals on Soil Surfaces", Jan. 02 Directive 91/414/EEC Annex II, amended by Commission Directive 95/36/EC
GLP:	yes (certified by Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz)

Introduction

A soil photolysis study was conducted with BAS 750 F to investigate the behaviour of BAS 750 F in soil under the influence of light. This study was conducted to GLP and according to draft OECD test guidelines; although the RMS identified deviations from the OECD guidelines as discussed below, these were not deemed significant enough to affect the conclusions of the study.

Information on the ^{14}C-labelled test materials used in the study is presented in Table 8.1.1.5-1. The RMS notes that, ideally, the Applicant would have radio-labelled the trifluoromethylphenyl ring also, in line with the OECD guidelines; however, because acceptable levels of material balances were recovered (see "Results and discussion" section below), and therefore, degradation of the trifluoromethylphenyl ring was not substantial, the RMS is of the opinion that this deviation from the guidelines did not have a significant effect on the outcomes of this study, on this occasion.

Table 8.1.1.5-1: Test materials

Substance code	BAS 750 F	
Reg number	5834378	
CAS number	1417782-03-6	
Chemical name (IUPAC)	(2*RS*)-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	
Molecular mass	397.78 g mol^{-1}	
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$	
Label	Triazole-3(5)-^{14}C	Chlorophenyl-U-^{14}C
Batch number	1062-2001	CFQ41561
Specific radioactivity of a.s. (MBq mg^{-1})	5.46	7.878
Radiochemical purity (%)	98.8	98.9
Purity (%)	98.9	99.1
Position of label		

In addition to these test materials, unlabelled BAS 750 F was used as a reference compound.

Test soils

Two batches of German agricultural soil LUFA 5M from LUFA (Landwirtschaftliche Untersuchungs- und Forschungsanstalt, Speyer, Germany) were used in this study and were sampled at a depth of 0-20 cm. Soil batch 13/1651/03 was used for the triazole-labelled test and batch 13/1651/02 was used for the chlorophenyl-labelled test; the experiments were not carried out at the same time. Given the similarity in the amount of photolysis observed (see 'results and discussion' section below) between the two experiments, the RMS is of the opinion that the differing soil parameters and the fact that the experiments were conducted at different times, had little effect on the outcomes of the study. Therefore, on this occasion, the RMS accepts the Applicant's approach.

After collecting the soil from the field, the soil was kept at room temperature until sieving. The Applicant states that the soil sampling was undertaken in accordance with OECD 307 guidelines and that no pesticides were used at the sites for, at least, the preceding 5 years. The soils were then passed through a 2 mm sieve, remoistened to approximately 8-12% soil moisture and stored at approximately 4 °C in the dark for < 3 months before use. An overview of soil parameters is listed in Table 8.1.1.5-2.

Table 8.1.1.5-2: Soil characteristics

Soil designation	**LUFA 5M** **BASF soil No. 13/1651/03** Germany (Origin LUFA Speyer)	**LUFA 5M** **BASF soil No. 13/1651/02** Germany (Origin LUFA Speyer)
GPS coordinates	N 49'16'19.33; E 8'24'13.77	N 49'16'19.33; E 8'24'15.77
DIN 4220 Particle size distribution *[%]* sand 0.063 – 2 mm silt 0.002 – 0.063 mm clay < 0.002 mm textural class	 54.6 33.5 11.9 loamy sand	 80.0 13.9 6.1 loamy sand
USDA Particle size distribution *[%]* sand 0.050 – 2 mm silt 0.002 – 0.050 mm clay < 0.002 mm textural class	 59.0 29.1 11.9 sandy loam	 82.8 11.1 6.1 loamy sand
Organic C *[%]*	2.08	2.03
Organic matter *[%]*[a)]	3.59	3.50
pH [H_2O]	7.9	7.9
pH [$CaCl_2$]	7.1	7.2
Cation exchange capacity *[$cmol^+ kg^{-1}$]*	11.4	11.4
Max. water holding capacity *[g per 100 g dry weight]*	25.6	25.2
Microbial biomass (start of study) *[mg C per 100 g dry soil]*	29.9	26.5

a) Organic matter = Organic C * 1.724

The RMS notes that the OECD guidelines state that a silty loam or clay loam soil, rather than a sandy soil (which the Applicant has used), should be selected. However, because the Applicant indicates the moisture of the soil was maintained throughout the study period, the RMS is of the opinion that this deviation from the guidelines did not have a significant impact on the validity of the study.

Experimental setup

The chlorophenyl-labelled test item was dissolved in 5 mL acetonitrile to create a stock solution containing 0.99 mg/mL a.s.. An application solution was prepared by dissolving 1.6 mL of the stock solution in 10 mL acetonitrile. The triazole-labelled test item was also dissolved in 5 mL acetonitrile to create a stock solution

containing 1.53 mg/mL a.s.. An application solution was prepared by dissolving 1.02 mL of the appropriate stock solution in 10 mL acetonitrile. The RMS accepts the use of acetonitrile because of the low water solubility of BAS 750 F.

Ten small aluminium dishes (88 mm x 43 mm x 12 mm) were filled with 30 g dry soil for the photolysis test and a further 10 dishes for the dark control test. The RMS notes that, according to the RMS's calculations, the Applicant was able to obtain a ~5mm layer of soil on the plate, assuming a bulk density of the soil of 1.5 g/cm^3 and an even distribution. The OECD guidelines state a 2mm layer of soil should be used. Therefore, the light might not have been able to penetrate to the bottom of the samples, meaning less photolysis is likely occur than if a shallower soil layer had been used. However, given that only very minor soil photolysis was observed (see 'Results and discussion' section below), the RMS is of the opinion that, although this deviation from the guidelines might have had a slight impact on the results, it was not enough to significantly affect the outcomes of the study.

The dishes were arranged in a rectangular bowl with a connected thermostat. The temperature of the dishes used for photolysis was adjusted and controlled by an external tempering unit (22 °C ± 1 °C) while the dishes for the dark control were put into an incubator at 22 °C ± 1 °C. The RMS notes that the OECD guidelines state the test systems should be kept at a constant temperature of 20 °C ± 2 °C; however, this slight deviation from the guidelines is not deemed significant enough to effect the outcomes of the study.

The test soils were adjusted to 60% of the maximum water holding capacity (MWHC). The RMS notes that the OECD guidelines state the soils should be kept at 75% MWHC; however, this slight deviation from the guidelines is not deemed significant enough to affect the outcomes of the study. The RMS notes that the OECD guideline suggests to additionally test completely dry soils. However, because BAS 750 F is hydrolytically stable (see section B.8.2.1.1), the RMS is of the opinion that further testing of dry soils is unlikely to result in significantly different conclusions.

The test soils were applied with the test item at a concentration corresponding to a proposed field application rate of 150 g/ha; the RMS deems this appropriate as this value is in line with the proposed application rate in the CP dossier. To achieve this application rate, 188 µL of the chlorophenyl-labelled application solution and 186 µL of the triazole-labelled application solution were applied to the appropriate soil dishes. The radiolabels were applied to separate test vessels. This equates to approximately 30 µg per dish, and therefore, 1 mg a.s./kg dry soil. Assuming a soil layer of 1 cm and bulk density of 1.5 g/cm^3, this equates to a field application rate of 150 g a.s./ha; the RMS notes that PEC_{soil} values are generally based on a soil layer of 5 cm (not 1 cm) giving an application rate of 750 g a.s./ha, however, this is not expected to have a significant effect on the conclusions of the study.

The incubation bowl was closed airtight with a quartz glass cover and the whole setup was continuously aerated with CO_2-depleted (0.5 M NaOH), and remoistened air via an air inlet and outlet. The OECD guidance states that the solvent should be evaporated from the soil thin-layers prior to the start of the irradiation process, however, the study does not state whether this was undertaken. However, even if this had not been undertaken, the RMS is of the opinion that the levels of photo-degradation observed would not have been significantly different, therefore, this would not have significantly affected the outcome of the study.

In order to trap potential volatiles (including $^{14}CO_2$), the emergent air was bubbled through three different trapping solutions: NaOH (0.5 M), ethylene glycol and H_2SO_4 (0.5 M).

The incubation bowl for photolysis was placed under a SUNTEST CPS plus (Atlas) equipped with a Xenon lamp emitting light with a spectrum similar to the intensity of sunlight, about 3 mW cm^{-2} (UVA range) and irradiated continuously. This corresponds to a clear summer day in Southern Germany (approximately 49° N). Wavelengths < 290 nm were filtered off (wavelength range 290 - 800 nm) to simulate natural sunlight. The RMS notes that the OECD guideline states to filter wavelengths <295 nm, however, this slight deviation from the guidelines is not expected to impact on the conclusions of the study.

To maintain the temperature, especially on the quartz glass surface to avoid rapid drying of the soil surface, the air space between the lamp and quartz glass was cooled by an air conditioning unit (Yeti, Seveso). The RMS notes that the OECD guidance states to pump cooling water through the base of the tank to control the temperature of the soil-coated plates; however, the Applicant has supplied a log of the recorded temperatures of the soil throughout the study period and the temperatures of the systems were maintained at a range of ~21.5 °C

to 22.5 °C. Therefore, the RMS is of the opinion that this deviation did not have a significant effect on the outcomes of the study.

To maintain the initial water content, the dishes were weighed at each incubation day and evaporated water was replaced.

Sampling was undertaken at 0, 1, 3, 6, 10 and 15 days after treatment (DAT) for chlorophenyl-labelled BAS 750 F and 0, 1, 3, 7, 10 and 15 DAT for triazole-labelled BAS 750 F. Two vessels were taken at each sampling time from each photolysis test system and the dark control (with exception of day 0, where no dark control samples were taken). At each sampling time, the respective volatile trapping solutions were removed.

For the day 0 samples, the soil was directly weighed in centrifuge cups and the appropriate amount of application solution (188 µL for the chlorophenyl-label and 186 µL for the triazole-label respectively) was directly added prior to analysis.

Analytical methods

Each soil sample was consecutively extracted three times with 40 mL of acetonitrile and twice with 40 mL of acetonitrile/water (1:1, v/v). For each extraction step, the suspension was shaken for 30 minutes. After each extraction step, solid and extract were separated by centrifugation at 13000 rpm for 10 minutes and then filtered. The three corresponding acetonitrile and two acetonitrile/water extracts were combined and measured for radioactivity by liquid scintillation counting (LSC).

After the last extraction, the soil residues were air-dried and stored at room temperature. For the determination of the amount of non-extractable residues (NER) by combustion, the residues were homogenised by milling. Three aliquots of each sample (up to 1 g) were combusted in a sample oxidiser and the trapped $^{14}CO_2$ was then analysed by LSC.

Further analysis was undertaken on the samples which recorded non-extractable residues >5% of the total applied radioactivity (TAR) to separate the humic and fulvic acids from the humin. The samples were extracted three times with 0.5 M NaOH on a rotary shaker (180 rpm for 7 hours) and then centrifuged (4500 rpm for 20 minutes). The supernatant of each sample was decanted and filtered into a volumetric flask. The soil residue was then washed twice washed with 25 mL water, centrifuged and the water decanted and filtered into a volumetric flask. All extracts were analysed by LSC and pooled together, representing both the fulvic and humic acid fraction. Since the amount of radioactivity did not exceed 5% TAR, no acidic precipitation of the fulvic acids was performed.

The soil residue after the last washing was air-dried, homogenised and the weight was determined. Three aliquots were combusted and analysed by LSC in order to determine the amount of radioactivity in the non-soluble humins.

The day 0 and day 15 samples for the two labels were characterised on a chiral HPLC column to verify the enantiomeric composition of the test substance. All samples were measured for radioactivity by LSC and were then analysed by HPLC to determine the metabolite pattern. A HPLC system consisting of, amongst other things, a HPLC DAD (G1315D – Agilent) was used for the main study analysis and a HPLC UV – Detector (UV-1575 – Jasko) was used for the chiral analysis.

The Applicant states that no specific calculation was conducted to determine the LOD or LOQ of the analytical procedure and that, due to the measured residue levels of BAS 750 F, LOD and LOQ were not considered in the kinetic evaluation. The RMS accepts the Applicant's justification.

The Applicant states that all samples were analysed as soon as possible. For storage, organic extracts and soil samples were kept in a freezer. The soil samples were stored in a hood at room temperature for drying prior to combustion. The RMS notes that the Applicant's description of storage time and conditions is rather vague. However, as shown in the storage stability tests (see methods of analysis section of the DAR (B.5.)), BAS 750 F is stable. Furthermore, the material balances recovered (see section below) are in excess of the lowest OECD recommended level of 90% TAR, therefore, there is no evidence of loss of residues.

Results and discussion

Mass balance

Total recoveries of radioactivity extracted from the soils are summarised in tables 8.1.1.5-3 to 8.1.1.5-6. The overall mean values for the material balance in the photolysis and in the dark control were in the range of 100.0 - 104.4% TAR; no samples recorded values outside the OECD recommended range of 90 - 110% TAR.

Carbon dioxide was the only volatile degradation product found in the trapping solutions. After 15 days of treatment, 3.5% TAR (chlorophenyl label) and 0.3% TAR (triazole label) were mineralised in the photolysis test and 1.2% and 0.1% TAR in the dark control.

Table 8.1.1.5-3: Recovery and distribution of radioactivity in soil LUFA 5M after treatment with chlorophenyl-^{14}C-labeled BAS 750 F and incubation under irradiated conditions [% TAR]

DAT	ACN	ACN/water	total extractable	non-extractable	volatiles*	material balance
0/I	92.4	4.4	96.8	1.2	0.0	97.9
0/II	96.7	4.3	101.0	1.1	0.0	102.1
0 mean	**94.5**	**4.4**	**98.9**	**1.1**	**0.0**	**100.0**
1/I	96.0	2.3	98.3	2.7	0.1	101.1
1/II	95.2	2.0	97.2	2.5	0.1	99.6
1 mean	**95.6**	**2.2**	**97.7**	**2.6**	**0.1**	**100.4**
3/I	96.7	2.3	99.0	3.4	0.2	102.6
3/II	97.4	2.7	100.1	3.5	0.2	103.7
3 mean	**97.1**	**2.5**	**99.5**	**3.4**	**0.2**	**103.2**
6/I	94.8	3.0	97.9	3.6	0.3	101.8
6/II	94.4	2.9	97.4	4.5	0.3	102.2
6 mean	**94.6**	**3.0**	**97.6**	**4.1**	**0.3**	**102.0**
10/I	91.7	2.7	94.4	4.2	0.6	99.3
10/II	94.6	2.6	97.2	4.6	0.6	102.4
10 mean	**93.2**	**2.6**	**95.8**	**4.4**	**0.6**	**100.8**
15/I	89.6	2.5	92.1	5.2	1.1	98.4
15/II	89.3	2.7	92.1	5.1	1.1	98.3
15 mean	**89.5**	**2.6**	**92.1**	**5.2**	**1.1**	**98.3**

TAR = total applied radioactivity
DAT = days after treatment
ACN = acetonitrile
* no other volatiles than CO_2 were found

Table 8.1.1.5-4: Recovery and distribution of radioactivity in soil LUFA 5M after treatment with chlorophenyl-^{14}C-labeled BAS 750 F and incubation under dark conditions [% TAR]

DAT	ACN	ACN/water	total extractable	non-extractable	volatiles*	material balance
1/I	97.3	3.0	100.3	2.4	0.1	102.8
1/II	97.8	1.8	99.6	2.9	0.1	102.6
1 mean	**97.6**	**2.4**	**99.9**	**2.6**	**0.1**	**102.7**
3/I	96.5	2.7	99.2	3.3	0.2	102.7
3/II	96.1	3.0	99.1	2.9	0.2	102.1
3 mean	**96.3**	**2.9**	**99.1**	**3.1**	**0.2**	**102.4**
6/I	94.9	2.8	97.7	3.2	0.3	101.1
6/II	95.9	2.6	98.4	3.2	0.3	101.9
6 mean	**95.4**	**2.7**	**98.0**	**3.2**	**0.3**	**101.5**
10/I	94.1	3.1	97.2	3.9	0.3	101.4
10/II	95.2	3.0	98.3	3.8	0.3	102.4
10 mean	**94.7**	**3.1**	**97.7**	**3.8**	**0.3**	**101.9**
15/I	94.5	3.3	97.8	4.5	0.4	102.6
15/II	91.7	3.3	95.0	4.7	0.4	100.0
15 mean	**93.1**	**3.3**	**96.4**	**4.6**	**0.4**	**101.3**

TAR = total applied radioactivity
DAT = days after treatment
ACN = acetonitrile
* no other volatiles than CO_2 were found

Table 8.1.1.5-5: **Recovery and distribution of radioactivity in soil LUFA 5M after treatment with triazole-^{14}C-labeled BAS 750 F and incubation under irradiated conditions [% TAR]**

DAT	ACN	ACN/water	total extractable	non-extractable	volatiles*	material balance
0/I	94.7	5.0	99.7	1.1	0.0	100.8
0/II	93.0	5.2	98.2	1.0	0.0	99.2
0 mean	**93.9**	**5.1**	**99.0**	**1.0**	**0.0**	**100.0**
1/I	100.1	1.8	101.9	1.5	0.0	103.4
1/II	100.3	1.8	102.1	1.6	0.0	103.8
1 mean	**100.2**	**1.8**	**102.0**	**1.5**	**0.0**	**103.6**
3/I	97.5	2.2	99.7	2.4	0.1	102.2
3/II	97.0	1.9	98.9	2.6	0.1	101.6
3 mean	**97.3**	**2.0**	**99.3**	**2.5**	**0.1**	**101.9**
7/I	96.3	2.8	99.0	4.0	0.1	103.2
7/II	97.2	2.5	99.7	4.2	0.1	104.1
7 mean	**96.7**	**2.6**	**99.3**	**4.1**	**0.1**	**103.6**
10/I	96.9	2.5	99.4	5.1	0.2	104.7
10/II	96.1	2.5	98.6	5.3	0.2	104.0
10 mean	**96.5**	**2.5**	**99.0**	**5.2**	**0.2**	**104.4**
15/I	94.1	3.3	97.4	7.2	0.3	104.9
15/II	93.4	3.2	96.6	6.5	0.3	103.5
15 mean	**93.8**	**3.3**	**97.0**	**6.9**	**0.3**	**104.2**

TAR = total applied radioactivity
DAT = days after treatment
ACN = acetonitrile
* no other volatiles than CO_2 were found

Table 8.1.1.5-6: Recovery and distribution of radioactivity in soil LUFA 5M after treatment with triazole-^{14}C-labeled BAS 750 F and incubation under dark conditions [% TAR]

DAT	ACN	ACN/water	total extractable	non-extractable	volatiles*	material balance
1/I	99.9	2.5	102.4	1.9	0.0	104.4
1/II	99.7	2.1	101.8	1.6	0.0	103.4
1 mean	**99.8**	**2.3**	**102.1**	**1.8**	**0.0**	**103.9**
3/I	98.6	2.1	100.8	2.5	0.1	103.3
3/II	100.4	2.3	102.7	2.4	0.1	105.2
3 mean	**99.5**	**2.2**	**101.7**	**2.5**	**0.1**	**104.3**
7/I	97.0	2.5	99.5	3.7	0.1	103.3
7/II	97.4	3.1	100.4	3.9	0.1	104.4
7 mean	**97.2**	**2.8**	**100.0**	**3.8**	**0.1**	**103.9**
10/I	96.2	3.3	99.5	4.1	0.1	103.7
10/II	97.4	2.8	100.2	3.8	0.1	104.0
10 mean	**96.8**	**3.0**	**99.8**	**4.0**	**0.1**	**103.9**
15/I	95.5	3.7	99.2	4.7	0.1	104.0
15/II	96.2	3.3	99.5	4.7	0.1	104.3
15 mean	**95.8**	**3.5**	**99.3**	**4.7**	**0.1**	**104.2**

TAR = total applied radioactivity
DAT = days after treatment
ACN = acetonitrile
* no other volatiles than CO_2 were found

Transformation of parent compound

Results of the radio-HPLC analyses are presented in tables 8.1.1.5-7 to 8.1.1.5-10.

After 15 days, the amount of extractable chlorophenyl-labelled BAS 750 F decreased to 87.3% TAR in the photolysis experiment and to 93.1% TAR in the dark control samples. The amount of extractable triazole-labelled BAS 750 F decreased after 15 days to 93.8% TAR in the photolysis experiment and to 95.8% TAR in the dark control samples. The decrease in extractable BAS 750 F was accompanied by an increase in non-extractable residues to 5.2-6.5 % AR in the irradiated samples and 4.6-4.7 % AR in the dark controls.

For both labels, several unknown degradation products were detected in the extracts, but none of them appeared in amounts higher than 1.17% TAR; therefore, further consideration of these degradates is not required.

Table 8.1.1.5-7: Radio-HPLC analysis of soil extracts after treatment of soil LUFA 5M with chlorophenyl-^{14}C-labeled BAS 750 F and incubation under irradiated conditions (sum of ACN extracts) [% TAR]

DAT	Total	BAS 750 F	Unknowns* t_R~								
		t_R~38.1'	38.8'	41.0'	41.2'	41.4'	41.6'	41.8'	42.0'	42.1'	42.2'
0 I	92.36	91.55	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.81
0 II	96.66	95.38	0.59	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.69
0 mean	**94.51**	**93.46**									
1 I	95.97	94.95	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.24	n.d.	0.78
1 II	95.17	94.72	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.45
1 mean	**95.57**	**94.83**									
3 I	96.70	96.15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.54
3 II	97.42	96.25	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.44	0.72
3 mean	**97.06**	**96.20**									
6 I	94.84	93.67	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.17	n.d.
6 II	94.42	93.58	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.39	0.25	0.20
6 mean	**94.63**	**93.63**									
10 I	91.74	90.70	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.04
10 II	94.63	93.17	0.46	n.d.	n.d.	n.d.	n.d.	0.43	0.57	n.d.	n.d.
10 mean	**93.18**	**91.94**									
15 I	89.62	87.42	n.d.	n.d.	0.93	n.d.	n.d.	0.18	n.d.	n.d.	1.09
15 II	89.34	87.14	0.33	0.24	0.20	0.27	0.10	0.21	0.37	n.d.	0.48
15 mean	**89.48**	**87.28**									

ACN = acetonitrile
TAR = total applied radioactivity
DAT = days after treatment
t_R = retention time [min]
n.d. = not detected
* all peaks are shown

Table 8.1.1.5-8: Radio-HPLC analysis of soil extracts after treatment of soil LUFA 5M with chlorophenyl-^{14}C-labeled BAS 750 F and incubation under dark conditions (sum of ACN extracts) [% TAR]

DAT	Total	BAS 750 F	Unknowns* t_R~								
		t_R~38.1'	40.9'	41.0'	41.2'	41.4'	41.6'	41.8'	42.0'	42.1'	42.2'
1 I	97.31	96.83	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.48
1 II	97.81	97.13	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.69
1 mean	**97.56**	**96.98**									
3 I	96.46	96.26	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.20
3 II	96.05	95.66	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	0.18	0.21
3 mean	**96.25**	**95.96**									
6 I	94.87	94.87	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
6 II	95.86	95.86	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
6 mean	**95.37**	**95.37**									
10 I	94.14	92.69	0.09	0.25	0.28	0.25	n.d.	0.41	0.18	n.d.	n.d.
10 II	95.20	95.20	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
10 mean	**94.67**	**93.95**									
15 I	94.47	94.47	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
15 II	91.69	91.69	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
15 mean	**93.08**	**93.08**									

ACN = acetonitrile
TAR = total applied radioactivity
DAT = days after treatment
t_R = retention time [min]
n.d. = not detected
* all peaks are shown

Table 8.1.1.5-9: **Radio-HPLC analysis of soil extracts after treatment of soil LUFA 5M with triazole-^{14}C-labeled BAS 750 F and incubation under irradiated conditions (sum of ACN extracts) [% TAR]**

DAT	Total	BAS 750 F	Unknown*
		t_R~38.6'	t_R~39.0'
0 I	94.69	94.69	n.d.
0 II	98.21**	93.04	n.d.
0 mean	**96.45**	**93.86**	
1 I	100.15	100.15	n.d.
1 II	100.32	100.32	n.d.
1 mean	**100.23**	**100.23**	
3 I	97.51	97.51	n.d.
3 II	97.02	96.87	0.15
3 mean	**97.27**	**97.26**	
7 I	96.25	96.25	n.d.
7 II	97.18	97.06	0.12
7 mean	**96.72**	**96.71**	
10 I	96.95	96.95	n.d.
10 II	96.07	96.07	n.d.
10 mean	**96.51**	**96.51**	
15 I	94.10	94.10	n.d.
15 II	93.40	93.40	n.d.
15 mean	**93.75**	**93.75**	

ACN = acetonitrile
TAR = total applied radioactivity
DAT = days after treatment
t_R = retention time [min]
n.d. = not detected
* only one unknown peak detected
** sum of ACN and ACN/H_2O extracts

Table 8.1.1.5-10: Radio-HPLC analysis of soil extracts after treatment of soil LUFA 5M with triazole-^{14}C-labeled BAS 750 F and incubation under dark conditions (sum of ACN extracts) [% TAR]

DAT	Total	BAS 750 F	Unknown
		t_R~38.6'	t_R~39.0'
1 I	99.92	99.92	n.d.
1 II	99.70	99.70	n.d.
1 mean	**99.81**	**99.81**	
3 I	98.61	98.61	n.d.
3 II	100.42	100.42	n.d.
3 mean	**99.52**	**99.52**	
7 I	97.02	97.02	n.d.
7 II	97.39	97.39	n.d.
7 mean	**97.21**	**97.21**	
10 I	96.25	96.25	n.d.
10 II	97.43	97.43	n.d.
10 mean	**96.84**	**96.84**	
15 I	95.45	95.45	n.d.
15 II	96.21	96.21	n.d.
15 mean	**95.83**	**95.83**	

ACN = acetonitrile
TAR = total applied radioactivity
DAT = days after treatment
t_R = retention time [min]
n.d. = not detected

The Applicant states that the chiral-HPLC analysis of the day 0 and day 15 samples revealed that the enantiomeric composition of both substances did not have any relevant differences in this time period. In chlorophenyl-labelled samples, an unknown peak was observed, with TAR values not exceeding 1.7%; the Applicant has not considered this peak further. Results of chiral HPLC analyses are shown in Table 8.1.1.5-11.

Table 8.1.1.5-11: Chiral HPLC analysis of selected soil extracts after treatment of soil LUFA 5M with chlorophenyl-^{14}C- and triazole-^{14}C-labeled BAS 750 F [% TAR]

DAT	Chlorophenyl-U-^{14}C-BAS 750 F						Triazole-3(5)-^{14}C-BAS 750 F			
	Unknown		*R*		*S*		*R*		*S*	
	t_R~	% TAR	t_R~	% TAR	t_R~	% TAR	t_R~	% TAR	t_R~	% TAR
0d I (PA)	6.30'	1.74	13.30'	45.64	15.53'	44.98	12.06'	48.19	14.13'	46.50
15d I (DC)	6.58'	1.40	13.38'	46.38	15.60'	46.68	12.23'	48.15	14.25'	47.30
15d I (PA)	6.37'	1.26	13.38'	44.89	15.58'	43.47	12.24'	47.29	14.27'	46.81

TAR = total applied radioactivity
DAT = days after treatment
t_R = retention time [min]
PA = photolysis sample
DC = dark control sample

Characterisation of non-extractable residues (NER)

The results of the non-extractable residue characterisation performed by humic substance fractionation are given in tables 8.1.1.5-12 and 8.1.1.5-13. Since the alkali-soluble radioactivity (humic acids) did not exceed 5% TAR, no further separation of fulvic acids was performed.

Table 8.1.1.5-12: Characterisation of NER in soil LUFA 5M after treatment with ^{14}C-BAS 750 F under irradiated conditions [% TAR]

DAT	Position of radiolabel	NER Initial	NaOH extraction	Soil residues after extraction	Sum*
15d I	chlorophenyl-^{14}C	5.2	2.3	2.3	4.6
10d I	triazole-^{14}C	5.1	2.9	1.6	4.5
15d II		7.2	4.2	2.0	6.1

TAR = total applied radioactivity
DAT = days after treatment
*The Applicant states the slight deviations from initial NER values have to be attributed to differing LSC results

Table 8.1.1.5-13: Characterisation of NER in soil LUFA 5M after treatment with ^{14}C-BAS 750 F under dark conditions [% TAR]

DAT	Position of radiolabel	NER Initial	NaOH extraction	Soil residues after extraction	Sum*
15d I	chlorophenyl-^{14}C	4.5	2.0	2.2	4.1
15d I	triazole-^{14}C	4.7	2.3	2.1	4.4

TAR = total applied radioactivity
DAT = days after treatment
*The Applicant states the slight deviations from initial NER values have to be attributed to differing LSC results

Kinetic analysis

The Applicant undertook a kinetic evaluation in order to derive degradation parameters as triggers for additional work (trigger endpoints). Kinetic analysis and calculation of $DegT_{50}$ and $DegT_{90}$ values was performed following the recommendations of the FOCUS Kinetics workgroup [*FOCUS v1.1 (2014)*]. The software package KinGUII (version 2) was used for the parameter fitting. IRLS was selected and the error tolerance and the number of iterations of the optimisation tool were set to 0.00001 and 100 respectively. The RMS has repeated the Applicant's modelling using CAKE v3.2 with OLS selected.

Replicate measurements were considered for the parameter estimation and the initial concentration of the applied test item was set to the material balance recovered at day 0; the RMS agrees with the Applicant's data handling methodology.

For the irradiated samples, as a first step, SFO and FOMC models were run and their visual and statistical fits compared, in line with Figure 7-1 in the FOCUS guidance. For both labels, the SFO and FOMC visual fits were very similar, however, the FOMC model resulted in an unacceptable statistical fit because the alpha and beta standard deviation error values were greater than the estimated parameters. Therefore, the SFO model results were used to derive appropriate triggering endpoints for both labels. The RMS obtained negligible differences in results to the Applicant, therefore, the Applicant's modelling results are presented below (unless otherwise stated). The graphical and statistical results of the SFO and FOMC models are presented in figures 8.1.1.5-1 and 8.1.1.5-2 and tables 8.1.1.5-14 and 8.1.1.5-15 respectively; due to the poor picture quality of the Applicant's kinetic graphs, the RMS's are presented below.

Figure 8.1.1.5-1: **SFO (left) and FOMC (right) graphical results for the chlorophenyl-labelled irradiated samples**

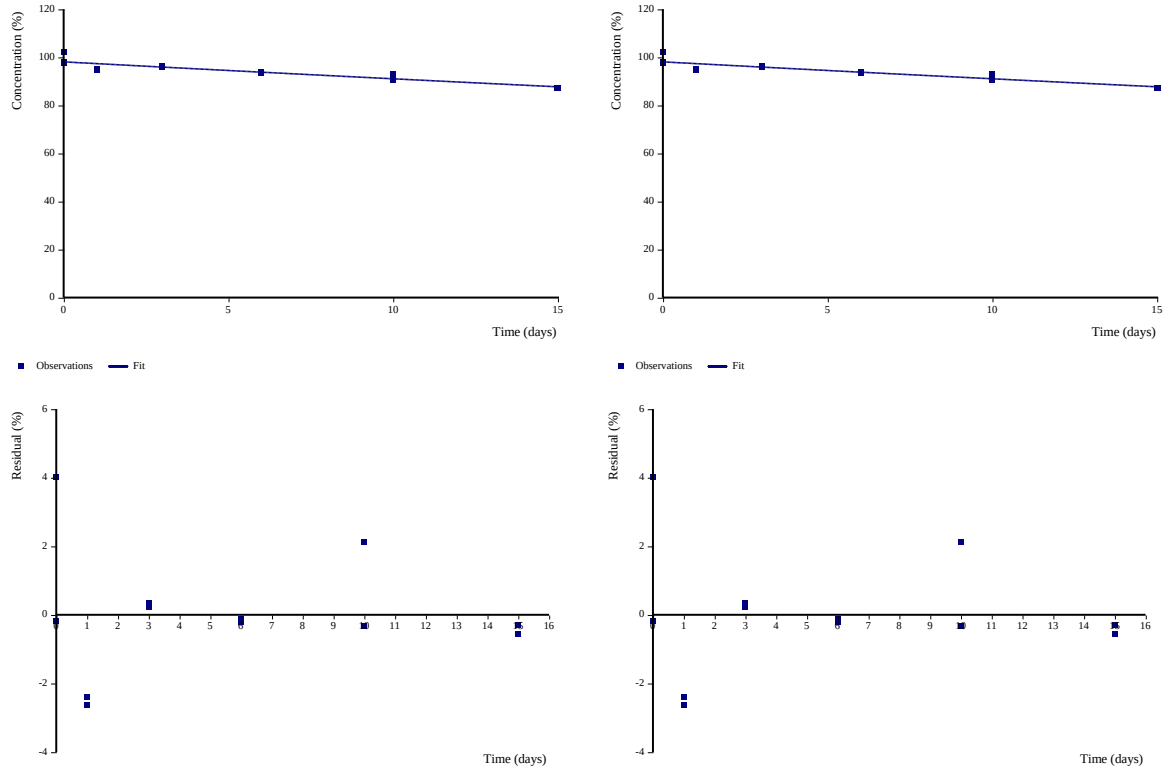


Figure 8.1.1.5-2: **SFO (left) and FOMC (right) graphical results for the triazole-labelled irradiated samples**

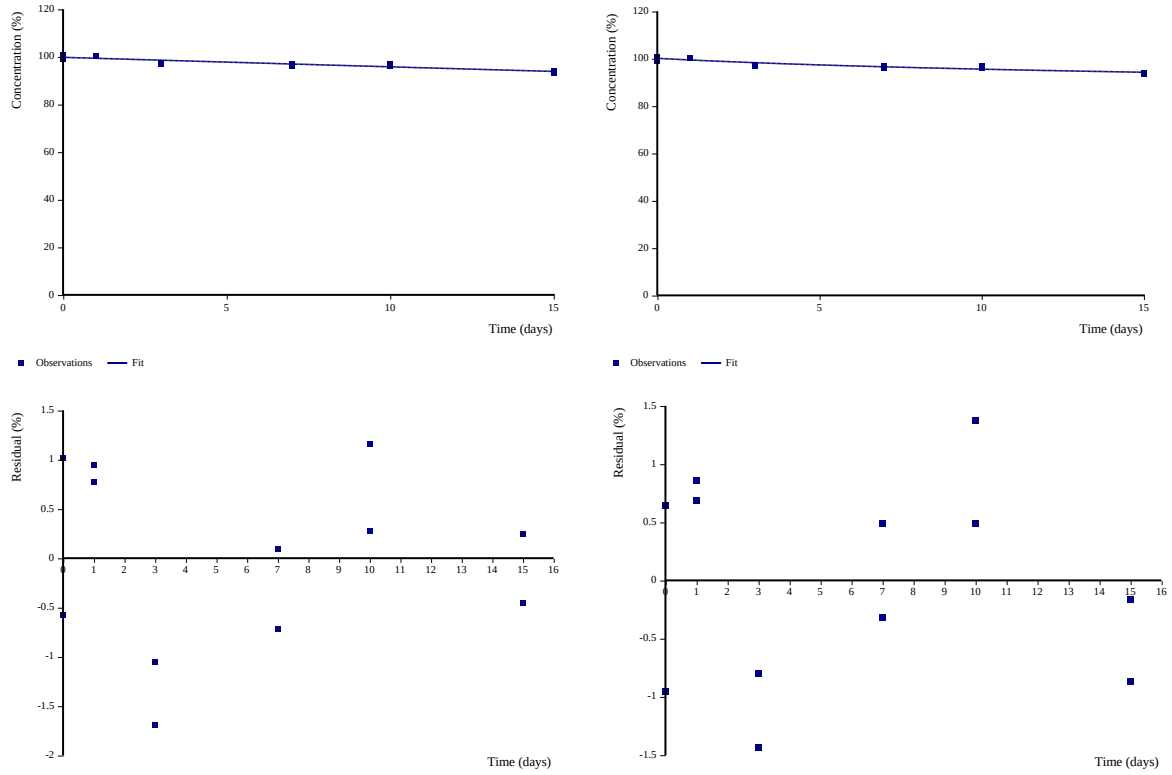


Table 8.1.1.5-14: **Statistical kinetic results of the chlorophenyl-labelled irradiated samples**

Parameter	SFO	FOMC
Visual fit	Very good	Very good
M0	98.1	98.1
K	0.007	n/a
t-test	<0.001	n/a
Alpha (st.dev.)	n/a	45.8 (426.5)
Beta (st.dev.)	n/a	6069 (56610)
χ^2	1.15	1.27
DT_{50}	93	93 (94.3[a)])
DT_{90}	309	313

a) DT_{50} value back-calculated from the DT_{90} value by dividing the DT_{90} by 3.32.

Table 8.1.1.5-15: **Statistical kinetic results of the triazole-labelled irradiated samples**

Parameter	SFO	FOMC
Visual fit	Very good	Very good
M0	99.8	100.2
K	0.004	n/a
t-test	<0.001	n/a
Alpha (st.dev.)	n/a	0.05 (0.06)
Beta (st.dev.)	n/a	7.38 (12.44)
χ^2	0.61	1.27
DT_{50}	170	>1000 ([a)])
DT_{90}	565	>1000

a) No back-calculation was undertaken due to the uncertainty of the DT_{90} value

The Applicant also undertook kinetic analysis on the dark control results for both labels; the same data handling and methodology undertaken for the irradiated results were undertaken for the dark control results also (the irradiated day 0 material balances were used for the dark controls analysis as no day 0 sampling was undertaken on the dark controls in the study).

For both labels, SFO and FOMC results were initially run and compared. In both cases, the FOMC model resulted in an unacceptable statistical fit because the beta standard deviation error values were greater than the estimated parameters. Therefore, the SFO model results were used to derive appropriate triggering endpoints for both labels. The RMS was able to replicate the Applicant's results and deems them appropriate. The graphical and statistical results of the SFO and FOMC models are presented in figures 8.1.1.5-3 and 8.1.1.5-4 and tables 8.1.1.5-16 and 8.1.1.5-17 respectively; due to the poor picture quality of the Applicant's kinetic graphs, the RMS's are presented below.

Figure 8.1.1.5-3: SFO (left) and FOMC (right) graphical results for the chlorophenyl-labelled dark control samples

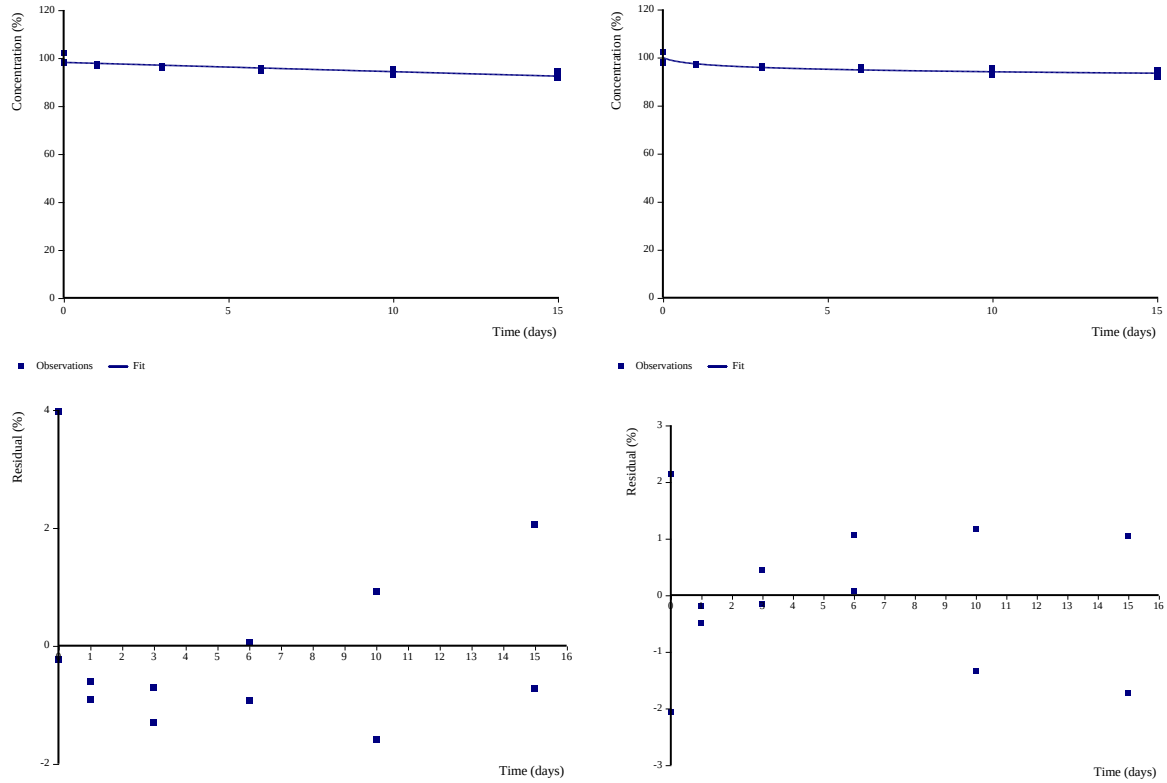


Figure 8.1.1.5-4: **SFO (left) and FOMC (right) graphical results for the triazole-labelled dark control samples**

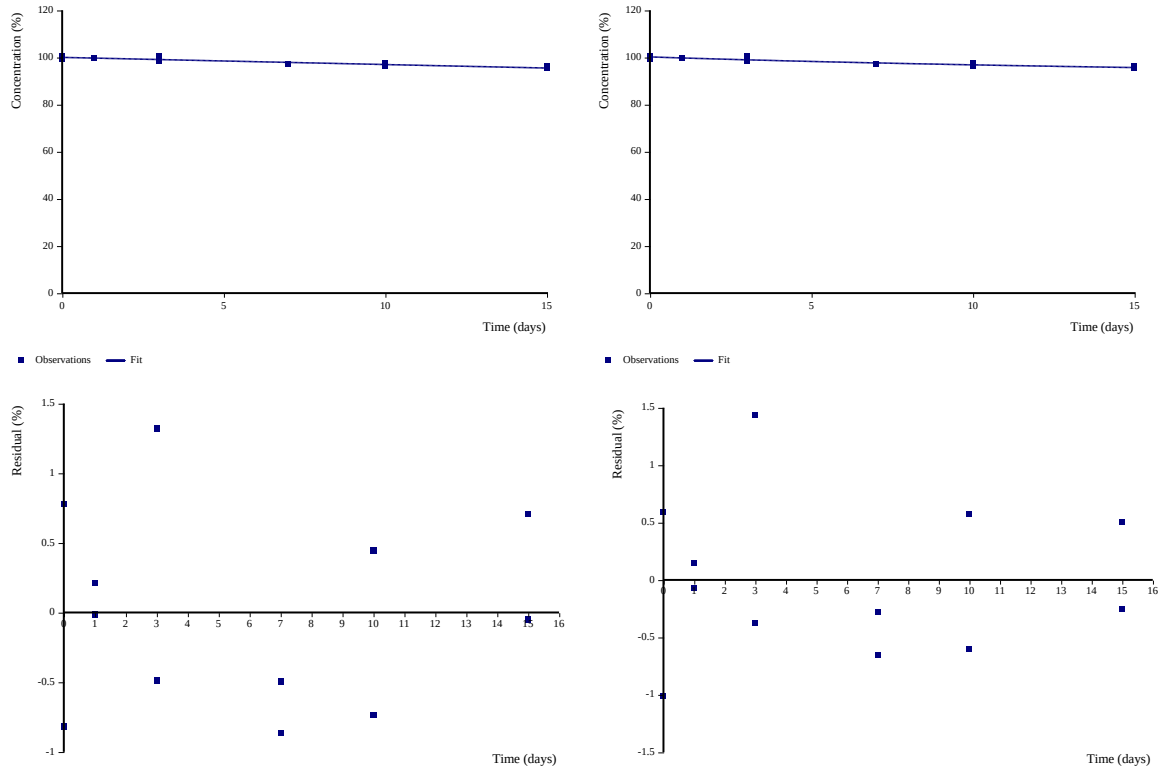


Table 8.1.1.5-16: **Statistical kinetic results of the chlorophenyl-labelled dark control samples**

Parameter	SFO	FOMC
Visual fit	Very good	Very good
M0	98.1	100.0
K	0.004	n/a
t-test	0.001	n/a
Alpha (st.dev.)	n/a	0.16 (0.007)
Beta (st.dev.)	n/a	0.24 (0.42)
χ^2	0.82	0.29
DT_{50}	173	>1000 ([a])
DT_{90}	574	>1000

a) No back-calculation was undertaken due to the uncertainty of the DT_{90} value

Table 8.1.1.5-17: **Statistical kinetic results of the triazole-labelled dark control samples**

Parameter	SFO	FOMC
Visual fit	Very good	Very good
M0	100.0	100.2
K	0.004	n/a
t-test	<0.001	n/a
Alpha (st.dev.)	n/a	0.06 (0.07)
Beta (st.dev.)	n/a	13.6 (22.5)
χ^2	0.29	0.27
DT_{50}	225	>1000 ([a])
DT_{90}	747	>1000

a) No back-calculation was undertaken due to the uncertainty of the DT_{90} value

Therefore, the soil residues for the irradiated and the dark control experiment could both be best described by SFO kinetics. As a result, the triggering endpoints will be the modelling endpoints also, summarised in Table 8.1.1.5-18 and Table 8.1.1.5-19. However, because little degradation was observed for either label in both irradiated and dark control samples, and the predicted DT_{50} values are extrapolated well beyond the study duration, the endpoints below should be viewed with extreme caution.

Table 8.1.1.5-18: Modelling and trigger endpoints for chlorophenyl-labelled BAS 750 F

Test system	DT_{50} *[d]*	DT_{90} *[d]*	Best-fit model	χ^2 error
Irradiated	93.05	309.09	SFO	1.15
Dark control	172.93	574.45	SFO	0.82

Table 8.1.1.5-19: Modelling and trigger endpoints for triazole-labelled BAS 750 F

Test system	DT_{50} *[d]*	DT_{90} *[d]*	Best-fit model	χ^2 error
Irradiated	169.99	564.69	SFO	0.61
Dark control	224.96	747.31	SFO	0.29

The arithmetical mean DT_{50} value of the two radio-labels in the irradiated samples is 131.5 days.

Conversion to natural sunlight

The Applicant has not undertaken conversion of the laboratory irradiation time into days of natural summer sunlight. Therefore, the RMS has undertaken these calculations using the following equation stated in the OECD guidance:

d = (h * r) / (0.75 * 12)
where: d = days of summer sunlight
h = hours of irradiation by the Xenon lamp
r = ratio of intensity (irradiance) of the Xenon radiation to that of summer sunlight
0.75 = correction for diurnal variation of natural sunlight
12 = conversion factor of hours to days

The study lasted 15 days of continuous irradiation which equates to 360 hours (15 * 24). The intensity of the xenon lamp stated by the Applicant was 3 mW/cm^2 which was stated as simulating a clear summer day at Limburgerhof, South Germany (approximately 49° N). Therefore, the irradiance ("r" value) is equivalent to 1. As a result, d = (360 * 1) / (0.75 * 12) = 40 days of summer sunlight at Limburgerhof.

The mean DT_{50} value of 131.5 days can then be corrected to 351 days (131.5 * (40 / 15)) natural sunlight. As this value is greater than the geometric mean DT_{50} value of 200 days calculated from the field dissipation studies (see section B.8.1.1.4), the RMS is of the opinion that photodegradation is likely to play only a limited role in the degradation of BAS 750 F in soil.

Conclusion

Irradiation in the soil photolysis experiments with chlorophenyl-labelled BAS 750 F and triazole-labelled BAS 750 F may show a limited influence of light on the degradation behaviour and metabolite formation in soil, but the data should be interpreted with care due to extrapolation of DT_{50} values well beyond the end of the study. Degradation in the irradiated samples occurred slowly but was generally faster than in the dark controls. No major metabolites were identified in the study.

B.8.1.2. Adsorption and desorption in soil

B.8.1.2.1. Adsorption/desorption of the active substance

Report: CA 7.1.3.1/1
Vasques A.C., 2015 a
Adsorption / desorption behavior of 14C-BAS 750 F on different US, Japanese and European soils
2014/3017870

Guidelines: OECD 106 (2000), EPA 835.1230, POP-PA.1005, SOP-PA.1005, POP-SG. 023 Manual de Radioprotecao da Unidade de Estudos Ambientais

GLP: yes
(certified by Instituto Nacional de Metrologia, Normalizacao e Qualidade Industrial - INMETRO, Rio de Janeiro, Brazil)

Introduction

A batch equilibrium adsorption/desorption study was undertaken for BAS 750 F according to OECD 106 guidelines. The adsorption/desorption characteristics of triazole-3(5)-^{14}C-labeled BAS 750 F were studied in eight different soils (2 US, 1 Japanese and 5 European), representing a range of soil types; in order to provide data for the evaluation of the environmental fate, including the potential for leaching, in the environment. The sampling details and physico-chemical properties of the soils are provided in Table 8.1.2.1-1.

Table 8.1.2.1-1: Soil characteristics

Soil designation	**Indiana**	**New Jersey**	**Obhiro**	**Fiorentino Pog. Ren. 1**	**La Gironda**	**Li10**	**LUFA 5M**	**LUFA 2.1**
Country	USA		Japan	Italy	Spain	Germany		
Abbreviation	IN	NJ	JP	FPR	LG	Li10	L5M	L 2.1
Sampling location/GPS coordinates	N 39 59 09.64 W 85 56 43.80	Latitude: 40.54487 Longitude: 74.99286	N 42 49 54.12 E 143 9 8.69	N 44 44 45.13 E 11 31 08.38	30S 026815 UTM 4108913	N 49 24 30 17 E 08 23 04 09	N 49 16 19.33 E 08 24 15.77	N 49 19 6.52 E 8 23 0.62
Collection date	02/05/2012	23/07/2011	05/10/2010	11/08/2010	18/10/2010	28/04/2011	04/10/2011	27/04/2011
Agricultural history of collection site	See table 8.1.2.1-2							
Collection procedures	Not given	Not given	Not given	Not given	Not given	Not given	Not given	Not given
Sampling depth (cm)	0-15	0-20	0-20	0-20	0-20	0-20	0-20	0-20
Soil arrival date at Applicant	Not given	Not given	27/06/2011	16/08/2010	25/10/2010	28/04/2011	04/10/2011	17/05/2011
Storage conditions	Not given	Not given	20 ± 5 ºC	20 ± 5 ºC	20 ± 5 ºC	20 ± 4 ºC	21ºC	17ºC
Storage duration (from collection date to study commencement (September 16th 2013))	1 year 3 months	2 years 2 months	2 years 11 months	3 years 1 month	2 years 11 months	2 years 5 months	1 year 11 months	2 years 5 months

DIN 4220 Particle size distribution *[%]* sand: 0.063 – 2 mm silt: 0.002 – 0.063 mm clay: <0.002 mm textural class	n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d.	n.d. n.d. n.d. n.d.	41.7 41.6 16.7 loamy sand	48.0 24.3 27.7 sandy clay loam	81.7 13.9 4.3 silty sand	n.d. n.d. n.d. n.d.	89.5 8.2 2.3 sand
USDA Particle size distribution *[%]* sand: 0.050 – 2 mm silt: 0.002 – 0.050 mm clay: <0.002 mm textural class	35 44 21 loam	30 44 26 loam	37.5 37.9 24.6 loam (volcanic ash)	49.4 33.9 16.7 loam	49.2 23.0 27.7 sandy clay loam	83.5 12.2 4.3 loamy sand	58 28 14 sandy loam	90.8 6.9 2.3 sand
Organic C *[%]*	1.22	1.0	3.4	1.00	1.22	0.95	1.10	0.60
Organic matter[a)] (calculated by RMS)	2.10	1.72	5.86	1.72	2.10	1.64	1.90	1.03
pH [H_2O]	5.7	6.8	6.9	8.2	8.3	6.9	7.4	6.5
pH [$CaCl_2$]	n.d.	n.d.	6.1	7.4	7.4	6.2	7.3	5.6
Cation exchange capacity *[$cmol^+ kg^{-1}$]*	11.6	8.3	17.2	11.8	26.3	5.5	10.6	-0.7
Max. water holding capacity *[g per 100 g dry weight]*	41.8	42.6	77.8	29.7	39.2	23.2	35.3	23.1
Microbial biomass (from certificate) *[mg C per 100 g dry soil]*	7.22	5.86	n.d.	n.d.	n.d.	23.6	11.69	n.d.

n.d. = not determined a) organic matter = organic carbon x 1.724

Table 8.1.2.1-2: Pesticide history of sampling sites

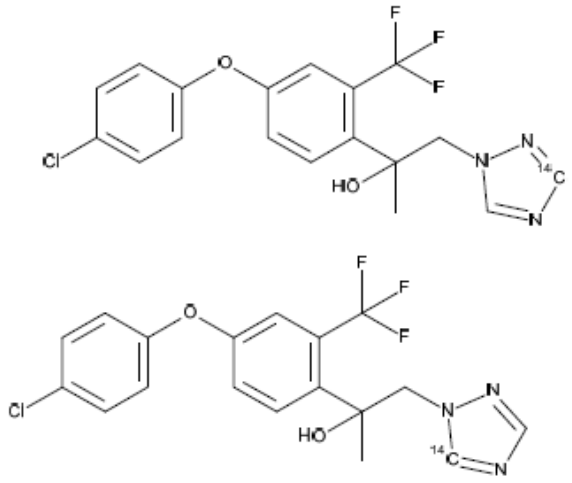
Soil	Year					
	2011	**2010**	**2009**	**2008**	**2007**	**2006**
IN	Anthem, Roundup	Balance, Harness, Surpass	Roundup	Lumax, Roundup, Distinct	Dual, Sencor, Quadris, Select, Sandea, Bravo W.Stik, Pounce	Balance Pro, Bicep II Magnum
NJ	None	None	None	None	None	None
JP	n/a	Pay-off ME	Silvacur	Frowncide, Prowl, Silvacur	Prowl, Gesaprim, Admire, Frownicide	Betanol EC, PAC, Orthene, Dithane M-45, Pay-off ME, Amilster, Plandom, Monceren
FPR	n/a	Glyphosate	Glyphosate	None	Terbuthylazine propachlor	Imazamox
LG	n/a	None	None	None	None	None
Li10	None	None	None	None	None	Not given
L5M	None	None	None	None	None	Not given
L2.1	None	None	None	None	None	Not given

The RMS notes there are issues with some of the soils used in this study (as can be seen in tables 8.1.2.1-1 and 8.1.2.1-2). The Obhiro soil (from Japan) is volcanic ash which, generally, is not appropriate for use in sorption studies in the EU. Documentation for the IN, JP and FPR soils provided by the Applicant indicated that pesticides had been applied to the soils in the preceding years before it was sampled. On transportation to the Applicant's laboratory in Brazil, the LG soil was quarantined at the Brazilian border by the Ministry of Agriculture, Livestock and Supply (Ministério da Agricultura, Pecuária e abastecimento). The soil was analysed for insects, bacteria, fungi, nematodes and weeds and was then sterilised by autoclave at 121ºC for two hours

before successful importation into the country. This process was not undertaken for the other soils. Further discussion on the implication of these issues is provided in the "discussion" section below.

Information on the ^{14}C-labelled test compound is included in table 8.1.2.1-3.

Table 8.1.2.1-3: Test compound details

Chemical formula	$C_{18}H_{15}ClF_3N_3O_2$
Chemical name	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molecular weight	397.78 g mol^{-1} (unlabeled)
Site of radiolabel	triazole-3(5)-^{14}C
Specific radioactivity	5.46 MBq mg^{-1}
Radiochemical purity	98.8%
Chemical purity	98.9%
Water solubility	Not given in report (stated as being 0.81 mg/L at 20ºC, pH 6.8 in the phys-chem section)
Structural formula[6] (^{14}C denotes position of label used)	

The test equipment used in this study is shown in table 8.1.2.1-4.

Table 8.1.2.1-4: Test equipment details

Test container	Centrifuge glass tubes with screw cap, volume: 43 mL
Temperature	Temperature controlled room; 20 ± 2 °C
Agitation	Horizontal on a mechanical shaker; 150 rpm
Parallel batches	2 replicates
Separation	Centrifuge; 2500 rpm for 10 minutes

In order to prepare the treatment solutions, the test item was diluted in 3 mL of acetonitrile to create a stock solution. From this, five concentrations of treatment solution, covering three orders of magnitude (1.0, 0.5, 0.1, 0.05 and 0.01 mg/L (named ST…A-E)), were created. For example, treatment solution A (STA) was prepared by taking an aliquot of 40.8 µL of the stock solution and diluting it to 200 mL with 0.01 mol/L aqueous $CaCl_2$. solution.

Tier 1: Preliminary Tests

Preliminary tests were conducted to determine the conditions of the definitive experiment. Preliminary studies included the stability of the test substance, adsorption of the test substance to test vessels, calculation of appropriate soil to solution ratios and adsorption and desorption equilibrium times. All experiments were performed in duplicate.

[6] Figure taken from Report CA 7.2.1.2/1 Zhixing Y., 2015a, "Aqueous photolysis of 14C-BAS 750 F" because the figure is clearer than that provided in the Vasques adsorption/desorption study report.

The radiochemical purity of the solution with the highest concentration, STA (1.0 mg/L), was determined by Radio-HPLC at the beginning of the study and monitored throughout. In order to demonstrate the stability of the test item in the working solutions, the solutions were analysed by radio-HPLC and the chromatograms were evaluated for the formation of any degradation products.

To determine if adsorption of the test substance to the test vessel (centrifuge glass tubes) occurred, the Applicant undertook a preliminary experiment using STA (1.0 mg/L) (without soil). The samples were analysed after 24 and 48 hours shaking, the results are given in table 8.1.2.1-5.

Table 8.1.2.1-5: Glassware adsorption Tier 1 test

Tube material	Test solution	Test period	Recovery (%)	Average recovery (%)	Average adsorption (%)
Glass	STA	24 hours	94.2	95.3	4.7
			96.3		
			99.5	101.9	-1.9
			104.2		
		48 hours	95.0	95.0	5.0
			95.1		
			101.2	102.8	-2.8
			104.4		

To demonstrate whether the test item was stable during the shaking for the test period, a control test, consisting of aliquots of STA (without soil), was shaken for 48 hours. After 48 h shaking, the solution was analysed by Radio-HPLC. From the control run, it was demonstrated that the test item in 0.01 mol/L $CaCl_2$ solution (without soil), shaken at 150 rpm for 48 hours, was stable.

The soil to solution ratio to be used for the main experiment was investigated using the soils JP and FPR at the highest test substance solution concentration (1.0 mg/L). Adsorption experiments were conducted by the 'indirect' method with duplicate vessels prepared at soil:solution ratios of 1:1, 1:5 and 1:10. The vessels were mixed at approximately 20°C for 24 hours in the dark. The solutions were then separated by centrifugation and analysed by liquid scintillation counting (LSC) and radio-HPLC.

A soil:solution ratio of 1:10 was chosen for the definitive test because this ratio provided adsorption amounts higher than 50%, but still enabled enough radioactivity in both phases (soil and solution) for accurate measurements (the mean % adsorption at this soil:solution ratio was 83.0% and 70.5% for soil JP and soil FPR respectively).

In addition to the treated samples, a blank run per soil was carried out in centrifugation tubes containing only soil and 0.01 mol/L aqueous $CaCl_2$ solution (without test item) and controls containing only STA (without soil). The samples were shaken for 48 hours, after which, they were weighed to enable the calculation of mass recoveries.

The extraction procedure for BAS 750 F consisted of three consecutive extractions of 2 g of the soil samples (after the removal of supernatant) with 20 mL of methanol and a further two extractions with 20 mL of methanol/water 1/1 (v/v) solution. At each extraction, the tubes were closed and then shaken horizontally on a mechanical shaker at 250 rpm for 30 minutes, then they were centrifuges at 2500 rpm for 10 minutes and the extracts were isolated.

The total aqueous phase considered in the calculations included the supernatant decanted from the soil after centrifugation and the remaining solution volume in the soil. To determine the solution volume in soil before extraction, soil samples were weighed before treatment, after treatment and after the removal of supernatant. The soils dried weights were used for the calculations.

Equilibration time experiments were performed with each soil at a soil:solution ratio of 1:10 at the highest proposed test substance concentration (1.0 mg/L). The test was done with five duplicates (one for each sampling time), in line with the parallel method. After intervals of 4, 8, 24, 32 and 48 hours the samples were removed and centrifuged. Supernatants were measured by LSC. Soils incubated for 48 hours were extracted; extracts and

supernatants were analysed by LSC and (for 48 h samplings) radio-HPLC. The results are given in table 8.1.2.1-6.

Table 8.1.2.1-6: Results of Tier 1 equilibrium test

Test item	Soil	Adsorption of the test item on soil (% adsorbed)				
		Shaking period (h)				
		4	8	24	32	48
^{14}C-BAS 750 F	IN	62.1	72.5	80.9	82.4	82.7
	NJ	61.9	72.4	75.5	76.8	78.9
	JP	81.7	88.0	90.0	91.2	92.2
	FPR	67.0	72.2	74.9	76.6	78.7
	LG	51.9	56.2	65.3	70.2	74.4
	Li10	68.0	69.6	73.9	72.7	74.6
	L5M	66.2	69.6	70.3	71.8	74.3
	L2.1	58.6	67.5	70.4	68.6	71.2

For all soils, except soil La Gironda, equilibrium was achieved within 24 hours. For soil La Gironda, adsorption equilibrium was not observed before 48 hours shaking. Therefore, for this soil, the test period used for the definitive, Tier 3, test was 48 hours (24 hours was selected as the equilibration time for the other soils).

The RMS notes that the Applicant provided confusing, and seemingly conflicting data, in regards to this equilibration test. Uncertainty surrounding the application amounts of BAS 750 F used in the test (the Applicant seemingly states an application amount of 21.1 µg was used but then goes onto state a value of 19.3 µg was used), whether direct and/or indirect calculation methods were used in the test and to the impact of small levels of unknown compounds detected in the HPLC analysis. However, in this instance, the RMS is of the opinion that, despite the confusion as to the exact methodology used in the equilibrium test, the test results are sufficient to indicate that an appropriate soil:solution ratio and length of equilibration time were used in the Tier 3 experiment.

The Applicant did not undertake Tier 2 experiments, stating these was not required as soils were pre-selected and a range of concentrations were investigated under Tier 3.

Tier 3: Adsorption and Desorption Isotherms

A soil:solution ratio of 1:10 and equilibration time of 24 hours was chosen for the main experiment for all soils, except for La Gironda soil, which was equilibrated for 48 hours.

Portions of the eight soils were weighed into centrifuge tubes. The soils were treated with the test item dissolved in 0.01 M $CaCl_2$ solution to achieve nominal concentrations of 1.0, 0.5, 0.1, 0.05 and 0.01 mg/L in the test vessels. The test was conducted in duplicate at each test substance concentration. Controls were prepared with only the treatment solution (no soil) in the tube and soil blanks were prepared by weighing soil in the tube and applying 0.01 M $CaCl_2$ solution (no test item). Following application, the vessels were mixed and stored at 20 ± 2°C in the dark for the equilibration time of 24 hours (La Gironda 48 hours). At the end of the equilibration period, each sample tube was centrifuged to separate the phases. No added filtration step was included to determine if particles >0.2 µm were removed from the solution (as indicated by the OECD 106 guidelines). The Applicant states that the centrifugation procedure is assumed to be suitable to remove particles >0.2 µm, however, if any particles were to remain then adsorption would be underestimated resulting in a more conservative risk assessment. The RMS accepts the Applicant's justification. The supernatants and extracts were analysed by LSC and radio-HPLC.

Following the adsorption procedure, fresh 0.01 M $CaCl_2$ solution was added to each vessel to replace the solution removed, including the sample blanks. The soil:solution mixtures were then mixed again for 24 hours (La Gironda 48 hours) equilibration time under the same conditions as described for adsorption. Solution and soil were separated by centrifugation. After each centrifugation, the supernatant solution was analysed by LSC and radio-HPLC; this process is referred to as desorption I. Another desorption step was performed with the soil samples left from desorption I (referred to as desorption II).

Results

The Applicant has supplied mass balances for the Tier 3 test for the STA samples. These are summarised in table 8.1.2.1-7. Adsorption to soil percentages between 63.7% (soil LG) and 85.3% (soil JP) were observed for the STA samples; these values are in line with OECD 106 guidance which states adsorption values >50% are preferential. The RMS notes that the mass balances are represented as %TAR, as opposed to %^{14}C-BAS 750 F. Given minor levels of unknown compounds were detected in the analysis (summed ~3.6%), the RMS notes that this could mean recoveries of BAS 750 F drop below the OECD recommended recovery percentage of 90%. However, the RMS is of the opinion that this is unlikely to affect the outcomes of the study to an extent where it would affect the resulting risk assessment.

Table 8.1.2.1-7: Mass balances from STA tier 3 samples

Soil	%TAR supernatant Adsorption	%TAR supernatant Desorption I	%TAR supernatant Desorption II	%TAR Extract	%TAR Combustion	Sum %TAR	Average % TAR
IN	14.8	8.7	5.1	56.4	6.75	91.8	91.7
	15.2	9.7	5.4	55.1	6.72	91.6	
NJ	19.7	10.5	6.0	46.8	8.43	91.5	91.4
	21.2	10.4	5.9	45.5	8.40	91.3	
JP	7.1	3.8	2.1	74.5	3.99	91.5	91.9
	7.1	4.0	1.8	75.2	4.25	92.4	
FPR	20.8	10.8	5.3	45.9	8.21	91.0	91.5
	21.1	10.9	5.2	46.4	8.35	91.9	
LG	26.9	14.6	8.4	45.3	-	95.2	92.8
	26.7	12.9	9.3	41.5	-	90.4	
Li10	23.4	12.7	7.0	47.8	1.34	92.2	92.7
	24.0	12.2	6.7	48.8	1.36	93.1	
L5M	23.0	12.5	6.3	46.7	2.45	91.0	91.9
	23.8	12.4	6.2	47.8	2.58	92.7	
L2.1	24.6	12.2	6.8	46.7	1.88	92.3	92.5
	24.6	11.8	6.7	47.9	1.75	92.7	

Adsorption isotherm testing for BAS 750 F resulted in Freundlich adsorption coefficients (K_F^{ads}) for the eight soils in the range of 24.53 to 126.14 mL/g, resulting in organic carbon normalised values (K_{FOC}^{ads}) from 2010 to 4931 mL/g.

Desorption isotherm testing for BAS 750 F resulted in Freundlich desorption coefficients for the eight soils in the range from 39.10 to 183.03 mL/g (K_F^{des1}) for the first desorption step and in the range from 60.02 to 300.82 mL/g (K_F^{des2}) for the second desorption step. The organic carbon normalized values ranged of 3205 to 7641 mL/g (K_{FOC}^{desI}) and from 4920 to 11019 mL/g (K_{FOC}^{desII}).

A summary of the experimental results is provided in table 8.1.2.1-8.

Table 8.1.2.1-8: Summary of adsorption and desorption isotherms tests of BAS 750 F on eight soils

Soil Name	Soil Type (USDA)	pH (H_2O)	Org. C [%]	Adsorption			Desorption I			Desorption II		
				K_F [mL/g]	1/n [-]	K_{FOC} [mL/g]	K_F [mL/g]	1/n [-]	K_{FOC} [mL/g]	K_F [mL/g]	1/n [-]	K_{FOC} [mL/g]
Indiana	Loam	5.7	1.22	48.46	0.95	3972.29	60.57	0.87	4964.39	82.77	0.85	6784.21
New Jersey	Loam	6.8	1.00	35.61	0.96	3560.75	55.12	0.92	5512.06	71.09	0.86	7109.39
Obhiro	Loam	6.9	3.40	126.14	1.01	3709.90	183.03	0.94	5383.27	300.82	0.89	8847.69
FPR	Loam	8.2	1.00	31.43	0.92	3143.03	46.47	0.88	4647.21	72.15	0.83	7214.67
La Gironda	Sandy clay loam	8.3	1.22	24.53	0.94	2010.28	39.10	0.93	3205.28	60.02	1.07	4919.91
Li10	Loamy sand	6.9	0.95	36.34	1.02	3824.78	44.63	0.90	4697.83	60.96	0.87	6417.22
LUFA 5M	Sandy loam	7.4	1.10	35.83	1.00	3251.56	46.59	0.89	4228.21	60.17	0.82	5460.28
LUFA 2.1	Sand	6.5	0.60	29.59	1.00	4930.94	45.85	0.92	7640.87	66.11	0.90	11019.15
Arithmetic mean	-	-	**1.31**	**45.99**	**0.975**	**3550.44**	**65.17**	**0.91**	**5034.89**	**96.76**	**0.89**	**7221.57**
Geometric mean	-	-	**1.16**	**39.93**	**0.974**	**3455.59**	**56.64**	**0.91**	**4901.29**	**81.03**	**0.88**	**7012.63**

Discussion

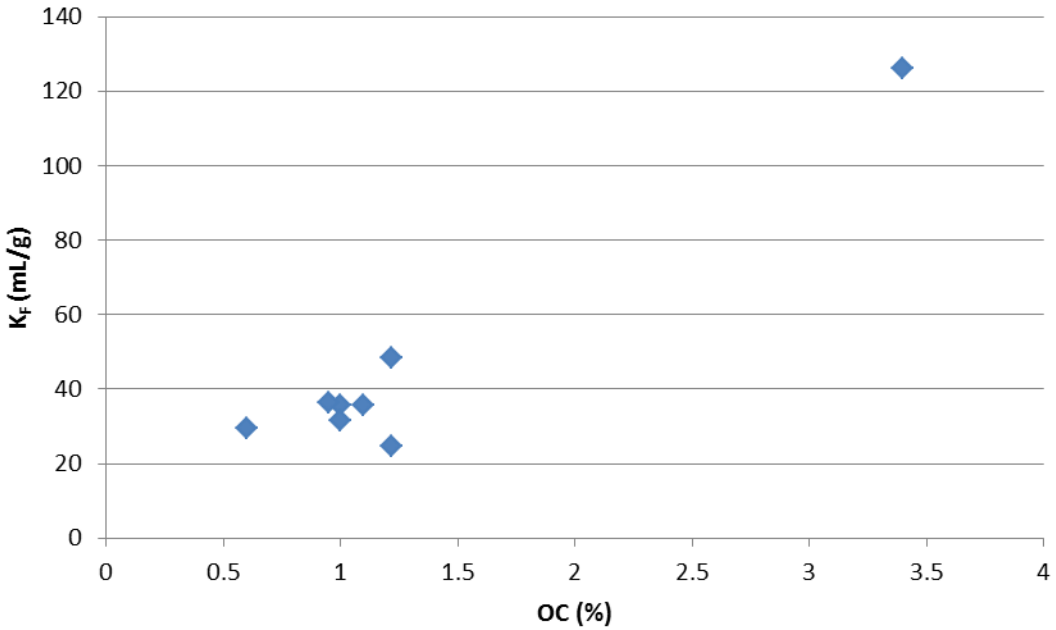
As noted after tables 8.1.2.1-1 and -2, there were issues with a number of the soils used in this study. The JP (Obhiro) soil is volcanic ash which is not generally accepted as an appropriate soil to use in European evaluations. However, the adsorption results of soil JP are in line with those observed for the other soil types; the mean K_{FOC} value excluding soil JP is 3527.066 mL/g. Therefore, the RMS is of the opinion that the JP soil results are, on this occasion, valid and appropriate for use in this European evaluation.

The RMS notes that, ideally, the soils used in sorption studies would not have had pesticides applied to them in the preceding years, prior to sampling. The RMS also notes that Silvacur, applied to soil JP in 2008 and 2009, contains tebuconazole as an active substance which is structurally similar to BAS 750 F (none of the other pesticides applied to the soils are believed to contain structurally similar active substances). However, the RMS is of the opinion that, because BAS 750 F was radiolabelled in this study, and Silvacur would not have been (and the tebuconazole is likely to have mostly been degraded), the recoveries of BAS 750 F in this study are unlikely to have been affected by the tebuconazole. Furthermore, the RMS is of the opinion that pesticide history is less critical for sorption studies than for soil degradation studies because microbial resistance is less likely to impact on adsorption/desorption results (microbial resistance is likely to affect degradation results). Therefore, the IN, JP and FPR soils sorption results are valid.

The RMS also notes that the LG soil was sterilised before the study took place. However, the RMS is of the opinion that this should not affect the calculated K_{OC} value as the test substance was shown to be stable with no/very little degradation observed for the non-sterilised soils in the study period.

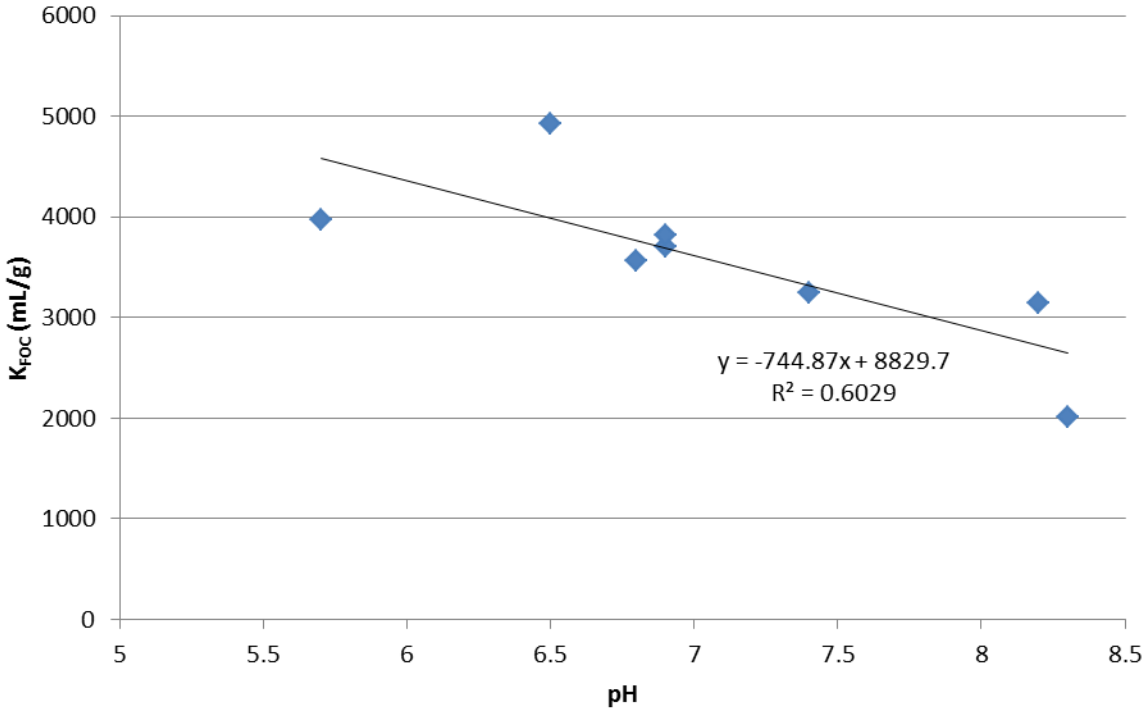
As shown in graph 8.1.2.1-1, there appears to be some relationship between K_F and the organic carbon (OC) of the soils. The RMS does note, however, analysis on soils with a larger variety of organic carbon percentages would have been beneficial in order to gain a clearer picture on the correlation between the K_F and OC.

Graph 8.1.2.1-1: Relationship between K_F and OC of the test soils



As shown in graph 8.1.2.1-2, there appears to be a slight relationship between the pH (in water) of the soils and the $K_{FOC.}$

Graph 8.1.2.1-2: Relationship between pH and K_{FOC} of the test soils



The mean K_{FOC} of the acidic soils (pH <7) is 3999.7 mL/g and the mean K_{FOC} of the alkaline soils (pH >7) is 2801.6 mL/g. The RMS notes that because both these K_{FOC} values would be classed as "slightly mobile", according to SSLRC classification, it is unlikely that calculating exposure estimates using both an acid and alkaline K_{FOC} value will result in significant differences to those calculated using an 'overall' K_{FOC} value. Therefore, the mean K_{FOC} (3455.6 mL/g) and 1/n (0.98) values of all soils are appropriate.

Conclusion

The RMS accepts the methodology that has been used by the Applicant in this study and is of the opinion that it generally follows the OECD 106 agreed guidance; the RMS, therefore, considers the final calculated results to be acceptable.

The adsorption behaviour of BAS 750 F was determined on eight different soils originating from the US (two soils), Japan (one soil), Italy (one soil), Spain (one soil), and Germany (three soils). The soils covered a range of pH from 5.7 to 8.3 (measured in water) and a range of organic carbon content from 0.60 to 3.4%.

The Freundlich adsorption coefficient K_F covered a range from 24.53 mL/g to 126.14 mL/g for the eight soils. The K_{FOC} values ranged from 2010.28 mL/g to 4930.94 mL/g with a mean value of 3455.6 mL/g (arithmetic mean 1/n value of 0.975).

The Freundlich desorption coefficients covered a range from 39.10 to 183.03 mL/g (K_F^{des1}) for the first desorption step and from 60.02 to 300.82 mL/g (K_F^{des2}) for the second desorption step. The organic carbon normalized values ranged from 3205 to 7641 mL g^{-1} (K_{FOC}^{des1}) and from 4920 to 11019 mL g^{-1} (K_{FOC}^{des2}).

B.8.1.2.2. Adsorption and desorption of metabolites, breakdown and reaction products

Report: CA 7.1.3.2/1
Szegedi, K., 2015 b
Estimation of adsorption coefficients of metabolites of BAS 750F with QSAR
2015/1260816
Guidelines: <none>
GLP: no

Introduction

Adsorption coefficients (K_{OC}) were estimated for the metabolites of BAS 750 F that were observed in the aqueous photolysis study and/or the water/sediment study.

Material and methods

The Applicant estimated the K_{OC} for the metabolites M750F003, M750F005, M750F006, M750F007 and M750F008 of BAS 750 F that occurred in the study on aqueous photolysis (see section B.8.2.1.2) and in the water/sediment study with BAS 750 F (see section B.8.2.2.3).

The QSAR methods implemented in the KocWIN 2.00 (EPISuite) tool were used [*US EPA (2000-2012) EPI Suite*]. Values obtained with the molecular connectivity index (MCI) were reported.

The RMS notes that, ideally, metabolite K_{OC} values should be derived from an appropriate study in order to obtain more accurate values. However, given that none of these metabolites were formed in soil (at concentrations >2%), on this occasion, the RMS deems the Applicant's QSAR approach valid.

Results and discussion

The resulting K_{OC} values are given in Table 8.1.2.2-1. The RMS has repeated the Applicant's modelling and can verify the Applicant's results.

Table 8.1.2.2-1: Estimated K_{oc} values for metabolites of BAS 750 F

Metabolite code	K_{OC} [mL g^{-1}]
M750F003	597.6
M750F005	7863
M750F006	4919
M750F007	3938
M750F008	17240

Conclusion

The K_{OC} values calculated by KocWIN are appropriate for use in the exposure assessments.

B.8.1.3. Mobility in soil

Report:	**KCA 7.1.4/1, Sandt H.J. van de, 2015a.**
Title:	Determination of foliar DT50 of Triazole (Bas 750 F) after application of BAS 750 01 F to wheat surfaces 2015/1130156
Guidelines:	EPA 875.2100
GLP	Yes Certified by Ministy of Health, Welfare and Sport, Itrecht, The Netherlands

The RMS identified the following critical issues with the study; these issues indicate that the study is not of a sufficient quality to be considered as part of a regulatory risk assessment. It should be noted that this is not an exhaustive list. Overall it was considered that the conditions are not comparable to that expected to occur under normal EU field conditions and the study report provides insufficient information of the study procedures.

The Applicant responded to these comments and the responses are shown (in grey below), and overall does not agree with the conclusion of the RMS. Overall the supplied information is insufficient to rule out that additional variables led to a decrease of BAS 750 F residues, for example precision of analytical technique rather than foliar processes expected to occur during normal field use.

Additionally as part of the response the applicant supplied a research note on the foliar uptake of BAS 750 F; the report did not include enough detail to determine the validity of the study. However within the research note it was indicated that the translocation of BAS 750 F is linked to the formulation, indeed the note indicates that the formulation (BAS 750 01 F) has been optimised for maximum uptake. As such the RMS questions whether, where rapid translocation is thought to be a significant dissipation pathway, and it is known that the formulation can influence said translocation, whether foliar DT50 studies can be considered at an active substance level, or whether the refinement should be considered for each formulation.

Applicant: the Applicant considers that the performed study was conducted in a technically and scientifically sound manner, according to GLP. Thus, the Applicant is convinced about the quality of the collected data. However, the performed measurement is one of the first examples of a new study type. As of the time of this response, and for sure the time of the study conduct, no agreed guideline has been proposed specifically for environmental ate area. However the study was conducted in accordance with an accepted study guideline to determine the dislodgeable foliar residues. Albeit not being a standard data requirement in the area of environmental fate the study is nevertheless it should be considered in line with standard data requirement for worker re-entry exposure assessment in the pesticide regulation. The Applicant understands that further discussion details with the RMS are necessary regarding the acceptability of the provided data. In the following the Applicant addresses individual concerns of the RMS.

The FOCUS surface water guideline has proposed an overly conservative default value for Foliar DT_{50} of 10 days to encompass all active ingredients (a.i.'s) with the possibility to indicate through experimental studies a more realistic parameter for an individual a.i. The regulatory agreed guidance that exists to an accepted guideline for this study type is the guideline for Operator Exposure generated by the US EPA or Dislodgeable Foliar Residues (or DFR; US EPA, OPPTS 875.2100). The only deviation from this regulatory acceptable study design and our study is simply the use of *weight* as a reference in the study performed by the applicant instead of using *leaf surface area* as a reference as done for DFR studies. The potential impacts of this difference are outlined below.

1. There is insufficient information contained within the final report to allow for the validation of the analytical methods. It is noted that the mass of leaf is which underwent the dislodging procedure is not reported; only approximately 20g is indicated within the report. No reference is made to further studies where validation of the methods has been conducted. No further comments on the analytical procedures are made, by the RMS, within this report.
   Applicant: Total mass of leaves underwent dislodging can vary depending on plant size and age. Active ingredient is considered to be uniformly distributed on plant leaves. This collecting representative samples provide the same information as it could be gathered after analysising the full leaf which

underwent dislodging. Additonally, collecting samples of known weights enables the comparability of data collected at different times.
Residues levels derived in the study will not be directly used in any context outside the study. The measured values were used only relative to each other to derive dissipation half lives. The measured residue levels build a consistent data set in it-self, which is sufficient for the goal of this study (determination of dissipation). Thus, no further validation of the analytical method is necessary

2. Section 5.5 of the report states the leaf area was measured but results were not reported because the leaf area meter was not of appropriate capacity to fulfil study plan requirements. Therefore, leaf area cannot be used to consider any potential of contribution of plant growth to the dilution of the active substance. Without this information an additional variable, which cannot be quantified, is introduced.
   Applicant: Although at a first glance one might expect that plant growth might substantially affect derived parameters, this is not the case for BAS 750F. Experimental data collected during formulation optimization of BAS 750 01F shows a rapid translocation of BAS 750 F into lower cell layers of plant leaves. The collected data showed that approximately 60% of was dissipated via this pathway from the plant leaves within two days after application. This fast dissipation time is short enough to consider effects of plant growth on potential dilution of surface attached BAS 750 F negligible. Details are presented in Kienle and Strobel (2016) Uptake of Revysol® (mefentrifluconazole) with BAS 750 01 F in wheat BASF DocID 2016/1270660.
3. It is unclear what the leaf area at the time of application and throughout the study was. Additionally the crop was grown within pots. No comparison of indoor pot grown cereals vs. outdoor field growth and crop densities has been provided. As such the impact cannot be quantified and the reliability of any data is further reduced.
   Applicant: Considering the answer provided above, differences in growth rate between fields and green house is not relevant for the determination of foliar DT50.
4. The trial is set up as a combined application for trial R14-275-01 (this study) and trial R14-276-01 – with no details. It states plot 1 was the control plot with 12 pots. Plot 2 contained 102 pots but only 15 pots were used for this study. Furthermore, it is reported that random leaves were taken during sampling. No further information on the location of the leaves, in relation to the plot and plant are provided. If, at the start of the study samples were randomly taken from the top they are likely to have a greater amount of the spray solutions. If at later stages they were randomly taken from the bottom, then the samples are likely to have less spray. This introduces another variable to the study which cannot be quantified and can impact the resulting DT_{50} value.
   Applicant: Initially it was desired to conduct a Foliar DT50 experiment as well as a Wash-off experiment to aid in the refinement of the PECs for BAS 750 F. This is the reason for the additional trial number. The experimental procedures for the Wash-off were less developed at this point than for the Foliar DT50. This portion of the study was therefore abandoned shortly after start of the study. it is stated in section 5.3 of the study report that collected leaves were "selected randomly from the entire plants". According to this procedure no top/bottom bias is expected.
5. There is no indication whether the time between application and the peak concentration allowed sufficient time for the formulation to dry. As such it cannot be ruled out that the loss was not due to liquid falling from the leaf to the soil. If the study design included any residue testing of the pot soil, such events could be accounted for within subsequent kinetic analysis. Overall 'run-off' from the leaf cannot be ruled out and the use of any DT50 value within FOCUS modelling is called into question.
   Applicant: The drying time between application and first sampling was deemed acceptable. The plants were visually inspected for dryness before the first samples were taken.
6. The application was carried out with a hand carried compressed air sprayer with 3.0m spraying boom fitted with a 6 flat fan nozzles XR 11003 VS at bar 3; however the report doesn't state whether a pressure regulator has been used. Overall the amount of chemical reaching each pot is highly uncertain, especially if no tank washing were performed or the sprayer ran out of liquid over the last few pots.
   Applicant: A pressure regulator was in fact utilized. The application was carried out under GLP conditions and the equipment and procedures were calibrated to ensure the accuracy of the method.
7. The application scheme is not in line with the proposed GAP (see below), no explanation as to why a lower dose was applied within the study; no justification was supplied within the study. Only one

concentration has been tested to date so any dose related behaviours cannot be ruled out. There is no indication within the study whether the first sampling point BAS 750 F concentrations are comparable to that expected to occur under normal agricultural practice.

Within the study the following application scheme was used:

Application No.	Application Date	Spray Volume (L/ha)	Actual product rate (L/ha)	Actual rate of active ingredient (g a.i./ha)	Growth Stage (BBCH)
1	10/11/14	199	0.993	98.25	30

The GAP considered as part of the risk assessment is:

F G or I	Application				Application Rate		
	Method	Timing	Number	Interval between applications (days)	L product/ ha	g a.s./ha	Water L/ha
F	Foliar Spray	BBCH 30-69	2	14	1.5	150	100-300

Applicant:A dose response is not to be expected from this study type. Application rates were selected to achieve similar load of plants as expected in the field.

8. The study was conducted indoors, whereas the product is expected to be applied to field (outdoor) crops. The only information on climatic conditions and irrigation is shown below.

Temperature °C	Humidity (%)	Drip Irrigation (L/m^2)	During the trial period Kristalon Blauw 19-6-20+3 and Nitric acid were applied via drip irrigation
Min 14.4 – Max 23.3	Min 55.7 – Max 92.8	1.6	

This is insufficient to provide any meaningful comparison to typical EU conditions. The RMS notes that throughout the study the crop receives fertilises via drip irrigation, this is not representative of typical agricultural practices and can improve the growth of the crops, which in turn could impact the foliar dissipation observed. Overall the combination of these conditions are expected to provide the crop with optimum growing conditions, with increased crop growth expected following application of a formulated product to outdoor conditions. This could impact the dissipation observed within the study, however due to the limited information within this study the impact cannot be quantified at this time.

Applicant: The goal of the study was to determine foliar DT50 without the influence of wash-off and potential surface loss process like photolysis. This can be excluded using drip irrigation and growing the plants indoor. Foliar irrigation or rain would have led to the wash-off of active ingredient from the plants. Additionally, as discussed above crop growth is not expected to fundamentally affect derived foliar DT50 in the particular case of BAS 750F. As discussed above, crop growth is not expected to fundamentally affect derived foliar DT50 in the particular case of BAS 750F.

9. Limited information on the soil used within the study have been provided; overall further characterisation of the soil should be conducted to allow for a full assessment of the relevant of the soil (to typical agricultural soils) to be conducted. From the available information (presented below), no overall conclusion on the appropriateness of the soil selection can be made.

Soil Type	Silt (%)	Soil pH	Soil % organic matter
River Clay	11	4.6	2.3

Furthermore, efficacy specialists have reported that the soil pH is untypical of field conditions for growth of wheat crops. Coupled with the high OC%, continual drop irrigation of fertiliser, very high humidity, the overall conditions during the study are far removed from typical field conditions.

Applicant: It is in no way envisioned that soil type, pH or constitution, other than influencing the overall health of the plant, could be seen to effect the foliar half-life of an applied pesticide.

10. It should be notes due to the deficiencies indicated above; a full review of the kinetic analysis has not been conducted. However it is noted that the 2HAA sample was corrected to be the time zero sample. None of the subsequent sampling points were corrected to account for this.

Applicant: Considering the results of Kienle and Strobel (2016), the most uptake of BAS 750F occurs within the first hours after application. Thus, setting the 0h values to the level of 2h leads to conservative parameter estimation.

Report:	*CA 7.1.4/1* *Sandt H.J. van de, 2015 a* *Determination of foliar DT50 of Triazole (BAS 750 F) after application of BAS 750 01 F to wheat surfaces* *2015/1130156*
Guidelines:	*EPA 875.2100*
GLP:	*yes* *(certified by Ministry of Health, Welfare and Sport, Utrecht, The Netherlands)*

EXECUTIVE SUMMARY

A foliar DT_{50} study was conducted with the fungicide BAS 750 01 F in a raw agricultural commodity of wheat to determine the decline of residues on plant leaves after application that are available for dislodging by a rainfall event. Default modelling parameter values may potentially be superseded by such experimentally derived, measured values. While currently no guideline exists for such an experimental study to supplant the conservative default, a similar study type in which a guideline exists is the Dislodgeable Foliar Residue for worker exposure from the EPA. This guideline was used as a template for this study with slight modifications to make the data more appropriate for environmental exposure assessments.

The test system was cultivated indoors and grown to the desired BBCH growth stage to give sufficient leaves to collect as well as mimic the desired growth stage set in the GAP (BBCH 30-39). The subsequent dislodging procedure is independent from the crop growth stage and therefore the Foliar DT_{50} values derived are considered valid for use in environmental data modeling.

The test item is applied using equipment that simulates commercial application to wheat. Whole leaf samples were taken at the given intervals and treated with the dislodging procedure.

The amount of residue on the leaf surfaces was determined with a dislodging procedure utilizing Aerosol OT-B (0.01%) as the dislodging solution. Subsequent analysis of the dislodging solution was performed via LC-MS/MS to indirectly determine the amount of BAS 750 F residues on the leaf surface.

Kinetic evaluation showed that the SFO model gave the best fit of the experimental data. The suitable DT_{50} value for modeling purposes is 2.1 days.

I. MATERIAL AND METHODS

A. MATERIALS

1. Test Material

Test item (formulation): *BAS 750 01 F*
Active substance (a.s.): *BAS 750 F (Reg. No. 5834378)*
Type of formulation: *EC*
Chemical name (IUPAC): *2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol*
CAS Number: *1417782-03-6*
Batch No.: *FD-140113-0006*
Content of a.s.: *100 g L^{-1} (nominal 100 g L^{-1}), actual 98.9 g L^{-1}*
Expiration date: *February 29, 2016*

Internal code: *BAS 750 F*
Chemical Formula: *$C_{18}H_{15}ClF_3N_3O_2$*
Molecular wt.: *397.8*
Reg. No.: *5834378*
Batch No.: *L85-12*
Purity: *99.4%*

2. Test system

The trial was designed with one treated plot and one non-treated (used for procedural recoveries) of wheat plants (variety, Trappe). The treated plot consisted of 102 pots with ± 35 plants each. From these 102 pots, leaves were selected for samples at random points throughout the plot. The plants were grown to growth stage BBCH 30 before application.

Crop Details

Test Crop and Variety/Cultivar: *Wheat – Trappe*
Sowing Date(s): *22/09/2014*
Plant density: *± 35 plants/pot (ø24 cm)*
Crop height: *± 30 cm*
Pot distance in the row: *0.325 m*
Pot distance between de row: *0.50 m*

Plot Details

General Plot Description: *Greenhouse*
Outdoor/ Indoor Situation: *Indoor test conditions*
Plot Dimensions (treated plot): *3.0 m (width) x = 12,0 m (length) = 36 m²*
102 pots with ± 35 plants/pot (ø24 cm) were treated
12 pots, ± 35 plants/pot (ø24 cm)
Plot Dimensions (untreated plot):
Number of Control Plots: *1*
Number of Treated Plots: *1*

Application Details

Table 7.1.4-1: Application details for BAS 750 01 F applied to wheat

Plot No.	*Application No.*	*Application date*	*Spray volume (L ha^{-1})*	*Actual product rate (L ha^{-1})*	*Nominal rate of active ingredient (g a.s. ha^{-1})*	*Actual rate of active ingredient (g a.s. ha^{-1})*	*Growth stage (BBCH)*
2	*1*	*10/11/2014*	*199*	*0.993*	*99.34*	*98.25*	*30*

Application Equipment: *Compressed air with spray boom*

Boom Width (m):	*3.0*
Nozzle Type:	*Teejet flat fan XR 11003 VS*
Number of Nozzles:	*6*
Pressure (bar):	*3.0*

B. STUDY DESIGN

1. Experimental conditions

The application was carried out in the greenhouse at growth stage BBCH 30 with a hand carried compressed air sprayer with 3.0 m spraying boom. The spray boom was fitted with 6 flat fan nozzles XR 11003 VS at 3 bar. The intended spray volume was 200 L ha^{-1}.

The application method was foliar application, chosen to simulate good agricultural practice (GAP). The spray solution was prepared by diluting the required quantity of the test item with tap water. The application rate was verified by sprayer calibration and confirmed by measuring the remaining volume. The rate achieved was calculated to be within ± 10% of that specified in the study plan.

The relevant test conditions such as relative air humidity, air temperature were all monitored during the study. Detailed information may be found in the original study report and/or the raw data.

2. Sampling

Whole leaf samples were taken after drying of the spray solution at 2 HAA (Hours After Application), 6 HAA, 24 HAA, 48 HAA, 4 DAA (Days After Application) and 7 DAA. Each sampling point consisted of 5 replicates. Each replicate consisted of leaves (BBCH 30) selected randomly from the plots to give ~20 g (80 leaves) of fresh weight leaf material. The leaves were cut from the stems at their base by the use of scissors. The leaves were then placed into pre-labelled containers before extraction.

Samples (extract solutions) were stored at -18 °C and shipped via overnight courier packed with dry ice. Complete details and records on storage and shipping can be found in the raw data associated with the study report.

3. Description of analytical procedures

Extraction of the cut leaf samples was performed immediately after collection. The residues of BAS 750 F were dislodged from the surface with the following procedure:

The dislodging solution was prepared by diluting 0.1 g of a Aerosol OT-B powder to 1000 mL using distilled deionized water. The dislodging solution was used within 6 hours.

200 mL of the dislodging solution (Water / Aerosol OT-B (0.01%)) was added to the bottle containing approximately 20 g of leaf material and the bottle was subsequently transferred to a reciprocating table shaker. The bottles were shaken at 250 rpm for a period of 10 minutes. The dislodging solution was decanted into a beaker and the bottle with the remaining leaves was subjected to a second dislodging process with another 200 mL of fresh dislodging solution (250 rpm, 10 minutes). The dislodging solution was also decanted from the bottle and the two dislodging solutions were combined in the beaker and thoroughly mixed. The extraction procedure employed is a relatively mild extraction technique but is thought to reflect accurately residues in which would be readily removed from the surface of the leaf due to environmental effects (i.e. rainfall event). While an overall mild extraction technique, the surfactant based dislodging solution is thought to represent a worst case extraction medium when compared with actual rainfall.

The residues that could be "extracted" by the dislodging procedure were considered to be available for wash off, bearing in mind that degradation as well as strong adsorption to plant surfaces as uptake into plant leaves could contribute to the reduction of the "available" residue fraction.

Two aliquots of 20 mL were obtained from the thoroughly mixed solutions and labelled as ship and retain specimens. These specimens were transferred to freezer storage before shipment to the analytical facility.

Fortification samples were generated to confirm the stability of BAS 750 F under the storage and shipping conditions. Two fortification solutions, one higher (1000x LOQ) and one lower (10x LOQ) concentration, were generated at the analytical facility and sent to the field test site (De Bredelaar). The solutions were then used to spike blank dislodging solutions at the desired concentrations to create the field fortifications.

BAS 750 F residues were determined by means of LC-MS/MS. For the analysis of the dislodging solutions the samples were only diluted with methanol. The limit of quantitation was set for dislodging solution at 5 µg L^{-1}.

4. Calculation of the degradation rate

Kinetic evaluation was performed in order to derive degradation parameters as modelling endpoints. Kinetic analysis and calculations of DT_{50} values for BAS 750 F was performed using data (residues dislodgeable from plant leaf surfaces) obtained from the in-life phase and following the recommendations of the FOCUS Kinetics workgroup [FOCUS (2006)] The software package KinGUI (version 2.2014.224.1704) was used for parameter fitting. The error tolerance and the number of iterations of the optimization tool were set to 10^{-6} and 100, respectively.

II. RESULTS AND DISCUSSION

For each sampling time point 5 replicates were analyzed. The results presented in Table 7.1.4-2 are mean values (n=5) of actual measured amounts from the dislodging solutions and were not corrected for the results obtained from the field fortifications. Residues of BAS 750 F were < LOQ immediately prior to the application (-0). Two hours after the application, 0.457 mg L^{-1} were observed and the residues of BAS 750 F decreased continuously to 0.037 mg L^{-1} at 168 hours (=7 days) after application.

Table 7.1.4-2: BAS 750 F in Dislodging solutions

	Sampling time (hours after application), (n=5)						
	- 0	***2 HAA***	***6 HAA***	***24 HAA***	***48 HAA***	***95 HAA***	***168 HAA***
Dislodging solution *[mg L^{-1}]*							
Rep 1	*<LOQ*	*0.428*	*0.404*	*0.325*	*0.278*	*0.130*	*0.036*
Rep 2	*<LOQ*	*0.472*	*0.408*	*0.327*	*0.285*	*0.091*	*0.046*
Rep 3	*<LOQ*	*0.483*	*0.444*	*0.338*	*0.307*	*0.078*	*0.034*
Rep 4	*<LOQ*	*0.411*	*0.440*	*0.350*	*0.261*	*0.102*	*0.033*
Rep 5		*0.489*	*0.437*	*0.386*	*0.244*	*0.102*	*0.035*
Average	*<LOQ*	*0.457*	*0.427*	*0.345*	*0.275*	*0.101*	*0.037*
Coefficient of variation		*7.6 %*	*4.5 %*	*7.2 %*	*8.7%*	*19.0 %*	*14.2 %*

HAA = Hours after application; LOQ = Limit of quantification

During the analysis of the study specimens, procedural recoveries were determined at two spiking levels. The mean recovery was 81.4% (n=2).
Field fortification experiments were conducted on the day of the crop treatment to investigate the stability of BAS 750 F under field specimen transport and storage conditions. The field fortification recoveries ranged from 84.6 % to 113.4 % (n=6). Non treated leaves were treated with extract solution and subsequently spiked with a known amount of BAS 750 F.
The kinetic evaluation (Table 7.1.4-3) showed that the SFO model fits the experimental data of the greenhouse trial (visually and statistically).

Table 7.1.4-3 Statistical and visual assessment of different kinetic models for BAS 750 F in the greenhouse trial R14-275-01

Step in FOCUS flowchart	***Kinetic model***	***χ^2 error [%]***	***p (t-test)***	***Visual assessment***	***DT_{50} [d]***	***DT_{90} [d]***
SFO	*SFO*	*5.3*	*k: <0.01*	*Good*	*2.1*	*7.1*
⇨ *The SFO visual fit is good; the residuals are randomly scattered around zero. The χ^2 error is low; the parameter k is significantly different from zero.* ⇨ ***Conclusion:*** *Use* ***SFO*** *to derive* ***modeling endpoints****.*						

The visual assessments of the residual plots show that SFO kinetics describes the best fit. The estimated dissipation rate constant is significantly different from zero as indicated by low p-values (t-test). The estimated DT_{50} value of 2.1 days is suitable for modeling.

III. CONCLUSION

The results obtained in the study demonstrate that the foliar DT_{50} of BAS 750 F was reliably determined for wheat surfaces. After analyzing the data under the guidance from the FOCUS kinetics working group the best fit was found using SFO kinetics. A foliar DT_{50} of 2.1 days was derived.

B.8.1.4. Summary of fate and behaviour in soil

The Applicant submitted three laboratory aerobic degradation studies (see section B.8.1.1.1) assessing the breakdown behaviour of BAS 750 F in four soils. All three studies were conducted at 20°C and over a period of 120 or 121 days; the studies were considered acceptable by the RMS. BAS 750 F was found to degrade to non-extractable residues at quantities ranging from 12.6% to 26.7% AR by the end of the study period. A maximum quantity of 9.7% AR was observed to mineralise to CO_2 by the end of the studies. No 'major' metabolites (metabolites occurring at concentrations >10%, >5% at two consecutive timepoints or >5% and increasing at study termination) were detected in the studies. Although it is not a legislative requirement, the Applicant proposes to consider the metabolite 1,2,4-triazole (M750F001) (which occurred at a maximum concentration of 5.1% AR) within the risk assessment due to its widespread occurrence in the environment; it is to be included in the soil and groundwater exposure calculations.

Kinetic analysis was undertaken on the degradation results from the four soils (see section B.8.1.1.2.1). For three of the four soils, BAS 750 F was observed to degrade (by best-fit kinetics) following FOMC degradation kinetics; for the other soil, LUFA 5M, BAS 750 F was observed to follow DFOP degradation best-fit kinetics. The minimum resulting DegT50 value calculated by the best-fit kinetics (non-normalised) was 434 days, indicating field dissipation studies are necessary. A detailed summary of the degradation kinetics in relation to Persistence criteria is presented in section B.8.1.5 below.

Although the best-fit degradation of BAS 750 F was found to follow biphasic kinetics, the SFO kinetic fits for each of the soils were deemed acceptable to derive modelling endpoints. The modelling $DegT_{50}$ values (normalised to 20°C and pF2) ranged between 104[7] and 477 days with a geometric mean value of 268 days. No evidence of pH dependence was observed for degradation in the four soils.

The Applicant submitted a study estimating the formation fraction of 1,2,4-triazole from BAS 750 F in a conservative manner (see section B.8.1.1.2.2). The RMS accepts, where the calculated formation fraction ranges from 0.12 to 0.64 (arithmetic mean – 0.4, where n=4); the outcomes are further considered in the groundwater risk assessment.

An anaerobic degradation study was submitted by the Applicant (see section B.8.1.1.3) assessing the degradation behaviour of BAS 750 F in anaerobic conditions in four soils; the study was considered acceptable by the RMS. BAS 750 F was observed to degrade slowly under anaerobic conditions and no relevant metabolites were detected. Kinetic analysis resulted in DT_{50} values in excess of 349 days for the soils (at 20°C and 50% MWHC).

Two field dissipation studies have been submitted by the Applicant (see sections B.8.1.1.4.1 and B.8.1.1.4.2). One study was based in the EU and the other in the USA; both studies were considered acceptable by the RMS. The studies monitored the dissipation behaviour of BAS 750 F and the potential formation of 1,2,4-triazole and M750F003 (detected at a maximum concentration of 1.8% in the aerobic laboratory degradation studies). Negligible amounts of 1,2,4-triazole were detected in the six EU trials and no residues of M750F003 were detected. In the US study, 1,2,4-triazole and M750F003 were detected in all six trial sites. However, given the interim nature of the US field study, the US results are not further considered at this time.

Kinetic analysis was conducted on the results from the six EU trials. The degradation behaviour of BAS 750 F was best described by SFO best-fit kinetics for four out of the six sites; the other two sites followed DFOP best-fit kinetics. The longest non-normalised $DegT_{50}$ of BAS 750 F occurred at the Italian site and was 846.6 days (SFO); this value is appropriate for use in the soil exposure calculations.

However, for all six trial sites, the SFO kinetic fits were deemed acceptable to derive the modelling endpoints. The normalised $DegT_{50}$ values ranged between 96.5 days and 610.8 days with a geometric mean value of 200.0 days. In line with the EFSA $DegT_{50}$ guidance, because the mean laboratory degradation rate of BAS 750 F was >240 days, the geometric mean value of 200 days from the field dissipation trials is appropriate for use in the surface water and groundwater exposure calculations.

[7] This value corresponds to the trifluoromethylphenyl degradation rate in soil NJ (see Table 8.1.1.2.1-8). When a geomean value is calculated with the results of the other radio-labels in soil NJ, a value of 118 days is calculated.

The Applicant submitted two soil accumulation studies (see section B.8.1.1.4.3), one with a test site in the UK, the other with a test site in Germany. Both studies are still ongoing and no residue data was presented. Therefore, these accumulation studies are not further considered at this stage.

An acceptable soil photolysis study was submitted by the Applicant (see section B.8.1.1.5) which determined the extent of degradation of BAS 750 F when exposed to a xenon lamp simulating 15 days of continuous natural light. Less than 10% degradation of BAS 750 F was observed in the study period and no new metabolites considering further investigation were detected. Kinetic analysis on the photodegradation of BAS 750 F indicated DT_{50} values of 93 and 170 days for the chlorophenyl and triazole labels respectively resulting in a mean value of 131.5 days. When converted to days of natural summer sunlight (at approximately 49° N), this equates to an average DT_{50} value of 351 days. When compared to the DT_{50} values of the laboratory degradation and field dissipation studies, light is expected to have a limited influence on the degradation behaviour of BAS 750 F in soil.

The adsorption and desorption behaviour of BAS 750 F was determined using 8 soils (see section B.8.1.2.1); the RMS noted a number of issues with the study, however, on balance, deemed the results acceptable. The K_{FOC} values ranged between 2010.28 mL/g to 4930.94 mL/g for the 8 soils. The geometric mean value was calculated as being 3455.6 mL/g and the arithmetic mean of the 1/n values was 0.975; these are appropriate for use in the exposure calculations.

The Applicant calculated K_{OC} values for the major metabolites detected in the aquatic photolysis and water/sediment study using KocWIN (see section B.8.1.2.2). The RMS accepted the Applicant's approach and the K_{OC} values calculated are appropriate for use in the surface water exposure calculations.

The Applicant also submitted a study with the aim of revising the default foliar DT_{50} value (see section B.8.1.3). However, the RMS identified a number of critical issues with the study resulting it in the astudy not being considered to be of sufficient quality to be considered further. As a result, the default foliar DT_{50} value of 10 days is appropriate for use in the exposure calculations.

The enantiomeric ratio was monitored throughout all relevant studies (where interactions with other chiral molecules could influence degradation of one isomer over the other). The analysis highlighted a slight shift of enantiomeric ratio from 50:50 to 45:55 observed in two soils of the aerobic soil metabolism study. All other observed matrices, studies and measurements showed a ~50:50 ratio throughout. The Applicant states that this slight change is not deemed a significant change and it is due to the inherent variation of the chiral methodology, which could also be seen in some of the 0 DAT samples, which were observed with ratios of 47:53. Furthermore, the Applicant states that this is supported by an in depth analysis of enantiomers done by the ECPA working group on chiral pesticides, which was based upon these statistical variances, which showed that that a *significant* change (i.e. one that could have an impact on the overall risk assessment) is deemed to be greater than 30%. Therefore the minor, insignificant shift in the enantiomeric ratio observed in soil is covered by the existing risk assessment using the racemic mixture.

The RMS notes that, at the time of writing, there is no agreed guidance on the approach to take when a shift in enantionmeric ratio is detected. The ECPA guidance document the Applicant refers to is believed to be "ECPA's position Stereoisomers: Proposal for Tiered Approach to Risk Assessment, position paper 06/05/11 – PP/11/JW/20664". The RMS notes that this position paper was referenced in the penthiopyrad evaluation (available on CIRCABC at: PLANT PROTECTION PRODUCTS AND THEIR RESIDUES > Library > Archive individual substances > Active Substances P-S > Penthiopyrad > Draft assessment report and addenda > Penthiopyrad_Addendum 4_Vol 3_B8_September 2012.doc), however, no indication as to its applicability for other active substances was included. The RMS is not aware of any other references to this guidance document in other active substance evaluations. Further discussion on potential differences in toxicity of the enantiomers is provided in section B.9.8 of the ecotoxicology product section of the dRR (Volume_3CP_PPP_B-9). No further consideration is made as to the significance of the shift in enatiomeric ratio in this section.

B.8.1.5. Assessment of Persistence in soil

In the following it will be discussed if BAS 750 F fulfils the P in soil criterion within the PBT (persistence, bioaccumulation and toxicity) and the vP criterion in the vPvB (very persistent very bioaccumulative) assessment, which are defined according to Section 3.7.2.1. and 3.7.3.1, respectively, of Annex II of EC Regulation 1107/2009 as follows:

An active substance, safener or synergist fulfils the persistence criterion where:

- *The half-life in soil is higher than 120 days.*

An active substance, safener or synergist fulfils the 'very persistent' criterion where:

- *the half-life in soil is higher than 180 days.*

The relevant endpoints for the persistence assessment were identified based on the DG SANCO working document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" [*SANCO 2012. DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides". Brussels: European Commission Health and Consumers Directorate-General. Report 25.09.2012 - rev. 3.*]. According to this document, when available, field degradation half-lives are relevant for the P and vP assessment.

The degradation of BAS 750 F was investigated in a laboratory soil degradation study in four aerobic soils (see chapter 7.1.1). Additionally, the degradation of BAS 750 F was investigated under field conditions. Field plots were set up in representative growing regions of Europe. Plots were covered by a layer of sand to exclude surface processes and to enable a straightforward generation of modeling $DegT_{50}$ as input for calculation of predicted environmental concentrations as recommended by EFSA (2014) [*EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014:12(5):3662*]. A kinetic evaluation was performed in order to derive best-fit field degradation parameters for BAS 750 F according to the FOCUS kinetics guidance (2006, 2014). An additional kinetic evaluation was performed to derive degradation parameters that can be used as input for modelling according to the EFSA (2014) guidance.

Due to the exclusion of surface processes $DegT_{50}$ derived from data collected in European field studies are appropriate for an initial conservative assessment of persistence of BAS 750 F in soil. Considering the $DegT_{50}$ values derived from these studies (see section B.8.1.1.4.1, Table B.1.1.4.1-27), BAS 750 F fulfils the criteria for both P and vP in soil.

B.8.2. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

B.8.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

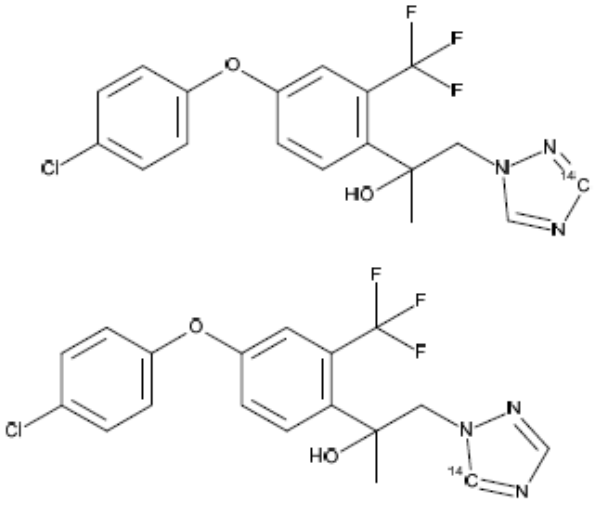
B.8.2.1.1. Hydrolytic degradation

Report:	CA 7.2.1.1/1 Hassink J., 2015 b BAS 750 F: Aqueous hydrolysis at four different pH values 2015/1046919
Guidelines:	OECD 111, EPA 835.2120, JMAFF No 12 Nosan No 8147
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)

Introduction

The abiotic hydrolysis of [triazole-3(5)-^{14}C]labelled BAS 750 F was investigated in sterile aqueous buffer solutions at pH values 4.0, 5.0, 7.0 and 9.0. The study was conducted to GLP and according to OECD 111 guidelines, however, deviations from the guidelines did occur (see 'Results and discussion' section for further information). Information on the ^{14}C-labeled test substance is provided in Table 8.2.1.1-1[8].

Table 8.2.1.1-1: Test compound information

Internal code	BAS 750 F
CAS No	1417782-03-6
Chemical name (IUPAC)	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Molecular mass	397.78 g mol^{-1}
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$
Specific radioactivity of Triazole-3(5)-^{14}C-label a.s.	5.57 MBq mg^{-1}
Radiochemical purity	99.2% (95.3%, determined within the study, Reg. No. 5863469 was identified as impurity)
Site of radiolabel[9] (^{14}C denotes position of label used)	

Test procedure

[8] Unless otherwise stated, all tables are modified from the Applicant's study report.
[9] Figure taken from Report CA 8.2.1.2/1 Zhixing Y., 2015a, "Aqueous photolysis of 14C-BAS 750 F" because the radiolabel site figure was not included in the Hassink hydrolysis report.

A stock solution of [triazole-3(5)-^{14}C]BAS 750 F was prepared in acetonitrile. The study report states 2.4 mg a.s. was dissolved in 5 mL of acetonitrile which equates to 0.42 mg/mL in the stock solution; the RMS notes that this in fact equates to 0.48 mg/mL (480 µg/mL). The report then goes onto state that 2 mL of stock solution was added to 20 mL acetonitrile to prepare an application solution, equating to 0.045 mg/mL; the RMS notes that this should equate to 0.044 mg/mL a.s ((0.48*2)/22) . The RMS deems the use of acetonitrile appropriate as the Applicant states the water solubility of the compound as being 0.81 mg/L (at 20°C, pH 6.8).

The Applicant states that 3.33 mL of application solution contained 150 µg a.s.; the RMS notes that 3.33 mL application solution contained 146.5 µg a.s ((0.044*3.33)*1000). The Applicant has confirmed the RMSs calculations as being correct. The RMS is of the opinion that this slight deviation is not expected to have a significant effect on the outcomes of the study.

The Notifer's study summary goes onto state that the 3.33 mL application solution was added to 500 mL of diluted buffer solution (these were diluted with bidest (double distilled) water (by a factor of 10) to avoid interactions with the test item), which corresponds to a final concentration of ~0.3 mg/L a.s.. Subsets of 50 mL were used for hydrolysis.

All buffer solutions were prepared from commercially available buffer concentrates (Titrisol, Merck, Darmstadt, Germany) by 10-fold dilution and sterile filtration. The following buffer concentrates were used:

pH 4: Titrisol 1.09884 (citrate – HCl)
pH 5: Titrisol 1.09885 (citrate – NaOH)
pH 7: Titrisol 1.09887 (phosphate)
pH 9: Titrisol 1.09889 (boric acid/KCl – NaOH)

The sterile samples were stored in a climatic chamber at a temperature of 25°C for 30 days in the dark. Sterility of the solutions was checked at each sampling time for the respective sample prior to analysis. The pH was checked for each sample after analysis. The RMS notes that the OECD 111 guidelines state, as a preliminary test, to undertake the test at a temperature of 50°C although this was not conducted in this case.

The sampling was performed at 0, 3, 10, 17, 21, 25 and 30 days after treatment. The OECD 111 Guideline recommends conducting the test with duplicate samples at each time point, but it appears that the Applicant only tested one sample at each time point.

All samples of the test solutions were analysed without a work-up. All samples were measured for radioactivity by liquid scintillation counting (LSC) and were analysed by radio-HPLC to determine the amount of test item and potential metabolites. Furthermore, the isomers of BAS 750 F were separated by a chiral HPLC method. The limit of detection (LOD) and limit of quantification (LOQ) of the LSC instrument was 0.121% total applied radioactivity (TAR) and 0.181% TAR respectively (background 0.06% TAR); and, for HPLC, the LOD was 0.603% TAR and the LOQ was 1.188% TAR. Samples were stored in the fridge until analysis. The Applicant has not stated the duration of storage, but has stated that samples were analysed as quickly as possible. Although the storage stability of samples was not specifically tested, the mass balance data is acceptable and HPLC analysis does not suggest degradation of sample residues during storage.

The Applicant did not estimate the half-life of BAS 750 F because they stated it was found to be stable under the test conditions.

Results and discussion

Total recoveries of radioactivity are summarised in Table 8.2.1.1-2. During the testing period of 30 days the material balance was in the range of 96.3% to 102.1% of the total applied radioactivity (TAR). No loss of radioactivity occurred.

Table 8.2.1.1-2: Recovery of radioactivity after treatment with ^{14}C-labeled BAS 750 F and incubation at pH 4-9 and 25°C

Days after treatment	pH 4	pH 5	pH 7	pH 9
	[% TAR] [a]	[% TAR] [a]	[% TAR] [a]	[% TAR] [a]
0	100.0	100.0	100.0	100.0
3	99.1	97.1	101.0	98.6
10	100.2	100.4	102.1	101.7
17	98.7	97.4	97.7	98.3
21	96.3	101.4	99.8	99.9
25	99.7	99.8	101.2	100.6
30	100.9	98.3	98.9	99.6

[a] Concentration of day 0 was set to 100% TAR

Results of radio-HPLC analyses are presented in Table 8.2.1.1-3 and Table 8.2.1.1-4.

No significant degradation products above 5% TAR occurred beside an impurity (identified as Reg.No. 5863469 - M750F006) that was already present in the test item at the beginning of the study, no significant increase of its concentration occurred.

Furthermore, no significant change in the isomer ratio of BAS 750 F was observed for each test (see Table 8.2.1.1-5).

Table 8.2.1.1-3: Radio-HPLC analysis after treatment with ^{14}C-labeled BAS 750 F and incubation at pH 4 and pH 5 and 25°C

Days after treatment	pH 4				pH 5			
	M750F 006	BAS 750 F	Others [a]	Sum	M750F 006	BAS 750 F	Others [b]	Sum
	[% TAR	[% TAR]	[% TAR	[% TAR]	[% TAR	[% TAR]	[% TAR	[% TAR
0	4.7	95.3	-	100.0	5.3	94.7	-	100.0
3	5.5	92.7	0.8	99.0	5.3	91.1	0.7	97.1
10	4.8	95.4	-	100.2	5.5	94.3	0.7	100.5
17	5.8	92.3	0.7	98.8	5.7	90.4	1.3	97.4
21	4.4	91.3	0.7	96.4	4.9	96.0	0.6	101.5
25	6.1	93.6	-	99.7	5.0	94.8	-	99.8
30	6.2	93.8	0.9	100.9	5.2	92.1	1.0	98.3

TAR = total applied radioactivity
[a] Sum of other peaks, each peak less than 1% TAR
[b] Sum of other peaks, each peak less than 2% TAR

Table 8.2.1.1-4: Radio-HPLC analysis after treatment with ^{14}C-labeled BAS 750 F and incubation at pH 7 and pH 9 and 25°C

Days after treatment	pH 7				pH 9			
	M750F 006	BAS 750 F	Others [a]	Sum	M750F 006	BAS 750 F	Others [a]	Sum
	[% TAR	[% TAR]	[% TAR	[% TAR]	[% TAR	[% TAR]	[% TAR	[% TAR
0	3.7	96.3	-	100.0	5.0	95.0	-	100.0
3	5.4	94.8	0.8	101.0	5.4	93.2	-	98.6
10	4.7	96.4	1.0	102.1	4.6	97.1	-	101.7
17	5.3	91.4	1.1	97.8	4.9	92.0	1.5	98.4
21	4.5	94.5	0.8	99.8	5.2	93.7	1.0	99.9
25	4.9	96.4	-	101.3	4.9	95.7	-	100.6
30	5.6	93.3	-	98.9	5.0	93.1	1.4	99.5

TAR = total applied radioactivity
[a] Sum of other peaks, each peak less than 2% TAR

Table 8.2.1.1-5: Chiral radio-HPLC analysis after treatment with ^{14}C-labeled BAS 750 F and incubation at pH 7-9 and 25°C

Days after treatment	pH	BAS 750 F		
		Isomer I	Isomer II	Sum
		[% TAR]	[% TAR]	[% TAR]
0	4	49.4	45.6	95.0
	5	47.8	48.4	96.2
	7	48.5	48.0	96.5
	9	50.2	46.3	96.5
30	4	50.1	47.3	97.4
	5	47.2	46.7	93.9
	7	46.4	48.7	95.1
	9	49.1	46.6	95.7

TAR = total applied radioactivity

The Applicant has not submitted any further hydrolytic results/studies. The RMS notes that according to OECD 111 guidelines, a Tier 1 preliminary test should be undertaken at 50°C, not 25°C as done in this study. However, given only minor (<10%) hydrolytic degradation was observed at each test pH at 25°C, and, therefore, the substance is stable at an environmentally relevant temperature, the RMS is of the opinion that no further hydrolysis studies are required.

Insufficient degradation occurred to calculate degradation half-lives.

Conclusion

BAS 750 F was stable in aqueous solution at pH 4, 5, 7 and 9 at 25°C. No degradation products at concentrations ≥2% TAR were detected and no change in the isomer ratio of the test item was observed.

B.8.2.1.2. Direct photochemical degradation

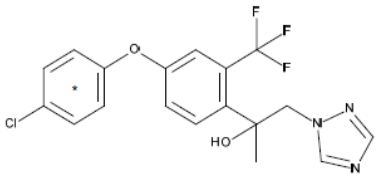
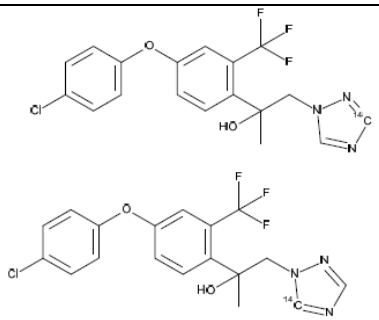
Report: CA 7.2.1.2/1
Zhixing Y., 2015 a
Aqueous Photolysis of 14C-BAS 750 F
2015/7000233
Guidelines: EPA 835.2240, OECD 316 (Photodegradation in Water), FIFRA 40 CFR 160
GLP: yes
(certified by United States Environmental Protection Agency)

Introduction

This study investigated the photolysis of BAS 750 F in HPLC grade water at 25ºC. Degradation DT_{50} values for parent and major photometabolites and the quantum yield were determined. The study was conducted to GLP and according to OECD test guideline 316, and there were no significant deviations that would affect the validity of the study. The Applicant did not undertake a preliminary (tier 1) test; instead, only the main (tier 2) test was undertaken. The RMS deems this acceptable.

Information on the ^{14}C-labeled test materials used in the study is presented in Table 8.2.1.2-1.

Table 8.2.1.2-1: Test materials

Substance code	BAS 750 F		
Reg number	5834378		
CAS number	1417782-03-6		
Chemical name (IUPAC)	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol		
Molecular mass	397.78 g mol^{-1}		
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$		
Label	[chlorophenyl-U-^{14}C]	[triazole-3(5)-^{14}C]	Unlabelled
Batch number	CFQ41561	1062-2001	L84-238
Specific radioactivity of a.s. (MBq mg^{-1})	7.878	5.46	n/a
Radiochemical purity (%)	98.9	98.8	n/a
Purity (%)	99.1	98.9	99.7
Position of label	 (* denotes position of ^{14}C label)		n/a

Test procedure

A pH 7 Buffer solution was used and prepared as follows: Boric acid (0.621 g) was transferred to a bottle and mixed with water (1 L) until all of the boric acid was in solution. After mixing, the pH of the solution was measured (pH 6) and adjusted to a pH of 7.08 by dropwise addition of NaOH (1 N). After preparation, the buffer was autoclaved.

Actinometer solution: A stock solution of 4-nitroacetophenone (PNAP) was prepared by transferring PNAP (0.0629 g) to a 100-mL volumetric flask followed by the addition of ACN (14 mL). The 4-nitroacetophenone was dissolved by sonication and diluted to 100 mL with sterile water (HPLC grade). An aliquot (3.4 mL) of the stock solution prepared above was added to a 500-mL volumetric flask followed by pyridine (800 µL) and diluted to 500 mL with sterile water (HPLC grade). The actinometer concentrations, therefore, were 2.6×10^{-5} M for PNAP and 0.02 M for pyridine.

The stock solutions were prepared by transferring a small amount of chlorophenyl or triazole labelled BAS 750 F to a 25 mL glass volumetric flask and diluting to volume with ACN. The flasks were vortexed to ensure a homogenous solution. The concentrations were checked by LSC and found to be approximately 0.13 mg mL^{-1} and 0.18 mg mL^{-1} for the Stk0001 (chlorophenyl label) and the Stk0002 (triazole label) solutions respectively.

Two 500 mL aliquots of pH 7 buffer solution were transferred to sterile screw-capped glass bottles (1 litre) and dosed using an auto pipette with 2.628 mL and 1.999 mL of Stk0001 and Stk0002, respectively. These were thoroughly mixed using manual shaking and sonication (for 10-15 minutes) to ensure homogenous distribution. For both test solutions (containing Stk0001 and Stk0002), aliquots (200 mL each) of the treated sample were transferred to two photolysis vessels (rep1 and rep2). These were then transferred to the photolysis apparatus.

Along with the [chlorophenyl-U-14C]-BAS 750 F and [triazole-3(5)-14C]-BAS 750 F test solutions, two portions of the actinometer solution (200 mL each) were transferred to two photolysis vessels (rep1 and rep2).

Photolysis was carried out in an Atlas SUNTEST® CPS+ unit with a xenon lamp equipped with filters to mimic sunlight (wavelengths < 290 nm were filtered out). Continuous illumination was employed throughout the study. The average light intensity was 571 W/m^2, equivalent to natural sunlight at 40°N latitude.

The photolysis setup consisted of a rectangular hollow box made of Plexiglas® equipped with a coolant inlet and outlet. The box consisted of 6 wells to house 6 photolysis glass vessels. Each glass vessel had an air inlet, air outlet and a quartz glass disc at the top. Two photolysis glass vessels were filled with 200 mL triazole-labelled BAS 750 F treated sterile pH 7 buffer solution, two photolysis glass vessels were filled with 200 mL chlorophenyl-labelled BAS 750 F treated sterile pH 7 buffer solution, and two photolysis glass vessels were filled with 200 mL of the actinometer solution. The RMS deems the pH used acceptable because the test substance is not susceptible to hydrolysis at pH 4-9 (see Section 8.2.1.1.).

Each duplicate set of vessels were connected to trapping solutions for the collection of volatile radioactivity (1 N NaOH for CO_2). $^{14}CO_2$ was trapped by continuously purging the atmosphere inside the reaction vessel with CO_2 free air and allowing the exiting air to bubble through 1N NaOH solution. Before the purging air was allowed to enter the test system, it was first purified by forcing the air through a 0.2 µm Acrodisc® filter. After filtration, CO_2 present in the air was removed by bubbling through an aqueous solution of NaOH (1N).

The concentration of ^{14}C-BAS 750 F in the buffer solution was approximately 0.7 mg L^{-1}. This test concentration is higher than the guideline recommended "half the water solubility", however, because of the low water solubility of BAS 750 F (0.81 mg L^{-1}), the Applicant deemed this necessary to achieve a concentration suitable enough for identification of the degradation products. The RMS accepts this justification as this change is not believed to have adversely affected the study outcome. The temperature of the photolysis solution was maintained at approximately 25 ± 1°C during irradiation by circulating cold water.

Control solutions of the test substance (^{14}C-BAS 750 F) in sterile test buffer (pH 7) were placed in sterilized containers, sealed and maintained in the dark at 25 ± 1°C. Aliquots from these dark control solutions were taken concurrently with the irradiated samples for analysis by LSC and HPLC.

Sterility was checked on the day of dosing and at the completion of the experiment period. No microbial growth was detected.

Samples were collected at 0, 0.25, 1, 2, 3, 6, 9, 13 and 15 days after treatment (DAT) during the irradiation period and analysed by LSC and HPLC to establish the rate of photolytic degradation of the parent and the formation and decline of the photolysis products. Selected samples were also analysed by LC-MS in order to facilitate the identification of the degradation products. The trapping solutions were analysed by LSC at each sampling interval with the exception of 0 DAT.

Each time-course sample (including volatile traps) were analysed by LSC (in triplicate) to determine the amount of radioactivity present in the solutions. Aliquots from each time-point were also analysed by HPLC. Aliquots of the dark control samples were analysed concurrently with the irradiated samples. Actinometer solutions used for quantum yield determination were also taken at each sampling time and analysed by HPLC. LOQ of the LSC method was 0.459% TAR (3.173µg L^{-1}) and LOD was defined as 2/3 of the LOQ or 0.306% TAR (2.116 µg L^{-1}). LOQ for the HPLC method was 0.312% TAR (2.158 µg L^{-1}) and LOD was defined as 2/3 of the LOQ or 0.208% TAR (1.439 µg L^{-1}).

Results and discussion

Chlorophenyl-label:
The material balance results for the irradiated samples of the chlorophenyl-labelled BAS 750 F treated buffers are given in Table 8.2.1.2-2. It ranged from 92.6-100.0% TAR. The amount of radioactivity collected in the volatile traps remained negligible throughout the study.

The material balance results for the dark control samples of the chlorophenyl-labelled BAS 750 F treated buffers are given in Table 8.2.1.2-3. The mean total radioactivity (% TAR) ranged from 90.1-100.0% TAR. The RMS notes there were 2 samples with a material balance <90% (the lower limit of the OECD acceptable range). However, because on each occasion the other replicate sample recorded a value within the acceptable range, and a reliable kinetic fit could be obtained with these samples included (see 'Kinetic evaluation' section below), the RMS does not deem this deviation to have had a significant impact on the outcomes of the study.

Table 8.2.1.2-2: Material balance of irradiated test systems for chlorophenyl-labelled BAS 750 F

DAT	Buffer [%TAR]	Volatiles traps [%TAR]	Material balance %TAR
0 rep 1	98.8	< LOQ	98.8
0 rep 2	101.2	< LOQ	101.2
0 mean	100.0	< LOQ	100.0
0.25 rep 1	91.7	< LOQ	91.7
0.25rep 2	95.1	< LOQ	95.1
0.25 mean	93.4	< LOQ	93.4
1 rep 1	94.2	< LOQ	94.2
1 rep 2	91.0	< LOQ	91.0
1 mean	92.6	< LOQ	92.6
2 rep 1	94.4	< LOQ	94.4
2 rep 2	97.0	< LOQ	97.0
2 mean	95.7	< LOQ	95.7
3 rep 1	95.4	< LOQ	95.4
3 rep 2	94.6	< LOQ	94.6
3 mean	95.0	< LOQ	95.0
6 rep 1	98.3	< LOQ	98.3
6 rep 2	98.7	< LOQ	98.7
6 mean	98.5	< LOQ	98.5
9 rep 1	97.9	< LOQ	97.9
9 rep 2	98.4	< LOQ	98.4
9 mean	98.1	< LOQ	98.1
13 rep 1	97.8	< LOQ	97.8
13 rep 2	97.3	< LOQ	97.3
13 mean	97.6	< LOQ	97.6
15 rep 1	98.0	< LOQ	98.0
15 rep 2	97.0	< LOQ	97.0
15 mean	97.5	< LOQ	97.5

TAR = Total applied radioactivity
DAT = Days after treatment
LOQ = Limit of quantification (0.459% TAR)

Table 8.2.1.2-3: Material balance of non-irradiated test systems for chlorophenyl-labelled BAS 750 F

DAT	Buffer [%TAR]	Volatiles traps [%TAR]	Material balance %TAR
0 rep 1	98.8	NA	98.8
0 rep 2	101.2	NA	101.2
0 mean	100.0	NA	100.0
0.25 rep 1	94.7	NA	94.7
0.25 rep 2	94.8	NA	94.8
0.25 mean	94.8	NA	94.8
1 rep 1	92.1	NA	92.1
1 rep 2	93.1	NA	93.1
1 mean	92.6	NA	92.6
2 rep 1	91.0	NA	91.0
2 rep 2	89.1	NA	89.1
2 mean	90.1	NA	90.1
3 rep 1	92.9	NA	92.9
3 rep 2	90.8	NA	90.8
3 mean	91.9	NA	91.9
6 rep 1	94.3	NA	94.3
6 rep 2	89.8	NA	89.8
6 mean	92.1	NA	92.1
9 rep 1	91.7	NA	91.7
9 rep 2	92.6	NA	92.6
9 mean	92.1	NA	92.1
13 rep 1	92.9	NA	92.9
13 rep 2	93.2	NA	93.2
13 mean	93.0	NA	93.0
15 rep 1	95.0	NA	95.0
15 rep 2	96.3	NA	96.3
15 mean	95.6	NA	95.6

TAR = Total applied radioactivity
DAT = Days after treatment
NA = Not applicable

Triazole- label:
The material balance results for the irradiated samples of the triazole-labelled BAS 750 F treated buffers are given in Table 8.2.1.2-4. The mean total radioactivity (% TAR) ranged from 95.6-104.8% TAR. The % TAR collected in the volatile traps remained negligible throughout the study.

The material balance results for the dark control samples of the triazole- labelled BAS 750 F treated buffers are given in Table 8.2.1.2-5. The mean total radioactivity (% TAR) ranged from 90.0-100.0% TAR. The RMS notes there was 1 sample with a material balance <90%. However, because the other replicate sample recorded a value within the acceptable range, and a reliable kinetic fit could be obtained with the sample included (see 'Kinetic evaluation' section below), the RMS does not deem this deviation to have had a significant impact on the outcomes of the study.

Table 8.2.1.2-4: Material balance of irradiated test systems for triazole-labelled BAS 750 F

DAT	Buffer [%TAR]	Volatiles traps [%TAR]	Material balance %TAR
0 rep 1	99.8	< LOQ	99.8
0 rep 2	100.2	< LOQ	100.2
0 mean	100.0	< LOQ	100.0
0.25 rep 1	99.2	< LOQ	99.2
0.25 rep 2	96.6	< LOQ	96.6
0.25 mean	97.9	< LOQ	97.9
1 rep 1	95.9	< LOQ	95.9
1 rep 2	96.3	< LOQ	96.3
1 mean	96.1	< LOQ	96.1
2 rep 1	96.1	< LOQ	96.1
2 rep 2	95.1	< LOQ	95.1
2 mean	95.6	< LOQ	95.6
3 rep 1	97.3	< LOQ	97.3
3 rep 2	97.3	< LOQ	97.3
3 mean	97.3	< LOQ	97.3
6 rep 1	100.2	< LOQ	100.2
6 rep 2	101.7	< LOQ	101.7
6 mean	100.9	< LOQ	100.9
9 rep 1	101.6	< LOQ	101.6
9 rep 2	102.5	< LOQ	102.5
9 mean	102.1	< LOQ	102.1
13 rep 1	103.2	< LOQ	103.2
13 rep 2	102.1	< LOQ	102.1
13 mean	102.7	< LOQ	102.7
15 rep 1	104.6	< LOQ	104.6
15 rep 2	105.1	< LOQ	105.1
15 mean	104.8	< LOQ	104.8

TAR = Total applied radioactivity
DAT = Days after treatment
LOQ = Limit of quantification (0.459% TAR)

Table 8.2.1.2-5: Material balance of non-irradiated test systems for triazole-labelled BAS 750 F

DAT	Buffer [%TAR]	Volatiles traps [%TAR]	Material balance %TAR
0 rep 1	99.8	NA	99.8
0 rep 2	100.2	NA	100.2
0 mean	100.0	NA	100.0
0.25 rep 1	93.1	NA	93.1
0.25 rep 2	94.1	NA	94.1
0.25 mean	93.6	NA	93.6
1 rep 1	93.4	NA	93.4
1 rep 2	90.2	NA	90.2
1 mean	91.8	NA	91.8
2 rep 1	92.4	NA	92.4
2 rep 2	94.7	NA	94.7
2 mean	93.5	NA	93.5
3 rep 1	90.6	NA	90.6
3 rep 2	89.4	NA	89.4
3 mean	90.0	NA	90.0
6 rep 1	90.0	NA	90.0
6 rep 2	91.4	NA	91.4
6 mean	90.7	NA	90.7
9 rep 1	91.2	NA	91.2
9 rep 2	92.6	NA	92.6
9 mean	91.9	NA	91.9
13 rep 1	92.3	NA	92.3
13 rep 2	93.9	NA	93.9
13 mean	93.1	NA	93.1
15 rep 1	99.4	NA	99.4
15 rep 2	95.6	NA	95.6
15 mean	97.5	NA	97.5

TAR = Total applied radioactivity
DAT = Days after treatment
NA = Not applicable

The identification of transformation products was based on molecular formulas derived from the ions detected in MS and MS/MS analyses. The structures of most metabolites were also confirmed by comparing data generated from metabolites to data generated from reference standards. The 15 DAT samples from both labels were analysed for final confirmation of the metabolites. A summary of the metabolites detected in the samples is shown in Table 8.2.1.2-6.

Table 8.2.1.2-6: Summary of metabolites detected

HPLC retention time (t_R) (min)	LC/MS retention time (min)	Nominal mass (Da) for unlabelled form	Proposed chemical formula (unlabelled)	Metabolite ID	Proposed identity
22.4	21.4	287	$C_{12}H_{12}F_3N_3O_2$	M750F003	Structure is confirmed with a reference standard
24.2	23.5	337	$C_{18}H_{15}N_3O_4$	M750F007	Structure is confirmed with a reference standard
26.3	25.3	379	$C_{18}H_{16}F_3N_3O_3$	M750F005	Structure is confirmed with a reference standard
26.7	25.7	355	$C_{18}H_{14}CIN_3O_3$	M750F008	Structure is confirmed with a reference standard
28.9	27.8	355	$C_{18}H_{14}CIN_3O_3$	M750F006	Structure is confirmed with a reference standard
31.2	29.7	397	$C_{18}H_{15}CIF_3N_3O_2$	BAS 750 F	Structure is confirmed with a reference standard

The results of the HPLC analysis for the irradiated chlorophenyl-labelled BAS 750 F treated buffer solutions are shown in Table 8.2.1.2-7. The HPLC analysis results showed that BAS 750 F was degraded very rapidly to a large number of products. BAS 750 F accounted for ~1.8% TAR at the end of study (15 DAT). The number of the degradation products increased with time and the degradation products M750F007, M750F005, M750F006, and M750F008 were observed in levels >5% TAR. The maximum levels observed for M750F007, M750F005, M750F006, and M750F008 were 37.0% TAR (15 DAT), 30.2% TAR (6, 9 and 15 DAT), 30.9% TAR (9 DAT), and 7.1% TAR (13 DAT), respectively. Four other degradation products were observed at levels of < 2% TAR and one of them (t_R of ~34.7 min) was stated by the Applicant to be an impurity from the chlorophenyl-labelled BAS 750 F test substance detected at every time point throughout the study (including 0 DAT); the RMS notes this compound was also detected at similar concentrations in the dark control samples, thus giving further weight to the argument that it is an impurity.

The results of the HPLC analysis for the non-irradiated chlorophenyl-labelled BAS 750 F treated buffer solutions are shown in Table 8.2.1.2-8. BAS 750 F is stable in the dark control samples. Only the parent compound was observed in the HPLC chromatograms with the exception of a few minor degradates or a slight impurity (degradates < 1% TAR and the impurity with t_R of ~34.2 min <2% TAR).

Table 8.2.1.2-7: HPLC quantitation of ^{14}C-residues in the irradiated test system for chlorophenyl-labelled BAS 750 F

	%TAR								
Compound t_R [min]	**~16.0**	**M750F007 ~24.2**	**M750F005 ~26.3**	**M750F008 ~26.7**	**~27.4**	**M750F006 ~28.9**	**~29.7**	**BAS 750 F ~31.2**	**~34.7**
DAT									
0 rep1	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	96.9	1.9
0 rep2	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	99.5	1.7
0 mean	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	98.2	1.8
0.25 rep1	< LOQ	< LOQ	4.6	< LOQ	< LOQ	3.5	< LOQ	81.6	2.0
0.25 rep2	< LOQ	< LOQ	4.5	< LOQ	< LOQ	4.2	< LOQ	84.9	1.5
0.25 mean	< LOQ	< LOQ	4.6	< LOQ	< LOQ	3.8	< LOQ	83.3	1.8
1 rep1	< LOQ	< LOQ	12.3	1.9	< LOQ	11.8	< LOQ	66.8	1.4
1 rep2	< LOQ	< LOQ	11.9	1.6	< LOQ	10.7	< LOQ	65.3	1.5
1 mean	< LOQ	< LOQ	12.1	1.7	< LOQ	11.2	< LOQ	66.1	1.4
2 rep1	< LOQ	1.8	17.7	3.6	< LOQ	17.1	< LOQ	52.8	1.4
2 rep2	< LOQ	2.4	19.7	2.7	< LOQ	17.8	< LOQ	53.2	1.3
2 mean	< LOQ	2.1	18.7	3.1	< LOQ	17.4	< LOQ	53.0	1.3
3 rep1	< LOQ	3.1	22.5	2.6	0.9	22.8	1.0	41.2	1.3
3 rep2	< LOQ	3.8	24.1	3.3	< LOQ	20.7	< LOQ	41.1	1.6
3 mean	< LOQ	3.5	23.3	2.9	0.4	21.8	0.5	41.1	1.4
6 rep1	< LOQ	10.1	29.2	5.3	< LOQ	28.4	1.1	23.0	1.3
6 rep2	< LOQ	13.1	30.2	5.6	< LOQ	29.6	1.4	18.0	0.8
6 mean	< LOQ	11.6	29.7	5.4	< LOQ	29.0	1.3	20.5	1.0
9 rep1	1.5	16.2	30.2	5.3	< LOQ	30.9	1.9	11.2	0.7
9 rep2	1.1	20.8	29.9	5.6	< LOQ	30.5	1.5	8.2	0.8
9 mean	1.3	18.5	30.1	5.4	< LOQ	30.7	1.7	9.7	0.8
13 rep1	1.0	31.3	27.9	7.0	1.0	24.3	1.3	3.5	0.6
13 rep2	1.4	33.2	26.0	7.1	< LOQ	25.6	1.5	2.6	< LOQ
13 mean	1.2	32.2	27.0	7.0	0.5	24.9	1.4	3.0	0.3
15 rep1	1.3	35.2	26.9	7.0	< LOQ	22.8	2.0	2.2	0.5
15 rep2	1.7	37.0	30.2	4.4	< LOQ	20.5	1.7	1.4	< LOQ
15 mean	1.5	36.1	28.6	5.7	< LOQ	21.7	1.9	1.8	0.3

TAR = Total applied radioactivity
t_R = HPLC retention time
DAT = Days after treatment
LOQ = Limit of quantification (0.312% TAR)

Table 8.2.1.2-8: HPLC quantitation of ^{14}C-residues in the dark control test system for chlorophenyl-labelled BAS 750 F

	%TAR			
Compound t_R [min]	**M750F005 ~26.3**	**M750F006 ~28.9**	**BAS 750 F ~31.2**	**~34.7**
DAT				
0 rep1	< LOQ	< LOQ	96.9	1.9
0 rep2	< LOQ	< LOQ	99.5	1.7
0 mean	< LOQ	< LOQ	98.2	1.8
0.25 rep1	< LOQ	< LOQ	93.0	1.7
0.25 rep2	< LOQ	< LOQ	93.4	1.4
0.25 mean	< LOQ	< LOQ	93.2	1.6
1 rep1	< LOQ	< LOQ	90.8	1.4
1 rep2	0.9	< LOQ	90.8	1.4
1 mean	0.4	< LOQ	90.8	1.4
2 rep1	< LOQ	< LOQ	89.7	1.3
2 rep2	0.7	0.9	86.3	1.2
2 mean	0.3	0.4	88.0	1.3
3 rep1	1.1	< LOQ	90.0	1.8
3 rep2	0.7	0.8	88.2	1.2
3 mean	0.9	0.4	89.1	1.5
6 rep1	< LOQ	< LOQ	92.4	1.9
6 rep2	< LOQ	< LOQ	87.9	1.9
6 mean	< LOQ	< LOQ	90.2	1.9
9 rep1	< LOQ	< LOQ	90.5	1.2
9 rep2	< LOQ	< LOQ	91.3	1.2
9 mean	< LOQ	< LOQ	90.9	1.2
13 rep1	< LOQ	< LOQ	91.2	1.7
13 rep2	< LOQ	< LOQ	91.7	1.4
13 mean	< LOQ	< LOQ	91.5	1.6
15 rep1	< LOQ	< LOQ	93.6	1.4
15 rep2	< LOQ	< LOQ	94.9	1.4
15 mean	< LOQ	< LOQ	94.2	1.4

TAR = Total applied radioactivity
t_R = HPLC retention time
DAT = Days after treatment
LOQ = Limit of quantification (0.312% TAR)

The results of the HPLC analysis for the irradiated triazole- labelled BAS 750 F treated buffer solutions are shown in Table 8.2.1.2-9. The HPLC analysis results also demonstrated that BAS 750 F was degraded very rapidly to a large number of products. BAS 750 F accounted for ~0.9% TAR at the end of study (15 DAT). The number of the degradation products increased with time and the degradation products M750F007, M750F005, M750F006, and M750F008 were observed at levels >5% TAR. The maximum levels observed for M750F007, M750F005, M750F006, and M750F008 were 46.1% TAR (15 DAT), 32.3% TAR (6 DAT), 30.6% TAR (6 DAT), and 7.9% TAR (13 DAT), respectively. A few other degradation products, including M750F002 and M750F003, were observed at levels of ≤3% TAR (identified by HPLC and retention time matching to known standards); both M750F002 and M750F003 were increasing at study termination, however, the 'major' metabolite criteria were not triggered in this study as their concentrations were <5%. The Applicant states the product with t_R of ~4.9 min (maximum level of ~3% TAR) was very likely M750F001 (1,2,4-triazole) based on its retention time as compared to the reference standard.

The results of the HPLC analysis for the non-irradiated triazole-labelled BAS 750 F treated buffer solutions are shown in Table 8.2.1.2-10. HPLC analysis demonstrated that BAS 750 F was stable in the dark control samples.

Table 8.2.1.2-9: HPLC quantitation of ^{14}C-residues in the irradiated test system for triazole-labelled BAS 750 F

	% TAR								
Compound t_R [min]	**~4.9**	**M750F002 ~20.1**	**M750F003 ~22.4**	**M750F007 ~24.2**	**M750F005 ~26.3**	**M750F008 ~26.7**	**M750F006 ~28.9**	**BAS 750 F ~31.2**	**All Other Peaks***
DAT									
0 rep1	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	99.8	< LOQ
0 rep2	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	100.2	< LOQ
0 mean	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	100.0	< LOQ
0.25 rep1	< LOQ	< LOQ	< LOQ	< LOQ	3.8	< LOQ	3.5	91.8	< LOQ
0.25 rep2	< LOQ	< LOQ	< LOQ	< LOQ	3.5	< LOQ	3.1	90.0	< LOQ
0.25 mean	< LOQ	< LOQ	< LOQ	< LOQ	3.6	< LOQ	3.3	90.9	< LOQ
1 rep1	1.3	< LOQ	< LOQ	1.1	12.4	1.5	12.3	67.2	< LOQ
1 rep2	1.1	< LOQ	< LOQ	1.0	12.2	1.0	12.7	68.2	< LOQ
1 mean	1.2	< LOQ	< LOQ	1.1	12.3	1.3	12.5	67.7	< LOQ
2 rep1	< LOQ	< LOQ	0.7	2.1	20.7	2.8	19.2	50.5	< LOQ
2 rep2	< LOQ	< LOQ	0.8	2.5	20.3	3.2	19.4	48.9	< LOQ
2 mean	< LOQ	< LOQ	0.7	2.3	20.5	3.0	19.3	49.7	< LOQ
3 rep1	1.3	0.5	1.1	4.4	24.8	4.0	24.6	36.5	< LOQ
3 rep2	1.5	0.4	1.4	5.6	25.9	4.1	23.6	34.8	< LOQ
3 mean	1.4	0.5	1.2	5.0	25.4	4.1	24.1	35.7	< LOQ
6 rep1	< LOQ	2.1	1.1	14.4	32.3	4.5	29.7	16.1	< LOQ
6 rep2	1.1	1.0	1.1	15.6	32.1	5.9	30.6	14.4	< LOQ
6 mean	0.6	1.5	1.1	15.0	32.2	5.2	30.2	15.2	< LOQ
9 rep1	1.7	1.6	1.3	24.1	31.5	6.7	29.0	5.8	< LOQ
9 rep2	1.9	1.9	1.2	26.2	30.1	5.7	28.7	4.8	2.0
9 mean	1.8	1.8	1.3	25.1	30.8	6.2	28.9	5.3	1.0
13 rep1	3.6	2.4	1.2	37.0	27.4	6.7	23.4	1.6	< LOQ
13 rep2	2.3	3.9	< LOQ	40.0	24.4	7.9	22.1	1.6	< LOQ
13 mean	2.9	3.2	0.6	38.5	25.9	7.3	22.7	1.6	< LOQ
15 rep1	3.0	3.4	1.3	41.8	24.9	6.8	21.0	0.9	1.4
15 rep2	2.7	3.2	1.8	46.1	24.2	5.4	20.9	0.9	< LOQ
15 mean	2.8	3.3	1.5	43.9	24.6	6.1	21.0	0.9	0.7

TAR = Total applied radioactivity
t_R = HPLC retention time
DAT = Days after treatment
LOQ = Limit of quantification (0.312% TAR)

Table 8.2.1.2-10: HPLC quantitation of ^{14}C-residues in the dark control test system for triazole-labelled BAS 750 F

	% TAR	
Compound t_R [min]	**~4.9**	**BAS 750 F ~31.2**
Days after treatment (DAT)		
0 rep1	< LOQ	99.8
0 rep2	< LOQ	100.2
0 mean	< LOQ	100.0
0.25 rep1	< LOQ	93.1
0.25 rep2	< LOQ	94.1
0.25 mean	< LOQ	93.6
1 rep1	< LOQ	93.4
1 rep2	< LOQ	90.2
1 mean	< LOQ	91.8
2 rep1	< LOQ	92.4
2 rep2	< LOQ	94.7
2 mean	< LOQ	93.5
3 rep1	< LOQ	90.6
3 rep2	< LOQ	89.4
3 mean	< LOQ	90.0
6 rep1	< LOQ	90.0
6 rep2	< LOQ	91.4
6 mean	< LOQ	90.7
9 rep1	1.5	89.7
9 rep2	< LOQ	92.6
9 mean	0.8	91.2
13 rep1	< LOQ	92.3
13 rep2	< LOQ	93.9
13 mean	< LOQ	93.1
15 rep1	< LOQ	99.4
15 rep2	< LOQ	95.6
15 mean	< LOQ	97.5

TAR = Total applied radioactivity
t_R = HPLC retention time
LOQ = Limit of quantification (0.312% TAR)

A chiral HPLC method which separates the *R*- and *S*-isomers of BAS 750 F was used to check the distribution of the *R*- and *S*-isomers of BAS 750 F. Results showed that the ratios of *R*- and *S*-isomers did not significantly change over time, as reported in Table 8.2.1.2-11. It can be concluded that both the *R*- and *S*- isomers of the racemic parent BAS 750 F are comparably degradable and there was no interconversion (isomerisation) between the *R* and *S* isomers.

Table 8.2.1.2-11: Chiral analysis

Sampling interval (DAT)	**Chloropheyl label**		**Triazole label**	
	14C-BAS 750 F R-Isomer (%)	14C-BAS 750 F S-Isomer (%)	14C-BAS 750 F R-Isomer (%)	14C-BAS 750 F S-Isomer (%)
0	49.7	50.3	50.7	49.9
1	52.1	47.9	50.8	49.2
3	48.5	51.5	49.4	50.6
15	43.3	56.7	46.5	53.5

Kinetic evaluation

The data generated in this study was analysed in accordance with FOCUS kinetic guidance to determine DT_{50}, and DT_{90} values for BAS 750 F and its photodegradation products. The results from both radiolabels were combined for the kinetic evaluation, so there are four replicate values at each time point. The Applicant used KinGUII v2 with IRLS selected and followed the 'triggering endpoint flowchart' (Figure 7-2 of Version 1.1 of the FOCUS kinetic guidance, 2014). The RMS repeated the Applicant's modelling using CAKE v3.2 with OLS selected.

Four metabolites (M750F005, M750F006, M750F007 and M750F008) in the irradiated samples were observed in levels > 5% TAR at two consecutive time points and/or were increasing at study termination. Two metabolites were not kinetically evaluated, as they were either increasing at the end of the study (M750F007), or there were too few sampling points beyond the maximum reported value (M750F008); conservative default DT_{50} values will be used for these metabolites. For the other two metabolites (M750F005, M750F006), the Applicant kinetically evaluated these from their maximum reported values onward. Both were observed to degrade following first order kinetics. The RMS notes that this is not the preferred method according to FOCUS guidance; where possible, the formation phase of the metabolites should also be modelled. Furthermore, the RMS notes that there were only four time points in the decline phase for M750F005 and three time points for M750F006; the FOCUS guidance recommends a minimum of 5 time points in order to obtain a statistically robust fit. Therefore, the RMS has modelled the formation and decline phases of the metabolites with the parent compound (results presented below).

As previously discussed, the compound detected at a HPLC retention time of 34.7 minutes at Time 0 in the chlorophenyl-labelled study is most likely an impurity of the parent compound. Therefore, the Applicant has not added the amounts detected back to the parent compound and it is not considered further in the kinetic evaluation. The RMS considers this approach acceptable and has used the same approach (the RMS set the Time 0 data points for M750F005 and M750F006 to zero.

The Applicant followed Figure 7-1 of the FOCUS guidance to determine the triggering endpoints whilst the RMS followed Figure 8-6. In both instances, SFO and FOMC models are initially compared. In both the Applicant's and RMS's modelling, the FOMC model did not result in a markedly improved visual and/or statistical fit (however, the RMS notes no FOMC data was provided for M750F006 by the Applicant), therefore, SFO models were used to determine the triggering endpoints; SFO models provided acceptable fits for the metabolites in the RMS's modelling. The Applicant's statistical results are presented Table 8.2.1.2-11 and the corresponding graphs in Figures 8.2.1.2-1 to 8.2.1.2-3. The RMS's modelled degradation pathway is presented in Figure 8.2.1.2-4 and statistical and graphical results in Table 8.2.1.2-12 and Figure 8.2.1.2-5 respectively.

Table 8.2.1.2-11: Summary of the Applicant's kinetic results for the aqueous photolysis of BAS 750 F and two metabolites

	BAS 750 F		**M750F005[a]**		**M750F006[a]**	
System	Irradiated, pH7					
Kinetic model	SFO	FOMC	SFO	FOMC	SFO	FOMC
Visual fit	Very good	Very good	Good	Good	Very good	Not provided
M_0	95.5	96.8	31.3	30.95	29.8	Not provided
K	0.3	n/a	0.02	n/a	0.06	n/a
T-test	<0.001	n/a	<0.001	n/a	<0.001	n/a
Alpha (st. dev.)	n/a	5.8 (2.1)	n/a	283 (66)	n/a	Not provided
Beta (st. dev.)	n/a	16.7 (6.7)	n/a	1422 (1.3)	n/a	Not provided
χ^2	3.9	3.1	1.9	2.4	0.05	Not provided
DT_{50}	2.3	2.1	34.8	34.8	12.4	Not provided
DT_{90}	7.6	8.2	115.6	116	41.3	Not provided

[a] Metabolites decline fit from peak reported value onward

Figure 8.2.1.2-1: SFO (left) and FOMC (right) fits for BAS 750 F

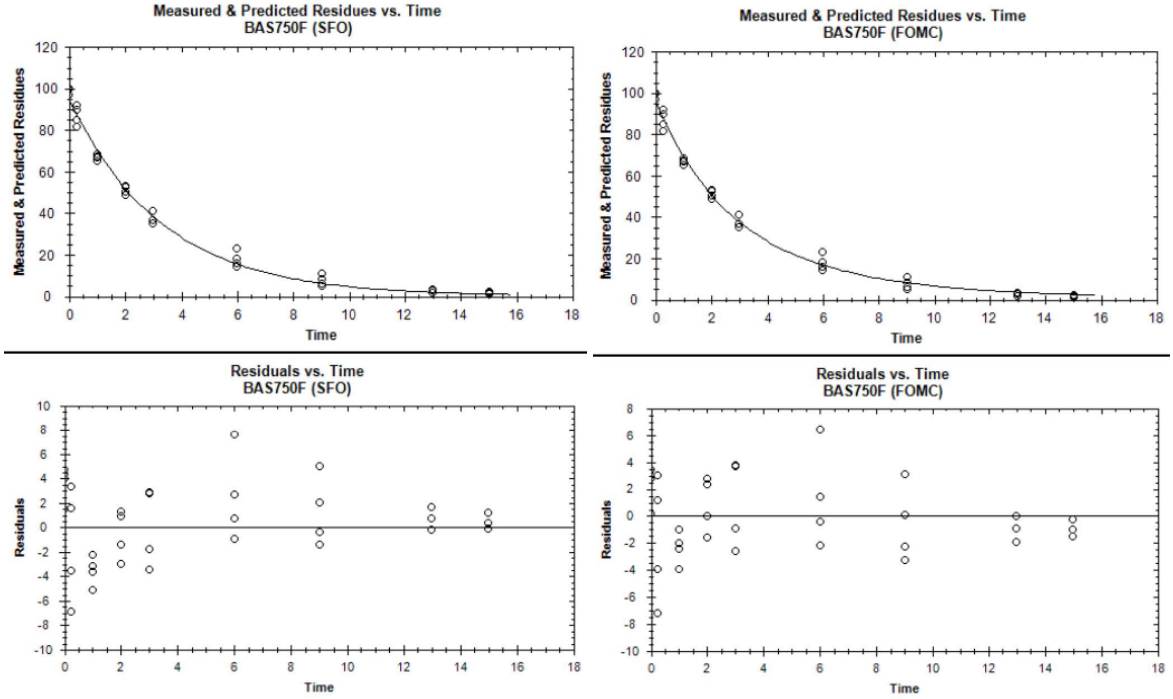


Figure 8.2.1.2-2: SFO (left) and FOMC (right) fits for M750F005

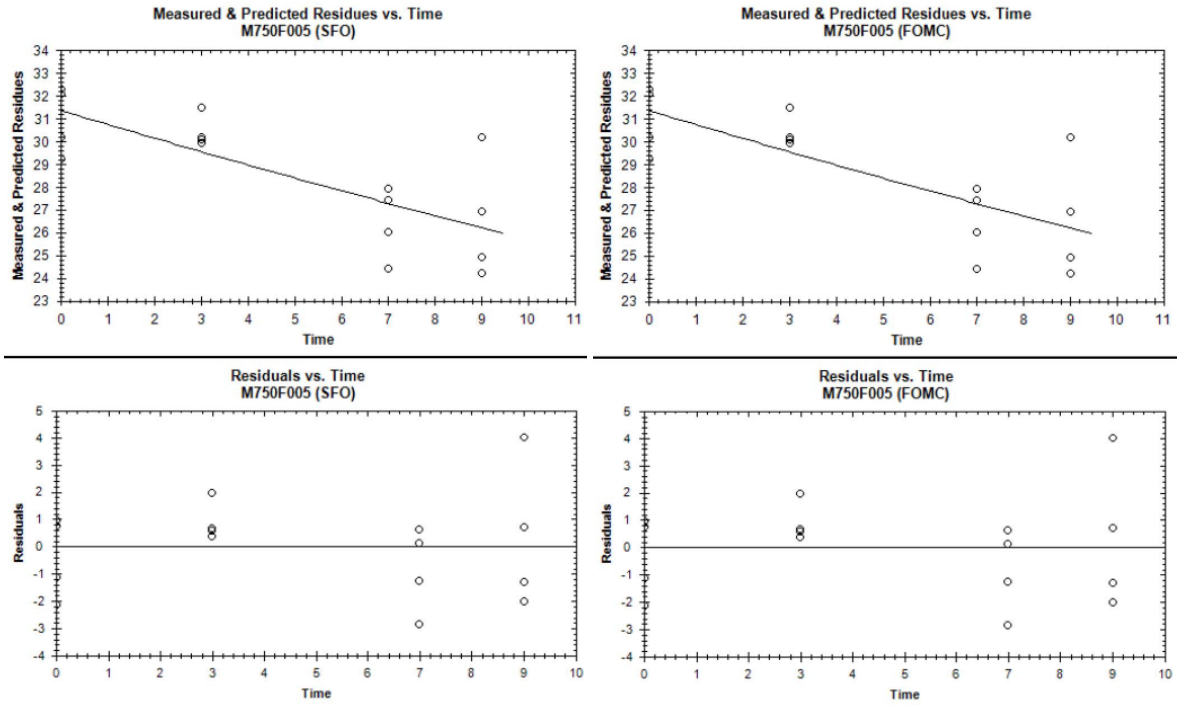


Figure 8.2.1.2-3: SFO fit for M750F006 (no FOMC fit was supplied)

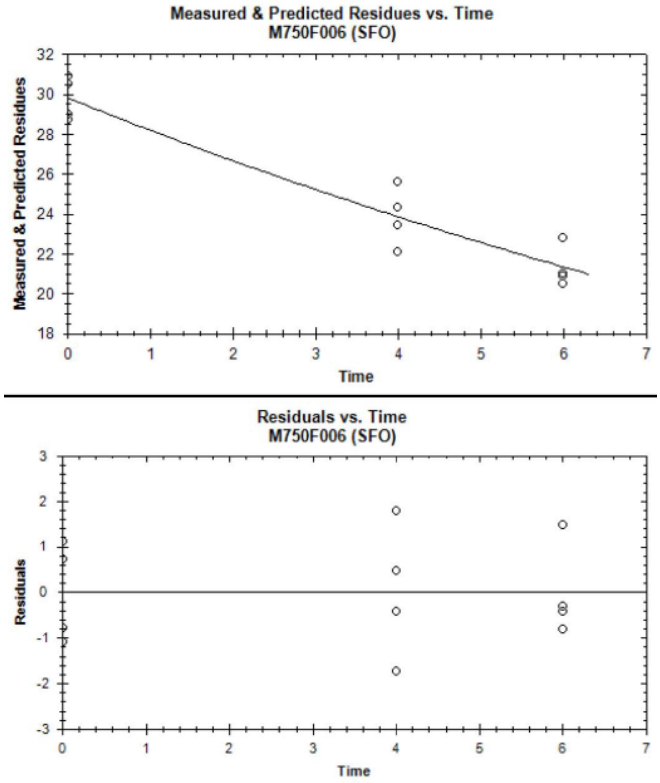


Figure 8.2.1.2-4: RMS's modelled degradation pathway of BAS 750 F to M750F005 (A1) and M750F006 (B1)

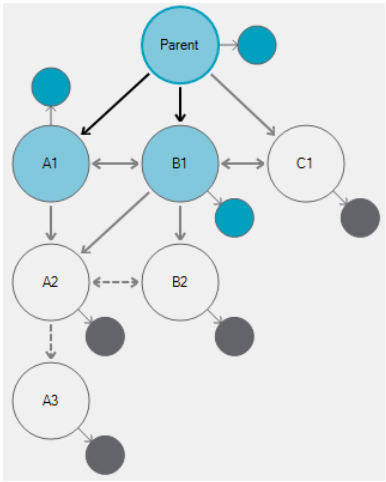
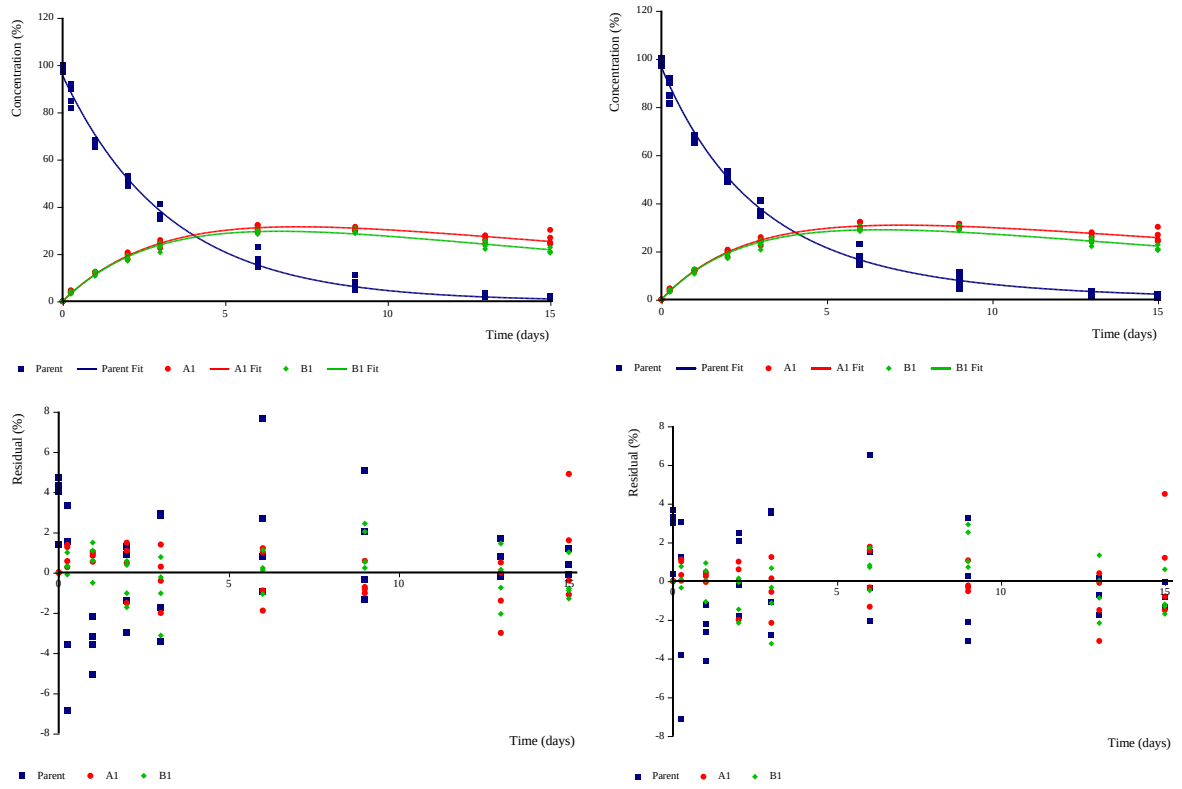


Table 8.2.1.2-12: Summary of the RMS's kinetic results for the aqueous photolysis of BAS 750 F and two metabolites

	BAS 750 F		M750F005		M750F006	
System	Irradiated, pH7					
Kinetic model	SFO	FOMC	SFO (SFO parent)	SFO (FOMC parent)	SFO (SFO parent)	SFO (FOMC parent)
Visual fit	Very good	Very good	Good	Good	Good	Good
M_0	95.5	96.5	n/a	n/a	n/a	n/a
K	0.3	n/a	0.05	0.04	0.06	0.05
T-test	<0.001	n/a	<0.001	<0.001	<0.001	<0.001
Alpha (st. dev.)	n/a	6.6 (1.8)	n/a	n/a	n/a	n/a
Beta (st. dev.)	n/a	19.4 (5.7)	n/a	n/a	n/a	n/a
χ^2	3.9	3.1	2.7	2.1	2.7	3.6
Form. fraction	n/a	n/a	0.46	0.45	0.46	0.45
DT_{50}	2.3	2.2	14.7	16.1	11.6	12.6
DT_{90}	7.6	8.2	48.8	53.6	38.6	41.9

Figure 8.2.1.2-5: RMS's SFO parent (left) and FOMC parent (right) fits (metabolites both SFO fits; A1 corresponds to M750F005, B1 corresponds to M750F006)



As Table 8.2.1.2-12 and Figure 8.2.1.2-5 show, the RMS is able to obtain acceptable SFO fits for both parent and metabolites when modelled together, and so thus is more in line with the preferred method stated in the FOCUS guidance. However, the Applicant has proposed the use of default DT_{50} values of 1000 days for both metabolites in the aquatic risk assessment due to the unreliability of their method and results. Because this will result in a more conservative risk assessment, the RMS accepts the Applicant's proposal.

Both the Applicant and the RMS obtained an acceptable SFO fit for BAS 750 F with the same DT_{50} value. Therefore, the appropriate triggering endpoint (and modelling endpoint because SFO is appropriate) is 2.3 days.

Default DT_{50} values of 1000 days for all photolytic metabolites (M750F005, M750F006, M750F007 and M750F008) are appropriate for use in the risk assessment.

The Applicant has calculated a quantum yield for BAS 750 F of 3.5×10^{-1}.

Conclusion

Rapid degradation of BAS 750 F was observed in the continuously irradiated samples with a half-life of 2.3 days. No degradation of ^{14}C-BAS 750 F was observed in the dark control samples. The quantum yield of BAS 750 F was determined to be 3.5×10^{-1}. It may be concluded that aqueous photolysis could play a significant role in the overall environmental degradation of BAS 750 F.

B.8.2.1.3. Indirect photochemical degradation

The Notifer has not submitted an indirect photolysis study, stating "Due to significant degradation under direct aquatic photolysis, investigations into indirect photolysis were not deemed necessary". The RMS accepts the Applicant's justification on this occasion.

B.8.2.2. Route and rate of biological degradation in aquatic systems

B.8.2.2.1. "Ready biodegradability"

Report: CA 7.2.2.1/1
Schwarz H., 2014 a
BAS 750 F - Determination of the ready biodegradability in the CO_2-evolution test
2014/1239574

Guidelines: OECD 301 B, ISO 9439, EPA 835.3110, (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to (EC) No 1907/2006 of European Parliament and of Council on the REACH - Part C.4

GLP: yes
(certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)

Introduction

The objective of the study was to determine the ready biodegradability of BAS 750 F in aerobic aqueous medium by measurement of the formed carbon dioxide. The study was undertaken to OECD 301b guidelines; no deviations from the guidelines occurred which would affect the validity of the study results.

The study was undertaken on non-radiolabelled BAS 750 F and aniline was used as the reference item; further information on the test compounds is provided in Table 8.2.2.1/1.

Table 8.2.2.1-1: Test material information

Internal code	BAS 750 F	Aniline
Reg number	5834378	01/0298-20
CAS number	1417782-03-6	62-53-3
Chemical name (IUPAC)	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	Aniline
Molecular mass	397.8 g mol^{-1}	93 g mol^{-1}
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$	C_6H_7N
Batch number	COD-001880	STBD5586V
Purity	98.6%	Not given

Study design

Test system

Municipal activated sludge from the wastewater treatment plant of Mannheim, Germany was used to determine the "Ready Biodegradability" of BAS 750 F. The inoculum was collected on 18 August 2014 from the aeration tank of the plant.

A suitable aliquot of the activated sludge suspension was sieved by a finely woven mesh with a mesh size about 1 mm. To reduce the content of inorganic carbon in the blank controls the activated sludge was aerated with carbon dioxide free air for about 48 hours at 22 ± 2°C. The RMS notes that the OECD 301 guidelines states that the activated sludge should be aerated for 5-7 days. However, given that the reference compound exhibited extensive biodegradation (see "Results" section), the RMS is of the opinion that this deviation from the guidelines did not significantly affect the outcome of the study.

The Applicant also indicates that, due to a technical malfunction, the test temperature fell slightly below 20°C at the end of exposure. Again, given that the reference compound exhibited extensive biodegradation, the RMS is of the opinion that this deviation did not significantly affect the outcome of the study

Experimental conditions

At the day of exposure the activated sludge suspension was washed one time with drinking water. Subsequently, the aeration was stopped and the sludge was allowed to settle. After settling, the supernatant was discarded and the remaining sludge suspension was filled up with drinking water and the concentration of the sludge was adjusted to 6.0 g L^{-1} dry weight. Aliquots of 7.5 mL were added to the test vessels to obtain an activated sludge concentration of 30 mg L^{-1} dry weight.

Test assays were prepared; comprising two blank control assays, two test substance assays, one inhibition control test assay, and one reference substance assay.

A mineral medium was prepared consisting of the following four solutions:

Solution A: 8.5 g KH_2PO_4 + 21.75 g K_2HPO_4 + 33.4 g Na_2HPO_4 x 2 H_2O + 0.5 g NH_4Cl in 1 L deionized water (pH value was adjusted to 7.4)
Solution B: 36.4 g $CaCl_2$ x 2 H_2O in 1 L deionized water
Solution C: 22.5 g $MgSO_4$ x 7 H_2O in 1 L deionized water
Solution D: 0.25 g in $FeCl_3$ x 6 H_2O in 1 L deionized water

15 mL solution A, 1.5 mL solution B, 1.5 mL solution C and 1.5 mL solution D was used for the preparation of the test assays, which were performed in 2 L incubation bottles filled up to a volume of 1.5 L with deionized water.

The incubation bottles were connected to two serial scrubbing bottles, containing 0.05 M NaOH solution for the adsorption of CO_2. The incubation bottles were stirred on magnetic stirrers; the aeration was performed with CO_2-free air.

For preparation of the test vessels with test substance and the inhibition control, the required amounts of the test substance were added to reach a concentration of 20 mg L^{-1} TOC (total organic carbon; corresponding to 37 mg/L test substance). Due to the poor water solubility of the test substance, the test vessels were treated for several minutes in an ultrasonic bath to ensure an even distribution of the test substance. The Applicant did not undertake any tests to ensure the homogeneity of the test substance, however, given that little variability in the results was exhibited (see 'results and discussion' section below), the RMS is of the opinion that this suggests the test substance was sufficiently distributed. The reference substance assay was treated with the reference item (aniline) to reach 20 mg TOC L^{-1} and 20 mg TOC L^{-1} in the inhibition control.

The pH values in the test vessels were measured and adjusted to 7.4 ± 0.2 (with 1 molar sulfuric acid), if necessary. Aliquots of activated sludge suspension were added to all test vessels, to adjust the concentration of activated sludge to 30 mg L^{-1} dry weight. The test assays were stirred using magnetic stirrers.

At the end of exposure, the pH values were measured in each test vessel. For stripping of CO_2 dissolved in the test medium, each test vessel was acidified by adding 2 mL of concentrated HCl. The concentration of dissolved organic carbon (DOC) in the blank controls and reference substance assays were determined. Since the test substance was insufficiently soluble in water, no DOC measurements could be performed from the test assay of the inhibition control and from the test substance test assays.

The aeration was continued for approximately 24 hours and the released CO_2 amounts in both traps of each test vessel were determined and added to the calculated amount of the previous day.

Sampling

At appropriate intervals, the total inorganic carbon (TIC) values of the adsorption solutions of the first trap were determined and used for the calculation of the produced CO_2. After each sampling, the second trap was moved forward and the new trap with fresh NaOH solution was placed into the second position. Each trap was analysed separately.

Samples for measurement of the dissolved inorganic carbon (DIC; validity criterion) from the blank control assays were taken. For determination of the decrease of dissolved organic carbon (DOC), samples were taken from the test vessels of the blank control and from the test vessel of the reference substance control and the DOC content was determined after centrifugation (~15 minutes at 4000 rpm).

Analytical methods

The TIC value of the freshly prepared NaOH solution was determined and considered using the calculation of the biogenic produced CO_2.

The TIC and DOC analyses were performed as repeat determination, using a TOC analyser equipped with an auto sampler. The system worked with a combustion/non-disperse infrared gas analysis method. For calibration of the TOC-Analyser, standard samples were measured before the start of measurements to prove the conformity with the calibration curve. The samples for TIC analysis (absorption solution) were measured without further treatment. The samples for the DOC analysis were centrifuged and analysed on the day of sampling.

The measured amount of CO_2 at the end of the test was compared with the calculated maximal theoretical production ($ThCO_2$) and indicated as a percentage of biodegradation.

Results and discussion

The degree of biodegradation of the test substance at the end of exposure (mean value) was < 10% $CO_2/ThCO_2$, while it was 91% for the reference substance and 39% in the inhibition control test. A summary of the degrees of biodegradation is presented in Table 8.2.2.1-2.

Table 8.2.2.1-2: Degree of biodegradation [% $CO_2/ThCO_2$]

Test duration [days]	Test assays				
	Reference substance	Inhibition control	Test substance 1	Test substance 2	Test substance mean
0	0	0	0	0	0
2	2	0	0	0	0
5	38	11	1	0	1
7	52	17	1	0	1
12	68	23	0	-1	-1
14	73	29	0	-1	-1
19	82	33	-1	-1	-1
21	86	35	-1	-1	-1
23	88	35	-2	-2	-2
27	90	36	-2	-1	-2
28	91	39	-4	0	-2

OECD 301 guidelines indicate that, for the test substance to be classed as 'ready biodegradable', degradation values should be >60%. Therefore, because only very minor degradation was observed, the test substance is not 'ready biodegradable'. Also, because the Day 14 result for the inhibition control vessel was >25% (29%), the test substance is not inhibitory either.

Mean concentrations of DOC decreased from 1.4 to 1.0 mg L^{-1} in the control assays and from 19.6 to 1.2 mg L^{-1} in the reference substance assays (representing a decrease of 99%).

Conclusion

BAS 750 F was not readily biodegradable in this carbon dioxide evolution test based on the quantitative determination of the formed carbon dioxide in the test substance assays by comparison with the calculated maximal theoretical CO_2 production.

B.8.2.2.2. Aerobic mineralisation in surface water

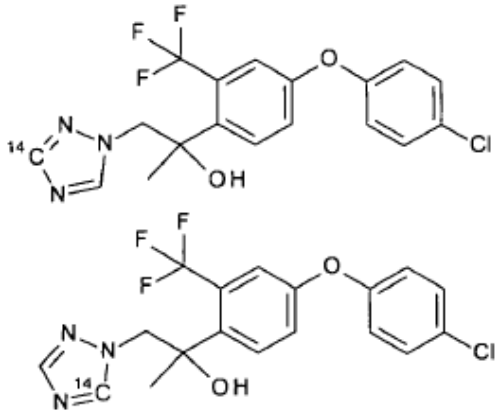
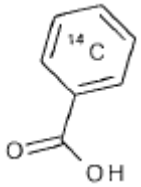
Report: CA 7.2.2.2/1
Michel A., 2015 a
14C-BAS 750F: aerobic mineralization in surface water
2015/1186902
Guidelines: OECD 309 (April 2004)
GLP: yes
(certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)

Introduction

The aerobic mineralisation and degradation rate of the fungicidal active substance BAS 750 F in an aquatic system under dark conditions was investigated. The test was undertaken to OECD 309 guidelines; no significant deviations from the guidelines occurred which would affect the validity of the outcomes of the study.

In addition to the parent compound, in order to prove the viability of the aqueous system, four test vessels were treated with benzoic acid. Information on the ^{14}C labelled test compounds are included in Table 8.2.2.2-1.

Table 8.2.2.2-1: Test materials

Substance code	BAS 750 F	Benzoic acid
Reg number	5834378	4005129
CAS number	1417782-03-6	65-85-0
Chemical name (IUPAC)	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	Benzoic acid
Molecular mass	397.78 g mol^{-1}	128.3
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$	$C_7H_6O_2$
Label	Triazole-3(5)-^{14}C	U-^{14}C
Batch number	1062-2201	QBC148_B12131-12110
Specific radioactivity of a.s. (MBq mg^{-1})	5.47	37.6
Radiochemical purity (%)	99.4	98.4
Purity (%)	98.2	Not provided
Position of label		

In addition to these, four reference items were used in the study:

- Unlabelled BAS 750 F (both enantiomers)
- Unlabelled 1,2,4-Triazole (M750F001)
- Unlabelled M750F003
- Unlabelled M750F006

The RMS notes that, preferably, the other rings of BAS 750 F would also have been radiolabelled. However, given that very little degradation was observed in this study (see "Results" section below), the RMS is of the opinion that, in this instance, it was acceptable to only radiolabel one ring.

Test system

Water was collected on May 29th, 2015 from Ranschgraben, a small stream east of Schifferstadt surrounded by a forest; no pesticides have been used in the immediate vicinity of the sampling site for at least the preceding 10 years. The site is located in Rhineland-Palatinate, in the south-western part of Germany.

The water was filtered through a 0.2 mm sieve, directly at the field sampling site. A small amount of surface sediment was also collected, passed through a 2 mm sieve and dried at room temperature. Water and sediment were stored at 4°C under dark conditions until filling into the test vessels.

The test system was characterised with respect to various hydrological characteristics; pH, O_2 content, redox potential and temperature of the water, as well as redox potential of the sediment, were measured directly at the site of sampling. The physico-chemical properties of the system are summarised in Table 8.2.2.2-2.

Table 8.2.2.2-2: River water and sediment characteristics

Designation **Origin**		**Ranschgraben** **Rhineland-Palatinate, Germany**	
Parameters measured at sampling site			
Temperature	[°C]	13.6	
pH (water)	-	7.20	
Oxygen concentration	[mg L^{-1}]	9.0	
Redox potential water	[mV]	265	
Redox potential sediment	[mV]	-220	
Parameters measured at 0 day sample			
Temperature	[°C]	20.9; 20.4; 20.7; 20.9 [a]	
pH (water)	-	8.06; 8.01; 8.01; 8.02 [a]	
Oxygen concentration	[mg L^{-1}]	8.8;8.8; 8.8; 8.8 [a]	
Redox potential water	[mV]	190; 196; 196; 167 [a]	
Redox potential sediment	[mV]	n.p.	
Water parameters			
Depth of sampling	[cm]	10-20	
Visual appearance	-	Clear	
TOC (total organic carbon)	[mg L^{-1}]	4.9	
DOC (dissolved organic carbon)	[mg L^{-1}]	3.8	
Hardness	[mmol L^{-1}]	0.09	
Carbonate hardness	[mmol L^{-1}]	0.63	
Total N	[mg L^{-1}]	0.49	
Total P	[mg L^{-1}]	0.227	
Microbial plate count	[colony forming units mL^{-1}]	Beginning [b]	End [c]
Bacteria		4720	5080
Fungi		48	26
Actinomycetes		136	66

[a] Four test vessels for the 0 day sampling (two replicates of the low concentration test and two replicates of the high concentration test)
[b] Water sample on the day of sampling
[c] Untreated water sample at the end of the incubation period
n.p. = not performed

Experimental conditions

A total number of 49 test vessels were prepared for incubation. Each flask was filled with 400 mL of water. In order to provide a minimum of mineral and nutrient source for the microbial population, a small concentration of

suspended solids was added to the water. For this, the dried sediment was grinded in an analytical mill and 0.508 g were suspended in 6 mL of water. 50 µL of the obtained suspension were pipetted into each test vessel to reach a concentration of sediment solids of about 0.01 g L^{-1}. The Applicant indicates, however, that the test system can still be considered as pelagic. The RMS disagrees with this statement however, on the basis that the experimental conditions are in line with the guidance for a 'suspended sediment' test, not pelagic. Table 8.2.2.2-3 illustrates the experimental setup. To provide sterile controls, six test vessels were sterilised in an autoclave (20 min at 120°C).

Table 8.2.2.2-3: Experimental setup

System	Test conc. [µg L^{-1}]	No. of test vessels
Test vessels		
triazole-3(5)-^{14}C-labelled-BAS 750 F	10	18
	100	18
Controls		
^{14}C-benzoic acid	10	4
untreated*	-	3
sterile - triazole-3(5)-^{14}C-labelled-BAS 750 F	100	6

* for water characterisation

The test vessels were placed on multiple magnetic stirrers and incubated at 20 ± 1°C in the dark, in a metabolism chamber providing the test vessels with a continuous flow of fresh air. A glass rod with an encapsulated small magnetic bar hanging from the test vessel screw cap slightly agitated the upper 1-2 cm water layer to keep the oxygen saturation at a sufficient level.

Application

Stock solution of BAS 750 F was prepared by dissolving 3 mg of test item in acetonitrile (ACN), resulting in a concentration of 2.125 mg/mL. This stock solution was then used to create an application solution for the higher test concentration (containing 1.544 g/L BAS 750 F) and an application solution for the lower test concentration (containing 0.177 g/L). A stock solution containing 0.205 g benzoic acid/L was also created and used to create an application solution of 0.022 g benzoic acid/L.

The nominal application rates of the test item were 10 µg L^{-1} and 100 µg L^{-1} for the low and the high application rates respectively. This was achieved by pipetting 25 µL of the corresponding application solutions into the upper water layer of the test vessels. The nominal application rate for viability control (^{14}C-benzoic acid treated vessels) was 10 µg L^{-1}. This rate was attained by treating four test vessels with 185µL of the ^{14}C-benzoic acid application solution. The sterilised test vessels were treated under sterile conditions to reach a nominal application rate of 100 µg L^{-1}.

After application of the test item, each test vessel was connected to the air stream leading to a trapping system of two gas washing bottles containing different trapping solutions. The first flask was filled with about 25 mL ethylene glycol to trap potential organic volatiles and the second flask with approximately 45 mL 1 M NaOH (amended with a coloured pH indicator) to trap $^{14}CO_2$ formed by mineralisation of the test substance.

The sterilised test vessels were kept closed and were not connected to the air flow system. They were only opened for a short period to be treated with test item under sterile conditions.

The test vessels treated with ^{14}C-benzoic acid were connected to a trapping system consisting of two volatile traps filled with 1 M NaOH (45 mL). After each sampling, the volatile traps were replaced by new traps containing fresh solutions.

The untreated control vessels were only connected to one volatile trap filled with ethylene glycol. One untreated control sample was used for microbial plate count at the beginning of the experiment. Two untreated control samples were used for system characterisation at the end of the experiment (63 days).

Sampling

Test vessels were sampled at 0, 3, 7, 14, 21, 35 and 63 days after treatment for both test variants (high and low concentration). The volatile traps collected at each sampling time were disconnected from the air stream and stored at room temperature until measurement. The sterile vessels (only high concentration test) were sampled after 21 and 63 days.

The parameters temperature, O_2 content, pH and redox potential of the water were recorded. The water from both vessels was combined and the sample was prepared for microbial plate counts.

Test vessels treated with ^{14}C-benzoic acid (and the NaOH traps) were sampled at 3, 8, 15, 22, 36 and 64 days after treatment.

The RMS notes that sampling began (on 02/06/2015) four days after the surface water was collected (on 29/05/2015), as opposed to the OECD 309 guideline of one day. However, given that the system was shown to still be microbially active (see "Results" section below), the RMS is of the opinion that this deviation from the guidelines did not affect the viability of the study.

Analytical methods

At each sampling date, the respective flasks were removed from the incubator. The water was then transferred into graduated cylinders and the test vessels were rinsed with approximately 10 mL of ACN. The ACN was added to the corresponding sample and the total volume was determined. For determination of the ^{14}C-concentration, three 1 mL aliquots were measured by LSC. A 25 mL aliquot of water was then filtered through a 70 µm filter and an aliquot of the filtrate was analysed by HPLC. No analysis was conducted on the filtered sediment. The RMS notes that, ideally, further analysis would have been undertaken on the sediment to determine if any a.s. had sorped to the sediment. However, given the high mass balances observed (see 'results and discussion' section below), the RMS is of the opinion that, on this occasion, little sorption occurred to the sediment and so the validity of the study is unaffected.

For water sampling of the test vessels treated with ^{14}C-benzoic acid, the test vessels were disconnected from the air flow system and the water volume in the test vessels were determined by weighing. Three 1 mL aliquots were taken per test vessel for LSC measurements. On day 15 and day 64, an aliquot of the water phase was subjected to HPLC analysis without further workup. The vessels were then reconnected to the air flow system.

Trapping solutions were transferred into 50 mL volumetric flasks filled to volume with distilled water. Three 1 mL aliquots were measured by LSC.

For the low concentration test, the LOD of the LSC instrumentation was 2 x background radioactivity (1.4% TAR) and the LOQ was 3 x background radioactivity (2.2%). The LOD of the HPLC instrumentation was 0.3% TAR and the LOQ was 0.5% TAR.

For the high concentration test, the LOD of the LSC instrumentation was 2 x background radioactivity (0.1% TAR) and the LOQ was 3 x background radioactivity (0.2%). The LOD of the HPLC instrumentation was 0.5% TAR and the LOQ was 1.0% TAR.

Results and discussion

Mass balance

The material balance for the suspended sediment test ranged from 93.6% TAR to 102.7% TAR. In the sterile vessels, the material balance ranged from 96.7 to 98.8% TAR. The material balance and the distribution of radioactivity in the suspended sediment test for the high concentration test is shown in Table 8.2.2.2-4 and the low concentration test in Table 8.2.2.2-5.

Table 8.2.2.2-4: Material balance and distribution of radioactivity after application of triazole3(5)-^{14}C-labeled-BAS 750 F to the suspended sediment test system Ranschgraben and incubation under dark conditions [% TAR]: High concentration

Days after treatment	Water	Volatiles Ethylene Glycol trap	Volatiles NaOH trap	Material balance
High concentration (100 µg L^{-1})				
0 I	99.8	n.p.	n.p.	99.8
0 II	100.2	n.p.	n.p.	100.2
0 mean	**100.0**	**n.p.**	**n.p.**	**100.0**
3 I	98.4	0.0	0.0	98.4
3 II	100.8	0.0	0.0	100.8
3 mean	**99.6**	**0.0**	**0.0**	**99.6**
7 I	97.1	0.0	0.0	97.1
7 II	98.3	0.0	0.0	98.3
7 mean	**97.7**	**0.0**	**0.0**	**97.7**
14 I	98.9	0.0	0.0	98.9
14 II	98.6	0.0	0.0	98.6
14 mean	**98.8**	**0.0**	**0.0**	**98.8**
21 I	98.7	0.0	0.0	98.7
21 II	96.2	0.0	0.0	96.2
21 mean	**97.4**	**0.0**	**0.0**	**97.5**
35 I	97.3	0.0	0.1	97.3
35 II	93.5	0.0	0.0	93.6
35 mean	**95.4**	**0.0**	**0.1**	**95.4**
63 I	97.6	0.0	0.1	97.7
63 II	94.0	0.0	0.1	94.1
63 mean	**95.8**	**0.0**	**0.1**	**95.9**
21 I (sterile)	96.7	n.p.	n.p.	96.7
21 II (sterile)	98.8	n.p.	n.p.	98.8
21 mean (sterile)	**97.8**	**n.p.**	**n.p.**	**97.8**
63 I (sterile)	98.4	n.p.	n.p.	98.4
63 II (sterile)	98.7	n.p.	n.p.	98.7
63 mean (sterile)	**98.6**	**n.p.**	**n.p.**	**98.6**

n.p. = not performed
TAR = total applied radioactivity

Table 8.2.2.2-5: Material balance and distribution of radioactivity after application of triazole3(5)-^{14}C-labeled-BAS 750 F to the suspended sediment test system Ranschgraben and incubation under dark conditions [% TAR]: Low concentration

Days after treatment	Water	Volatiles Ethylene Glycol trap	Volatiles NaOH trap	Material balance
Low concentration (10 µg L^{-1})				
0 I	100.2	n.p.	n.p.	100.2
0 II	99.8	n.p.	n.p.	99.8
0 mean	**100.0**	**n.p.**	**n.p.**	**100.0**
3 I	100.1	0.0	0.0	100.1
3 II	98.7	0.0	0.0	98.8
3 mean	**99.4**	**0.0**	**0.0**	**99.4**
7 I	98.6	0.0	0.0	98.6
7 II	95.1	0.0	0.0	95.2
7 mean	**96.9**	**0.0**	**0.0**	**96.9**
14 I	97.4	0.0	0.0	97.5
14 II	96.7	0.0	0.0	96.7
14 mean	**97.1**	**0.0**	**0.0**	**97.1**
21 I	97.8	0.0	0.0	97.8
21 II	95.0	0.0	0.0	95.0
21 mean	**96.4**	**0.0**	**0.0**	**96.4**
35 I	95.0	0.0	0.1	95.1
35 II	98.7	0.0	0.1	98.7
35 mean	**96.9**	**0.0**	**0.1**	**96.9**
63 I	99.8	0.1	2.9	102.7
63 II	93.7	0.0	0.1	93.8
63 mean	**96.7**	**0.1**	**1.5**	**98.3**

n.p. = not performed
TAR = total applied radioactivity

In general, no significant differences were found in BAS 750 F behaviour between the high and the low test concentrations.

The amount of radioactivity in the water ranged from 93.7% TAR to 99.8% TAR after 63 days. For all suspended sediment test samples and sampling time points, the radioactivity in the volatile traps never exceeded 3.0% TAR indicating a low rate of mineralisation.

The control vessels treated with ^{14}C-benzoic acid showed that the system Ranschgraben was microbially active. After 64 days, 60.5 - 90.1% TAR were evolved as $^{14}CO_2$. The average material balance over the four replicates ranged from 80.5% to and 90.2% TAR (Table 8.2.2.2-6).

Table 8.2.2.2-5: Mean material balances and distribution of radioactivity after application of ^{14}C-benzoic acid (%TAR)

Days after treatment	Water	Volatiles	Sum
0	n.p.	n.p.	n/a
3	74.3	15.9	90.2
8	51.0	33.9	84.9
15	33.2	47.3	80.5
22	25.0	57.5	82.5
36	17.3	66.1	83.4
64	9.0	72.9	81.9

Physicochemical parameters of the test systems

During the incubation with ^{14}C-BAS 750 F, the O_2 saturation in the water of system was always > 65%. The redox potential in the water ranged from +146 to + 275 mV demonstrating overall aerobic conditions. The pH values were measured in the range 7.01 to 8.41.

Characterisation and identification of residues in water

No significant degradation of BAS 750 F was observed. After 63 days, between 90.2% TAR and 94.8% TAR could still be recovered as unchanged parent for the different concentrations. An overview of active ingredient and metabolites for the water samples is presented in Table 8.2.2.2-6.

Two peaks were detected in very low amounts. They were assigned to the metabolites M750F003 and M750F006 by comparison of the retention times with those of the reference substances. The metabolite M750F003 reached maxima of 1.3% TAR and 4.1% TAR after 63 days in the high concentration test and the low concentration test respectively. M750F006 reached maxima of 1.9% TAR and 4.8% TAR after 21 days, in the high concentration test and the low concentration test respectively. Additionally, two peaks were detected in the HPLC chromatograms in minor amounts. They never exceeded 0.7% TAR and were therefore not further investigated.

The sterile controls showed in principle the same results as the viable test vessels. After 63 days, 98.6% TAR could be attributed to BAS 750 F. No metabolites were detected at the end of the incubation.

Table 8.2.2.2-6: Metabolite overview for water after application of triazole3(5)-^{14}C-labeled-BAS 750 F to the suspended sediment test system Ranschgraben and incubation under dark conditions [% TAR]

Days after treatment	Total t_R ~	M750F003 25.3'	M750F006 32.9'	BAS 750 F 35.3'	Others*
High concentration (100 µg L^{-1})					
0 I	99.8	n.d.	1.2	98.4	0.2
0 II	100.2	n.d.	1.2	98.9	0.2
0 mean	**100.0**	**n.d.**	**1.2**	**98.6**	0.2
3 I	98.4	n.d.	1.3	96.9	0.2
3 II	100.8	n.d.	1.3	99.5	n.d.
3 mean	**99.6**	**n.d.**	**1.3**	**98.2**	0.1
7 I	97.1	0.3	0.9	95.7	0.2
7 II	98.3	0.3	1.1	96.8	0.1
7 mean	**97.7**	**0.3**	**1.0**	**96.2**	0.1
14 I	98.9	0.4	1.0	97.2	0.2
14 II	98.6	0.8	1.7	96.2	n.d.
14 mean	**98.8**	**0.6**	**1.4**	**96.7**	0.1
21 I	98.7	0.7	1.5	96.3	0.2
21 II	96.2	0.9	2.3	93.0	n.d.
21 mean	**97.4**	**0.8**	**1.9**	**94.7**	0.1
35 I	97.3	1.0	1.2	94.9	0.3
35 II	93.5	1.4	1.4	90.4	0.3
35 mean	**95.4**	**1.2**	**1.3**	**92.7**	0.3
63 I	97.6	1.4	0.8	94.8	0.6
63 II	94.0	1.2	0.8	91.9	n.d.
63 mean	**95.8**	**1.3**	**0.8**	**93.3**	0.3
21 I (sterile)	96.7	n.d.	1.1	95.6	n.d.
21 II (sterile)	98.8	n.d.	0.9	97.9	n.d.
21 mean (sterile)	**97.8**	**n.d.**	**1.0**	**96.8**	**n.d.**
63 I (sterile)	98.4	n.d.	n.d.	98.4	n.d.
63 II (sterile)	98.7	n.d.	n.d.	98.7	n.d.
63 mean (sterile)	**98.6**	**n.d.**	**n.d.**	**98.6**	**n.d.**
Low concentration (10 µg L^{-1})					
0 I	100.2	n.d.	1.1	99.1	n.d.
0 II	99.8	n.d.	1.3	98.5	n.d.
0 mean	**100.0**	**n.d.**	**1.2**	**98.8**	**n.d.**
3 I	100.1	n.d.	n.d.	100.1	n.d.
3 II	98.7	n.d.	n.d.	98.7	n.d.
3 mean	**99.4**	**n.d.**	**n.d.**	**99.4**	**n.d.**
7 I	98.6	n.d.	1.8	96.2	0.5
7 II	95.1	n.d.	2.1	93.0	n.d.
7 mean	**96.9**	**n.d.**	**2.0**	**94.6**	**0.3**
14 I	97.4	1.2	1.6	94.6	n.d.
14 II	96.7	0.5	1.6	94.1	0.6
14 mean	**97.1**	**0.9**	**1.6**	**94.4**	**0.3**
21 I	97.8	4.3	3.7	89.8	n.d.
21 II	95.0	2.4	5.9	86.6	n.d.
21 mean	**96.4**	**3.4**	**4.8**	**88.2**	**n.d.**
35 I	95.0	3.9	3.0	87.3	0.8
35 II	98.7	3.5	2.2	93.0	n.d.
35 mean	**96.9**	**3.7**	**2.6**	**90.1**	**0.4**

63 I	99.8	4.7	2.2	92.8	n.d.
63 II	93.7	3.5	n.d.	90.2	n.d.
63 mean	**96.7**	**4.1**	**1.1**	**91.5**	**n.d.**

t_R = retention time
n.d. = not detected
* = sum of several peaks (each individual peak <0.7% TAR)

Enantiomer specific analyses

In addition to the quantification of the parent, enantiomer-specific analyses were performed. The obtained ratios for BAS 750 F (*R*) and BAS 750 F (*S*) was about 1:1 for all analysed samples (high concentration) (Table 8.2.2.2/7). This demonstrates that, under the test conditions, no chiral inversion nor chiral differentiation in degradation was observed.

Table 8.2.2.2-7: Results of enantiomer ratio analysis

DAT	BAS 750 F in water (%TAR)	Expressed as %ROI in chromatogram		Expressed as %TAR of sample	
		2R BAS 750 F	2S BAS 750 F	2R BAS 750 F	2S BAS 750 F
High Concentration (100 µg/L)					
0 I	98.4	50.2	49.8	49.4	49.0
0II	98.9	54.2	45.8	53.6	45.2
0 mean	**98.6**	**52.2**	**47.8**	**51.5**	**47.1**
35 I	94.9	49.2	50.8	46.7	48.2
35 II	90.4	52.8	47.2	47.7	42.7
35 mean	**92.7**	**51.0**	**49.0**	**47.2**	**45.5**
63 I	94.8	51.6	48.4	48.9	45.9
63 II	91.9	48.6	51.4	44.7	47.2
63 mean	**93.3**	**50.1**	**49.9**	**46.8**	**46.6**

Degradation of the reference test item

The Applicant did not undertake a kinetic evaluation of BAS 750 F degradation rates stating that no significant degradation was observed under the applied test conditions. The RMS accepts the Applicant's justification.

Conclusion

From the obtained results, it can be concluded that BAS 750 F is not significantly degraded in a pure water environment as indicated in the suspended sediment test. After 63 days more than 90% TAR was recovered as unchanged active substance.

No kinetic evaluation of BAS 750 F degradation was performed since no significant degradation was observed under the applied test conditions.

B.8.2.2.3. Water/sediment studies

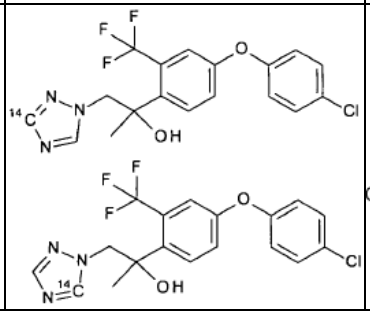
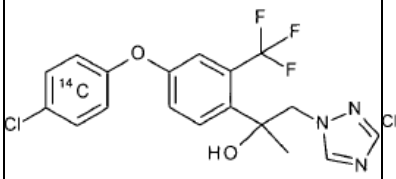
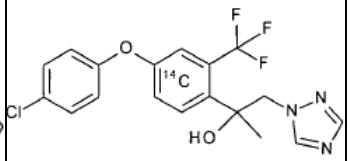
Report: CA 7.2.2.3/1
Ebert D.,Dalkmann P., 2015 a
Aerobic aquatic metabolism of BAS 750 F (Reg.No. 5834378)
2015/1000941
Guidelines: OECD 308, EPA 835.4300
GLP: yes
(certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)

Introduction

This study was designed to determine the route and rate of degradation of BAS 750 F in two water sediment systems under aerobic conditions. The study was conducted to GLP and according to OECD test guideline 308; there were no significant deviations that would affect the validity of the study.

Information on the ^{14}C-labeled test materials used in the study is presented in Table 8.2.2.3-1.

Table 8.2.2.3-1: Test materials

Substance code	BAS 750 F		
Reg number	5834378		
CAS number	1417782-03-6		
Chemical name (IUPAC)	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol		
Molecular mass	397.78 g mol^{-1}		
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$		
Label	Triazole-3(5)-^{14}C	Chlorophenyl-U-^{14}C	Trifluoromethylphenyl-U-^{14}C
Batch number	1062-2001	CFQ41561	CFQ42039
Specific radioactivity of a.s. (MBq mg^{-1})	5.46	7.878	8.288
Radiochemical purity (%)	98.8	98.9	98.3
Purity (%)	98.9	99.1	96.3
Position of label			

In addition to these, four reference items were used in the study:

- Unlabelled BAS 750 F
- Both labelled and unlabelled 1,2,4-Triazole
- Unlabelled M750F003

Test waters and sediments

Two natural water/sediment systems were collected on November 15, 2013 (for the chlorophenyl- and triazole-label experiments), and May 21, 2014 (for the trifluoromethylphenyl-label experiment). Both sampling sites are located in the South-Western part of Germany. One system is designated as "Berghäuser Altrhein" (BA), a pond-like side arm of the river Rhine south of Speyer surrounded by a forest. The second system is designated as "Ranschgraben" (RG), a small stream east of Schifferstadt surrounded by a forest; no pesticides have been used at the test sites for at least the preceding 10 years. The RMS notes that the OECD guidelines state there should be a >2% difference in organic carbon content of the two test systems. Whilst this was the case for the trifluoromethylphenyl-labelled experiment, the difference in organic carbon for the chlorophenyl and triazole-labelled experiments was only ~1%. However, given the marked difference in texture and sediment pH of the test systems, the RMS is of the opinion that the test systems were suitably different from each other and this slight deviation from the guidelines is not expected to significantly affect the outcomes of the study.

The sediment was passed through a 2 mm sieve and the water was filtered through a 0.2 mm filter. Water and sediment were filled into the test vessels 1 – 3 days after collection from the field sites. The physico-chemical properties of the systems are summarised in Table 8.2.2.3-2.

Table 8.2.2.3-2: Characterisation of the water/sediment systems

Water			**Berghäuser Altrhein**				**Ranschgraben**			
Field sampling			**Nov 15, 2013**		**May 21, 2014**		**Nov 15, 2013**		**May 21, 2014**	
Temperature [a]	[°C]		9.1		22.9		6.7		16.6	
pH [a]			7.4		8.40		7.30		7.10	
Redox potential [a]	[mV]		281		263		273		219	
O_2 content [a]	[mg L^{-1}]		7.4		21.7		9.9		8.2	
Total N	[mg L^{-1}]	beginning	0.79		0.30		0.84		0.30	
		end	1.02		0.90		1.82		1.72	
Total P	[mg L^{-1}]	beginning	0.09		0.06		0.13		0.22	
		end	1.07		0.29		0.73		0.27	
TOC / org. C	[mg L^{-1}]	beginning	5.6		3.0		6.0		4.6	
		end	10.0		6.7		6.1		4.7	
Water hardness	[mmol L^{-1}]		1.62		2.72		1.44		0.90	
Bacteria	[cfu mL^{-1}]	beginning	3.76×10^3		3.36×10^2		5.58×10^3		3.56×10^2	
		end	5.76×10^3		1.78×10^3		6.24×10^3		3.0×10^2	
Fungi	[cfu mL^{-1}]	beginning	14		0		8		0	
		end	4		26		0		0	
Actinomycetes	[cfu mL^{-1}]	beginning	0		4		10		0	
		end	10		22		0		2	
Sediment			**Berghäuser Altrhein**				**Ranschgraben**			
Batch No.			**13/1725/01 14/1725/01**		**14/1725/02 14/1725/03**		**13/1723/01 14/1723/01**		**14/1723/02 14/1723/03**	
Sampling depth*	[cm]		0 - 20		0 – 10		0 - 10		0 - 10	
pH	(H_2O)		7.9		7.2		5.5		6.4	
	($CaCl_2$)		7.1		7.0		5.2		6.0	
Redox potential*	[mV]		-134		-407		-402		-322	
Total N	[mg kg^{-1}]	beginning	1900		5000		2100		1300	
		end	1700		4600		1800		1300	
Total P	[mg kg^{-1}]	beginning	790		815		632		352	
		end	503		815		235		317	
TOC / org. C	[%]	beginning	1.80		6.27		2.94		2.00	
		end	1.79		6.10		2.79		1.72	
CEC	[$cmol^+$ kg^{-1}]		17.7		33.3		7.6		4.5	
Particle size distribution			USDA	DIN 4220	USDA	DIN 4220	USDA	DIN 4220	USDA	DIN 4220
Clay	[%]		27.7	22.7	31.8	31.8	4.6	4.6	4.1	4.1
Silt	[%]		55.0	57.0	54.7	55.0	6.5	7.7	6.0	6.7
Sand	[%]		22.3	20.3	13.5	13.2	88.9	87.8	89.9	89.2
Soil type			silty loam	Silt loam	silty clay loam	silty clay	fine sand	sand	fine sand	sand
Bacteria	[cfu g^{-1}]	beginning	4.46×10^6		4.26×10^6		9.6×10^5		4.58×10^5	
		end	9.1×10^5		3.98×10^5		5.02×10^5		5.48×10^5	
Fungi	[cfu g^{-1}]	beginning	3.1×10^4		3.94×10^4		2.22×10^3		7.2×10^2	
		end	4.32×10^3		1.6×10^3		6.2×10^2		2.8×10^4	
Actinomycetes	[cfu g^{-1}]	beginning	9.6×10^3		6.4×10^2		3.2×10^3		1.68×10^3	
		end	1.68×10^4		8.4×10^3		3.4×10^3		8.2×10^3	

CEC = Cation exchange capacity
TOC = Total organic carbon
[a] measured directly at sampling site

Test procedure

A total of 49 flasks were prepared for each water/sediment system and radiolabel: 13 flasks per radiolabel (10 sampling + 3 reserve samples) and 1 flask per radiolabel for incubation under sterile conditions. In addition, 7 untreated flasks were prepared for system characterisation at the end of the incubation.

The flasks were filled with approximately 185 g (BA) or 140 g (RG) of wet sediment and 300 mL of the respective water. This corresponded to a sediment layer of ~2.5 cm and a water layer of ~7 cm. After being filled with sediment and water, the flasks were allowed to equilibrate for 15 days (chlorophenyl and triazole label) or 19 days (trifluoromethylphenyl label) before treatment under dark conditions. One flask per system and chlorophenyl and triazole labels were heat sterilised (at 121°C for 30 minutes) prior to the application of the test item.

Appropriate amounts (20 µL) of the respective application solutions (prepared in acetonitrile) were pipetted to the water surface to achieve a nominal concentration of 11 µg test item per test vessel. This corresponded to a field application rate of about 300 g active substance per ha assuming overspray over a 1 m deep water body. The amount of test item per test vessel was calculated for a 300 mL water volume. The Applicant chose this application rate in order to allow reliable quantitative and qualitative assessment of metabolites that potentially form in the system.

During incubation, the test vessels were continuously aerated and the upper water layer was slightly agitated to keep the oxygen saturation at a sufficiently high level. Each test vessel was connected to a volatile trapping system of two gas washing flasks containing different trapping solutions for potential ^{14}C-volatiles (ethylene glycol and 0.5 M NaOH).

Equilibration and subsequent incubation was carried out in an incubator at a temperature of 20 ± 1 °C in the dark.

The equilibration was monitored by measuring redox potential of water and sediment, temperature, O_2-content and pH of randomly selected flasks at intervals of 2-4 days. After treatment, the same parameters were measured in each sample before workup.

Samples were taken at 0, 0.25, 1, 3, 7, 14, 30, 56, 78 and 100 days after treatment (DAT) for the chlorophenyl- and triazole-label experiments and at 0, 3, 7, 14, 28, 56, 78, 100 days after treatment for the trifluoromethylphenyl-label experiment. After 101 days, the sterile vessels were worked up (chlorophenyl and triazole label only).

The Applicant states that the results obtained with the chlorophenyl- and triazole-labelled test items can be considered as duplicates for test item and common metabolites. Because the experiment with the trifluoromethylphenyl-labelled test item was conducted at a later date, duplicate measurements were performed at 0, 56 and 100 DAT. The RMS notes that, ideally, duplicate samples would have been undertaken per test label per sampling point; especially given some of the material balances (see relevant section below) were outside the OECD 308 recovery range of 90-110%. However, given the vast majority of mass balances were within an acceptable recovery range and similar results were observed for the different labels, on this occasion, the RMS accepts this deviation from the study guidelines.

Methods of analysis

Water
The water was decanted from the test vessels and its volume determined. The samples were homogenised by shaking in a round bottom flask; aliquots were measured by LSC and radio-HPLC.

Sediment
For extraction, the sediment samples of the incubation experiment were transferred into centrifuge tubes, the extraction solvent added and the centrifuge tubes placed on a rotary shaker (270 rpm for 20 minutes). After each extraction step, the phases were separated by centrifugation (9000 rpm for 5 minutes). The extracts were collected in volumetric flasks and analysed for radioactivity by LSC.

The sediment samples were extracted in a first step with acetonitrile, then with acetonitrile/water (50/50, v/v), and then a further two more times with pure acetonitrile. Since there was still a considerable amount of water left in the sediments after water decantation, the first extraction with pure acetonitrile is considered as an acetonitrile/water extraction. In the case that the fourth extraction contained more than 3% of the total applied radioactivity (TAR), a fifth extraction with acetonitrile was added. For one test vessel (Ranschgraben, chlorophenyl-label, 100 days), a third extraction step with 95 mL of acetonitrile/water (50/50, v/v) was performed.

The four or five corresponding acetonitrile and acetonitrile/water extracts were combined and each volumetric flask was rinsed with acetonitrile or acetonitrile/water which was also added to the extracts. Aliquots of the combined solution were measured again for radioactivity by LSC to ensure no material losses due to adsorption to the glass walls had occurred. For HPLC analysis, aliquots of the pooled extracts were evaporated to dryness and re-dissolved in acetonitrile/water (80/20, v/v). After ultrasonication and centrifugation, aliquots were checked for recovery with LSC (recoveries were between 92-111% TAR) and then analysed by radio-HPLC.

The extracted sediment was dried at room temperature and homogenised using an analytical mill. The amount of non-extractable radioactive residues (NER) in the extracted sediment was determined by combustion of aliquots in an oxidiser.

The limit of quantification (LOQ) was set to 3 times the background noise and the limit of detection (LOD) was set to 2 times the background noise. For the chlorophenyl-labelled test items, this corresponded to a LOQ of 0.218% TAR in the water phase and 0.073% TAR in the sediment phase and a LOD of 0.145% TAR in the water phase and 0.048% TAR in the sediment phase.

Characterisation of bound residues

The non-extractable radioactivity in sediment was further characterised in selected samples (28 day sample of trifluoromethylphenyl label, 30 day sample of chlorophenyl- and triazole-label, and 100 day samples for all three labels) by separation into fulvic acids, humic acids and humins.

For each sample, the dried sediment (25 g) was extracted three times with 0.5 M NaOH. The radioactivity in the extracts of each extraction step was determined by LSC.

The corresponding extracts of a sample were then combined and acidified with HCl to pH 1-2 to precipitate the acid-insoluble humic acids. For the precipitation phase, the samples were kept in a refrigerator for 65 hours. After centrifugation, the radioactivity in the supernatant (fulvic acids) was determined by LSC.

The precipitate (humic acids) was re-dissolved in 0.5 M NaOH and the solution measured for radioactivity. The remaining non-extractable radioactivity in the sediment (humins) was determined by combustion.

The fulvic acid fraction of four selected samples (100 days, both systems, chlorophenyl and triazole label) was further investigated by HPLC. Recovery after HPLC was checked for the 100 day BA triazole label sample and accounted for 117.4%.

Volatiles
Radioactivity in the volatile trapping solutions (ethylene glycol and NaOH) was determined by LSC.

Results and discussion

The material balance in the test vessels ranged from 90.6% to 98.5% TAR (chlorophenyl-label), from 88.5% to 99.8% TAR (triazole-label), and from 93.5% to 100.2% TAR (trifluoromethylphenyl-label). One test vessel of the trifluoromethylphenyl-label exhibited a lower material balance, amounting to 82.0% TAR. Results of the distribution of radioactivity are presented in Table 8.2.2.3-3 and Table 8.2.2.3-4.

As indicated above, although some test vessels resulted in material balances outside of the OECD 308 guideline range, given the infrequent nature of these results and the other labels providing acceptable balances for the time points when these occur, and that acceptable kinetic fits could be obtained with these time points included, the RMS is of the opinion that they do not significantly affect the outcome of the study.

Chlorophenyl label
Corresponding to the decline of radioactivity in the water phase the radioactivity in the sediment increased in both systems, reaching 81.9% and 88.2% TAR at 30 and 78 DAT in the systems BA and RG, respectively. At the end of incubation, the radioactivity in the sediment phase decreased to 75.1% and 84.4% TAR for the respective test systems. 49.8% and 65.3% of the applied radioactivity (systems BA and RG, respectively) in the sediment was still extractable with acetonitrile and acetonitrile/water. The non-extracted radioactivity (NER) amounted to 25.3% and 19.1% TAR at the end of the incubation period, while 9.6% and 5.1% TAR were mineralised to CO_2.

Triazole label
Similar to the chlorophenyl-labelled test item, the radioactivity in the water phase declined during the incubation period resulting in increasing amounts of radioactivity in the sediment phase reaching 81.5% and 87.3% TAR at 30 and 56 DAT for the test systems BA and RG, respectively. Until study end, the radioactivity related to the sediment phase decreased to 78.9% and 86.5% TAR for the respective test systems. The non-extracted residue amounted to 26.6% and 17.0% TAR at the end of the incubation period, while only small amounts (0.8% and 0.5% TAR) were degraded to $^{14}CO_2$ in test system BA and RG, respectively.

Trifluoromethylphenyl label
Similar to the chlorophenyl-and triazole-labelled test items, the radioactivity in the water phase declined during the incubation period resulting in increasing amounts of radioactivity in the sediment phase reaching 92.9% and 91.8% TAR at 78 and 100 DAT for the test systems BA and RG, respectively. The non-extracted residue amounted to 18.8% and 22.4% TAR at the end of the incubation period, while only small amounts (1.5% and 0.5% TAR) were degraded to $^{14}CO_2$ in test system BA and RG, respectively.

Table 8.2.2.3-3: Material balance and distribution of radioactivity after application of ^{14}C-labeled BAS 750 F to water/sediment system Berghäuser Altrhein and incubation under dark conditions [% TAR]

days after treatment	vessel	[% TAR]												
		water	sediment									volatiles		material balance
			ACN/H_2O 1	ACN/H_2O 2	ACN/H_2O 3	ACN 1	ACN 2	ACN 3	total extractable	NER	total	ethylene-glycol	NaOH (CO_2)	
Berghäuser Altrhein; chlorophenyl-label														
0	VG01	92.1	2.5	0.8	n.p.	0.3	0.1	n.p.	3.8	0.1	3.9	n.p.	n.p.	96.1
0.25	VG02	77.3	12.1	3.5	n.p.	1.6	0.6	n.p.	17.8	1.1	19.0	0.0	0.0	96.3
1	VG03	55.8	24.8	6.0	n.p.	3.0	1.2	n.p.	35.0	1.9	36.9	0.0	0.0	92.7
3	VG04	39.7	35.6	8.3	n.p.	7.8	2.3	n.p.	53.9	3.1	57.1	0.0	0.1	96.9
7	VG05	24.6	44.4	12.6	n.p.	5.1	2.5	n.p.	64.7	5.9	70.6	0.0	0.5	95.8
14	VG06	15.5	47.4	12.3	n.p.	7.8	2.1	n.p.	69.6	7.4	77.0	0.0	1.3	93.8
30	VG07	10.5	45.1	12.9	n.p.	6.7	3.0	n.p.	67.8	14.1	81.9	0.0	3.6	96.1
56	VG08	8.4	37.6	11.9	n.p.	6.2	2.9	n.p.	58.6	19.7	78.3	0.0	6.1	92.8
78	VG09	6.1	31.6	11.8	n.p.	6.3	3.5	n.p.	53.2	23.4	76.7	0.0	9.1	91.9
100	VG10	6.1	29.0	13.4	n.p.	5.6	1.9	n.p.	49.8	25.3	75.1	0.1	9.6	90.8
101(s)	VG14	7.6	47.6	19.2	n.p.	9.6	4.2	n.p.	80.5	9.0	89.5	n.p.	n.p.	97.1
Berghäuser Altrhein; triazole-label														
0	VG15	95.9	0.4	0.1	n.p.	0.0	0.0	n.p.	0.6	1.1	1.6	n.p.	n.p.	97.5
0.25	VG16	81.1	12.2	3.2	n.p.	1.4	0.5	n.p.	17.3	1.3	18.6	0.0	0.0	99.8
1	VG17	60.1	24.7	5.6	n.p.	2.8	1.5	n.p.	34.6	2.3	36.9	0.0	0.0	97.0
3	VG18	47.0	32.6	8.0	n.p.	6.4	1.9	n.p.	48.9	2.6	51.5	0.0	0.0	98.6
7	VG19	25.7	44.3	13.5	n.p.	6.4	3.0	n.p.	67.1	4.7	71.8	0.0	0.1	97.6
14	VG20	20.2	47.7	11.3	n.p.	8.9	2.3	n.p.	70.1	6.2	76.3	0.0	0.2	96.7
30	VG21	16.1	46.4	13.2	n.p.	7.1	3.3	n.p.	70.0	11.4	81.5	0.0	0.1	97.6
56	VG22	15.1	40.8	12.9	n.p.	6.8	2.6	n.p.	63.1	18.1	81.3	0.1	0.2	96.7
78	VG23	16.1	32.9	15.5	n.p.	6.4	3.6	n.p.	58.4	21.1	79.5	0.0	0.4	96.0
100	VG25	16.8	32.7	11.8	n.p.	5.0	2.8	n.p.	52.2	26.6	78.9	0.0	0.8	96.6
101 (s)	VG28	7.9	49.4	19.4	n.p.	8.6	3.5	n.p.	80.8	8.5	89.4	n.p.	n.p.	97.3
Berghäuser Altrhein; trifluoromethylphenyl-label														
0	VG57	97.2	0.0	0.0	n.p.	0.0	0.0	n.p.	0.0	0.0	0.0	n.p.	n.p.	97.3
	VG58	98.9	0.0	0.0	n.p.	0.0	0.0	n.p.	0.0	0.0	0.0	n.p.	n.p.	98.9
	mean	**98.1**	**0.0**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**0.0**	**0.0**	**-**	**-**	**98.1**
3	VG59	33.8	9.9	17.4	n.p.	11.6	4.3	2.3	45.5	2.7	48.2	0.0	0.0	82.0
7	VG62	22.0	32.3	21.5	n.p.	12.0	3.6	n.p.	69.3	4.9	74.3	0.0	0.0	96.2
14	VG60	13.8	34.1	23.2	n.p.	14.2	4.5	1.8	77.8	4.5	82.3	0.0	0.1	96.2
28	VG61	9.6	29.7	27.2	n.p.	11.5	6.3	3.8	78.5	9.7	88.3	0.0	0.2	98.1
56	VG63	5.8	22.5	27.8	n.p.	16.5	6.7	3.2	76.7	14.9	91.7	0.0	0.3	97.7
	VG64	4.9	30.2	26.8	n.p.	13.8	5.0	2.5	78.4	12.1	90.6	0.0	0.5	95.9
	mean	**5.3**	**26.4**	**27.3**	**-**	**15.1**	**5.9**	**2.9**	**77.6**	**13.5**	**91.1**	**0.0**	**0.4**	**96.8**
78	VG66	3.5	38.4	20.7	n.p.	10.0	5.3	3.0	77.4	15.6	92.9	0.0	0.6	97.0
100	VG67	3.6	31.4	19.6	n.p.	12.1	6.2	3.1	72.4	18.6	91.1	0.0	1.2	95.9
	VG70	4.2	36.6	19.9	n.p.	8.2	4.8	2.1	71.6	19.0	90.6	0.1	1.7	96.6
	mean	**3.9**	**34.0**	**19.7**	**-**	**10.1**	**5.5**	**2.6**	**72.0**	**18.8**	**90.8**	**0.0**	**1.5**	**96.2**

ACN = Acetonitrile
NER = Non-extractable radioactive residues
n.p. = Not performed
(s) = Sterile vessels
TAR = Total applied radioactivity

Table 8.2.2.3-4: Material balance and distribution of radioactivity after application of ^{14}C-labeled BAS 750 F to water/sediment system Ranschgraben and incubation under dark conditions [% TAR]

days after treatment	vessel	[% TAR]												
		water	sediment									volatiles		material balance
			ACN/H_2O 1	ACN/H_2O 2	ACN/H_2O 3	ACN 1	ACN 2	ACN 3	total extractable	NER	total	ethylene-glycol	NaOH (CO_2)	
Ranschgraben; chlorophenyl-label														
0	VG29	97.7	0.4	0.1	n.p.	0.0	0.0	n.p.	0.5	0.2	0.8	n.p.	n.p.	98.5
0.25	VG30	75.2	13.6	4.7	n.p.	1.8	0.6	n.p.	20.6	0.8	21.4	0.0	0.0	96.6
1	VG31	56.9	21.1	8.1	n.p.	4.2	1.5	n.p.	35.0	2.2	37.2	0.0	0.1	94.2
3	VG32	35.5	33.0	12.0	n.p.	5.8	1.8	n.p.	52.7	2.1	54.8	0.0	0.3	90.6
7	VG33	23.8	43.3	15.6	n.p.	6.5	2.3	n.p.	67.7	4.2	71.9	0.0	0.5	96.2
14	VG35	13.6	44.2	17.5	n.p.	7.8	2.6	n.p.	72.2	5.7	77.9	0.0	1.1	92.7
30	VG36	7.8	48.5	16.6	n.p.	6.9	2.6	n.p.	74.5	10.1	84.7	0.0	2.2	94.7
56	VG37	4.1	44.1	17.0	n.p.	7.6	2.7	n.p.	71.4	16.1	87.5	0.0	2.8	94.4
78	VG39	3.7	40.6	17.2	n.p.	8.3	3.9	n.p.	69.9	18.3	88.2	0.0	4.7	96.6
100	VG40	3.2	38.9	14.7	6.3	4.0	1.5	n.p.	65.3	19.1	84.4	0.0	5.1	92.8
101 (s)	VG42	4.9	45.4	22.5	n.p.	10.9	3.9	n.p.	82.6	10.1	92.7	n.p.	n.p.	97.5
Ranschgraben; triazole-label														
0	VG43	95.0	1.1	0.4	n.p.	0.2	0.1	n.p.	1.8	0.3	2.1	n.p.	n.p.	97.1
0.25	VG44	74.4	13.8	5.2	n.p.	2.1	0.6	n.p.	21.7	0.7	22.4	0.0	0.0	96.9
1	VG45	51.6	21.7	8.1	n.p.	4.3	1.5	n.p.	35.5	1.4	36.9	0.0	0.0	88.5
3	VG46	42.5	33.1	11.4	n.p.	5.8	1.8	n.p.	52.1	1.8	53.9	0.0	0.1	96.5
7	VG47	23.0	43.9	16.4	n.p.	6.8	2.4	n.p.	69.4	3.2	72.6	0.0	0.1	95.7
14	VG48	14.8	45.3	17.9	n.p.	7.7	2.4	n.p.	73.4	4.0	77.4	0.0	0.2	92.3
30	VG49	9.7	48.8	18.4	n.p.	7.5	2.7	n.p.	77.4	7.6	85.0	0.0	0.0	94.7
56	VG50	8.1	45.4	17.8	n.p.	8.0	3.0	n.p.	74.2	13.1	87.3	0.0	0.3	95.7
78	VG51	8.2	40.6	18.1	n.p.	8.4	4.0	n.p.	71.1	15.6	86.6	0.1	0.2	95.2
100	VG52	7.9	40.4	16.8	n.p.	9.3	3.0	n.p.	69.5	17.0	86.5	0.0	0.5	94.8
101 (s)	VG58	4.9	45.0	20.9	n.p.	10.4	3.8	n.p.	80.1	10.0	90.1	n.p.	n.p.	95.0
Ranschgraben; trifluoromethylphenyl-label														
0	VG71	99.1	0.0	0.0	n.p.	0.0	0.0	n.p.	0.0	0.1	0.1	n.p.	n.p.	99.2
	VG72	101.1	0.0	0.0	n.p.	0.0	0.0	n.p.	0.0	0.0	0.0	n.p.	n.p.	101.1
	mean	**100.1**	**0.0**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**0.1**	**0.1**	**-**	**-**	**100.2**
3	VG73	37.8	33.5	12.4	n.p.	6.0	1.9	n.p.	53.9	1.8	55.7	0.0	0.0	93.5
7	VG74	22.8	43.5	16.8	n.p.	7.0	2.2	n.p.	69.4	2.8	72.3	0.0	0.0	95.1
14	VG75	16.2	49.0	16.1	n.p.	7.3	2.3	n.p.	74.7	3.8	78.6	0.0	0.1	94.9
28	VG76	10.9	46.6	19.8	n.p.	8.2	2.7	n.p.	77.3	8.4	85.7	0.0	0.2	96.8
56	VG77	7.7	45.8	19.7	n.p.	7.9	3.2	n.p.	76.6	12.3	88.9	0.0	0.3	96.9
	VG78	6.8	46.3	20.6	n.p.	7.9	3.7	n.p.	78.6	12.2	90.8	0.0	0.0	97.6
	mean	**7.3**	**46.1**	**20.1**	**-**	**7.9**	**3.5**	**-**	**77.6**	**12.3**	**89.9**	**0.0**	**0.1**	**97.3**
78	VG81	5.9	44.2	19.1	n.p.	8.7	3.3	n.p.	75.3	15.6	90.9	0.0	0.3	97.1
100	VG82	5.6	41.7	16.8	n.p.	7.8	3.2	n.p.	69.5	22.8	92.3	0.0	0.5	98.4
	VG84	5.6	39.2	18.2	n.p.	8.3	3.5	n.p.	69.2	22.0	91.2	0.0	0.5	97.3
	mean	**5.6**	**40.4**	**17.5**	**-**	**8.0**	**3.4**	**-**	**69.4**	**22.4**	**91.8**	**0.0**	**0.5**	**97.8**

ACN = Acetonitrile
NER = Non-extractable radioactive residues
n.p. = Not performed
(s) = Sterile vessels
TAR = Total applied radioactivity

An overview of the active ingredient and metabolite results are presented in Tables 8.2.2.3-5 to 8.2.2.3-10.

Water phase

Chlorophenyl label
The chlorophenyl-labeled test item dissipated fast from the water phase, decreasing to 1.9% TAR in system BA and 3.2% TAR in system RG after 100 days.

Several unknown metabolites were detected (≤ 2.2% TAR). As these metabolites do not reach concentrations >5%, and therefore the potential to be classed as 'major' metabolites, these do not need to be classed further.

Triazole label
Similar to the chlorophenyl-labeled test item, triazole-labeled BAS 750 F dissipated fast from the water phase, decreasing to 2.3% TAR in system BA and 2.9% TAR in system RG at 100 DAT.

Several metabolites were detected; two of them occurred continuously and could be assigned to known metabolites M750F001 (1,2,4-triazole) and M750F003 (cleavage product having lost chlorophenyl ring). For system BA, M750F001 was detected in increasing amounts, reaching a maximum of 10.2% TAR at the end of the incubation period. For system RG, detected amounts of M750F001 were low (≤ 1.1% TAR). Detected amounts of metabolite M750F003 reached a maximum of 2.5% and 3.8% TAR in system BA and RG, respectively. None of the other metabolites exceeded 0.3% TAR at any sampling date.

Trifluoromethylphenyl label
Fast dissipation of BAS 750 F from the water phase was also observed with the trifluoromethylphenyl-label. Detected amounts decreased to 0.7% TAR in system BA and 2.9% TAR in system RG after 100 days of incubation.

Several metabolites were detected; one metabolite could be assigned to the known metabolite M750F003, reaching a maximum of 3.4% (56 DAT) and 2.7% (100 DAT) TAR in system BA and RG, respectively. Because M750F003 was increasing at study termination in the RG system, it can be classed as a major metabolite. None of the other metabolites exceeded 1.7% TAR at any sampling date.

Sediment phase

Chlorophenyl label
Detected amounts of chlorophenyl-labeled test item extracted from the sediment phase reached a maximum of 67.6% (14 DAT) and 71.5% TAR (30 DAT) in system BA and system RG, respectively. After 100 days, extractable amounts declined to 48.8% TAR in system BA and to 61.6% TAR in system RG.

The metabolite M750F032 was also detected, predominately in the RG system. It was detected at a maximum concentration of 2.3% at 30 DAT and 100 DAT; because the maximum concentration decreases after 30 DAT before increasing again, the RMS is of the opinion that the metabolite can be classed as minor.

Several other metabolites were detected, none of these recorded concentrations >5% and they were not increasing at study termination.

Triazole label
Detected amounts of triazole-labelled BAS 750 F extracted from the sediment phase reached a maximum of 68.5% (14 DAT) and 74.9% TAR (30 DAT) in system BA and system RG respectively. After 100 days, amounts of BAS 750 F declined to 45.6% TAR in system BA and to 64.4% TAR in system RG.

Three metabolites were found in the sediment extracts of both test systems. Two of them were assigned to the known metabolites M750F001 and M750F003. While M750F003 was measured in both test systems, M750F001 occurred only in sediment extracts of test system BA, reaching a maximum of 4.9% TAR after 100 days and was still increasing at study termination. M750F003 occurred in maximum amounts of 2.0% TAR (BA) and 3.3% TAR (RG), and was increasing at study termination in the RG system. The metabolite M750F032 reached a maximum concentration of 2.1% TAR at 56 DAT in the RG system; it was not detected in the BA system.

The metabolite M750F001 (1,2,4-triazole) was detected at maximum concentration of 15.1% TAR, at day 100, in the whole water/sediment BA test system.

Trifluoromethylphenyl label
Detected amounts of trifluoromethylphenyl-labeled BAS 750 F extracted from the sediment phase reached a maximum of 75.7% (28 DAT) and 74.9% TAR (28 DAT) in system BA and system RG respectively. After 100 days, extractable amounts declined to 62.1% TAR in system BA and to 67.3% TAR in system RG.

Similarly as observed for the triazole label, in test system BA, the concentrations of metabolite M750F003 were increasing at study termination in the sediment phase (maximum of two replicates: 5.9% TAR, 100 DAT in the BA system) (maximum of two replicates: 1.8% TAR, 100 DAT in the RG system). Therefore, the maximum quantity of M750F003 detected in the whole water/sediment system was 8.5% TAR, 100 DAT in the BA system (based on the mean replicate values).

Several other metabolites were detected, however, not at concentrations >5%.

Sterilised assays

All results of the analysis of the sterilised test vessels are presented in the same tables as the results of the viable test vessels. For the trifluoromethylphenyl-labelled test item, no sterilised incubations were performed.

The sterilised samples (101 days) showed somewhat higher concentrations of BAS 750 F in water and sediment than the 100 day samples of the viable vessels. Chlorophenyl-labelled BAS 750 F was detected in amounts of 6.7% (BA) and 3.9% TAR (RA) in the water samples, the triazole-labelled test item amounted to 7.5% and 4.5% TAR. 78.9% and 80.5% TAR (BA) and 80.5% and 80.1% TAR (RA) were detected in the pooled sediment extracts of the sterilised test vessels at 101 days. Nearly all radioactivity recovered in the water phases or sediment extracts consisted of unchanged parent.

The non-extractable residues in the sterilised test vessels were significantly lower (8.5% –10.1% TAR) than those of the viable incubations (17.0% – 26.6% TAR) indicating that degradation of BAS 750 F in sediment by incorporation into the humic substance matrix is enhanced in the presence of an active microbial population.

Table 8.2.2.3-5: Metabolite overview for the water and sediment phase after application of chlorophenyl-U-^{14}C-BAS 750 F to the water/sediment system Berghäuser Altrhein [% TAR]

days after treatment	vessel No.	[% TAR]					
		^{14}C total	unknown	unknown	BAS 750 F	unknown	sum others[a]
		~t_{Ret}	7.3	8.1	35.6	38.8	
water							
0	VG01	92.1	-	-	90.8	-	1.3
0.25	VG02	77.3	-	-	75.2	-	2.1
1	VG03	55.8	-	-	55.4	-	0.4
3	VG04	39.7	0.3	-	39.4	-	-
7	VG05	24.6	0.4	0.7	22.8	0.2	0.5
14	VG06	15.5	0.6	1.0	13.6	-	0.4
30	VG07	10.5	1.9	1.4	6.7	0.1	0.5
56	VG08	8.4	2.1	1.6	3.2	-	1.4
78	VG09	6.1	1.5	1.7	2.5	-	0.5
100	VG10	6.1	2.2	1.2	1.9	-	0.7
101 (s)	VG14	7.6	-	-	6.7	0.1	0.9
sediment							
0	VG01	3.8	-	-	3.8	-	-
0.25	VG02	17.8	-	-	17.8	-	-
1	VG03	35.0	-	-	33.9	0.5	0.6
3	VG04	53.9	-	-	52.3	1.0	0.6
7	VG05	64.7	-	-	63.3	1.4	-
14	VG06	69.6	-	-	67.6	1.3	0.7
30	VG07	67.8	-	-	64.8	1.9	1.1
56	VG08	58.6	-	-	56.3	1.5	0.7
78	VG09	53.2	-	-	49.4	1.9	1.9
100	VG10	49.8	-	-	48.8	1.1	-
101 (s)	VG14	80.5	-	-	78.9	1.0	0.5

TAR = Total applied radioactivity
t_{Ret} = Retention time [min]
(s) = Sterile vessels
[a] Sum of several peaks, each individual peak <1.0% TAR

Table 8.2.2.3-6: Metabolite overview for the water and sediment phase after application of triazole-3(5)-^{14}C-BAS 750 F to the water/sediment system Berghäuser Altrhein [% TAR]

days after treatment	vessel No.	[% TAR]				
		^{14}C total	M750F001 (1,2,4-triazole)	M750F003	BAS 750 F	sum others[a]
		~t_{Ret}	5.7	25.4	35.7	
water						
0	VG15	95.9	1.6	-	94.3	-
0.25	VG16	81.1	0.9	-	80.2	-
1	VG17	60.1	0.8	-	59.3	-
3	VG18	47.0	1.1	0.3	45.7	-
7	VG19	25.7	1.4	0.6	23.0	0.8
14	VG20	20.2	2.3	1.3	16.6	-
30	VG21	16.1	4.4	2.0	8.6	1.0
56	VG22	15.1	7.9	1.8	4.5	0.9
78	VG23	16.1	9.4	2.2	3.9	0.8
100	VG25	16.8	10.2	2.5	2.3	1.8
101 (s)	VG28	7.9	0.2	0.2	7.5	-
sediment						
0	VG15	0.6	n.a.	n.a.	n.a.	n.a.
0.25	VG16	17.3	-	-	17.3	-
1	VG17	34.6	-	-	34.6	-
3	VG18	48.9	-	-	48.9	-
7	VG19	67.1	-	-	67.1	-
14	VG20	70.1	0.6	-	68.5	1.0
30	VG21	70.0	1.6	1.0	67.5	-
56	VG22	63.1	3.6	1.3	58.3	-
78	VG23	58.4	3.5	2.0	52.9	-
100	VG25	52.2	4.9	1.7	45.6	-
101 (s)	VG28	80.8	-	-	80.5	0.3

TAR = Total applied radioactivity
t_{Ret} = Retention time [min]
n.a. = Not analysed
(s) = Sterile vessels
[a] Sum of several peaks, each individual peak <1.0% TAR

Table 8.2.2.3-7: Metabolite overview for the water and sediment phase after application of trifluoromethylphenyl-ring-^{14}C-BAS 750 F to the water/sediment system Berghäuser Altrhein [% TAR]

days after treatment	vessel No.	[% TAR]						
		^{14}C total	M750F003	M750F032	BAS 750 F	unknown	unknown	sum others[a]
		~t_{Ret}	25.2	32.7	35.4	36.9	38.0	
water								
0	VG57	97.2	-	-	94.5	0.6	2.1	-
	VG58	98.9	-	-	96.6	0.4	1.9	-
	mean	**98.1**	**-**	**-**	**95.5**	**0.5**	**2.0**	**-**
3	VG59	33.8	-	-	33.6	-	0.3	-
7	VG62	22.0	0.6	0.3	20.4	-	0.6	-
14	VG60	13.8	0.6	0.3	12.5	-	0.3	0.1
28	VG61	9.6	2.5	0.3	6.6	-	-	0.2
56	VG63	5.8	3.4	0.1	1.6	-	0.1	0.5
	VG64	4.9	3.0	0.1	1.0	-	-	0.8
	mean	**5.3**	**3.2**	**0.1**	**1.3**	**-**	**0.0**	**0.6**
78	VG66	3.5	3.0	-	0.4	-	-	0.1
100	VG67	3.6	2.9	-	0.6	-	-	-
	VG70	4.2	3.3	0.1	0.7	-	-	-
	mean	**3.9**	**3.1**	**0.1**	**0.7**	**-**	**-**	**-**
sediment								
0	VG57	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	VG58	0.0	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	mean	**0.0**	**-**	**-**	**-**	**-**	**-**	**-**
3	VG59	45.5	-	-	45.1	-	-	0.4
7	VG62	69.3	0.7	0.7	66.8	1.1	-	-
14	VG60	77.8	1.2	1.1	73.5	1.0	-	0.9
28	VG61	78.5	0.7	2.1	75.7	-	-	-
56	VG63	76.7	3.8	1.8	69.9	-	0.7	0.5
	VG64	78.4	2.7	2.1	73.6	-	-	-
	mean	**77.6**	**3.3**	**1.9**	**71.8**	**-**	**0.4**	**0.3**
78	VG66	77.4	4.6	2.8	69.3	-	0.7	-
100	VG67	72.4	5.0	2.6	63.4	-	0.8	0.7
	VG70	71.6	5.9	3.1	60.8	0.8	1.1	-
	mean	**72.0**	**5.4**	**2.8**	**62.1**	**0.4**	**0.9**	**0.4**

TAR = Total applied radioactivity
t_{Ret} = Retention time [min]
n.a. = Not analysed
(s) = Sterile vessels
[a] Sum of several peaks, each individual peak <1.0% TAR

Table 8.2.2.3-8: Metabolite overview for the water and sediment phase after application of chlorophenyl-U-^{14}C-BAS 750 F to the water/sediment system Ranschgraben [% TAR]

days after treatment	vessel No.	[% TAR]					
		^{14}C total	M750F032	BAS 750 F	unknown	unknown	sum others[a]
		~t_{Ret}	32.9	35.7	38.8	39.5	
water							
0	VG29	97.7	-	93.7	-	1.2	2.8
0.25	VG30	75.2	-	74.2	-	1.0	-
1	VG31	56.9	-	56.2	-	0.5	0.3
3	VG32	35.5	-	34.8	-	0.2	0.5
7	VG33	23.8	0.4	22.8	0.2	0.1	0.4
14	VG35	13.6	-	13.3	-	-	0.3
30	VG36	7.8	-	7.3	-	-	0.5
56	VG37	4.1	-	4.1	-	-	-
78	VG39	3.7	-	3.7	-	-	-
100	VG40	3.2	-	3.2	-	-	-
101 (s)	VG42	4.9	-	3.9	-	0.1	0.9
sediment							
0	VG29	0.5	n.a.	n.a.	n.a.	n.a.	n.a.
0.25	VG30	20.6	-	19.0	0.6	0.7	0.3
1	VG31	35.0	-	34.4	-	0.6	-
3	VG32	52.7	0.8	50.6	0.5	0.5	0.4
7	VG33	67.7	-	67.7	-	-	-
14	VG35	72.2	1.4	70.0	0.9	-	-
30	VG36	74.5	2.3	71.5	0.6	-	-
56	VG37	71.4	1.8	68.4	1.2	-	-
78	VG39	69.9	2.1	67.0	0.8	-	-
100	VG40	65.3	2.3	61.6	0.8	-	0.6
101 (s)	VG42	82.6	0.4	80.5	-	1.2	0.5

TAR = Total applied radioactivity
t_{Ret} = Retention time [min]
n.a. = Not analysed
(s) = Sterile vessels
[a] Sum of several peaks, each individual peak <1.0% TAR

Table 8.2.2.3-9: Metabolite overview for the water and sediment phase after application of triazole-3(5)-^{14}C-BAS 750 F to the water/sediment system Ranschgraben [% TAR]

days after treatment	vessel No.	[% TAR]					
		^{14}C total	M750F001 (1,2,4,-triazole)	M750F003	M750F032	BAS750F	Sum others[a]
		~t_{Ret}	5.9	25.4	32.8	35.7	
Water							
0	VG43	95.0	-	-	-	95.0	-
0.25	VG44	74.4	0.8	-	-	73.6	-
1	VG45	51.6	0.7	0.3	-	50.5	-
3	VG46	42.5	0.6	0.2	-	41.6	-
7	VG47	23.0	0.4	0.6	-	22.0	-
14	VG48	14.8	0.7	0.6	-	13.3	0.2
30	VG49	9.7	0.5	1.4	0.1	6.9	0.8
56	VG50	8.1	0.4	3.1	-	4.3	0.3
78	VG51	8.2	1.0	3.3	-	3.8	-
100	VG52	7.9	1.1	3.8	-	2.9	-
101 (s)	VG56	4.8	0.2	0.2	-	4.5	0.1
sediment							
0	VG43	1.8	n.a.	n.a.	n.a.	n.a.	n.a.
0.25	VG44	21.7	-	-	-	21.7	-
1	VG45	35.5	-	-	-	35.5	-
3	VG46	52.1	-	-	-	51.1	-
7	VG47	69.4	-	-	-	69.4	-
14	VG48	73.4	-	-	0.9	72.5	-
30	VG49	77.4	-	1.9	0.6	74.9	-
56	VG50	74.2	-	1.7	2.1	70.4	-
78	VG51	71.1	-	1.9	1.6	67.5	-
100	VG52	69.5	-	3.3	1.8	64.4	-
101 (s)	VG56	80.1	-		-	80.1	-

TAR = Total applied radioactivity
t_{Ret} = Retention time [min]
n.a. = Not analysed
(s) = Sterile vessels
[a] Sum of several peaks, each individual peak <1.0% TAR

Table 8.2.2.3-10: Metabolite overview for the water and sediment phase after application of trifluoromethylphenyl-ring-^{14}C-BAS 750 F to the water/sediment system Ranschgraben [% TAR]

days after treatment	vessel No.	[% TAR]					
		^{14}C total	M750F003	BAS 750 F	unknown	unknown	sum others[a]
		~t_{Ret}	25.3	35.4	37.0	38.1	
water							
0	VG71	99.1	-	96.6	0.5	2.0	-
	VG72	101.1	-	97.5	1.0	1.3	1.2
	mean	**100.1**	**-**	**97.1**	**0.7**	**1.7**	**0.6**
3	VG73	37.8	0.2	36.0	0.6	1.1	-
7	VG74	22.8	0.4	21.8	0.2	0.2	0.2
14	VG75	16.2	0.5	14.8	0.1	0.3	0.6
28	VG76	10.9	2.0	8.7	-	-	0.2
56	VG77	7.7	2.1	5.7	-	-	-
	VG78	6.8	1.7	5.1	-	-	-
	mean	**7.3**	**1.9**	**5.4**	**-**	**-**	**-**
78	VG81	5.9	2.3	3.4	-	-	0.1
100	VG82	5.6	2.7	2.9	-	-	-
	VG84	5.6	2.7	2.9	-	-	-
	mean	**5.6**	**2.7**	**2.9**	**-**	**-**	**-**
Sediment							
0	VG71	0.0	n.a.	n.a.	n.a.	n.a.	n.a.
	VG72	0.0	n.a.	n.a.	n.a.	n.a.	n.a.
	mean	**0.0**	**-**	**-**	**-**	**-**	**-**
3	VG73	53.9	-	53.9	-	-	-
7	VG74	69.4	-	69.4	-	-	-
14	VG75	74.7	-	73.3	-	0.8	0.6
28	VG76	77.3	-	74.9	-	-	2.5
56	VG77	76.6	1.4	73.6	-	-	1.6
	VG78	78.6	0.8	75.3	1.6	0.9	-
	mean	**77.6**	**1.1**	**74.4**	**0.8**	**0.5**	**0.8**
78	VG81	75.3	1.6	73.7	-	-	-
100	VG82	69.5	1.6	67.1	-	-	0.8
	VG84	69.2	1.8	67.5	-	-	-
	mean	**69.4**	**1.7**	**67.3**	**-**	**-**	**0.4**

TAR = Total applied radioactivity
t_{Ret} = Retention time [min]
n.a. = Not analysed
(s) = Sterile vessels
[a] Sum of several peaks, each individual peak <1.0% TAR

Chiral HPLC

Results of the chiral radio-HPLC analyses are summarised in Table 8.2.2.3-11.

No shift in the enantiomeric ratio of BAS 750 F in sediment extracts (chlorophenyl- and triazole-label) was detected.

Table 8.2.2.3-11: Chiral radio-HPLC analysis of water samples and sediment extracts after incubation with ^{14}C-labelled BAS 750 F [% ROI]

Matrix	Days after treatment	total radioactivity in sample [% TAR]	Enantiomer 1 [% ROI] t_{Ret} 20.7 min	Enantiomer 2 [% ROI] t_{Ret} 21.9 min
chlorophenyl-label Berghäuser Altrhein				
water	30	10.5	52.1	47.9
sediment extract	30	67.8	51.2	48.8
sediment extract	100	49.8	50.1	49.9
chlorophenyl-label Ranschgraben				
water	30	7.8	49.4	50.6
sediment extract	30	74.5	52.2	47.8
sediment extract	100	65.3	51.0	49.0
triazole-label Berghäuser Altrhein				
water	30	16.1	50.6	49.4
sediment extract	30	70.0	51.2	48.8
sediment extract	100	52.2	50.9	49.1
triazole-label Ranschgraben				
water	30	9.7	50.9	49.1
sediment extract	30	77.4	50.4	49.6
sediment extract	100	69.5	51.8	48.2

TAR = total applied radioactivity
ROI = "region of interest" = peak area with regard to the total integrated peak area in a chromatogram

Characterisation of non-extractable residues (NER)

Results of the humic substance fractionation are summarized in Table 8.2.2.3-12.

About one-third to one-half of the bound radioactivity could be released by harsh NaOH extraction. The rest was still bound to the soil matrix. After fractionation of the NaOH extract into fulvic acids and humic acids, about one-half to three quarters were found in the fulvic acids and one-half to one quarter in the humic acids of test system Berghäuser Altrhein. In test system Ranschgraben, about one-third to one-half were found in the fulvic acids and one-half to two-thirds in the humic acids.

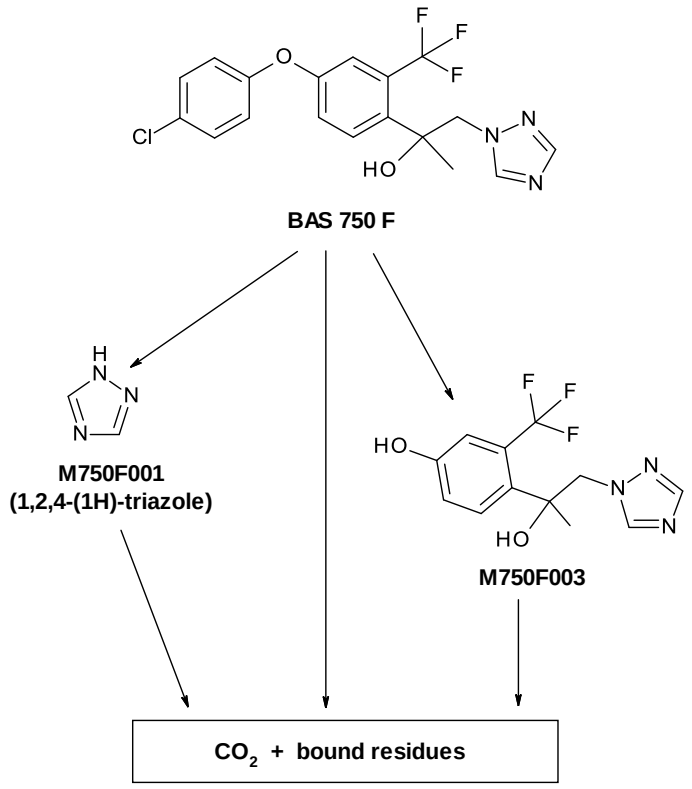
Table 8.2.2.3-12: Distribution of radioactivity between fulvic acids, humic acids and humins after application of ^{14}C-BAS 750 F to water/sediment systems

sediment sample	DAT	vessel No.	[% TAR]					Recovery [%]
			total NER	fulvic acids	humic acids	humins	sum	
Berghäuser Altrhein (chlorophenyl-label)	30	VG07	14.1	2.7	1.6	8.7	13.0	91.8
	100	VG10	25.3	4.8	3.3	15.4	23.5	93.0
Berghäuser Altrhein (triazole-label)	30	VG21	11.4	3.5	0.9	6.8	11.2	98.4
	100	VG25	26.6	10.4	2.7	13.5	26.7	100.0
Berghäuser Altrhein (trifluoromethylphenyl-label)	28	VG61	9.7	1.3	1.5	6.3	9.0	92.7
	100	VG70	19.0	3.4	2.9	10.1	16.4	86.3
Ranschgraben (chlorophenyl-label)	30	VG36	10.1	1.3	2.2	4.9	8.4	82.7
	100	VG40	19.1	2.5	4.2	8.2	14.9	78.0
Ranschgraben (triazole-label)	30	VG49	7.6	1.7	1.8	4.3	7.8	103.1
	100	VG52	17.0	4.1	3.9	7.5	15.5	91.6
Ranschgraben (trifluoromethylphenyl-label)	28	VG76	8.4	1.4	2.2	4.7	8.2	98.0
	100	VG82	22.8	3.4	5.4	10.6	19.3	84.5

DAT = Days after treatment
NER = Non-extractable radioactive residues
TAR = Total applied radioactivity

A proposed route of degradation of BAS 750 F in water/sediment systems is given in Figure 8.2.2.3-1.

Figure 8.2.2.3-1: Proposed (major) route of degradation of BAS 750 F in water/sediment systems



Kinetic evaluation

The Applicant undertook a kinetic evaluation in order to derive degradation parameters as persistence endpoints as well as modelling endpoints. Kinetic analysis and calculation of $DegT_{50}$ and $DegT_{90}$ values was performed following the recommendations of the FOCUS Kinetics workgroup [*FOCUS (2006)*]. The RMS notes that endpoints for 1,2,4-triazole have already been discussed and agreed upon by the PRAPeR committee (December 2013) and the Applicant has proposed the use of default values for M750F003 in the aquatic risk assessment. Therefore, a kinetic evaluation of these metabolites has not been undertaken.

The Applicant used the software package KinGUI (version 2) with the error tolerance and the number of iterations of the optimisation tool were set to 0.00001 and 100 respectively. The RMS has repeated the Applicant's modelling using CAKE v3.2 with Ordinary Least Square selected.

Kinetic evaluation at Level P-I (one-compartment approach) was performed for BAS 750 F degradation in the total system as well as dissipation from the water and sediment phase of the test systems. At Level P-II (two-compartment approach: water and sediment), the kinetic analysis considered the degradation in water and sediment and the partitioning between both phases.

At Level P-I, persistence endpoints were derived from the kinetic models that provided the best fit to the measured data. The goodness-of-fit was evaluated by visual assessment, χ^2 minimum error, and type-I-error rate (t-test). Modelling endpoints were derived preferably from the SFO model. The Applicant did not undertake any back-calculations to determine the persistence DT_{50} endpoint; SANCO guidance (Brussels, 25.09.2012-rev. 3) states that persistence DT_{50} values should be obtained by dividing the DT_{90} by 3.32 when the DT_{90} is calculated not estimated. For both test systems, the total system DT_{90} values were estimated beyond the study period therefore, the RMS deems the Applicant's approach acceptable. However, for the water systems, the DT_{50} should be back-calculated as the DT_{90} values were calculated. For expediency, the RMS has indicated what the back-calculated DT_{50} values are for each kinetic model for each water/sediment compartment (when applicable).

The results obtained with the three differently labelled test items were pooled and regarded as replicates for kinetic evaluation. At Level P-I and P-II of the analysis, the kinetic evaluation started on the day of treatment (i.e. 0 DAT). The initial concentration of the test substance in the total system and in water was set to the material balance recovered at 0 DAT. Accordingly, the initial concentration in the sediment phase was assumed to be zero at Level P-II. The assessment of dissipation in sediment at Level P-I requires kinetics to be fitted to the corresponding decline data, starting from the maximum observed concentration in the compartment. The dissipation of the test item was thus evaluated starting at the day of maximum occurrence that was defined as 0 days after maximum concentration (0 DAMC). All later time points were adjusted accordingly as days after maximum concentrations (DAMC).

The RMS agrees with the Applicant's approach and can validate their results, therefore, the Applicant's results are presented as follows.

<u>System BA – Level P-I</u>

In order to derive persistence endpoints for the total system, water system and sediment system, SFO and FOMC models were initially run and compared (in line with FOCUS guidance). In the case of the total system and the water system, the Applicant states the FOMC model provided a better visual and/or statistical fit, therefore, DFOP and HS models were run and compared to the FOMC model.

For the total system, the DFOP model provided the best visual fit. However, the DFOP K1 t-test value was 0.237. Although this value is >0.1, because the 'g' value is very small (0.08), the Applicant states it can be disregarded. Therefore, given the DFOP model provided the best visual fit and the other statistical results were acceptable (and the HS K1 t-test value was also >0.1), the Applicant deemed it appropriate for this model to provide the persistence endpoints.

The RMS notes that it is the initial phase of the total system data, when the a.s. is rapidly portioning to sediment, that is less well described by the SFO model; the SFO fit is very similar to the K2 curve of the DFOP fit. As a result, the RMS notes the SFO model could be considered acceptable in determining the persistence endpoints. Furthermore, the RMS notes that there is very little difference between the DT_{50} values calculated by the SFO

and DFOP models (125.5 and 122.2 days respectively) and both of these are greater than the persistence trigger value for the sediment compartment of 120 days. Therefore, in this instance, the RMS deems the Applicant's results acceptable.

For the water system, the FOMC model provided the best visual and statistical fit, therefore, this model was selected to provide the persistence endpoints.

For the sediment system, the SFO model provided a better visual and statistical fit than the FOMC model, therefore, the SFO model was selected to provide the persistence endpoints.

Figures 8.2.2.3-2 to -4 and summarise the results of the SFO fits and relevant biphasic fits. Table 8.2.2.3-13 summarises the statistical results from the different models. All figures and results are taken from the Applicant's study report.

Figure 8.2.2.3-2: Total system SFO, FOMC and DFOP model fits for the BA System

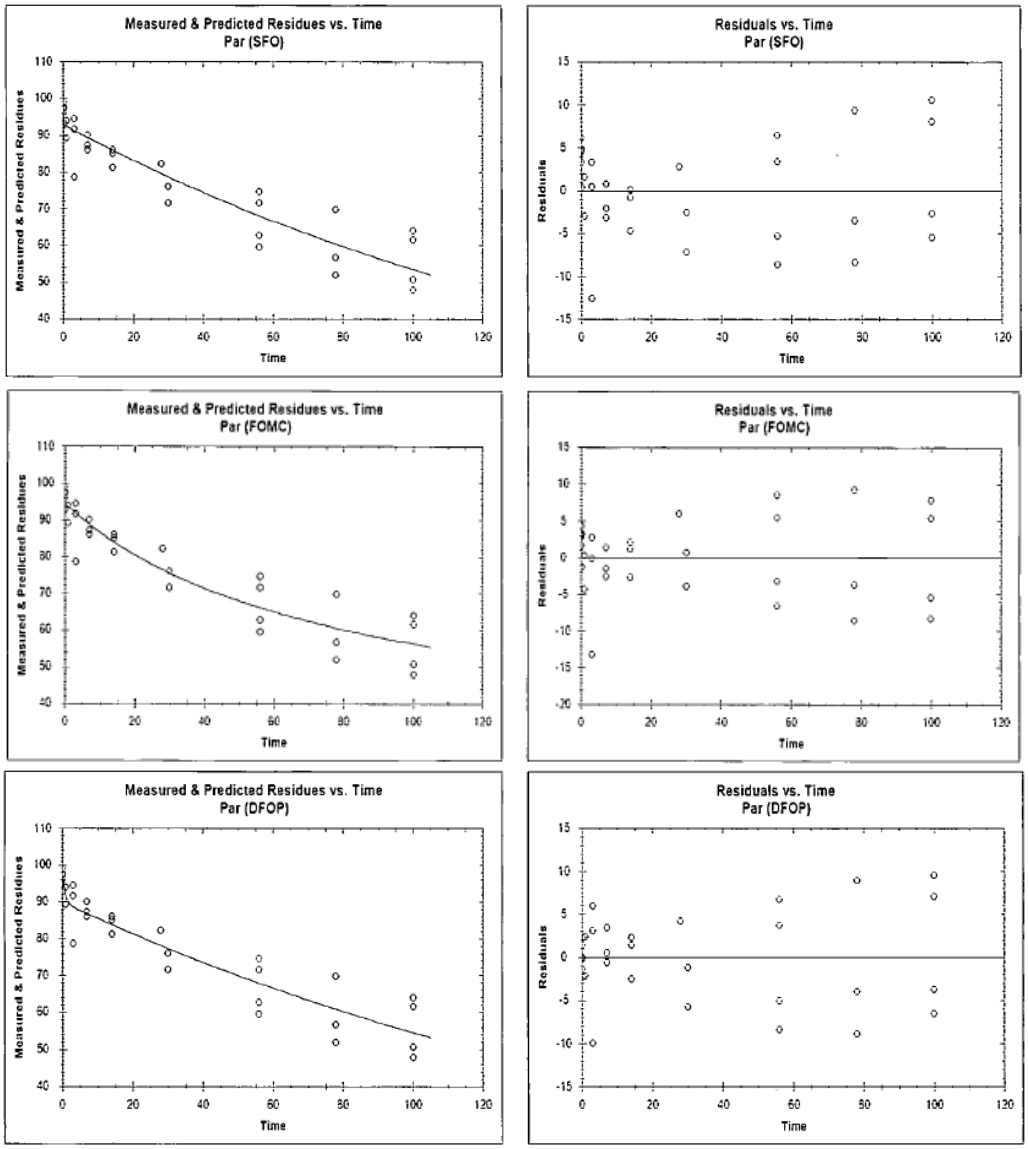


Figure 8.2.2.3-3: Water system SFO and FOMC model fits for the BA system

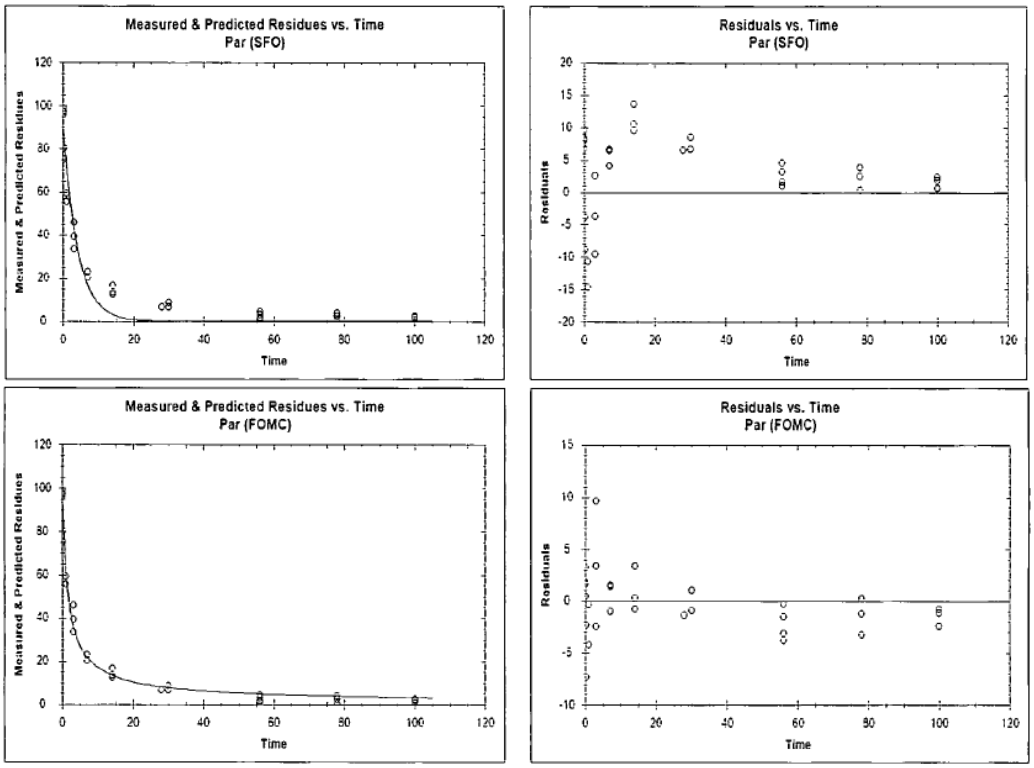


Figure 8.2.2.3-4: Sediment system SFO and FOMC model fits for the BA system

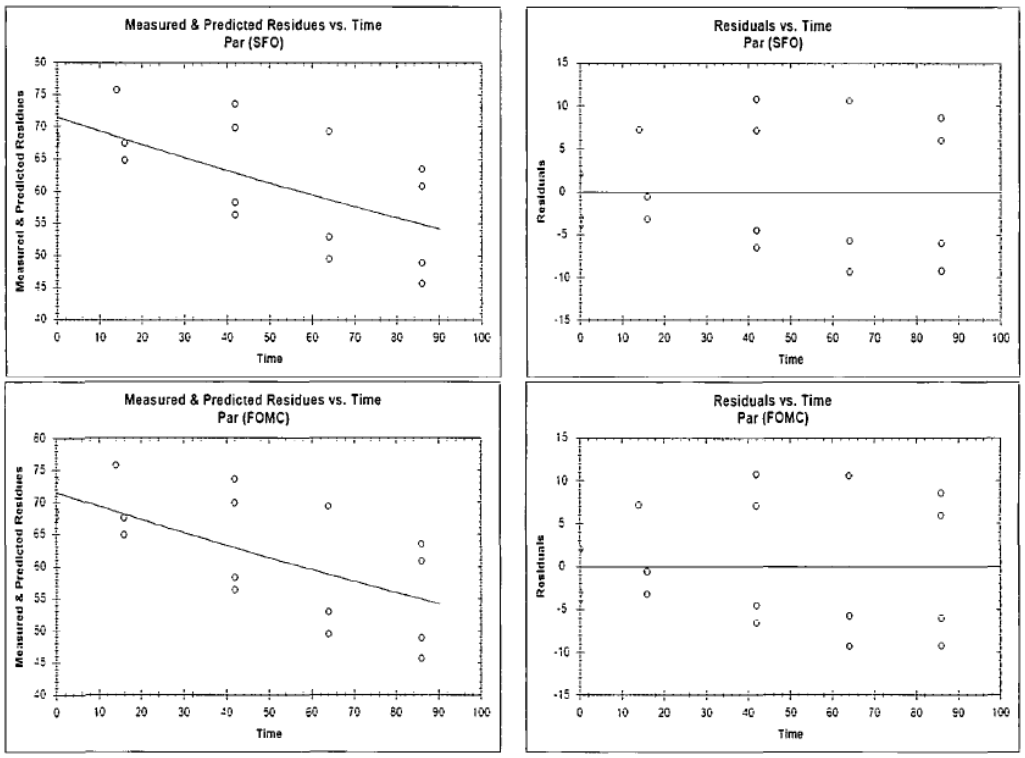


Table 8.2.2.3-13: Statistical results of the different model fits for the BA system

System	Model	M0	Chi^2 (%)	t-test	DT_{50} (d)	DT_{90} (d)
Total system	SFO	92.8	2.75	<0.001	125.5	416.9
	FOMC	94.5	2.60	Acceptable[a)]	167.9 (n/a[c)])	>1000
	DFOP	97.5	2.00	K1: 0.237 K2: <0.001	122.2 (133.7[b)])	444.0
	HS	97.3	2.01	K1: 0.113 K2: <0.001	122.6 (133.7[b)])	443.9
Water system	SFO	89.3	19.13	<0.001	2.9	9.5
	FOMC	95.7	6.40	Acceptable[a)]	1.7 (6.6[b)])	21.9
	DFOP	96.5	7.35	K1: <0.001 K2: <0.001	1.5 (5.6[b)])	18.6
	HS	95.6	8.81	K1: <0.001 K2: <0.001	1.3 (5.6[b)])	18.5
Sediment system	SFO	71.5	4.00	0.002	224.8	746.7
	FOMC	71.5	4.41	Acceptable[a)]	224.8 (225.2[b)])	747.6
	DFOP	Not modelled				
	HS	Not modelled				

a) For FOMC, instead of a t-test, the alpha and beta error values are compared against the estimated parameters; if lower, the FOMC model is considered acceptable
b) Value back-calculated from the DT_{90} by dividing the DT_{90} by 3.32
c) Back-calculation could not be undertaken due to the uncertainty of the DT_{90} value

In order to derive modelling endpoints, the acceptability of the SFO model fit is considered in the first instance. For both the total system (Figure 8.2.2.3-2) and the sediment system (Figure 8.2.2.3-4), the SFO fit was considered acceptable for deriving modelling endpoints.

For the water system however, due the high Chi^2 value and poor visual fit, the SFO model was considered unacceptable. Because >90% dissipation occurred in the water phase in the study period, FOMC, DFOP and HS models were run and compared against each other. As highlighted above for the persistence endpoints, the FOMC model provided the best visual and statistical fit (indicated by the low Chi^2 value). Therefore, this model was used to derive the modelling endpoints. The modelling DT_{50} is back calculated from the DT_{90} (21.9 days) by dividing the DT_{90} by 3.32; therefore, the appropriate modelling DT_{50} is 6.6 days.

System RG – Level P-I

In order to derive persistence endpoints for the total system, water system and sediment system, SFO and FOMC models were initially run and compared (in line with FOCUS guidance). In the case of the total system and the water system, the Applicant states that the FOMC model provided a better visual and/or statistical fit, therefore, DFOP and HS models were run and compared to the FOMC model.

For the total system, the Applicant states that the HS model provided the best visual and statistical fit, therefore, this model was selected to provide the persistence endpoints. The RMS notes that, as described for the BA system, it is the initial data points that are less well described by the SFO fit, when the a.s. is partitioning to sediment. Also, the DT_{50} values are very similar for the SFO and biphasic fits (excluding FOMC) (~213 days). Therefore, the RMS is of the opinion that the SFO fit could be used to determine the persistence endpoints. However, because both the SFO and HS fits will result in DT_{50} values greater than the persistence trigger (120 days in sediment), the RMS deems the Applicant's results acceptable on this occasion.

For the water system, the FOMC model provided the best visual and statistical fit, therefore, this model was selected to provide the persistence endpoints.

For the sediment system, the SFO model provided a better visual and statistical fit than the FOMC model, therefore, the SFO model was selected to provide the persistence endpoints.

Figures 8.2.2.3-5 to -7 and summarise the results of the SFO fits and relevant biphasic fits (i.e. HS for the total system and FOMC for the water system). Table 8.2.2.3-14 summarises the statistical results from the different models. All figures and results are taken from the Applicant's study report.

Figure 8.2.2.3-5: Total system SFO, FOMC, DFOP and HS model fits for the RG system

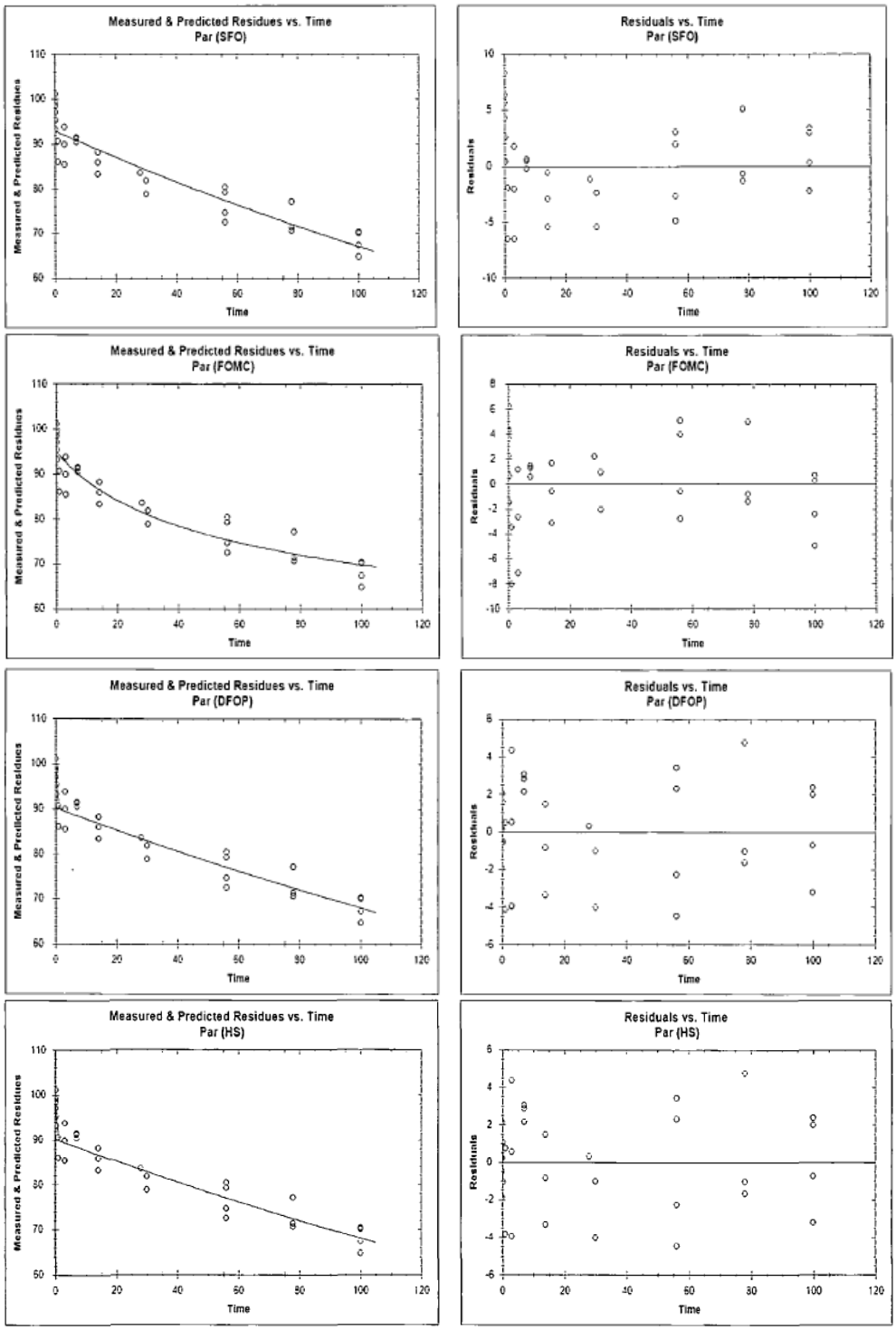


Figure 8.2.2.3-6: Water system SFO and FOMC model fits for the RG system

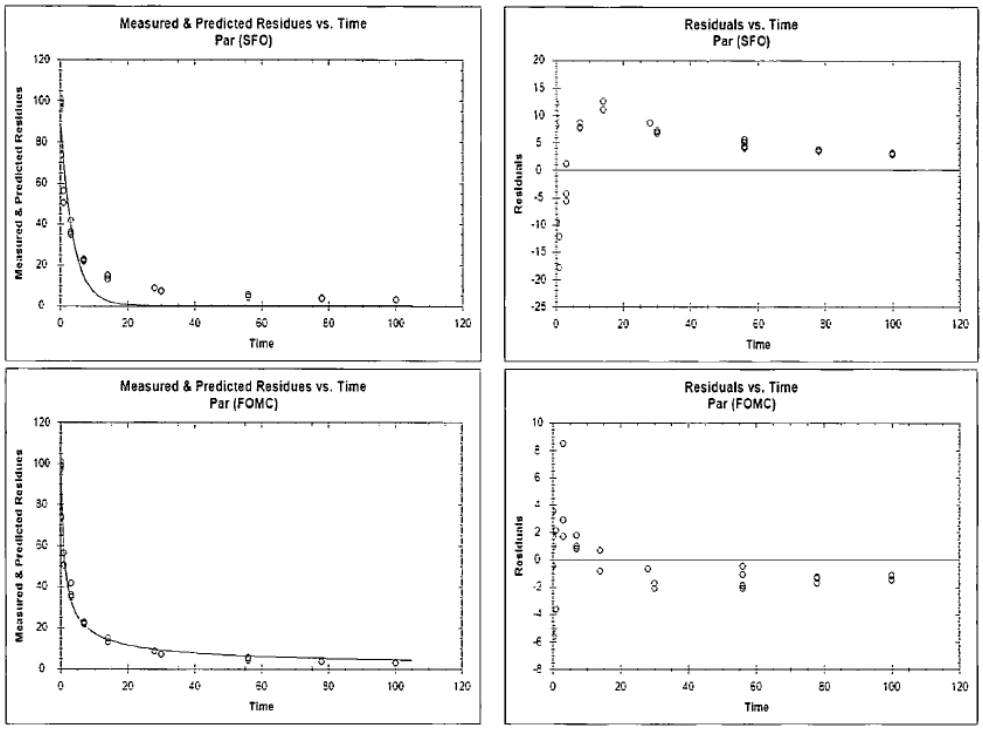


Figure 8.2.2.3-7: Sediment system SFO and FOMC model fits for the RG system

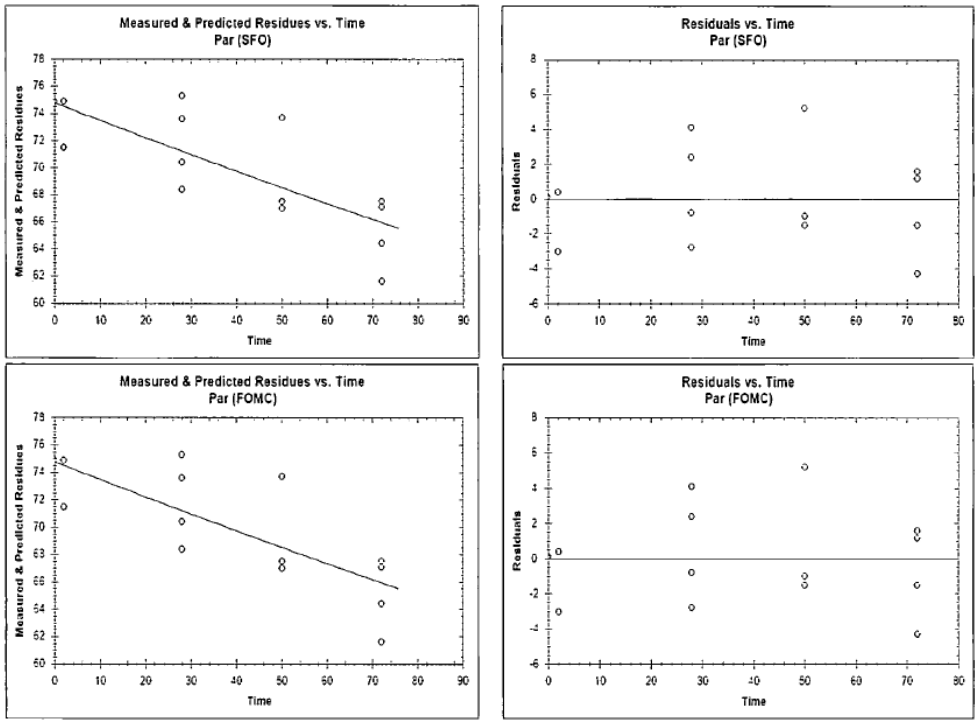


Table 8.2.2.3-14: Statistical results of the different model fits

System	Model	M0	Chi^2 (%)	t-test	DT_{50} (d)	DT_{90} (d)
Total system	SFO	92.8	2.74	<0.001	212.8	707.1
	FOMC	94.9	2.52	Acceptable[a)]	>1000 (n/a[c)])	>1000
	DFOP	99.1	1.36	K1: 0.064 K2: <0.001	212.7 (236.3[b)])	784.6
	HS	99.0	1.32	K1: 0.030 K2: <0.001	213.1 (236.6[b)])	785.6
Water system	SFO	89.0	23.03	<0.001	2.6	8.7
	FOMC	97.6	6.69	Acceptable[a)]	1.3 (7.9[b)])	26.2
	DFOP	98.3	9.31	K1: <0.001 K2: <0.001	1.0 (5.6[b)])	18.5
	HS	96.4	11.31	K1: <0.001 K2: <0.001	1.1 (6.0[b)])	20.0
Sediment system	SFO	74.8	0.97	<0.001	395.6	>1000
	FOMC	74.8	1.10	Acceptable[a)]	395.7 (n/a[c)])	>1000
	DFOP	Not modelled				
	HS	Not modelled				

a) For FOMC, instead of a t-test, the alpha and beta error values are compared to the estimated parameters; if the error values are lower, the FOMC model is considered acceptable
b) Value back-calculated from the DT_{90} by dividing the DT_{90} by 3.32
c) Back-calculation could not be undertaken due to the uncertainty of the DT_{90} value

In order to derive modelling endpoints, the acceptability of the SFO model fit is considered in the first instance. For both the total system (Figure 8.2.2.3-5) and the sediment system (Figure 8.2.2.3-7), the SFO fit was considered acceptable for deriving modelling endpoints.

For the water system however, due the high Chi^2 value and poor visual fit, the SFO model was considered unacceptable. Because >90% dissipation occurred in the water phase in the study period, FOMC, DFOP and HS models were run and compared against each other. As highlighted above for the persistence endpoints, the Applicant states that the FOMC model provided the best visual and statistical fit (indicated by the low Chi^2 value). Therefore, this model was used to derive the modelling endpoints. The modelling DT_{50} is back calculated from the DT_{90} (26.2 days) by dividing the DT_{90} by 3.32; therefore, the appropriate modelling DT_{50} is 7.9 days.

The Applicant also conducted a P-II assessment; the kinetic analysis considered the degradation in water and sediment taking into account the partitioning between the two phases. However, the P-II evaluation could not be accepted according to FOCUS guidance because of the failure of the degradation parameter in water (k_w) and sediment (k_{sed}) regarding the t-test.

The RMS has repeated the Applicant's P-II modelling using ModelMaker and also obtained failures of the t-test for both test systems for both k_w and k_{sed} values. However, the P-I modelling provided accurate enough water/sediment endpoints. Therefore, the following DT_{50}/DT_{90} values for BAS 750 F in water/sediment systems (P-I-level) are appropriate (Table 8.2.2.3-15):

Table 8.2.2.3-15: Persistence and modelling endpoints for BAS 750 F (Level P-I)

Compartment	System	Persistence endpoints				Modelling endpoints		
		Model	DT_{50} [d]	DT_{90} [d]	chi^2	Model	DT_{50} [d]	chi^2
Total system	Berghäuser Altrhein	DFOP	122.2	444.0	2.0	SFO	125.5	2.8
	Ranschgraben	HS	213.1	785.6	1.3	SFO	212.8	2.7
Water	Berghäuser Altrhein	FOMC	6.6[a)]	21.9	6.4	FOMC	6.6[a)]	6.4
	Ranschgraben	FOMC	7.9[a)]	26.2	6.7	FOMC	7.9[a)]	6.7
Sediment	Berghäuser Altrhein	SFO	224.8	746.7	4.0	SFO	224.8	4.0
	Ranschgraben	SFO	395.6	>1000	1.0	SFO	395.6	1.0

a) Calculated as $DT_{50} = DT_{90}/3.32$

Conclusion

Overall, it can be concluded that BAS 750 F dissipates at a fast rate from the water phase and degrades at a moderate rate in the sediment when incubated in water/sediment systems under dark conditions.

Metabolite M750F001 (1,2,4-triazole) is formed by split-off of the triazole ring from the parent molecule. It reached maximum amounts of 10.2% TAR in the water and 4.9% TAR in the sediment phase. M750F003 is formed after split-off of the chlorophenyl ring, which is then further degraded to CO_2 as shown with the chlorophenyl-labelled test item. M750F003 occurred in maximum amounts of 3.8% TAR in the water and 5.4% TAR in the sediment phase. All other metabolites never exceeded 2.8% TAR.

For the parent compound, best-fit DT_{50} values in the water phase were 6.6 and 7.9 days for the systems Berghäuser Altrhein and Ranschgraben, respectively. In the sediment, parent DT_{50} values were determined to be 224.8 and 395.6 days. For the total system, DT_{50} values of 122.2 and 213.1 days were calculated for the respective test system. No kinetic modelling was undertaken for the above metabolites because 1,2,4-triazole has already agreed endpoints and the Applicant proposed to use default values in the exposure calculations for M750F003.

B.8.2.3. Degradation in the saturated zone

The Applicant states that, due to its low leaching potential (geometric mean of K_{foc} = 3456 mL g-1), BAS 750 F is not expected to reach deeper soil layers or saturated zones. Therefore, the Applicant states that investigations on the degradation in the saturated zone are considered to be not necessary. The RMS accepts the Applicant's justification.

B.8.2.4. Potential effects of water treatment processes

Article 4 Section 3 (b) refers to the impact of water treatment processes on water-borne residues of active substances and metabolites, i.e. the capability of water treatment processes to form potentially harmful substances when degrading the water-borne residue.

At present there is no definitive approach to consider the above. Currently the RMS recommends following the approach detailed below:

- An initial screening step based on examination of substance structure for potential formation of harmful degradates/metabolites/residues;
- If these harmful degradates/metabolites/residues are predicted, then risk management-based approaches should be invoked.
- If risk management leads to severe restrictions, then applicants should consider the generation of degradation data to disprove the prediction.
- If the prediction is confirmed, modelling or monitoring data showing levels of these harmful degradates are below 0.1 µg/l will have to be generated by the applicant(s) for the restrictions to be lifted.

The Applicant has submitted the following in regards to the potential impact of water treatments works on BAS 750 F:

> *Currently there is neither a guideline for testing the effect of water treatment on pesticides (or other chemicals) nor is there a risk assessment procedure. Since conditions of water treatment are extremely variable across Europe (different treatment methods and intensities used in different sequences on different types of raw waters) it is currently not possible to comprehensively assess the potential formation of harmful by-products during drinking water production. An experimental guideline is essential because the effect of ozonolysis or chlorination strongly depends on treatment conditions (e.g. duration, applied concentration, properties of the raw water) which should be representative for real water treatment plants.*
>
> *In the absence of such guidance documents an evaluation was made based on knowledge on the chemistry of BAS 750 F and its degradation products and applying chemical principles.*
>
> *Experimental data on the aerobic degradation of BAS 750 F in soil demonstrate that the degradation pathway is mineralization, formation of the minor metabolite M750F001 (1,2,4-triazole), and formation of some other minor metabolites. The greatest sink observed for BAS 750 F in aerobic soil was formation of bound residues. Details are presented in chapter 8.1.1 on this study. BAS 750 F was found to be hydrolytically stable at all pH values tested (pH 4-9) at 25°C (see chapter 8.2.1.1). In an aerobic water/sediment study under dark conditions BAS 750 F was observed to quickly partition from the water phase to the sediment phase, as expected due to the high K_{OC} value. Moderate amounts of the metabolites M750F001 (1,2,4-triazole) and M750F003 as well as some minor metabolites were observed. Mineralization was low and the main sink was found to be bound residues. Details are presented in chapter 8.2.2.3. Under irradiated conditions in sterile buffer, BAS 750 F is converted to the metabolites M750F005, M750F006, M750F007, and M750F008 as well as some additional minor metabolites. Details are presented in chapter 8.2.1.2.*
>
> *Neither BAS 750 F nor its metabolites contain any comparable aliphatic side chains as present in the chemical structure of tolylfluanid, which caused the problem of nitrosamine formation during water treatment for drinking water production. No N-nitrosamine formation is expected for BAS 750 F and its metabolites, since no secondary amine function is present. The only nitrogen-containing moiety is the electron-deficient heteroaromatic triazole ring, which has little propensity towards electrophilic attack of either ozone or NO+.*
>
> *With chlorine-based treatments, chlorination or hydroxylation and the possible loss of substituted chlorinated and hydroxylated structures is conceivable. However, when chlorine enters water it reacts chemically with any organic matter found in the water. There is always some organic matter in natural*

waters and by-products of this reaction include e.g. trihalomethanes. Any potential harmful degradation products resulting from any organic matter in the water treatment process will be eliminated in subsequent clean-up steps by using e.g. activated carbon filtration or sand filter beds.

It is therefore highly unlikely that water treatment processes such as ozonation or chlorination will result in the formation of by-products that would require a detailed health risk assessment. Consequently, further investigation into the effect of water treatment processes on the nature of residues present in surface water and groundwater is not considered necessary.

The RMS has consulted the RMS's Chemistry specialist who confirmed the Applicant's argument that the formation of nitrosamines is not expected based on the structure of BAS 750 F. However, the RMS considers that Article 4 Section 3 (b) refers to potential formation of any harmful substances, and should not be restricted to nitrosamine formation alone. In addition, the RMS notes that the consideration of chlorination processes provided by the Applicant is more general in nature and there is some uncertainty with regards to specific potential ozonation and chlorination processes on BAS 750 F in wastewater treatment works (WwTWs). However the RMS accepts that there is no definitive approach to addressing the Article 4 Section 3 (b) requirements. Overall, given nitrosamine formation is not expected based on accepted structural arguments, and that large quantities of BAS 750 F and its metabolites are not expected to occur at WwTWs, the RMS is of the opinion that there is minimal risk of significant levels of harmful degradation products forming as a result of water treatment processes on BAS 750 F. The Applicant's case is therefore accepted and no further information is required.

B.8.2.5. Summary of fate and behaviour in water

The Applicant submitted a hydrolytic degradation study (see section B.8.2.1.1) of BAS 750 F over 30 days, 25°C and at pH 4, 5, 7 and 9; the study was considered acceptable by the RMS. BAS 750 F was shown to be stable over these ranges with only negligible degradation occurring. Insufficient degradation occurred to be able to conduct kinetic analysis.

An aqueous photolysis study was conducted in pure water at pH 7 and at 25°C (see section B.8.2.1.2). The study lasted 15 days with the samples continuously exposed to a xenon lamp to mimic natural light; the study was considered acceptable by the RMS. BAS 750 F was observed to degrade rapidly over the study period with four 'major' metabolites being formed: M750F005, M750F006, M750F007 and M750F008.

Kinetic analysis was undertaken on the photolytic degradation of BAS 750 F; the a.s. was observed to follow SFO kinetics and a DT_{50} value of 2.3 days was calculated. Kinetic analysis was also conducted on M750F005 and M750F006; analysis could not be undertaken on the other two photolytic metabolites because M750F007 was still increasing at study termination and there were too few data points in the decline phase for M750F008. The DT_{50} values calculated by the RMS for M750F007 and M750F008 were 14.7 and 11.6 days respectively. However, the Applicant proposed using default DT_{50} values of 1000 days in the surface water exposure calculations for all four metabolites. Given this will result in a more conservative risk assessment, the RMS accepts the Applicant's proposal.

The Applicant submitted a study determining the ready biodegradability of BAS 750 F (see section B.8.2.2.1). The study lasted 28 days and was undertaken at 22 ± 2°C using activated sludge. Only very minor biodegradation was observed in the test period, therefore, BAS 750 F is not readily biodegradable.

The aerobic mineralisation of BAS 750 F was tested to OECD 309 guidelines (see section B.8.2.2.2). Stream water was used containing suspended sediment; the RMS considered the study acceptable. Very little degradation (<5%) and mineralisation occurred throughout the 63 day study period for both test concentration (10 µg/L and 100 µg/L), therefore, kinetic analysis could not be undertaken.

The behaviour of BAS 750 F in two water/sediment systems was investigated by the Applicant (see section B.8.2.2.3). The study was conducted over 100 days and at 20 ± 1 °C in the dark; the RMS considers the study acceptable. BAS 750 F was observed to dissipate rapidly from the water phase, mostly partitioning to sediment. By the end of the study period, <5% BAS 750 F was detected in the water phase with 45.6 to 67.3% in the sediment phase. Two major metabolites were detected in the study: 1,2,4-triazole (M750F001) and M750F003. 1,2,4-triazole was detected at a maximum concentration of 10.2% in the water phase and 4.9% in the sediment phase at day 100. M750F003 was detected at a maximum concentration of 3.3% in the water phase and 5.9% in the sediment phase at day 100; the mean (M750F003) day 100 values in water and sediment were 3.1% and 5.4% respectively. A maximum amount of 9.6% AR was observed to mineralise to CO_2 and a maximum 26.6% was observed to degrade to non-extractable residue.

Level P-I kinetic analysis was undertaken on the water/sediment results. For both test systems, BAS 750 F was observed to follow biphasic best-fit kinetics in the total systems; the DFOP model was most appropriate for system BA and HS was most appropriate for system RG. $DegT_{50}$ values of 122.2 and 213.1 days were calculated in systems BA and RG respectively. In the water phase, both test systems followed FOMC best-fit kinetics with back-calculated $DissT_{50}$ days of 6.6 and 7.9 calculated. In the sediment phase, both test systems were observed to follow SFO best-fit kinetics. The sediment $DissT_{50}$ values calculated were 224.8 and 395.6 days.

To derive modelling endpoints, the SFO fits were deemed acceptable for the total system and sediment system for both test systems; FOMC kinetics were still considered as most appropriate for the water system. The total system $DegT_{50}$ modelling endpoints for systems BA and RG were 125.5 and 212.8 days respectively (geometric mean value of 163.4 days). Because BAS 750 F was observed to quickly to the sediment phase, the Applicant proposed assigning the level P-I total system geomean DT_{50} value (163.4 days) to the sediment compartment in the surface water exposure calculations and assigning the default DT_{50} of 1000 days to the water compartment. The RMS accepts the Applicant's approach.

No kinetic analysis of the major metabolites arising from the water/sediment study was undertaken as 1,2,4-triazole has already agreed EU endpoints and M750F003 was assigned default DT_{50} values of 1000 days.

The Applicant has submitted a case justifying why the formation of nitrosamines is not expected to occur from the degradation of BAS 750 F at WwTWs (see section B.8.2.4). The RMS accepts the Applicant's justification.

Further consideration of BAS 750 F's persistence in the water environment is presented in section B.8.2.6.

As indicated in section B.8.1.4, the Applicant monitored the enantiomeric ration of BAS 750 F. The largest isomeric shift occurred in the aqueous photolysis study where ratios of 43.3:56.7 were detected. Further consideration of this is provided in section B.9.8 of the ecotoxicology product section of the dRR (Volume_3CP_PPP_B-9). No further consideration is made as to the significance of the shift in enatiomeric ratio in this section.

B.8.2.6. Assessment of persistence in water and sediment

The criteria for a pesticide to be classed as 'Persistent' or 'very Persistent' is outlined within Annex II of EC Regulation 1107/2009. For the water and sediment compartments, these are as follows:

An active substance, safener or synergist fulfils the persistence criterion where:

- The half-life in marine water is higher than 60 days,
- The half-life in fresh or estuarine water is higher than 40 days,
- The half-life in marine sediment is higher than 180 days,
- The half-life in fresh or estuarine water sediment is higher than 120 days

An active substance, safener or synergist fulfils the 'very persistent' criterion where:

- the half-life in marine, fresh- or estuarine water is higher than 60 days,
- the half-life in marine, fresh- or estuarine water sediment is higher than 180 days

As indicated in section B.8.2.1.1, BAS 750 F was found to be hydrolytically stable at pH 4-9, 25°C. However, in the aqueous photolysis study (section B.8.2.1.2), BAS 750 F was observed to degrade quickly with a DT_{50} of 2.3 days.

Within the water/sediment study (section B.8.2.2.3), BAS 750 F was observed to quickly partition to sediment; this is expected given the high K_{OC} value. Due to the high K_{OC} value and the rapid dissipation from water, the sediment compartment is determined to be the major degradation compartment. The RMS notes that the SANCO guidance (Brussels, 25.09.2012 –rev.3), states that, in regards to biphasic kinetic fits for persistent endpoints, the DT_{90} value should be divided by 3.32, provided the DT_{90} value is calculated not estimated. For both water/sediment test systems, the DT_{90} was extrapolated beyond the study period. Therefore, it is not appropriate to divide the DT_{90} by 3.32 to obtain an appropriate persistence DT_{50} on this occasion. However, the RMS notes that, if the sediment persistence half-life threshold of 120 days is multiplied by 3.32, the resulting DT_{90} value is 398.4 days. As both test systems estimated a DT_{90} greater than this value, the RMS considers that BAS 750 F can be classed as 'Persistent' in the sediment system.

The RMS notes that photolysis in water can rapidly degrade BAS 750 F. However, in the absence of photolytic degradation, as shown by the hydrolysis and aerobic mineralisation studies (section B.8.2.2.2), BAS 750 F degrades slowly in the water environment. Because the extent of photolysis in the natural surface water environment is unclear and BAS 750 F has been shown to quickly partition to sediment, the true persistence of BAS 750 F in water is unclear. Without further data on the influence of photolysis on natural water bodies, BAS 750 F is classified as potentially persistent.

If the sediment 'very Persistent' threshold of 180 days is multiplied by 3.32, the resulting DT_{90} value is 597.6 days. Given the total system DT_{90} values were 444 and 786 days, it is unclear if BAS 750 F can be classed as 'very Persistent' in the sediment system. However, it should be noted that BAS 750 F has already been classified as very persistent in soil, as such, even if further data was produced, it would not alter the overall classification of BAS 750 F.

B.8.3. FATE AND BEHAVIOUR IN AIR

B.8.3.1. Route and rate of degradation in air

Report:	CA 7.3.1/1 Hassink J., 2015 a Photochemical oxidative degradation of BAS 750 F (QSAR estimates) 2015/1005046
Guidelines:	EC 1107/2009 of the European Parliament
GLP:	no

Introduction

The degradation rates for reactions of BAS 750 F with OH radicals and ozone in the atmosphere were calculated using the AOPWIN program based on ATKINSON's increment method.

Material and methods

The degradation rate resulting from attack of OH-radicals was calculated by the Applicant with the AOPWIN Program (Atmospheric Oxidation Program for Microsoft Windows 3.1, Version 1.88, Syracuse Research Corp. 1997) based on ATKINSON's increment method [*Atkinson, R. (1987): A Structure-Activity Relationship for the Estimation of Rate Constants for the Gas-Phase Reactions of OH Radicals with Organic Compounds, Int.J. Chem. Kin. 19, 799*].

The degradation rate resulting from attack of ozone was calculated according to an OECD method [*Anonymous (1992): The rate of photochemical transformation of gaseous organic compounds in air under tropospheric conditions. OECD Environment Monographs No. 61, OECD, Paris*].

The degradation rate of BAS 750 F with OH-radicals was estimated based on the structural formula. The SMILE notation used for BAS 750 F in AOPWIN was:

c1cc(CL)ccc1Oc2cc(C(F)(F)(F))c(C(O)(C)Cn3ncnc3)cc2

Results and discussion

Assuming a pseudo-first order reaction, the degradation half-life was calculated by taking into account the diurnally and seasonally averaged concentration of hydroxyl-radicals in the troposphere. The total rate constant was estimated to be $k_{OH} = 6.4193 \times 10^{-12}$ cm^3 molecule^{-1} s^{-1}.

Considering a weighted global average tropospheric hydroxyl-radical concentration of 1.5×10^6 mol cm^{-3}, the half-life for the degradation of BAS 750 F by OH-radicals was calculated according to Equation 8.3.1-1.

Equation 8.3.1-1 Estimation of the atmospheric degradation half-life (t1/2) of BAS 750 F

$$t_{1/2} = \ln 2 / (6.4193 \times 10^{-12} \times 1.5 \times 10^{6}) \text{ s}$$
$$= 19.995 \text{ h}$$
$$= \underline{1.666 \text{ d (12 h day)}}$$

The RMS can replicate the Applicant's results and deems them appropriate.

Conclusion

Based on the results of the atmospheric degradation half-life of BAS 750 F ($t_{1/2}$ = 1.666 d), it can be concluded that the substance will be degraded by photochemical processes in the troposphere. Hence, due to its degradation in air, it can be concluded that there is low risk of long-range transport of BAS 750 F.

B.8.3.2. Transport via air

Due to BAS 750 F's low vapour pressure (3.2×10^{-6} Pa at 20°C and 6.5×10^{-6} Pa at 25°C) and a calculated half-life of 1.67 days, long range transport is not expected to be a significant transport route for BAS 750 F.

The vapour pressure of BAS 750 F is also below the $FOCUS_{air}$ triggers for short range transport; i.e. 10^{-5} Pa at 20°C for substances applied to plants and 10^{-4} Pa at 20°C for substances applied to soil.

B.8.3.3. Local and global effects

No effects are expected since transport via air is highly unlikely (for details see above).

B.8.3.4. Summary of fate and behaviour in air

The atmospheric half-life of BAS 750 F was calculated as being 1.67 days (12 hour day). Because of this, and its low vapour pressure, BAS 750 F is unlikely to be transported long and short distances.

B.8.4. MONITORING DATA CONCERNING FATE AND BEHAVIOUR OF THE ACTIVE SUBSTANCE, METABOLITES, DEGRADATION AND REACTION PRODUCTS

The Applicant states that, being a new active substance, there is no monitoring information available for BAS 750 F. The RMS accepts this.

B.8.5. REFERENCES RELIED ON

BAS 750 F

A literature search on BAS 750 F was performed by the Applicant in accordance with the EFSA guidance (EFSA Journal 2011;9(2):2092). The process of selection of relevant scientific peer-reviewed open literature was done in two steps:

The first selection step for relevance was based on summary records (e.g. titles, abstracts, index terms, keywords).

- Obviously irrelevant records were tagged as "Ballast". This ballast was controlled by scientific experts in the corresponding subject areas and was not further processed.
- Summary records which appear to be relevant and those of unclear relevance were tagged as "Hit" and went to the next level of evaluation.

The "hits" were further evaluated by the scientific experts and categorised into "not relevant", "not reliable", and "used for dossier".

The substance name, structure, CAS number, isomers, mixtures, metabolites, common names and trade names were searched, for Fate and Behaviour, in the following databases:

- CAPLUS
- BIOSIS
- CABA

No date span was included in the search.

The results of the search are included in Table 8.5-1.

Table 8.5-1: Results of literature search

Database:	Total	CAPLUS Chemical Abstracts Plus	BIOSIS	CAB Abstracts
Justification for choosing the source:		The Chemical Abstracts (CA) database covers all areas of Biochemistry, Chemistry and Chemical engineering, and related sciences. Sources include over 8,000 journals, patents from 38 national patent offices and two international patent organizations, technical reports, books, conference proceedings, and dissertations. Electronic only journals and Web preprints are also	BIOSIS Previews® is the largest and most comprehensive life science database in the world. Amongst others subject coverage includes Agriculture, Biochemistry, Biophysics, Botany, Environmental Biology, Physiology, Toxicology. Sources include periodicals, journals, conference proceedings, reviews, reports, patents, and short communications. Nearly 6,000 life source journals, 1,500 international	The CAB Abstracts database covers worldwide literature from all areas of agriculture and related sciences including Agriculture, Agricultural chemicals, Animal sciences and production, Crop protection, Crop sciences and production, Environment, Soils and fertilizers. Sources for CABA include journals, books, reports, published theses, conference proceedings, and patents.

Database:	Total	CAPLUS Chemical Abstracts Plus	BIOSIS	CAB Abstracts
		covered. Bibliographic terms, indexing terms, roles, CAS Registry Numbers, International Patent Classification, and abstracts are searchable.	meetings as well as review articles, books, and monographs are reviewed for inclusion. Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are all searchable.	Bibliographic information, indexing terms, abstracts, and CAS Registry Numbers are searchable.
Date span of the source:		1907 – to present	1926 – to present	1973 – to present
Date of main search:		2015-12-04	2015-12-04	2015-12-04
Date span of the search:		no time limitation	no time limitation	no time limitation
Date of the latest database update included in the search:		20151203/UP	20151202/UP	20151202/UP
Total number of summary records for BAS 750 F and Metabolites / (1H)1,2,4-Triazole Metabolite retrieved:		14 / 224	0 / 4	0 / 0
Total number of summary records after removing duplicates:	14 / 226	14 / 224	0 / 2	0 / 0
Total number of summary records retrieved after first selection step:	0 / 6	0 / 6	0 / 0	0 / 0
Category: E-Fate	6			
Category: E-Fate Ballast	234	14 / 218	0 / 2	0 / 0

The Applicant states that the hits did not contribute to the risk assessment and were therefore not further discussed in the dossier.

The RMS considers the search parameters used by the Applicant acceptable. The RMS also accepts the Applicant's decision to not further consider the results of the search; this is to be expected as BAS 750 F is a new active substance.

<u>1,2,4-Triazole</u>

A literature search on triazole derived metabolites (TDMs) was performed by the Triazole Derivatives Metabolite Group (TDMG). The chemical names were searched in the following databases:

- MEDLINE
- EMBASE
- EMBAL
- ESBIOBASE
- AGRICOLA
- BIOSIS

- CABA
- CAPLUS
- FSTA
- FROSTI
- GEOREF
- TOXCENTER
- PQSCITECH
- PASCAL
- SCISEARCH
- ANABST

In total, 1095 studies were identified in the initial search. The Applicant states that none were found to be relevant for this dossier submission or add to the overall risk assessment, therefore, all of the references were excluded from further assessment.

The RMS considers the search parameters used by the Applicant acceptable. The RMS also accepts the Applicant's decision to not further consider the results of the search.

Data Point	**Author(s)**	**Year**	**Title** **Company Report No.** **Source (where different from company)** **GLP or GEP status** **Published or not**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
KCA 7.1.1.1/1	Staudenmaier H. Dalkmann P.	2015a	Aerobic soil metabolism of BAS 750 F 2014/1275177 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.1.1/2	Staudenmaier H. Dalkmann P.	2015a	Aerobic soil metabolism of Trifluoromethylphenyl-labeled BAS 750 F 2015/1003306 BASF SE, Limburgerhof, Germany Fed.Rep. yes	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 7.1.1.2/1	Leed M.G.	2015 a	Anaerobic soil metabolism of 14C-BAS 750 F 2014/7003496 BASF Crop Protection, Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.1.3/1	Hassink J. Delgado M.	2014 a	Soil photolysis of BAS 750 F 2014/1181666 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.1.1/1	Staudenmaier H. Dalkmann P.	2015 b	Degradation of BAS 750 F in soil under aerobic conditions 2014/1275178 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA	Platz K.	2015	Normalized modelling DegT50	No	No	Not	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
7.1.2.1.1/2		a	endpoints of BAS 750 F derived from laboratory soil degradation experiments 2015/1239053 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished			applicable	
KCA 7.1.2.1.2/1	Szegedi K.	2015 a	Estimation of the formation fraction of 1,2,4-triazole from BAS 750F BASF SE, Limburgerhof, Germany Fed.Rep. 2015/1260802 no Unpublished	No	Yes	Not applicable	BASF
KCA 7.1.2.1.2/2	Szegedi K.	2016 c	Estimation of the formation fraction of 1,2,4-triazole (M750F001) from BAS 750F using modelling endpoints BASF SE, Limburgerhof, Germany Fed.Rep. 2016/1234478 no Unpublished	No	Yes	Not applicable	BASF
KCA 7.1.2.2.1/1	Schaeufele M.	2015 d	Field soil dissipation study of Reg.No. 5834378 in the formulation EXP 5834378 F-AV on	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			bare soil at six sites in Europe, 2013 2015/1046920 Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom yes Unpublished				
KCA 7.1.2.2.1/2	Schaeufele M.	2015 e	Final report amendment No. 1: Field soil dissipation study of Reg.No. 5834378 in the formulation EXP 5834378 F-AV on bare soil at six sites in Europe, 2013 2015/1242234 Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/3	Jacobson B. et al.	2016 a	Terrestrial field dissipation of the fungicide BAS 750 F following broadcast applications of BAS 750 01 F (EC) or BAS 750 UA F (SC) 2015/7006396 Waterborne Environmental Inc., Leesburg VA, United	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			States of America yes Unpublished				
KCA 7.1.2.2.1/4	Studenroth S. Pape L.	2015 a	Kinetic evaluation of a field dissipation study with BAS 750 F conducted in 2013 to 2015: Determination of best-fit and modeling endpoints according to FOCUS 2015/1249176 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 7.1.2.2.1/5	Staudenmaier H. Dalkmann P.	2015 b	Investigation of the extractability of BAS 750 F in samples from 14C soil degradation studies 2015/1182724 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/6	Brewin S.	2015 a	Storage stability of residues of BAS 750 F- Reg.No. 5834378 and its metabolite	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Reg.No. 5924326 in soil when stored at approximately -20°C for 540 days - Interim Report 2015/1050221 Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom yes Unpublished				
KCA 7.1.2.2.1/7	Brewin S.	2015 b	Interim report Amendment No. 1: Storage stability of residues of BAS 750 F- Reg.No. 5834378 and its metabolite Reg.No. 5924326 in soil when stored at approximately -20°C for 540 days - Interim Report 2015/1249072 Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.1/8	Brewin S.	2016 a	Storage stability of residues of BAS 750 – Reg.No. 5834378 and its metabolite Reg.No.5924326 in soil when stored at approximately -20°C	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			for 650 days 2015/1106725 Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom yes Unpublished				
KCA 7.1.2.2.1/9	Geschke S.	2015 a	Determination of storage stability of BAS 555 F (Metconazole) and its metabolite 1,2,4-Triazole in soil 2015/1204922 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.2.2.2/1	Schaeufele M.	2015 b	Final Interim report No.1 - Accumulation behaviour of BAS 750 F in soil under field conditions in the United Kingdom following repeated application onto winter wheat over several years 2015/1076325 Envigo CRS Limited, Suffolk IP23 7PX,	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			United Kingdom yes Unpublished				
KCA 7.1.2.2.2/2	Schaeufele M.	2015 c	Final Interim report No.1 - Accumulation behaviour of BAS 750 F in soil under field conditions in Germany following repeated application onto winter barley over several years 2015/1076326 Envigo CRS Limited, Suffolk IP23 7PX, United Kingdom yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.3.1.1/1	Vasques A.C.	2015 a	Adsorption / desorption behavior of 14C-BAS 750 F on different US, Japanese and European soils 2014/3017870 BASF SA, Guaratingueta, Brazil yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.1.3.1.1/2	Vasques A.C.	2016 a	AMENDET FINAL REPORT Adsorption / desorption behavior of 14C-BAS 750 F	No	Yes	Data for first Approval	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			on different US, Japanese and European soils 2016/3003661 BASF SA, Guaratingueta, Brazil yes Unpublished				
KCA 7.1.3.1.2/1	Szegedi K.	2015 b	Estimation of adsorption coefficients of metabolites of BAS 750F with QSAR 2015/1260816 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 7.1.4/1	Sandt H.J. van de	2015 a	Determination of foliar DT50 of Triazole (BAS 750 F) after application of BAS 750 01 F to wheat surfaces 2015/1130156 De Bredelaar BV, Elst, Netherlands yes Unpublished	No	Yes	Data for first Approval	BASF
KCA	Hassink J.	2015	BAS 750 F: Aqueous hydrolysis at four	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
7.2.1.1/1		b	different pH values 2015/1046919 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished			Approval	
KCA 7.2.1.2/1	Zhixing Y.	2015 a	Aqueous Photolysis of 14C-BAS 750 F 2015/7000233 BASF Crop Protection, Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.2.2.1/1	Schwarz H.	2014 a	BAS 750 F - Determination of the ready biodegradability in the CO2-evolution test 2014/1239574 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.2.2.2/1	Michel A.	2015 a	14C-BAS 750F: aerobic mineralization in	No	Yes	Data for first	BASF

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			surface water 2015/1186902 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished			Approval	
KCA 7.2.2.3/1	Ebert D. Dalkmann P.	2015 a	Aerobic aquatic metabolism of BAS 750 F (Reg.No. 5834378) 2015/1000941 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data for first Approval	BASF
KCA 7.3.1/1	Hassink J.	2015 a	Photochemical oxidative degradation of BAS 750 F (QSAR estimates) 2015/1005046 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF