

DATA EVALUATION RECORD

STUDY	
PC No. 128008	BAS 510 F
CAS No. 188425-85-6	§164-2
DP Barcode D278387	
FORMULATION-00-ACTIVE INGREDIENT	

STUDY ID 45405215

Fent, G. 2001. Degradation and distribution of BAS 510 F in a water-sediment system under outdoor conditions. Unpublished study performed by Staatliche Lehr- und Forschungsanstalt für Landwirtschaft, Weinbau und Gartenbau (SLFA), Neustadt an der Weinstraße, Germany, and BASF Aktiengesellschaft, Limburgerhof, Germany, and sponsored by BASF Corporation, Agricultural Products, Research Triangle Park, NC. BASF Registration Document No.: 2000/1017038. Study initiated June 15, 2000 and completed February 14, 2001.

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ABSTRACT

Field Dissipation - Aquatic and Aquatic Impact

Aquatic dissipation of [diphenyl- ^{14}C]2-chloro-*N*-(4'-chloro-biphenyl-2-yl)-nicotinamide (BAS 510 F, radiochemical purity >98%) under field conditions was studied in vessels containing water/loamy sand sediment (1.95 L water:400 g wet wt. sediment) collected from a pond in south-western Germany. The vessels containing the water/sediment systems were maintained in larger water baths outdoors in a lysimeter station at Neustadt an der Weinstraße, Germany. The experiment was carried out in compliance with OECD Principles of GLP (C/97/186 Final, 1997) and Federal Republic of Germany GLP Regulations (Chemikaliengesetz, Anhang 1 vom 25, 1994). [Diphenyl- ^{14}C]BAS 510 F was applied to the water surface of each water/sediment system at 0.24 mg a.i./L water using a single application. The applied rate corresponded to the concentration expected if the maximum field application rate for BAS 510 F of 700 g a.i./ha was distributed in water to a depth of 30 cm. The treated test vessels were protected against rainfall.

Vessels containing treated water/sediment were collected at 0 (1-2 hours), 1, 2, 7, 14, 30, 58, 103 and 120 days post-application. Water samples were analyzed directly. Sediment samples were sequentially extracted with acetonitrile:0.01 M calcium chloride (1:1, v:v) and acetonitrile. Water and sediment extracts were analyzed by reverse-phase HPLC with radioactivity and UV detection. Identification of parent BAS 510 F was made by comparison to an unlabeled reference standard; it was not specified whether identification was made by co-chromatography or comparison to relative retention time. Identification of one transformation product was done by reverse-phase HPLC/MS-ESI mode.

Parent [^{14}C]BAS 510 F in the total water/loamy sand sediment system gradually decreased from 96.15%-96.88% of the applied at 0-2 days to 53.74% at 30 days and was 45.70% at 120 days. In the water layer, [^{14}C]BAS 510 F decreased from 96.15% at day 0 to 51.86% at 14 days and 25.70% at 58 days, and was 19.17-19.84% at 103-120 days. In the sediment, [^{14}C]BAS 510 F increased from 0.02% at day 0 to 22.06-24.04% at 14-58 days and was 26.53-28.21% at 103-120 days. No major transformation products of [^{14}C]BAS 510 F were detected in the water layers or sediment extracts. One minor transformation product, tentatively identified as *p*-chloro-benzoic acid, was detected in the water layer at a maximum of 9.42% of the applied at 30 days. An additional unidentified [^{14}C]compound in the water layer and up to seven unidentified [^{14}C]compounds in sediment extracts were each detected at $\leq 1.2\%$ of applied. Extractable [^{14}C]residues increased to 30.69-32.07% at 103-120 days and non-extractable [^{14}C]residues increased to 48.27% at 103 days and were 20.46% at 120 days.

During the 120-day study, recoveries of radiolabeled material in the total water/sediment systems were 92.59-97.44% of the applied at 0-14 days posttreatment, 77.42% at 30 days, 83.32% at 58 days, 100.18% at 103 days, and 73.16% at 120 days. Total [^{14}C]residues gradually partitioned into the sediment with distribution ratios (water:sediment) of *ca.*

10:1 at day 1, 3:1 at 7 days, 2:1 at 14 days, 1:1 at 30 days, 1:2 at 58 days, 1:4 at 103 days and 1:2 at 120 days.

Under field conditions, [^{14}C]BAS 510 F appeared to dissipate in a bi-phasic pattern from the water layer to the sediment with an initial half-life of 19 days and secondary half-life of 122 days and from the total water/sediment system with an initial half-life of 35 days and secondary half-life of >400 days. However, half-life values were affected by poor material balances at several of the sampling intervals.

The major route of dissipation of BAS 510 F under aquatic field conditions was movement from the water layer to sediment with subsequent formation of non-extractable residues.

Results Synopsis:

Test system:	Water/loamy sand sediment from pond in Germany.
Half-life values:	
water:	
- overall (0-120 days):	53.2 days ($r^2 = 0.851$).
- initial (0-30 days):	19.2 days ($r^2 = 0.979$).
- secondary (30-120 days):	122.1 days ($r^2 = 0.981$).
total system:	
- overall (0-120 days):	110.5 days ($r^2 = 0.788$).
- initial (0-30 days):	35.0 days ($r^2 = 0.989$).
- secondary (30-120 days):	443.7 days ($r^2 = 0.901$).
Major transformation products:	None.
Minor transformation products:	<i>p</i> -Chloro-benzoic acid. Up to seven unidentified [^{14}C]compounds.

Study Acceptability:

This study is classified as unacceptable. The experimental design was not appropriate for the collection of data intended to satisfy the aquatic field dissipation data requirement under Subdivision N Guideline 164-2. The results of the study are not scientifically valid because material balances were incomplete at several sampling intervals, with up to 26.84% of the applied radioactivity unaccounted for at study termination, and the registrant's assumption that missing radioactivity was due to formation of $^{14}\text{CO}_2$ is not supported by results from BAS 510 F aqueous phototransformation and aerobic aquatic biotransformation studies (MRIDs 45405206 and 45405214, respectively). Additionally, a foreign soil was utilized.

MATERIALS AND METHODS

Samples (400 g wet wt.) of sieved (2-mm) loamy sand sediment (84% sand, 4% silt, 12% clay, organic carbon 1.6%, redox potential -130 mV, pH and CEC not determined, p. 26), collected from the Kellmetschweiher pond in south-western Germany, were transferred to fourteen 2-L glass vessels (height 240 mm, diameter 110 mm) and flooded with 1.95 L of filtered (0.2-mm) water (pH 8.8, redox potential 235 mV, oxygen saturation 96%, total

organic carbon 16.8 mg/L, hardness 1.04 mmol/L, p. 26) collected from the same location; depths of the water and sediment layers were *ca.* 20 cm and 2 cm, respectively (p. 16). The vessels containing the water/sediment samples were covered with aluminum foil to prevent algal growth and placed outdoors in the lysimeter station at SLFA in large water baths (size not specified) to simulate the temperature conditions of a larger body of water (pp. 17, 32). Clear plexiglass covers were positioned 30 cm above the vessels to guard against rainfall, but were removed when rain was not forecast. Following an 8-day equilibration period, the aluminum foil was removed and [diphenyl- ^{14}C]BAS 510 F [2-chloro-*N*-(4'-chloro-biphenyl-2-yl)-nicotinamide, radiochemical purity >98%, specific activity 6.27 MBq/mg (3.6×10^5 dpm/ μg), Batch No. 641-2017, BASF, p. 14], dissolved in acetonitrile, was applied to the water layer of each of twelve of the water/sediment systems via pipet at 0.24 mg a.i./L water (0.46 mg a.i. per water/sediment system) on July 5, 2000; final concentration of the cosolvent was 0.05%. The remaining two water/sediment systems were treated at the same rate with unlabeled BAS 510 F (purity 99.3%, Lot No. 01183-190) to serve as controls. Data loggers were used to record air temperature above the vessels and water temperature in one control vessel. Oxygen saturation, pH and redox potential in the water layer and redox potential in the sediment layer of the control vessels were determined at 1- to 3-day intervals throughout the study (pp. 27, 28).

Duplicate [^{14}C]BAS 510 F-treated water/sediment systems were removed at day 0 (1-2 hours) posttreatment, then single vessels were removed at 1, 2, 7, 14, 30, 58, 103 and 120 days posttreatment (pp. 16, 18). Water and sediment were separated by decanting the water and transferring the sediment to centrifuge tubes.

Water layers were analyzed directly by HPLC. Sediment samples were extracted three times each with acetonitrile:0.01 M calcium chloride (1:1, v:v) and acetonitrile; extraction volumes were 200 mL (p. 18). For each extraction, sediment:extract was shaken on a rotary shaker for 20 minutes at 150 rpm and the sediment and extract were separated by centrifugation. Like extracts were combined, then aliquots (volume not specified) were analyzed for total radioactivity by LSC. Prior to HPLC analysis, the acetonitrile:0.01 M calcium chloride and acetonitrile extracts were combined and concentrated to 50 mL using rotary evaporation. Aliquots (amount not specified) of extracted sediment were combined with cellulose (*ca.* 0.4 g cellulose/g soil), dried at 40°C, homogenized (method not specified), then analyzed for total radioactivity by LSC following combustion (pp. 18, 19). Non-extractable [^{14}C]residues in the sediment were not further characterized.

Water and sediment extracts were analyzed by reverse-phase HPLC under the following conditions: Lichrospher 100 RP-18 column (10 x 250 mm, 10 μm particle size), Lichrospher 100 RP-18 guard column (10 x 10 mm, 10 μm particle size), gradient mobile phase combining (A) water:acetonitrile:formic acid (90:10:0.1, v:v) and (B) water:acetonitrile:formic acid (10:90:0.1, v:v) [percent A:B at 0 min. 100:0 (v:v), 20 min. 0:100, 30 min. 0:100, 40 min. 100:0, 45 min. 100:0], injection volume not specified, flow rate 4.0 mL/minute, UV (254 nm) and radioactivity detection (pp. 19, 38-41). Parent [^{14}C]BAS 510 F in the water layers and sediment extracts was identified by comparison to an unlabeled reference standard; it was not specified whether identification was made by co-chromatography or comparison to relative retention time (pp. 14, 15).

To identify transformation products of [diphenyl- ^{14}C]BAS 510 F, aliquots of 14- and 30-day water layers were concentrated by solid phase extraction (Bakerbond SPE C-18 column); collected eluate was freeze-dried and the resulting residue re-dissolved in acetonitrile:water (100:200 μL , p. 20). Reverse-phase HPLC conditions were as follows: UH003 Nucleosil 120-5 C-18 column (parameters not specified), gradient mobile phase combining (A) water:acetonitrile:formic acid (95:5:0.2, v:v) and (B) water:acetonitrile:formic acid (5:95:0.2, v:v) [percent A:B at 0 min. 100:0 (v:v), 20 min. 80:20, 30 min. 79.9:20.1, 75 min. 0:100, 80 min. 0.1:99.9, 80.5 min. 100:0], injection volume 100 μL , flow rate 0.6 mL/minute, UV (wavelength not specified) and radioactivity detection (p. 25). MS conditions were as follows: PE-SCIEX QstarPulsar SN K0020009 MS, electrospray ionization (ESI); additional conditions could not be determined. Identification of [^{14}C]transformation products was made by comparison to unlabeled reference standards; it was not specified whether identification was made by co-chromatography or comparison to relative retention time (pp. 14, 15).

The limit of quantitation for LSC analyses was twice background dpm (quantitative value not provided, p. 19). Detection limits for HPLC and LC/MS analyses were not provided.

RESULTS/DISCUSSION

In control water/sediment systems during the 8-day pre-incubation and 120-day study following treatment with unlabeled BAS 510 F at 0.24 mg/L water, pH values were 7.7-9.6, oxygen saturation values were 57-109%, and redox potentials were +27 to +209 mV in the water layer and -184 to +110 in the sediment layer (pp. 27, 28, 34). The mean water temperature was 18.1°C (min. 8.6°C, max. 28.5°C) and mean air temperature was 16.9°C (min. 0.8°C, max. 38.4°C; pp. 20, 33).

In water/sediment systems treated with diphenyl- ^{14}C]BAS 510 F [2-chloro-*N*-(4'-chloro-biphenyl-2-yl)-nicotinamide, radiochemical purity >98%] at 0.24 mg a.i./L water, recoveries of radiolabeled material were 92.59-97.44% of the applied at 0-14 days posttreatment, decreased to 77.42% at 30 days, then increased to 83.32% at 58 days and 100.18% at 103 days, then decreased to 73.16% at 120 days (pp. 29, 35).

Parent [diphenyl- ^{14}C]BAS 510 F in the total water/loamy sand sediment system gradually decreased from 96.15%-96.88% of the applied at 0-2 days to 53.74% at 30 days and was 45.70% at 120 days (Attachment 2). In the water layer, [^{14}C]BAS 510 F decreased from 96.15% at day 0 to 51.86% at 14 days, 25.70% at 58 days and was 19.17-19.84% at 103-120 days (p. 30). In the sediment, [^{14}C]BAS 510 F increased from 0.02% at day 0 to 22.06-24.04% at 14-58 days and was 26.53-28.21% at 103-120 days (p. 31). Following application of [^{14}C]BAS 510 F to the surface of the water layer, total [^{14}C]residues gradually partitioned into the sediment with distribution ratios (water:sediment) of *ca.* 10:1 at day 1, 3:1 at 7 days, 2:1 at 14 days, 1:1 at 30 days, 1:2 at 58 days, 1:4 at 103 days and 1:2 at 120 days (Attachment 2).

[^{14}C]BAS 510 F appeared to dissipate from the water layer to the sediment with an initial half-life of 19 days ($r^2 = 0.979$) and secondary half-life of 122 days ($r^2 = 0.981$) and from the

total water/sediment system with an initial half-life of 35 days ($r^2 = 0.989$) and secondary half-life of >400 days. Half-life values for the dissipation of [^{14}C]BAS 510 F were determined by the reviewer using least squares linear regression analysis assuming dissipation followed first-order kinetics calculated by Corel Quattro Pro 8 software; dissipation appeared bi-phasic (Attachment 2).

No major transformation products of [diphenyl- ^{14}C]BAS 510 F were detected in the water layer or sediment extracts. One minor transformation product, tentatively identified as *p*-chloro-benzoic acid (BASF code M510F64), was detected in the water layer at a maximum 9.42% of applied at 30 days posttreatment and was 1.90% at 120 days (pp.21, 30). An additional unidentified [^{14}C]compound (R_t 4.4 min.) was detected in the water layer at <1% of applied and up to seven unidentified [^{14}C]compounds were detected in sediment extracts each at $\leq 1.2\%$ of applied (pp. 21, 22, 40, 41).

Extractable [^{14}C]residues increased from 0.04% of applied at day 0 to 32.07% at 103 days and were 30.69% at 120 days and non-extractable [^{14}C]residues increased from <0.04% to 48.27% and 20.46% at the same intervals (p. 29).

DEFICIENCIES/DEVIATIONS

1. Material balances were incomplete with up to 26.84% of the applied radioactivity unaccounted for at study termination. The registrant attributed the missing radioactivity to formation of $^{14}\text{CO}_2$; however, results of studies investigating the aqueous phototransformation of BAS 510 F at 3 mg a.i./L in pH 5 acetate buffer solution for up to 15 days (MRID 45405206) and the aerobic aquatic biotransformation of BAS 510 F (2 labels utilized) at 0.24 mg a.i./L water in water/loamy sand and water/loam sediment systems for up to 100 days (MRID 45405214) do not support that assumption. In both the aqueous phototransformation and aerobic aquatic biotransformation studies, there was no significant (<1% of applied radioactivity) production of $^{14}\text{CO}_2$ or [^{14}C]organic volatiles; material balances were $\geq 92.5\%$ of the applied radioactivity for both studies. It is noted that the material balances did not follow a distinct pattern of loss. Because the loss of parent compound from the system was not explained, the study does not provide useful information on the aquatic dissipation of the compound. Additionally, the experimental design was not appropriate for the collection of data intended to satisfy the aquatic field dissipation data requirement under Subdivision N Guideline 164-2.
2. The registrant reported that the biotransformation product detected in the water layer (R_t ca. 16.7 min.) at a maximum 9.42% of applied was identified as *p*-chloro-benzoic acid by reverse-phase HPLS/MS (pp. 21, 42). However, there was no chromatogram of reference standard *p*-chloro-benzoic acid for comparison and it was not listed as one of the reference standards used during analyses (pp. 14, 15). Clarification by the registrant is necessary.
3. The test substance, [diphenyl- ^{14}C]BAS 510 F (radiochemical purity >98%), used in this study is not considered a typical end-use product. Subdivision N Guidelines (164-2) require the use of a typical end-use product for the conduct of aquatic field dissipation studies.

4. Storage of samples prior to analysis was inadequately described; storage temperature and length of storage prior to analysis for the water samples and sediment extracts were not provided. The registrant reported that water and sediment were separated and the sediment extracted the day the sample was collected (p. 18). Water layers, sediment extracts and extracted sediment were then stored refrigerated or frozen (temperatures not specified) until analysis. Sediment extracts were analyzed within one month, but storage length for water samples prior to analysis was not reported.
5. The sediment was not completely characterized; pH and CEC values were not reported.
6. The limit of quantitation for LSC analyses was reported as twice background dpm, but a quantitative value was not provided. Detection limits for HPLC and HPLC/MS analyses were not provided.
7. Microbial biomass profiles for the water prior to use were 8.14×10^2 CFU/mL bacteria, 2 CFU/mL fungi and 0 CFU/mL actinomycetes, and for the sediment 4.77×10^6 CFU/g bacteria, 4.39×10^4 CFU/g fungi and 2.52×10^4 CFU/g actinomycetes (p. 26).
8. The following typographical error was noted in section 3.4.2. *Sediment*: it was reported that the sediment was extracted with acetonitrile:water (1:1, v:v), when the sediment was actually extracted with acetonitrile:0.01 M CaCl_2 (1:1, v:v; pp. 18, 23).
9. The registrant reported that the application rate used in this study (0.24 mg a.i./L water) corresponded to the concentration expected when the maximum field application rate for BAS 510 F of 700 g a.i./ha was equally distributed in water to a depth of 30 cm (p. 17). That application rate would yield a concentration of 233 μg a.i./L or 466 μg a.i. per vessel based on the volume of water used (ca. 2 L).
10. The registrant reported that this study was conducted in "consideration of" BBA Guidelines (Part IV, 5-1, 12/1990) and in compliance with OECD Principles of GLP (C/97/186 Final, 1997) and Federal Republic of Germany GLP Regulations (Chemikaliengesetz, Anhang 1 vom 25, 1994; pp. 3, 12). Signed and dated Data Confidentiality, GLP, and Quality Assurance statements were provided (pp. 2-7).
11. BAS 510 F chemical name 2-chloro-*N*-(4'-chlorobiphenyl-2-yl)-nicotinamide, as presented in the study report, was identified as the IUPAC name by the Compendium of Pesticide Common Names (<http://www.hclrss.demon.co.uk/nicobifen.html>). The CAS name 2-chloro-*N*-(4-chloro[1,1-biphenyl]-2-yl)-3-pyridinecarboxamide was also obtained from the Compendium of Pesticide Common Names. The following BAS 510 F synonyms were obtained from USEPA/OPP Chemical Databases (<http://www.cdpr.ca.gov/cgi-bin/epa/chemidetriris.pl?pccode=128008> and (http://www.cdpr.ca.gov/cgi-bin/mon/bycode.pl?p_chemcode=5790): 2-chloro-*N*-(4'-chlorobiphenyl-2-yl)-nicotinamide, nicobifen, and BAS 516 02 F.

12. The following references were cited in the study:

Analytical raw data from the test site BASF. 2001. Degradation and distribution of BAS 510 F in a water/sediment system under outdoor conditions.

BBA: Richtlinien für die Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren, Teil IV, 5-1, 12/1990. Abbaubarkeit und Verbleib von Pflanzenschutzmitteln im Wasser/Sediment System.

ATTACHMENT 1
Quattro Pro 8 Workbook

Aquatic Field Dissipation of [^{14}C]BAS 510 F in Water-Loamy Sand Sediment
MRID 45405215

[Diphenyl- ^{14}C]BAS 510 F in water-loamy sand sediment
Half-life; dissipation from water + sediment

All intervals

BAS 510 F		
Day	%AR	Ln(%AR)
0	96.17	4.56612
1	96.88	4.57347
2	96.15	4.56591
7	82.11	4.40806
14	75.90	4.32942
30	53.74	3.98416
58	49.26	3.89711
103	48.05	3.87224
120	45.70	3.8221

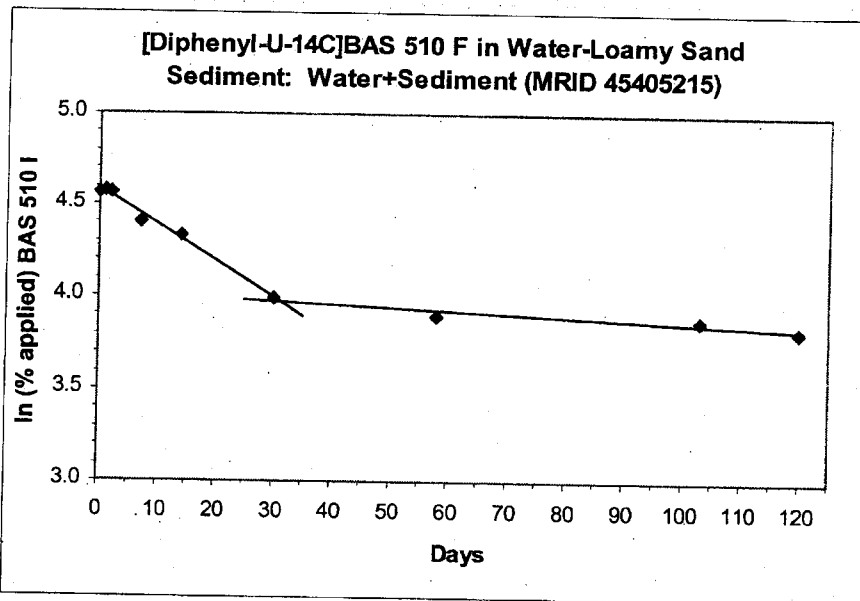
Regression Output:

Constant	4.458
Std Err of Y Est	0.161
R Squared	0.788
No. of Observations	9
Degrees of Freedom	7

X Coefficient(s) -0.00627
Std Err of Coef. 0.00123

half-life 110.5 days

*AR = Applied Radioactivity
Linear regression analysis performed
using Corel Quattro Pro 8.
Results from pp. 30, 31 of study report.



Bi-phasic Half-life Determinations

[Diphenyl- ^{14}C]BAS 510 F in water-loamy sand sediment
Water + Sediment

Initial Half-life; 0-30 days.

BAS 510 F		
Day	%AR	Ln(%AR)
0	96.17	4.566117
1	96.88	4.573473
2	96.15	4.565909
7	82.11	4.40806
14	75.90	4.329417
30	53.74	3.984158

Regression Output:

Constant	4.583
Std Err of Y Est	0.026
R Squared	0.989
No. of Observations	6
Degrees of Freedom	4

X Coefficient(s) -0.019798
Std Err of Coef. 0.001026

half-life 35.0 days

Secondary Half-life; 30-120 days.

BAS 510 F		
Day	%AR	Ln(%AR)
30	53.74	3.984158
58	49.26	3.897112
103	48.05	3.872242
120	45.70	3.822098

Regression Output:

Constant	4.0153
Std Err of Y Est	0.0261
R Squared	0.901
No. of Observations	4
Degrees of Freedom	2

X Coefficient(s) -0.00156
Std Err of Coef. 0.000365

half-life 443.7 days

**Aquatic Field Dissipation of [¹⁴C]BAS 510 F in Water:Sediment
MRID 45405215**

[Diphenyl-U-¹⁴C]BAS 510 F in water-loamy sand sediment

Half-life; dissipation from water

All intervals

BAS 510 F		
Day	%AR	Ln(%AR)
0	96.15	4.56591
1	88.50	4.483
2	84.33	4.43474
7	63.32	4.1482
14	51.86	3.94855
30	31.68	3.45569
58	25.70	3.24649
103	19.84	2.9877
120	19.17	2.95335

Regression Output:

Constant	4.287
Std Err of Y Est	0.269
R Squared	0.851
No. of Observations	9
Degrees of Freedom	7

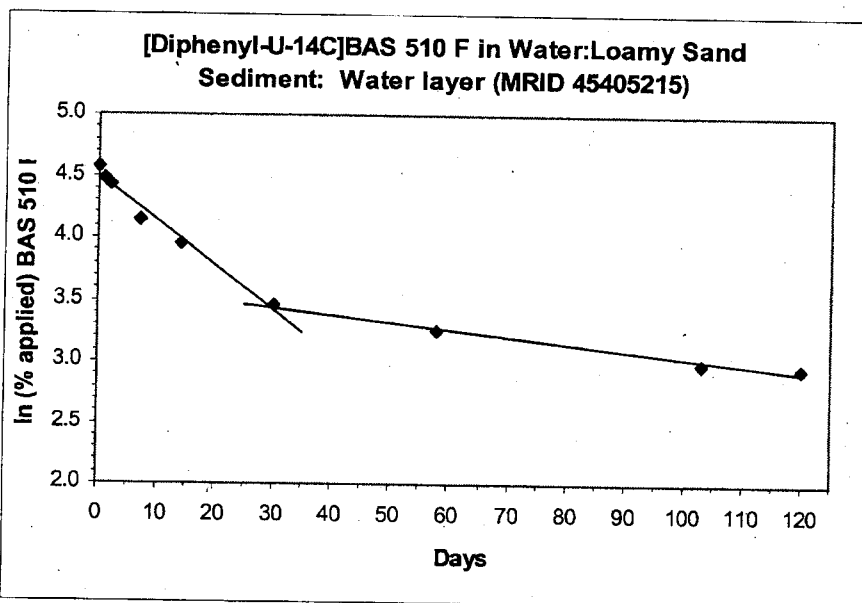
X Coefficient(s)	-0.01302
Std Err of Coef.	0.00206

half-life 53.2 days

*AR = Applied Radioactivity

Linear regression analysis performed using Corel Quattro Pro 8.

Results from p. 30 of study report.



Bi-phasic Half-life Determinations

**[Diphenyl-U-¹⁴C]BAS 510 F in water-loamy sand sediment
Water layer**

Initial Half-life; 0-30 days.

BAS 510 F		
Day	%AR	Ln(%AR)
0	96.15	4.565909
1	88.50	4.483003
2	84.33	4.434738
7	63.32	4.148201
14	51.86	3.948548
30	31.68	3.455686

Regression Output:

Constant	4.498
Std Err of Y Est	0.067
R Squared	0.979
No. of Observations	6
Degrees of Freedom	4

X Coefficient(s)	-0.036121
Std Err of Coef.	0.002615

half-life 19.2 days

Secondary Half-life; 30-120 days.

BAS 510 F		
Day	%AR	Ln(%AR)
30	31.68	3.455686
58	25.70	3.246491
103	19.84	2.9877
120	19.17	2.953347

Regression Output:

Constant	3.6022
Std Err of Y Est	0.04
R Squared	0.981
No. of Observations	4
Degrees of Freedom	2

X Coefficient(s)	-0.00568
Std Err of Coef.	0.000561

half-life 122.1 days

Aquatic Field Dissipation of [¹⁴C]BAS 510 F in Water:Loamy Sand Sediment
MRID 45405215

[¹⁴C]Residue Water phase:Sediment Ratios

Day	Water (%AR)	Sediment (%AR)	Ratio W:S	Ratio S:W
0	96.15	0.04	2403.8	0.0
1	88.50	8.93	9.9	0.1
2	84.33	13.11	6.4	0.2
7	70.59	22.20	3.2	0.3
14	60.90	31.69	1.9	0.5
30	41.10	36.32	1.1	0.9
58	28.33	54.99	0.5	1.9
103	19.84	80.34	0.2	4.0
120	22.01	51.15	0.4	2.3

Results (% AR) from p. 29 of the study report.