



Document Title

**Additional summaries originally submitted in baseline dossier of the
fate and behaviour in the environment
for
Flurtamone**

Section 7: Fate and behaviour in the environment

*This document is copyright protected and requires
the consent of Bayer AG (or its respective affiliate).
Any distribution, reproduction or publication requires
the consent of Bayer AG (or its respective affiliate).
Any use of the document for regulatory or
any other commercial purpose is prohibited and constitutes
a violation of the underlying license agreement.*

Date

2014-05-28

Author(s)



Bayer CropScience AG



M-489623-01-3



OWNERSHIP STATEMENT

This document, the data contained in it and copyright therein are owned by Bayer CropScience. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Bayer CropScience.

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either:

- From Bayer CropScience; or
- From other applicants once the period of data protection has expired.

This document is copyright protected. Any distribution, reproduction or public use without the consent of Bayer AG (or its respective affiliates) for regulatory purposes or any other commercial purpose is prohibited and constitutes a violation of the underlying license agreement.



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

Table of Contents

	Page
CA 7.1 - Fate and behaviour in soil	5
CA 7.1.1 - Route of degradation in soil	5
CA 7.1.1.2 - Anaerobic degradation	5
See anaerobic study (██████████ and ██████████ C.M., 1999, M-183875-01-1) summarised under CA 7.1.2.1.3.	5
CA 7.1.2 - Rate of degradation in soil	5
CA 7.1.2.1 - Laboratory studies	5
CA 7.1.2.1.3 - Anaerobic degradation of the active substance	5
██████████ and ██████████ C.M., 1999, M-183875-01-1	5
CA 7.3 - Fate and behaviour in air	11
CA 7.3.2 - Transport via air	11
██████████, G. P.; ██████████, M. M. 1995, M-210848-01-1	11
██████████, R. 1995, M-210853-01-1	14

This document is copyright protected.
 Any distribution, reproduction or publication requires
 the consent of Bayer AG (or its respective affiliate).
 Any use of the document or its content for regulatory or
 any other commercial purpose is prohibited and constitutes
 a violation of the underlying license agreement.



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

Introduction

Flutamone is an herbicidal active substance and was included into Annex I of Directive 91/414 in 2003 (Directive 2003/84/EC, dated 25th of September 2003, Entry into Force 1st of January 2004.

Data on the fate and behavior of flutramone in soil, water, sediment and air were submitted within the EU Dossier (Baseline Dossier), which resulted in the Annex I inclusion under Directive 91/414/EEC in 2003. In the Supplemental Dossier for renewal of approval of flutramone, presented on 30 April 2014 only those environmental fate studies were described in sections 7.1 to 7.5 which were not submitted within the Baseline Dossier. However, for a better understanding of the behaviour of flutramone in soil, water and sediment, and air, short summaries including the results of all environmental fate studies were given additionally in the Supplemental Dossier.

In addition, this document now provides the summaries of 2 studies originally submitted and evaluated within the EU Dossier (Baseline Dossier) for which the specific request to have the summaries available was received from RMS Czech Republic on 14 May 2014.

This document is copyright protected. Any distribution, reproduction or publication requires the consent of Bayer AG (or its respective affiliates). Any use of the document or its content for regulatory or commercial purposes is prohibited and constitutes a violation of the underlying license agreement.

Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

CA 7.1 - Fate and behaviour in soil

CA 7.1.1 - Route of degradation in soil

CA 7.1.1.2 - Anaerobic degradation

See anaerobic study ([redacted] and [redacted] C.M., 1999, [M-183875-01-1](#)) summarised under CA 7.1.2.1.3.

CA 7.1.2 - Rate of degradation in soil

CA 7.1.2.1 - Laboratory studies

CA 7.1.2.1.3 - Anaerobic degradation of the active substance

[redacted] and [redacted] C.M., 1999, [M-183875-01-1](#)

In an anaerobic study ([redacted] and [redacted] C.M., 1999, [M-183875-01-1](#)) conducted to the old EU guideline, in which treatment was made to an already anaerobic system, no significant degradation of flurtamone was observed (find the summary below). A new study, designed to meet current guidelines, was conducted and presented in the supplemental dossier.

Report:

KCA-7.1.2.1.3/01; [redacted], M. B.; [redacted] C. M. 1999

Title:

(14C)-flurtamone anaerobic soil degradation

Organisation:

[redacted]

Report No.:

[M-183875-01-1](#)

Publication:

Published in Baseline dossier

Dates of experimental work:

June 1998 – Nov 1998

Guidelines:

EU (=EEC): 95/30/EC, Section 7.1.1.2.2 ETAC: Procedure 1.2 (1)

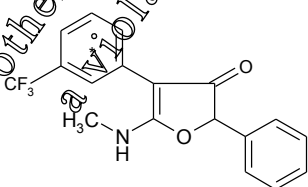
Deviations:

Not specified

GLP/GEP

yes

The route and rate of degradation of [¹⁴C]-flurtamone was studied under anaerobic conditions in a clay loam from the United Kingdom.



Trifluoromethylphenyl-UL-¹⁴C-flurtamone

* = position of radiolabel

The clay loam soil was collected fresh from a field in the UK, sieved to 2 mm and stored for 2 months at 4 °C prior to use. The characteristics of the soil are shown in below Table 1.

Prior to treatment, soil and water were dispensed into flasks and connected to the incubation system for 48 days to establish anaerobic conditions. The test system consisted of flasks containing 100 g soil



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

(dry weight basis) which were flooded with an overlying layer of deionized water. The depth of the surface water was approximately 2 cm above the soil surface and was maintained throughout the course of the study. Humidified nitrogen was passed through each treated flask continuously to maintain anaerobic conditions. The effluent gas from each flask passed sequentially through a trap containing ethylene glycol, to trap volatile organic components, followed by two traps containing potassium hydroxide, to trap carbon dioxide. Additional samples were prepared as controls to monitor anaerobic conditions by measuring pH and redox potential and the viability of the test system by determination of biomass. All samples were incubated in the dark at 20 ± 2 °C. The redox potential in soil and water phases and the pH of the water phase were monitored throughout the study. Conditions remained anaerobic, with redox potentials (Eh) of <200 mV in both soil and water phases throughout the study. The pH of the water phase remained between pH 7 and 9 throughout the experimental period.

This document is copyright protected by Bayer AG. Any distribution, reproduction or publication of this document without the consent of Bayer AG (or its respective regulatory authorities) is prohibited and constitutes a violation of the underlying license agreement.

**Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)****Table 1 Physico-chemical characteristics of the soil used in a flurtamone anaerobic soil study**

Characteristic / Code	Units	98/09
Origin	Country	UK
Location	City or Township	Boarded Barn Farm, Ongar, Essex
<u>Particle Size Analysis, ADAS:</u>		
Total Sand	(0.063 - 2.00 mm)	27.72%
Silt	(0.002 - 0.063 mm)	49.13%
Clay	(< 0.002 mm)	23.15%
Textural Class	ADAS	clay loam
<u>Particle Size Analysis, USDA</u>		
Total Sand	(0.05 - 2.0 mm)	36.09%
Silt	(0.002 - 0.05 mm)	40.9%
Clay	(<0.002 mm)	23.01%
Textural Class	USDA	Loam
pH	Water	7.8
	1M HCl	6.6
	0.01M CaCl ₂	6.4
Organic Carbon	%	2.0
Organic Matter	%	3.4
Cation Exchange Capacity		
Ca _{exchangeable}	Meq/100g	1.1
Mg _{exchangeable}	Meq/100g	0.8
Na _{exchangeable}	Meq/100g	0.1
K _{exchangeable}	Meq/100g	0.5
Mn _{exchangeable}	Meq/100g	<0.05
Total	Meq/100g	12.2
Maximum water holding capacity	%	59.78
Initial Soil Biomass	µg C/g soil	80
Final Soil Biomass	µg C/g soil	27

Treatment. [¹⁴C]-flurtamone, labelled in the trifluoromethylphenyl ring, was applied to the water layer of flooded anaerobic soil samples at an application rate equivalent to 388 g/ha. The radiochemical purity and specific activity of the test item were 100% and 5.99 MBq/mg. This was achieved by the dropwise addition of an aliquot (20 µL) of an acetonitrile solution of radiolabelled flurtamone onto the water surface.

Sampling. Duplicate flasks of soil were analysed after 0, 3 hours, 6 hours, 1, 3, 7, 14, 28, 56 and 119 days incubation. Untreated samples were analysed for biomass at the beginning and end of the experiment.

Sample processing. For each analysis, the water and soil were separated and analysed separately. Soil was extracted initially with a mixture of 1M sodium hydrogen sulphate solution and methanol, 7.5 : 100 by volume (Extract 1) followed by two further extractions with methanol (Extract 2). Extractions were conducted at ambient temperature on a wrist action shaker. In addition, from day 14 onwards soil residues were extracted twice with methanol water, (50:50 by volume), using a sonic probe (Extract 3). A final soxhlet extraction with acetonitrile/water, (80:20 by volume, Extract 4) was conducted for the 56 and 119 day samples. Radioactivity in the water phase, extracted from soil, in the volatile traps and in the post-extract soil residues was quantified.

**Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)**

The water samples were analysed directly at time-points up to 7 days, from then on water samples were concentrated by freeze drying prior to chromatographic analysis. The soil extracts from each sample were concentrated separately using a Turbo-vap concentrator prior to further analysis. Procedural recoveries of radioactivity on concentration showed no unacceptable losses.

Extracts were analysed against authentic reference standards by reverse phase HPLC and results verified by normal-phase TLC. Selected samples of each extract type were analysed by LC/MS.

Quantitative analysis. Radioactivity in the water phase, extracted from soil and in the volatile traps was quantified by liquid scintillation counting (LSC). Following extraction, soil residues were air dried, ground to a fine powder and the radioactivity remaining unextracted quantified by combustion and LSC.

Qualitative analysis. The HPLC system comprised a Kromasil KR100 % column connected to a UV detector (set at 235 nm) and a radiodetector (Packard 525 with a liquid cell or Lablogic β -Ram with a solid cell). The mobile phase was a gradient of acetonitrile/water (30:70, v/v) against acetonitrile/water (70:30, v/v).

TLC was conducted on silica gel 60 F254 plates. The solvent system for development was chloroform/acetic acid (90:10, v/v). The samples were co-chromatographed with non-labelled reference standards. After development and drying the plates were examined under UV light to allow the non-labelled standards to be located and then the distribution of radioactivity on the plates was determined by use of an Amnis Radioanalytical Imaging System.

LC-MS was carried out with a VG QUATTRO triple quadrupole mass spectrometer. Electrospray ionisation in positive ion mode was used. A Kromasil KR100 5C8 column was connected to this and to a radioactivity monitor (Reeve Model 9701) and UV detector (set at 235 nm). The mobile phase was a gradient of acetonitrile/water (30:70, v/v) against acetonitrile/water (70:30, v/v).

Findings:

The mass balance recovery at each time-point (Table 2) ranged from 94.6% to 102.7% with an overall mean recovery of 99.0%. Radioactivity was rapidly transferred from the water to the underlying soil and after 4 months *ca.* 5% remained in the water. There was a corresponding increase in the radioactivity extracted from soil with *ca.* 85% extracted from the soil by the end of the incubation period. The levels of unextractable radioactivity remained low throughout the incubation period at \leq 8%. No significant volatile products were produced throughout the study ($<$ 0.1%).



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

In both water and soil the major component at all time-points was flurtamone (Table 3). The amount of flurtamone in the water declined from 91.4% at time zero to 5.0% at 119 days with no other component present at > 2% at any time-point. In soil the amount of flurtamone increased from 8.6% after 3 hours to 86.5% after 56 days and 84.7% after 119 days. No other soil component was detected exceeding 1% throughout the incubation period.

Table 2 Distribution of radioactivity following treatment of soil with ¹⁴C flurtamone under anaerobic conditions (expressed as % of applied radioactivity, mean of duplicate values)

Time (days)	% applied radioactivity in:								
	Water Phase	Ambient Extracts			Soxhlet Extract	Total Soil Extracted	Unextracted soil residue	Volatiles	Total
		1	2	3					
0	91.42	2.49	0.39	na	na	2.88	0.2	na	94.62
0.125	85.46	8.61	1.82	na	na	10.43	1.18	0.03	97.10
0.25	82.53	11.88	3.68	na	na	15.56	1.61	0.02	99.72
1	71.21	18.17	7.18	na	na	25.35	2.7	0.02	99.33
3	52.22	29.00	13.99	na	na	42.99	4.7	0.02	99.45
7	44.42	36.35	15.31	na	na	51.66	5.61	0.01	102.70
14	27.71	43.35	17.97	5.60	na	66.91	5.55	0.02	100.19
28	16.91	51.82	19.07	6.03	na	76.92	8.26	0.01	102.10
56	9.11	51.04	21.66	6.5	na	86.52	2.04	0.02	98.39
119	5.28	46.20	22.00	5.15	na	84.7	0.04	0.04	96.10

na = not applicable

This document is copyright protected and requires the consent of Bayer AG (or its respective affiliates) for any distribution, reproduction or publication. Any use of the document for any other commercial purpose is prohibited and constitutes a violation of the underlying license agreement.

**Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)****Table 3 Characterisation of radioactivity (by HPLC) following treatment of soil with [¹⁴C]-flurtamone under anaerobic conditions (expressed as % of applied radioactivity, mean of duplicate values)**

Time (days)	% of applied radioactivity as:					
	Total		Flurtamone		Others ¹	
	Water Phase	Soil Extracts	Water Phase	Soil Extracts	Water Phase	Soil Extracts
0	91.42	2.88	91.42	2.49 ²	0	0
0.125	85.46	10.43	85.46	8.61 ²	0	0
0.25	82.53	15.56	81.89	11.88 ²	0.55	0
1	71.21	25.35	70.75	25.20	0.46	0.06
3	52.22	42.99	52.22	42.95	0	0.04
7	44.42	51.66	44.42	51.66	0	0
14	27.71	66.91	27.33	66.96	0.36	0
28	16.91	76.92	16.74	76.92	0.17	0
56	9.11	86.52	9.03	86.52	0.08	0
119	5.28	84.74	4.95	84.74	0	0

¹Others consists of traces of 4 separate components²Only Extract 1 was analysed in the initial time points due to the low level of radioactivity present in Extract 2. The values for Total Soil Extracts represent the sum of radioactivity in all extracts

Flurtamone degraded slowly in clay loam soil under anaerobic conditions although it was rapidly dissipated from the water to the underlying soil. The best-fit rate of dissipation from the water phase was calculated assuming three compartment decay analysis using the model KIM. The rate of degradation in the total anaerobic system has been calculated from the data given in the report assuming single-exponential first order kinetics for the total system. DT₅₀ values of 5.8 days for the water phase and 1780 days for the total system were obtained (see IIA-7.2.4).

Conclusion:

Flurtamone was rapidly dissipated from the water to the underlying soil and then slowly degraded in the clay loam soil under anaerobic conditions. Approximately 90% of the applied radioactivity remained in the combined aqueous and soil extracts as flurtamone at the end of 119 days. Less than 0.1% of the radioactivity was detected as volatile products. Unextracted soil bound residues accounted for 6% of the applied flurtamone at the end of the study.

The dissipation half-life for the transfer of flurtamone from the water phase to the soil phase was calculated to be 5.8 days. Very little degradation of flurtamone was observed in the study with no unique anaerobic degradation products formed.

Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

CA 7.3 - Fate and behaviour in air

CA 7.3.2 - Transport via air

█, G. P.; █, M. M. 1995, [M-219948-01-1](#)

Report: Reference is made to dossier P-008922-01
KCP-9.1.2/01; █, G. P.; █, M. M. 1995

Title: Soil surface volatility of flurtamone formulated as EXP30930 (German ref.: RPA 30930H)

Organisation: █

Report No.: [M-219948-01-1](#)

Publication: Published in Baseline dossier

Dates of experimental work: April 1995 – May 1995

Guidelines: BBA: IV, 6-1

Deviations: Not specified

GLP/GEP yes

Material and Methods:

The objective of the study was to investigate the volatilization of flurtamone when applied to soil in a commercial formulation. Radiolabelled flurtamone was used as the test substance. It had the batch number CSL-92-418-46-35 and a specific activity of 5.81 MBq/mg. The stated radiopurity was > 90.5% and was re-purified before use. The radiolabelled flurtamone was mixed into a commercial formulation 'EXP30930'. The formulation contained flurtamone at 253 g/L and diflufenican at 105 g/L. A sample of the test substance was dissolved in acetone (1 mL). Its radiopurity was determined by TLC to be 99.4%. A sample of the formulation EXP30930 was mixed with water and an aliquot of the [¹⁴C]-flurtamone solution was added. Aliquots of this final treatment solution were taken for radioassay.

Treatment. The application of the test solution was made to a sandy soil (Speyer 2.1). The residual water content of the soil was determined by oven-drying at 105°C. A portion, equivalent to 230 g of dried soil was weighed into the soil container and sufficient water added to bring it to 60% of maximum water holding capacity. Ten microcap covers were placed on the top of the soil to allow the determination of the amount of compound present on the soil at the beginning of the test. The solution was sprayed on to the soil (area 225 cm² of a total sprayed area of 720 cm²) by use of a micro-spraying system (air brush) to give an application rate equivalent to about 250 flurtamone g/ha. Immediately after application the soil container was transferred into the volatilization chamber.

The volatilization chamber, made of glass, consisted of three parts: the soil container, a wind tunnel and a sampling chamber. The wind tunnel had an air inlet and openings to allow the introduction of an anemometer and a surface thermometer probe. It was thermostatically controlled (by water circulation). The sampling chamber contained Raschig rings to mix the air passing over the soil and a dispatching chamber from where the air was passed through a trap. An opening permitted the introduction of a hygro-thermometer probe. The sampling chamber was attached to the wind tunnel just before the beginning of the experiment.

**Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)**

When the treated soil was placed in the tunnel and the system was running, washed and dehumidified air from a compressor, regulated by a manometer, passed through a container of calcium chloride solution, resulting in the air arriving in the volatilization chamber having a relative humidity of about 40%. After passing over the soil the air reached the sampling chamber and a portion of it was pumped through two traps. Each trap contained about 3 g of Amberlite XAD2 resin with silica wool on each side.

The volumes of air passing through the traps, and that not passing through the traps, were measured by use of gas meters. The climatic parameters (soil temperature, air speed, air hygrometry and air temperature) were recorded via the surface thermometer probe, the anemometer probe and the hygro-thermometer probe and transferred to a computer. The target operating conditions were:

- relative air humidity about 35%
- laminar air flow about 1.0 m/s
- air temperature about 20°C
- soil temperature about 20°C

The exact values were monitored every 30 minutes.

Sampling.

Determination of the amount of flutamide on the soil surface at the beginning of the experiment (time 0) was achieved by removal of the microscope covers directly after application and the washing of them with acetonitrile. The acetonitrile wash was then radioassayed. At each sampling interval of 1, 3 and 6 hours the one trap was replaced by a new one. The removed trap was extracted with acetonitrile and the extract was radioassayed. At the final sampling interval of 24 hours both traps (one having been in position for the entire 24 h period and the other from 6 to 24 h) were extracted and the radioactivity in the extracts was quantified. The entire soil sample was extracted with acetonitrile and the total radioactivity determined. The chamber and Raschig rings were washed with acetone, that was then radioassayed.

Quantitative analysis. The amounts of radioactivity in the various extracts and washes was determined by the liquid scintillation counting (LSC) of aliquots.

Qualitative analysis. Thin layer chromatography (TLC) was used to analyse the treatment solution and soil extracts. For this analysis the extract samples were evaporated to dryness under vacuum and redissolved in 1 mL acetonitrile. Aliquots of this (10 µL) were applied to the TLC plates. The plates used were silica gel 60F254 and the solvent systems used were chloroform/tetrahydrofuran/acetic acid (95:5:1, v/v/v) and chloroform/isopropanol/acetic acid (280:20:1, v/v/v). After development and drying the plates were analysed by use of an automatic TLC-linear analyzer (Berthold).

Findings:



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

The mean relative air humidity was 39.6%, the mean air temperature was 22°C, the mean airflow speed was 1.36 m/s and the mean soil temperature was 19.9°C. From the amount of radioactivity recovered from the microscope covers it was calculated the amount of radioactivity on the soil at the beginning of the experiment was 176.21 kBq. The amount of flurtamone was 521 µg, equivalent to an application rate of 244 g/ha.

The quantitative radioactivity determinations showed that after 24 hours the radioactivity in the traps amounted to about 0.1% of applied radioactivity. The sum in the replaced traps covering the 0 to 1, 1 to 3, 3 to 6 and 6 to 24 h periods amounted to 0.11% of applied radioactivity, whilst that in the trap that was in position from 0 to 24 h amounted to 0.10%. Less than 0.1% of applied radioactivity was recovered from the volatilisation chamber and 110.4% was extracted from the soil. The recovery and distribution of applied radioactivity is summarized in table 4.

Table 4 Recovery and distribution of applied radioactivity from a flurtamone soil surface volatility experiment

Fraction	Radioactivity as		
	kBq	% applied	normalised
Air	0.15	0.10	0.08
Chamber	0.15	0.09	0.08
Soil	174.49	110.38	99.83
Total	194.79	110.57	100.00

The TLC results showed that there was no degradation of flurtamone over the course of the study.

Conclusion:

The results obtained show that < 0.1% of flurtamone was volatilized from a soil surface when it had been applied as a commercial formulation.



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

██████, R. 1995, [M-210853-01-1](#)

Report: KCA-7.3. 1 /02; ██████, R. 1995
Title: Investigation of the volatilization of 14C-Flurtamone formulated according to EXP30930 from plant surfaces under laboratory conditions

Organisation: ██
Report No.: [M-210853-01-1](#)
Publication: Published in Baseline dossier
Dates of experimental work: Not specified
Guidelines: BBA: IV, 6-1
Deviations: Not specified
GLP/GEP yes

Material and Methods:

The objective of the study was to determine the volatilization rate of flurtamone when applied to plants in a commercial formulation. This was conducted in two experiments, P1 and P2. Radiolabelled flurtamone was used as the test substance. It had the batch number CSL-92-419-46-35 and a specific activity of 5.81 MBq/mg. The radio purity was 90.5%. The radiolabelled flurtamone was mixed into a commercial formulation ‘EXP30930’. This formulation contained flurtamone at 250 g/L and diflufenican at 100 g/L. On each of two occasions a sample of the test substance was dissolved in methanol (1 mL). An aliquot of the formulation EXP30930 was mixed with water and homogenized. The dissolved ¹⁴C-flurtamone was added and the mixture homogenized. Aliquots were taken for radioassay.

Treatment. The application of the test solutions was made to French beans (Canadian Wonder, at the blossoming stage). Two rows of plants were used for each experiment. The application chamber was a closed chamber made of stainless steel. The nozzle of a computer controlled spraying system projected into the chamber. In order to simulate real use conditions the nozzle was of a type used in commercial agriculture (Tea Jet type 8001 E). The experimental platform, made of stainless steel and on which the plants stood, was transferred into the chamber and fixed on an adjustable vertical suspender. It had an experimental surface area of 0.5 m² and a depth of 10 cm. The rows of plants were sprayed from a distance of 35 cm between the nozzle and the tips of the plants. Paper covers were used in the course of the application and the radioassay of these and of tissues used for decontamination of the chamber allowed the determination of application losses. The soil in which the plants stood was covered with filter papers. Radioassay of these allowed the determination of the amount of radioactivity applied to the plants.

After application the experimental platform was transferred into the volatilization chamber. This consisted of an air-conditioning system suitable for production of an air temperature of 20±2°C and a relative humidity of 50±10%. Air temperature, humidity and wind-speed were recorded. The conditioned air moved to an equalization chamber where turbulence caused by the blower were calmed. The conditioned air was divided into two parallel streams, a fast one with a height of 10 cm to simulate outdoor wind speeds of about 1 m/s above the plant stand and a slow one with a height of

**Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)**

80 cm to simulate air exchange rates in plant stands (of up to 0.3 m/s). After having passed through the volatilization chamber the air was sampled and then discharged through a filter that retained the radioactivity.

Sampling. The air sampling was effected by use of probes suitable for isokinetic air sampling. The probes, one in each air channel, were fitted to glass vessels, each containing three polyurethane foam plugs to absorb volatile compounds. A pre-test had been conducted to confirm the stability of the test substance in these plugs. During the experiments these were renewed at 1, 3 and 6 hours. Aliquots of each air sample were then passed through distilling columns (Vigreux) and freezing-traps to remove the humidity. They were then passed through four glass columns filled with a mixture of ethanolamine/phenylethylamine/ethylene glycol/diethylglycolmonobutylether (in equal parts by volume).

Quantitative analysis. Determination of the application losses included the measurement of radioactivity remaining in the glassware used for the application solution, on the paper covers in the application chamber and on the inner surface of the application chamber. Quantification of these losses was achieved by rinsing the glassware with acetone and radioassay of the acetone by liquid scintillation counting (LSC) of aliquots. The paper covers were extracted twice with acetone that was then radioassayed and the paper residue was also radioassayed by the combustion of sub-samples and LSC of the trapped carbon dioxide produced. The amounts of radioactivity in the acetone-moistened tissue papers, used to decontaminate the interior of the application chamber, were determined by combustion-LSC without any extraction step. All losses were deducted from the total initial radioactivity to allow calculation of the amount actually applied to the experimental area (0.5 m²). When the amount of radioactivity in the filter paper covering the soil during spraying had been measured, in the same way as that on the paper covers, described above, it was subtracted from the amount calculated to have been applied to the experimental area to give the amount applied to the plants.

The polyurethane foam plugs were extracted with acetone and the extract was radioassayed. At the end of each experiment (24 h) the plants were homogenized in acetone. The radioactivity content of the extract was measured by direct LSC of aliquots and the post-extract residues were radioassayed by combustion-LSC.

Qualitative analysis. Thin layer chromatography (TLC) was used to analyse application solutions, the extracts of the foam plugs (including stability pre-test) and plant extracts. The plates used were silica gel 60F254 and the solvent system was chloroform/tetrahydrofuran/acetic acids (95:5:1, v/v/v). After development and drying the plates were analysed by use of an automatic TLC-linear analyzer (Berthold).



Document MCA: Section 7 Fate and behaviour in the environment (add. summaries ex Baseline dossier)

Findings:

The pre-test on the stability of the radiolabelled flurtamone in the foam plugs showed that it was stable over the longest time period used in the experiments (18 hours, that is 6 to 24 hours after the start of the experiment).

The TLC results on the application solution for experiment R1 showed that the radioactivity of the test substance was > 99%. The calculated amount of radioactivity applied to the plants was 547.78 kBq and this value was the basis for further calculations. The total air volume of the upper channel was 342.32 m³/h and the sample volume was 18.11 m³/h. The total air volume of the lower channel was 124.22 m³/h and the sample volume was 9.24 m³/h. The only upper channel foam plug extract to contain levels of radioactivity above the detection limit was that from the first plug taken at the 1 hour sampling time-point. This contained 0.16 kBq which equated to 502 kBq in the total air through-put.

This document is copyright protected and requires the consent of Bayer AG (or its respective affiliates). Any use of the document or its content for regulatory or any other commercial purpose is prohibited and constitutes a violation of the underlying license agreement.