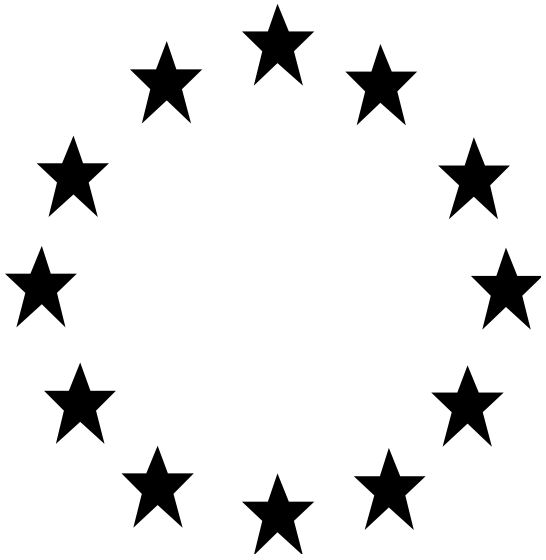

Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State Austria for the existing active substance

FLUAZINAM

of the third stage (part A) of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

Volume 3, Annex B, B.8

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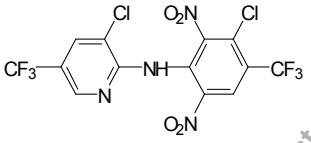
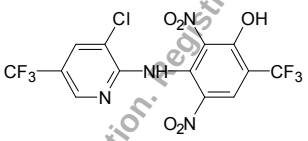
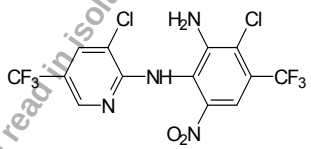
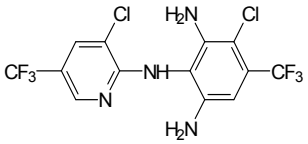
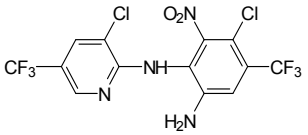
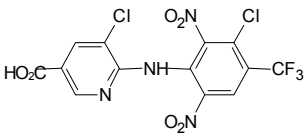
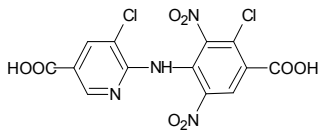
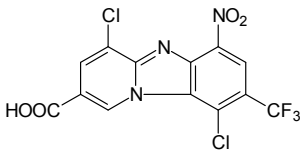
Annex B

Fluazinam

B.8 Environmental fate and behaviour

B.8 Environmental fate and behaviour

Table B.8-1: Overview of parent compound, metabolites and identified degradation products mentioned in the section "environmental fate and behaviour".

Code	Common name	Chemical name	Chemical Structure	Occurrence
IKF-1216 B1216 PP192 (parent compound)	Fluazinam	3-Chloro-*N*-(3-chloro-5-trifluoromethyl-2-pyridyl)-α,α,α-trifluoro-2,6-dinitro-p-toluidine (3-chloro-N-(3-chloro-2,6-dinitro-4-ααα-trifluorotolyl)-5-trifluoromethyl-2-pyridylamine)		
Compound XII	HYPA	5-(3-chloro-5-trifluoromethyl-2-pyridylamino)-α,α,α-trifluoro-4,6-dinitro-*o*-cresol		-major in aerobic soil -minor in anaerobic soil -minor in photolysis -minor in water/sediment study
Compound VII	MAPA	2-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-*α,α,α*--trifluoro-5-nitro-*m*-toluidine		-major in anaerobic soil -minor in aerobic soil -minor in water/sediment study
Compound VIII	DAPA	4-chloro-2-(3-chloro-5-trifluoromethyl-2-pyridylamino)-5-trifluoromethyl-*m*-phenylenediamine		-major in anaerobic soil -minor in aerobic soil -minor in water/sediment study
	AMPA	4-chloro-6-(3-chloro-5-trifluoromethyl-2-pyridylamino)-*α,α,α*-trifluoro-5-nitro-*m*-toluidine		-minor in soil photolysis study -minor in aqueous photolysis -major in water/sediment study
	CAPA	5-Chloro-6-(3-chloro-2,6-dinitro-4-trifluoromethylanilino) nicotinic acid		-major in hydrolysis study
	DCPA	6-(4-Carboxy-3-chloro-2,6-dinitroanilino)-5-chloronicotinic acid		-major in hydrolysis study
	G-504	4,9-dichloro-6-nitro-8-(trifluoromethyl)-pyrido-[1,2-*a*]benzimidazole-2-carboxylic acid		-major in aqueous photolysis

B.8.1 Route and rate of degradation in soil (Annex IIA 7.1.1, Annex IIIA 9.1.1)

B.8.1.1 Route of degradation

B.8.1.1.1 Aerobic degradation in soil

Reference: Bharti, H. and Bewick, D.W. (1985): B1216 (PP192): Degradation in Soil (Report RJ 04444B).

Guideline: Not specified

GLP: Yes

Material and methods:

Metabolism and degradation of ^{14}C-phenyl and ^{14}C-pyridyl labelled fluazinam was investigated in two fresh soils under a range of experimental conditions in the laboratory (see table below):

Table B.8.1.1.1-1: Overview of experimental conditions used in the study

soil	treatment	Incubation conditions	Nominal applic. rate	Sampling intervals (days)							
Sandy loam "18 Acres"	^{14}C-phenyl ai $^{+}$ ^{14}C-pyridyl ai $^{+}$	aerobic 20° C	1 kg/ha	0	7	14	30 * §	60	90	180	360
	^{14}C-phenyl ai ^{14}C-pyridyl ai	aerobic 20° C	5 kg/ha	0	7		30		90		
	^{14}C-phenyl ai	aerobic 20° C sterile	1 kg/ha	0	7	14	30				
	^{14}C-phenyl ai ^{14}C-pyridyl ai	aerobic 10° C	1 kg/ha		7	14	30	60			
	^{14}C-phenyl ai ^{14}C-pyridyl ai	flooded 20° C	1 kg/ha	0	7		30	60	90		
Loamy sand "Frensham"	^{14}C-phenyl ai ^{14}C-pyridyl ai	aerobic 20° C	1 kg/ha	0	7		30 *		90	180	360

* these treatments provided duplicate 30 day samples for an "aged" column leaching study.
§ 5 samples were incubated in the larger flooded soil pots and were flooded at day 30. These soils were sampled after a further 30, 60 and 90 days incubation.
+ additional larger pots of soil, corresponding to these treatments were incubated to provide material for ^{14}C-metabolite identification.

The radiochemical purities of the ^{14}C-phenyl and ^{14}C-pyridyl labelled fluazinam were >99%, the specific activities were found to be 652 dps/µg and 658 dps/µg, respectively.

The two soils were maintained at 40% MHC (at zero suction). Solutions of the radiochemicals in acetone were applied drop wise to the surface of the soil in each pot. The effluent air from each incubation unit was passed through one tube of 0.05 M sulphuric acid (to absorb organic bases), one tube of 2-methoxyethanol (to catch other organic volatiles) and two tubes of ethanolamine (to absorb $^{14}CO_2$). The radioactivity in the traps was

periodically quantified by LSC.

Soils were extracted with acetonitrile, filtered and the debris refluxed with acetonitrile for 3 hours. Extracted soil debris was analysed by combustion and LSC. Unextracted soil residues in the sample with the largest NER fraction (i.e. ^{14}C-phenyl labelled, flooded at day 30 and analysed 90 days after flooding) were further characterised by refluxing the soil for 3 hours in 0.1 M $Na_4P_2O_7$ and then partitioning the extracts with a series of organic solvents. The surface waters of the flooded soils were analysed separately. Analyses were carried out by TLC as well as HPLC and GC/MS for confirmation purposes. Generally only those soil extracts and surface water extracts which contained >5% AR were analysed by TLC.

Table B.8.1.1.1-2: Soil Characteristics

Soil (ISSS)	% sand	% silt	% clay	% OM	pH (water)	CEC (meq/100g)	MHC (zero suction)	MHC (1/3 bar)
Sandy loam "18 Acres"	61	17	22	4.4	6.9	16	62	20
Loamy sand "Frensham"	79	13	8	1.7	6.4	5	48	90

Findings:

In the two soils incubated aerobically for 361 days the radiolabel in $^{14}CO_2$ was 1.8% to 6.3% AR and was about the same for both label positions. The volatile radioactivity was almost entirely in the ethanolamine traps and was attributed to $^{14}CO_2$. Exaggerated application rate and lower temperature reduced the rate of CO_2 evolution. Anaerobic conditions reduced mineralization in case of both radiolabels. Mineralisation was negligible under sterile conditions. The amount of radioactivity extracted from the soil was >90% AR at the start of the study and gradually decreased over the incubation period, except for sterile soils. The unextracted radioactivity reached 41.4% to 42.2% AR in the sandy loam soil and 26.1% to 27.9% in the loamy sand soil after 361 days. The levels of unextractable radioactivity were generally higher in the soils incubated under flooded conditions than in those incubated under aerobic conditions but were similar for both positions of labelling. The majority of the acetonitrile extractable radiocarbon was recovered in the first, cold, extraction with up to only 20% recovered in the second, reflux, extraction. Extractions carried out under reflux conditions with basic and neutral sodium pyrophosphate solution and at room temperature with the neutral extractant released an additional 33.2%, 23.3% and 18.2% AR, respectively. The majority of the sodium pyrophosphate extracted residue remained water soluble despite the extractions carried out with a number of organic solvents under a range of conditions. The levels of the applied radiocarbon from the ^{14}C-phenyl and ^{14}C-pyridyl labelled fluazinam treatments found in the surface waters of the flooded sandy loam soil were ≤5.0% during the 90 day incubation (flooded at zero time). In the same soil flooded after 30 days the waters contained ≤3.7% AR. For details on distribution of radioactivity in soil see tables below:

Table B.8.1.1.1-3: Distribution of radioactivity in soil (in % AR)

DAT	1st extract		2nd extract		NER		$^{14}CO_2$		recovery	
	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label
Sandy loam _ aerobic – 20° C – 1 kg ai/ha										
0	88.7	101.5	Na	Na	4.0	1.5	Na	Na	92.6	103.0
7	83.1	79.0	Na	4.5	12.4	9.1	0.1	<0.1	95.6	92.7
14	72.3	68.7	2.9	3.3	16.4	16.8	0.2	0.1	91.9	88.9
30	66.1	64.0	3.2	2.4	23.8	21.9	0.5	0.3	93.6	88.6
60	56.5	48.5	2.8	3.2	29.0	32.5	1.4	0.7	89.7	84.9
90	49.6	48.3	4.0	4.1	37.1	35.5	2.2	1.2	92.9	89.1
180	39.7	37.4	2.4	3.4	43.8	47.2	4.4	2.4	90.2	88.0
361	23.1	19.4	14.6	15.6	42.2	41.4	6.3	4.7	86.5	83.3
Sandy loam _ aerobic – 20° C – *5 kg ai/ha*										
0	94.8	96.1	Na	na	2.0	2.1	Na	Na	96.8	98.2
7	84.2	85.2	Na	Na	9.8	10.8	0.1	<0.1	94.0	96.0
14	76.7	78.3	3.0	3.5	14.3	15.1	0.2	0.1	94.2	97.0
30	73.3	75.6	2.6	3.2	19.0	18.8	0.4	0.2	95.3	97.8
60	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
90	61.5	66.1	4.1	3.5	26.7	28.0	0.9	0.4	93.2	98.1
180	43.0	53.7	3.8	3.3	36.0	34.9	1.6	1.0	89.4	93.3
361	na	na	na	na	na	na	na	na	na	na
Sandy loam _ aerobic – 20° C – 1 kg ai/ha - *sterile*										
0	102.6	-	Na	-	1.5	-	Na	-	104.1	-
7	104.6	-	Na	-	4.6	-	<0.1	-	109.1	-
14	96.8	-	3.7	-	5.6	-	<0.1	-	105.0	-
30	98.0	-	2.7	-	6.2	-	<0.1	-	106.9	-
60	Na	-	Na	-	Na	-	Na	-	Na	-
90	Na	-	Na	-	Na	-	Na	-	Na	-
180	Na	-	Na	-	Na	-	Na	-	Na	-
361	Na	-	na	-	na	-	na	-	na	-
Sandy loam _ aerobic – *10° C* – 1 kg ai/ha										
0	99.0	96.1	Na	Na	2.2	2.2	Na	Na	101.2	98.3
7	91.1	82.3	Na	Na	6.8	6.5	<0.1	<0.1	97.9	88.7
14	96.8	82.3	3.2	2.1	11.2	9.3	<0.1	<0.1	101.2	93.9
30	82.7	81.1	2.2	2.1	13.4	13.0	0.1	<0.1	98.5	96.1
60	72.8	69.0	3.2	3.5	21.3	19.4	0.5	0.2	97.8	92.1
90	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
180	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
361	na	na	na	na	na	na	na	na	na	na
Sandy loam _ *anaerobic (zero time)* – 20° C – 1 kg ai/ha *										
0	88.5	87.1	Na	Na	3.3	3.6	Na	Na	96.7	94.2
7	66.9	63.0	Na	Na	28.5	9.1	<0.1	<0.1	98.0	74.8
14	59.8	57.7	4.1	3.8	28.6	26.7	<0.1	<0.1	95.3	90.6

DAT	1st extract		2nd extract		NER		$^{14}CO_2$		recovery	
	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label
30	48.8	42.7	7.3	6.1	29.6	33.9	0.2	0.1	90.4	87.3
60	41.7	41.3	7.1	6.5	43.2	41.2	0.6	0.1	95.6	92.3
90	34.3	36.3	7.9	7.5	46.9	41.6	0.8	0.2	93.3	89.1
180	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
361	na	na	na	na	na	na	na	na	na	na
Sandy loam _ *anaerobic (day 30)* – 20° C – 1 kg ai/ha **										
0	-	-	-	-	-	-	Na	Na	-	-
7	-	-	-	-	-	-	0.1	<0.1	-	-
14	-	-	-	-	-	-	0.2	0.1	-	-
30	-	-	-	-	-	-	0.5	0.3	-	-
60	51.0	51.4	3.1	3.3	36.2	33.2	0.8	0.5	94.9	91.5
90	31.5	30.6	4.4	3.9	50.5	48.5	1.3	0.8	90.6	87.2
180	21.5	19.4	5.0	5.2	60.6	59.8	2.0	1.3	91.8	89.2
361	na	na	na	na	na	na	na	na	na	na
Loamy sand _ aerobic – 20° C – 1 kg ai/ha										
0	90.7	101.8	Na	Na	1.5	1.3	Na	Na	92.3	103.1
7	89.3	92.3	Na	Na	6.1	6.3	0.1	<0.1	95.4	98.7
14	86.2	86.7	2.1	2.4	7.1	7.4	0.2	0.1	95.6	96.5
30	84.2	82.9	1.9	2.1	26.4	9.8	0.4	0.1	112.9	94.9
60	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
90	72.6	69.6	3.4	3.8	16.7	15.8	1.2	0.4	93.9	89.6
180	51.7	57.6	2.0	2.8	21.2	25.4	2.7	1.3	78.0	88.5
361	38.2	35.3	18.6	19.6	27.9	26.1	3.5	1.8	88.2	84.0

* additionally 2.4% - 5% AR were found in the surface water phase
** additionally 2.6% - 3.7% AR were found in the surface water phase

In aerobic soils compound XII (HYPA) reached levels up to 11.4% AR. The highest levels were found after 14-30 days. Lower levels of this metabolite were found in flooded soil. The presence of compound XII in both the oxidising environment of aerobic soils and the reducing environment of the flooded soils lead to the suggestion that this metabolite was formed via a hydrolytic mechanism.

A major degradation product under anaerobic conditions was found to be compound VII (MAPA). In soils flooded at day 0 compound VII reached a maximum of 29.8% AR, declining to <2% after 90 days. In soils flooded at day 30 the maximum amount was 9.0% AR, declining to <1.0% after 90 days. In aerobic soils this metabolite reached ≤2.5%.

Compound VIII (DAPA) accounted for up to 12.0% AR in the flooded soils, the highest levels being reached after 90 days. This metabolite was not detected in significant amounts (≤1.9% AR) in aerobic soils.

The only other radioactive area of any importance in the chromatograms of the acetonitrile extracts of soil was located at the origin. This “origin material” accounted for up to 17.0% AR in the aerobic soils and up to 32.2% AR in the flooded soils (highest level after 60 days in

each case). The “origin material” was not determined in this study, it is obviously very polar, and may be due, at least in part, to the interaction of fluazinam reduction products (i.e. compound VII and VIII) with soil organic matter. The organo-soluble fraction derived from the sodium pyrophosphate extraction of the acetonitrile unextractable residue remained entirely at the origin of the TLC plate. Since sodium pyrophosphate is a soil organic matter extractant this result also tend to imply that soil organic matter is associated with the “baseline” material. Not identified radioactive material, summarised under “others” accounted for 0.3% - 4% AR over all samples with one single maximum amount of 12.6% AR in the loamy sand soil under standard conditions at day 14 (phenyl-label).

No radioactive degradation products were detected which were unique to either the phenyl or pyridyl ring of fluazinam. Cleavage of the bridging amino group is therefore not an important degradative pathway in soil.

Table B.8.1.1.1-4: Distribution of radioactivity in soil extracts (in % AR)

DAT	fluazinam		MAPA (compound VII)		DAPA (compound VIII)		HYPA (compound XII)		“Origin”	
	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label
Sandy loam _ aerobic – 20° C – 1 kg ai/ha										
0	77.0	88.9	<0.5	<0.5	<0.5	<0.5	3.3	3.2	4.5	5.2
7	67.2	58.2	1.8	<0.5	1.0	<0.5	5.1	6.1	6.0	9.3
14	53.7	51.2	1.8	1.9	0.3	0.9	8.2	8.0	7.0	5.5
30	48.0	46.7	1.2	0.8	0.6	0.8	7.8	6.4	6.5	5.5
60	40.7	25.0	1.6	1.0	0.2	1.3	6.5	7.7	5.4	10.7
90	31.8	34.5	2.5	1.9	1.3	1.6	8.1	7.1	8.1	5.1
180	26.1	21.2	1.2	0.4	<0.5	<0.5	5.1	9.3	5.0	45.3
361	9.5	6.8	1.4	1.6	<0.5	<0.5	6.2	7.0	16.0	13.5
Sandy loam _ aerobic – 20° C – *5 kg ai/ha*										
0	91.3	91.3	<0.5	<0.5	0.5	0.5	0.8	1.1	0.9	1.9
7	72.4	72.2	1.4	1.0	<0.5	1.3	4.8	3.9	5.3	5.2
14	52.8	56.4	2.0	1.6	1.9	0.9	9.0	10.6	5.0	6.6
30	46.5	52.4	1.0	2.2	1.5	0.5	11.4	10.6	10.3	6.7
90	49.5	55.0	2.5	1.6	0.7	1.1	7.6	7.0	4.3	3.2
180	41.2	40.6	1.3	1.0	0.6	0.4	5.0	9.1	2.2	4.2
Sandy loam _ aerobic – 20° C – 1 kg ai/ha - *sterile*										
0	99.8	-	<0.5	-	<0.5	-	<0.5	-	0.8	-
7	88.3	-	<0.5	-	<0.5	-	<0.5	-	9.6	-
14	95.2	-	<0.5	-	<0.5	-	<0.5	-	0.5	-
30	92.1	-	<0.5	-	<0.5	-	<0.5	-	5.0	-

DAT	fluazinam		MAPA (compound VII)		DAPA (compound VIII)		HYPA (compound XII)		"Origin"	
	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label	Phenyl-label	Pyridyl-label
Sandy loam _ aerobic – *10° C* – 1 kg ai/ha										
0	90.7	88.5	<0.5	<0.5	<0.5	1.0	1.6	1.7	3.2	2.6
7	80.3	72.3	0.5	<0.5	1.2	1.0	3.7	3.7	5.0	4.4
14	79.8	74.2	<0.5	0.6	<0.5	<0.5	2.1	2.4	2.0	2.6
30	67.8	66.1	<0.5	0.5	0.3	0.3	5.1	4.0	8.8	6.5
60	42.3	54.1	1.4	1.0	0.8	<0.5	7.8	6.9	17.0	5.6
Sandy loam _ *anaerobic (zero time)* – 20° C – 1 kg ai/ha										
0	80.5	82.3	<0.5	<0.5	<0.5	0.7	2.3	1.0	3.1	1.4
7	22.8	23.5	20.8	21.3	0.6	1.0	6.0	5.4	11.6	9.9
14	5.4	6.4	31.2	27.4	3.4	3.7	4.9	4.5	13.0	11.4
30	1.4	1.9	2.2	2.6	2.7	4.9	6.5	6.8	29.2	23.7
60	1.6	1.8	1.6	1.5	3.3	7.4	7.2	5.0	32.2	23.9
90	0.9	1.6	1.5	1.7	12.0	11.6	3.1	4.2	18.9	15.5
Sandy loam _ *anaerobic (day 30)* – 20° C – 1 kg ai/ha										
60	16.9	18.3	3.3	3.0	1.5	1.0	10.9	11.0	13.2	10.1
90	5.0	10.4	9.0	6.4	1.5	1.4	3.6	4.8	11.9	9.9
180	1.0	1.0	1.3	1.3	3.4	2.5	2.7	3.8	14.5	10.1
Loamy sand _ aerobic – 20° C – 1 kg ai/ha										
0	85.3	97.0	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	1.8	1.0
7	72.2	85.1	0.5	<0.5	0.8	1.0	5.9	3.1	6.3	3.6
14	66.5	74.2	<0.5	<0.5	<0.5	<0.5	3.6	5.6	3.6	4.3
30	77.5	77.6	<0.5	<0.5	<0.5	<0.5	2.1	2.1	3.2	3.2
90	68.4	65.4	<0.5	<0.5	<0.5	<0.5	3.2	3.5	3.3	2.3
180	45.3	44.3	<0.5	0.8	<0.5	<0.5	2.9	4.8	2.0	5.1
361	30.2	24.7	0.9	1.1	<0.5	<0.5	4.6	5.5	6.2	16.6

The levels of extractable fluazinam declined significantly in all except the sterile soils. The decline of fluazinam in all the other soils was attributed to microbial degradation. The half-life of fluazinam in the sandy loam soil and the loamy sand soil under standard conditions (application rate 1 kg ai/ha) was calculated to be 48 days and 165 days, respectively. Degradation following application at 5 kg ai/ha was slower, with a DT_{50} of 72 days. Under lower temperatures (10° C) a half-life of >60 days was calculated. Under anaerobic conditions degradation was enhanced. In the soil, where flooding occurred on day 30 a DT_{50} value of 32 days was calculated. Flooding the soil at day 0 yielded a half-life of 4 days. The degradation rates presented in this study can be considered as estimations only as no

information was given about the method applied. Degradation rates have been calculated by averaging the values of the two different label positions.
The RMS calculated the degradation rates of the two label positions separately (20 °C samples) on the basis of single 1st order kinetics. The results are as follows:

Sandy loam 1 kg		phenyl label	pyridyl label	average both labels
aerobic	DT_{50}	96.4 d	63.3 d	79.9 d
	DT_{90}	320 d	210 d	265 d
	r^2	0.914	0.814	
Loamy sand 1 kg		phenyl label	pyridyl label	
aerobic	DT_{50}	263 d	189 d	226 d
	DT_{90}	873 d	628 d	751 d
	r^2	0.895	0.952	
Sandy loam 5 kg		phenyl label	pyridyl label	
aerobic	DT_{50}	174 d	171 d	173 d
	DT_{90}	578 d	568 d	573 d
	r^2	0.619	0.563	
Sandy loam 1 kg		phenyl label	pyridyl label	
anaerobic day 30	DT_{50}	17.4 d	34.0 d	25.7 d
	DT_{90}	57.7 d	113 d	85.4 d
	r^2	0.994	0.996	
Sandy loam 1 kg		phenyl label	pyridyl label	
anaerobic zero time	DT_{50}	3.8 d	3.9 d	3.9 d
	DT_{90}	12.6 d	12.8 d	12.7 d
	r^2	0.619	0.563	

It is indicated that fluazinam degrades somewhat slower under aerobic conditions when labelled at the phenyl ring. When applying exaggerated rates (5 kg ai /ha) degradation can not be well described by simple 1st order kinetics (correlation coefficients too low). A biphasic degradation pattern was indicated.

Conclusions:

Fluazinam is metabolised by microbial activity. The main metabolic pathway is the formation of bound residues (up to 47.2 % AR NER after 180 days under standard conditions). Metabolites which would indicate cleavage of the bridging amino group were not observed. Mineralisation (formation of CO_2) amounted for up to 6 % AR after one year under standard conditions. Under aerobic conditions HYPA was the major metabolite which is formed by dechlorination and subsequent hydroxylation of the phenyl ring of fluazinam. Low temperatures and exaggerated application rate reduced metabolism of fluazinam. Under anaerobic conditions MAPA and DAPA were the major metabolites which are formed by reduction of NO_2-groups of the phenyl ring of the parent compound. Degradation of

fluazinam and formation of NER are enhanced under anaerobic conditions but mineralization seems lower.

The calculations of degradation rates in this study were not considered valid. Recalculations on the basis of current guidance are presented in a new study: Gurney, A. (2005), chapter B.8.1.2.1 below. Also in this new study the two label positions were not considered separately. However, for PEC_{SOIL} calculations this averaging was accepted by the RMS. For PEC_{GW} calculations laboratory data were not used.

Comment (RMS): Although no guideline was stated the study is considered acceptable

Reference: Mawad, N. (2003): Metabolism and degradation of 14C-fluazinam in one soil incubated under aerobic conditions. (Study 844056).

Guideline: SETAC (Europe), 1995, part 1 and OECD Draft Guideline ("Aerobic and Anaerobic Transformation in Soil Systems"), 2000

GLP: Yes

Material and methods:

The purpose of this study was to determine the metabolism and rate of degradation of a mixture of ^{14}C-U-phenylring-labelled (5.01 MBq/mg specif. radioactivity, 100% purity) and ^{14}C-pyridylring-labelled (5.10 MBq/mg specif. radioactivity, 100% purity) fluazinam and its metabolite HYPA in one fresh field soil (sandy loam) incubated under aerobic conditions at 20 ± 2° C. Soil was maintained at 40% MWHC. The applied concentration of the test substance was 0.99 mg ai/kg soil (dw) which corresponds to 0.74 kg ai/ha if a soil depth of 5 cm and a soil density of 1.5 g/cm^3 are assumed.

For each metabolism flask the out coming air was passed through a trapping system equipped with absorption traps containing ethylene glycol and 2N NaOH to trap organic volatiles and $^{14}CO_2$, respectively. Radioactivity in the traps was monitored by LSC at each exchange interval. Ethylene glycol and sodium hydroxide solutions were exchanged after 36 and 192 days of incubation due to the low amount of volatiles formed. Barium hydroxide precipitations were carried out for the sodium hydroxide solution on day 36 in order to confirm that the radioactivity was solely $^{14}CO_2$. Individual soil samples were taken at different intervals, duplicate samples were taken only at day 28. Soil samples were extracted at room temperature with methanol : phosphoric acid (99.5 : 0.5; v/v) up to four times; Soxhlet extraction was carried out with methanol : phosphoric acid (99.5:0.5; v/v) once, (only on day 7 of incubation) and with acetonitrile : water (4 : 1; v/v) once, (from day 14 onwards). From day 0 to day 14 of incubation the radioactivity of the extracts at room temperature and Soxhlet were measured by LSC individually. From day 28 onwards all extracts were combined and aliquots were concentrated. Radioactivity recovered was determined by LSC. Thereafter, the concentrated extracts were submitted to HPLC and TLC analysis.

The experimental data were analysed by using ModelMaker Vers. 3.04. Degradation rates were calculated on the basis of non-linear first order kinetic.

Table B.8.1.1.1-5: Soil Characteristics

Soil (USDA)	% sand	% silt	% clay	% OC	pH ($CaCl_2$)	CEC (meq/100g)	% MWHC (pF 1.0)	Biomass (mg C/100g)
Sandy loam "Pappelacker"	71.1	21.9	7.0	1.1	7.1	6.9	45.4	Start: 21.4 day 120: 22.8 day 217: 16.4

Findings:

Extraction with methanol/phosphoric acid up to four times, recovered the majority of extractable radioactivity from the soil sample. Soxhlet extraction contributed a maximum of 8.4% AR (day 70). The total extractable radioactivity steadily decreased over time to 55.2% AR on day 48. Thereafter it continued to decrease to 49.1% on day 70 and to 43.4% AR at study termination (day 158). The amount of non-extractable radioactivity was high increasing form 3.7% AR on day 0 to 43-46% AR between day 70 and 158. The mineralization of fluazinam to CO_2 accounted for a maximum of 4.2% AR. Other volatile compounds collected did not exceed 0.4% AR. One major metabolite was detected which was characterised as HYPA. The maximum amount (13.9% AR) was reached after 48 days of incubation. Up to 14 minor degradation products were detected. None of them individually exceeded 4.7% AR during the whole incubation period. For details see tables below:

Table B.8.1.1.1-6: Distribution of radioactivity (% AR) after aerobic incubation of 14C-fluazinam

DAT	Extractable	NER	CO_2	Recovery	Fluazinam	HYPA
0	96.0	3.7	na	99.7	96.0	Nd
2	93.3	6.8	<0.1	100.1	93.3	Nd
7	84.1	13.2	0.3	97.6	72.8	6.5
14	77.7	20.7	0.7	99.2	57.5	10.8
28*	58.9	35.0	2.0	96.2	26.3	9.1
48	55.2	38.8	3.3	97.5	16.4	13.9
70	49.1	43.0	4.2	96.8	7.8	11.3
120	44.2	46.4	2.7	93.3	4.5	10.6
158	43.3	43.4	3.3	90.6	2.9	8.3

* duplicate samples with almost identical results
na...not analysed
nd...not detected

The decline of fluazinam was described by the following model:

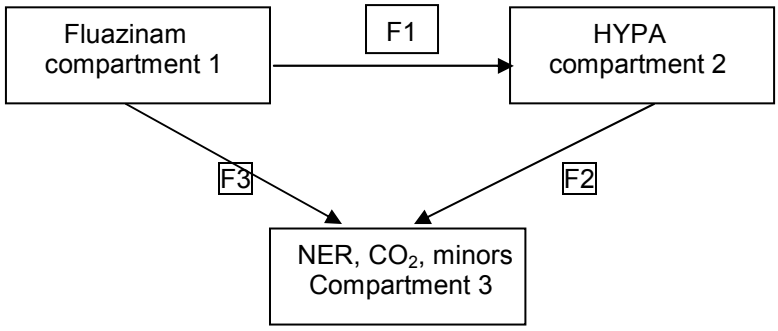


Figure B. 8.1.1.1-1: Compartment model for fluazinam degradation

The DT_{50} for fluazinam and its main metabolite HYPA were calculated to be 17.1 days and 105.2 days, respectively (r^2: 0.992). The corresponding k values are 0.04061 and 0.006587.

Conclusions:

The results of the study are comparable to the outcome of the first metabolism study. HYPA was found as the major soil metabolite (max. 13.9 % AR after 48 days of incubation) besides a number of minor metabolites. The formation of NER was high amounting for up to 46 % AR after 120 days.

DT_{50} values calculated by the compartment model ModelMaker Vers. 3.04. were 17.1 days for fluazinam and 105 days for HYPA (non-linear 1st order kinetics).

Comment (RMS): Study considered acceptable

B.8.1.1.2 Supplementary soil degradation studies

Investigations on the behaviour of fluazinam in soil under anaerobic conditions were included in the study of Bharti, H. and Bewick, D.W. (1985; Report RJ 04444B), see chapter B.8.1.1.1 above.

B.8.1.2 Rate of degradation

B.8.1.2.1 Aerobic degradation of the active substance

Reference: Ryan, J. and Sapiets, A. (1992): FLUAZINAM: Laboratory soil degradation study (BBA). (Report RJ 1391B).

Guideline: BBA Guideline

GLP: Yes

Material and methods:

The purpose of this study was to investigate the degradation rate of unlabelled fluazinam in one soil. Soil moisture was maintained at 40% MHC and samples were kept at 20 ± 2° C. Fluazinam was added to the soil in a concentration of 0.75 mg/kg soil (dw) which is equivalent to 0.56 kg ai/ha. Duplicate samples were removed and extracted by refluxing with acetonitrile and analysed for fluazinam residues by GC with electron capture detection. The

half life in soil was calculated using Timme and Frehse models.

Table B.8.1.2.1-1: Soil Characteristics

Soil	% sand	% silt	% clay	% OC	pH *	CEC (meq/100g)	% MWHC (0.33 bar)	Biomass (mg C/100g)
Sandy soil Speyer 2.2	87	7	6	1.8	5.4	6.8	12.9	Start: 69.7 after 1 y: 15.4

* method not stated

Findings:

It is stated in this study that the mean recovery of fluazinam was 94% with a range of 77-112%, over the fortification rage 0.1-0.75 mg/kg. In the table below the results of the analysis of the soil samples are given:

Table B.8.1.2.1-2: Fluazinam residue levels in soil (mean of duplicate samples)

DAT	Residue (mg/kg)
0	0.69 (i.e. 92 % of applied)
7	0.63
14	0.59
28	0.38
56	0.32
85	0.23
182	0.13
287	0.09 (i.e. 13 % of day 0)
331	0.08
364	0.09

A DT_{50} value of 55 days was calculated by the method of Timme and Frehse. The second order model was the best fit with r^2 of 0.958. The DT_{90} was calculated from the regression line, and was found to be 494 days. The decrease in degradation rate over last six months of the study is probably due to the reduced biomass content.

Conclusions:

The calculations of degradation rates were not considered valid. Recalculations on the basis of current guidance are presented in: Gurney, A. (2005), below.

Comment (RMS): Study considered acceptable

Reference: Gurney, A. (2005a): Kinetic calculations for degradation of fluazinam in soil under laboratory and field conditions. (Study A07132).

Guideline: GD on Estimating Persistence and Degradation Kinetics form Environmental Fate Studies on Pesticides in EU Registration (Sanco/10058/2005 vers. 1.0)

GLP: Not applicable

Material and methods:

Kinetic calculations were performed with the ModelMaker compartmental modelling software. Half-lives for fluazinam under laboratory and field conditions were calculated according to single 1st order kinetics following guidance from the FOCUS Kinetics Workgroup.

In the laboratory study of Mawad, N. (2003; Study 844056) a single 1st order half-life for fluazinam was already calculated using ModelMaker, therefore it was not necessary to re-analyse the results of the study. The remaining studies were re-analysed. The results of the kinetic calculations for half-lives in soil under laboratory conditions are shown in the table below:

Table B.8.1.2.1-3: Kinetic analyses of fluazinam in soil under laboratory conditions

Reference	soil	DT_{50} in original study (d)	Recalculated SFO DT_{50} (d)	r^2
Bharti, H.; Bewick, D.W. (1985)	Sandy loam („18 Acres“)	48	79.7	0.884
	Loamy sand („Frensham“)	165	221.7	0.936
Mawad, N. (2003)	Sandy loam (“Pappelacker”)	17.1	17.1	0.992
Ryan, J.; Sapiets, A. (1992)	Sandy soil (Speyer 2.2)	55	61.8	0.960
Arithm. mean			**95.1**	
Geom. Mean			**65.7**	
Median			**70.8**	

Conclusions:

The calculations were accepted by the RMS.

B.8.1.2.2 Aerobic degradation of relevant metabolites, degradation and reaction products

Reference: van der Gaauw, A. (2002): Degradation rate of HYPA in three soils incubated under aerobic conditions. (Study 842279).

Guideline: SETAC (Europe), 1995, Part 1; OECD Draft Guideline, Aerobic and Anaerobic Transformation in Soil Systems, 2000; Dutch Guideline, Behaviour of the product and its metabolites in soil, water and air, Part G.1., 1991

GLP: Yes

Material and methods:

The purpose of the study was to investigate the degradation rate of unlabelled HYPA (99.7% purity), the major soil metabolite of fluazinam, in three freshly sampled soils. Soils were incubated at 20 ± 2° C in the dark, the moisture content was adjusted to 40% MWHC. The test item was applied to soils at a nominal concentration of 0.16 mg/kg soil (dw). Duplicate samples of soils were taken and extracted up to four times with methanol : phosphoric acid (99.5 : 0.5; v/v). Aliquots of the extracts where then subjected to LC/MS analysis for determination of levels of HYPA (LOQ: 0.005 mg/kg soil).

The method of analysis of HYPA was validated with recovery experiments using fortified samples which were handled in the same way as the treated samples. Soil samples were treated for fortification, the measured amounts detected in fortified samples of day 0 for the three soils were taken as 100% AR.

Degradation rates were calculated by applying non-linear first-order reaction kinetics.

Table B.8.1.2.2-1: Soil Characteristics

Soil (USDA classif.)	% sand	% silt	% clay	% OC	pH ($CaCl_2$)	CEC (meq/100g)	% MWHC (pF 1.0)	Biomass (mg C/100g)
Speyer 2.1 sand	87.2	9.0	2.8	0.9	5.2	6.0	30.0	Start: 30.1 end: 19.9
Speyer 2.2 loamy sand	75.3	16.6	8.1	2.3	5.6	11.0	50.0	Start: 26.4 end: 22.9
Senozan clay loam	20.4	47.4	32.2	1.0	6.2	19.51	61.4	Start: 32.2 end: 22.9

Findings:

The mean recoveries from samples fortified with HYPA were 97.5%, 96.7% and 94.3% for the three soils. HYPA was degraded most rapidly in soil Speyer 2.2 and Senozan amounting to 36.3% and 24.4% AR after 119 and 120 days of incubation, respectively. In soil Speyer 2.1 HYPA represented an amount of 55.2% AR after 119 days. The following DT_{50} and DT_{90} values for HYPA were calculated using first order degradation kinetics:

Table B.8.1.2.2-2: Degradation rates of HYPA in soil under standard conditions

Soil	DT_{50}	DT_{90}	r^2
Speyer 2.1	148 d *	490 d	0.9955

Speyer 2.2	77 d	245 d	0.9582
Senozan	54 d	179 d	0.9611
Arithmetic mean:	**95.0 ****	**305**	
Geometric mean:	**83.9**	**278**	

* value used for PEC_{SOIL} calculations
** value used for PEC_{GW} modelling

Table B.8.1.2.2-3: Decrease of HYPA in three different soils (mean of duplicate samples; % AR)

DAT	Speyer 2.1	Speyer 2.2
0	97.3	102.7
3	83.0	11.4
17	88.5	79.1
28	75.7	66.6
60	71.2	56.3
89	64.9	45.2
119	55.2	36.3
	Senozan	
0	100.0	
7	84.7	
15	78.8	
28	52.8	
60	46.1	
91	27.1	
	24.4	
134	21.0	

Conclusions:
The degradation of soil metabolite HYPA was investigated in three soils. Calculated DT_{50} and DT_{90} values were in the range of 54 to148 days and 179 to 490 days, respectively (non-linear 1st order kinetics). The high DT_{90} value in soil Speyer 2.1 may be due to reduction of microbial biomass until the end of the study.
Comment (RMS): Study considered acceptable

B.8.1.3 Photolysis

Reference: Lentz, N.R., Korsch, B.H. (2001): A photolysis study of IKF-1216 (fluazinam) on soil. (Document nr. 5313-95-0011-EF-002).
Guideline: US EPA, subdiv. N, 161-3

GLP: Yes

Material and methods:

The objective of this study was to investigate the rate and route of photolysis of fluazinam on soil. Fluazinam labelled in the phenyl ring (57.3 mCi/mmol specif. activity, >97% radioachem. purity) or in the pyridyl ring (66.2 mCi/mmol specif. activity, >97% radioachem. purity) was exposed to simulated sunlight (xenon arc lamp with filters) with a 12-hour light/12-hour dark cycle for 30 days at 25 ± 2° C. The intensity of the irradiation over the range of 250-750 nm was monitored throughout the study and compared to that of measured natural sunlight. The natural sunlight was measured at 0825 and 1335 hours on June 5, 1991 in Painesville, Ohio. Soil samples were moistened to 75% of 1/3 bar. The test substance was applied at a rate equivalent to 3.55 ppm and 3.32 ppm, respectively, for the phenyl ring labelled and pyridyl ring labelled fluazinam. The volatile organic traps were charged with 1 g of Tenax TA™ resin, the CO_2 traps were charged with 50 mL of 1 N NaOH. The presence of $^{14}CO_2$ was verified using barium chloride. Duplicate soil samples were extracted 3 times with acetone : 0.1 N HCl, 90 : 10 (v/v). Attempts were made to release additional ^{14}C from the post extracted solids of day 28 and day 30 samples. Light-exposed and dark control samples were analysed by radio-HPLC. Additionally GC/MS was used for identification purposes. For calculating degradation rates linear regression analysis was performed and graphed with Excel.

Table B.8.1.3-1: Soil Characteristics

Soil	% sand	% silt	% clay	% OM	pH *	CEC (meq/100g)	% FMC (1/3 bar)	Bulk density (g/cm^3)
Loamy sand	76.4	17.2	6.4	2.19	7.0	6.37	8.37	1.35

* method not stated

Findings:

The photolysis half-lives on soil were 32.1 and 21.2 days for the phenyl ring labelled and the pyridyl ring labelled fluazinam, respectively. The half-lives in the dark controls were 68.6 days and 69.3 days. The rates of conversion of fluazinam to extractable degradation products, bound residues and to CO_2 were all more rapid for light-exposed soil than for dark controls. In the organic extractable fraction fluazinam was identified in amount of 35.7% (phenyl label) and 32.7% AR (pyridyl label) after 30 days. Two other components were identified by GC/MS. The large component was identified as HYPA accounting for an average of 6.2% AR for both test substances. The lesser component was identified as the mono-reduction product AMPA in amounts of 4.3% and 5.1% AR for the phenyl label and the pyridyl label, respectively. In contrast for the dark control samples the parent was till present at 66.4% (phenyl label) and 71.4% AR (pyridyl label). HYPA accounted for 4.9% and 3.9% AR. For the dark control samples AMPA represented less than1% AR. Additionally one polar fraction and two other not identified minor fractions amounted individually for up to 2.5% AR in the light-exposed samples and up to 0.7% AR in the dark controls. The amount of bound residues accounted for 26.5% (phenyl label) and 16.8% (pyridyl label) after 30 days. In the

dark controls the amounts were 10.8% and 9.0% AR. By day 30 the amount of $^{14}CO_2$ accounted for an average of 2.4% AR in the light-exposed samples and 0.2% AR in the dark controls.

Table B.8.1.3-2: Distribution of radioactivity (% AR) after application of fluazinam on soil (photolysis)

DAT	extractable	NER	CO_2	recovery	fluazinam	HYPA	AMPA
light							
0	98.8 /* 99.3	1.2 / 0.7	na / na	100.0	94.7 / 96.3	1.0 / 0.4	0.8 / 0.4
3	89.1 / 92.2	7.0 / 5.7	0.2 / 0.3	96.3 / 98.2	79.8 / 83.7	2.2 / 1.3	2.1 / 1.8
5	81.9 / 81.5	11.1 / 8.8	0.3 / 0.5	93.3 / 90.8	69.5 / 70.1	3.1 / 1.6	2.8 / 2.4
7	80.5 / 80.1	13.5 / 12.1	0.5 / 0.8	94.5 / 93.0	63.7 / 65.5	5.2 / 3.4	2.9 / 3.1
10	78.5 / 71.2	10.1 / 13.7	0.7 / 1.1	89.3 / 86.0	66.3 / 58.5	3.2 / 3.3	2.7 / 2.6
14	70.2 / 71.5	20.0 / 15.1	1.0 / 1.4	91.2 / 88.0	49.9 / 57.0	5.3 / 3.9	4.1 / 2.9
21	69.8 / 69.5	16.3 / 17.2	1.5 / 2.0	87.6 / 88.7	49.6 / 47.8	5.4 / 5.6	3.8 / 4.4
28	61.6 / na	24.5 / na	2.2 / na	88.3 / na	36.2 / na	6.8 / na	4.5 / na
30	69.8 / 66.1	26.5 / 16.8	2.2 / 2.5	98.5 / 85.4	35.7 / 32.7	6.2 / 6.1	4.3 / 5.1
dark							
0	98.8 / 99.3	1.2 / 0.7	Na / na	100.0	94.7 / 96.3	1.0 / 0.4	0.8 / 0.4
3	87.0 / 99.0	3.5 / 4.0	0.1 / 0.0	90.6 / 103.0	82.6 / 94.6	1.3 / 1.0	0.8 / 0.5
5	91.1 / 94.1	4.9 / 4.6	0.1 / 0.1	96.1 / 98.7	86.0 / 89.8	1.5 / 1.1	0.8 / 0.5
7	90.0 / 94.4	4.8 / 5.0	0.1 / 0.1	94.9 / 99.5	85.2 / 89.9	1.8 / 1.3	0.7 / 0.5
10	88.8 / 82.0	6.3 / 6.9	0.2 / 0.1	95.3 / 89.0	82.3/ /77.1	2.6 / 1.8	0.9 / 0.6
14	74.2 / 83.1	7.2 / 7.5	0.2 / 0.1	81.6 / 90.7	86.4 / 77.9	2.3 / 1.7	0.8 / 0.7
21	83.2 / 85.8	10.5 / 8.1	0.3 / 0.1	94.0 / 94.0	75.0 / 78.3	4.1/ 3.3	0.9 / 0.8
28	77.5 / 79.2	9.6 / 8.3	0.3 / 0.1	87.4 / 87.6	68.7 / 71.9	4.5 / 3.5	0.9 / 0.6
30	78.5 / 78.4	9.0 / 10.8	0.3 / 0.1	87.8 / 89.3	66.4 / 71.4	4.9 / 3.9	0.9 / 0.7

Day 0 samples were set to 100%

* phenyl ring label / pyridylring label

Conclusions:

Photolysis significantly increases degradation of fluazinam on soil. The half-lives given in the study for the dark controls averaged 69 days versus 22.2 days for the light-exposed samples (12 hours light/dark cycle). The light intensity was comparable to southern European conditions. Under both light and dark conditions conversion to bound residues was the main pathway. Conversion to bound residues was more extensive for the light-exposed samples. In general, photolysis appears to accelerate reactions that occur in soil under dark conditions. The presence of HYPA at comparable levels in the dark control and the light-exposed samples suggests it is a product of soil metabolism. AMPA, however, is found in the light-exposed samples at levels of up to 5% versus levels of <1% in the dark controls.

The RMS calculated the degradation rates of the two label positions separately on the basis of single 1st order kinetics. The results are as follows:

		DT_{50}	DT_{90}
Dark	phenyl	71.5 d	238 d
	Pyridyl	68.0 d	226 d
Light	phenyl	21.5 d	71.5 d
	Pyridyl	19.6 d	65.1 d

Comment (RMS): Study considered acceptable

B.8.1.4 Field studies

European trials

Reference: Kennedy, S.H. (1996): Fluazinam soil degradation study following applications to potatoes and bare ground (UK, 1995). (Study CEMS-451)

Guideline: EU Registration Directive 91/414/EEC Annex III.

GLP: Yes

Material and methods:

Two soil degradation trials were carried out with fluazinam in the UK during 1995-1996 in typical commercial potato-growing areas, one in Lincolnshire and one in Cornwall, in order to determine the residues of fluazinam and its major metabolite HYPA. Shirlan 50 SC (batch 181YF8053) containing 500 g/L fluazinam was applied on ten occasions (7-10 day interval) at 0.3 kg ai/ha to both bare ground and cropped plots (3 x 25 metres) at each site. In each case plant and soil samples were taken immediately after final application. Soil samples were taken at intervals up to 12 months after the final application.

The cropped plots were drilled in April 1995 and the crops were grown under normal commercial conditions. A desiccant was applied before harvest. At the Cornwall site this application was made on the same day as the final application of Shirlan and at the Lincolnshire site it was made 3 days after the final Shirlan application.

Exceptionally dry weather conditions were experienced at the Lincolnshire site in 1995 during June, July and August when the total rainfall figures were 18.1, 12.1 and 5.9 mm, respectively compared with the long-term averages for those months of 53.0, 53.0 and 63.0 mm. Irrigation, equivalent to 5 mm rainfall was therefore applied to all plots during mid-August to prevent crop failure. For details see table below:

Table B.8.1.4-1: Summary of the weather conditions

	Cornwall			Lincolnshire		
	mean °C	**mm rainfall**	**Sunshine hrs**	**mean °C**	**mm rainfall**	**Sunshine hrs**
June	13.9	13.5	248	13.6	18.1	184
July	17.3	23.9	225	19.0	12.1	255
August	19.0	14.4	297	18.6	5.9	260
September	13.0	144.9	139	13.8	58.0	133
October	12.4	79.2	100	12.9	16.3	143

	Cornwall			Lincolnshire		
	mean °C	mm rainfall	Sunshine hrs	mean °C	mm rainfall	Sunshine hrs
November	7.5	179	78	7.3	51.9	66
December	2.4	123.7	51	2.0	57.1	48
January	4.2	152.1	20	3.2	34.5	20
February	2.6	102.7	96	2.4	43.9	84
March	4.4	93.3	75	3.7	15.6	60
April	7.6	20.0	Nd	8.3	23.6	149
May	8.5	47.2	Nd	9.2	32.4	175
June	13.5	44.8	Nd	14.6	20.2	236
July	15.9	22.8	Nd	16.8	15.5	253
August	14.8	36.8	Nd	16.9	45.9	191
September	-	-	-	13.6	9.5	130

Table B.8.1.4-2: Application dates and weather conditions at each application

Application no.	% ground cover	Crop growth stage	Date of application	°C air	Wind (m/s)	Light conditions	% humidity	°C soil	Soil moisture
Cornwall									
1	80	39	21.6.95	23.1	0-0.2	bright	63	15.7	moist
2	95	55	29.6	27.6	0-0.2	bright	32	19.0	dry
3	95	61	6.7	20.7	0.3-1.5	dull	71	16.8	dry
4	99	69	13.7	19.0	0.3-1.5	diffuse	79	16.2	dry
5	99	75	20.7	24.0	0-0.2	diffuse	70	20.3	moist
6	90	79	27.7	27.1	0-0.2	diffuse	50	19.0	dry
7	85	92	3.8	32.3	0.3-1.5	bright	31	20.3	dry
8	75	92	10.8	32.6	3.5-5.4	bright	35	20.4	dry
9	50	92	17.8	34.3	0-0.2	bright	45	22.4	dry
10	35	93	24.8	25.0	3.5-5.4	diffuse	44	19.5	moist
Lincolnshire									
1	65	31	20.6.95	24.7	1.6-3.4	bright	73	23.3	dry
2	75	33	28.6.	24.1	1.6-3.4	bright	61	22.0	dry
3	80	41	6.7.	22.1	1.6-3.4	bright	62	17.4	dry
4	85	42	14.7.	22.1	0.3-3.4	bright	78	21.8	dry
5	90	42	22.7.	21.4	1.6-3.4	bright	74	16.8	dry
6	90	43	2.8.	28.0	1.6-3.4	bright	56	20.8	dry
7	90	45	9.8	25.3	1.6-3.4	bright	58	17.4	dry
8	90	45	16.8.	24.0	0.3-1.5	bright	61	18.6	moist
9	85	46	23.8.	21.7	1.6-3.4	bright	67	18.6	dry
10	80	48	31.8.	18.7	1.6-3.4	diffuse	60	17.1	dry

Potato samples were taken from the untreated and treated cropped plots immediately after the final application after the test substance had dried. Soil samples were taken from all the plots by taking a maximum of 15 cores (13 cores minimum) along a diagonal line across the plot, using soil corer 5 cm x 10 cm for day 0 samples and 2.5 cm x 20 cm for the other intervals.

Fluazinam and HYPA were extracted from soil samples by refluxing in acetonitrile. Residues were then determined either by GC with electron capture detection (fluazinam) or HPLC/UV (HYPA).

The residue levels in table below have been corrected for the mean procedural recovery value and are given on a dry weight basis. The LOQ was set to 0.01 mg/kg for both the parent and the metabolite in soil.

Table B.8.1.4-3: Soil Characteristics (20 cm)

Soil (USDA classif.)	% sand	% silt	% clay	% OM	pH ($CaCl_2$)	CEC (meq/100g)
"Cornwall" Clay loam	23	45	32	5.2	6.6	17.3
"Lincolnshire" Sandy clay loam	70	8	22	2.3	7.5	14.3

Findings:

Residues of fluazinam in potato plant samples taken from the treated plots immediately after the final application were similar for both sites. The mean values of duplicate samples were 31 mg/kg and 39 mg/kg for the Cornwall site and the Lincolnshire site, respectively. No quantifiable residues (<0.05 mg/kg) were found in the samples taken form the control plot at either site.

Individual residues of the parent and its metabolite in soil samples are given in the tables below.

Table B.8.1.4-4: Residues of fluazinam and metabolite HYPA in soil (0-10 cm) after application of 10 x 300 g ai/ha on bare ground (in mg/kg dw)

Days after final treatment (nominal)	Cornwall		Lincolnshire	
	fluazinam	HYPA	fluazinam	HYPA
0	0.61	0.09	0.38	0.05
7	0.51	0.02	0.49	0.07
14	0.67	0.04	0.45	0.08
28	0.25	0.04	0.15	0.06
56	0.20	0.04	0.17	0.09
216	0.08	0.07	0.05	0.03

Days after final treatment (nominal)	Cornwall		Lincolnshire	
	fluazinam	HYPA	fluazinam	HYPA
250	0.06	0.05	0.08	0.05
370	0.02	0.05	0.01	0.04

Table B.8.1.4-5: Residues of fluazinam and metabolite HYPA in soil (0-10 cm) after application of 10 x 300 g ai/ha on cropped plots (in mg/kg dw)

Days after final treatment (nominal)	Cornwall		Lincolnshire	
	fluazinam	HYPA	fluazinam	HYPA
0	0.26	0.03	0.28	0.02
7	0.07	<0.01	0.19	<0.01
14	0.25	0.01	0.20	0.04
28	0.06	0.01	0.05	0.01
56	0.05	0.01	0.08	0.03
216	0.15	0.01	0.06	0.03
250	0.04	0.02	0.02	0.02
370	<0.01	<0.01	0.01	0.02

No residues were found in any of the soil samples taken form the control plots. Fluazinam residues in the 0-10 cm soil layer taken from bare ground plots declined throughout the trial at both sites from an initial residue of 0.61 mg/kg to 0.02 mg/kg after 363 days for the Cornwall site and from 0.38 mg/kg to 0.01 mg/kg after 371 days for the Lincolnshire site. No quantifiable residues (>0.01 mg/kg) were found in the 10-20 cm soil layer, except at day 250 (0.01 mg/kg) at the Cornwall site and at day 7 (0.02 mg/kg), day 14 (0.01 mg/kg) and day 250 (0.01 mg/kg) at the Lincolnshire site.

A similar pattern of fluazinam residues was found in soil samples of the cropped plots. Residues were considerably lower, declining from 0.26 mg/kg at day 0 to <0.01 mg/kg until the end of the study at the Cornwall site, and from 0.28 mg/kg to 0.01 mg/kg at the Lincolnshire site. Below 10 cm soil layer no quantifiable residues were found except on day 28 (0.01 mg/kg) and day 250 (0.02 mg/kg) at the Cornwall site, and day 7 (0.02 mg/kg) and day 250 (0.02 mg/kg) at the Lincolnshire site.

No measurable amounts of HYPA were found in all of the 10-20 cm soil samples.

Degradation rates were calculated from the residues for the bare ground plots of the 0-10 cm soil layer. Linear regressions of transformed residue concentration on untransformed or transformed time were carried out according to Timme and Frehse (best fit).

Table B.8.1.4-6: Degradation of fluazinam in the field (UK)

Site	plot	Function	DT_{50}	DT_{90}	r^2
"Cornwall" Clay loam	Bare ground	1.5 order	37	193	0.89
"Lincolnshire" Sandy clay loam	Bare ground	1.0 order	77	254	0.71

Conclusions:
After application of Shirlan 50 SC on bare ground and on potato crops at 2 UK sites at application rates of 10 x 300 g ai/ha, residues mainly remained in the top 10 cm soil layers. The maxima amounts of HYPA found in the top soil layers of the bare ground treatments were 0.09 mg/kg soil at both sites. For fluazinam, with maxima of 0.67 mg/kg and 0.49 mg/kg soil at the two sites respectively, degradation rates were calculated. These calculations were not considered valid. Recalculations on the basis of current guidance are presented in: Gurney, A. (2005), end of chapter B.8.1.4 below.
Comment (RMS): Study considered acceptable

Reference: Burke, S.R. and Sapiets, A. (1992): Fluazinam: Soil dissipation study (Germany, 1991-92). (Report RJ 1368B) and Burke, S.R. and Sapiets, A. (1993): Fluazinam: Residue levels of the metabolite R270682 ("HYPA") in soil from a dissipation study carried out in Germany during 1991-92. (Report RJ 1443B)
Guideline: EU Registration Directive 91/414/EEC Annexe III.
GLP: Yes
Material and methods:
Four soil dissipation trials were carried out in Germany during 1991-1992 with fluazinam as a 50% w/v SC formulation applied at a rate equivalent to 1.35 kg ai/ha on bare soil. The soil properties were as follows:

Table B.8.1.4-7: Soil Characteristics

Soil	Soil profile	% sand	% silt	% clay	% OM	pH *	CEC (meq/100g)
"Varendorf" loamy sand	0-10	76	20	4	1.3	6.1	4.8
"Klein Zecher" sandy loam	0-10	70	26	4	1.5	6.1	4.8
"Ottersweier" clay	0-30	36	42	22	0.8	5.3	7.8
"Sollern" clay loam	0-30	27	40	33	2.2	6.8	14.3

*method not stated

At zero time soil samples were taken to a depth of 10 cm (5 cm i.d.), all the other samples down to a depth of 30 cm (2.3 cm i.d.). For every interval all the cores were divided into 10

cm horizons which were combined to give one sample per depth. Soil samples were extracted with refluxing acetonitrile for ninety minutes (fluazinam) or three hours (HYPA). Quantitative determination was carried out by GC with electron capture detection (fluazinam) or HPLC (UV absorption). The limit of determination was 0.01 mg/kg for both substances. The mean recovery of fluazinam was 87% and for HYPA 85%. The half-life of fluazinam in soil was calculated using the Timme and Frehse models.

Table B.8.1.4-8: Summary of the weather conditions

	Varendorf			Klein Zecher			Ottersweier			Sollern		
	mean °C	mm rainfall	Sunshine hours	mean °C	mm rainfall	Sunshine hours	mean °C	mm rainfall	Sunshine hours	mean °C	mm rainfall	Sunshine hours
June	14	152	155	-	-	-	-	-	-	-	-	-
July	20	27	316	19	31	297	21	102	268	18	114	254
August	18	47	224	17	60	217	20	6	307	17	83	254
September	15	39	179	14	46	176	17	141	182	14	82	175
October	9	19	155	8	54	142	9	52	95	7	13	134
November	5	41	51	5	57	46	5	91	25	3	51	35
December	2	50	50	2	63	46	1	57	34	-2	66	55
January	2	30	34	2	37	57	1	35	77	-1	13	67
February	4	37	57	4	27	30	3	49	69	1	40	66
March	5	52	99	5	65	103	7	96	106	4	90	102
April	8	50	155	8	54	134	9.8	48	185	7	64	151
May	-	-	-	-	-	-	16	47	245	14	6	284

Table B.8.1.4-9: Application dates and weather conditions at each application

Location	Date of application	°C air	Wind (m/s)	% cloud cover	% humidity
Varendorf	5.6.91	13	3	50	80
Klein Zecher	3.7.91	20	calm	10	85
Ottersweier	17.7.91	24	0-1	30 (dull)	high
Sollern	16.7.91	24	calm	30	68

Findings:

The residues of fluazinam and HYPA in soil over the time of the study are detailed in the table below.

Table B.8.1.4-10: Residues (mean) of fluazinam and HYPA in soil (0-10 cm) after application of 1.35 kg ai/ha on bare ground (in mg/kg dw)

DAT (nominal)	Varendorf loamy sand		Klein Zecher sandy loam		Ottersweier clay		Sollern clay loam	
	fluazinam	HYPA	fluazinam	HYPA	fluazinam	HYPA	fluazinam	HYPA
0	0.79	<0.01	0.70	<0.01	1.00	<0.01	0.92	<0.01

DAT (nominal)	Varendorf loamy sand		Klein Zecher sandy loam		Ottersweier clay		Sollern clay loam	
	fluazinam (i.e. 70%)*	HYPA	fluazinam (i.e. 63%)*	HYPA	fluazinam (i.e. 87%)*	HYPA	fluazinam (i.e. 78%)*	HYPA
7	0.53	<0.01	0.33	0.01	0.60	<0.01	0.71	0.01
14	0.49	<0.01	0.02	0.01	0.40	<0.01	0.47	0.01
28	0.36	<0.01	0.13	0.01	0.35	<0.01	0.18	0.02
62	0.20	<0.01	0.05	<0.01	0.12	<0.01	0.17	0.02
91	0.10	<0.01	0.03	0.01	0.10	<0.01	0.06	0.01
125	0.09	<0.01	0.03	<0.01	0.07	<0.01	0.07	0.02
182	0.07	<0.01	0.01	<0.01	0.07	<0.01	0.06	0.01
247	0.02	<0.01	0.01	<0.01	0.05	<0.01	0.06	<0.01
306	0.08	<0.01	<0.01	<0.01	0.03	<0.01	0.02	0.01

* calculating with the mean dry weight of the soils the nominal test concentration is 1.13 mg/kg soil (10 cm soil layer)

The 10-20 cm and 20-30 cm soil horizons contained no measurable residues of fluazinam at any sampling interval. The residues of the metabolite HYPA were below the LOD of 0.01 mg/kg in the 0-10 cm soil layer with a few exceptions at the “Klein Zecher” site and the “Sollern” site, where residues up to 0.02 mg/kg were found at some sampling occasions. HYPA was not detected in deeper soil layers.

The calculated half-lives for fluazinam according to Timme and Frehse (best fit) were as follows:

Table B.8.1.4-11: Degradation of fluazinam in the field (Germany)

Soil	DT_{50}	DT_{90}	r^2
“Varendorf” loamy sand	15	161	0.973
“Klein Zecher” sandy loam	6	67	0.968
“Ottersweier” clay	13	144	0.937
“Sollern” clay loam	11	127	0.900

Conclusions:

After application of a 50 % (w/v) SC formulation of fluazinam at an application rate of 1 x 1.35 kg ai/ha on bare soil at four sites in Germany residues remained in the top 10 cm soil layer. 63-87 % of the applied amount of fluazinam were detected at day 0 (0-10 cm soil layer). Residues of the metabolite HYPA were below the LOD of 0.01 mg/kg soil (0-10 cm) over the whole study period of 306 days. A few exception were seen at two of the four sites (maximum 0.02 mg/kg soil). Degradation rates were calculated for fluazinam. These calculations were not considered valid. Recalculations on the basis of current guidance are

presented in: Gurney, A. (2005), end of chapter B.8.1.4 below.

Comment (RMS): Study considered acceptable

US trials

Reference: Crawford, C.J. and Dillon, K.A. (1995a): Dissipation of residues of fluazinam and its metabolites (MAPA, HYPA and CAPA) from soil in Washington (Study 93-0091; Document 5687-93-0091-CR-001)

Guideline: EPA Pesticide Assessment Guideline, 164-1

GLP: Yes

Material and methods:

The objective of this study was to determine the patterns of mobility, degradation and dissipation of fluazinam and its metabolites MAPA, HYPA and CAPA under field conditions. The study was carried out near Ephrata, Washington (US), a region which is representative for growing potatoes and dry beans. Soil was sampled from a field planted to dry beans which received four applications of fluazinam 500 F (batch ASC-66825-0301; 41.1% w/w fluazinam), each equivalent to 0.5 kg ai/ha (intervals ca. two weeks). Before and after each application soil was sampled from one untreated and three replicate treated plots down to a depth of 91 cm. After the last application soil was also sampled at fourteen different time intervals through 527 DAT. Beans were planted on 27. May 93, fluazinam applications were made on 8. June, 23. June, 7. July and 19. July 93. Rotational crops were planted on 19. Oct. 93 (wheat) and 15. April 94 (radish and spinach).

Residues of fluazinam and metabolites were extracted from soil using acidic methanol. An aliquot of the solution was partitioned into an organic solvent and analysed for fluazinam and MAPA by GC with electron-capture-detector. Another aliquot was partitioned for HYPA into an organic solvent and a portion was then methylated. HYPA was also determined by GC with electron-capture-detector. A third aliquot of the extraction mixture was partitioned for CAPA into an organic solvent and methylated using a different method than that for HYPA. Fortification experiments yielded in mean recoveries for fluazinam and the three metabolites of 91-101% (range: 60-140%).

Table B.8.1.4-12: Soil Characteristics

Depth (cm)	Soil texture	% sand	% silt	% clay	% OM	pH (H_2O)	CEC (meq/100g)	% moisture (1/3 bar)
0 - 30.5	Loamy sand	77	20	3	0.7	6.9	11.9	12.0
30.5 - 61	Loamy sand	87	10	3	0.4	7.2	12.3	8.1
61 - 91	Loamy sand	85	12	3	1.0	8.3	12.8	6.5

In the desert region where this study was conducted the 10-year historical average rainfall levels have been measured in Quincy, Washington at only 190 mm/year. During the one-year period following the experimental start date of this study the plots received a total of 160 mm of natural precipitation plus a total of 1135 mm of irrigation.

Table B.8.1.4-13: Summary of the weather conditions

	mean % rel. humidity	mean °C (air)	mean °C (0-15.2 cm soil)	mean wind (m/h)	mm rainfall
June ´93	57	17.4	22	4.8	10.4
July	62	18.1	23	3.7	40
August	53	20	24	3.3	0.0
September	53	16.5	19.7	2.4	1
October	63	11	14.4	2.3	1.3
November	73	-0.3	3.5	3.4	4.6
December	95	0	0.5	2.4	27.4
January ´94	97	1.4	1.4	1.9	28.2
February	85	0.5	1.4	4.1	13
March	59	7.6	7.6	3.5	2.5
April	65	12	15.2	4.4	22
May	59	15.8	20.4	3.7	0.65
June	55	18.2	24	3.7	0.73
July	45	23.5	29.3	3.4	1.3
August	48	21.6	28	3.1	6
September	51	18.5	23.7	2.6	1.3
October	66	9.8	14.4	3.2	24.3
November	85	1.6	4	3.1	21
December	83	-0.5	1.2	3.1	18

Findings:

Residues detected during the study were primarily fluazinam and were found mainly in the 0 - 15.2 cm soil layer. There was only one reportable value of fluazinam below 15.2 cm which was 0.02 mg/kg (one of the three plots). Since there was no appreciable movement downward of fluazinam or any of the metabolites, samples extending 45 cm from the soil surface were not further analysed. Residues of fluazinam generally increased with each application to a maximum mean of 0.46 mg/kg immediately after the last application. The residues then decreased gradually over time. After 527 days no fluazinam at or above the LOQ was detected in any of the plots. The metabolite HYPA was detected sporadically only in the top soil layer and never exceeded 0.02 mg/kg. No MAPA was detected in any of the study samples. With the exception of a detection at 0.01 mg/kg in the 15.2 – 30.4 cm sample from one of the three plots taken on day 420 after the last application, no CAPA was found in any of the samples.

Table B.8.1.4-14: Residues (mean of three plots) of fluazinam and metabolites in soil (0-15.2 cm) after application of 4 x 0.5 ai/ha on beans (in mg/kg dw)

Time point	fluazinam	MAPA	HYPA	CAPA
Post-treatment 1	0.15	Nd	Nd	Nd
Pre-treatment 2	0.07	Nd	0.01*	Nd

Time point	fluazinam	MAPA	HYPA	CAPA
Post-treatment 2	0.20	Nd	Nd	Nd
Pre-treatment 3	0.14	Nd	Nd	Nd
Post-treatment 3	0.23	Nd	Nd	Nd
Pre-treatment 4	0.26	Nd	Nd	Nd
Post-treatment 4 (= day 0)	0.46	Nd	Nd	Nd
3	0.29	Nd	0.01*	Nd
7	0.28	Nd	0.01*	Nd
14	0.21	Nd	Nd	Nd
21	0.15	Nd	Nd	Nd
30	0.12	Nd	Nd	Nd
60	0.21	Nd	Nd	Nd
91	0.07	Nd	Nd	Nd
122	0.06	Nd	0.01*	Nd
182	0.05	Nd	0.02*	
270	0.09	Nd	Nd	
364	Nd	Nd	Nd	
420	0.01	Nd	Nd	
479	0.01	Nd	Nd	
527	nd	Nd	Nd	

*in one of the three replicates only

The degradation pattern of fluazinam appeared to be bi-phasic with faster loss occurring in the earlier stage. A two-compartment model (DFOP) was applied to calculated degradation rates. The calculated DT_{50} value was 9 days. A second statistical model, incorporating the dependence of degradation of fluazinam residues on soil temperature resulted in a DT_{50} of 23 days. Calculated DT_{90} was 241 days. Correlation coefficients are missing.

Conclusions:

The kinetic evaluation of fluazinam dissipation in this study was not accepted by the RMS. The results of this study were not considered in the risk assessment as enough valid European field trials are available. Thus, this study is considered non-essential.

Reference: Crawford, C.J. and Dillon, K.A. (1995b): Dissipation of residues of fluazinam and its metabolites (MAPA, HYPA and CAPA) from soil in North Dakota. (Study 93-0111; Document 5687-93-0111-CR-001)

Guideline: EPA Pesticide Assessment Guideline, 164-1

GLP: Yes

Material and methods:

The objective of this study was to determine the patterns of mobility, degradation and

dissipation of fluazinam and its metabolites MAPA, HYPA and CAPA under field conditions. The study was carried out near Kempton, North Dakota (US), a region which is representative for growing dry beans. Soil was sampled from a field planted to dry beans which received two applications of fluazinam 500 F (batch ASC-66825-0301; 41.1% w/w fluazinam), each equivalent to 1 kg ai/ha (intervals ca. four weeks). The first broadcast application of Fluazinam 500F was made at early emergence of the bean plants. Before and after each application soil was sampled from one untreated and three replicate treated plots down to a depth of 122 cm. After the last application soil was also sampled at eleven different time intervals through 476 DAT. Due to saturated subsoil, cores were taken to only 86 to 99 cm for the 7 and 14 day samples. Due to heavy rainfall, standing water was present on the treated plots and the 3 day samples could not be taken. Frozen ground and snow cover prevented successful sampling for the 180 day and 540 day soils. Beans were planted on 25. May 93, fluazinam applications were made on 24. June and 23. July 93. Rotational crops were planted on 9. Sept. 93 (wheat) and 19. April 94 (lettuce and beets).
The methods for soil extraction and analysis for fluazinam and metabolites were the same as described in the study above. Fortification experiments yielded in mean recoveries for fluazinam and the three metabolites of 93-104% (range: 60-135%).

Table B.8.1.4-15: Soil Characteristics

Depth (cm)	Soil texture	% sand	% silt	% clay	% OM	pH (H_2O)	CEC (meq/100g)	% moisture (1/3 bar)
0 - 30.5	Sandy loam	69	16	15	2.0	7.2	19.0	
30.5 - 61	Sandy loam	69	14	17	0.7	8.4	27.9	
61 - 91	Sandy loam	69	14	17	0.4	8.5	27.2	
91 - 122	Sandy loam	67	18	15	0.3	8.3	26.7	

Table B.8.1.4-16: Summary of the weather conditions

	mean °C (air)	mean °C (soil)	average min - max or overall average % rel. humidity	mean wind (m/h)	precipitation mm
June ´93	19.5	ng	67 - 54	7.7	172
July	18.4	ng	error	6.0	270
August	18.8	ng	55 - 61	6.5	111
September	11.2	ng	96 - 45	7.9	12.7
October	5.2	ng	error	10.0	4
November	-4.4	-2.1	ng	ng	197 (snow)
December	-10.4	-4.0	ng	ng	24.6
January ´94	-21	-6.7	ng	ng	25.4
February	-17.2	-6.9	ng	ng	17.8
March	-1.8	-1.4	ng	ng	10.1
April	ng	ng	ng	ng	ng

	mean °C (air)	mean °C (soil)	average min - max or overall average % rel. humidity	mean wind (m/h)	precipitation mm
May	14.3	ng	61.1	9.6	55.6
June	18.3	ng	74.6	6.5	65.3
July	18.4	ng	81.0	6.2	134
August	17.8	ng	67.3	6.0	138
September	15.0	ng	64.8	6.5	47
October	8.4	ng	67.4	91	75

ng … not given

Findings:

Residues detected during the study were primarily of fluazinam and were found mainly in the 0-15.2 cm soil layer. Taking into account some reanalyses of individual plot samples there was only one reportable value for fluazinam below 15.2 cm (day 31, 15.2-30.5 cm layer). Since there was no appreciable downward movement of fluazinam or any of its metabolites, soil samples extending below 46 cm from the soil surface were not further analysed.
The highest residue of fluazinam was detected on day 7 after the last application at 0.5 mg/kg in the top soil layer. There was considerable rainfall after the last application, preventing sampling at day 3. The rainfall may have washed fluazinam fro the plant leaves causing the overall higher values in the treated plots at day 7 versus day 0. The residues decreased gradually and after 476 days no fluazinam at or above the LOQ (i.e. 0.01 mg/kg) was detected in any of the plots. HYPA was detected at several sample intervals in the top depth samples but did not exceed 0.06 mg/kg soil (single value). CAPA was detected in a single replicate 0-15.2 cm samples from day 21 at 0.02 mg/kg. No MAPA was found in any of the samples (LOQ of the metabolites: 0.01 mg/kg).

Table B.8.1.4-17: Residues (mean of three plots) of fluazinam and metabolites in soil (0-15.2 cm) after application of 2 x 1 kg ai/ha on beans (in mg/kg dw)

Time point	fluazinam	MAPA	HYPA	CAPA
Post-treatment 1	0.24	Nd	Nd	Nd
Pre-treatment 2	0.08	Nd	0.05	Nd
Post-treatment 2 (= day 0)	0.20	Nd	Nd	Nd
7	0.33	0.02*	0.05	Nd
14	0.22	Nd	0.03	Nd
21	0.22	Nd	0.02	0.02*
31	0.17	Nd	0.02	Nd
61	0.07	Nd	Nd	Nd
91	0.06	Nd	Nd	Nd

Time point	fluazinam	MAPA	HYPA	CAPA
118	0.07	Nd	0.01*	Nd
270	0.05	Nd	Nd	Nd
357	0.03	Nd	0.01*	Nd
418	0.02	Nd	Nd	Nd
476	nd	Nd	Nd	Nd

*in one of the three replicates only

On the basis of a single 1st order kinetic model the half-life of fluazinam was calculated to be 49 days.

Conclusions:

A correlation coefficient is missing for the kinetic evaluation of fluazinam dissipation. The results of this study were not considered in the risk assessment as enough valid European field trials are available. Thus, this study is considered non-essential.

Reference: Crawford, C.J. and Dillon, K.A. (1995c): Dissipation of residues of fluazinam and its metabolites (MAPA, HYPA and CAPA) from soil in California. (Study 93-0108; Document 5687-93-0108-CR-001)

Guideline: EPA Pesticide Assessment Guideline, 164-1

GLP: Yes

Material and methods:

The objective of this study was to determine the patterns of mobility, degradation and dissipation of fluazinam and its metabolites MAPA, HYPA and CAPA under field conditions. The study was carried out near Porterville (36° N), California (US), a region which is representative for growing dry beans. Soil was sampled from a field planted to dry beans which received four applications of fluazinam 500 F (batch ASC-66825-0301-0306; 41.1% w/w fluazinam), each equivalent to 0.5 kg ai/ha (nominal) with intervals of ca. four weeks. However, the second application was low (0.31 kg ai/ha) and the fourth was adjusted to make up the difference (0.7 kg ai/ha). Before and after each application, soil was sampled from one untreated and three replicate treated plots down to a depth of 122 cm. After the last application soil was also sampled at eleven different time intervals through 360 DAT. Beans were planted on 28. July 93, fluazinam applications were made on 17. September, 15. October, 12. November and 10. December 93. Rotational crops were planted on 20.-21. January 94 and 13. April 94 (wheat, radish and kale).

Residues of fluazinam and metabolites were extracted from soil using acidic methanol. An aliquot of the solution was partitioned into an organic solvent and analysed for fluazinam and MAPA by GC with electron-capture-detector. Another aliquot was partitioned for HYPA into an organic solvent and a portion was then methylated. HYPA was also determined by GC with electron-capture-detector. A third aliquot of the extraction mixture was partitioned for CAPA into an organic solvent and methylated using a different method than that for HYPA.

Fortification experiments yielded in mean recoveries for fluazinam and the three metabolites of 92-105% (range: 60-135%).

Table B.8.1.4-18: Soil Characteristics

Depth (cm)	Soil texture	% sand	% silt	% clay	% OM	pH (H_2O)	CEC (meq/100g)
0 - 15	Loamy sand	74	22	4	0.9	8.0	9.2
15-30	Loamy sand	80	18	2	0.5	8.2	7.6
30-45.7	Sand	88	10	2	0.3	8.6	5.0
45.7-61	Sand	94	6	0	0.1	8.6	4.1
61-76	Sand	94	4	2	0.1	8.7	3.6
76-91	Sand	92	6	2	0.3	8.8	4.4
91-107	Sand	94	6	0	0.2	8.6	3.0
107-122	Sand	94	6	0	0.2	8.6	3.1

Table B.8.1.4-19: Summary of climatic conditions

	°C average min - max soil temp. (0-5 cm)	mm rainfall + irrigation
September 93	ng	44.4
October	13.3 – 29.4	52.8
November	6.6 – 25	77.2
December	0.5 – 5.6	56.9
January ´94	0.0 – 12.2	115
February	2.2 – 17.2	76.0
March	7.2 – 27.2	102
April	11.7 – 36	79.5
May	13.9 – 35	54.8
June	19.4 – 40.6	88.9
July	27.2 – 43.3	146
August	32.2 – 42.2	178
September	19.4 – 38.9	203
October	13.9 – 30.6	140
November	10.0 – 16.7	88.4
December	6.7 – 13.3	50.3

ng ... not given

Table B.8.1.4-20: Application dates and weather conditions at each application

Date of application	°C air	Wind (m/h)	% cloud cover	% rel. humidity
17.09.93	29.4	2	Clear	30
15.10.93	20.6	0-1	70%	80

12.11.93	18.3	1	clear	74
10.12.93	20.0	none	20%	50

Findings:

Residues detected during the study were primarily of fluazinam and were found mainly in the 0-15 cm soil layer. Taking into account some re-analyses of individual plot samples there were only two reportable values for fluazinam below 15 cm (0.01 mg/kg, which is the LOQ). It was assumed that contamination during sampling took place. Since there was no appreciable downward movement of fluazinam or any of its metabolite, soil samples extending below 46 cm were not further analysed. At day 123 and day 182 no fluazinam or metabolites at or above the LOQ were detected in any of the plots. Therefore samples from remaining intervals were not analysed.

No HYPA or MAPA were detected in any of the study samples. With the exception of a possibly spurious detection at 0.02 mg/kg in the upper soil layer from one of the three plots, taken 13 days after the last application, no CAPA was found in any of the samples.

Table B.8.1.4-21: Residues (mean of three plots) of fluazinam and metabolites in soil (0-15.2 cm) after application of 4 x 0.5 ai/ha on beans (in mg/kg dw)

Time point	fluazinam	MAPA	HYPA	CAPA
Post-treatment 1	0.04	Nd	Nd	Nd
Pre-treatment 2	Nd	Nd	Nd	Nd
Post-treatment 2	0.03	Nd	Nd	Nd
Pre-treatment 3	Nd	Nd	Nd	Nd
Post-treatment 3	0.06	Nd	Nd	Nd
Pre-treatment 4	0.02	Nd	Nd	Nd
Post-treatment 4 (= day 0)	0.19	Nd	Nd	Nd
3	0.12	Nd	Nd	Nd
7	0.08	Nd	Nd	Nd
13	0.08	Nd	Nd	0.02*
21	0.14	Nd	Nd	Nd
31	0.02	Nd	Nd	Nd
63	0.03	Nd	Nd	Nd
92	0.01	Nd	Nd	Nd
123	Nd	Nd	Nd	Nd
182	Nd	Nd	Nd	Nd

*in one of the three replicates only

Residues of fluazinam in the upper soil layer were lower than expected based on the application rate until the final application of the test substance. The dry bean crop canopy probably intercepted some of the residue.

On the basis of a single 1st order kinetic model the half-life of fluazinam was calculated to be

20 days. Due to numerous missing temperature data and other temperature recording difficulties the dependence of the rate constant on soil temperature was not investigated.

Conclusions:

The climatic conditions of the location of the study are not representative for the European Union. Residues of fluazinam immediately after the first application are very low. Kinetic evaluation: According to visual inspection the curve fitting seems to be unacceptable. Correlation coefficients are missing. The study was not accepted by the RMS. Results of this study are not considered in the risk assessment. Thus, this study is regarded as non-essential.

Reference: Crawford, C.J. and Dillon, K.A. (1995d): Dissipation of residues of fluazinam and its metabolites (MAPA, HYPA and CAPA) from soil in Georgia. (Study 93-0104; Document 5687-93-0104-CR-001)

Guideline: EPA Pesticide Assessment Guideline, 164-1

GLP: Yes

Material and methods:

The objective of this study was to determine the patterns of mobility, degradation and dissipation of fluazinam and its metabolites MAPA, HYPA and CAPA under field conditions. The study was carried out near Montezuma (32.3° N), Georgia (US), a region which is representative for growing peanuts. Soil was sampled from a field planted to peanuts which received four applications of fluazinam 500 F (batch ASC-66825-0301-0306; 41.1% w/w fluazinam), each equivalent to 0.5 kg ai/ha (nominal) with intervals of ca. four weeks. Before and after each application soil was sampled from one untreated and three replicate treated plots down to a depth of 122 cm. After the last application soil was also sampled at twelve different time intervals through 419 DAT. Peanuts were planted on 16. May 93, fluazinam applications were made on 15. June, 13. July, 10. August and 9. September 93. Rotational crops were planted on 9. November 93 (wheat, radish and turnip).

Extraction methods and analyses for fluazinam and its metabolites were the same as in the other US studies above. Fortification experiments yielded in mean recoveries for fluazinam and the three metabolites of 88-105% (range: 60-136%).

Table B.8.1.4-22: Soil Characteristics

Depth (cm)	Soil texture	% sand	% silt	% clay	% OM	pH (H_2O)	CEC (meq/100g)
0 - 15	Sandy loam	75.6	16	8.4	1.14	6.5	3.18
15-30	Sandy loam	77.6	12	10.4	0.71	6.5	3.18
30-45.7	Sandy clay loam	69.6	14	16.4	0.22	5.7	3.26
45.7-61	Sandy clay loam	69.6	10	20.4	0.33	5.4	2.85
61-91	Sandy clay loam	63.6	12	24.4	0.16	5.1	3.37
91-122	Sandy clay loam	65.6	10	24.4	0.11	5.0	5.48

Rainfall plus irrigation amounted for 134 mm between the first and the second application, 133 mm between the second and the third application and 62 mm between the third and the fourth application.

Table B.8.1.4-23: Summary of climatic conditions

	°C min and max value in air	°C min and max value in soil (0-10 cm)	% rel. humidity	mm rainfall + irrigation
June 93	17 – 36	26 - 34	29 - 90	121
July	20 – 38	29 - 42	60 - 95	67
August	17 – 38	24 - 41	22 - 96	55
September	8.3 – 36	23 - 36	35 - 96	52
October	2.2 – 31	14 - 30	35 - 96	132
November	-2.2 – 28	7.8 - 22	24 - 97	141

Findings:

Residues detected during the study were primarily of fluazinam and were found mainly in the 0-15.2 cm soil layer. Taking into account some reanalyses of individual plot samples there were only two reportable values for fluazinam below 15.2 cm, both in the 15.2 – 30.5 cm soil layer. One was on day 60 after the last application in one plot (0.02 mg/kg) and the other was in one plot sampled after the first application (0.07 mg/kg). This may have resulted from contamination during sampling.

The metabolite HYPA was detected in only one top depth samples at 0.01 ppm (= LOQ). MAPA was detected at one interval in the 0-15 cm depth samples from two plots also at only 0.01 mg/kg. No CAPA was found in any of the samples.

Table B.8.1.4-24: Residues (mean of three plots) of fluazinam and metabolites in soil (0-15.2 cm) after application of 4 x 0.5 ai/ha on peanuts (in mg/kg dw)

Time point	fluazinam	MAPA	HYPA	CAPA
Post-treatment 1	0.11	Nd	Nd	Nd
Pre-treatment 2	0.02	Nd	Nd	Nd
Post-treatment 2	0.15	Nd	Nd	Nd
Pre-treatment 3	0.05	Nd	Nd	Nd
Post-treatment 3	0.12	Nd	Nd	Nd
Pre-treatment 4	0.07	Nd	Nd	Nd
Post-treatment 4 (= day 0)	0.12	Nd	Nd	Nd
3	0.02	Nd	Nd	Nd
7	0.07	Nd	Nd	Nd

13	0.05	Nd	Nd	Nd
21	0.07	Nd	Nd	Nd
30	0.09	Nd	Nd	Nd
60	0.03	Nd	Nd	Nd
90	0.02	Nd	Nd	Nd
120	Nd	Nd	Nd	Nd
180	0.01	Nd	Nd	Nd
272	Nd	Nd	Nd	Nd
358	Nd	Nd	Nd	Nd
419	Nd	Nd	Nd	Nd

Nd … <0.01 mg/kg (LOQ)

For fluazinam the half life was estimated to be 17 days on the basis of single 1st order kinetics. The early application values were included in the calculations because of the erratic nature of the 0 to 30 day data. The increase in residue form day 7 to day 30 and the higher values than predicted from the calculation at day 60 and day 90 may have been due to late season loading of fluazinam to the soil system from residues on crop detritus. An attempt was made to investigate the dependence of the degradation rate of fluazinam under conditions of this study on soil temperature but no detectable association was identified.

Conclusions:

The climatic conditions of the location of the study are not representative for the European Union. Further, from the measured residue data no reliable degradation rate can be calculated. The study was not accepted by the RMS. Results of this study are not considered in the risk assessment. Thus, this study is regarded as non-essential.

New kinetic calculations considering the European field trials

Reference: Gurney, A. (2005a): Kinetic calculations for degradation of fluazinam in soil under laboratory and field conditions. (Study A07132).

Guideline: GD on Estimating Persistence and Degradation Kinetics form Environmental Fate Studies on Pesticides in EU Registration (Sanco/10058/2005 vers. 1.0)

GLP: Not applicable

Material and methods:

Kinetic calculations were performed with the ModelMaker compartmental modelling software. Half-lives for fluazinam under laboratory and field conditions were calculated according to single 1st order kinetics following guidance from the FOCUS Kinetics Workgroup.

The results of the kinetic calculations for half-lives in soil under field conditions are shown in the table below:

Table B.8.1.4-25: Kinetic analyses for fluazinam in soil under field conditions

Reference	Locations of trial	soil	DT_{50} in orig. study (d)	DT_{90} in orig. study (d)	Recalculated SFO DT_{50} (d)	r^2
Kennedy, S.H (1996)	Cornwall, UK	Clay loam	37	193	35.0	0.881
	Lincolnshire, UK	Sandy clay loam	77	254	40.8	0.816
Burke, S.R.; Sapiets, A. (1992)	Varendorf, D	Loamy sand	15	161	28.0	0.975
	Klein Zecher, D	Sandy loam	6	67	8.3	0.984
	Ottersweier, D	clay	13	144	13.4	0.972
	Sollern, D	Clay loam	11	127	16.2	0.982
Arithm. mean					**23.6**	
Geom. Mean					**20.4**	
Median					**22.1**	

Grey shaded: value used for PEC_{soil} calculations
Remark: The low-level residues detected in the 10-20 cm soil layer in the field dissipation studies were added to the residues in the 0-10 cm layer when calculating degradation rates.

Conclusions:

The calculations were accepted by the RMS.

Additionally a time-step normalisation procedure was used to determine field half-lives at reference temperature suitable for simulation modelling. The procedure was carried out as described in FOCUS (2005).

The equations of the FOCUS PELMO model were used for the time-step normalisation procedure. First, the soil temperature was estimated from the air temperature using the following equation:

$$T_{act} = T_{prev} + (T_{air} - T_{prev}) \times 0.346 \times \exp(-0.027028 \times d)$$

where T_{act} = actual soil temperature (°C)
T_{prev} = soil temperature of previous day (°C)
T_{air} = daily average air temperature (°C)
d = depth of soil compartment (cm)

Fluazinam is strongly adsorbed in soil and therefore a depth of 5 cm was used in the calculations to reflect the fact that most of the compound will remain in the top soil layer.

Day lengths were then corrected based on the soil temperature using the following equations:

$$D_{Norm} = D \times f_{temp}$$

$$f_{temp} = Q_{10} \times \exp(T_{act} - T_0)/10$$

where D_{Norm} = normalised day length (days)
D = 1 d
f_{temp} = correction factor for soil temperature
Q_{10} = 2.2
T_{act} = actual soil temperature (°C)

T_0 = reference soil temperature, i.e. 20° C

The cumulative normalised time intervals between sampling dates were then used in single 1st order kinetic calculations with ModelMaker.

In case of the German field trials daily air temperature data were available. In case of the UK trials only monthly average value were available. Therefore in this case daily values were assumed to be the same as the monthly averages for the purpose of the normalisation calculations.

Results:

Table B.8.1.4-26: Results of kinetic analyses of field studies normalised to 20 °C

Reference	Locations of trial	soil	DT_{50} (d) field Standard kinetic calculations	DT_{50} (d) field Normalised (20°C) kinetic calculations	r^2
Kennedy, S.H (1996)	Cornwall, UK	Clay loam	35.0	23.8	0.882
	Lincolnshire, UK	Sandy clay loam	40.8	25.7	0.820
Burke, S.R.; Sapiets, A. (1992)	Varendorf, D	Loamy sand	28.0	20.8	0.961
	Klein Zecher, D	Sandy loam	8.3	8.4	0.990
	Ottersweier, D	clay	13.4	13.5	0.967
	Sollern, D	Clay loam	16.2	13.6	0.983
Arithm. mean			23.6	**17.6**	
Geom. Mean			20.4	**16.4**	
Median			22.1	**17.2**	

Grey shaded: value used for PEC_{GW} calculations ($FOCUS_{GW}$ modelling)

Conclusions:

Calculations accepted by the RMS

B.8.1.5 Summary

Table B.8.1.5-1: Summary of degradation and metabolism of fluazinam in soil

Type of study	test item	concen-tration	soil	temp.	Degradation rates (single 1st order kinetics)	major metabolites	reference/ study acceptable
Laboratory aerobic	[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] fluazinam	1 kg/ha	Sandy loam	20°C	Phenyl: DT_{50}: 96.4 * DT_{90}: 320 Pyridyl: DT_{50}: 63.3 DT_{90}: 210	HYPA max. 8.2% AR (day 14)	Bharti & Bewick 1985/yes
		5 kg/ha		20 °C	Phenyl: DT_{50}: 174 * DT_{90}: 578 Pyridyl: DT_{50}: 171	HYPA max. 11.4 % (day 30)	

Type of study	test item	concen-tration	soil	temp.	Degradation rates (single 1st order kinetics)	major metabolites	reference/ study acceptable
					DT_{90}: 568		
		1 kg/ha		10 °C	Not enough datapoints for calcul., therefore Arrh. equ. (Q_{10}: 2.2) → Phenyl: DT_{50}: 212 * Pyridyl: DT_{50}: 139	HYPA max. 7.8% AR (day 60)	
Aerobic sterile				20 °C	Almost no degradation	none	
Laboratory anaerobic (flooding on day 0)				20 ° C	Phenyl: DT_{50}: 3.8 * DT_{90}: 12.6 Pyridyl: DT_{50}: 3.9 DT_{90}: 12.8	MAPA max. 31.2% (day 14) DAPA max. 12% (day 90) HYPA max. 7.2% (day 60)	
Laboratory aerobic			Loamy sand	20 °C	Phenyl: DT_{50}: 263 * DT_{90}: 873 Pyridyl: DT_{50}: 189 DT_{90}: 628	HYPA max. 5.9% (day 7)	
		0.74 kg /ha	Sandy loam	20 ° C	Mixture of the two labels: Fluazinam: DT_{50}: 17 HYPA: DT_{50}: 105	HYPA max. 13.9% (day 48)	Mawad 2003/yes
	Fluazinam unlabelled	0.56 kg/ha	Sandy soil	20 °C	DT_{50}: 61.8	Metabolism not investigated	Ryan & Sapiets 1992/yes
	HYPA unlabelled	0.16 mg/kg	Sand	20 °C	DT_{50}: 148 DT_{90}: 490	Metabolism not investigated	van der Gaauw 2002/yes
			Loamy sand		DT_{50}: 77 DT_{90}: 245		
			Clay loam		DT_{50}: 54 DT_{90}: 179		
Photolysis	[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] fluazinam	3.5 mg/kg	Loamy sand	25 °C	Dark / light * Phenyl: DT_{50}: 71.5 / 21.5 DT_{90}: 238 / 71.5 Pyridyl: DT_{50}: 68 / 19.6 DT_{90}: 226 / 65	HYPA max. 6.8% (day 28)	Lentz & Korsch 2001/yes
Field (UK)	Shirlan 50 SC	10 x 0.3 kg ai/ha (bare ground)	Clay loam	16 months duration	DT_{50}: 35.0 normalised 20°C: 23.8	HYPA max. 0.09 mg/kg dw	Kennedy 1996/yes
			Sandy clay loam		DT_{50}: 40.8 normalised 20°C: 25.7	HYPA max. 0.09 mg/kg dw	
Field (Germany)	50 % w/v SC formulation	1.35 kg ai/ha (bare soil)	Loamy sand	12 months duration	DT_{50}: 28.0 normalised 20°C: 20.8	HYPA <0.01 mg/kg dw	Burke & Sapiets 1992/yes
			Sandy loam		DT_{50}: 8.3 normalised 20°C: 8.4	HYPA max. 0.01 mg/kg dw	
			Clay		DT_{50}: 13.4 normalised 20°C: 13.5	HYPA <0.01 mg/kg dw	
			Clay loam		DT_{50}: 16.2 normalised 20°C: 13.6	HYPA max. 0.02 mg/kg dw	

* recalculated values of the RMS

Fluazinam is metabolised by microbial activity. The main metabolic pathway is the formation of bound residues, which were found in amounts of up to 47.2 % of applied radioactivity after 180 days in laboratory studies under standard conditions. Metabolites which would indicate cleavage of the bridging amino group were not observed. Mineralization (formation of CO_2) amounted for up to 6 % applied radioactivity after one year under standard conditions. Under aerobic conditions HYPA was the major metabolite which is formed by hydrolysis of the phenyl ring chlorine of fluazinam to a hydroxyl group. The maximum amount found in laboratory studies under standard conditions was 13.9 % AR, after 48 days of incubation. MAPA and DAPA, which are formed by reduction of one or both NO_2 groups, respectively, on the phenyl ring of fluazinam, were found in minor amounts.
Under anaerobic conditions MAPA and DAPA were the major metabolites, whereas HYPA was found only in minor amounts. Degradation of fluazinam is accelerated and formation of NER is enhanced under anaerobic conditions but mineralization (CO_2 formation) seems lower.

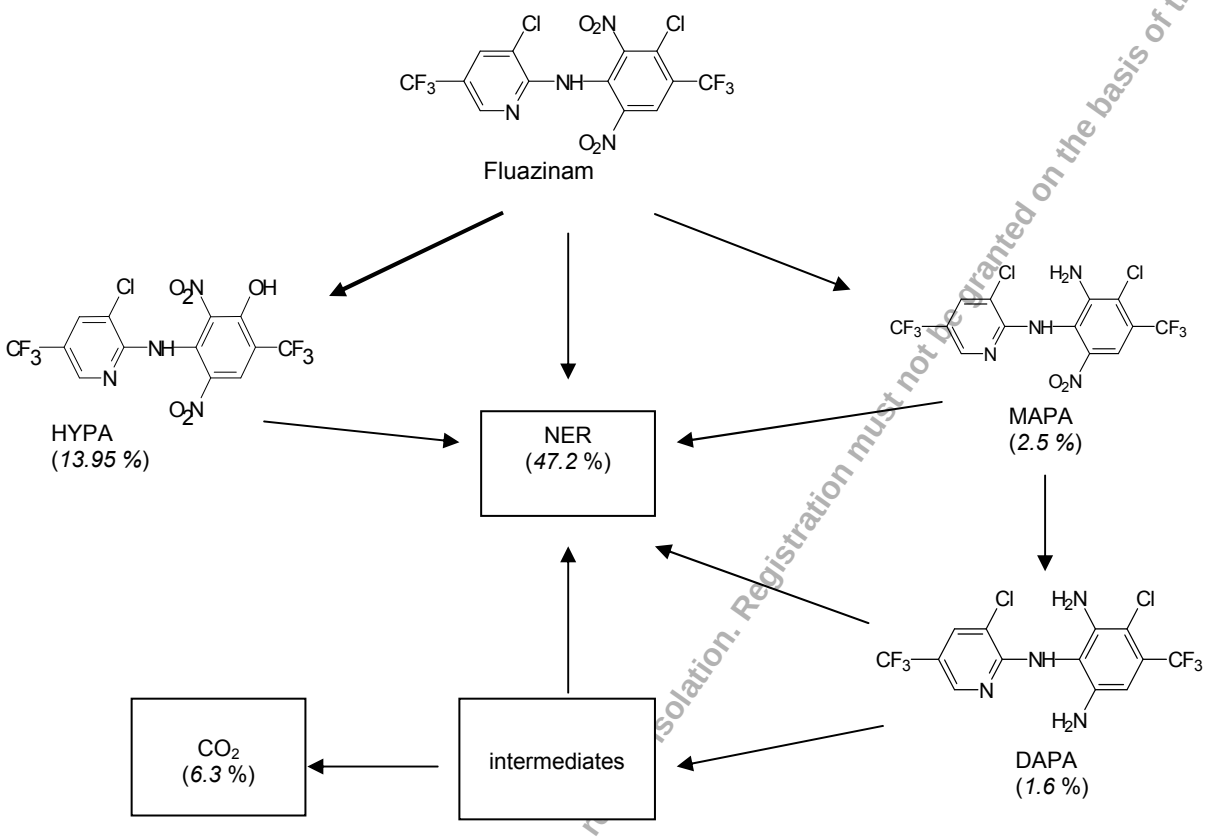


Figure B.8.1.5-1: Proposed metabolic pathway of fluazinam in aerobic soil (values in brackets: maximum amounts reached in laboratory studies)

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

B.8.2.1 Adsorption and desorption

B.8.2.1.1 Adsorption and desorption of the active substance

Reference: Galicia, H. and Völkl, S. (1991): Soil adsorption/desorption of fluazinam (IKF-1216) on four soils. (RCC project no. 282306)

Guideline: OECD Guideline 106 (1981) and EPA Subdiv. N (1982)

GLP: Yes

Material and methods:

Adsorption and desorption of nitrophenyl-labelled ^{14}C-fluazinam (batch 89-48; 129.0 µCi/mg spec. radioactivity, purity 97.9%) was determined in four different soils. Results of a pre-test showed that the adsorption of fluazinam reached an equilibrium within 2 hours. Solubility tests indicated that a maximum of about 1.0 mg/L of the test substance was soluble in an aqueous solution. Based on this, the chosen test concentrations were 1.0, 0.5, 0.1 and 0.05 mg/L. A ratio of 1:5 (w/w) of soil to aqueous phase (0.01 M $CaCl_2$) was chosen.

As reference material and if necessary for dilution of the radioactive substance, unlabelled fluazinam was used (batch LOT 8303-2).

For eight additional vessels (set up for the highest test concentration) a mass balance was

performed. In addition the aqueous phases of these samples were analysed by TLC to determine the amount of parent molecule remaining in the aqueous phase.
Two desorption cycles were carried out by shaking soil samples after decantation of the aqueous phases for 16 hours with untreated $CaCl_2$-solution.
Radioactivity in soil samples were measured by combustion and LSC. TLC analyses were carried out with two solvent systems, hexane/diethyl ether and chloroform/ethyl acetate.
A correction factor was included in the calculations with the Freundlich adsorption equation to account for the loss or adsorption to the walls of the centrifugation tubes which was determined for each soil separately. Based on the recoveries resulting from the mass balances, the correction factor was calculated from the difference of the recovery of radioactivity in soils and aqueous phases and the amount of radioactivity initially applied. The correction factors were 17.8%, 3.1%, 5.7% and 0% for soils I to IV, respectively. All calculations are based on corrected amounts applied.

Table B.8.2.1.1-1: Soil Characteristics

Soil (USDA classif.)	% sand	% silt	% clay	% OC	pH *	CEC (meq/100g)
I sand Speyer 2.1	88.0	4.8	7.2	0.48	6.0	3.6
II loamy sand Speyer 2.2	78.8	12.4	8.8	2.55	6.0	7.2
III silt loam Itingen II	24.4	52.2	23.4	1.42	7.7	27.9
IV clay loam Diegten	24.8	37.2	38.0	2.0	7.1	23.4

*method not stated

Findings:
The Freundlich adsorption constants obtained are reported in the table below. These constants were shown to be a linear function with respect to the organic carbon content of the soils.
The equilibrium amounts (in % AR, mean of duplicate samples) for soils I to IV determined in the aqueous phase were 13.4%, 3.7%, 6.1% and 3.9%, respectively. The adsorbed amounts of the four soils were 68.8%, 93.3%, 88.2% and 105.5%, respectively. Considering the soil-water systems (without the amount of radioactivity adsorbed to the vessel walls), between 82.2% and 109.4% of the radioactivity applied was recovered. The total desorbed amounts in the four soils ranged from 10.5% to 15.2% of the initially adsorbed radioactivity for soil I, for soil II from 2.5% to 3.6%, for soil III from 4.3% to 4.7% and for soil IV from 2.8% to 3.9%.
TLC analyses of the radioactivity in the aqueous phase for the four soil-water systems showed that after 2 hours of equilibrium time, besides fluazinam two unknown metabolites were detected in amounts not exceeding 2.3% AR. In soil III an additional unknown

metabolite represented 0.3% AR. The amount of fluazinam present in the aqueous phases reached 10.7%, 2.0%, 3.7% and 1.9% AR on soils I to IV, respectively.

Table B.8.2.1.1-2: Calculated adsorption constants

soil	K_f (mL/g)	1/n	Correlation coefficient	% OC	K_{foc} (mL/g)
I sand Speyer 2.1	11.12	0.6204	0.9903	0.48	2 316
II loamy sand Speyer 2.2	43.48	0.6813	0.9953	2.55	1 705
III silt loam Itingen II	27.19	0.6504	0.9928	1.42	1 915
IV clay loam Diegten	37.88	0.6492	0.9938	2.0	1 894
Arithmetic mean:					**1 958**
Geometric mean:					**1 945**

Grey shaded: used for PEC_{GW} modelling

Table B.8.2.1.1-3: Calculated desorption constants (1st desorption step)

soil	K_f (mL/g)	1/n	Correlation coefficient	% OC	K_{foc} (mL/g)
I sand Speyer 2.1	33.64	0.876	0.9979	0.48	7 008
II loamy sand Speyer 2.2	506.5	1.109	0.9997	2.55	19 863
III silt loam Itingen II	130.5	0.948	0.9992	1.42	9 192
IV clay loam Diegten	368.7	1.087	0.9984	2.0	18 433

Conclusions:

Fluazinam shows low mobility in batch equilibrium studies. The calculated K_{OC} values were in the range of 1 705 to 2 316 mL/g. The results obtained indicate that a large percentage of fluazinam is irreversibly adsorbed onto soils with different properties. Increasing adsorption (K_f) was observed with increasing organic matter content. The adsorption constants were calculated on the basis of mass concentrations.

B.8.2.1.2 Adsorption and desorption of relevant metabolites, degradation and reaction products

Reference: Muller, K. and Lane, M.C.G. (1993): Fluazinam: Adsorption and desorption properties in soil of R270682 ("HYPA"), a major soil metabolite. (Report RJ 1308B)
Guideline: OECD guideline no. 106 (1981)
GLP: Yes
Material and methods:
The adsorption and desorption properties of phenyl labelled ^{14}C-"HYPA" (purity >99%, 1.86 Gbq mmol^{-1} specific activity) were studied in six soils of four textural classes. To inhibit degradation of the compound all soils were sterilised by gamma irradiation prior to use. Results of a pre-test showed that the adsorption of HYPA reached an equilibrium within 6 hours. The test compound was added to soil : water slurries at five rates of application: 0.8, 2.0, 4.0 and 20.0 and 100.0 mg/kg soil. A soil : water (0.01 M $CaCl_2$) ratio of 1:20 was chosen due to the relatively high adsorption of HYPA to soil. The study was carried out on all six soils with a 24-hour adsorption step followed by a single desorption step over the same period. Samples were also generated as treatment controls to determine if the chemical adsorbed to the tubes. The radioactivity in soil samples was determined by combustion and LSC, TLC analyses were carried out after extraction of the soils three times with acetonitrile. LSC and TLC analyses were also carried out with samples of the aqueous phase (supernatants). A mass balance was calculated from all the analytical results of the representative samples.

Table B.8.2.1.2-1: Soil Characteristics

Soil (USDA classif.)	% sand	% silt	% clay	% OM (% OC)	pH (water)	CEC (meq/100g)	MHC 1/3 bar (% moisture content)
Sandy loam "Kenny Hill" UK	78	8	14	5.3 (3.1)	7.7	9.5	12.6
Sandy loam "East Anglia" UK	78	9	13	3.2 (1.9)	8.1	5.4	11.8
Loamy sand "Gayton" UK	83	5	12	3.1 (1.8)	7.9	10.3	9.9
Coarse sand "Lilly field" UK	90	4	6	0.8 (0.5)	5.7	2.1	3.3
Silty clay loam "Nebo" UK	19	53	28	2.5 (1.5)	5.0	17.5	29.0
Sandy loam "Salmonds bridge" UK	59	24	17	2.7 (1.6)	4.7	9.9	16.1

Findings:
Recoveries of radioactivity from various samples assessed ranged from 87 to 103% (average 95%) of that nominally applied. TLC analysis of the aqueous and soil extracts from

the soil : water slurries after the adsorption and desorption stages identified only “HYPA” and a small amount (<8.2%) of ^{14}C-labelled material entrained on the baseline of the silica plates. This demonstrated that there had been little or no degradation of “HYPA” during the equilibration period. Results are summarised in the tables below:

Table B.8.2.1.2-2: Calculated adsorption constants

soil	K_f (mL/g)	1/n	Correlation coefficient	% OM	pH	K_{foc} (mL/g)
“Kenny Hill”	14	not stated	>0.99	5.3	7.7	450
“East Anglia”	13	0.84	>0.99	3.2	8.1	700
“Gayton”	8.1	not stated	>0.99	3.1	7.9	450
“Lilly field”	4.3	not stated	>0.99	0.8	5.7	920
“Nebo”	19	0.75	>0.99	2.5	5.0	1 300
“Salmonds bridge”	26	not stated	>0.99	2.7	4.7	1 700
Arithmetic mean (considering all soils):						**920***
Arithmetic mean (considering only the first 4 soils):						**630****
Geometric mean:						**813**
Median:						**810**

Grey shaded: used for PEC_{GW} modelling:
*: $FOCUS_{GW}$ modelling done by the notifier
**: $FOCUS_{GW}$ modelling done by the RMS

Table B.8.2.1.2-3: Calculated desorption constants

soil	1/n	% OM	pH	K_{OC} (mL/g)
“Kenny Hill”	not stated	5.3	7.7	620
“East Anglia”	not stated	3.2	8.1	610
“Gayton”	not stated	3.1	7.9	1 100
“Lilly field”	not stated	0.8	5.7	3 100
“Nebo”	not stated	2.5	5.0	1 900
“Salmonds bridge”	not stated	2.7	4.7	2 200

Adsorption of “HYPA” appeared to be strong in all soils. Average K_d values in the six soil ranged from 6.6 (“Lilly field”) to 51 (“Salmonds bridge”).The results indicated that adsorption is related to soil organic matter content. K_{OC} values indicate that adsorption of “HYPA” to organic matter increased with decreasing pH. The pKa for the “HYPA” has been determined to be 2.9. This would suggest that in the more acidic soils in this study increasing proportions of the compound would be in the associated form and this state being more hydrophobic is likely to be more strongly adsorbed to soil organic matter.

In alls six soils the adsorption K_d values decreased with increasing rate of application of

"HYPA". This is probably due to some saturation of the stronger adsorption site. However, at no concentration did further adsorption cease, even at the highest rate of application. The three acidic soil showed the least linearity.

Data indicate that adsorption of "HYPA" to soil is not completely reversible. The average percentage of adsorbed test substance desorbed across all the applied rate in each soil range from 25 to 48%.

Conclusions:

"HYPA" shows medium to low mobility in batch equilibrium studies. The calculated K_{OC} values were in the range of 450 to 1 700 mL/g. In acidic soils higher K_{OC} values were observed compared to alkaline soils.

B.8.2.2 Mobility in the soil

B.8.2.2.1 Column leaching studies

Reference: Burke, S.R. and Clarke, D.M. (1992): Fluazinam: Leaching of formulated material in soil columns. (Report RJ 1234B)

Guideline: BBA Guideline part IV, 4-2

GLP: Yes

Material and methods:

The mobility of fluazinam, formulated as a suspension concentrate (formulation YF7604B, 50SC; 37.7% w/w fluazinam) was determined by leaching in 30 cm soil columns (5 cm i.d.). The columns were uniformly packed with air-dried 1 mm sieved soils. Triplicate columns containing each soil type were prepared, two of which were to be treated with fluazinam and a third as an untreated control. Fluazinam was applied at a rate equivalent to 750 g ai/ha to the saturated soil columns and eluted with 393 cm^3 of deionised water, which is equivalent to 200 mm of rainfall, within 48 hours at 20 ± 2° C.

An aliquot of the leachate was adsorbed onto empore filter discs and eluted with ethyl acetate. Final quantitative determination was by HPLC using UV-detection. The limit of determination was 2 µg/L of leachate.

Table B.8.2.2.1-1: Soil Characteristics

Soil (USDA classif.)	% sand	% silt	% clay	% OM	pH (water)	CEC (meq/100g)
Speyer 2.1 sand	89	7	4	1.4	5.4	3.5
Speyer 2.2 loamy sand	84	11	5	5.1	5.7	8.2
Speyer 2.3 sandy loam	71	18	11	2.5	6.7	8.3

Findings:

From the application of fluazinam at a rate equivalent to 750 g ai/ha on sand, loamy sand and sandy loam soils residues of fluazinam in the leachates were below the LOD (i.e. <2

µg/L). Therefore less than 2% of that applied leached through the soil columns.

Conclusions:

According to the results of the column leaching study it is unlikely that normal agricultural use of fluazinam will result in significant contamination of ground water.

B.8.2.2.2 Lysimeter studies

Fluazinam shows strong adsorption to soil with a mean K_{OC} of 1958 L/kg. For "HYPA", the major metabolite of fluazinam in soil, the mean K_{OC} value is 920 L/kg. Results of a column leaching study showed low tendency of fluazinam to leach. Lysimeter or field leaching studies are not required.

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

Reference: McFadden, J.J. (2003): Terrestrial and aquatic PEC values for fluazinam (IKF-1216) and risk assessment for the use on potato in the EU. (Document no. 014891-1).

Guideline: none stated

GLP: Not applicable

Material and methods:

This report provides a review of the environmental fate of fluazinam, predicted environmental concentration of fluazinam in soil, groundwater and surface water and potential risk to non-target organisms in the environment.

Conclusions:

This study was accepted by the RMS only in part.

Some of the degradation rates of fluazinam which were taken as basis for PEC calculations were considered not valid. For PEC_{SOIL} calculations mean degradation rates and adsorption parameters were used instead of worst case values.

However, new PEC calculations have been provided. See the respective sections below.

Reference: Gurney, A. (2005): Kinetic calculations for degradation of fluazinam in soil under laboratory and field conditions. (Study A07132).

Guideline: GD on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration (Sanco/10058/2005 vers. 1.0)

GLP: Not applicable

Material and methods:

In this study also new PECsoil calculations were presented. The assumptions made for these calculations were as follows:

Table B.8.3-1: Input parameters for the PECS calculations for Fluazinam and HYPA

FLUAZINAM	
Application:	10 x 200 g ai/ha
Minimum spray interval:	7 days
Crop:	Potatoes
Growth stage at last treatment:	BBCH 95-97
Plant interception:	50% – 80%
Soil bulk density:	1.5 kg/L
Mixing depth:	5 cm
Half-life in soil:	40.8 days (worst case value from field dissipation studies)
HYPA	
Maximum formation of metabolite:	13.9% (from laboratory studies with the parent)
Half-life in soil:	148 days (worst case value from laboratory studies with HYPA)

For the PECsoil calculations degradation rates of fluazinam derived from European field dissipation studies were used (Germany and UK). The four field trials conducted at different locations in the USA were not considered as they showed a lot of deficiencies (see particular study). Thus they were considered as not essential for the evaluation process of fluazinam.

Results:

Table B.8.3-2: Predicted initial concentrations of fluazinam in soil (mg/kg)

Application no.	Days after first applic.	Application rate (g ai/ha)	BBCH growth stage	Crop interception	PEC_{SOIL} after application
1	0	200	20-39	50 %	0.133
2	7	200	20-39	50 %	0.252
3	14	200	40-89	80 %	0.277
4	21	200	40-89	80%	0.299
5	28	200	40-89	80 %	0.319
6	35	200	40-89	80%	0.336
7	42	200	40-89	80 %	0.352
8	49	200	40-89	80%	0.366
9	56	200	90-99	50 %	0.458
10	63	200	90-99	50 %	**0.540**

Grey shaded: Value used for risk assessment (soil organisms)

Table B.8.3-3: Predicted actual and time-weighted average concentrations of fluazinam in soil

PEC_{SOIL} fluazinam (mg/kg dry soil) Half-life 40.8 d		Single application 200 g ai/ha actual	Single application 200 g ai/ha TWA	Multiple application 10 x 200 g ai/ha (after last application) actual	Multiple application 10 x 200 g ai/ha (after last application) TWA
Initial		0.133	-	0.540	-
Short term	**24 h**	0.131	0.132	0.531	0.536
	2 d	0.129	0.131	0.522	0.531
	4 d	0.125	0.129	0.505	0.522
Long term	**7 d**	0.118	0.126	0.480	0.509
	21 d	0.093	0.112	0.378	0.454
	28 d	0.083	0.106	0.336	0.430
	50 d	0.057	0.090	0.231	0.364
	100 d	0.024	0.064	0.099	0.260
	365 d	<0.001	0.021	0.001	0.087

Table B.8.3-4: Predicted actual and time-weighted average concentrations of HYPA in soil

PECSOIL HYPA (mg/kg dry soil) Half-life 148 d formation 13.9 %		Single application 200 g ai/ha actual	Single application 200 g ai/ha TWA	Multiple application 10 x 200 g ai/ha Actual (after last application)	Multiple application 10 x 200 g ai/ha TWA (after last application)
Initial		0.018	-	0.114	-
Short term	**24 h**	0.018	0.018	0.113	0.114
	2 d	0.018	0.018	0.113	0.113
	4 d	0.017	0.018	0.112	0.113
Long term	**7 d**	0.017	0.018	0.110	0.112
	28 d	0.016	0.017	0.100	0.107
	50 d	0.014	0.016	0.090	0.102
	100 d	0.011	0.014	0.071	0.091
	365 d	0.003	0.009	0.021	0.055

Grey shaded: Value used for risk assessment (soil organisms)

For soil metabolite HYPA an environmental plateau concentration in soil was calculated by the RMS. Assuming a worst case DT_{50} of 148 days, incorporation into 5 cm soil, a soil density of 1.5 g/cm^3 and ten applications per year a plateau level of 0.107 mg/kg soil was reached after 3 years.

Conclusions:

The maximum concentration of fluazinam in soil after ten applications was calculated to be

0.54 mg/kg (dw). For the main soil metabolite HYPA a maximum of 0.114 mg/kg was calculated after ten applications of 200 g fluazinam/ha on potatoes.
For HYPA a theoretical environmental plateau concentration of 0.107 mg/kg soil is reached after 3 years if fluazinam is applied according to the GAP (RMS calculations).
Remark: The calculations are considered acceptable by the RMS

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

B.8.4.1 Abiotic degradation

B.8.4.1.1 Hydrolysis

Hydrolysis of active substance

Reference: Flude, D. (1985): B-1216: Hydrolysis at pH 5, pH 7 and pH 9 at 22 °C (Report RJ O383B).

Guideline: not stated

GLP: no

Test item: ^{14}C-IKF-1216-B[^{14}C-Phenyl] Fluazinam, radiochemical purity: >98.4%, batch no.: not stated and ^{14}C-IKF-1216-Py[2,6-^{14}C-Pyridine] Fluazinam, radiochemical purity: >98.4%, batch no.: not stated

Material and methods:

The rate of hydrolysis of ^{14}C-fluazinam (test concentration ~ 0.005 mg/L) was investigated in sterile aqueous buffer solutions at pH 5, 7 and 9 at 22°C in the dark. One flask of each pH and radiolabel was taken at 0, 5, 10, 20 and 28 days and analysed by LSC (determine total radioactivity) and HPLC (determine amounts of ^{14}C-fluzinam and possible hydrolysis products)

Findings:

Table 8.4.1.1-1: Percentage of fluazinam and metabolite CAPA at various sampling times.

Sampling time [d]	[^{14}C-Phenyl] fluazinam						[2,6-^{14}C-Pyridine] fluazinam					
	pH 5		pH 7		pH 9		pH 5		pH 7		pH 9	
	ai	CAPA	ai	CAPA	ai	CAPA	ai	CAPA	ai	CAPA	ai	CAPA
0	95	0	87	0	88	4	97	0	93	0	-**	
5	-*		86	7	57	35	95	0	92	4	57	37
10	97	0	77	16	32	64	98	0	91	8	27	64
20	90	0	65	29	12	84	98	0	-*		12	85
28	92	0	63	34	13	81	95	0	-*		6	84

-* = Samples were microbially contaminated.
-** = Not quantified

Assuming a first order reaction kinetic the half-life of fluazinam was estimated. Calculations are based on mean values of both labels.

Table 8.4.1.1-2: Half-life of fluazinam

	pH 5	pH 7	pH 9
DT50 [d]	stable	42	5.6
Correlation factor	-	-0.96	-0.98

Conclusion:

At pH 5 (temperature 22 °C) fluazinam is hydrolytically stable. However with increasing pH values a hydrolytic degradation of fluazinam was noted: at pH 5 DT_{50} = 42 d and at pH 9 DT_{50} = 5.6 d. One major degradation product was identified as CAPA.

Comment (RMS): The study was performed without GLP and the study design was not in accordance with current guidelines, therefore the study was considered not acceptable.

Reference: van der Gaauw, A. (2003): ^{14}C-Fluazinam: Hydrolysis at Three Different pH Values. (RCC study no. 846211)

Guideline: OECD 111; 92/69/EEC part C.7; EPA OPPTS 835.2110; SETAC (Europe) Part 9

GLP: yes

Test item: [^{14}C-Phenyl] Fluazinam, radiochemical purity: 100%, batch no.: 96-J29; [2,6-^{14}C-Pyridine] Fluazinam, radiochemical purity: 97.7%, batch no.: 96J30

Material and methods:

The abiotic hydrolysis of ^{14}C-labelled fluazinam (concentration: 0.04 – 0.05 mg/L) was investigated in sterile aqueous buffer solutions at pH 4, 7 and 9. Incubation at pH 4 was performed at 50 °C for up to 5 days, whereas for pH 7 and 9 it was conducted at 25°C and 50°C for up to 29 or 56 days. During the incubation time periodically, the pH of each buffer solution was recorded and test samples were taken and analysed by LSC (total radioactivity), HPLC and TLC (radioactive fractions).

Findings:

All test solutions remained sterile and no significant variation of temperature and pH value was observed throughout the study. Mean recoveries of total radioactivity for both labels were between 95.8 ± 5.0 % (pH 4, 50°C) and 103.6 ± 2.4 % (pH 7, 50°C).

At pH 4 fluazinam was not degraded by hydrolysis. After 5 days at 50 °C, mainly unchanged parent was found for both labels in respective test samples.

At pH 7, fluazinam was rapidly hydrolyzed. CAPA was the only hydrolysis product formed at 25 °C, representing 92.3% (label I) and 95.1% (label II) of the applied radioactivity after 29 days. At 50 °C the major metabolite CAPA was steadily hydrolyzed to DCPA with a DT_{50} value of about 32 days. At the end of incubation DCPA was found in amounts of 70.9 % (label I, day 56) and 38 % (label II day 28) of the applied radioactivity. DCPA was resistant to further degradation. For both labels, an additional minor hydrolysis product was detected at a maximum level of 5 % on day 29.

At pH 9, hydrolysis of fluazinam was similarly rapid comparable to that at pH 7. CAPA was again the major hydrolysis product formed at 25 °C, representing 94.0% (label I) and 102.6% (label II) of the applied radioactivity at the end of incubation (day 29). At 50 °C CAPA was steadily hydrolyzed to DCPA with a DT_{50} value of about 8 days. DCPA represented 95.5% and 95.4% of the applied radioactivity for labels I and II, respectively, at day 29. No further degradation of this major metabolite was observed.

Table 8.4.1.1-3: Balance and distribution of radioactivity in the buffer solutions (in % AR) at 25 °C (phenyl label/pyridyl label)

days	fluazinam	CAPA	total	days	fluazinam	CAPA	DCPA	total
		pH 7				pH 9		
0	94.0 / 100.0	Nd / nd	94.0 / 100.0	**0**	97.4 / 100.0	2.6 / nd	Nd	100.0 / 100.0
2	55.5 / -	38.9 / -	94.4 / -	**1**	77.2 / 88.6	23.9 / 12.2	Nd	101.1 / 100.9
5	40.9 / 27.5	57.6 / 72.3	98.5 / 99.9	**2**	69.5 / -	30.6 / -	Nd	100.1 / -
10 / 15	31.4 / 5.2	64.5 / 94.5	96.0 / 99.6	**5**	36.8 / 39.7	63.0 / 62.0	Nd	99.8 / 101.7
20	3.1 / -	93.9 / -	96.9 / -	**20 / 15**	4.3 / 6.5	96.5 / 94.7	Nd	100.8 / 101.2
29	5.8 / 6.1	92.3 / 95.1	98.1 / 101.2	**29**	2.7 / nd	94.0 / 102.6	5.5	102.2 / 102.6

By applying first-order reaction kinetics, the rate of hydrolysis of fluazinam for pH 7 and 9 at 25°C and 50°C, as well as the rate of hydrolysis of CAPA at 50 °C was calculated. The experimental data obtained were analyzed by non-linear regression using the program MicroCal Origin (v 3.5). The results of DT_{50} and DT_{90} values are shown at table 8.4.1.1-3.

Table 8.4.1.1-4: DT50 and DT90 for fluazinam and its metabolite CAPA

	pH 4	pH 7		pH 9	
	50 °C	25 °C	50 °C	25 °C	50 °C
[^{14}C-Phenyl] Fluazinam					
DT_{50} [d]	stable	4.5	0.1	3.5	0.2
DT_{90}		14.8	0.4	11.6	0.6
r^2	-	0.970	0.997	0.997	0.995
[2.6-^{14}C-Pyridine] Fluazinam					
DT_{50}	stable	2.7	0.2	3.9	0.1
DT_{90}		9.1	0.6	13.0	0.3
r^2	-	0.996	0.994	0.998	0.999
CAPA					
DT_{50}	stable	-	31.7	-	7.7
DT_{90}		-	105.3	-	25.7
r^2	-	-	0.997	-	0.999

Conclusion:

Under acid conditions (pH 4) fluazinam is stable to hydrolysis at 25 °C. Under more neutral and alkaline conditions fluazinam is rapidly hydrolysed with DT_{50} values between 2.7 and 4.5 d (pH 7) and 3.5 to 3.9 d (pH 9) to form metabolite CAPA. At 50 °C CAPA is steadily hydrolysed to DCPA. This degradation product was shown to be stable to hydrolysis. Half lives of CAPA at 50 °C were estimated to be 31.7 d (pH 7) and 7.7 d (pH 9).

Comment (RMS): Study considered acceptable.

B.8.4.1.2 Photolysis

Photochemical Degradation of active substance

Reference: Lentz, N.R. and Korsch, B.H. (1995): A Photolysis Study of IKF-1216 (Fluazinam) in Water at pH 5 (Final Report; Document no 5312-94-0119-EF-002) and Lentz, N.R. and Korsch, B.H. (1994): A Photolysis Study of IKF-1216 (Fluazinam) in Water at pH 5 (Part 1, interim report); (Report no. 5312-94-0119-EF-001)

Guideline: U.S. EPA, Subdivision N, 161-2.

GLP: yes, with the exception that the NMR analyses performed at the University of Akron were not done under GLP.

Test item: ^{14}C-IKF-1216-B [^{14}C-Phenyl] Fluazinam, radiochemical purity > 99 %, batch no.: 0571; ^{14}C-IKF-1216-Py [2,6-^{14}C-Pyridine] Fluazinam, radiochemical purity > 97 %, batch no.: 0696

Material and methods:

The direct photolytic degradation of [^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] labelled fluazinam (0.049 µg/mL) was investigated in sterile aqueous buffer solution at pH 5. Test samples were exposed to simulated sunlight (xenon arc light) under 12-hour light/ 12-hour dark cycle for up to 30 days. The temperature was maintained at 25 ± 1 °C during the study. At appropriate sample intervals, light exposed and dark control samples were analysed by radio-HPLC and LSC. Additionally for the identification of degradation products analyses by HPLC, LC/MS and NMR were conducted. Calculations of half life and rate constant were performed with linear regression analyses by the computer program Excel.

Findings:

Results of dark controls: Mean recovery: 93.5 % and 93.7 %. No significant degradation of test substance was noted.

Table 8.4.1.2-1: Distribution of [14C-Phenyl] Fluazinam and its degradation products (≥ 10 %) expressed as % of AR in light exposed samples

day	IKF-1216	polars	fraction 15-18	G-504	CO_2	recovery
0	96.6	0.2	0.7	0.3	-	98.9
1	63.8	1.7	12.0	9.8	-	95.2
3	36.0	6.9	20.2	15.2	-	89.9
5	14.8	16.7	25.2	16.3	-	85.6

day	IKF-1216	polars	fraction 15-18	G-504	CO_2	recovery
7	8.7	18.3	25.7	14.6	3.0	80.9
10	6.1	21.8	23.9	17.1	3.7	82.5
14	1.9	33.9	20.4	12.4	6.4	83.8
21	1.7	33.3	18.8	9.7	13.0	85.2
28	1.0	38.2	17.4	8.9	17.7	90.4
30	0.9	37.2	17.2	6.4	17.7	85.5

Polars: Multi-component water soluble mixture with different chemical behaviour depending on label position. No individual component accounting for > 10 % AR.
Fraction 15-18: No single component exceeds 10 % of AR.

Table 8.4.1.2-2: Distribution of [2,6-14C-Pyridine] Fluazinam and its degradation products (≥ 10 %) expressed as % of AR in light exposed samples

day	IKF-1216	polars	fraction 15-18	G-504	CO_2	recovery
0	99.0	0.3	0.4	0.3	-	101.3
1	65.0	3.4	12.2	6.2	-	96.4
3	40.0	8.8	20.4	11.6	-	92.1
5	25.6	13.6	23.7	12.9	-	88.7
7	10.6	18.8	25.2	14.0	7.1	88.3
10	6.2	22.9	24.1	12.1	9.3	87.2
14	1.7	30.7	20.2	9.0	12.2	83.5
21	1.6	31.5	19.7	7.9	14.0	83.9
28	0.7	37.9	17.7	4.8	16.0	84.2
30	0.9	37.0	18.8	6.3	16.0	87.1

Polars: Multi-component water soluble mixture with different chemical behaviour depending on label position. No individual component accounting for > 10 % AR.
Fraction 15-18: No single component exceeds 10 % of AR.

Identified minor metabolites: AMPA (max. 4.1 % after 10 days) and HYPA (amounts not stated)

Summary of photolytic degradation steps:

- Reduction and hydrolysis of NO_2, Cl and CF_3 substituents
- Cleavage between phenyl and pyridine ring
- Ring opening leading to complex mixtures of polar compounds
- Oxidative fragmentation with CO_2 production (from both labels)

Table 8.4.1.2-3: Calculted DT50 and rate constante of [14C-Phenyl] and [2,6-14C-Pyridine] Fluazinam

test substance	DT50 [d]	k [d^{-1}]	r^2
[^{14}C-Phenyl] Fluazinam	2.5	-0.2728	0.977

[2,6-^{14}C-Pyridine] Fluazinam	2.5	-0.2827	0.994

Conclusion:

[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] labelled fluazinam was rapidly degraded during aqueous photolysis at pH 5 (sterile buffer) and 25 °C. The half life was calculated to be 2.5 d for both labels. Multitude of photolytic degradation products results from a complex degradation pathway with reduction and hydrolysis of NO_2, Cl and CF_3 substituents, the cleavage between the ring systems, ring opening and oxidative fragmentation with CO_2 production. The only major metabolites for both labels are G-504 (max. 17.1 % after 10 days) and CO_2 (max. 17.7 % at day 30).

Comment (RMS):

The recoveries in this study from day 5 onwards are low (81 % – 88 % AR). However, the RMS considers the data sufficient to clarify the metabolic pathway of fluazinam under the influence of light. Thus the study is considered sufficient for further risk assessment.

B.8.4.2 Biological degradation

B.8.4.2.1 Ready biodegradability

Reference: Grützner, I. (2000): Ready Biodegradability of Fluazinam in a Manometric Respirometry Test. Report No. 774898

Guideline: OECD 301F; EU EEC, C.4-D

GLP: yes

Test item: Fluazinam, purity of 98.4%, batch no.: A629/1995

Material and methods:

The ready biodegradability of fluazinam was studied in a “28-Day-Manometric Respirometry Test”. 100 mg/L of the test substance was dissolved in test water (purified water and stock solutions of mineral components, adjusted to pH 7.4) and than inoculum (activated sludge from a water treatment plant with a final concentration of 30 mg dry material per litre) was added. Fluazinam was tested in duplicates. Additionally two inoculum controls (without test substance), two procedure controls (with reference substance sodium benzoate), an abiotic (without inoculum and poisoned with mercury dichloride) and a toxicity control (with test and reference substance) were prepared. All test flasks were incubated in the dark for 28 days at 22 °C with continuous stirring. The oxygen consumption, temperature and the pH were recorded at appropriate time intervals. The percent biodegradation of test substance was calculated as ratio of BOD (biochemical oxygen demand of test item) to $ThOD_{NH4\ or\ NO3}$ (theoretical oxygen demand of test item without or with nitrification) x 100.

Findings:

Abiotic control: No significant degradation of test substance.

Toxicity control: After 14 days the biodegradation rate was 63 % based on $ThOD_{NH4}$ and

50 % based on $ThOD_{NO3}$, thus the test substance had no inhibitory effect on activated sludge micro organisms.

Procedure control: After 28 days the biodegradation rate was 95 % based on ThOD.

Inoculum control: After 28 days the BOD in the test flasks was 7 and 18 mg O_2/L (arithmetic mean 12.5 mg O_2/L).

Test substance: After 28 days the BOD in the test flasks was 12 and 14 mg O_2/L (arithmetic mean 13 mg O_2/L). The biodegradation rate was 1 % based on $ThOD_{NH4}$ and 0 % based on $ThOD_{NO3}$. Therefore fluazinam is not ready biodegradable.

Conclusion: Fluazinam is not readily biodegradable under test conditions within 28 days.

Comment (RMS): Study considered acceptable.

B.8.4.2.2 Water/Sediment Study

Aerobic water/sediment study

Reference: Goodyear, A. (1997): ^{14}C-Fluazinam: Biodegradation in Natural Water-Sediment Systems. Report No. 38/188-1015

Guideline: BBA Guidelines, Part IV, Section 5-1; proposed UK Guidelines for the Conduct of Biodegradability Tests on Pesticides in Natural Sediment-Water Systems (1992)

GLP: yes

Test item: [^{14}C-Phenyl] Fluazinam, radiochemical purity > 98 %, batch no.: 89-48P2; [2,6-^{14}C-Pyridine] Fluazinam, radiochemical purity > 98 %, batch no.: 84-J15P2

Material and methods:

The aerobic aquatic metabolism and degradation of [^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] labelled fluazinam were studied in two water-sediment systems. Approx. 0.032 mg test substance (field application rate ~ 200 g/ha) per test vessels were applied and were incubated at 20°C under aerobic conditions in darkness for up to 100 days.

The sediment with associated water was sampled at two sites in natural environment:

System 1: „Virgina water“, Chatsworth, Derbyshire, UK

System 2: „Emperor Lake“, Windsor Berkshire, UK

The characterisations of both systems are given in table B.8.4.2.2-1.

After sampling a 2.5 cm sediment layer was filled into each incubation vessel (borosilicate glass cylinders with ca. 4.5 cm diameter) and covered with 6 cm depth of associated water. Test vessels were acclimatised to test conditions up to 75 d („Emperor Lake“) and 76 d („Virginia water“). All test units were gently shaken by an orbital shaker and moistened air was passed over water surface. During the acclimatisation period oxygen content and redoxpotential were monitored until test systems were considered as equilibrated. Then the test substance was applied drop wise onto the water surface of each vessels. The effluent air from each incubation unit was passed through a series of traps (one ethanediol trap, one 2 % paraffin in xylene trap, two 0.1 M sodium hydroxide traps) to collect volatile degradation products. One sample per label position was taken for analysis after 0, 6, 24 and 48 hours

and 7, 14, 30, 61 and 100 days. The dissolved radioactivity of samples was analysed by HPLC and TLC. Additionally pH, redoxpotential and oxygen content were measured at these sampling times. Non-extractable residues in the sediment (from day 30 and 100 sampling intervals) were characterised by extraction with 0.5 M sodium hydroxide. Further acid hydrolysis and fractionation of soil organic matter into humic- and fulvic acids were performed.

Table B.8.4.2.2-1: Physical and chemical properties of the two test systems:

Parameter	System 1: „Virginia Water“	System 2: „Emperor Lake“
Water		
Temperature* (below surface) [°C]	9	4.7
pH*	6.9	5.6
O_2-concentration [%]* at surface/5cm above sediment	79.3	96
total hardness [mg/L as $CaCO_3$] **	134/205	71/52
DOC [mg C/L]**	23.7/29.4	16.6/20.3
total nitrogen [mg/L]**	15.4/4.2	<0.1/2.1
total phosphorous [mg/L]**	0.2/0.7	0.1/0.6
Sediment		
pH*	6.6	5.8
C_{org} [%]	3.3	4.3
total nitrogen [%]	0.2	0.2
total phosphorus [mg/kg]	480	560
cation exchange capacity [meq/100 g soil]	9.7	10.0
biomass [µg C/g]**	442/171	371/223
texture (BBA) particle size distribution: sand [%]: silt [%]: clay [%]:	slightly loamy sand 88 5 7	medium loamy sandy 75 16 9

* parameter was measured at the time of sampling
** parameter was measured at start and end of the study

Findings:

The two systems did not differ significantly in their texture, C_{org}-content and microbial biomass.

It was stated in the study that the metabolic pathway of phenyl and pyridyl labelled fluazinam was similar, thus results from both treatments were combined and expressed as mean values in table B.8.4.2.2-2. Only degradation products which exceeded 10 % of applied radioactivity are mentioned in the table below. Minor metabolites identified are not mentioned in table B.8.4.2.2-2.

Table B.8.4.2.2-2: Radioactivity distribution, partitioning and balance of fluazinam (results in % of applied radioactivity) during the degradation in water- and sediment phase within the "Virginia water" and "Emperor Lake" system

System 1: "Virginia water" (loamy sand)											
day	**water**	**EXT.R-sed.**	**NER**	**CO_2**	**Total**	**ai water**	**ai sed.**	**AMPA water**	**AMPA sed.**	**xx* water**	**xx* sed**
0	67.3	30.6	1.0	-	99.1	67.0	18.0	nd	7.0		1.4
0.25	69.4	27.1	1.2	nd	99.2	68.9	13.8	nd	7.7		1.3
1	62.5	32.1	2.9	nd	99.5	59.2	12.8	nd	10.7		1.8
2	36.5	50.0	6.4	nd	96.9	34.0	21.5	nd	14.4	2.9	3.8
7	22.2	48.6	16.9	nd	94.6	11.4	6.5	1.4	19.4	2.3	7.2
14	7.6	48.8	30.1	0.2	96.0	0.5	1.7	1.7	21.9	2.6	13.2
30	3.3	37.3	47.2	0.4	94.3	0.2	1.3	0.5	9.9	3.1	15.0
61	3.3	28.9	49.4	1.2	88.5	1.0	7.3	0.4	5.5	1.7	9.4
100	2.0	27.4	55.1	2.0	91.1	-	1.7	-	8.7	0.9	10.7
System 2: "Emperor Lake" (sandy loam)											
day	**water**	**EXT.R-sed.**	**NER**	**CO_2**	**Total**	**ai water**	**ai sed.**	**AMPA water**	**AMPA sed.**	**xx* water**	**xx* sed**
0	68.5	27.4	2.5	-	98.4	67.7	18.4	nd	4.6		1.1
0.25	65.4	31.1	2.0	nd	98.5	63.9	19.8	nd	5.2		1.8
1	46.8	45.7	4.9	nd	97.5	43.5	28.2	nd	8.1	0.5	2.5
2	42.9	48.5	7.2	nd	98.8	36.4	32.4	nd	7.2	1.8	2.5
7	31.2	43.9	19.0	nd	94.1	20.2	13.8	0.3	15.7	0.6	7.4
14	18.9	42.6	33.5	0.1	95.9	6.2	7.9	0.6	14.3	1.7	11.3
30	14.7	37.9	42.8	0.4	96.1	2.7	13.6	0.4	7.1	3.1	10.5
61	8.5	27.4	55.3	1.7	93.1	0.4	3.9	0.1	6.0	2.3	10.5
100	7.2	21.9	54.3	2.2	85.8	-	2.1	-	2.5	-	12.2

EXT.R-sed: extractable residues in sediment
NER: non extractable residues in sediment
nd: not detected
xx*: total unknowns, mixture of several polar compounds where individual substance did not exceed 2 % AR

Table B.8.4.2.2-3: Maximum concentrations (results in % AR from HPLC analyses) of metabolites HYPA, DAPA, MAPA and AMPA in water and sediment phase within the "Virginia water" (system1) and "Emperor Lake" (system 2)

metabolite	system	Label position	water		sediment	
			max [%]	time [d]	max [%]	time [d]
Minor metabolites						
HYPA	**1**	pyridyl	3.2	7	2.7	7
		phenyl	4.0	7	3.2	14
	2	pyridyl	5.1	14	3.6	30

metabolite	system	Label position	water max [%]	water time [d]	sediment max [%]	sediment time [d]
		phenyl	5.2	7	2.7	30
DAPA	1	pyridyl	4.5	7	7.0	7
		phenyl	1.0	7	9.2	7
	2	pyridyl	0.3	30	1.0	100
		phenyl	1.0	14	2.0	14
MAPA	1	pyridyl	0.2	7, 14	5.2	2
		phenyl	0.6	14	4.3	7
	2	pyridyl	0.1	14	3.0	7
		phenyl	0.1	14	7.2	7
Major metabolite						
AMPA	1	pyridyl	1.9	7	20.2	2
		phenyl	2.5	14	26.7	14
	2	pyridyl	0.9	14	12.7	14
		phenyl	0.4	14	18.9	7

Route of degradation:

Under aerobic aquatic conditions fluazinam was converted to a mixture of at least four metabolites by hydrolysis of the phenyl ring chlorine to a hydroxyl group (HYPA) and reduction of one or both nitro groups (AMPA, MAPA and DAPA). Further degradation products were mainly bound as non-extractable residue to sediment. The mineralization to CO_2 was very low.

Characterisation of NER:

Table B.8.4.2.2-4: Fractionation of NER in sediment, results expressed as mean values of both labels

sample	humin	humic acid	fulvic acid	fulvic acid DCM phase	fulvic acid aqu. phase
system 1, 30 d	35.8	8.9	2.6	0.3	2.4
system 1, 100 d	36.8	1.6	16.7	0.3	16.9
system 2, 30 d	31.1	7.4	4.5	0.5	4.1
system 2, 100 d	36.1	8.6	9.6	1.0	8.3

Half-life calculation:

Table B.8.4.2.2-5: Disappearance times of fluazinam from "Virginia water" and "Emperor Lake" water/sediment systems calculated with Timme & Frehse degradation model (square root 1st order regression)

system	water DT_{50} [d]	water DT_{90} [d]	total system DT_{50} [d]	total system DT_{90} [d]
"Virginia water"	0.8 (r^2: 0.72)	9.2 (r^2: 0.72)	2.9 (r^2: 0.68)	32.1 (r^2: 0.68)
"Emperor lake"	1.2 (r^2: 0.95)	12.7 (r^2: 0.95)	3.2 (r^2: 0.96)	35.4 (r^2: 0.96)

The RMS calculated the degradation rates of the two label positions separately on the basis of single 1st order kinetics. Degradation was calculated starting with the respective highest value observed in the sediments. Formation was not considered. The results are as follows:

FLUAZINAM:

"Virginia" water		phenyl label	pyridyl label	average both labels
	DT_{50}	1.93 d	2.85 d	2.4 d
	DT_{90}	6.41 d	9.47 d	7.9 d
	r^2	0.969	0.986	
"Emperor" water		phenyl label	pyridyl label	
	DT_{50}	1.84 d	4.25 d	3.0 d
	DT_{90}	6.12 d	14.1 d	10.1 d
	r^2	0.942	0.982	
"Virginia" sediment		phenyl label	pyridyl label	
	DT_{50}	2.42 d	3.35 d	2.9 d
	DT_{90}	8.03 d	11.1 d	9.6 d
	r^2	0.969	0.944	
"Emperor" sediment		phenyl label	pyridyl label	
	DT_{50}	6.41 d	9.5 d	7.9 d
	DT_{90}	21.3 d	31.5 d	26.4 d
	r^2	0.76	0.77	
"Virginia"		phenyl label	pyridyl label	
whole system	DT_{50}	3.3 d	2.93 d	3.1 d
	DT_{90}	10.9 d	9.72 d	10.3 d
	r^2	0.996	0.977	
"Emperor"		phenyl label	pyridyl label	
whole system	DT_{50}	5.23 d	6.2 d	5.7 d
	DT_{90}	17.36 d	20.58 d	19.0 d
	r^2	0.956	0.983	

AMPA:

"Emperor" sediment		phenyl label	pyridyl label	
	DT_{50}	24.0 d	43.7 d	33.9 d
	DT_{90}	79.8 d	145.2 d	112.5 d
	r^2	0.954	0.906	

Conclusions:

In this study dissipation half lives for fluazinam of about 1 day from the water phase and 3 days from the whole system were calculated by the method of Timme and Frehse. Recalculated half life values (calculated by the RMS) were in the range of 1.84 and 4.25 days for the water phase. For the whole systems recalculated (RMS) single 1st order DT_{50} values were in the range of 2.9 to 6.2 days. Fluazinam was degraded to a mixture of four identified metabolites: HYPA was formed by the hydrolysis of the phenyl ring chlorine to a

hydroxyl group. AMPA, MAPA and DAPA were formed by reduction of one or both nitro groups. Only AMPA was reported as major metabolite with amounts of max. 21.9 % AR (i.e. maximum mean of both labels; system 1, day 14) in sediment. Other identified metabolites were found with short peak levels of up to ≤ 8.1 % AR (mean of both labels) and were considered as minor (not relevant) by the RMS. The main dissipation process was the binding of degradation products to non-extractable residue in sediment. The mineralization to CO_2 was very low.

Comments (RMS):

The study offered following deficiencies:

- The two tested sediments (both with coarse texture and high organic carbon content) do not differ significantly from each other in texture, C_{org}-content and microbial biomass. Further they do not represent the "worst case water/sediment system" for dissipation of test substance from water. This case would be represented by a sediment with coarse texture plus low organic carbon content.
- Only one sample per sampling time and test series and label position (^{14}C-phenyl and ^{14}C-pyridyl label) was analysed, recommend are replicates for analysis.
- DT_{50} calculations are based on the method of Timme & Frehse, but data produced by this degradation model are not appropriate as input parameter for FOCUS Surface Water calculations. Square root 1st order regression analyses with only 4 data points were used. Recalculations on the basis of single 1st order kinetics were done by the RMS.

Study was considered acceptable. For details of the selection of input parameters for PEC_{SW} calculations and handling of the shortcomings of the study see chapter B.8.6.1.

B.8.4.3 Summary and Assessment

Table B.8.4.3-1 Summary of fate and behaviour of fluazinam in water.

Type of study	test item	concen-tration	matrix	temp.	half-life	major metabolite	reference/ study acceptable
Hydrolysis	[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] fluazinam	0.005 mg/L	aqueous buffer solution: pH 5, 7, 9	22 °C	pH 5: stable pH 7: 42 d pH 9: 5.6 d	CAPA	Flude 1985/no
	[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] fluazinam	0.04 – 0.05 mg/L	sterile aqueous buffer solution: pH 4, 7, 9	25 °C	[^{14}C-Phenyl]/[2,6-^{14}C-Pyridine] ai: pH 7: 4.5/2.7 d pH 9: 3.5/3.9 d	CAPA	van der Gaauw 2003/yes
				50 °C	^{14}C-Phenyl]/[2,6-^{14}C-Pyridine] ai: pH 4: stable pH 7: 0.1/0.2 d pH 9: 0.2/0.1 d CAPA: pH 7: 31.7 d pH 9: 7.7 d DCPA: stable	CAPA DCPA	
Photolysis	[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] fluazinam	0.049 mg/L	sterile aqueous buffer solution: pH 5	25 °C	both labels: 2.5 d	G-504, CO_2	Lentz & Kosch 1995/yes

Type of study	test item	concen-tration	matrix	temp.	half-life	major metabolite	reference/ study acceptable
Ready biodegradability	fluazinam	100 mg/L	test solution according OECD 301F (pH 7.4) + inoculum (activated sludge)	22 °C	biodegradation rate: 1 % (based on $ThOD_{NH4}$)→ not readily biodegradable		Grützner 2000/yes
Water/Sediment Study	[^{14}C-Phenyl] and [2,6-^{14}C-Pyridine] fluazinam	application rate: 200 g/ha	water/sediment aerobic condition, S1: loamy sand, C_{oeg}: 3.3 % S2: sandy loam, C_{oeg}: 3.4 %	20 °C	Fluazinam * S1 water phenyl: 1.93 d pyridyl: 2.85 d sediment phenyl: 2.42 d pyridyl: 3.35 d S2 water phenyl: 1.84 d pyridyl: 4.25 d sediment phenyl: 6.4 d pyridyl: 9.5 d	AMPA Sediment: phenyl: 26.7% (day 14) pyridyl: 20.2% (day 2)	Goodyear 1997/yes

* recalculated by the RMS

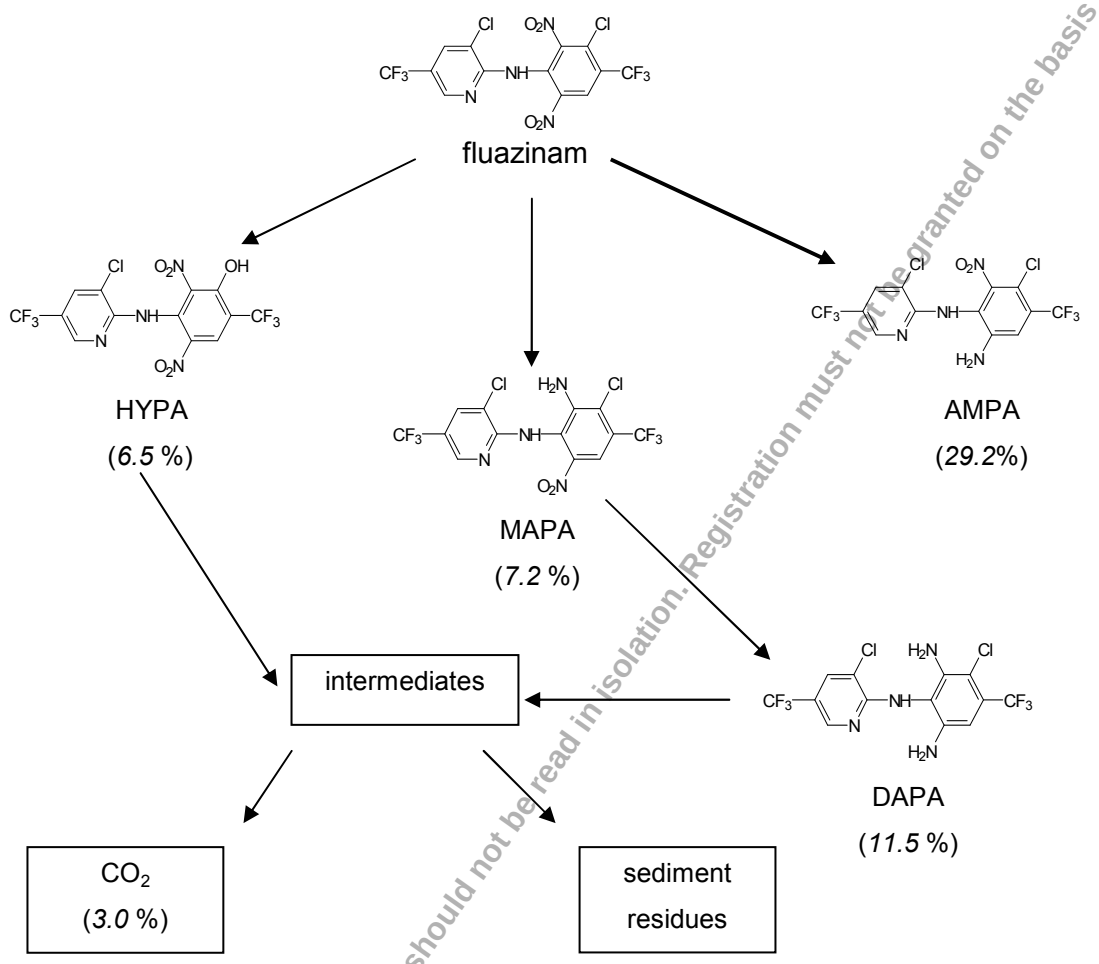


Figure B.8.4.3-1: Proposed metabolic pathway of fluazinam in water/sediment systems
(*values in bracketc: maxima observed in the whole system for a single label position*)

B.8.5 Impact on water treatment procedures (Annex IIIA 9.2.2)

In a test with activated sludge from a wastewater treatment system an EC_{50} of 118 mg ai/L was observed. The inhibitory effect of fluazinam on *Pseudomonas putida* was low, with an observed EC_{50} of >1.53 mg ai/L. The water solublility of fluazinam is 0.135 mg/L at pH 7. It is considered very unlikely that fluazinam will enter water treatment plants in amounts that will lead to effects on water treatment procdures, when fluazinam is applied according to the GAP.

B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{sw}, PEC_{gw}) (Annex IIIA 9.2.1, 9.2.3)

B.8.6.1 Predicted environmental concentrations in surface water (PEC_{SW})

Reference: McFadden, J.J. (2003): Terrestrial and aquatic PEC values for fluazinam (IKF-1216) and risk assessment for the use on potato in the EU. (Document no. 014891-1).

Guideline: none stated

GLP: Not applicable

Material and methods:

This report provides a review of the environmental fate of fluazinam, predicted environmental concentration of fluazinam in soil, groundwater and surface water and potential risk to non-target organisms in the environment.

Conclusions:

This study was accepted by the RMS only in part.

Some of the degradation rates of fluazinam which were taken as basis for PEC calculations were considered not valid. For PEC_{SOIL} calculations mean degradation rates and adsorption parameters were used instead of worst case values.

In the water/sediment study the "Emperor Lake" data for AMPA allowed calculation of a DT_{50} for AMPA using 5 consecutively declining data points from day 7 to day 100. Water/sediment combined data (different label positions were combined too) were used for the calculation. A simple linear exponential decay was assumed (rate of formation was not considered) and resulted in a DT_{50} value of 32 days (r^2: 0.945).

However, new PEC calculations have been provided. See new study below.

Reference: Görge, G. (2005): Estimation of the environmental concentrations of fluazinam and its metabolite AMPA in surface water. (RCC study no. A17267)

Guideline: "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC"; SANCO/4802/2001

GLP: Not applicable

Material and methods:

Predicted concentrations in surface water were determined using FOCUS Surface Water calculations. Initial screening calculations were performed for fluazinam and AMPA using the FOCUS Step 1 and 2 calculator. Additional calculations were performed at Step 3 for parent fluazinam, using the six FOCUS scenarios specified for potato cropping. A total of eight applications (maximum possible in SWASH) were considered in all scenarios except in scenarios D6 (Thiva) and R2 (Porto) for which 6 applications were considered due to the shorter cropping period. In addition, single applications of 200 g /ha were simulated for each scenario.

The following parameters were used for modelling:

Table B.8.6.1-1: Inputparameters used for FOCUS surface water modelling

Application:	10 x 200 g ai/ha
Application date:	June – September (FOCUS step 1 and 2)
Interception:	50 % average (FOCUS step 1 and 2)
Crop:	Potatoes
Foliar extraction coefficient:	0.0160 x (solubility)$^{0.3832}$ (wash off factor from crop = 0.01/cm)
Plant uptake factor	0.5
	FLUAZINAM
Molecular weight (g/mol)	465.1
Half-life 20 °C (d):	Soil: 16.4 (geom. mean of normalised field half-lives)
	Water: 3.1
	Sediment: 12.1
Half life on crop	0.1 days *
K_{foc} (mL/g):	1 958 (mean value)
1/n	0.9 (default)
Vapour pressure (Pa at 20 °C):	7.5 x 10^{-3}
Solubility in water (mg/L at 20 °C):	0.135
	AMPA
Molecular weight (g/mol)	435.1
Half-life 20 °C (d):	Soil: 95 (arithm. mean of HYPA laboratory half-lives)
	Water: 32
	Sediment: 32
K_{foc} (mL/g):	920 (mean of HYPA values)
Solubility in water (mg/L at 20 °C):	0.14
Max. occurrence (% AR):	Soil: 2.2
	Water/sediment: 23.7

* From foliar dislodgeabel residue study (Kenyon, 2001) – see section B.6.14.3.1

Metabolite AMPA was assumed to occur in soil at the same maximum percentage as its isomer MAPA, i.e. 2.2 %, and the average soil DT_{50} and K_{FOC} were assumed to be equal to those of the major soil metabolite HYPA, 95 days and 920 days, respectively.

In the water /sediment study fluazinam disappeared from the water phase with DT_{50} values between 1.84 days and 4.25 days (single 1st order kinetic, calculated by the RMS). Fluazinam labelled at the pyridyl ring side showed a little slower disappearance. Taking the arithmetic mean of this worse case label position (two water/sediment systems) yields in a mean of 3.6 days. The mean of all DT_{50} values (both labels) is 2.7 days. In the FOCUS calculations submitted the mean value of the whole system half lives from the original study

(i.e. 3.1 days) was used. These half lives have been calculated in the original study by the method of Timme and Frehse and had not been accepted by the RMS. The overall mean half-life for the whole system is 4.4 days when calculated on the basis of single 1st order kinetics (calculated by the RMS). However, the mean half life of fluazinam in the water phase was calculated to be 2.7 days when taking the recalculated values of the RMS on the basis of single 1st order kinetics. Taking only the worse label position the mean value is 3.6 days. Therefore the modelling input parameter of 3.1 days for disappearance time from the water phase was accepted by the RMS.

Dissipation of fluazinam from sediment was fitted using simple 1st order kinetics following the peak measured values at 2 days. Dissipation rates in sediment were calculated using a simple compartmental model (ModelMaker). The results of the two different label positions in the original study were averaged as well as the results from TLC and HPLC analyses. DT_{50} values of 3.0 days (r^2 = 0.905; "Virginia sediment") and 12.1 days (r^2 = 0.726; "Emperor sediment") were calculated. The worst case value of 12.1 days was used for $FOCUS_{SW}$ calculations.

AMPA was the only major metabolite found in the two water/sediment test systems with an average (label positions) maximum value of 23.7 % AR in the sediment (only very low levels in the water phase). The data of the pond system ("Emperor lake") allowed calculation of a degradation rate resulting in a DT_{50} of 32 days (McFadden, J.J. (2003); study above). This rather conservative value was used for the degradation rate in both the water and sediment phases as input parameters for $FOCUS_{SW}$ calculations. This value was accepted by the RMS.

Table B.8.6.1-2: Application and cropping data used for the FOCUS calculations (step 3)

Scenario	Location	Number of applications	Day of 1st application	Day of last application
D3 ditch	Vredepeel	8	14/6	1/9
D4 pond	Skousbo	8	24/6	11/9
D4 stream	Skousbo	8	24/6	11/9
D6 ditch (1st) *	Thiva	6	3/5	7/7
R1 pond	Weiherbach	8	8/6	25/8
R1 stream	Weiherbach	8	8/6	25/8
R2 stream	Porto	6	5/4	23/6
R3 stream	Bologna	8	23/5	10/8

*only the 1st of two possible cultivation periods was taken into account for the modelling since this is the more important one from an agronomical point of view due to highest disease pressure during that time

It is stated that even though the GAP includes up to ten applications, it is considered that acute and chronic risk are not significantly affected by consideration of the maximum eight applications in SWASH. This was also supported by the course of PEC in water where the maximum peak concentration was either similar after each application or reached even clearly before the latest (8th) application. With regard to PEC in sediment this is not true for

the scenarios D3 and D4. However, the maximum concentrations in these scenarios are clearly lower than the overall maximum PEC_{sed} that was found in scenario R1/stream subsequent to the 2nd application.

Results:

A detailed presentation of the results of the FOCUS calculations is given in the tables below:

- Step 1 calculations:

Table B.8.6.1-3a: Actual concentrations in surface water: Step 1

Region /Rate	Compound	PEC Surface Water (µg L^{-1}) (Days after loading)										
		0	1	2	4	7	14	21	28	42	50	100
N. & S. EU	Fluazinam	203	152	121	77.6	39.7	8.29	1.73	0.36	0.02	<0.01	0.00
10 x 200 g/ha	AMPA	10.2	7.82	7.66	7.33	6.87	5.90	5.07	4.36	3.22	2.71	0.92

Table B.8.6.1-3b: Time-weighted average concentrations in surface water: Step 1

Region /Rate	Compound	TWAEC Surface Water (µg L^{-1}) (Days after loading)									
		1	2	4	7	14	21	28	42	50	100
N. & S. EU	Fluazinam	177	157	127	96.9	58.5	40.4	30.5	20.4	17.1	8.56
10 x 200 g/ha	AMPA	9.03	8.39	7.94	7.58	6.98	6.48	6.03	5.28	4.90	3.28

Table B.8.6.1-4a: Actual concentrations in sediment: Step 1

Region /Rate	Compound	PEC Sediment (µg kg^{-1} dry weight) (Days after loading)										
		0	1	2	4	7	14	21	28	42	50	100
N. & S. EU	Fluazinam	3620	2970	2380	1520	777	162	33.9	7.10	0.31	0.05	0.00
10 x 200 g/ha	AMPA	56.7	72.0	70.4	67.4	63.2	54.3	46.7	40.1	29.6	24.9	8.43

Table B.8.6.1-4b: Time-weighted average concentrations in sediment: Step 1

Region /Rate	Compound	TWAEC Sediment (µg kg^{-1} dry weight) (Period in days after loading)									
		1	2	4	7	14	21	28	42	50	100
N. & S. EU	Fluazinam	3290	2980	2450	1870	1130	782	591	395	332	166
10 x 200 g/ha	AMPA	64.3	67.8	68.3	67.0	62.8	58.7	54.8	48.1	44.7	30.0

- Step 2 calculations:

Table B.8.6.1-5a: Actual concentrations in surface water: Step 2

Region /Rate	Compound	PEC Surface Water (µg L^{-1}) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
N. EU	Fluazinam	6.13	4.87	4.40	3.60	2.66	1.32	0.65	0.32	0.08	0.04	0.00
10 x 200 g/ha	AMPA	1.11	0.97	0.95	0.91	0.85	0.73	0.63	0.54	0.40	0.34	0.11
S. EU	Fluazinam	9.02	7.17	6.49	5.30	3.92	1.94	0.96	0.47	0.12	0.05	0.00

10 x 200 g/ha	**AMPA**	1.35	1.21	1.18	1.13	1.06	0.91	0.78	0.67	0.50	0.42	0.14

Table B.8.6.1-5b: Time-weighted average concentrations in surface water: Step 2

Region /Rate	Compound	TWAEC Surface Water (µg L^{-1}) (Period in days after global maximum									
		1	**2**	**4**	**7**	**14**	**21**	**28**	**42**	**50**	**100**
N. EU	**Fluazinam**	5.50	5.07	4.53	3.92	2.92	2.26	1.81	1.26	1.07	0.54
10 x 200 g/ha	**AMPA**	1.04	1.00	0.96	0.93	0.86	0.80	0.75	0.65	0.61	0.41
S. EU	**Fluazinam**	8.10	7.46	6.67	5.78	4.30	3.33	2.67	1.86	1.58	0.79
10 x 200 g/ha	**AMPA**	1.28	1.23	1.19	1.15	1.07	0.99	0.93	0.81	0.75	0.50

Table B.8.6.1-6a: Actual concentrations in sediment: Step 2

Region /Rate	Compound	PEC Sediment (µg kg^{-1} dry weight) (Days after global maximum)										
		0	**1**	**2**	**4**	**7**	**14**	**21**	**28**	**42**	**50**	**100**
N. EU	**Fluazinam**	119	112	102	83.2	61.5	30.4	15.0	7.43	1.82	0.81	0.01
10 x 200 g/ha	**AMPA**	8.92	8.73	8.55	8.18	7.67	6.59	5.66	4.87	3.59	3.02	1.02
S. EU	**Fluazinam**	175	166	150	123	90.7	44.8	22.2	11.0	2.68	1.20	0.01
10 x 200 g/ha	**AMPA**	11.1	10.9	10.6	10.2	9.53	8.19	7.04	6.05	4.46	3.75	1.27

Table B.8.6.1-6b: Maximum time-weighted average concentrations in sediment: Step 2

Region /Rate	Compound	TWAEC Sediment (µg kg^{-1} d.w.) (Period in days after global maximum									
		1	**2**	**4**	**7**	**14**	**21**	**28**	**42**	**50**	**100**
N. EU	**Fluazinam**	116	111	102	89.0	66.6	51.7	41.5	29.0	24.5	12.4
10 x 200 g/ha	**AMPA**	8.83	8.73	8.55	8.28	7.70	7.17	6.69	5.86	5.45	3.65
S. EU	**Fluazinam**	171	164	150	131	98.2	76.2	61.1	42.7	36.2	18.2
10 x 200 g/ha	**AMPA**	11.0	10.9	10.6	10.3	9.57	8.91	8.31	7.28	6.77	4.53

The time-weighted averages at Step 2 were calculated after absolute maximum concentrations, i.e. using the default option. The maximum initial predicted environmental concentration in surface water at Step 2 for AMPA was 1.35 µg/L and the max. PECsed for AMPA was 11.1 µg/kg. Step 3 calculations were performed only for parent fluazinam.

- Step 3 calculations / single application:

Table B.8.6.1-7a: Actual concentrations of fluazinam in surface water: Step 3

Scenario	Water Body	PEC Surface Water (µg L^{-1}) (Days after global maximum)									
		Global Max	**1**	**2**	**4**	**7**	**14**	**21**	**28**	**42**	**50**
D3	**Ditch**	1.045	0.032	0.001	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Scenario	Water Body	PEC Surface Water (µg L^{-1}) (Days after global maximum)									
		Global Max	1	2	4	7	14	21	28	42	50
D4	Pond	0.042	0.020	0.010	0.002	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Stream	0.866	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
D6	Ditch	1.028	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
R1	Pond	0.042	0.019	0.009	0.002	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Stream	0.726	<0.001	<0.001	<0.001	<0.001	0.002	<0.001	0.034	<0.001	<0.001
R2	Stream	0.958	<0.001	<0.001	<0.001	<0.001	<0.001	0.041	<0.001	<0.001	<0.001
R3	Stream	1.023	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table B.8.6.1-7b: Time-weighted average concentrations of fluazinam in surface water: Step 3

Scenario	Water Body	Maximum TWAEC Surface Water (µg L^{-1}) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.342	0.175	0.088	0.051	0.025	0.017	0.013	0.008	0.007	0.004
D4	Pond	0.029	0.022	0.014	0.008	0.004	0.003	0.002	0.001	0.001	0.001
	Stream	0.053	0.027	0.013	0.008	0.004	0.003	0.002	0.001	0.001	0.001
D6	Ditch	0.205	0.103	0.052	0.030	0.015	0.010	0.007	0.005	0.004	0.002
R1	Pond	0.029	0.021	0.013	0.008	0.006	0.004	0.003	0.002	0.002	0.001
	Stream	0.129	0.065	0.032	0.019	0.018	0.014	0.012	0.010	0.008	0.004
R2	Stream	0.079	0.039	0.020	0.011	0.008	0.006	0.005	0.003	0.003	0.002
R3	Stream	0.233	0.117	0.059	0.034	0.017	0.013	0.010	0.007	0.006	0.003

Table B.8.6.1-8a: Actual concentrations of fluazinam in sediment: Step 3

Scenario	Water Body	PEC Sediment (µg kg^{-1} dry weight) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.234	0.206	0.176	0.133	0.093	0.048	0.027	0.017	0.007	0.004	<0.001
D4	Pond	0.030	0.029	0.027	0.021	0.016	0.008	0.005	0.003	0.001	0.001	<0.001
	Stream	0.038	0.033	0.029	0.022	0.016	0.008	0.005	0.003	0.001	0.001	<0.001
D6	Ditch	0.147	0.125	0.107	0.079	0.054	0.027	0.015	0.009	0.003	0.002	<0.001
R1	Pond	0.028	0.027	0.025	0.021	0.027	0.016	0.010	0.012	0.007	0.004	<0.001
	Stream	0.127	0.111	0.098	0.078	0.058	0.047	0.057	0.047	0.022	0.013	0.001
R2	Stream	0.057	0.050	0.043	0.034	0.024	0.035	0.038	0.024	0.010	0.031	0.003
R3	Stream	0.165	0.141	0.120	0.089	0.061	0.030	0.027	0.023	0.009	0.006	<0.001

Table B.8.6.1-8b: Time-weighted average concentrations of fluazinam in sediment: Step 3

Scenario	Water Body	Maximum TWAEC Sediment (µg kg^{-1} dry weight) (Period in days)									
		1	2	4	7	14	21	28	42	50	100

Scenario	Water Body	Maximum TWAEC Sediment (µg kg^{-1} dry weight) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.228	0.216	0.191	0.161	0.116	0.091	0.074	0.053	0.045	0.023
D4	Pond	0.030	0.030	0.028	0.026	0.020	0.016	0.013	0.010	0.008	0.004
	Stream	0.036	0.034	0.030	0.025	0.018	0.014	0.012	0.009	0.007	0.004
D6	Ditch	0.140	0.130	0.114	0.095	0.067	0.052	0.042	0.030	0.025	0.013
R1	Pond	0.028	0.028	0.027	0.024	0.024	0.021	0.018	0.016	0.014	0.008
	Stream	0.122	0.115	0.104	0.090	0.075	0.069	0.067	0.062	0.057	0.032
R2	Stream	0.054	0.050	0.044	0.038	0.030	0.029	0.029	0.025	0.023	0.017
R3	Stream	0.157	0.147	0.128	0.106	0.076	0.063	0.054	0.041	0.036	0.019

- Step 3 calculations / multiple applications:

Table B.8.6.1-9a: Actual concentrations of fluazinam in surface water: Step 3

Scenario	Water Body	PEC Surface Water (µg L^{-1}) (Days after global maximum) Scenario Water										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.572	0.028	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
D4	Pond	0.023	0.012	0.006	0.002	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Stream	0.496	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.003
D6	Ditch	0.618	0.018	0.001	<0.001	<0.001	0.001	<0.001	<0.001	<0.001	<0.001	<0.001
R1	Pond	0.058	0.025	0.011	0.009	0.001	0.001	0.001	0.002	<0.001	<0.001	<0.001
	Stream	0.633	<0.001	<0.001	<0.001	<0.001	<0.001	0.282	<0.001	<0.001	<0.001	<0.001
R2	Stream	0.571	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.004	<0.001	<0.001
R3	Stream	0.560	0.001	<0.001	<0.001	0.140	<0.001	<0.001	<0.001	<0.001	0.095	<0.001

Table B.8.6.1-9b: Time-weighted average concentrations of fluazinam in surface water: Step 3

Scenario	Water Body	Maximum TWAEC Surface Water (µg L^{-1}) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.190	0.099	0.050	0.029	0.029	0.029	0.028	0.023	0.023	0.016
D4	Pond	0.017	0.013	0.008	0.005	0.005	0.005	0.004	0.003	0.003	0.002
	Stream	0.050	0.025	0.012	0.007	0.006	0.005	0.004	0.003	0.003	0.002
D6	Ditch	0.192	0.098	0.049	0.028	0.028	0.027	0.020	0.018	0.019	0.011
R1	Pond	0.046	0.035	0.025	0.017	0.012	0.009	0.010	0.008	0.007	0.004
	Stream	0.278	0.158	0.102	0.085	0.056	0.041	0.040	0.033	0.029	0.015
R2	Stream	0.144	0.076	0.038	0.030	0.019	0.015	0.015	0.014	0.013	0.007
R3	Stream	0.128	0.065	0.056	0.036	0.034	0.029	0.026	0.024	0.024	0.017

Table B.8.6.1-10a: Actual concentrations of fluazinam in sediment: Step 3

Scenario	Water Body	PEC Sediment (µg kg^{-1} dry weight) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.214	0.194	0.170	0.133	0.100	0.059	0.038	0.026	0.014	0.011	0.003
D4	Pond	0.036	0.035	0.033	0.029	0.023	0.014	0.010	0.007	0.004	0.003	0.003
	Stream	0.053	0.047	0.042	0.034	0.025	0.015	0.010	0.008	0.004	0.003	0.005
D6	Ditch	0.186	0.164	0.142	0.109	0.077	0.108	0.046	0.023	0.144	0.046	<0.001
R1	Pond	0.087	0.083	0.077	0.064	0.067	0.051	0.033	0.031	0.012	0.008	0.001
	Stream	0.979	0.912	0.850	0.747	0.629	0.522	0.510	0.429	0.243	0.181	0.017
R2	Stream	0.270	0.246	0.224	0.190	0.152	0.102	0.070	0.073	0.030	0.019	0.001
R3	Stream	0.192	0.169	0.147	0.113	0.155	0.154	0.102	0.136	0.174	0.078	0.003

Table B.8.6.1-10b: Time-weighted average concentrations of fluazinam in sediment: Step 3

Scenario	Water Body	Maximum TWAEC Sediment (µg kg^{-1} dry weight) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.210	0.202	0.182	0.158	0.155	0.152	0.146	0.130	0.120	0.096
D4	Pond	0.036	0.036	0.035	0.032	0.030	0.026	0.024	0.020	0.020	0.018
	Stream	0.050	0.048	0.043	0.037	0.031	0.027	0.024	0.019	0.017	0.014
D6	Ditch	0.181	0.171	0.153	0.130	0.116	0.111	0.102	0.088	0.084	0.058
R1	Pond	0.086	0.085	0.084	0.080	0.071	0.064	0.060	0.059	0.056	0.035
	Stream	0.958	0.927	0.869	0.797	0.703	0.641	0.619	0.532	0.481	0.274
R2	Stream	0.261	0.250	0.231	0.208	0.169	0.143	0.126	0.116	0.111	0.077
R3	Stream	0.185	0.175	0.155	0.146	0.137	0.131	0.126	0.125	0.125	0.096

Predicted concentrations at Step 3 were significantly lower than those obtained at Step 2. The maximum initial predicted environmental concentration in surface water at Step 3 for fluazinam was 1.045µg/L. The maximum initial predicted environmental concentration in sediment at Step 3 for fluazinam was 0.979 µg/kg.

Table B.8.6.1-11: Summary of maximum PECSW values (FOCUS Step 1, 2 and 3)

Region	Scenario	Water body	compound	PEC_{sw} (max)
Step 1 (10 x 200 g ai/ha)				
N & S EU	-	-	Fluazinam	203 µg/L
	-	-	AMPA	10.2 µg/L
Step 2 (10 x 200 g ai/ha)				
S EU	-	-	Fluazinam	9.02 µg/L
	-	-	AMPA	1.35 µg/L

Region	Scenario	Water body	compound	PEC_{SW} (max)
Step 3 (values from single application)*				
-	D3	Ditch		1.045 µg/L
-	D4	Pond		0.042 µg/L
-		Stream		0.866 µg/L
-	D6	Ditch	Fluazinam	1.028 µg/L
-	R1	Pond		0.042 µg/L
		Pond		0.058 µg/L**
-		Stream		0.726 µg/L
-	R2	Stream		0.958 µg/L
-	R3	Stream		1.023 µg/L

*assuming single application resulted in the highest PEC values, except for scenario R1 pond **multiple application calculation

The PEC_{SW} calculations submitted were accepted by the RMS. But the calculations only account for aquatic systems with relatively high organic carbon content in the sediment. The dissipation half lives from the water phase are based on a water/sediment study containing similar sediment systems – e.g. 3.3 % and 4.3 % C_{org}; CEC: 9.7 and 10 meq/100 g soil; 88 % and 75 % sand. A clear correlation between the adsorption of fluazinam to soils (K_f values) and the C_{org} content of soils was observed in batch/equilibrium studies. No correlation was found between adsorption and clay content of soils.

Conclusions:

The PEC_{SW} water calculations submitted were accepted by the RMS. However, it has to be mentioned that the substance parameters are based on a water/sediment study including two systems with very similar and rather high organic carbon content (3.3 % and 4.3 % C_{org}) in sediment. A statement in this regard was submitted by the notiefier (Gurney, A. 2005a), which is summarised below.

No data concerning the entry of the main soil metabolite HYPA into surface water by run-off, erosion or drainage were submitted. These data are outstanding.

Reference: Gurney, A. (2005b): Defence of the water-sediment study and selection of the aquatic half-life for FOCUS surface water caluclations. (RCC study no. A44280-A)

Guideline: not applicable

GLP: Not applicable

Material and methods: Statement

Fluazinam is expected to degrade rapidly in the water phase by hydrolysis. Although stable to hydrolysis at pH 4, at environmentally relevant pH values Fluazinam degraded with half-lives

of 4.5 and 2.7 days (pH 7) and 3.5 and 3.9 days at pH 9 (25 °C; Gaauw, A.; 2003). It is stated that hydrolysis half-life provides an upper bound for the degradation half-life in the water phase under the biologically active conditions of natural waters. The notifier does not expect a retardation of fluazinam dissipation from the water phase if the organic carbon content of sediments is lowered.

Reference: Gurney, A. (2005c): Estimation of the environmental concentrations of fluazinam in surface water. (RCC study no. A44280)

Guideline: FOCUS (2004): "Landscape and Mitigation Factors in Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations"; "Landscape and Mitigation Factors in Aquatic Risk Assessment. Volume 2. Detailed Technical Reviews".

GLP: Not applicable

Material and methods:

Predicted concentrations in surface water were determined using FOCUS Surface Water Step 4 calculations in order to determine the drift and runoff mitigation provided by 5 m unsprayed buffers. A total of eight application (maximum possible in SWASH) were considered in all of the six standard FOCUS potato scenarios except in scenarios D6 (Thiva) and R2 (Porto) for which 6 applications were considered due to the shorter cropping period. In addition, single applications of 200 g/ha were simulated for each scenario. With the exception of drift and runoff mitigation measures, all input parameters used in the Step 4 calculations were the same as those previously used in the Step 3 calculations (Görge, 2005; study above).

Table B.8.6.1-12: Reduction of drift for potatoes due to unsprayed buffer strips

No. of apps.	Drift %ile per event	Buffer width	Integrated drift over the width of the water body over (% applied)			Integrated drift over the width of the water body over (mg a.i. m^{-2})**		
			1m wide ditch	1m wide stream*	30m wide pond	1m wide ditch	1m wide stream*	30m wide pond
1	90	Default+	1.5936	1.4894	0.2122	0.3187	0.2978	0.0424
		5m	0.5224	0.6269	0.1896	0.1045	0.1254	0.0379
6	70	Default+	0.9379	0.8748	0.1229	0.1876	0.1750	0.0246
		5m	0.3046	0.3655	0.1097	0.0609	0.0731	0.0219
8	67	Default+	0.8706	0.8125	0.1147	0.1741	0.1625	0.0229
		5m	0.2836	0.3403	0.1024	0.0567	0.0680	0.0205

+ the FOCUS default buffers for potatoes are: 1.3 m ditch, 1.8 m stream, 3.8 m pond
* for streams, the drift value for a ditch at the corresponding buffer distance was multiplied by a factor of 1.2 to account for the additional input via drift from the upstream watershed
** calculated using an application rate of 200 g a.i. ha^{-1}.

In the run-off scenarios (R1-R3), mitigation was applied to reflect the reduction in runoff due to vegetative filter strips in addition to the drift reution described above. The level of

reduction in pesticide loss to surface water due to vegetation buffer strips was assumed to be 50 % at 5 m (*Winkler, 2001*: Konzept zur Bewertung des Eintrags von Pflanzenschutzmitteln in Oberflächen- und Grundwasser unter besonderer Berücksichtigung des Oberflächenabflusses (Dokumentation zu Modell EXPOSIT). Umweltbundesamt – Einvernehmensstelle Pflanzenschutzgesetz, Berlin, 27.09.2005 and *Klöppel, et al. 1997*: Herbicide transport by surface runoff and herbicide retention in a filter strip – rainfall and runoff simulation studies. Chemosphere 35 (1/2), 129-141).

Runoff is reduced by vegetative filter strips predominantly due to infiltration, which reduces runoff mass flux and runoff volume by the same percentage at the edge of a treated field. The FOCUS stream scenarios assume a 1-hectare treated field is fed by runoff from a 100-hectare upstream catchment (total 101 hectares), 20 hectares of which is treated by a pesticide (i.e. 21 ha are treated). Thus it can be assumed that, although the pesticide mass flux wil be reduced by 50 % due to vegetative filter strips of 5 m alongside the treated fields, the reduction in runoff volume will be lower because only 20 % of the upstream catchment is buffered by the vegetative filter strips. The total reduction in runoff volume due to a 5 m filter strip is therefore 50 % x 21/101 = 10.4 %. For the pond runoff scenario (R1) it was conservatively assumed that the reduction in runoff volume was equal to the reduction in runoff mass loadings.

Table B.8.6.1-13: Reduction of runoff inputs for potatoes due to vegetative filter strips

Buffer width	Stream runoff scenarios (R1, R2, R3)		Pond runoff scenario (R1)	
	Reduction in runoff mass loadings (%)	Reduction in runoff volume (%)	Reduction in runoff mass loadings (%)	Reduction in runoff volume (%)
5m	50	10.4	50	50

Results:

The maximum initial predicted environmental concentration in surface water was 0.43 µg/L. The maximum initial predicted environmental concentration in sediment was 0.50 µg/kg. For details see tables below:

Table B.8.6.1-14: Actual concentrations of fluazinam in surface water: single application

Scenario	Water Body	PEC Surface Water (µg L^{-1}) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.342	0.010	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4	Pond	0.038	0.018	0.009	0.002	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Stream	0.364	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D6	Ditch	0.337	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
R1	Pond	0.038	0.017	0.008	0.002	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Stream	0.305	< 0.001	< 0.001	< 0.001	< 0.001	0.001	< 0.001	0.018	< 0.001	< 0.001	< 0.001
R2	Stream	0.403	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.022	< 0.001	< 0.001	< 0.001	< 0.001

R3	**Stream**	0.431	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Table B.8.6.1-15: Time-weighted average concentrations of fluazinam in surface water: single application

Scenario	Water Body	Maximum TWAEC Surface Water (µg L^{-1}) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	**Ditch**	0.112	0.057	0.029	0.017	0.008	0.006	0.004	0.003	0.002	0.001
D4	**Pond**	0.027	0.020	0.012	0.007	0.004	0.002	0.002	0.001	0.001	0.001
	Stream	0.022	0.011	0.006	0.003	0.002	0.001	0.001	0.001	< 0.001	< 0.001
D6	**Ditch**	0.067	0.034	0.017	0.010	0.005	0.003	0.002	0.002	0.001	0.001
R1	**Pond**	0.026	0.019	0.012	0.007	0.004	0.003	0.002	0.002	0.001	0.001
	Stream	0.067	0.034	0.017	0.010	0.009	0.007	0.006	0.005	0.004	0.002
R2	**Stream**	0.033	0.017	0.008	0.005	0.003	0.003	0.002	0.001	0.001	0.001
R3	**Stream**	0.098	0.049	0.025	0.014	0.007	0.006	0.005	0.003	0.003	0.001

Table B.8.6.1-16: Actual concentrations of fluazinam in sediment: single application

Scenario	Water Body	PEC Sediment (µg kg^{-1} dry weight) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	**Ditch**	0.077	0.068	0.059	0.045	0.032	0.017	0.010	0.006	0.002	0.001	< 0.001
D4	**Pond**	0.027	0.026	0.024	0.019	0.014	0.008	0.005	0.003	0.001	0.001	< 0.001
	Stream	0.016	0.014	0.012	0.010	0.007	0.004	0.002	0.001	0.001	< 0.001	< 0.001
D6	**Ditch**	0.048	0.042	0.036	0.027	0.019	0.009	0.005	0.003	0.001	0.001	< 0.001
R1	**Pond**	0.026	0.025	0.023	0.019	0.020	0.012	0.007	0.008	0.004	0.002	< 0.001
	Stream	0.066	0.059	0.052	0.041	0.031	0.025	0.031	0.026	0.012	0.007	0.001
R2	**Stream**	0.024	0.021	0.019	0.015	0.011	0.017	0.020	0.012	0.005	0.017	0.001
R3	**Stream**	0.070	0.060	0.051	0.039	0.027	0.013	0.013	0.012	0.005	0.003	< 0.001

Table B.8.6.1-17: Time-weighted average concentrations of fluazinam in sediment: single application

Scenario	Water Body	Maximum TWAEC Sediment (µg kg^{-1} dry weight) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	**Ditch**	0.075	0.072	0.064	0.054	0.040	0.031	0.025	0.018	0.016	0.008
D4	**Pond**	0.027	0.027	0.026	0.023	0.018	0.014	0.012	0.009	0.008	0.004
	Stream	0.015	0.014	0.013	0.011	0.008	0.006	0.005	0.004	0.003	0.002
D6	**Ditch**	0.046	0.043	0.038	0.032	0.023	0.018	0.014	0.010	0.009	0.004

Scenario	Water Body	Maximum TWAEC Sediment (µg kg^{-1} dry weight) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
R1	Pond	0.026	0.025	0.024	0.022	0.020	0.017	0.014	0.012	0.010	0.006
	Stream	0.064	0.061	0.055	0.047	0.039	0.036	0.036	0.032	0.030	0.017
R2	Stream	0.023	0.021	0.019	0.017	0.015	0.014	0.014	0.012	0.011	0.009
R3	Stream	0.067	0.062	0.055	0.046	0.033	0.028	0.025	0.019	0.017	0.009

Table B.8.6.1-18: Actual concentrations of fluazinam in surface water: multiple applications

Scenario	Water Body	PEC Surface Water (µg L^{-1}) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.186	0.009	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
D4	Pond	0.021	0.011	0.006	0.002	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Stream	0.207	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.003
D6	Ditch	0.200	0.006	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
R1	Pond	0.033	0.015	0.007	0.002	< 0.001	0.001	0.002	0.002	0.001	0.001	< 0.001
	Stream	0.296	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.156	< 0.001	< 0.001	< 0.001	< 0.001
R2	Stream	0.239	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.002	< 0.001	< 0.001
R3	Stream	0.234	< 0.001	< 0.001	< 0.001	0.078	< 0.001	< 0.001	< 0.001	< 0.001	0.053	< 0.001

Table B.8.6.1-19: Time-weighted average concentrations of fluazinam in surface water: multiple applications

Scenario	Water Body	Maximum TWAEC Surface Water (µg L^{-1}) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.062	0.032	0.016	0.009	0.009	0.009	0.009	0.008	0.008	0.005
D4	Pond	0.015	0.012	0.007	0.005	0.005	0.004	0.003	0.003	0.003	0.002
	Stream	0.021	0.010	0.005	0.003	0.003	0.002	0.002	0.001	0.001	0.001
D6	Ditch	0.062	0.032	0.016	0.009	0.009	0.009	0.007	0.006	0.006	0.003
R1	Pond	0.027	0.020	0.014	0.010	0.007	0.006	0.006	0.006	0.005	0.003
	Stream	0.155	0.087	0.056	0.045	0.029	0.021	0.021	0.017	0.015	0.008
R2	Stream	0.080	0.042	0.021	0.015	0.009	0.007	0.007	0.007	0.006	0.003
R3	Stream	0.060	0.031	0.027	0.017	0.016	0.014	0.012	0.011	0.011	0.008

Table B.8.6.1-20: Actual concentrations of fluazinam in sediment: multiple applications

Scenario	Water Body	PEC Sediment (µg kg^{-1} dry weight) (Days after global maximum)										
		Global Max	1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.072	0.065	0.058	0.046	0.034	0.020	0.013	0.009	0.005	0.004	0.001
D4	Pond	0.032	0.031	0.030	0.026	0.020	0.013	0.009	0.007	0.004	0.003	0.003
	Stream	0.022	0.020	0.018	0.015	0.011	0.007	0.005	0.003	0.002	0.001	0.005
D6	Ditch	0.062	0.055	0.048	0.037	0.027	0.037	0.016	0.008	0.048	0.016	< 0.001
R1	Pond	0.055	0.053	0.049	0.041	0.046	0.038	0.027	0.023	0.009	0.006	0.001
	Stream	0.500	0.466	0.434	0.381	0.321	0.265	0.262	0.223	0.124	0.090	0.009
R2	Stream	0.140	0.127	0.116	0.098	0.079	0.052	0.036	0.038	0.015	0.010	0.001
R3	Stream	0.091	0.080	0.070	0.055	0.080	0.072	0.052	0.066	0.082	0.039	0.001

Table B.8.6.1-21: Time-weighted average concentrations of fluazinam in sediment: multiple applications

Scenario	Water Body	Maximum TWAEC Sediment (µg kg^{-1} dry weight) (Period in days)									
		1	2	4	7	14	21	28	42	50	100
D3	Ditch	0.071	0.068	0.062	0.054	0.053	0.052	0.050	0.044	0.041	0.033
D4	Pond	0.032	0.032	0.031	0.029	0.026	0.024	0.022	0.018	0.018	0.016
	Stream	0.021	0.020	0.018	0.016	0.013	0.012	0.010	0.008	0.008	0.006
D6	Ditch	0.060	0.057	0.051	0.044	0.039	0.037	0.035	0.030	0.028	0.020
R1	Pond	0.055	0.054	0.052	0.050	0.046	0.043	0.040	0.039	0.038	0.024
	Stream	0.489	0.474	0.444	0.407	0.358	0.327	0.318	0.274	0.247	0.140
R2	Stream	0.135	0.129	0.120	0.107	0.087	0.073	0.064	0.058	0.056	0.039
R3	Stream	0.088	0.083	0.074	0.073	0.066	0.064	0.062	0.062	0.062	0.047

Table B.8.6.1-22: Summary of maximum PECSW values (FOCUS Step 4: 5 m buffer zone)

Scenario	Water Body	PEC_{sw} (µg L^{-1})				PEC_{sed} (µg kg^{-1})			
		Max	1d TWA	2d TWA	28d TWA	Max	1d TWA	2d TWA	28d TWA
D3	Ditch	0.342*	0.112*	0.057*	0.009	0.077*	0.075*	0.072	0.050
D4	Pond	0.038*	0.027*	0.020*	0.003	0.032	0.032	0.032	0.022
	Stream	0.364*	0.022*	0.011*	0.002	0.022	0.021	0.020	0.010
D6	Ditch	0.337*	0.067*	0.034*	0.007	0.062	0.060	0.057	0.035
R1	Pond	0.038*	0.027	0.020	0.006	0.055	0.055	0.054	0.040
	Stream	0.305*	0.155	0.087	0.021	0.500	0.489	0.474	0.318

Scenario	Water Body	PEC_{sw} (µg L^{-1})				PEC_{sed} (µg kg^{-1})			
		Max	1d TWA	2d TWA	28d TWA	Max	1d TWA	2d TWA	28d TWA
R2	Stream	0.403*	0.080	0.042	0.007	0.140	0.135	0.129	0.064
R3	Stream	0.431*	0.098*	0.049*	0.012	0.091	0.088	0.083	0.062

Note: values are maximum results from either single or multiple applications
*assuming single application resulted in the highest PEC values

Conclusions:

The calculations were accepted by the RMS

B.8.6.2 Predicted environmental concentrations in ground water (PEC_{GW})

Reference: Vercruysse, F. (2005): Predicted environmental concentrations in groundwater (PEC_{GW}) after PELMO simulation for the active ingredient fluazinam (IKF-1216) and its metabolite HYPA. (Study IBE1216-EF0506-01; Document 5687-93-0091-CR-001)

Guideline: "FOCUS Groundwater Scenarios in the EU Plant Protection Product Review Process"; Sanco/321/2000 rev2

GLP: Not applicable

Material and methods:

Groundwater modelling was carried out to evaluate the predicted leaching potential for fluazinam and its metabolite HYPA. Calculations were conducted using FOCUS PELMO 3.3.2 and the FOCUS groundwater scenarios. The following parameters were used for the modelling:

Table B.8.6.2-1: Inputparameters used for FOCUS groundwater modelling

Application:	10 x 200 g ai/ha
Application date:	4 weeks post emergence
Interception:	50% at each application
Crop:	Potatoes
Volatilisation:	0
Plant uptake:	0
Correction routines for temperature and soil moisture:	enabled
	FLUAZINAM
Half-life (d):	16.4 (simple 1st order half-lives from field trials normalised to reference soil temperature,

	20°C)
Depth factor for degradation:	FOCUS default
K_{foc}:	1 958
1/n:	FOCUS default
	HYPA
Half-life (d):	95 (arithmetic mean from 20° C laboratory study, no moisture correction)
Depth factor for degradation:	FOCUS default
K_{foc}:	920
1/n:	FOCUS default
Formation in soil:	9.7% (average occurrence in laboratory studies with fluazinam)

The following degradation pathway was implemented in FOCUS PELMO using the respective rate constants for each transformation pathway:

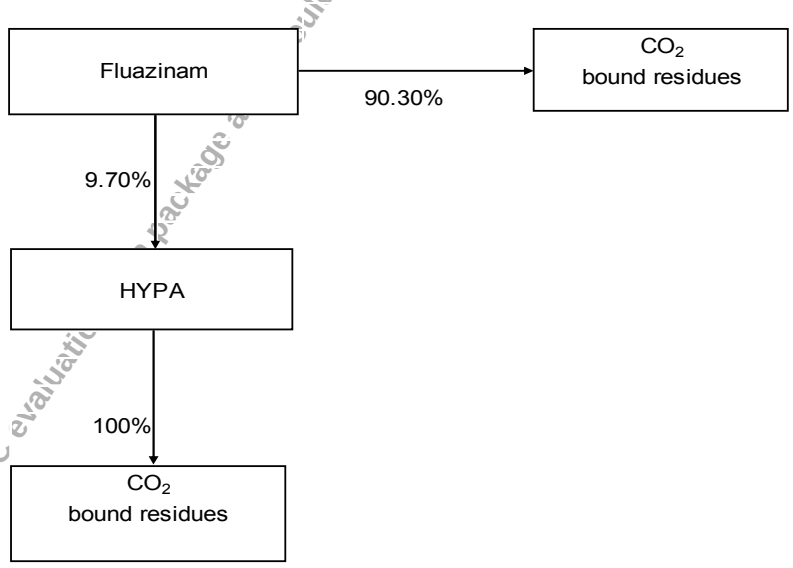


Figure B.8.6.2-1: Metabolism scheme for fluazinam used for groundwater modelling

Results:

Table B.8.6.2-2: Predicted 80th percentile annual average concentrations at 1 m depth of fluazinam and HYPA after application of 10 x 200 g ai/ha on potatos

Scenario	Calculated PEC_{GW} µg/L)	
	fluazinam	**HYPA**
Châteaudun	<0.001	<0.001
Hamburg	<0.001	<0.001
Jokioinen	<0.001	<0.001
Kremsmünster	<0.001	<0.001
Okehampton	<0.001	<0.001
Piacenza	<0.001	<0.001
Porto	<0.001	<0.001
Sevilla	<0.001	<0.001
Thiva	<0.001	<0.001

Conclusions:

According to FOCUS PELMO modelling the predicted 80th percentile annual average concentrations at 1 m depth of fluazinam and its main soil metabolite HYPA are predicted to be <0.001 µg/L. Unacceptable contamination of groundwater is not expected to occur if fluazinam is applied according to good agricultural practice and according to the proposed use.

FOCUS PELMO modelling for HYPA was re-done by the RMS for the following reasons:

+ From the batch/equilibrium study (Muller et al, 1993; Report RJ 1308B) with HYPA the two acidic soils were considered not typically for potato growing areas. For these two soils significant higher K_{OC} values were observed than with the four other soils, which are considered more relevant by the RMS. Therefore the arithmetic mean of these four soils was used for the modelling (K_{OC}: 630)
+ A transformation factor for HYPA was calculated with the multi compartment model ModelMaker vers. 4.0. As basis for this calculation the data from the metabolism and degradation study of Mawad, 2003 (Study 844056) were taken as in this study the formation of HYPA was highest.

The modelling was done in the same way as in the study of Vercruysse (2005) above with the following changes:

DT_{50} HYPA: **105** days

DT_{50} fluazinam: 16.4 days (no change)

Formation factor fluazinam →HYPA: **0.193** (i.e. 19.3 %)

The R^2 was 0.994

Findings:
Predicted 80th percentile annual average concentrations of HYPA at 1 m depth after application of 10 x 200 g fluazinam /ha on potatoes : <0.001 µg/L in all of the nine FOCUS scenarios.

B.8.7 Fate and behaviour in air

B.8.7.1 Rate and route of degradation in air

Reference: Atkinson, R. (1993): Estimation of hydroxyl radical reaction rate constants: Fluazinam. (Report RIC 1832)
Guideline: not applicable
GLP: not applicable
Material and methods:
The room temperature rate constant for the gas-phase reaction of the OH radical with fluazinam was calculated using the estimation method of Atkinson. It was assumed that for fluazinam the overall OH radical reaction rate constant k_{OH} is given by: k_{OH} = k(pyridine ring) + k(aromatic ring) + k(interaction with the >NH group).
Findings:
The following rate constants have been calculated:
k(pyridine ring): ca. 1.2 x 10^{-12} cm^3/molecule/s
k(aromatic ring): 2.5 x 10^{-13} cm^3/molecule/s
OH radical interaction with the >NH group is calculated to have a rate constant of 6.0 x 10^{-11} cm^3/molecule/s. This estimate was considered highly uncertain and may well be a gross overestimate for the >NH group in fluazinam.
Use of these estimates leads to a calculated overall rate constant of: k_{OH} = 6.1 x 10^{-11} cm^3/molecule/s, with 98% of this estimated overall rate constant being calculated to be due to OH radical interaction with the >NH group.
Assuming an average global tropospheric OH radical concentration of 1.6 x 10^6 molecules/cm^3 for a 12 hour daytime period a tropospheric lifetime of fluazinam of 2.8 hours (reaction during daylight hours) is calculated.
However, if OH radical interaction with the >NH group is much less important than calculated, then the lifetime of fluazinam will be much longer. It is stated that, in fact, if the OH radical interaction with the >NH group is neglected then the overall OH radical reaction rate constant is k_{OH} = 1.5 x 10^{-12} cm^3/molecule/s and the lifetime of fluazinam becomes ca. 10 days.
The RMS recalculated the tropospheric half-life of fluazinam with the computer program AOPWIN vers. 1.91. Assuming a 12 hour daytime cycle and an OH concentration of 1.5 x 10^6 molecules/cm^3 the calculated half-life of fluazinam was 163 days. The large differences of the results can be again related to how the bridge amine nitrogen is handled.

Conclusions:
On the basis of the available data it can be assumed that the half-life of fluazinam by photochemical oxidative degradation in air is >2 days.

Volatilisation

Reference: Kuet, S.F. (1994): Fluazinam: Volatilization from soil and leaf surfaces following application as a SC formulation. (Report RJ 1770B)
Guideline: not stated
GLP: Yes
Material and methods:
The purpose of this study was to investigated the volatilisation of fluazinam from both soil and leaf surface. ^{14}C-fluazinam, radio labelled in the 2,6-pyridyl positions (batch 84-J15, specific activity 1.9 GBq mmol^{-1}) and formulated as a suspension concentrate was applied to soil (Speyer 2.1) and leaf (French bean, *Phaseolus vulgaris*) surfaces at application rates equivalent to 200 and 204 g ai/ha, respectively. The ^{14}C-fluazinam was formulated as a 2.5% suspension concentrate with "Shirlan 50% SC blank" formulation mixture (YF 8053). The treated plots were maintained in duplicate in a constant air stream between 1 and 2 m/s for up to 24 hours. Analyses were carried out 0, 1, 3, 6, 20 and 24 hours after placing the pots in the air flow. Soil was kept at 60% WHC, air temperature and relative humidity were monitored throughout the period of each experiment. The degree of volatilisation at each time point was established by determining the radioactivity remaining in the samples as a percentage of the radioactivity recovered at zero time. Soil samples were extracted by ultrasonication with acetonitrile twice for ca. 5 minutes. The soil was finally washed with acetone. The extracts were separated from the debris by filtration under vacuum. In some cases, where the recovery was low, the soil was further extracted with acetonitrile. The amounts of radioactivity contained in the extracts were measured using LSC. The amounts of radioactivity contained in solid samples were determined by combustion analysis in conjunction with LSC.
TLC was used to measure the purity of the radiochemical prior to isotopic dilution, before formulation, and for pre- and post- application purity checks of the treatment solution.
Findings:
In the soil experiment the temperature varied between about 15.5° C and 22°C during the experimental period. Relative humidity was in the range of about 44% and 68%. In the leaf experiment temperature varied between approx. 12° C and 27° C. Relative humidity was in the range of about 40% and 80%. Radioactive recoveries of 91.3% and 97.2% of zero time were obtained from the soil and leaf studies, respectively, after 24 hours.
Conclusion:
After 24 hours about 9% and 3% of fluazinam were volatilised from soil and leaf surface, respectively, under the experimental conditions applied.
Acceptance of study: The study was not accepted by the RMS. According to the phys./chem.

parameters of fluazinam this substance is expected to have a medium to high potential for volatilisation. With a vapour pressure of 7.5 ± 0.8 x 10^{-3} Pa (20° C), a water solubility of 0.135 mg/L and a resulting Henry's law constant of 25.9 Pa x m³ x mol^{-1} (20°C) fluazinam has a rather high potential for being available in air. As fluazinam is intended to be applied to the crop, volatilisation from plant surface will be more important than volatilisation from soil. Especially in the leaf surface experiment part of this study, the climatic conditions deviated drastic from the standard conditions: The first 5 hours of the experiment air temperature was above 20 °C, with a peak of approximately 23 °C. The following approx. 17 hours (out of 24 hours of the experiment) the air temperature was below 20 °C with a minimum of about 12 °C. During the last two hours temperature climbed up to 27 °C. Relative air humidity was below 50 % (about 40 %) during the first 4 hours, the following approximately 18 hours relative air humidity increased up to 80 %, falling down to about 45 % for the last 2 hours. Further, it is not expected that volatilisation from plant surface is that much lower than from soil, as the results of this study suggest. A standardised new study would be necessary, to investigate volatilisation behaviour of fluazinam from soil and leaf surface experimentally in a more reliable way.

B.8.8 Predicted environmental concentration in air (PEC_a) (Annex IIIA 9.3)

According to the phys./chem. parameters of fluazinam this substance is expected to have medium to high potential for volatilisation. With a vapour pressure of 7.5 ± 0.8 x 10^{-3} Pa (20° C), a water solubility of 0.135 mg/L and a resulting Henry's law constant of 25.9 Pa.m³.mol^{-1} (20°C) fluazinam has a rather high potential for being available in air. On the basis of the available data it can be concluded that the half-life of fluazinam by photochemical oxidative degradation in air most probably is >2 days. Absorption of light above 290 nm was shown for fluazinam with a molar extinction coefficient (**ε**) >10. The quantum yield (Φ) of fluazinam was stated to be 1.7 x 10^{-5} mole/Einstein (pH 6 distilled water).
Hydrolytic (pH 7 and 9; 25 °C) and aqueous photolytic degradation of fluazinam was observed, with DT_{50} values <4 days.
For the time being no harmonised model/method to calculate concentrations in air is available.

B.8.9 Additional information

Reference: Matsubayashi, Y., Kato, Y. and Ogyu, S. (2000): Rate of degradation of fluazinam and impurity-5 in aerobic soils (Document no. F-204)
Guideline: not stated
GLP: no
Material and methods:
This study was conducted to determine the rate of degradation of fluazinam and impurity-5 in three Japanese soils after application of Omega 500F (a 50 % suspension concentrate of fluazinam technical) at a rate of 1.0 mg ai/kg under aerobic conditions at 25° C. Soils were maintained at 45-50 % WHC. Soil samples were extracted with methanol containing 0.5 %

phosphoric acid by shaking 30 minutes. After centrifugation supernatants were mixed with 0.2 % acetic acid solution and extracts were applied to Sep-Pak HLB (OASYS 60 mg) previously conditioned with methanol containing 0.2 % acetic acid solution. Elution was carried out with acetonitrile. The residues of fluazinam and impurity-5 in the soil samples were analysed by LC/MS/MS with electro spray ionisation interface. Linear regression analyses were performed with Microsoft Excel for Windows 98, version 7 and DT_{50} and DT_{90} values calculated. The recovery of the method over a range of concentrations ranged from 90 to 106 % for fluazinam and from 83 to 95 % for impurity-5.

Table B.8.9-1: Soil Characteristics

Soil ISSS classif.	% sand	% silt	% clay	% OC	pH (H_2O)	CEC (meq/100g)	% MWHC	Biomass (mg C/100g)
Light clay "Ushiku" (volcanic ash)	ns	ns	38.2	2.57	6.5	25.2	99.4	ns
Clay loam "Anjo" (mineral)	ns	ns	24.0	1.88	7.0	15.6	67.0	ns
Clay loam "Nagano" (mineral)	ns	ns	13.0	2.88	6.7	14.0	59.0	ns

ns … not stated

Findings:

The results of the soil analyses are summarised in the table below:

Table B.8.9.-2: Degradation of fluazinam and impurity-5 in three soils

	fluazinam		Impurity-5	
DAT	**mg/kg***	**%**	**µg/kg***	**%**
"Ushiku" soil				
0	1.02	100	1.89	100
1	0.91	89.2	1.09	57.7
3	0.83	81.4	0.53	28.0
7	0.64	62.7	0.20	10.6
14	0.45	44.1	0.08	4.2
30	0.23	22.5	0.01	0.5
DT_{50}	11.7 days		1.3 days	
DT_{90}	50.3 days		7.8 days	
"Anjo" soil				
0	1.06	100	1.90	100
1	0.96	90.6	1.33	70.0

	fluazinam		Impurity-5	
DAT	**mg/kg***	**%**	**µg/kg***	**%**
3	0.90	84.9	0.84	44.2
7	0.74	69.9	0.40	21.1
14	0.54	50.9	0.18	9.5
30	0.34	32.1	0.06	3.2
DT_{50}	16.8 days		2.3 days	
DT_{90}	55.7 days		13.9 days	
"Nagano" soil				
0	1.03	100	1.89	100
1	0.93	90.3	1.35	71.4
3	0.85	82.5	0.93	49.2
7	0.72	69.9	0.54	28.6
14	0.66	64.1	0.34	17.9
30	0.41	40.8	0.10	5.8
DT_{50}	22.6 days		2.7 days	
DT_{90}	90.5 days		21.8 days	

*mean values of triplicate samples

Conclusions:

Based on the results of this study it can be concluded that impurity-5 degrades much faster in aerobic soils than the active substance fluazinam. From the environmental point of view impurity-5 is not considered as a relevant impurity.

Reference: Matsunaga, Y., Kanza, T. (2000): The stability of fluazinam (Omega 500 F formulation) and impurity-5 on glass surface and on plant foliage (Document no. F-205)

Guideline: not stated

GLP: no

Material and methods:

The objective of this study was to compare the rates of disappearance of fluazinam and impurity-5 in several media, spray deposit on leaf surfaces and on glass surfaces, which was prepared by dilution of fluazinam formulation. The formulation Omega 500 F, a 50 % (w/v) suspension concentrate of fluazinam technical containing impuitiy-5 in an amount of 0.2 % (w/w) was applied on cover glass, which were then placed on Petri dish and dried at room temperature in the dark for one hour. The Petri dishes were covered with quartz glass prior to exposure to light. The dark controls were covered with aluminium foil. The dishes were placed in an incubator equipped with artificial lamps and irradiated with approximately 40

000 lux at 20 ° C and 30° C for up to 24 hours (Tin-Na lamp method) or with approximately 100 000 lux at 20° C (xenon lamp method, SUNTESTER XF-180). The cover glasses were washed with acetonitrile and each solution was analysed for fluazinam and impurity-5 with HPLC and LC/MS/MS, respectively. Further, the formulation was sprayed on kidney beans (1-2 leaf stage), potato plants (9-10 leaf stage) and peanut plants (8-9 leaf stage) at an application rate of 2.24 kg ai/ha. Plants were held for 1 hour to allow the spray solution to dry on the leaves. Then the pots were transferred to a green house where the temperature was kept at 25 °C during day time (14 hours) and at 20° C during night time (10 hours). It is stated that in case of peanut plants the greenhouse temperature was kept at above 15° C. The collected leaves for each sampling time were washed with acetonitrile. Analyses were carried out with HPLC and LC/MS/MS. Additionally some peanut plants were kept under outdoor conditions. The temperature of the outdoor was 26° C and the light intensity was 110 000 lux at the time that plants were transferred outdoors.

After rinsing the leaves, the leaves were homogenised and extracted with acetonitrile. The extracts were analysed for the residue of impurity 5 using LC/MS/MS.

Method validation as performed. In all fortification levels with the two substances the resulting recovery was >90 %.

Findings:

The results are summarised in the following tables:

Table B.8.9.-3: Photostability of fluazinam and impurity-5 on a glass surface in the EYELATRON (Tin-Na lamp) at 20° C / 30° C

hours	Fluazinam		Impurity-5		ratio
	mean µg	% of initial	mean ng	% of initial	impurity/fluazinam
0	41.1 / 42.8	100 / 100	79.8 / 80.6	100 / 100	0.20 / 0.19
0.25	41.8 / 42.4	101.8 / 99.0	79.3 / 78.7	99.4 / 97.7	0.19 / 0.19
0.5	42.0 / 43.0	102.2 / 100.4	79.5 / 78.4	99.7 / 97.3	0.19 / 0.18
1	41.3 / 43.0	100.4 / 100.5	74.7 / 75.9	93.7 / 94.2	0.18 / 0.18
2	42.0 / 43.3	102.1 / 101.2	72.2 / 72.3	90.5 / 89.7	0.17 / 0.17
4	41.0 / 42.6	99.7 / 99.6	62.0 / 63.3	77.7 / 78.5	0.15 / 0.15
6	41.2 / 43.0	100.2 / 100.5	57.1 / 55.5	71.6 / 68.9	0.14 / 0.13
24	42.6 / 40.9	103.6 / 95.6	29.4 / 29.8	36.8 / 37.0	0.07 / 0.07

hours	Fluazinam		Impurity-5		ratio
	mean µg	% of initial	mean ng	% of initial	impurity/fluazinam
Dark controll					
6	41.3 / 43.4	100.5 / 101.3	83.3 / 77.8	104.4 / 96.5	0.20 / 0.18
24	41.9 / 42.8	101.9 / 100.0	87.4 / 76.7	109.5 / 95.2	0.21 / 0.18

Table B.8.9.-4: Photostability of fluazinam and impurity-5 on a glass surface in SUNTESTER (Xe lamp) at 20° C

hours	Fluazinam		Impurity-5		ratio
	mean µg	% of initial	mean ng	% of initial	impurity/fluazinam
0	44.2	100	79.9	100	0.18
0.25	44.7	101.1	37.7	47.3	0.08
0.30	44.0	99.6	24.8	31.2	0.06
1	43.1	97.4	17.9	22.5	0.04
2	43.1	97.4	14.5	18.2	0.03
4	39.7	89.7	13.4	16.8	0.03
6	38.3	86.7	11.8	14.8	0.03
24	31.5	71.3	6.4	8.1	0.02

Table B.8.9.-5: Stability of fluazinam and impurity-5 on leaves of Kidney bean / potato

days	Fluazinam		Impurity-5		ratio
	mean µg/cm^2	% of initial	mean ng/cm^2	% of initial	impurity/fluazinam
0	2.50 / 3.95	100 / 100	4.12 / 6.24	100 / 100	0.16 / 0.17
1	2.57 / 2.93	100.4 / 81.7	1.17 / 1.59	28.4 / 25.5	0.05 / 0.05
3	2.12 / 3.20	84.9 / 89.1	0.63 / 1.00	15.3 / 16.1	0.03 / 0.03
7	1.68 / 2.89	67.1 / 80.5	0.45 / 0.72	10.8 / 11.5	0.03 / 0.02
14	1.01 / 1.39	40.5 / 38.7	0.25 / 0.31	6.1 / 5.0	0.02 / 0.02

Table B.8.9.-6: Stability of fluazinam and impurity-5 on leaves of peanut (greenhouse / outdoor)

days	Fluazinam		Impurity-5		ratio
	mean µg/cm²	% of initial	mean ng/cm²	% of initial	impurity/fluazinam
0	1.20 / 0.63	100 / 100	1.71 / 1.10	100 / 100	0.14 / 0.17
1 / 0.5	0.91 / 0.71	75.4 / 111.9	0.71 / 0.81	41.7 / 74.0	0.08 / 0.12
3 / 1	0.87 / 0.71	72.9 / 111.9	0.41 / 0.61	23.9 / 55.6	0.05 / 0.09
7 / 2	0.77 / 1.04	64.0 / 165.4	0.26 / 0.74	15.4 / 67.0	0.03 / 0.07
14 / 3	0.54 / 0.89	44.6 / 141.6	0.15 / 0.55	8.6 / 50.3	0.03 / 0.06

In the study to evaluate the stability of fluazinam and impurity-5 on the surface of foliage of peanut under outdoor conditions, treatments were made both with and without the addition of the adjuvant Silwet L77. When no adjuvant was added, the amount of fluazinam varied widely from 100.0 % at initial time to 165.4 % at 2 hours (see table B.8.9.-6). This was attributed to uneven application and spread of the residue on the leaves. Despite the wide variation in the amount of fluazinam the percentage of impurity-5 decreased gradually to 50.0 % of the initial value at 3 hours after application. With the addition of adjuvant (results not included in the table), the variation in the fluazinam amount was smaller that without adjuvant. Impurity-5 was found at an amount of 3.00 ng/cm^2 foliage just after the application. After 3 hours the amount of impurity-5 decreased to 0.65 ng/cm^2 (21.7 % of initial amount), whereas the amount of fluazinam decreased from 1.59 µg/cm^2 at initial time to 1.14 µg/cm^2 after 3 hours (72.1 % of initial time). The ratio of impurity-5 to fluazinam decreased to 0.06 (after 14 days) from 0.19 % (at initial time).

In addition, residual amount of impurity-5 absorbed in foliage of the plants was investigated. In all species of plants the residual amount of impurity-5 was analysed at day 1 and 7 the amount absorbed by foliage of the plants was below the limit of detection in all species at both dates of analysis.

Conclusions:

When comparing stability of fluazinam and impuritiy-5 on glass surfaces and plant leaves under light conditions, impurity-5 was seen to be much less stable than fluazinam under all conditions evaluated.

B.8.10 Definition of the residue (Annex IIA 7.3)

Soil:	Fluazinam, HYPA
Groundwater:	Fluazinam
Surface water:	Fluazinam, G-504 (from aqueous photolysis)
Sediment:	Fluazinam, AMPA
Air:	Fluazinam

B.8.11 References relied on

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N-R/NR	Owner
Annex II Data and Information					
AII, 7.1.1.1.1	Bharti H., Bewick, D.W.	1985	B-1216 (PP192): Degradation in Soil. ICI Plant Protection Division, Report No. RJ0444B. GLP, unpublished	N	ISK
AII, 7.1.1.1.1	Mawad, N.	2003	Metabolism And Degradation Of ^{14}C-Fluazinam In One Soil Incubated Under Aerobic Conditions. RCC Ltd, Report No.844056 GLP, unpublished	Y	ISK
AII, 7.1.1.1.2	Lentz, N.R., Korsch, B.H.	2001	A Photolysis Study of IKF-1216 (Fluazinam) on Soil. Ricerca, Inc., Amended Report No. 5313-95-0011-EF-002 GLP, unpublished	Y	ISK
AII, 7.1.1.2.	Ryan, J., Sapiets, A.	1992	Fluazinam: Laboratory Soil Degradation Study (BBA) ICI Agrochemicals, Report No. RJ1391B GLP, unpublished	N	ISK
AII, 7.1.1.2.1 = AII, 7.1.1.1.1	Bharti H., Bewick, D.W.	1985	B-1216 (PP192): Degradation in Soil. ICI Plant Protection Division, Report No. RJ0444B. GLP, unpublished	N	ISK
AII, 7.1.1.2.1	van der Gaauw, A.	2002	Degradation Rate of HYPA in Three Soils Incubated Under Aerobic Conditions. RCC Ltd, Report No. 842279 GLP, unpublished	Y	ISK
AII, 7.1.1.2.1 = AII,7.1.1.1.1	Mawad, N.	2003	Metabolism And Degradation Of ^{14}C-Fluazinam In One Soil Incubated Under Aerobic Conditions. RCC Ltd, Report No.844056 GLP, unpublished	Y	ISK
AII, 7.1.1.2.1 AII, 7.1.1.2.2	Gurney A.	2005 a	Kinetic calculations for degradation of fluazinam in soil under laboratory and field conditions RCC Ltd report no. A07132, July 1, 2005 Not GLP, unpublished	Y	ISK
AII, 7.1.1.2.2	Kennedy, S.H.	1996	Fluazinam Soil Degradation Study Following Applications to Potatoes and Bare Ground (UK, 1995). CEM Analytical Services Ltd., Report No. CEMS-451 GLP, unpublished	N	ISK

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N-R/NR	Owner
AII, 7.1.1.2.2	Burke, S. R., Sapiets, A.	1992	Fluazinam: Soil Dissipation Study (Germany, 1991-1992). ICI Agrochemicals, Report No. RJ1368B GLP, unpublished	N	ISK
AII, 7.1.1.2.2	Burke, S. R., Sapiets, A.	1993	Fluazinam: Residue Levels of the Metabolite R270682 ("HYPA") in Soil From a Dissipation Study Carried Out in Germany During 1991-1992. ICI Agrochemicals., Report No. RJ1443B GLP, unpublished	N	ISK
AII, 7.1.2	Galicia, H., Völkl, S.	1991	Soil Adsorption/ Desorption of Fluazinam (IKF-1216) on Four Soils. RCC Umweltchemie AG, Report No. 282306 GLP, unpublished	N	ISK
AII, 7.1.2	Muller, K., Lane, M. C. G.	1993	Fluazinam: Adsorption and Desorption Properties in Soil of R270682 ("HYPA"), a Major Soil Metabolite. ICI Plant Protection Division, Report No. RJ1308B GLP, unpublished	N	ISK
AII, 7.2.1.1 = AII, 2.9.1	van der Gaauw, A.	2003	^{14}C-Fluazinam: Hydrolysis at Three Different pH Values. RCC Ltd, Report No. 846211 GLP, unpublished	Y	ISK
AII, 7.2.1.2 = AII, 2.9.2	Lentz N.R., Korsch B.H.	1994	A photolysis Study of IKF-1216 in water at pH 5 (part 1) Ricerca, report no. 5312-94-0119-EF-001, Interim report, December 20, 1994 GLP, unpublished	N	ISK
AII, 7.2.1.2 = AII, 2.9.2	Lentz, N.R., Korsch, B.H.	1995	A Photolysis Study of IKF-1216 (Fluazinam) in Water at pH 5. Ricerca, Inc., Report No. 5312-94-0119-EF-002 GLP, unpublished	N	ISK
AII, 7.2.1.3.1	Grützner, I.	2000	Ready Biodegradability of Fluazinam in a Manometric Respirometry Test. RCC Ltd, Report No. 774898 GLP, unpublished	Y	ISK
AII, 7.2.1.3.2	Goodyear, A.	1997	^{14}C-Fluazinam: Biodegradation in Natural Water-Sediment Systems. Covance Laboratories, Report No. 38/188-1015 GLP, unpublished	N	ISK
AII, 7.2.2	Atkinson, R.	1993	Estimation of Hydroxyl Radical Reaction Rate Constants: Fluazinam. Ricerca Inc., Report No. RIC 1832 Not GLP, unpublished	N	ISK

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N-R/NR	Owner
Annex III Data and Information					
AIII, 9.1.1.1			See Confidential Bibliography		
AIII, 9.1.1.2 = AII, 7.1.1.2.2	Kennedy, S.H.	1996	Fluazinam Soil Degradation Study Following Applications to Potatoes and Bare Ground (UK, 1995). CEM Analytical Services Ltd., Report No. CEMS-451 GLP, unpublished	N	ISK
AIII, 9.1.1.2 =AII, 7.1.1.2.2	Burke, S. R., Sapiets, A.	1992	Fluazinam: Soil Dissipation Study (Germany, 1991-1992). ICI Agrochemicals, Report No. RJ1368B GLP, unpublished	N	ISK
AIII, 9.1.1.2 = AII, 7.1.1.2.2	Burke, S. R., Sapiets, A.	1993	Fluazinam: Residue Levels of the Metabolite R270682 (“HYPA”) in Soil From a Dissipation Study Carried Out in Germany During 1991-1992. ICI Agrochemicals., Report No. RJ1443B GLP, unpublished	N	ISK
AIII, 9.1.1.2/04 = AII, 7.1.1.2.2/04	Crawford, C. J., Dillon, K. A.	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in Washington. Ricerca, Inc., Report No. 5687-93-0091-CR-001 GLP, unpublished	N	ISK
AIII, 9.1.1.2/05 = AII, 7.1.1.2.2/05	Crawford, C. J., Dillon, K. A.	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in North Dakota. Ricerca, Inc., Report No. 5687-93-0111-CR-001 GLP, unpublished	N	ISK
AIII, 9.1.1.2 = AII, 7.1.1.2.2	Crawford, C. J., Dillon, K. A.	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in California. Ricerca, Inc., Report No. 5687-93-0108-CR-001 GLP, unpublished	N	ISK
AIII, 9.1.1.2 = AII, 7.1.1.2.2	Crawford, C. J., Dillon, K. A.	1995	Dissipation of Residues of Fluazinam and Its Metabolites (MAPA, HYPA and CAPA) from Soil in Georgia. Ricerca, Inc., Report No. 5687-93-0104-CR-001 GLP, unpublished	N	ISK
AIII, 9.1.2.1	Burke, S.R., Clarke, D.M.	1992	Fluazinam: Leaching of Formulated Material in Soil Columns. ICI Agrochemicals, UK, Report No. RJ1234B GLP, unpublished	N	ISK

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N-R/NR	Owner
AIII, 9.1.3	McFadden, J.J.	2003	Terrestrial and Aquatic PEC Values for Fluazinam (IKF-1216) and Risk-Assessment for the Use on Potato in the EU Ricerca, Inc., Report No. 014891-1. GLP, unpublished	Y	ISK
AIII, 9.2 = AIII, 9.1.3	McFadden, J.J.	2003	Terrestrial and Aquatic PEC Values for Fluazinam (IKF-1216) and Risk-Assessment for the Use on Potato in the EU Ricerca, Inc., Report No. 014891-1. Not GLP, unpublished	Y	ISK
AIII, 9.2.3	Görge G.	2005	Estimation of the environmental concentrations of fluazinam and its metabolites AMPA in surface water RCC, report no. A17267, July 20, 2005 Not GLP, unpublished	Y	ISK
AIII, 9.2.3	Gurney, A.	2005 c	**Estimation of the environmental concentrations of fluazinam in surface water. FOCUS surface water step 4 calculations** **RCC Ltd., Report No. A44280** **Not GLP, unpublished**	Y	ISK
AIII, 9.2.3	Gurney, A.	2005 b	**Fluazinam Defence of water-sediment half-lives used in FOCUS surface water calculations** **RCC Ltd., Report No. A44280-A** **Not GLP, unpublished**	Y	ISK
AIII, 9.2.1	Vercruysse F.	2005	Predicted environmental concentrations in groundwater (PECgw) after PELMO simulation for the active ingredient fluazinam (IKF-1216) and its metabolite HYPA ISK Biosciences Europe SA, report no. IBE1216-EF0506-01, June 24, 2005 Not GLP, unpublished	Y	ISK
AIII, 9.3			See Confidential Bibliography		