	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*24-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	7.1.3	Adsorption/desorption screening test

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*25-10-2007*	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

98/8 Doc IIIA section No.	7.1.4.1	Field study on accumulation in the sediment

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*25-10-2007*	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

98/8 Doc IIIA section No.	**7.2.1**	**Aerobic degradation in soil, initial study**
91/414 Annex IIA point addressed	**7.1.1.1.1**	**Aerobic degradation in soil**

		Official use only
Reference point (location) in dossier	**7.2.1/01**	
Title:	Metabolism and Rate of Degradation of [23- ^{14}C]-Labelled NOA 422601 (Avermectin B_{1a}) under Aerobic and Anaerobic Laboratory Conditions in one Soil at 20°C	
Project/Report number:	99AG07	
Author(s):	Nicollier G.	
Date of report:	13/06/2001	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	19/11/1999 to 2/3/2001	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Nicollier, G. (2001)	GLP statement	:	yes
Type of study	:	degradation in soil	Guideline	:	BBA IV, 4-1; draft OECD
Year of execution	:	1999 - 2001	Acceptability	:	acceptable (aerobic part)
Test substance	:	[23-^{14}C]-avermectin B_{1a}, batch [redacted] radiochemical purity [redacted]			

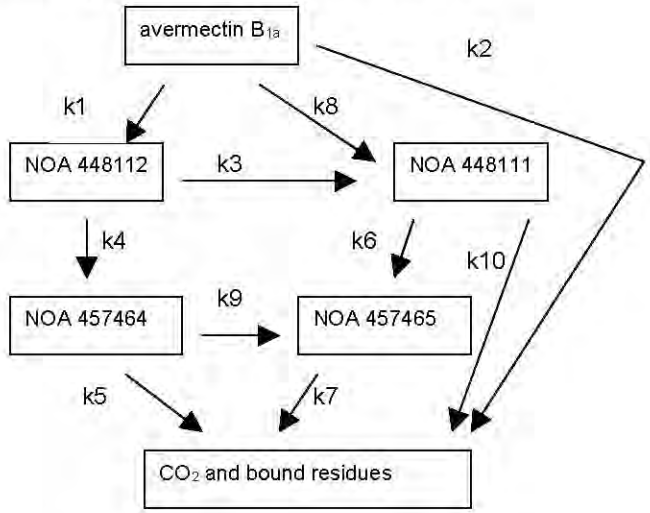
Substance	Soil type	Condition	Dose [mg/kg]	T [° C]	OM [%]	pH	pF	Duration [d]	DT_{50} [d]
^{14}C-avermectin B_{1a}	loam	aerobic	0.22	20	3.2	7.3	2	365	18.8
NOA 448111 (from parent)	loam	aerobic		20	3.2	7.3	2	365	50.6
NOA 448112 (from parent)	loam	aerobic		20	3.2	7.3	2	365	30.1
NOA 457464 (from parent)	loam	aerobic		20	3.2	7.3	2	365	99.0
NOA 457465 (from parent)	loam	aerobic		20	3.2	7.3	2	365	173

Description

Soil. Loam (Gartenacker, CH): CEC 126.7 mmol/kg, MWHC 66.84 %, bulk density 0.96 kg/L, microbial biomass 28.4 mg C/100 g. Air dried, 2 mm sieved.
Method. Avermectin B_{1a} was applied to the soil as a solution in acetone, application rate ca. 0.22 mg/kg. Aerobic incubation: 40 % of WHC, ventilation with moistened air. Aerobic/anaerobic incubations: first 27 days as aerobic, then water-logging with deionised water and ventilation with N_2. Incubation at 20 ± 2 °C in the dark. Effluent air passed through volatile traps (ethylene glycol and 2 N NaOH). Duplicate soil samples taken at regular time points for 365 days (aerobic) or 120 days (anaerobic). Microbial biomass determined at start and end according to Anderson and Domsch (1978).
Analysis. Extraction at room temperature with acetonitrile/water 8:2 (v/v; 200 U/min, 30 min), centrifugation at 2000 rpm (10 min, 20 °C), repeated two to three times, extracts combined. Soil further extracted with acetonitrile under reflux for 2 hours. Analysis of extracts by LSC and 2D-TLC, HPLC-UV (220 nm) used for additional quantification. Additional harsh extraction of selected samples (day 168 aerobic, day 120 anaerobic) by reflux with acetonitrile/water (4:1) at 80 °C for 2 hours, and acetonitrile/0.1 N HCl (9:1) at 80 °C for 2 hours. Extracts analysed by LSC. Bound residues (after reflux step) determined by LSC after combustion. Organic matter

fractionation by precipitation with NaOH and HCl. Volatiles analysed by LSC, CO_2 confirmed by $BaCO_3$-precipitation.
Reference compounds for HPLC and TLC: abamectin, desoleandrosyl-avermectin B_{1a} (NOA 419150) and CGA 172534. LOQ determined for aerobic day-7 sample and defined as 3 x background: 0.3 % of AR for LSC, 0.7 - 1.7 µg/kg for HPLC, 0.1 - 3 µg/kg for TLC. Identification of metabolites by NMR and LC/MS.
Calculations. Rate constants for degradation of avermectin B_{1a} and concurrent formation and decline of metabolites, CO_2 and bound residues were estimated with ModelMaker 3.03. Based on the proposed degradation pathway in soil (see the figure below) and assuming first-order kinetics, the following scheme and equations were implemented in ModelMaker:

Figure: Modelled degradation pathway of avermectin B_{1a} in soil.



NOA 448111 : 8a-oxo-avermectin B_{1a}
NOA 448112 : 8a-hydroxy- avermectin B_{1a}
NOA 457464 : 4,8a-dihydroxy-avermectin B_{1a}
NOA 457465 : 8a-oxo-4-hydroxy-avermectin B_{1a}

DT_{50}, avermectin B_{1a} = ln2/(k1 +k2 + k8)
DT_{50}, NOA 448111 = ln2/(k6 + k10)
DT_{50}, NOA 448112 = ln2/(k3 + k4)
DT_{50}, NOA 457464 = ln2/(k5 + k9)
DT_{50}, NOA 457465 = ln2/(k7)

Results

Microbial biomass at end 38.0 mg C/100 g.
Aerobic incubation: Distribution of radioactivity for aerobic incubation is given in the table below. Maximum levels are indicated in bold. Organic volatiles were < 0.1 % of AR.

Table: Distribution of radioactivity after aerobic incubation of avermectin B_{1a} in loam soil. All values in % of AR.

Time [d]	Extractable[1]	Bound residues	CO_2	Recovery	Avermectin B_{1a}	NOA 448111	NOA 448112	NOA 457464	NOA 457465
0	97.9	0.7	-	98.6	97.9	< LOD	< LOD	< LOD	< LOD
3	98.6	2.5	0.1	101.2	86.8	3.1	5.5	0.2	< LOD
7	94.9	5.2	0.3	100.4	68.2	6.4	9.0	0.9	0.5
14	90.5	8.5	0.8	99.8	51.9	7.5	13.2	2.6	1.3
28	84.0	13.6	1.8	99.5	33.2	**10.3**	**15.7**	5.5	3.1
56	71.0	21.0	4.9	96.8	16.7	9.1	13.9	8.9	5.1
90	63.4	25.3	7.8	96.4	9.2	8.0	8.8	**9.3**	7.8
120	55.2	29.0	11.8	96.0	5.7	4.8	5.2	9.0	8.2
168	49.8	29.7	14.8	94.4	4.5	3.4	3.4	8.2	**8.5**
240	39.4	33.6	23.6	96.6	3.5	4.1	1.1	6.2	8.3
294	34.7	32.3	23.5	90.6	2.3	1.3	0.9	4.5	7.1
365	30.6	**33.9**	**27.6**	92.1	1.4	0.9	0.7	3.8	6.5

1: sum of ACN/water and reflux

Additional harsh extraction of day-168 samples released 5.7 % of AR. Bound residues were associated to equally to fulvic and humic acids and humin.

Aerobic/anaerobic incubation: Redox potential of water phase 85 and 17 mV on days 0 and 7 after water-logging, declining to values around -80 mV as from day 66. Redox potential in soil -60 to -102 mV until day 20, thereafter -120 to -330 mV. Distribution of radioactivity for the aerobic/anaerobic incubation is given in the table below. Organic volatiles accounted for < 0.2 % of AR. Abamectin and metabolites in the water phase accounted for maximum 1.5 % of AR.

Table: Distribution of radioactivity after aerobic/anaerobic incubation of avermectin B_{1a} in loam soil. All values in % of AR.

Time after water-logging [d]	Water	Soil		CO_2	Recovery	Soil				
		Extractable[1]	Bound residues			Avermectin B_{1a}	NOA 448111	NOA 448112	NOA 457464	NOA 457465
0	7.3	83.5	12.4	2.0	97.9	30.6	8.2	**14.2**	4.4	**2.8**
3	5.5	82.3	12.6	1.9	96.8	29.8	**9.5**	**14.2**	3.8	2.3
7	6.1	82.1	12.8	1.9	96.8	26.8	7.0	12.2	3.9	1.5
14	4.3	87.4	16.0	2.1	96.5	21.8	9.9	10.5	3.0	1.6
28	4.4	76.2	17.8	2.2	96.2	18.6	9.5	9.1	2.6	1.7
56	4.5	71.8	22.9	2.5	97.3	16.6	7.6	7.1	2.2	2.2
91	4.2	69.8	24.8	2.7	97.3	16.9	6.9	7.6	**2.7**	**2.8**
120	4.3	67.2	28.4	3.0	98.7	15.4	4.9	7.8	3.2	2.7

1: sum of ACN/water and reflux

One unknown fraction reached a maximum of 11.9 % of AR on day 56, but was shown to consist of numerous sub-fractions upon re-analysis with a different TLC-system, single fractions accounted for at most 2.5 % of AR. Harsh extraction of day-120 samples released 6.1 % of AR. Bound residues mainly associated with humin. DT_{50}- and DT_{90}-values as estimated by ModelMaker are shown in the table below, total r^2 was 0.9872.

Table: DT_{50}-values for avermectin B_{1a} and metabolites reported by author.

Compound	Conditions	DT_{50} [d]		DT_{90} [d]
avermectin B_{1a}	aerobic	18.0		59.6
	anaerobic	276	extrapolated	
NOA 448111	aerobic	32.5		108.0
	anaerobic	122		-
NOA 448112	aerobic	35.4		117.8
	anaerobic	270	extrapolated	-
NOA 457464	aerobic	105.2		349.4
	anaerobic	-		-
NOA 457465	aerobic	83.3		276.8
	anaerobic	-		-

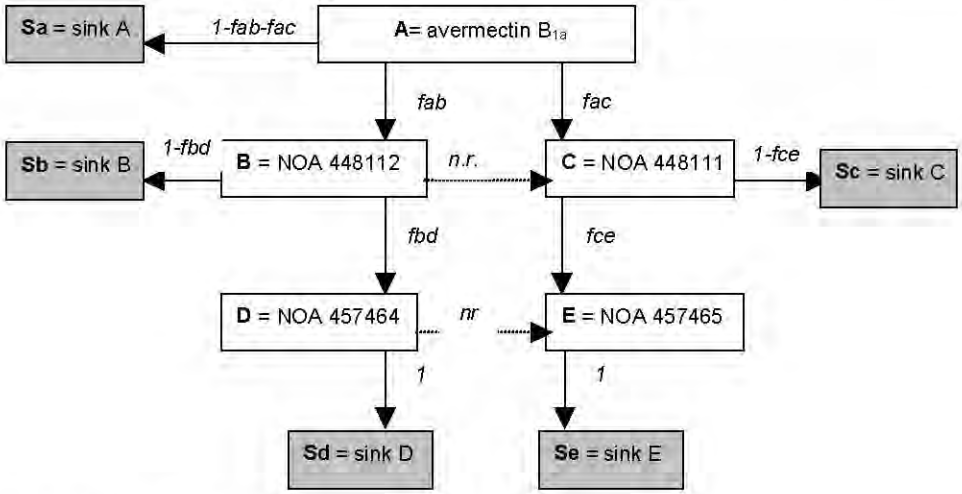
Remarks by RMS

Dose equivalent to ca. 8 times highest single field rate for analytical reasons. Soil history not clear, described as "… not been treated during previous 5 years in any way which could severely affect microbial populations." Extraction method differs slightly from validated soil analysis method RAM 412/01, where acetonitrile/water 70:30 v/v is used instead of 80:20 (see Document IIIA reference point 4.2 (a)/01). Total regression coefficient of ModelMaker fit is mainly determined by degradation of parent, regression coefficients for individual equations not supplied.

Aerobic incubation: DT_{50} for avermectin B_{1a} is recalculated by non-linear fit of first order kinetics. DT_{50}-values for metabolites NOA 448111, NOA 448112, NOA 457464 and NOA 457465 are recalculated using the Berkely-Madonna program following to the recommendations of the FOCUS degradation kinetics working group[1]. Simultaneous decline of avermectin B_{1a} and formation and decline of metabolites was assumed to proceed according to the figure below. The contribution of each pathway to the total fit was tested beforehand, and the routes from NOA 448112 to NOA 448111 and from NOA 457464 to NOA 457465 were shown to be not relevant.

[1]FOCUS. 2004. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in EU Registration. The final report of the Work group on Degradation Kinetics of FOCUS (FOrum for the Co-ordination fo pesticide fate models and their USe). Version 1, draft 29 ebruary 2004.

Figure: Modelled degradation pathway of avermectin B_{1a} in soil. Figures next to arrows indicate fractions.



d/dt (B) = ka*fab*A - kb*B
d/dt (C) = ka*fac*A - kc*C
d/dt (D) = kb*fbd*B - kd*D
d/dt (E) = kc*fce*C - ke*E
d/dt (Sa) = ka*(1-fab-fac)*A
d/dt (Sb) = kb*(1-fbd)*B
d/dt (Sc) = kc*(1-fce)*C

The DT_{50} for avermectin B_{1a} calculated in this way is similar to the value obtained by fitting the data for the parent alone, and the latter method is used for avermectin B_{1a}. The recalculated DT_{50}-values for metabolites are given in the table below.

Table: Recalculated DT_{50}-values for metabolites of avermectin B_{1a}.

Compound	Conditions	DT_{50} [d]	r^2	Error [%]	Method
avermectin B_{1a}		18.8	0.9875		single non-linear fit of parent, 1st order kinetics
NOA 448111	aerobic	50.6	0.86	19.6	simultaneous fit of parent and metabolites with Berkely-Madonna
NOA 448112	aerobic	30.0	0.98	11.0	
NOA 457464	aerobic	99.0	0.99	16.5	
NOA 457465	aerobic	173	0.98	9.6	

For NOA 448111 and 457464, errors are higher than allowed according to FOCUS (15 %). Visual inspection of the plots shows that the relatively high error for NOA 448111 is mainly caused by the data for days 3 and 240. For NOA 457464, the residuals for day 14 and 28 are relatively high. Because r^2 is acceptable in both cases, the results are accepted. Differences with author's figures may be due to the fact that 1) author normalised data to 100 % recovery, 2) did not include the route from NOA 488112 to bound residues and CO_2, and 3) did include the routes from NOA 448112 to NOA 448111 and from NOA 457464 to NOA 457465.
Aerobic/anaerobic incubation: Anaerobic conditions (redox potential lower than -100 mV) were established in soil only 28 days after water-logging (55 days after application). Almost 80 % of applied avermectin B_{1a} was already degraded by that time, only additional 3 % of AR disappeared during anaerobic phase. The DT_{50}'s of this incubation are not used for risk assessment.
The following results are used for risk assessment:

- maximum formation percentages of metabolites: 10.3 % for NOA 448111, 15.7 % for NOA 448112, 9.3 % for NOA 457464 and 8.5 % for NOA 457465.
- DT_{50}: 18.8 days for avermectin B_{1a}, 50.6 days for NOA 448111, 30.1 days for NOA 448112, 99.0 days for NOA 457464 and 173 days for NOA 457465.
- bound residues after 100 days: 25.3 % of AR (day-90 value)
- mineralisation after 100 days: 8.7 % of AR (day-90 value)

Syngenta endpoint(s) in originally submitted Document III A Section 7:
DT_{50}: 18 days for avermectin B_{1a}, 32.5 days for NOA 448111, 35.4 days for NOA 448112, 105.2 days for NOA 457464 and 83.3 days for NOA 457465.
CO_2 after 90 days: 7.8% of AR (see also table further above, maybe typing error in RMS remarks of DAR)

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	7.2.2.1	Aerobic degradation in soil, futher studies
91/414 Annex IIA points addressed	7.1.1.1.1 7.1.1.2.1	Aerobic degradation in soil Rate of degradation in soil

		Official use only
Reference point (location) in dossier	**7.2.2.1/01**	
Title:	Rate of Degradation of [23- ^{14}C]-labelled NOA 422601 (Avermectin B_{1a}) in one Soil under various Laboratory Conditions at 10°C, 20°C and 30°C	
Project/Report number:	00DA07	
Author(s):	Adam D.	
Date of report:	30/05/2001	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	20/6/2000 to 25/1/2001	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Adam, D. (2001a)	GLP statement	:	yes
Type of study	:	degradation in soil	Guideline	:	BBA IV, 4-1; draft OECD
Year of execution	:	2000-2001	Acceptability	:	acceptable
Test substance	:	[23-^{14}C]-avermectin B_{1a}, batch [redacted], radiochemical purity [redacted]			

Substance	Soil type	Condition	Dose [mg/kg]	T [° C]	OM [%]	pH	pF	Duration [d]	DT_{50} [d]
^{14}C-avermectin B_{1a}	silt loam	aerobic	0.1	30	4.0	7.2	2.5	120	16.6
^{14}C-avermectin B_{1a}	silt loam	aerobic	0.1	20	4.0	7.2	2.5	120	23.3
^{14}C-avermectin B_{1a}	silt loam	aerobic	0.1	10	4.0	7.2	2.5	120	50.6
^{14}C-avermectin B_{1a}	silt loam	aerobic	0.1	30	4.0	7.2	4.0	120	24.4
NOA 448111 (from parent)	silt loam	aerobic		20	4.0	7.2	2.5	120	40.5
NOA 448112 (from parent)	silt loam	aerobic		20	4.0	7.2	2.5	120	26.8
NOA 457464 (from parent)	silt loam	aerobic		20	4.0	7.2	2.5	120	48.5
NOA 457465 (from parent)	silt loam	aerobic		20	4.0	7.2	2.5	120	59.8

Description

Soil. Silt loam (Gartenacker, CH): CEC 157 mmol/kg, MWHC 67.9 %, microbial biomass 95.2 mg C/100 g. Air dried, 2 mm sieved.
Method. Avermectin B_{1a} was applied to the soil as a solution in acetone, application rate ca. 0.1 mg/kg. Incubation at 8.6 ± 0.1 and 19.5 ± 0.1 °C in the dark, both at 40 % of WHC, and 30.2 ± 0.2 °C in the dark at 25 and 40 % of WHC. Effluent air passed through volatile traps (ethylene glycol and 2 N NaOH). Soil sampled in duplicate at regular time points for 120 days, single samples on days 3, 14 and 56. Microbial biomass determined at start and end according to Anderson and Domsch (1978).
Analysis. Extraction at room temperature with acetonitrile/water 8:2 (v/v; 200 rpm, 30 min), centrifugation at 2000 rpm (5 min). Soil further extracted with acetonitrile under reflux for 6 hours, reflux and cold extracts combined and analysed by LSC and 2D-TLC and/or HPLC-UV (220 nm). Additional harsh extraction of day-120 samples by reflux with acetonitrile/water (4:1) at 80 °C for 2 hours, and acetonitrile/0.1 N HCl (9:1) at 80

°C for 2 hours. Extracts analysed by LSC. Bound residues (after reflux step) determined by LSC after combustion. Organic matter fractionation by precipitation with NaOH and HCl. Volatiles analysed by LSC, CO_2 confirmed by $BaCO_3$-precipitation. Reference compounds for HPLC and TLC: abamectin, NOA 448111, NOA 448112, NOA 457464,and NOA 457465 (all isolated and identified in previous study). LOQ determined for day-28 sample of 20 °C and defined as 3 x background: 0.5 % of AR for LSC, 0.07 - 0.08 µg/kg for HPLC, 0.5 - 1.5 µg/kg for TLC.

Calculations. Rate constants for degradation of avermectin B_{1a} and concurrent formation of metabolites, CO_2 and bound residues estimated with ModelMaker 3.03, using the scheme presented above for Study 1 and assuming first-order kinetics.

Results

Microbial biomass at end 51.7 mg C/100 g. Distribution of radioactivity for respective incubations is given in the table below. Maximum levels are indicated in bold. Organic volatiles were ≤ 0.1 % of AR.

Table: Distribution of radioactivity after aerobic incubation of avermectin B_{1a} in loam soil. All values in % of AR.

Incubation	Time [d]	Extractable[1]	Bound residues	CO_2	Recovery	Avermectin B_{1a}	NOA 448111	NOA 448112	NOA 457464	NOA 457465
30 °C, 40 % WHC	0	99.1	1.0	-	100.0	93.4	2.3	< LOD	< LOD	< LOD
	3[2]	94.9	3.3	0.3	98.5	82.4	1.5	4.9	0.4	< LOD
	7	92.8	4.2	0.4	97.3	65.6	7.1	7.7	1.3	0.7
	14[2]	87.0	7.7	1.0	95.7	49.7	8.1	11.5	2.5	2.2
	28	78.6	17.9	2.8	99.3	29.3	**13.8**	**13.0**	4.1	2.4
	56[2]	61.6	27.3	7.7	96.5	8.9	8.1	7.6	**6.3**	**6.2**
	90	61.5	26.4	6.6	94.6	8.6[2]	7.7[2]	8.0	4.5	4.1
	120	45.6	**34.9**	**17.0**	97.5	3.7	4.3	3.5	3.2	6.0
20 °C, 40 % WHC	0	97.1	1.3	-	98.4	92.6	1.5	< LOD	< LOD	< LOD
	3[2]	95.4	2.3	0.1	97.8	81.0	2.9	3.4	0.3	< LOD
	7	96.4	2.9	0.2	99.6	72.3	5.2	6.4	1.0	0.3
	14[2]	93.7	5.0	0.7	99.4	58.5	**10.6**	10.4	1.8	1.1
	28	86.3	8.9	1.5	96.8	39.4	9.0	**13.0**	3.9	1.8
	56[2]	74.4	19.1	3.9	97.4	16.0	10.2	11.3	7.2	4.8
	90	67.6	24.0	6.5	98.0	8.1	8.5	7.2	**9.9**	**8.2**
	120	63.1	**26.9**	**8.1**	98.1	6.7	7.3	6.0	8.4	7.0
10 °C, 40 % WHC	0	94.9	1.2	-	96.1	90.0	1.8	< LOD	< LOD	< LOD
	3[2]	96.0	1.8	< 0.1	97.8	85.3	2.4	2.3	< LOD	< LOD
	7	100.5	1.7	0.1	102.3	86.1	3.7	4.7	0.6	< LOD
	14[2]	98.7	2.7	0.2	101.5	78.0	4.6	8.1	0.9	< LOD
	28	95.5	5.9	0.4	101.8	64.9	5.6	11.2	1.6	0.7
	56[2]	89.3	9.2	1.0	99.6	46.0	7.0	13.2	3.1	1.6
	90	90.3	11.7	1.4	103.5	32.0	**10.8**	**15.0**	4.7	2.3
	120	82.5	**13.8**	**1.4**	97.8	22.6	**10.8**	12.7	**7.1**	**4.4**
30 °C, 25 % WHC	0	98.1	1.2	-	99.3	93.0	2.2	< LOD	< LOD	< LOD
	3[2]	98.3	3.2	0.1	101.6	85.7	4.1	3.9	0.2	< LOD
	7	95.1	4.5	0.2	99.8	73.3	5.5	7.5	0.7	< LOD
	14[2]	90.8	7.5	0.6	99.0	58.6	7.0	10.9	2.0	1.6
	28	82.3	14.9	1.9	99.1	41.5	7.1	12.3	3.1	2.7
	56[2]	76.0	20.6	3.8	100.5	18.6	**9.3**	**12.9**	7.3	6.6
	90	73.4	23.4	6.0	102.7	10.2	8.9	9.9	8.8	8.2
	120	66.3	**26.6**	**8.2**	101.2	5.6	7.5	7.6	**9.0**	**9.2**

1: sum of ACN/water and reflux
2: single samples

Unknown metabolites accounted for at most 4.9 % of AR. The following DT_{50}- and DT_{90}-values were derived using ModelMaker (see table below):

Table: DT_{50}-values for avermectin B_{1a} and metabolites as reported by author.

Compound	Conditions	DT_{50} [d]	DT_{90} [d]
avermectin B_{1a}	30 °C, 40 % WHC	16.0	53.1
	20 °C, 40 % WHC	21.3	70.6
	10 °C, 40 % WHC	52.7	175
	30 °C, 25 % WHC	22.7	75.3
NOA 448111	30 °C, 40 % WHC	32.6	108.2
	20 °C, 40 % WHC	42.4	140.9
	10 °C, 40 % WHC	-	-
	30 °C, 25 % WHC	49.1	163.0
NOA 448112	30 °C, 40 % WHC	22.7	75.3
	20 °C, 40 % WHC	35.6	118.2
	10 °C, 40 % WHC	-	-
	30 °C, 25 % WHC	41.3	137.1

Remarks by RMS

Dose equivalent to ca. 3 times highest single field rate for analytical reasons. Soil history not clear, described as "… not been treated during previous 5 years in any way which could severely affect microbial populations." Validated soil analysis method RAM 412/01 uses acetonitrile/water 70:30 v/v for extraction (see Document IIIA reference point 4.2 (a)/01), here 80:20 is used. Regression coefficients for ModelMaker-fit not supplied. DT_{50} for avermectin B_{1a} is recalculated by non-linear fit of first order kinetics. DT_{50}-values for metabolites are recalculated with Berkely-Madonna as described above (Document IIIA reference point 7.2.1/01), recalculation is done for 20 °C, 40 % WHC only. A summary of recalculated DT_{50}-values is given in the table below:

Table: Recalculated DT_{50}-values for avermectin B_{1a} and metabolites.

Compound	Conditions	DT_{50} [d]	r^2	Error [%]	Method
avermectin B_{1a}	30 °C, 40 % WHC	16.6	0.9923		single non-linear fit of parent, 1st order kinetics
	20 °C, 40 % WHC	23.3	0.9961		
	8.6 °C, 40 % WHC	59.4	0.9970		
	30 °C, 25 % WHC	24.4	0.9961		
NOA 448111	20 °C, 40 % WHC	40.5	0.86	18.3	simultaneous fit of parent and metabolites with Berkely-Madonna
NOA 448112		26.8	0.98	8.2	
NOA 457464		48.5	0.99	8.3	
NOA 457465		59.8	0.98	12.6	

The error for NOA 448111 is > 15 %, this is mainly caused by time points 14 and 28 days, but result is considered acceptable. From the DT_{50}-values for avermectin B_{1a} it is concluded that moisture content has a slight influence on DT_{50}. Actual temperature at 10 °C was 8.6 °C, DT_{50} at 10 °C is calculated by fitting the Arrhenius equation for 40 % WHC. The constants Ea and A are derived by linear regression of ln(k) versus 1/T: Ea is 10.0 kcal/mole, A is 12.5/s. Using these parameters, calculated DT_{50} for avermectin B_{1a} at 10 °C is 50.6 days. The following results are used for risk assessment:

- maximum formation percentages of metabolites (20 °C, 40 % WHC): 13.8 % for NOA 448111, 13.0 % for NOA 448112, 9.9 % for NOA 457464 and 8.2 % for NOA 457465
- DT_{50} (20 °C, 40 % WHC): 23.3 days for avermectin B_{1a}, 40.5 days for NOA 448111, 26.8 days for NOA 448112, 48.5 days for NOA 457464 and 59.8 days for NOA 457465
- bound residues after 100 days (20 °C, 40 % WHC): 24.0 % of AR (day-90 value)
- mineralisation after 100 days (20 °C, 40 % WHC): 6.5 % of AR (day-90 value)
- DT_{50} for avermectin B_{1a} at 10 °C: 50.6 days (calculated value)

Remarks (Syngenta): Inconsistency in DAR
maximum formation percentages of metabolites (20 °C, 40 % WHC)
13.8 % (NOA 448111) refers to 30°C, the corresponding value for 20°C is 10.6%.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.1/02**	
Title:	Rate of Degradation of [23- ^{14}C]-labelled NOA 422601 (Avermectin B_{1a}) in Various Soils under Aerobic Laboratory Conditions at 20°C	
Project/Report number:	01RP02	
Author(s):	Phaff R.	
Date of report:	13/08/2003	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	18/6/2001 to 15/11/2002	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Phaff, R. (2003)	GLP statement	:	yes
Type of study	:	degradation in soil	Guideline	:	BBA IV, 4-1; draft OECD
Year of execution	:	2001-2003	Acceptability	:	acceptable
Test substance	:	[23-^{14}C]-avermectin B , batch [redacted], radiochemical purity [redacted]			

Substance	Soil type	Condition	Dose [mg/kg]	T [° C]	OM [%]	pH	pF	Duration [d]	DT_{50} [d]
^{14}C-avermectin B_{1a}	loamy sand	aerobic	0.125	20	2.4	7.4[1]	2.5	196	23.6
^{14}C-avermectin B_{1a}	sandy clay loam	aerobic	0.125	20	4.3	5.8[1]	2.5	196	11.2
^{14}C-avermectin B_{1a}	silty clay loam	aerobic	0.125	20	2.4	7.9[2]	3.5	196	49.6
NOA 448111 (from parent)	loamy sand	aerobic		20	2.4	7.4[1]	2.5	196	45.3
NOA 448111 (from parent)	silty clay loam	aerobic		20	2.4	7.9[2]	3.5	196	45.4
NOA 448112 (from parent)	loamy sand	aerobic		20	2.4	7.4[1]	2.5	196	26.9
NOA 448112 (from parent)	silty clay loam	aerobic		20	2.4	7.9[2]	3.5	196	75.4
NOA 457464 (from parent)	loamy sand	aerobic		20	2.4	7.4[1]	2.5	196	59.5
NOA 457465 (from parent)	loamy sand	aerobic		20	2.4	7.4[1]	2.5	196	137

1: pH-KCl
2: pH-H_2O

Description

Soils. Loamy sand (Pappelacker, CH): CEC 74 mmol/kg, MWHC 49.2 %, bulk density 1.4 kg/L, microbial biomass 33.6 mg C/100 g. Sandy clay loam (Bracknell, UK): CEC 197 mmol/kg, MWHC 60.4 %, bulk density 0.9 kg/L, microbial biomass 64.2 mg C/100 g. Silty clay loam (Marsillagues, F): CEC 178 mmol/kg, MWHC 52.6 %, bulk density 1.2 kg/L, microbial biomass 78.0 mg C/100 g. All soils air dried, sieved and stored at 5 °C. Autoclaved loamy sand (30 min, 120 °C) as sterile control.
Method. Avermectin B_{1a} was applied to the soil as a solution in acetone, application rate ca. 0.125 mg/kg. Soil moistened to 40 % of WHC and incubation at 20 °C in the dark. Effluent air passed through volatile traps (ethylene glycol and 2 N NaOH). Duplicate samples on days 0, 7, 28, 57, 126 and 196, single samples on days 3, 14, 91 and 161, sterile soil sampled in duplicate on days 7, 57 and 196. Microbial biomass determined at end according to Anderson and Domsch (1978).
Analysis. Extraction at room temperature with acetonitrile/water 4:1 (175-200 rpm, 30 min, 20 °C), centrifugation at 2000 rpm (10 min, 20 °C). Extraction repeated two times, extracts combined and analysed by LSC, 2D-TLC and HPLC-UV (220 nm). Soil further Soxhlet extracted with acetone for 4 hours, extracts analysed by LSC, 2D-TLC, confirmation of selected samples by HPLC-UV. Additional harsh extraction of day-126 samples by reflux with acetonitrile/water (4:1) at 80 °C for 2 hours, and acetonitrile/0.1 N HCl (9:1) at 80

°C for 2 hours. Extracts analysed by LSC and TLC. Bound residues (after Soxhlet step) determined by LSC after combustion. Organic matter fractionation by precipitation with NaOH and HCl. Volatiles analysed by LSC, CO_2 confirmed by $BaCO_3$-precipitation. Reference compounds for HPLC and TLC: avermectin B_{1a}, NOA 448111, NOA 448112, NOA 457464 and NOA 457465. LOQ determined for silty clay loam samples (day 14 and 196) and defined as 3 x background: 0.4 % of AR for LSC, 0.6 - 0.9 µg/kg for TLC.
Calculations: Rate constants for degradation of avermectin B_{1a} and concurrent formation of metabolites, CO_2 and bound residues estimated with ModelMaker 3.03, using the scheme presented above for Study 1 and assuming first-order kinetics.

Results

Microbial biomass at end 22.3, 56.1 and 47.6 mg C/100 g for loamy sand, sandy clay loam and silty clay loam, respectively. Distribution of radioactivity for respective soils is given in the table below. Maximum levels are indicated in bold.

Table: Distribution of radioactivity after aerobic incubation of avermectin B_{1a} in loam soil. All values in % of AR.

Incubation	Time [d]	Extractable[1]	Bound residues	CO_2	Recovery	Avermectin B_{1a}	NOA 448111	NOA 448112	NOA 457464	NOA 457465
loamy sand	0	100.8	0.1	-	100.9	98.0	< LOD	0.6	0.5	< LOD
	3[2]	102.1	1.0	< LOD	103.1	95.2	1.2	3.1	< LOD	< LOD
	7	96.7	2.0	0.1	98.8	84.0	1.8	4.3	0.3	0.3
	14[2]	96.1	4.1	0.3	100.6	71.8	4.3	7.7	0.7	0.8
	28	85.2	10.4	1.2	96.9	40.3	**9.1**	**13.4**	3.6	3.0
	57	72.3	18.3	4.3	95.0	16.7	8.7	10.6	6.4	5.7
	91[2]	57.0	23.3	5.1	85.5	8.1	5.7	6.9	**7.6**	6.1
	126	55.8	28.4	9.7	93.8	4.9	4.4	3.9	7.1	**9.9**
	161[2]	44.6	30.9	15.5	91.1	5.7	3.2	1.2	5.1	8.9
	196	40.3	**33.0**	**18.7**	92.1	4.0	1.6	1.0	5.4	8.9
sandy clay loam	0	99.9	0.0	-	99.9	95.8	0.5	< LOD	< LOD	0.2
	3[2]	101.9	1.0	0.1	102.9	90.1	1.8	< LOD	< LOD	1.9
	7	94.3	5.4	0.1	99.8	59.9	3.5	< LOD	0.4	**3.9**
	14[2]	86.4	14.0	0.7	101.1	40.9	**3.8**	0.6	0.1	3.3
	28	66.8	26.2	2.3	95.4	15.4	2.6	0.7	0.3	2.2
	57	50.5	34.8	6.4	91.7	9.9	1.8	**0.9**	**0.2**	0.6
	91[2]	41.9	39.1	12.4	93.4	8.3	1.4	**0.9**	0.1	0.3
	126	39.1	39.6	12.5	91.3	6.9	1.1	0.7	0.5	0.2
	161[2]	35.7	43.3	**12.9**	91.9	5.1	0.6	0.2	< LOD	0.1
	196	34.3	**44.1**	12.5	90.9	5.1	1.0	0.5	< LOD	0.2
Silty clay loam	0	99.6	0.1	-	99.6	98.2	0.2	0.1	< LOD	< LOD
	3[2]	95.9	0.7	< LOD	99.6	91.3	0.5	1.5	0.1	< LOD
	7	102.7	1.2	< LOD	103.9	93.2	1.1	2.9	0.2	< LOD
	14[2]	97.1	3.2	0.2	100.5	81.4	3.0	4.8	0.3	< LOD
	28	90.0	6.2	0.5	96.7	61.8	4.2	7.1	0.6	0.4
	57	81.4	11.2	1.2	93.7	44.2	5.1	8.1	1.8	2.0
	91[2]	73.4	18.4	4.1	95.8	26.8	4.7	**8.8**	3.1	2.3
	126	65.3	22.9	4.1	92.3	18.2	**6.0**	7.6	3.1	2.5
	161[2]	56.3	27.2	6.9	90.4	12.4	5.3	6.0	**5.5**	**5.2**
	196	48.1	**30.0**	**13.4**	91.5	6.6	3.5	4.0	2.2	2.6
sterile loamy sand	7	98.6	0.1	< LOD	98.7					
	57	97.0	0.3	< LOD	97.3					
	196	96.1	0.7	< LOD	96.9					

1: sum of ACN/water and soxhlet
2: single samples

Unknown metabolites accounted for at most 2.1 - 8.4 % of AR, one metabolite with code U8 reached levels of > 5 % of AR on two or more consecutive time points in soils in sandy clay loam and silty clay loam. Extractable radioactivity in sterile soil was present as unchanged avermectin B_{1a}. Estimated DT_{50}- and DT_{90}-values are given in the table below, total r^2 for ModelMaker estimates was 0.9737 - 0.9924. For sandy clay loam, DT_{50} of avermectin B_{1a} was also estimated separately using a two-compartment first-order kinetic model.

Table: DT_{50}-values for avermectin B_{1a} and metabolites reported by author

Compound	Soil	DT_{50} [d]	DT_{90} [d]	Notes
avermectin B_{1a}	loamy sand	25.4	84.4	
	sandy clay loam	11.6	38.5	
	sandy clay loam	10.7	53.9	separate fit, two-compartment, r^2 0.9904
	silty clay loam	52.2	173.3	
NOA 448111	loamy sand	20.9	69.3	
	silty clay loam	49.5	164.4	
NOA 448112	loamy sand	27.7	92.1	
	silty clay loam	50.3	167.1	DT_{90} extrapolated
NOA 457464	loamy sand	99.7	331.2	DT_{90} extrapolated
	silty clay loam	41.5	137.8	DT_{90} extrapolated
NOA 457465	loamy sand	192.2	638.4	extrapolated values
	silty clay loam	22.2	73.7	

Remarks by RMS

Dose equivalent to ca. 4 times highest single field rate for analytical reasons. Soil history not clear, described as "… not been treated during previous 5 years in any way which could severely affect microbial populations." Validated soil analysis method RAM 412/01 uses acetonitrile/water 70:30 v/v for extraction (see Document IIIA reference point 4.2 (a)/01), here 80:20 is used. Total regression coefficient of ModelMaker fit is mainly determined by degradation of parent, regression coefficients for individual equations not supplied.
DT_{50} of avermectin B_{1a} is recalculated by non-linear fit of first order kinetics. DT_{50}-values for metabolites are recalculated with Berkely-Madonna as described above. Because metabolite concentrations in sandy clay loam were all < 5 % of AR, recalculation was not performed for this soil. NOA 457464 and NOA 457465 were not included in the fit for silty clay loam, because levels were > 5 % on one time point only (t = 161 days). A summary of recalculated DT_{50}-values is given in the table below.

Table: Recalculated DT_{50}-values for avermectin B_{1a} and metabolites.

Compound	Soil	DT_{50} [d]	r^2	Error [%]	Method
avermectin B_{1a}	loamy sand	23.6	0.9926	-	single non-linear fit of parent, 1st order kinetics
	sandy clay loam	11.2	0.9737	-	
	silty clay loam	49.6	0.9955	-	
NOA 448111	loamy sand	45.3	0.94	14.8	
	silty clay loam	45.4	0.98	7.4	
NOA 448112	loamy sand	26.9	0.97	11.4	simultaneous fit of parent and metabolites with Berkely-Madonna
	silty clay loam	75.4	0.93	13.5	
NOA 457464	loamy sand	59.5	0.97	11.1	
NOA 457465	loamy sand	137	0.97	13.3	

The following results are used for risk assessment:

- maximum formation percentages of metabolites: 9.1 % for NOA 448111, 13.4 % for NOA 448112, 7.6 % for NOA 457464 and 9.9 % for NOA 457465
- DT_{50}: 23.6, 11.2 and 49.6 days for avermectin B_{1a}, 45.3 and 45.4 days for NOA 448111, 26.9 and 75.4 days for NOA 448112, 59.5 days for NOA 457464 and 137 days for NOA 457465.
- bound residues after 100 days: 18.4 - 39.1 % of AR (day-91 value)
- mineralisation after 100 days: 4.1 - 12.4 % of AR (day-91 value)
- identity of U8 should be addressed

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.1/03**	
Title:	Fate of Avermectin B_{1a} in soil under aerobic and anaerobic conditions	
Project/Report number:	Not stated	
Author(s):	Ku, C.C and Jacob, T. A.	
Date of report:	16/08/1983	
Published:	Not published	
Testing facility:	Merck, Sharp & Dohme Research Laboratories, Rahway, New Jersey, USA	
Study dates	Not stated	
GLP:	No	
Reliability indicator	2	

Reference/notifier	:	Ku, C.C. and Jacob, T.A. (1983a)	GLP statement	:	no
Type of study	:	degradation in soil	Guideline	:	not specified
Year of execution	:	1983	Acceptability	:	acceptable
Test substance	:	[3,7,11,13,23-^{14}C]-avermectin B_{1a}, radiochemical purity [redacted] [5- H]-avermectin B_{1a}, radiochemical purity [redacted]			

Substance	Soil type	Condition	Dose [mg/kg]	T [° C]	OM [%]	pH	pF	Duration [d]	DT_{50} [d]
^{3}H-avermectin B_{1a}	sandy loam	aerobic	0.1	ambient	1.1	6.8	2.5	168	26.9
^{3}H-avermectin B_{1a}	sandy loam	aerobic	1.0	ambient	1.1	6.8	2.5	168	22.3
^{3}H-avermectin B_{1a}	sandy loam	aerobic	50	ambient	1.1	6.8	2.5	168	42.6
^{14}C-avermectin B_{1a}	sandy loam	aerobic	1.0	ambient	1.1	6.8	2.5	84	15.1
^{14}C-avermectin B_{1a}	sandy loam	aerobic	1.0	ambient	1.1	6.8	2.5	112	47.0
^{3}H-avermectin B_{1a}	sand	aerobic	1.0	ambient	0.6	8.0	2.5	252	65.7
^{3}H-avermectin B_{1a}	clay	aerobic	0.1	ambient	1.3	6.8	2.5	252	34.9
^{3}H-avermectin B_{1a}	clay	aerobic	1.0	ambient	1.3	6.8	2.5	448	44.9

Description

Soils. Sandy loam (Lufkin, USA): CEC 93 mmol/kg, FC 14.4 %, bulk density 1.2 kg/L. Clay (Houston, USA): CEC 331 mmol/kg, FC 38.6 %, bulk density 1.08 kg/L. Sand (construction grade): CEC 39 mmol/kg, FC 1.54 %, bulk density 1.54 kg/L. All soils air dried, 35-mesh sieved.

Methods.

Aerobic incubations:

a. Soil samples of all types were treated with ^{3}H-avermectin B_{1a}, application rates 0.1, 1 or 50 mg/kg. Soils were moistened to 75 % of FC and incubated uncapped at ambient temperature, 90 % RH.

b. Sandy loam samples were treated with 1 mg/kg ^{14}C-avermectin B_{1a}, treatment and incubation as described above.

c. Bulk sample of sandy loam was treated with ^{3}H-avermectin B_{1a} at 10 mg/kg, covered with aluminium foil and incubated at ambient temperature.

Aerobic/Anaerobic incubation: Sandy loam was treated with ^{14}C-avermectin B_{1a} at 1 mg/kg. Test containers were flushed with N_2 immediately after treatment and flooded with distilled water, vials were sealed. Other samples

were kept under aerobic conditions for one month after which anaerobic conditions were established and maintained for three months. According to results section, another part of the samples was incubated aerobically.
Biometer flask studies: Sandy loam was treated with ^{14}C-avermectin B_{1a} at 10 mg/kg and moistened with distilled water. Flasks were incubated at 25 °C in the dark, outgoing air was passed through 1 N NaOH traps. Trapping solution was replaced weekly and analysed by LSC. $^{14}CO_2$ was confirmed by precipitation with $BaCl_2$, analysis of volatiles by LSC after acidification with HCl and extraction with dichloromethane.
Analysis. Extraction by shaking with acetonitrile (3 x 30 min), combined extracts analysed by LSC and TLC. Bulk sample and soil treated with 50 mg/kg and additionally extracted with acetone:water 9:1. Selected extracts analysed by HPLC-UV (254 nm). Water phase of selected samples analysed by LSC to determine degradation of ^{3}H-avermectin B_{1a} to tritiated water, water additionally extracted with dichloromethane to determine organic volatiles. Bound residues analysed by LSC after combustion. Isolated metabolites analysed by MS and NMR and Fourier-transformed infrared (FTIR) spectral data obtained.

Results

Aerobic incubations: Distribution of radioactivity for the respective soils and incubations is given in the table below. Maximum levels are indicated in bold.

Table: Distribution of radioactivity after aerobic incubation of ^{3}H- and ^{14}C-avermectin B_{1a} in different soils. All values in % of AR.

Incubation	Time [d]	Avermectin B_{1a}	M7	M4	M12	Bound residues	Volatiles[1]	Lost
sandy loam	0	95.1	0	0	0	4.9	not analysed,	0
^{3}H-avermectin B_{1a}	7	93.2	0	0	0	4.9	volatiles included	1.9
0.1 mg/kg	14	67.3	7.3	0	5.3	6.8	in fraction lost	10.7
	28	44.4	16.7	4.8	3.3	15.5		11.7
	56	21.6	**18.5**	6.9	**9.2**	21.4		18.4
	84	15.4	17.0	**7.9**	5.0	30.1		20.4
	168	5.3	13.3	7.4	4.1	**35.0**		34.9
sandy loam	0	94.7	0	0	0	5.3	not analysed,	0
^{3}H-avermectin B_{1a}	7	83.1	5.1	0	0	6.0	volatiles included	5.8
1.0 mg/kg	14	60.9	12.3	0	8.6	7.3	in fraction lost	10.9
	28	35.5	17.4	6.3	11.8	9.3		19.7
	56	18.0	**20.1**	**10.4**	**11.9**	17.6		18.1
	84	9.1	14.8	8.6	4.7	23.7		36.0
	112	7.1	13.5	6.7	3.2	**27.5**		39.0
	168	3.6	-[2]	7.9	2.9	19.8		52.0
sandy loam	0	96.0	0.4		0	3.0	0	0
^{3}H-avermectin B_{1a}	14	81.0	8.3		0.8	2.4	0.3	2.3
50 mg/kg	28	62.9	13.1		0.8	3.0	1.9	10.7
	56	36.8	**16.1**		9.0	6.2	7.8	7.3
	112	16.8	15.5		**9.2**	8.5	16.6	13.5
	168	5.8	5.9		5.3	**12.2**	**27.6**[2]	24.4
sandy loam	0	99.0	0	0	0	1.0	not analysed,	0
^{14}C-avermectin B_{1a}	14	50.3	12.0	2.1	12.0	6.9	volatiles included	10.9
1.0 mg/kg	28	25.2	**16.1**	4.4	**13.1**	10.9	in fraction lost	21.7
	56	11.0	8.9	5.4	10.9	15.8		34.9
	84	8.1	8.4	**6.2**	8.0	**18.8**		38.3
sand	0	99.2	0	0	0	0.8	0	0
^{3}H-avermectin B_{1a}	14	65.8	6.4	0.6	**10.6**	2.5	0.7	4.5
1.0 mg/kg	28	64.9	9.7	1.0	6.5	3.8	2.9	3.9
	56	47.4	13.2	1.7	9.0	7.2	8.2	6.3
	84	40.1	18.2	3.1	8.0	7.1	11.7	6.6
	112	22.9	15.1	3.2	7.8	11.8	16.5	14.5
	168	21.9	**20.1**	5.5	7.6	12.5	22.5	5.7
	252	9.8	15.8	**6.4**	6.1	**17.3**	**31.7**	6.2
Clay	0	94.9	0	0	0	5.1	not analysed,	0
^{3}H-avermectin B_{1a}	21	54.6	11.2	3.0	8.8	9.1	volatiles included	9.1
0.1 mg/kg	28	47.8	13.4	5.0	10.9	13.1	in fraction lost	5.1
	56	29.6	18.4	9.7	**12.1**	17.2		13.0
	84	19.4	**18.7**	**11.6**	9.8	20.2		19.2
	112	12.5	14.4	10.3	8.3	21.2		33.3
	168	12.0	14.3	9.9	7.0	**26.3**		29.3
	252	7.5	13.7	7.7	5.0	21.2		42.2

1: figure not readable from table
2: found condensed in water

Table (cont.)

Incubation	Time [d]	Avermectin B_{1a}	M7	M4	M12	Bound residues	Volatiles[1]	Lost
Clay	0	94.4	0	0	0	5.6	0	0
^{3}H-avermectin B_{1a}	28	60.4	4.9	1.4	8.4	10.1	2.6	10.5
1.0 mg/kg	56	31.6	6.0	2.6	7.3	11.5	6.6	7.7
	84	22.4	13.0	7.5	8.4	**17.0**	12.6	13.8
	112	22.7	**14.8**	**8.1**	**11.8**	15.8	17.9	6.0
	168	11.3	8.5	7.7	7.2	13.8	25.6	11.2
	252	11.2	11.4	4.2	7.4	18.1	33.4	10.4
	448	8.1	5.2	2.1	4.3	16.8	**45.5**	8.7

1: figure not readable from table
2: found condensed in water

Fraction M7 was identified as an equilibrium mixture of the 8a-hydroxy derivative (= NOA 488112) and the corresponding ring-opened aldehyde derivative. Fraction M4 and M12 were not identified. Other unknown fractions accounted for < 10 % of AR. Based on the relatively high fraction lost, also in samples where volatiles were trapped, authors suggest that trapping was inefficient. Volatiles from the 50 mg/kg incubation did not contain organic compounds, and were considered to consist of tritiated water. In a separate experiment, specific activity of ^{3}H-avermectin B_{1a} was shown to be unchanged, and according to authors, release of ^{3}H may thus result from metabolic oxidation of the parent or metabolites at the C-5 position.
Aerobic/anaerobic incubation: In samples that were incubated anaerobically immediately after application, no apparent degradation occurred during 3 months (data not given) and there was a lack of bound residues. Authors conclude that formation of bound residues is attributable to binding between soil and degradation products, but not to the parent compound. Distribution of radioactivity in aerobic and aerobic/anaerobic samples is given in the table below. Maximum levels are indicated in bold.

Table: Distribution of radioactivity after aerobic/anaerobic incubation of ^{14}C-avermectin B_{1a} in sandy loam. All values in % of AR.

Incubation	Time [d]	Avermectin B_{1a}	M7	M4	M12	Bound residues	Lost
aerobic	0	97.9	0	0	0	2.1	0
	28	59.6	10.5	1.7	9.3	32	8.3
	56	45.8	15.0	3.5	11.1	7.7	12.1
	84	27.7	**17.6**	**4.7**	**14.6**	11.6	19.7
	112	18.4	11.8	4.5	13.7	**27.4**	19.6
28 days aerobic, then anaerobic	56	54.6	13.2	2.9	7.6	2.9	0
	84	43.3	**14.1**	**5.6**	9.6	6.1	1.9
	112	41.6	13.9	3.1	**11.2**	**6.2**	10.7

From comparison of day 112 samples, authors conclude that degradation is reduced under anaerobic conditions.
Biometer flask studies: Cumulative CO_2 trapped during 21-weeks was 3.2 % of AR.

Remarks by RMS

Dose rates equivalent to ca. 3.5, 35 and 1750 time highest field rate. Non GLP-study. Report is unclear with respect to methods. Soil history not reported. Extraction method deviates from validated soil analysis method RAM 412/01, which uses acetonitrile/water 70:30 v/v for extraction (see Document IIIA reference point 4.2 (a)/01). Anaerobic incubations: redox potential not measured and data not reported. Aerobic incubations: description of methods does not mention trapping of volatiles, whereas according to results trapping was included in some incubations. In cases where volatiles were trapped, mass balance is almost always > 85 % of AR. DT_{50}'s for avermectin B_{1a} are recalculated by non-linear fit of first order kinetics (see table below).

Table: Recalculated DT_{50}-values for avermectin B_{1a}.

Soil	Label	Application rate [mg/kg]	DT_{50} [d]	r^2
sandy loam	^{3}H	0.1	26.9	0.9785
	^{3}H	1.0	22.3	0.9900
	^{3}H	50	42.6	0.9967
	^{14}C	1.0	15.1	0.9903
	^{14}C	1.0	47.0	0.9916
sand	^{3}H	1.0	65.7	0.9471
clay	^{3}H	0.1	34.9	0.9679
	^{3}H	1.0	44.9	0.9563

There is no clear evidence of a dose-related delay in degradation. The following results are used for risk assessment:

- DT_{50} for avermectin B_{1a} (aerobic, ambient temperature): 26.9, 22.3, 42.6, 15.1, and 47 days in sandy loam, 66 days in sand, and 34.9 and 44.9 days in clay.
- 20.1 % formation of NOA 448112 (in equilibrium with corresponding ring-cleaved structure).
- 6.2 - 13.1 % formation of unknown metabolites.

Syngenta endpoint(s) in originally submitted Document III A Section 7:
DT_{50} for avermectin B_{1a} (aerobic) : 20, 20 and 40 days in sandy loam, 47 days in sand, and 28 and 36 days in clay.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.1/04**	
Title:	Metabolism and Rate of Degradation of [23-^{14}C]- Labelled NOA 422601 (Avermectin B_{1a}) under Aerobic and Anaerobic Laboratory Conditions in one Soil at 20°C.	
Project/Report number:	99AG07	
Author(s):	Nicollier, G.	
Date of report:	13/06/2003	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	19/11/1999 to 2/3/2001	
GLP:	Yes	

Reliability indicator	1	

For the corresponding study summary see 98/8 Doc IIIA section No. 7.2.1 (reference point 7.2.1/01).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.1/05**	
Title:	Rate of Degradation of [23-^{14}C]-labelled NOA 422601 (Avermectin B_{1a}) in one soil under various Laboratory Conditions at 10°C, 20°C and 30°C	
Project/Report number:	00DA07	
Author(s):	Adam, D.	
Date of report:	30/5/2001	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	20/6/2000 to 25/1/2001	
GLP:	Yes	
Reliability indicator	1	

For the corresponding study summary see 98/8 Doc IIIA section No. 7.2.2.1 (reference point 7.2.2.1/01).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	

Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.1/06**	
Title:	Rate of Degradation of [23-^{14}C]- Labelled NOA 422601 (Avermectin B_{1a}) in Various Soils under Aerobic Laboratory Conditions at 20 °C.	
Project/Report number:	01RP02	
Author(s):	Phaff, R.	
Date of report:	13/08/2003	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	18/6/2001 to 15/11/2002	
GLP:	Yes	
Reliability indicator	1	

For the corresponding study summary see 98/8 Doc IIIA section No. 7.2.2.1 (reference point 7.2.2.1/02).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	-
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.1/07**	
Title:	Fate of Avermectin B_{1a} in soils under aerobic and anaerobic conditions	
Project/Report number:		
Author(s):	Ku, C and Jacob, T. A.	
Date of report:	16/08/1983	
Published:	Not published	
Testing facility:	Merck, Sharp & Dohme Research Laboratories, Rahway, New Jersey, USA	
Study dates	Not stated	
GLP:	No	
Reliability indicator	1	

For the corresponding study summary see 98/8 Doc IIIA section No. 7.2.2.1 (reference point 7.2.2.1/03).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*25-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	

Acceptability Remarks	[redacted]
	COMMENTS FROM ....
Date Materials and Methods Results and discussion Conclusion Reliability Acceptability Remarks	

98/8 Doc IIIA section No.	**7.2.2.2**	**Field soil dissipation and accumulation**
91/414 Annex IIA point addressed	**7.1.1.2.2**	**Rate of degradation - field studies**

Field dissipation trial in Vouvry, Switzerland in 2002:

		Official use only
Reference point (location) in dossier	**7.2.2.2/01**	
Title:	Dissipation Study with Abamectin in or on Soil in Switzerland, During 2002	
Project/Report number:	RJ3377B	
Author(s):	Emburey, S. N.	
Date of report:	02/10/2003	
Published:	Not published	
Testing facility:	Syngenta, Bracknell, UK	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Emburey, S.N. (2003)	GLP statement	:	yes
Type of study	:	field dissipation	Guideline	:	not specified
Year of execution	:	2002	Acceptability	:	acceptable
Test substance	:	A-8612 A (Vertimec 018 EC), batch [redacted], purity 19.5 g as/L, fluid			

Substance	Location	Soil type	Land use	Dose [g as/ha]	Date of application	OM [%]	pH	Duration [d]	$DT_{50,field}$ avermectin B_{1a} [d]
Vertimec 018 EC	Vouvry, CH	sandy loam	application on bare soil, grass cover thereafter	24.4[1]	May 21st	1.4	7.5	120	1.8

1: based on analysed content of 19.5 g as/L; 22.5 g as/ha nominal

Description

Location. Test site Les Barges, Vouvry, CH. Sandy loam, CEC 90 mmol/kg. Field grown with maize, grass and winter wheat/winter rape during previous three years. Test material was not used in that period (1999 - 2001).
Application and plot maintenance. A single treatment plot (30 x 6 m^2) and a control plot (6 x 6 m^2; 24 m distance from treatment plot) were sown with grass four days before application. Test substance was applied by broadcast spray on 21 May 2002 in a single treatment of 1.25 L/ha in 500 L water/ha (24.4 g as/ha, based on actual content of 19.5 g as/L; 22.5 g as/ha when based on nominal content of 18 g as/L). Dry weather, 24 °C and no wind during application. Grass cover was kept below 20 cm height by regular mowing.
Sampling. Samples were taken from the control plot on the day of application and 120 days thereafter, from the treated plot prior to and immediately after application and on days 1, 2, 3, 7, 14, 30, 59 and 120. Sampling with a 5 cm diameter corer, 30 cm depth, 20 cores per sampling date for treated plot and five for the control. Cores were deep frozen and cut into 10 cm layers (controls into 0 - 10 and 10 - 30 cm), corresponding depths were pooled and homogenised with dry ice. Samples were stored deep frozen for up to 13 months.

Analysis. Soil samples were analysed according to method RAM 412/01. Soil was extracted twice with acetonitrile/water (70:30, v/v), combined extracts were cleaned-up by solid phase extraction and analysed by HPLC-MS/MS. Reference substances: avermectin B_{1a}, NOA 427011 ([8,9-Z]-avermectin B_{1a}), NOA 421704 (avermectin B_{1b}), NOA 448111, NOA 448112, NOA 457464 and NOA 457465. LOQ was 0.5 µg/kg for avermectin B_{1a} and metabolites. Concurrent recovery 92 - 104 % at 0.001, 0.01 and 0.02 mg/kg.
Calculations. DT_{50} of avermectin B_{1a} calculated using ModelManager 1.1 using first order kinetics (SFO) and first order multi compartment modelling (FOMC).

Results

Weather data. Minimum temperature 6.9 - 13.7 °C between May 21st and June 4th, average minimum temperature from June 5th to September 18th 12.9 - 13.8 °C. Maximum temperature 13.9 - 24.8 °C between May 21st and June 4th, average maximum temperature from June 5th to September 18th 22.5 - 24.8 °C. Overall average 16.0 °C. Total precipitation 433.6 mm. Total sunshine 765 hours.
Residues. Residues of avermectin B_{1a} in 0 - 10 cm layer are given in the table below, values were corrected if concurrent recovery was < 100 %. Based on nominal application rate, 10 cm depth and soil bulk density 1500 kg/m^3, recovery on t = 0 was 87 %. Metabolites were always below LOQ, except for NOA 427011, NOA 448112 and NOA 421704 which were detected at levels of 0.6 or 0.7 µg/kg on the day of application. No residues in control and below 10 cm in treated samples.

Table: Residues of avermectin B_{1a} after bare soil application of Vertimec 018 EC.

Time [d]	Avermectin B_{1a} [µg/kg]
0	13
1	7.5
2	4.3
3	4.8
7	2.6
14	1.5
30	1.0
59	< 0.5
120	< 0.5

DT_{50} calculated as 1.8 days (SFO; r^2 0.9021) and 1.3 days (FOMC; r^2 0.9873) using data points 0 to 30 days.

Remarks by RMS

Additional information of notifier to RMS: abamectin not used in 2002 prior to trial. Based on analysed content in formulation of 19.5 g as/L, recovery on t = 0 is 80 % of applied. DT_{50} recalculated by non-linear fit of first order kinetics same as given by author. The result $DT_{50,field}$ 1.8 days for avermectin B_{1a} and no metabolites > 0.7 µg/kg (5 - 6 % of initial concentration of parent) are used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Field dissipation trial in Bavaria, Germany in 2002:

		Official use only
Reference point (location) in dossier	**7.2.2.2/02**	
Title:	Residues of Abamectin after application of A8612A on soil, Germany 2002.	
Project/Report number:	gbg724002	
Author(s):	Simon, P.	
Date of report:	24/09/2003	
Published:	Not published	
Testing facility:	Syngenta Agro GmbH, Maintal, Germany,	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Simon, P. (2003)	GLP statement	:	yes
Type of study	:	field dissipation	Guideline	:	BBA IV, 3 - 3
Year of execution	:	2002	Acceptability	:	acceptable
Test substance	:	A 8612 A (Vertimec 018 EC), batch [redacted] purity 19.5 g as/L, fluid			

Substance	Location	Soil type[1]	Land use	Dose [g as/ha]	Date of application	OM [%]	pH	Duration [d]	$DT_{50,field}$ avermectin B_{1a} [d]
Vertimec 018 EC	Wallersdorf-See, D	silty loam	bare soil	24.4[2]	May 21st	1.0	6.2[3]	121	< 1

1: 0 - 10 cm
2: based on analysed content of 19.5 g as/L; 22.5 g as/ha nominal
3: pH-KCl

Description

Location. Test site Wallersdorf-See, Bavaria, D. Silty loam (0 - 10 cm), CEC 154 mmol/kg. FC 29.7 %. Field grown with sugar beets during previous year, and treated with metamitron, chloridazon, epoxiconazole and calcium ammonium nitrate.
Application and plot maintenance. A single treatment plot (120 m^2) was treated with the test substance using a wheeled plot sprayer on 10 June 2002 in a single treatment of 1.25 L/ha in 300 L water/ha (24.4 g as/ha, based on actual content of 19.5 g as/L; 22.5 g as/ha when based on nominal content of 18 g/L). Control plot (60 m^2) was not treated. Dry weather, 24 °C and no wind during application. Two applications of glyphosate (Roundup Ultra, 5 L/ha, July 22nd and October 11th 2002).
Sampling. Samples were taken from the control plot on the day of application and 121 days thereafter, from the treated plot prior to application and on days 1, 2, 3, 7, 14, 28, 57 and 121. Sampling with a 5 cm diameter corer, 30 cm depth, 20 cores per sampling date. Cores were deep frozen and cut into 10 cm layers, corresponding depths were pooled and homogenised with dry ice.
Analysis. Soil samples were analysed according to method RAM 412/01. Soil was extracted twice with acetonitrile/water (70:30, v/v), combined extracts were cleaned-up by solid phase extraction and analysed by HPLC-MS/MS. Reference substances: avermectin B_{1a}, NOA 427011 (8,9 Z avermectin B_{1a}), NOA 421704 (avermectin B_{1b}), NOA 448111, NOA 448112, NOA 447464 and NOA 457465. LOQ was 0.5 µg/kg for avermectin B_{1a} and metabolites. Concurrent recovery 76 - 89 % at 0.001 and 0.02 mg/kg.
Calculations. DT_{50} of avermectin B_{1a} calculated using ModelManager 1.01 using first order kinetics (SFO) and first order multi compartment modelling (FOMC).

Results

Weather data. Minimum temperature 3.7 - 18.5 °C, maximum 7.0 - 32.8 °C. Average daily temperature 6.0 - 25.6 °C, overall average 17.3. Total precipitation from June to September 538 mm (monthly values 79.6 - 204 % of long-term average).
Residues. Residues of avermectin B_{1a} in 0 - 10 cm layer decreased from 6.1 µg/kg on the day of application to 1.2 µg/kg on day 1, 0.7 µg/kg on day 2 and < LOQ as from day 3 (values are corrected for concurrent recovery). Metabolites were always below LOQ, no residues in control and below 10 cm in treated samples.
DT_{50} calculated as 0.5 days (SFO; r^2 0.9898) and 0.2 days (FOMC; r^2 1) using data points 0, 1 and 2 days.

Remarks by RMS

Soil type given as clay loam by author. Additional information of notifier to RMS states that abamectin was never used on the site prior to the trial. Based on analysed content in formulation of 19.5 g as/L, soil depth 10 cm and soil bulk density 1500 kg/m^3, recovery on t = 0 is 38 % of applied. Too few data points for accurate model fit. The result $DT_{50,field}$ < 1 day and no metabolites > 0.5 µg/kg (ca. 8 % of initial concentration of parent) is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Field dissipation trials in Alsace, France and Bavaria, Germany in 1996:

		Official use only
Reference point (location) in dossier	**7.2.2.2/03**	
Title:	Determination of the residues and estimation of degradation profile for abamectin and its 8,9-Z isomer on bare soil resulting from abamectin application by ground equipment in Europe	
Project/Report number:	70017-01	
Author(s):	Oberwalder, C. Barnard, G. and Gibbons, C.	
Date of report:	23/07/1997	
Published:	Not published	
Testing facility:	Site location: Bavaria, Germany, ABC Laboratories Europe Ltd, Coleraine, N. Ireland	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

		Official use only
Reference point (location) in dossier	**7.2.2.2/04**	
Title:	Determination of the residues and estimation of degradation profile for abamectin and its 8,9-Z isomer on bare soil resulting from abamectin application by ground equipment in Europe	
Project/Report number:	70017-02	
Author(s):	Oberwalder, C. Barnard, G. and Gibbons, C.	
Date of report:	23/07/1997	
Published:	Not published	
Testing facility:	Site location: Alsace, France, ABC Laboratories Europe Ltd, Coleraine, N. Ireland	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Oberwalder, C. (1997ab; field part) Barnard, G. and Gibbons, C. (1997ab; analytical part)	GLP statement	:	yes
Type of study	:	field dissipation	Guideline	:	in-house protocols
Year of execution	:	1996	Acceptability	:	acceptable
Test substance	:	abamectin 1.8 % EC, batch [redacted] purity 18 g as/L, fluid			

Substance	Location	Soil type	Land use	Dose [g as/ha]	Date of application	OM [%]	pH	Duration [d]	$DT_{50,field}$ avermectin B_{1a}[1] [d]
abamectin 18 g/L	Neu-Ulm, D	silty loam	bare soil	27	June 12th	5.6	7.6	110	< 1
abamectin 18 g/L	Wissembourg, F	silt	bare soil	27	June 11th	1.5	5.7	112	< 1

1: including [8,9-Z]- avermectin B_{1a}

Description

Locations. Neu-Ulm, Bavaria, D. Silty loam, bulk density 1195 kg/m^3, microbial biomass 157 mg C/100 g (0 - 10 cm). Field grown with maize during previous year, grass-clover mixture sown in April 1996 was destroyed 14 days before application using a rotary harrow. Abamectin had not been used on the field.
Wissembourg, Alsace, F. Silt, bulk density 1280 kg/m^3, microbial biomass 70 mg C/100 g (0 - 10 cm). Field grown with maize during previous two months, destroyed 14 days before application using a roto tiller. Abamectin had not been used on the field. Pesticides used prior to the trial were alachlor (2.4 kg as/ha), carbofuran (0.6 kg as/ha), dicamba (0.19 kg as/ha), atrazine (0.68 kg as/ha) and bromoxynil (0.45 kg as/ha).
Application and plot maintenance. Three treatment plots (100 m^2 each, 2 m distance) were treated with the test substance using an air operated sprayer in June 1996 in a single treatment of 1.5 L/ha in 300 - 500 L water/ha (27 g as/ha). A control plot (100 m^2, 31 - 31.5 m distance from treated plot) was left untreated. Dry weather, 26 - 27 °C and almost no wind during application. Spray deposit was checked with plastic trays with soil. Site maintenance: glyphosate (Roundup, 5 L/ha, Germany: July 12th and 29th 1996; France: July 18th 1996).
Sampling. Samples were taken from the control plot immediately before application and 14 and 110 days thereafter, from the treated plot prior to and immediately after application and on days 1, 2, 3, 7, 14, 28, 50 and 110 (France: 49 and 112 days). Sampling 0 - 10 cm depth with a 5 cm diameter corer, 10 - 30 cm depth with a 3

cm diameter corer), 10 cores per sampling date. Cores were deep frozen and cut into 10 cm layers, corresponding depths were pooled and homogenised with dry ice.
Analysis. Soil samples were analysed according to Merck Research Laboratories method 8003 and its amendments. Soil was soxhlet extracted with acetonitrile/water (50:50) for two hours. Water was added to the extract, the solution passed through a preconditioned C_8 SPE column and column was eluted with acetonitrile. Eluate extracted three times with hexane, and combined hexane phases passed through preconditioned aminopropyl SPE column. Column washed with hexane, toluene and dichloromethane and eluted with 50:50 acetonitrile/dichloromethane. Eluate evaporated to dryness, taken up in acetonitrile. Derivatisation by addition of 2:1 acetonitrile/trifluoroacetic anhydride and 1-methylimidazole. Analysis by HPLC with fluorescent detection. The derivative represents the sums of parent avermectin B_{1a} or B_{1b} and their respective [8,9-Z]-isomers. Reference substance: avermectin B_1 in the form of a glycerol formal reference standard, lot L-676,863-038A005, avermectin B_{1a} 0.819 % and avermectin B_{1b} 0.054 %. Method was validated with different soils, recovery 70 - 95 % for avermectin B_{1a} at 2.1 - 52.4 ng/g (overall mean 83 %, RSD 9.8 %, n = 22), 74 - 111 % for avermectin B_{1b} at 1.9 and 3.8 ng/g (overall mean 90 %, RSD 12 %, n = 11), and 70 - 90 % for the 8,9-Z isomer at 2.0 - 25 ng/g (overall mean 79 %, RSD 7.5 %, n = 15). LOQ 1 ng/g, LOD 0.5 ng/g.
Calculations. DT_{50} calculated by non-linear fit of ^{10}log transformed concentration in soil versus time.

Results

Weather data. Germany: average temperature between 11.8 and 21.8 °C, overall average 16.5 °C. Total precipitation 267 mm (total for June, July and August 10 % lower than long-term average), sunshine 658 hours. France: average temperature between 13.4 and 25.7 °C, overall average 17.4 °C. Total precipitation 182 mm (total for August and September 33 and 67 % lower than long-term average; June and July comparable), sunshine 824 hours.
Concurrent recovery in fortified soil was 74 - 106 %, average 93 % (Germany) and 73 - 103 %, average 92 % (France). Initial residues were 62 - 67 % (Germany) and 44 - 76 % (France) of nominal applied. No residues were found at > 10 cm depth.
Average residues of avermectin B_{1a} in 0 -10 cm are given in the table below.

Table: Residues of avermectin B_{1a} and [8,9-Z]- avermectin B_{1a} in 0 -10 cm. Values are average of three replicates.

Time [d]	Avermectin B_{1a} + [8,9-Z]-avermectin B_{1a} [µg/kg]	
	Germany	France
0	15.6	11.3
4 h	10.5	8.3
6 h	8.6	7.7
1	4.4	3.1
3	1.7	< LOQ
7	< LOQ	< LOD
14	< LOQ	< LOD
21	0.6	< LOD
> 28	< LOD	< LOD

DT_{50} calculated as 5.5 hours for Germany and 4.8 hours for France.

Remarks by RMS

Analysis method differs from validated method RAM 412/01. Calculation of initial recovery is not clear: trays had surface of 20 x 20 cm, with application rate 27 g as/ha expected residue is 108 µg per tray. Analysed amounts were on average 32.5, 29.8 and 30.5 µg (Germany) and 30.2, 21.2 and 32.6 µg (France), which is 28 - 30 and 20 - 30 % of nominal. Residues in 0 - 10 cm are 69 and 54 % of expected on t = 0 based on reported soil bulk density. In notifier's document MII-section 5, the sum of avermectin B_{1b} and its [8,9-Z]-isomer in 0 -10 cm on t = 0 is given as 1.94 µg/kg for Germany and 1.49 µg/kg for France. These figures are not mentioned in the reports, and cannot be deduced from the raw data tables, because it is not clear whether reported concentrations in ppb refer to soil or soil extracts. $DT_{50,field}$ is recalculated with non-linear fit of first order kinetics as 0.5 days for Germany (r^2 0.9532) and is < 1 day for France. The result $DT_{50,field}$ < 1 day for avermectin B_{1a} plus [8,9-Z]-avermectin B_{1a} is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Field dissipation trials in Champagne, France and the Po Valley, Italy in 1997:

		Official use only
Reference point (location) in dossier	**7.2.2.2/05**	
Title:	Determination of the residues and estimation of degradation profile for abamectin and its 8,9-Z isomer on bare soil resulting from abamectin application by ground equipment in Europe	
Project/Report number:	70093	
Author(s):	Oberwalder, C. McCambley, C	
Date of report:	01/05/1998	
Published:	Not published	
Testing facility:	Site location: Po Valley, Italy ABC Laboratories Europe Ltd, Coleraine, N. Ireland	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

		Official use only
Reference point (location) in dossier	**7.2.2.2/06**	
Title:	Determination of the residues and estimation of degradation profile for abamectin and its 8,9-Z isomer on bare soil resulting from abamectin application by ground equipment in Europe	
Project/Report number:	70094	
Author(s):	Oberwalder, C. McCambley, C	
Date of report:	05/05/1998	
Published:	Not published	
Testing facility:	Site location: Champagne, France ABC Laboratories Europe Ltd, Coleraine, N. Ireland	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Oberwalder, C. (1998ab; field part) McCambley, C. (1998ab; analytical part)	GLP statement	:	yes
Type of study	:	field dissipation	Guideline	:	in-house protocols
Year of execution	:	1997	Acceptability	:	acceptable
Test substance	:	abamectin 1.8 % EC (18 g as/L), batch [redacted], fluid			

Substance	Location	Soil type	Land use	Dose [g as/ha]	Date of application	OM [%]	pH	Duration [d]	$DT_{50,field}$ avermectin B_{1a}[1] [d]
abamectin 18 g/L	Dugliolo, I	loam	bare soil	27	April 24th	1.8	7.6	28	< 1
abamectin 18 g/L	Juzancourt, F	loam	bare soil	27	May 30th	1.6	6.3	28	< 1

1: including [8,9-Z]-avermectin B_{1a}

Description

Locations. Dugliolo, Po Valley, I. Loam, microbial biomass 49.9 mg C/100 g (0 - 20 cm). Preceding crop wheat. Abamectin had not been used on the field, and no fertilisers applied during previous year. Pesticides used prior to the trial were MCCP (0.68 kg as/ha), bromoxynil (0.198 kg as/ha), ioxynil (0.182 kg as/ha) and glyphosate (0.63 kg as/ha).

Juzancourt, Champagne, F. Loam, microbial biomass 173.1 mg C/100 g (0 - 10 cm). Preceding crop lucerne, which was ploughed under 14 days before application using a roto tiller. Abamectin had not been used on the field. Pesticides used prior to the trial were deltamethrin (0.625 kg as/ha), hexazinone (0.45 kg as/ha), paraquat (0.1 kg as/ha) and glyphosate (2.16 kg as/ha), PKMg-fertilisation in previous year.

Application and plot maintenance. Three plots (100 m^2 each, 2 - 5 m distance) were treated with the test substance using an air operated sprayer in April or May 1997 in a single treatment of 1.5 L/ha in 300 - 500 L water/ha (27 g as/ha). A control plot (100 m^2, 30 m distance from treated plot) was left untreated. Dry weather, 14 - 17 °C, wind 2.5 m/s (Italy) or no wind (France) during application. Spray deposit was checked with plastic trays with soil. No pesticide treatment during trial.

Sampling. Sampling as described above before and after application and on days 1, 4 (France 3), 7, 15, 21 and 28.

Analysis. As described above.

Results

Weather data. Italy: average temperature between 10 and 21 °C, overall average 13 °C. Total precipitation 1099 mm (or 109.9 mm, see Remarks by RMS), radiation 170 - 616 cal/cm^2.d. France: average temperature between 12 and 21 °C, overall average 13 °C. Total precipitation 111 mm (52 - 90 above long term average), sunshine 186 hours.
Concurrent recovery in fortified soil was 70 - 100 %, average 87 % (Italy) and 71 - 107 %, average 86 % (France). Initial residues were 61 - 69 % (Italy) and 58 -82 % (France) of nominal applied. No residues were found at > 10 cm depth. Average residues of avermectin B_{1a} in 0 -10 cm are given in the table below.

Table: Residues of avermectin B_{1a} and [8,9-Z]-avermectin B_{1a} in 0 -10 cm. Values are average of three replicates.

Time [d]	Avermectin B_{1a} + [8,9-Z]-avermectin B_{1a} [µg/kg]	
	Italy	France
0	13.7	11.0
3 h	5.4	10.7
6 h	3.3	3.9
12 h	2.3	2.0
1	1.5	3.4
3		< LOQ
4	1.1	
7	< LOQ	< LOQ
14		< LOD
15	< LOD	
21	< LOD	< LOD
28	< LOD	< LOD

Remarks by RMS

Analysis method differs from validated method RAM 412/01.
Precipitation figures for Italy seem very high, probably decimal is missing. Reported value for May (51 mm) is not consistent with sum of individual dates during that month (855 mm or 85.5 mm when decimal is missing). Reported values for April and May are 50 % lower and 38 % higher than long-term average (72 mm for April and 37 mm for May).
Calculation of initial recovery is not clear: trays had surface of 20 x 20 x 5 cm, with application rate 27 g as/ha expected residue on 400 cm^2 is 108 µg per tray. Analysed amounts were on average 30.2, 33.4 and 29.6 µg (Italy) and 39.8, 28.1 and 29.1 µg (France), which is 27 - 31 and 35- 37 % of nominal. Residues in 0 - 10 cm are 76 and 61 % of expected on t = 0 based on soil bulk density of 1500 kg/m^3. In document MII-section 5, the sum of avermectin B_{1b} and its [8,9-Z]-isomer in 0 -10 cm on t = 0 is given as 1.32 µg/kg for Italy and 1.04 µg/kg for France. These figure are not mentioned in the reports, and cannot be deduced from the raw data tables, because it is not clear whether reported concentrations in ppb refer to soil or soil extracts. The result $DT_{50,field}$ < 1 day for avermectin B_{1a} plus [8,9-Z]-avermectin B_{1a} in Italy and France is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	EVALUATION BY RAPPORTEUR MEMBER STATE *27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

[redacted]
COMMENTS FROM ...
Date
Materials and Methods
Results and discussion
Conclusion
Reliability
Acceptability
Remarks

98/8 Doc IIIA section No.	7.2.2.3	Extent and nature of bound residues

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*27-10-2007*	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

98/8 Doc IIIA section No.	**7.2.2.4**	**Other soil degradation studies**
91/414 Annex IIA point addressed	**7.1.1.1.2**	**Supplementary soil degradation studies - soil photolysis**

		Official use only
Reference point (location) in dossier	**7.2.2.4/01**	
Title:	Soil Photolysis of [23-^{14}C]-Labelled NOA422601 (Avermectin B_{1a}) under Laboratory Conditions	
Project/Report number:	00RP04	
Author(s):	Phaff R.	
Date of report:	14/12/2001	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	26/9/2000 to 1/10/2001	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Phaff, R. (2001)	GLP statement	:	yes
Type of study	:	soil photolysis	Guideline	:	US-EPA 540/9-82-021, Section 161-3 95/36/EC
Year of execution	:	2000-2001	Acceptability	:	acceptable
Test substance	:	[23-^{14}C]-avermectin B_{1a}, batch [redacted] radiochemical purity [redacted]			

Substance	Soil type	T [° C]	OM [%]	pH	Light source	Wavelength [nm]	Duration [d]	Transformation at end [%]	$DT_{50,photo}$ [d]
^{14}C-avermectin B_{1a}	loam/silt loam	24.5	3.4	7.1	Xenon	> 290	28	81	13

Description

Soil. Loam/silt loam (Gartenacker, CH): CEC 127 mmol/kg, MWHC 68.5 %, microbial biomass 36.9 mg C/100 g. Soil 2 mm sieved and moisture content adjusted to 75 % FC.
Method. Soil thin layers were prepared on glass plates (15 cm^2), test substance was applied equally over surface as solution in ethylacetate, total amount 14.1 µg/15 cm^2 (0.09 kg/ha). Plates were irradiated for 28 days in a Suntest exposure unit with a Xenon lamp with UV-filter (λ > 290 nm), 12:12 hours L:D. Irradiation corresponded to 47 days at 30 – 50 °N. Dark controls were kept under identical conditions. Duplicate samples were taken at regular time points, volatiles trapped in 2 N NaOH. Light intensity monitored.
Analysis. Extraction three times by shaking with acetonitrile/water (80:20 v/v) for 30 min at 175 rpm. Extracts combined after centrifugation and analysed by LSC, followed by 2D-TLC. Selected samples analysed additionally by HPLC-UV (220 nm). Bound residues determined by LSC after combustion. Day-21 samples submitted to harsh extraction by reflux with acetonitrile/water (4:1) at 80 °C for 2 hours, and acetonitrile/0.1 N HCl (9:1) at 80 °C for 2 hours. Organic matter fractionation by precipitation with NaOH and HCl. $^{14}CO_2$ analysed by LSC. LOQ determined for day-15 and -21 irradiated samples and defined as 3 x background: 0.2 % of AR for LSC, 10 µg/kg for TLC, 0.01 – 0.02 µg/kg for HPLC.
Calculations. DT_{50} and DT_{90} estimated by non-linear fit of first order kinetics.

Results

Light intensity 84.7 ± 3.8 W/m^2, which is a factor of 1.264 times higher than at 30 – 50 °N. Distribution of radioactivity in irradiated and dark samples is given in the table below.

Table: Distribution of radioactivity in irradiated soil and dark controls. All values in % of AR.

Incubation	Time [d]	Extractable	Bound residues	CO_2	Recovery	Avermectin B_{1a}	NOA 448111	NOA 448112
irradiated	0	102.5	0.3	< LOD	102.8	100.3	1.0	< LOD
	2[1]	85.0	15.6	0.4	101.0	67.7	4.1	2.6
	4	91.9	9.1	0.7	101.7	77.3	3.6	2.9
	6	84.8	13.6	1.6	100.1	66.7	4.1	2.8
	10	82.9	16.2	2.5	101.5	52.4	3.7	**4.0**
	15	76.4	18.8	3.1	98.3	42.4	3.4	3.5
	21	70.1	22.6	4.5	97.2	28.6	**5.7**	3.3
	28	63.4	**25.9**	**7.6**	96.9	19.5	4.5	3.1
dark	0	103.7	0.3		104.0	101.2	0.9	0.9
	2	101.3	1.5		102.8	97.5	2.7	2.7
	4	103.3	1.5		104.8	99.5	1.5	1.5
	6	100.6	2.3	< LOD	102.9	96.5	1.5	1.5
	10	100.4	2.5		102.9	92.2	2.3	2.3
	15	98.4	3.5		102.0	87.0	**4.6**	**4.6**
	21	98.8	4.6		103.5	90.4	3.4	3.4
	28	96.4	**5.3**		101.8	86.0	3.3	4.1

1: considered outlier by authors, not used in calculations

Harsh extraction released 6.9 % of AR, remaining activity about equally distributed over humin, humic and fulvic acid fraction. DT_{50} for avermectin B_{1a} was calculated as 119.5 days in dark controls and 11.6 days in irradiated samples. $DT_{50,photolysis}$ after correction for dark controls reported as 12.9 days, corresponding to 21.7 days at 30 – 50 °N.

Remarks by RMS

Dose ca. 4 times higher than highest single field rate. Validated soil analysis method RAM 412/01 uses acetonitrile/water 70:30 v/v for extraction (see Document IIIA reference point 4.2 (a)/01). Recalculation of DT_{50} gives same values. The result $DT_{50,photolysis}$ 13 days (22 days at 30 – 50 °N) is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.2.4/02**	
Title:	Photodegradation of Avermectin B_{1a} in Water and Soil Environment	
Project/Report number:	01RP02	
Author(s):	Ku, C. C. and Jacob, T. A	
Date of report:	31/10/1983	
Published:	Not published	
Testing facility:	Merck Sharp & Dohme Research Laboratories, Rahway, New Jersey 07065, USA	
Study dates	Not stated	
GLP:	No	
Reliability indicator	1	X

Reference/notifier	:	Ku, C.C. and Jacob, T.A. (1983b)	GLP statement	:	no
Type of study	:	soil photolysis	Guideline	:	not specified
Year of execution	:	1983	Acceptability	:	not acceptable
Test substance	:	[5-^{3}H]-avermectin B_{1a}, radiochemical purity [redacted]			

Substance	Soil type	T [° C]	OM [%]	pH	Light source	Wavelength [nm]	Duration [h]	Transformation at end [%]	$DT_{50,photo}$ [d]
^{3}H-avermectin B_{1a}	clay loam				natural	> 290	31		

Description

Soil. Clay loam (Houston, USA): characteristics not given. Air dried.
Method. Soil thin layers were prepared by spreading a slurry of soil and methanol (1.3 g/mL) on glass plates (20 x 20 cm^2). Plates were air dried at room temperature. Test substance (0.0425 mg) was applied in methanol to prescored (1 x 1 inch) spots, and plates were exposed to sunlight for 31 hours. Dark control was treated similarly and wrapped in aluminium foil.
Analysis. At each sampling time, spots were scraped off and transferred to a small glass column which was eluted with 10 mL ethylacetate, followed by 10 mL methanol. Eluents were analysed by LSC and HPLC-UV (245 nm). Remaining soil was analysed by LSC after combustion. Identification of metabolites by MS and NMR.
Calculations. DT_{50} estimated by linear interpolation.

Results

Recovered avermectin B_{1a} in irradiated samples is given in the table below.

Table: Recovered avermectin B_{1a} after irradiation. All values in % of AR.

Time [h]	Avermectin B_{1a} Ethylacetate	Methanol	Recovery
0	93.1	5.7	98.8
1	84.7	6.4	91.1
2	82.7	6.2	88.9
4	78.0	6.9	84.9
8	70.5	8.6	79.1
16	56.8	6.4	63.2
31	27.3	5.3	32.6

DT_{50} estimated as ca. 21 hours.

Remarks by RMS

Soil characteristics and temperature not reported. Light intensity not specified. Recovery of analysis methods not given, no mass balance. Results for dark controls not given. The result is not used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.2.3.1**	**Adsorption and desorption in accordance with new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**
91/414 Annex IIA point addressed	**7.1.2**	**Adsorption and desorption**

		Official use only
Reference point (location) in dossier	**7.2.3.1/01**	
Title:	Adsorption / Desorption of [23-^{14}C]-NOA 422601 (Avermectin B_{1a}) in Various Soils	
Project/Report number:	99MO05	
Author(s):	Morgenroth, U.	
Date of report:	13/02/2001	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	18/4/2000 to 30/8/2000	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Morgenroth, U. (2001)	GLP statement	:	yes
Type of study	:	soil adsorption	Guideline	:	OECD 106; US-EPA Subdivision N, section 163-1
Year of execution	:	2000	Acceptability	:	acceptable
Test substance	:	[23-^{14}C]-avermectin B_{1a}, batch [redacted], radiochemical purity [redacted]			

Substance	Soil type	OM [%]	Clay [%]	CEC [mmol/kg]	pH	T [° C]	Ratio Soil/water [g/mL]	$K_{F,ADS}$ [L/kg]	[1/n]	K_{OC} [L/kg]	K_{OM} [L/kg]
^{14}C-avermectin B_{1a}	loamy sand 1	2.6	5.9	84	5.8	20	0.02	87.2	0.961	5701	3307
	loamy sand 2	1.7	3.1	77	7.6	20	0.02	77.3	0.961	7893	4578
	sandy loam	2.2	13.1	97.8	7.4	20	0.02	76.8	0.950	6004	3482
	loam	4.5	11.9	158	7.1	20	0.02	178	1.001	6875	3988
	silt loam	8.6	23.3	321	7.2	20	0.02	334	1.013	6682	3876

Description

Soils. As presented in header, loamy sand 1 from Borstel (D), loamy sand 2 from Pappelacker (CH), sandy loam from Schwaderloch (CH), loam from Gartenacker (CH) and silt loam from Vetroz (CH). Soils air dried and 2 mm sieved.

Methods. Pre-test to determine shaking time, soil solution ratio, stability and glass adsorption.

Final test: Soil samples (2 g) were equilibrated with 50 mL 0.01 M $CaCl_2$ for 24 hours in glass tubes. Test substance was added to soil in 50 mL 0.01 M $CaCl_2$ solution, final concentrations 0, 0.005, 0.01, 0.025, 0.05 and 0.1 µg/L. Shaking for 48 hours at 120 rpm, two replicates per concentration. Overlying water was analysed by LSC after centrifugation, amount adsorbed wascalculated from difference with initial concentration. Desorption by shaking for 24 hours with 0.01 M $CaCl_2$, solutions were analysed by LSC and desorption step repeated with fresh solution. Remaining radioactivity in soil after second desorption step was analysed by LSC after combustion. Tubes were rinsed with acetonitrile to determine adsorption to glass.

Mass balance experiment: Adsorption step as described above with two replicates at 0.1 µg/L. Supernatant was counted by LSC, partitioned with methylene chloride, organic and inorganic phases were counted. Organic phase

was concentrated and analysed with 2D-TLC and HPLC-UV (220 nm). Tubes were rinsed with acetonitrile/water. Remaining soil was extracted once with acetonitrile and four times with acetonitrile/water (9/1, v/v), combined extracts were analysed by LSC, 2D-TLC and HPLC. Non-extractable radioactivity was determined by LSC after combustion.
Calculations. Freundlich adsorption coefficient and 1/n were obtained by non-linear regression of concentrations in soil versus concentrations in solution.

Results

Mass balance experiment. Overall recovery 91.7 - 98.4 % of AR. Non-extractable radioactivity ≤ 1.6 %of AR, < 1 % of AR adsorbed to glass. Test substance was stable during experiment.
Adsorption/desorption experiment. Overall recovery 93.0 - 98.1 % of AR, adsorption to glass ≤ 2.4 % of AR. K_F, 1/n and K_{OC} as given in header. K_{OM} was calculated as K_{OC}/1.724.

Remarks by RMS

Soil-solution ratio low but 65 - 91 % adsorption in pre-test. The results K_{OM} 3307, 3482, 3876, 3988 and 4587 L/kg are used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.3.1/02**	
Title:	Sorption/desorption of avermectin B_{1a} with clay, silt and sand soils	
Project/Report number:	Not stated	
Author(s):	Gruber, V. F. and Wislocki, P. G.	
Date of report:	30/09/1988	

Published:	Not published	
Testing facility:	Merck Research Laboratories, Three Bridges, New Jersey, USA	
Study dates	Not stated	
GLP:	No	
Reliability indicator	1	

Reference/notifier	:	Gruber, V.F. and Wislocki, P.G. (1988)	GLP statement	:	no
Type of study	:	soil adsorption	Guideline	:	not specified
Year of execution	:	1988	Acceptability	:	acceptable
Test substance	:	[5-^{3}H]-avermectin B_{1a}, batch [redacted] [redacted] 1.06 mg/mL solution in methanol			

Substance	Soil type	OM [%]	Clay [%]	CEC [mmol/kg]	pH	T [° C]	Ratio Soil/water [g/mL]	$K_{F,ADS}$ [L/kg]	[1/n]	K_{OC} [L/kg]	K_{OM} [L/kg]
[5-^{3}H-avermectin B_{1a}	silt loam	2.1	26.8	125	7.5	room	0.2	18.2	0.798	1495	867
	clay loam	4.8	30.8	392	6.6	room	0.2	134	0.988	4814	2792
	sand	0.1	2.8	15	7.5	room	0.2	6.99	0.856	12052	6990

Description

Soils. As presented in header, silt loam from Three Bridges, NJ, clay loam from Houston, TX and sand from Lakeland, FA (all USA). Soils air dried and ≤ 35 mesh sieved.
Methods. Pre-test to determine equilibrium time.
Final test: Soil samples (2 g) were mixed with 10 mL 0.01 M $CaSO_4$ solution, test substance was added in 20 µL methanol, final concentrations were based on soil weight 0, 0.0056, 0.0292, 0.233, 2.17 µg/g. Shaking for 16 hours at room temperature, two replicates per concentration. Overlying water was analysed by LSC after centrifugation, amount adsorbed was calculated from difference with initial concentration. Solutions of highest concentration were analysed by HPLC. Desorption by shaking for 16 hours with 0.01 M $CaSO_4$, solutions analysed by LSC. Remaining soil after desorption was extracted with methanol by shaking for 16 hours, extracts were analysed by LSC.
Calculations. Freundlich adsorption coefficient and 1/n were calculated by linear regression of log-transformed concentrations in soil versus log-transformed concentrations in solution.

Results

Overall recovery 89.6 - 111 % of AR, average 102 %. Test substance was stable during experiment. K_F and 1/n as given in header. Values for 1/n in sand and silt indicate that K_D is concentration dependent. From graph of K_D at 0.233 µg/g versus OM-content, average K_{OM} is determined as 2868 L/kg, K_{OC} is 1.724 x K_{OM} = 4944 L/kg.

Remarks by RMS

K_{OM} in header was calculated as K_F x 100/% OM, K_{OC} as 1.724 x K_{OM}. K_{OM} values are relatively low as compared to the previous study. Because of the relatively high soil/water ratio, equilibrium concentrations in water may have been very low. As analysis was performed by LSC, adequate detection is assumed to have been possible though. OM-content of sand is not representative for agricultural soils. The results K_{OM} 867 and 2792 L/kg are used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	

Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.3.1/03**	
Title:	Adsorption / Desorption of NOA 448111 and 448112 in Various Soils	
Project/Report number:	01GN07	
Author(s):	Nicollier, G.	
Date of report:	21/02/2002	
Published:	Not published	
Testing facility:	Not applicable	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Nicollier, G. (2002a)	GLP statement	:	yes
Type of study	:	soil adsorption	Guideline	:	OECD 106; US-EPA Subdivision N, section 163-1
Year of execution	:	2001-2002	Acceptability	:	acceptable
Test substance	:	8a-oxo-avermectin B_{1a} (NOA 448111), batch [redacted] chemical purity [redacted] white powder 8a-hydroxy-avermectin B_{1a} (NOA 448112), batch [redacted], chemical purity [redacted] appearance white powder			

Substance	Soil type	OM [%]	Clay [%]	CEC [mmol/kg]	pH	T [° C]	Ratio Soil/water [g/mL]	$K_{F,ADS}$ [L/kg]	[1/n]	K_{OC} [L/kg]	K_{OM} [L/kg]
NOA 448111	loamy sand	1.7	3.11	77.2	7.56	20	0.05	38.3	0.835	3912	2269
	loam/silt loam	4.5	11.9	158.2	7.13	20	0.02	78.4	0.826	3027	1756
	sandy clay loam	4.3	21.0	196.8	5.83	20	0.02	128	0.827	5052	2319
NOA 448112	loamy sand	1.7	3.11	77.2	7.56	20	0.05	15.9	0.857	1626	943
	loam/silt loam	4.5	11.9	158.2	7.13	20	0.02	28.4	0.796	1098	637
	sandy clay loam	4.3	21.0	196.8	5.83	20	0.02	78.9	0.961	3104	1801

Description

Soils. As presented in header, loamy sand from Pappelacker (CH), loam/silt loam from Gartenacker (CH), sandy clay loam from 18 Acres (UK). Soils had not been treated during the last five years. Soils air dried and 2 mm sieved.
Methods. A pre-test was performed to determine shaking time, soil solution ratio, stability and glass adsorption. Final test: Soil samples (2 or 5 g) were equilibrated with 100 mL 0.01 M $CaCl_2$ for 48 hours in glass tubes, soils were centrifuged and test substance was added in 49 - 99 µL 0.01 M $CaCl_2$ solution. Final concentrations 0, 0.1, 0.2, 0.5, 0.75 and 1.0 µg/L. Shaking for 24 (NOA 488111) or 48 hours (NOA 488112) at 200 rpm, two replicates per concentration. Overlying water was decanted after centrifugation, and 0.7 mL aliquots were analysed by HPLC-UV after addition of 0.3 mL acetonitrile (total volume 1 mL; 285 nm for NOA 488111, 243 nm for NOA 448112). Amount adsorbed was calculated from difference with initial concentration. Desorption by shaking for 24 hours with 0.01 M $CaCl_2$, solutions analysed by HPLC. Tubes rinsed with acetonitrile to determine adsorption to glass.
Mass balance experiment: Adsorption step as described above with two replicates at 1.0 µg/L. Supernatant was removed and analysed by HPLC. Remaining soil was extracted three times with acetonitrile/water (8/2, v/v), combined extracts analysed by HPLC.
Calculations. Freundlich adsorption coefficient and 1/n were obtained by linear regression of log-transformed concentrations in soil versus log-transformed concentrations in solution.

Results

Mass balance experiment. Overall recovery 98.3 - 100.3 % for NOA 488111 and 89.5 - 101.9 % for NOA 488112. Test substances were stable during experiment.
Adsorption/desorption experiment. Adsorption to glass below LOD. K_F, 1/n and K_{OC} as given in header. K_{OM} calculated as K_{OC}/1.724. Deviations of 1/n from 1 indicate slight concentration dependent sorption. For both compounds, K_F was related to % clay (r^2 0.996 and 0.898), but not to % OM.

Remarks by RMS

High regression coefficient for relation between K_F and clay content is indicative, as only three soils are included. The results K_{OM} 1756, 2269 and 2319 L/kg for NOA 448111 and 637, 943 and 1801 L/kg for NOA 448112 are used for risk assessment, dependency of sorption on clay content will be considered.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	

Reliability
Acceptability
Remarks

		Official use only
Reference point (location) in dossier	**7.2.3.1/04**	
Title:	Adsorption / Desorption of NOA 457464 in Various Soils,	
Project/Report number:	01GN09	
Author(s):	Nicollier, G.	
Date of report:	09/08/2002	
Published:	Not published	
Testing facility:	Not applicable	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Nicollier, G. (2002b)	GLP statement	:	yes
Type of study	:	soil adsorption	Guideline	:	OECD 106; US-EPA Subdivision N, section 163-1
Year of execution	:	2001-2002	Acceptability	:	acceptable
Test substance	:	4,8a-dihydroxy-avermectin B_{1a} (NOA 457464), batch [redacted] chemical purity [redacted] appearance white amorph			

Substance	Soil type	OM [%]	Clay [%]	CEC [mmol/kg]	pH	T [° C]	Ratio Soil/water [g/mL]	$K_{F,ADS}$ [L/kg]	[1/n]	K_{OC} [L/kg]	K_{OM} [L/kg]
NOA 457464	loamy sand	1.7	3.11	77.2	7.56	20	0.05	16.9	0.890	1690	994
	loam/silt loam	4.4	11.9	158.2	7.13	20	0.02	28.0	0.902	1082	636
	sandy clay loam	4.3	21.0	196.8	5.83	20	0.02	61.3	0.944	2423	1426

Description

Soils. As presented in header, loamy sand from Pappelacker (CH), loam/silt loam from Gartenacker (CH), sandy clay loam from 18 Acres (UK). Soils had not been treated during the last five years. Soils air dried and 2 mm sieved.

Methods. Pre-test was performed to determine shaking time, soil solution ratio, stability and glass adsorption. Final test: Soil samples (2 or 5 g) were equilibrated with 100 mL 0.01 M $CaCl_2$ for 48 hours in glass tubes, soils centrifuged and test substance was added in 49 - 98 µL 0.01 M $CaCl_2$ solution. Final concentrations were 0, 0.1, 0.2, 0.5, 0.75 and 1.0 µg/L. Shaking for 48 hours at 200 rpm, two replicates per concentration. Overlying water was decanted after centrifugation, and 0.7 mL aliquots were analysed by HPLC-UV after addition of 0.3 mL acetonitrile (total volume 1 mL; 252 nm). Amount adsorbed was calculated from difference with initial concentration. Desorption by shaking for 24 hours with 0.01 M $CaCl_2$, solutions were analysed by HPLC. Tubes were rinsed with acetonitrile to determine adsorption to glass.

Mass balance experiment: Adsorption step as described above with two replicates at 1.0 µg/L. Supernatant was removed and analysed by HPLC. Remaining soil was extracted three times with acetonitrile/water (7/3, v/v), combined extracts were analysed by HPLC. Tubes were rinsed with acetonitrile.

Calculations. Freundlich adsorption coefficient and 1/n were obtained by linear regression of log-transformed concentrations in soil versus log-transformed concentrations in solution.

Results

Mass balance experiment. Overall recovery 95.1 - 105.5 %. Test substance was stable during experiment.

Adsorption/desorption experiment. Adsorption to glass 0.2 - 1.3 %. K_F and 1/n as given in header. K_{OM} calculated as K_{OC}/1.724. Deviation of 1/n from 1 in loamy sand indicates slight concentration dependent sorption. K_F was related to % clay (r^2 0.947), but not to % OM.

Remarks by RMS

High regression coefficient for relation between K_F and clay content is indicative, as only three soils are included. The results K_{OM} 636, 994 and 1426 L/kg are used for risk assessment, dependency of sorption on clay content will be considered.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.3.1/05**	
Title:	Adsorption / Desorption of NOA 457465 in Various Soils,	
Project/Report number:	01GN10	
Author(s):	Nicollier, G.	
Date of report:	30/09/2002	
Published:	Not published	
Testing facility:	Not applicable	
Study dates	Not applicable	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Nicollier, G. (2002c)	GLP statement	:	yes
Type of study	:	soil adsorption	Guideline	:	OECD 106; US-EPA Subdivision N, section 163-1
Year of execution	:	2001-2002	Acceptability	:	acceptable
Test substance	:	4-hydroxy-8a-oxo-avermectin B_{1a} (NOA 457465), batch [redacted] chemical purity [redacted] appearance white amorph			

Substance	Soil type	OM [%]	Clay [%]	CEC [mmol/kg]	pH	T [° C]	Ratio Soil/water [g/mL]	$K_{F,ADS}$ [L/kg]	[1/n]	K_{OC} [L/kg]	K_{OM} [L/kg]
NOA 457465	loamy sand	1.7	3.11	77.2	7.56	20	0.05	32.7	0.791	3338	1936
	loam/silt loam	4.5	11.9	158.2	7.13	20	0.02	66.6	1.005	2573	1492
	sandy clay loam	4.3	21.0	196.8	5.83	20	0.02	148	1.011	5813	2267

Description

Soils. As presented in header, loamy sand from Pappelacker (CH), loam/silt loam from Gartenacker (CH), sandy clay loam from 18 Acres (UK). Soils had not been treated during the last five years. Soils were air dried and 2 mm sieved.

Methods. Pre-test was performed to determine shaking time, soil solution ratio, stability and glass adsorption. Final test: Soil samples (2 or 5 g) were equilibrated with 100 mL 0.01 M $CaCl_2$ for 48 hours in glass tubes, soils werer centrifuged and test substance was added in 49 - 99 µL 0.01 M $CaCl_2$ solution. Final concentrations 0, 0.1, 0.2, 0.5, 0.75 and 1.0 µg/L. Shaking for 24 hours at 200 rpm, two replicates per concentration. Overlying water was decanted after centrifugation, and 0.7 mL aliquots were analysed by HPLC-UV after addition of 0.3 mL acetonitrile (total volume 1 mL; 282 nm). Amount adsorbed was calculated from difference with initial concentration. Desorption by shaking for 24 hours with 0.01 M $CaCl_2$, solutions were analysed by HPLC. Tubes were rinsed with acetonitrile to determine adsorption to glass.

Mass balance experiment: Adsorption step as described above with two replicates at 1.0 µg/L. Supernatant was removed and analysed by HPLC. Remaining soil was extracted three times with acetonitrile/water (7.5/2.5, v/v), combined extracts were analysed by HPLC. Tubes were rinsed with acetonitrile.

Calculations. Freundlich adsorption coefficient and 1/n were obtained by linear regression of log-transformed concentrations in soil versus log-transformed concentrations in solution.

Results

Mass balance experiment. Overall recovery 90.4 - 99.7 %. Test substance was stable during experiment.

Adsorption/desorption experiment. Adsorption to glass < 0.09 %. K_F, 1/n and K_{OC} as given in header. K_{OM} calculated as K_{OC}/1.724. Deviation of 1/n from 1 in loamy sand indicates slight concentration dependent sorption. K_F was related to % clay (r^2 0.952), but not to % OM.

Remarks by RMS

High regression coefficient for relation between K_F and clay content is indicative, as only three soils are included. The results K_{OM} 1492, 1636 and 2267 L/kg are used for risk assessment, dependency of sorption on clay content will be considered.

Remarks (Syngenta):
typing errors in header of CP DAR (NOA code and batch No.)
correct: NOA 457465, batch [redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.2.3.2**	**Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**
91/414 Annex IIA point addressed	**7.1.3**	**Column leaching studies**

		Official use only
Reference point (location) in dossier	**7.2.3.2/01**	
Title:	Mobility of Avermectin B_{1a} in Soils	
Project/Report number:		
Author(s):	Ku, C. C. and Jacob, T. A.	
Date of report:	14/11/1983	
Published:	Not published	
Testing facility:	Merck, Sharp & Dohme, New Jersey, USA	
Study dates	Not stated	
GLP:	No	
Reliability indicator	1	X

Reference/notifier	:	Ku, C.C. and Jacob, T.A. (1983c)	GLP statement	:	no
Type of study	:	soil TLC soil (aged) column leaching	Guideline	:	not specified
Year of execution	:	1983	Acceptability	:	not acceptable
Test substance	:	[5-^{3}H]-avermectin B_{1a}, radiochemical purity [redacted] [3,7,11,13,23-^{14}C]-avermectin B_{1a}, radiochemical purity [redacted]			

Substance	Soil type	Aged [d]	OM [%]	pH	Clay [%]	CEC [mmol/kg]	Column length [cm]	Water layer [cm]	Leaching time [d]	Leached [%]
^{3}H-avermectin B_{1a}	sand		0.9	5.6	2.8	15	38	57	28	7.8[1]
	sandy loam		1.1	7.5	14.8	87	38	57	28	2.5[1]
	clay loam		4.8	6.6	30.8	392	38	57	28	7.2[1]
	silt loam		2.1	7.5	26.8	125	38	57	28	3.1[1]
^{3}H-avermectin B_{1a}	sand	29	0.9	5.6	2.8	15	38	58	28	3.8[1] + 0.3[2]
	sandy loam	29	1.1	7.5	14.8	87	38	58	28	2.7[1] + 0.2[3]
	clay loam	29	4.8	6.6	30.8	392	38	58	28	1.4[1]
	silt loam	29	2.1	7.5	26.8	125	38	58	28	5.9[1] + 0.5[3]

1: polar metabolites
2: non-polar metabolites
3: avermectin B_{1a}

Description

Soils. Soils as presented in header, all from USA. Sand from Lakeland, FA, bulk density 1730 kg/m^3; sandy loam from Lufkin, TX, soil bulk density 1420 kg/m^3; clay loam from Houston, TX, soil bulk density 1300 kg/m^3; silt loam from Three Bridges, NJ, soil bulk density 1120 kg/m^3. Additional soil types for TLC: Loam from Riverside (CA), pH 6.7, 2.5 % OM, CEC 123 mmol/kg, soil bulk density 1230 kg/m^3 and sand from Samford (FA), pH 5.6, 0.9 % OM, CEC 21 mmol/kg, soil bulk density 1570 kg/m^3. All soils air dried and ≤ 35 mesh sieved.
Methods.

TLC. Soil plates prepared by spreading a slurry of 60 g soil, 3 g $CaSO_4$ and 15 - 35 mL water onto 20 x 20 glass plates. Plates were air dried at room temperature. ^{14}C-Avermectin B_{1a} and ^{14}C-labelled pesticide standards 2,4-D, Temik, Mirex and Parathion were applied, plates were developed ca. 15 cm with water and analysed by autoradiography.
Column leaching. Soils were packed in glass columns (Ø 4.2 cm) to a height of 38 cm. ^{3}H-avermectin B_{1a} (10 µg) was applied in 1 mL methanol to four columns per soil type, two control columns were applied with methanol only. Two cm of untreated soil was added and columns were wrapped in aluminium foil. Per soil type, two treated columns and one control were aged for 29 days, the other set was leached immediately. Leaching with ca. 760 - 800 mL water over 28 days (50 - 100 mL per 2 -3 days), total amount of water was ca. 56 - 58 cm. Leachate was collected and soils were split into 6 cm layers, all segments were air dried and pulverised.
Chemical analysis. Leachate was analysed by LSC. Water was azeotroped with 1-butanol by rotary evaporation under reduced pressure. Resulting residue was re-dissolved in methanol and analysed by HPLC. Total radioactivity in soil layers was analysed by LSC after combustion. Soil from 0 - 6 cm was extracted twice with acetonitrile and once with methanol/water (9:1, v/v) by shaking for 30 min. and centrifuges. Combined extracts were analysed by HPLC-UV (245 nm), remaining soil was analysed by LSC after combustion.

Results

TLC. Avermectin B_{1a} did not move from the origin, Rf value 0. Rf for mirex and parathion also 0, Temik and 2,4-D had Rf-values of 0.60 - 1.0 and 0.39 - 1.0, respectively.
Column leaching. Distribution of radioactivity after leaching is shown in the table below.

Table: Distribution of radioactivity after leaching. All values are % of AR.

Aged/non-aged	Soil type	Depth [cm]	Soil	Leachate	Avermectin B_{1a}	Polar metabolites	Non-polar metabolites	Non-extractable
non-aged	sand	0 - 6	86		19.8	35.9		30.3
		6 - 12	6.2					
		> 12	0					
		Total	92.2	7.8	0	7.8	0	
	sandy loam	0 - 6	91.0		45.5	19.7		25.9
		6 - 12	6.5					
		> 12	0					
		Total	97.5	2.5	0	2.5	0	
	clay loam	0 - 6	92.0		49.1	11.1		21.8
		6 - 12	0.8					
		> 12	0					
		Total	92.8	7.2	0	7.2	0	
	silt loam	0 - 6	83.3		54.5	0		28.8
		6 - 12	9.2					
		12 - 18	3.7					
		18 - 24	0.7					
		> 24	0					
		Total	96.9	3.1	0	3.1	0	
aged	sand	0 - 6	92.4		21.1	40.1		31.2
		6 - 12	3.5					
		> 12	0					
		Total	95.9	4.1	0	3.8	0.3	
	sandy loam	0 - 6	95.8		62.9	14.3		18.6
		6 - 12	1.3					
		> 12	0					
		Total	97.1	2.9	0.2	2.7	0	
	clay loam	0 - 6	98.6		55.6	6.2		36.8
		> 6	0					
		Total	98.6	1.4	0	1.4	0	
	silt loam	0 - 6	79.4		48.3	7.2		23.9
		6 - 12	4.7					
		12 - 18	5.2					
		18 - 24	2.8					
		24 - 30	0.7					
		> 38	0.8					
		Total	93.6	6.4	0.5	5.9	0	

Authors state that radioactivity in deeper soil layers and in leachate of silt loam may be due to chanelling effects.

Remarks by RMS

Analysis methods differ from validated methods for soil and water as described in Document IIIA reference point 4.2 (a)/01.

TLC. Results of TLC are not used for risk assessment, as no reliable K_{OM} can be derived.

Column leaching. It is remarkable that the sum of total radioactivity in soil and leachates is always exactly 100 %, and that the fractions avermectin B_{1a}, polar metabolites and non-extractable in the 0 - 6 cm layer count up to exactly the same value as reported for total radioactivity in that layer. Figures for non-extractable radioactivity thus seem to have been derived from the difference of total and extractable, but from the method description it appears that non-extractables have been actually measured. Apparently, some corrections for extraction and/or combustion efficiency have been made. The same goes for leachates, where the sum of parent and metabolites is exactly the same as total radioactivity.

In aged sand, sandy loam and clay loam, fractions of avermectin B_{1a} are similar to or higher than in non-aged soil. This indicates degradation of avermectin B_{1a} in non-aged columns was comparable to or higher than in the aged columns. Only for silt loam, the additional 29-days ageing period resulted in a higher formation of polar metabolites as compared to non-aged soil. As radioactivity was found in all leachates, with non-aged values in sand and clay loam being higher than in silt loam, chanelling may also have occurred in other soils.

K_{OM} for avermectin B_{1a} is calculated as $K_{S/L}$ x 100/% OM, with $K_{S/L} = [D/X_p - \theta]/\rho$, where D = thickness of applied water layer [cm], X_p = penetration depth [cm], θ = moisture volume fraction (default 0.4) and ρ = dry soil

bulk density [kg/L]. Penetration depth is defined as the distance from the top of the column to the bottom of the layer in which 50 % of AR was reached, with correction for 2 cm untreated soil. Results are given in the table below.

Table: Penetration depth, soil bulk density and calculated K_{OM}

Aged/non-aged	Soil type	D [cm]	X_p [cm]	ρ [kg/L]	$K_{S/L}$ [L/kg]	K_{OM} [L/kg]
non-aged	sand	57	10	1.73	3.06	340
	sandy loam	57	10	1.42	3.73	339
	clay loam	57	10	1.30	4.08	85
	silt loam	57	4	1.12	12.4	590
aged	sand	58	10	1.73	3.12	347
	sandy loam	58	4	1.42	9.93	903
	clay loam	58	4	1.30	10.8	225
	silt loam	58	10	1.12	4.82	2295

Although penetration depth in aged silt loam is higher than in other soils, calculated K_{OM} is in line with values determined in batch equilibrium experiments. For non-aged silt loam and the other soils, K_{OM}-values are much lower, indicating that packing of columns may not have been correct. The results are not used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

		Official use only
Reference point (location) in dossier	**7.2.3.2/02**	
Title:	Leaching and Sorptivity Characteristics of Aged Soil Residues of [23 ^{14}C]-Labelled NOA 422601 in two Soil Types after 200 mm Artificial Rainfall	
Project/Report number:	01DA03	

Author(s):	Adam, D	
Date of report:	16/07/2002	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland	
Study dates	19/07/2001 to 7/01/2002	
GLP:	Yes	
Reliability indicator	1	

Reference/notifier	:	Adam, D. (2002)	GLP statement	:	yes
Type of study	:	aged column leaching	Guideline	:	BBA IV, 4-2; OECD draft
Year of execution	:	2001-2002	Acceptability	:	acceptable
Test substance	:	[23-^{14}C]-avermectin B_{1a}, batch [redacted], radiochemical purity [redacted]			

Substance	Soil type	Aged	OM	pH	Clay	CEC	Column length	Water layer	Leaching time	Leached	K_{OM}
		[d]	[%]		[%]	[mmol/kg]	[cm]	[cm]	[d]	[%]	[L/kg]
^{14}C-avermectin B_{1a}	loam/silt loam	20	0.9	5.6	2.8	15	38	20	2	0.2	
	loamy sand	20	1.1	7.5	14.8	87	38	20	2	< 0.1	

Description

Soils. Soils as presented in header. Loam/silt loam from Gartenacker (CH), microbial biomass 529 mg C/kg, bulk density 1100 kg/m^3; loamy sand from Pappelacker (CH), microbial biomass 383 mg C/kg, soil bulk density 1400 kg/m^3. Soils stored under greenhouse conditions for one months, air dried and 2 mm sieved before use.

Methods.
Ageing. Soils samples were put into incubation flasks (78.5 cm^2) and treated with ^{14}C-avermectin B1a in 230 µL acetonitrile, total concentration ca. 1 mg/kg. Samples were incubated for 20 days at 20 ± 2 °C in the dark. Volatiles were trapped in ethylene glycol and NaOH and residual radioactivity was determined after 20 days.
Column leaching. Untreated soil was packed in glass columns (Ø 4 cm, 40 cm length) to a height of 38 cm and saturated with 0.01 M $CaCl_2$ over two days. A 2 cm layer of aged soil, with monuron added as a reference substance (0.250 - 0.252 mg in acetone), was put on top of the columns. Columns were leached with 20 cm 0.01 M $CaCl_2$ (251 mL) over 48 hours. Two columns per soil type. Leachate was collected in up to five fractions, soils were split into 15 sections of 2 cm.
Chemical analysis. Aged soil was extracted three times with acetonitrile/water (80/20 v/v) at 200 rpm for 30 min, and once with acetonitrile. Extracts were analysed by LSC. Combined extracts concentrated by evaporation, analysis by LSC, HPLC-UV (245 nm) and/or 2D-TLC (^{14}C-avermectin B_{1a}). Soil layers were extracted three times with acetonitrile/water, and processed as described above. Additional concentration by C_{18}-SPE was included for segments 4 - 6 cm. Non-extractable residue analysed by LSC after combustion. Leachates were concentrated and analysed by LSC, fractions with > 0.5 % of AR were analysed for parent and metabolites. Trapping solutions were analysed by direct LSC, CO_2 confirmed by $BaCO_3$-precipitation. Reference substances: avermectin B_{1a}, NOA 448111, NOA 448112, NOA 457464, NOA 457465 and monuron. LOQ (determined for selected soil sample and defined as 3 x background): 0.03 % of AR for LSC, 0.17 - 0.47 µg/kg for TLC, 4.7 - 6.0 µg/kg for HPLC of avermectin B_{1a} and metabolites.
Calculations. K_{OM} estimated from linear regression of log-RMF versus measured log K_{OC} for 30 pesticides, where RMF = leaching distance of test substance/leaching distance of monuron.

Results

Ageing. Distribution of radioactivity after ageing is given in the table below. Organic volatiles were < LOD. Various unknown fractions were detected, maximum 2.7 % of AR.

Table: Distribution of radioactivity after ageing. All values are % of originally AR.

Soil	Extractable	CO_2	Non-extractable	Recovery	Avermectin B_{1a}	NOA 448111	NOA 448112	NOA 457464	NOA 457465
loam/silt loam	88.0	0.9	9.5	98.4	46.6	7.9	12.3	2.4	3.0
loamy sand	84.6	1.3	9.5	95.4	39.4	8.9	14.3	3.6	2.8

Column leaching. Distribution of radioactivity in soil and leachates after percolation is shown in the table below. Values represent % of applied aged residue on the column.

Table: Distribution of radioactivity in leachate and soil after leaching. All values are % of AR on the column after ageing.

Soil type	Depth [cm]	Extractable	Non-extractable	Total	Avermectin B_{1a}	NOA 448111	NOA 448112	NOA 457464	NOA 457465
loam/silt loam	0 - 2	65.7	7.8	73.5	34.6	6.2	10.5	2.1	1.3
	2 - 4	21.5	2.2	23.6	10.2	1.8	3.5	0.7	0.3
	4 - 6	2.0	0.2	2.2	0.5	0.1	0.2	0.1	< 0.1
	> 6	0.1 - 0.7	< 0.1 - 0.1	0.2 - 0.8					
	Total soil	92.9	10.5	103.4	45.3	8.2	14.1	2.9	1.7
	Leachate			0.5	0.2	< 0.1	< 0.1	< 0.1	< 0.1
loamy sand	0 - 2	46.2	5.5	51.8	22.0	5.3	7.9	1.8	1.5
	2 - 4	33.4	2.1	36.6	14.6	2.7	6.3	1.6	0.8
	4 - 6	1.4	0.1	1.5	0.3	0.1	0.1	0.1	< 0.1
	> 6	0.1 - 0.8	< 0.1 - 0.1	0.2 - 1.5					
	Total soil	85.1	9.1	94.3	36.8	8.1	14.3	3.4	2.4
	Leachate			0.9	< 0.1	< 0.1	< 0.1	< LOD	< 0.1

Recovery of monuron was 89.6 - 91.6 %, leaching distance was 22 - 24 cm. Leaching distance was determined as 4 cm for avermectin B_{1a} and metabolites in both soils. RMF and K_{OC} were 0.182 and 2523 L/kg for loam/silt loam and 0.174 and 2707 L/kg for loamy sand.

Remarks by RMS

Validated soil analysis method RAM 412/01 uses acetonitrile/water 70:30 v/v for extraction (see see Document IIIA reference point 4.2 (a)/01). As < 50 % of the aged residue was accounted for by avermectin B_{1a}, penetration depth and K_{OM} cannot be established. The result no leaching of avermectin B_{1a} and metabolites is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.3.1**	**Phototransformation in air (estimation method), including identification of breakdown products**
91/414 Annex IIA point addressed	**7.2.2**	**Rate and route of degradation in air**

		Official use only
Reference point (location) in dossier	**7.3.1/01**	
Title:	Atmospheric Oxidation of MK-936 (abamectin) by hydroxyl radicals rate estimation	
Project/Report number:	95A98016SM	
Author(s):	Stamm, E.	
Date of report:	10/03/1998	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	
Study dates	Not applicable	
GLP:	Not applicable	
Reliability indicator	1	

Reference/notifier	:	Stamm, E. (1998)	GLP statement	:	not applicable
Type of study	:	estimation atmospheric oxidation rate	Guideline	:	not applicable
Year of execution	:	1998	Acceptability	:	acceptable
Test substance	:	not applicable			

Description

The rate of atmospheric oxidation of abamectin by hydroxyl radicals is estimated with the Atmospheric Oxidation program V 1.82, based on the method of Atkinson (1988).

Results

The overall OH rate constant was 629 x 10^{-12} cm^3/molecule.s, the DT_{50} was 12.2 minutes. The overall ozone rate constant was 121 x 10^{-17} cm^3/molecule.s, the DT_{50} was 13.6 minutes. The estimated half-life of abamectin is < 1 hour.

Remarks by RMS

The result $DT_{50,air}$ < 1 hour is used for risk assessment (24 hour day).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*27-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	7.3.2	Fate and behaviour in air, further studies

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:		
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*27-10-2007*	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

98/8 Doc IIIA section No.	**7.4**	**Effects on aquatic organisms**

98/8 Doc IIIA section No.	**7.4.1**	**Aquatic toxicity, initial tests *(headline)***

98/8 Doc IIIA section No.	**7.4.1.1 / 01**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 01**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/01**	
Title:	Acute toxicity of L-676, 863-00V50 to rainbow trout (*Salmo gairdneri*)	
Project/Report number:	BW-81-7-940	
Author(s):	[redacted]	
Date of report:	July 1981	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	06 to 10 July 1981.	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	[redacted] (1981)	GLP statement	:	no
Type of study	:	fish, acute toxicity	Guideline	:	US EPA 1975
Year of execution	:	1981	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted], chemical purity [redacted] appearance white coloured powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	Onchorhynchus mykiss	static	12 ± 1	6.9 – 7.3	96	LC_{50}	3.6

Description

Methods. Toxicity of technical abamectin to rainbow trout (*Onchorhynchus mykiss*) was tested under static conditions. Rainbow trout was commercially obtained and acclimated to test conditions for at least 14 days, length 29 – 38 mm at start. Nominal concentrations 0.46, 0.78, 1.3, 2.2, 3.6 and 6.0 µg/L as pure active ingredient, control, solvent control (acetone 0.4 mL/L). Dilution with reconstituted water, total hardness 40 mg $CaCO_3$/L, conductivity 120 µmhos/cm, pH 7.5. One replicate with 15 L test solution, 10 fish per test vessel. Daily observations.
Conditions. Temperature 12 ± 1 °C, 16:8 h L:D, no aeration, no feeding.Test vessels were capped.
Calculations and statistics. LC_{50}-values were calculated using binomial probability.

Results

No mortality in the controls and at 0.46 - 2.2 µg/L, 70 % mortality at 3.6 µg/L, 100 % mortality at 6.0 µg/L (reched after 48 hours). Sublethal effects as from 48 hours at 1.3 µg/L and higher. 24-hours LC_{50} > 6.0 µg/L, 48-hours LC_{50} 4.6 µg/L (95 % CL 3.6 – 6.0 µg/L), 72- and 96-hours LC_{50} 3.6 µg/L (95 % CL 2.2 – 6.0 µg/L), 96-hours NOEC 0.78 µg/L, all based on nominal concentrations and corrected for purity of the test compound.

Remarks by RMS

Water quality parameters within accepted range. Temperature was set lower than recommended temperature range of OECD 203 (13 - 17°C) and starting lengths were lower than recommended by OECD (5.0 ± 1.0 mm), this is not considered to have influence the outcome. The result 96-hours LC_{50} 3.6 µg/L, based on nominal concentrations is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*28-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 02**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 02**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/02**	
Title:	Acute toxicity of L-676, 863-00V50 technical to bluegill (*Lepomis macrochirus*).	
Project/Report number:	BW-81-6-901.	
Author(s):	[redacted]	
Date of report:	June 1981.	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	08 to 12 June 1981.	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	[redacted] (1981)	GLP statement	:	no
Type of study	:	fish, acute toxicity	Guideline	:	US EPA 1975
Year of execution	:	1981	Acceptability	:	not acceptable
Test substance	:	abamectin technical, batch [redacted], chemical purity [redacted] appearance white coloured powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Lepomis macrochirus*	static	21-22	6.7 - 7.5	96	LC_{50}	9.6

Description

Methods. Toxicity of technical abamectin to bluegill (*Lepomis macrochirus*) was tested under static conditions. Bluegills were commercially obtained and acclimated to test conditions for at least 14 days, length 23 - 36 mm at start. Nominal concentrations 3.5, 5.8, 9.7, 16, 27, 45 and 75 µg/L, control, solvent control (acetone, 0.5 mL/L). Dilution with reconstituted water, total hardness 42 mg $CaCO_3$/L, 120 µmhos/cm conductivity, pH 7.4. On replicate with 15 L of test solution, 10 bluegills.
Conditions. Temperature 21 - 22 °C, 16:8 h L:D, no aeration, no feeding.
Calculations and statistics. Moving average angle analysis and probit analysis were used to calculate LC_{50}-values.

Results

Oxygen concentration decreased in all treatments, DO after 96 h 1.0 mg/L in solvent control and 3.5 µg/L, and 1.4 – 4.6 mg/L in the other treatments.
No mortality in the control and solvent control, and at 3.5 and 5.8 µg/L. Mortality was 20 % at 9.7 µg/L treatment and 100 % 16 µg/L and higher. Lethargy and changes in coloration were reported at 9.7 µg/L and higher concentrations. 24-hours LC_{50} reported as 29 µg/L (95 % CL 23 – 37 µg/L), 48-hours LC_{50}19 µg/L (95 % CL 14 – 26 µg/L), 72-hours LC_{50} 14 µg/L (95 % CL 9.7 – 18 µg/L) and 96-hours LC_{50} 9.6 µg/L (95 % CL 5.8 – 16 µg/L), 96-hours NOEC 5.8 µg/L, all based on nominal concentrations.

Remarks by RMS

DO decreased to 11 % of air saturation in a number of test vessels. Test solutions were cloudy in several test vessels including the solvent control, on multiple occasions. Therefore, it is unclear which effects were due to exposure of the fish to the test substance. The result is not used for risk assessment.

Syngenta endpoint(s) in originally submitted Document III A Section 7:
The 96-hour LC_{50} for bluegill estimated by binomial probability was 9.6 µg abamectin/L (95% confidence interval 5.8 - 16 µg/L). The NOEC was 5.8 µg/L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*28-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 03**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 03**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/03**	
Title:	The acute toxicity of avermectin B_1 to carp (*Cyprinus carpio*).	
Project/Report number:	MSD 150/85381	
Author(s):	[redacted]	
Date of report:	20/05/1985	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	25 February to 01 March 1985.	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	

Reliability indicator	2.	X

Reference/notifier	:	[redacted] (1985)	GLP statement	:	yes
Type of study	:	fish, acute toxicity	Guideline	:	OECD 203, 1992
Year of execution	:	1985	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted] appearance white crystalline powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Cyprinus carpio*	flow-through	21 ± 1	7.8 – 7.9	96	LC_{50}	42

Description

Methods. Toxicity of technical abamectin to carp (*Cyprinus carpio*) was tested under flow-through conditions. Carps were commercially obtained and acclimated to test conditions for 14 days, length 53 ± 0.55 mm at start. Nominal concentrations 10, 18, 32, 56 and 100 µg/L, control. Dilution with dechlorinated tap water, total hardness 320 mg $CaCO_3$/L pH 7.8 - 7.9, renewal rate 1.5 L/h. One replicate with 20 L, 10 fish per vessel
Conditions. Temperature 21 ± 1 °C, 16:8 h L:D, aeration, no feeding.
Calculations and statistics. LC_{50}-values were calculated using Thompson and Weil (1952).

Results

No mortality in control and 10 - 32 µg/L, full mortality at 56 µg/L after 96 hours, 100 % mortality within 24 hours at 100 µg/L. Sublethal effects at 56 µg/L as from 24 hours. 24-hours LC_{50} 72 µg/L (95 % CL 64 – 81 µg/L), 48-hours LC_{50} 64 µg/L (95 % CL 53 – 78 µg/L), 72-hours LC_{50} 54 µg/L (95 % CL 44 – 67 µg/L), 96-hours LC_{50} 42 µg/L (95 % CL 32 – 56 µg/L).

Remarks by RMS

Water quality parameters within accepted range. Larger fish were used in the present study than recommended in the OECD guideline 203. The authors argued that larger fish were used since fish of 3 cm length were too small to transport safely and that such fish are only available for 1 – 2 months per year. Recalculation with Spearman-Kärber yielded similar LC_{50}–values. The result 96-hours LC_{50} 42 µg/L, based on nominal concentrations, is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*28-10-2007*
Materials and Methods	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 04**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 04**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/04**	
Title:	Acute toxicity of MK-0936 technical to channel catfish (*Ictalurus punctatus*)	
Project/Report number:	32978	
Author(s):	[redacted]	
Date of report:	29/05/1985	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	17 to 21 May 1985.	
GLP:	Yes.	

Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	[redacted] (1985)	GLP statement	:	yes
Type of study	:	fish, acute toxicity	Guideline	:	US EPA 1975
Year of execution	:	1985	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Ictalurus punctatus*	static	21 - 23	7.1 – 7.6	96	LC_{50}	24

Description

Methods. Toxicity of abamectin technical to channel catfish (*Ictalurus punctatus*) was tested under static conditions. Catfish were commercially obtained and acclimated to test conditions for at least 14 days, length 36 ± 0.18 mm at start. Nominal concentrations 5.6, 10, 18, 32, 56 and 100 µg/L as pure abamectin, control, solvent control (DMF, 0.1 mL/L). Positive control antimycin A. Dilution water reconstituted water, total hardness 40 - 45 mg $CaCO_3$/L, pH 7.2 – 7.6. Two replicates. with five fish each, 15 L water. Weight and length measurements on control group at termination of test.
Conditions. Temperature 22 ± 1 °C, 16:8 h L:D, aeration, no feeding.
Calculations and statistics. LC_{50}-values were calculated using binomial probability.

Results

DO decreased to 44 – 64 % of air saturation after 96 hours. No mortality in controls, solvent controls, 5.6 - 18 µg /L. At higher concentrations, mortality was 100% after 96 hours. Sublethal effects at 18 µg/L and higher. 24-hours LC_{50} 42 µg/L (95 % CL 32 – 56 µg/L), 48-hours LC_{50} 27 µg/L (95 % CL 18 – 56 µg/L), 96-hours LC_{50} 24 µg/L (95 % CL 18 – 32 µg/L), 96-hours NOEC 10 µg/L, all based on nominal concentrations after correction for purity of the test compound. For antimycin A, the 96 hours LC_{50} of 4.2 µg/L was reported to be within confidence intervals reported in the literature (Berger et al. 1969).

Remarks by RMS

DO within accepted limits for 72 hours. The result LC_{50} 24 µg/L, based on nominal concentrations and corrected for purity of the test compound, is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*28-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 05**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 05**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/05**	
Title:	Dynamic acute toxicity of avermectin B1a to bluegill sunfish (*Lepomis macrochirus*)	
Project/Report number:	30261	
Author(s):		
Date of report:	26/04/1983, revised 24/10/1983.	
Published:	Not published.	
Testing facility:		
Study dates	05 to 12 April 1983.	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and	

	demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	[redacted] (1983)	GLP statement	:	yes
Type of study	:	fish, 7 days toxicity	Guideline	:	EPA 1975
Year of execution	:	1983	Acceptability	:	acceptable
Test substance	:	avermectin B_{1a}, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
avermectin B_{1a}	*Lepomis macrochirus*	flow-through	21 - 22	7.8 – 8.1	96	LC_{50}	7.2

Description

Methods. Toxicity of avermectin B_{1a} to bluegill sunfish (*Lepomis macrochirus*) was tested under flow-through conditions. Sunfish were purchased from a commercial supplier and were acclimated to test conditions for at least 14 days, length 40 mm at start. Nominal concentrations 0.59, 1.4, 2.3, 4.9 and 10 µg/L, solvent control. Dilution with natural well, total hardness 255 mg $CaCO_3$/L, conductivity 500 µmhos/cm, pH 8.2. One replicate with 20 fish, 40 L water, renewal rate 6.3 L/h. Daily observations. At termination of the study, length and weight of remaining fish were determined.
Conditions. Temperature 21 - 22 °C, 16:8 h L:D, no aeration, no feeding.
Calculations and statistics. LC_{50}-values were calculated using moving average angle and binomial probability.

Results

No mortality in solvent control and at 0.59 - 2.3 µg/L, 5 % mortality at 4.9 µg/L after 72 hours. At 10 µg/L, mortality was 5 % after 72 hours and increased to 100 % after 144 hours. 96-hours LC_{50} reported as 7.2 µg/L (95 % CL 6.4 – 8.2 µg/L), 120-hours LC_{50} 7.0 µg/L (95 % CL 6.0 – 8.2 µg/L), 144- and 168-hours LC_{50} 6.7 µg/L (95 % CL 4.9 - 10 µg/L).

Remarks by RMS

Water quality parameters within accepted range. Information about composition of solvent control and standard deviation of fish length is lacking probably because an appendix was not included in the report. Length of sunfish used for testing is twice the length recommended by OECD 203. Solvent control was not defined. However, since solvent control mortality was 0 %, the result 96-hours LC_{50} 7.2 µg/L, based on nominal concentrations, is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

Syngenta endpoint(s) in originally submitted Document III A Section 7:
A lethal threshold was estimated to be 6.7 µg/L since no significant mortality greater than 5% was observed after 5 days of exposure. The no observed effect concentration of avermectin B_{1a} was 2.3 µg/L.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 06**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 06**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/06**	
Title:	NOA-427011: A 96-hour flow-through acute toxicity test with the rainbow trout (*Oncorhynchus mykiss*)	
Project/Report number:	108A-214A	
Author(s):	[redacted]	
Date of report:	11/01/2000	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	06 to 10 December 1999.	
GLP:	Yes.	

Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	[redacted] (2000a)	GLP statement	:	yes
Type of study	:	fish, acute toxicity	Guideline	:	OECD 203, 1992
Year of execution	:	1999-2000	Acceptability	:	acceptable
Test substance	:	[8,9-Z]-avermectin B_{1a} (NOA 427011), chemical purity [redacted] appearance white crystalline powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
[8,9-Z]-avermectin B_{1a}	*Oncorhynchus mykiss*	flow-through	13.3 – 13.7	8.1 – 8.3	96	LC_{50}	5.1

Description

Methods. Toxicity of [8,9-Z]-avermectin B_{1a} to rainbow trout (*Oncorhynchus mykiss*) was tested under flow-through conditions. Trout eggs were purchased from a commercial supplier and were hatched and held in the culture facility of the performing laboratory. Fish were acclimated for 48 hours to test conditions, length 41 – 44 mm at start. Nominal concentrations 0.94, 1.9, 3.8, 7.5 and 15 µg/L as pure compound, control, solvent control (DMF). Dilution with natural well water passed through a sand filter, total hardness 136 mg $CaCO_3$/L, conductivity 310 µmhos/cm, pH 8.2. Two replicates with 10 fish each, 15 L water per test vessel, renewal rate 7.5 L/h. Daily observations.
Conditions. Temperature 13.5 ± 1 °C, 16:8 h L:D, no aeration, no feeding.
Chemical analysis. Samples collected at beginning and termination of test. Analysis by HPLC-UV after extraction with dichloromethane, LOQ 0.5 µg/L, recovery 100 %.
Calculations and statistics. LC_{50}-values were determined using the program of Stefan (1977) or by visual interpretation. NOEC was determined by visual interpretation of mortality and clinical observation data.

Results

Actual concentrations were 69 - 81 % of nominal at start and 73 - 88 % of nominal at end. Mean measured concentrations were 0.73, 1.4, 3.1, 5.9 and 12 µg/L (72 - 81 % of nominal). No mortality in controls and solvent controls, and at 0.73 - 3.1 µg/L, 60 % mortality at 5.9 µg/L, 100% at 12 µg/L, first deaths after 48 hours. Sublethal effects at 5.9 µg/L. 24-hours LC_{50} > 12 µg/L, 48-hours LC_{50} 12.0 µg/L, 72-hours LC_{50} 8.0 µg/L (95 % CL 5.9 - 12 µg/L) and 96-hours 5.1 µg/L (95 % CL 3.1 – 12 µg/L). LC_{50}-values for the 24, 72 and 96 h exposure periods were calculated using binomial probability and the LC_{50} for 48 hours of exposure was based on visual interpretation.

Remarks by RMS

Water quality parameters within accepted limits. Length of trout used for testing is smaller than recommended by OECD 203, this is not considered to have influenced results. Recalculation with Spearman-Kärber yielded similar LC_{50}-values. The result 96-hours LC_{50} 5.1 µg/L, based on mean measured concentrations, is used for risk assessment.

Syngenta endpoint(s) in originally submitted Document III A Section 7:
The 96-hour LC_{50} of NOA-427011 to *O. mykiss* was 5.4 µg/L, and the NOEC was 3.1 µg/L (mean measured).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 07**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 07**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/07**	
Title:	Acute toxicity of MK-936 to the sheepshead minnow (*Cyprinodon variegatus*)	
Project/Report number:	ESE No 85-347-0100-2130	
Author(s):	[redacted]	
Date of report:	October 1985	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	13 to 17 September 1985.	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	[redacted] (1985)	GLP statement	:	yes
Type of study	:	fish, acute toxicity	Guideline	:	ASTM 1982
Year of execution	:	1985	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Cyprinodon variegatus*	semi-static	19 - 21	8.1 – 8.4	96	LC_{50}	15

Description

Methods. Toxicity of technical abamectin to sheepshead minnow was tested under semi-static conditions. Minnows were purchased from a commercial supplier and were acclimated to test conditions for 17 days, length 12 ± 1 mm at start. Nominal concentrations 4.7, 7.8, 13, 22, 36 and 60 µg/L as pure active ingredient, control, solvent control (acetone 0.1 mL/L). Dilution with filtered natural seawater (5 µm-mesh), salinity 19-20 ‰, total hardness 40 - 45 mg $CaCO_3$/L, pH 8.1 – 8.4, renewal after 48 hours. One replicate with 10 fish, 9 L water per vessel.
Conditions. Temperature 19 - 21 °C, 14:10 h L:D, no aeration, no feeding,
Calculations and statistics. LC_{50}-values were calculated using moving average angle method.

Results

No mortality in control, solvent control, 4.7 and 7.8 µg/L, At 13 - 36 µg/L 60 - 90 % mortality after 96 hours, 100 % mortality after 24 hours 60 µg/L. All surviving fish at 13 - 36 µg/L were immobile. 24-hours LC_{50} 18 µg/L (95 % CL 14 - 25 µg/L), 48-hours LC_{50} 16 µg/L (95 % CL 11 - 20 µg/L), 72- and 96-hours LC_{50} 15 µg/L (95 % CL 11 - 20 µg/L), all based on nominal concentrations of pure active ingredient.

Remarks by RMS

Water quality paramters within accepted limits. The result LC_{50} 15 µg/L, based on nominal concentrations and corrected for purity of the test compound, is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 08**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 06**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/08**	
Title:	Acute toxicity of MK 936 tech. (abamectin) to fathead minnow (*Pimephales promelas*) in a 96-hour flow-through test.	
Project/Report number:	2021843.	
Author(s):		
Date of report:	14/11/2003	
Published:	Not published.	
Testing facility:		
Study dates	09 June – 18 September 2003	
GLP:	Yes.	

Deficiencies:	None	
Reliability indicator	1.	

Reference/notifier	:	[redacted] (2003a)	GLP statement	:	yes
Type of study	:	fish, acute toxicity	Guideline	:	oECD 203
Year of execution	:	2003	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted]			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Pimephales promelas*	flow-through	23.5	7.8 – 7.9	4 days	LC50	14.7 (actually)

Description

Methods. The acute toxicity of abamectin (technical, purity 86.2%; batch no.VS094K0) to the fathead minnow Pimephales promelas was tested under GLP according to OECD Guideline 203. The test was carried out under flow-through conditions for 96 h. The mean body length of the fish was 3.6 ± 0.2 cm, the mean body weight was 0.44 ± 0.08 g. After an equilibrium phase of 1 week 7 fish per test concentration were introduced in a flow-through system (60 L aquaria) and exposed to nominal concentrations of 4.6, 10, 22, 46 and 100 µg/L, a solvent control and a water control. Dimethylformamid (100 µL/L) was used as the solvent vehicle. Test water: local tap water, hardness 204 mg $CaCO_3$/L. The actual concentrations were determined during the equilibrium phase and on days 0, 2 and 4 of the exposure phase by HPLC with UV detection.
Conditions. Water temperature: 23-24 °C. Photoperiod: 16 h light (50-500 lx), 8 h dark.
Fish were observed for visual abnormalities and mortality after 6, 24, 48, 72 and 96 hours.
Calculations and statistics. The LC_{50} was calculated by Moving Average Interpolation.

Results

The actual concentrations of abamectin in the test media ranged from 44% to 75% of nominal during the equilibrium phase. During the exposure phase the concentrations ranged from 66-74% on day 0 to 39-62% on day 2, and 61-66% of nominal on day 4. In the 100 µg/L (nominal) concentration the actual concentration was 76% after 1 day. Mean measured test concentrations were 2.6, 5.6, 12, 31 and 72 µg/L.
The pH during the test was 7.8-7.9; DO: 7.2-8.6 mg/L; temperature: 23-24 °C.
In the controls and in the 4.6 and the 10 µg/L concentrations no mortalities and no visual symptoms were observed. In the 22 µg/L concentration 2-3 fish were apathetic or on the bottom after 72 h and 96 h and 1 fish died after 96 h. In the 46 µg/L concentration 5, 6, 6 and 7 fish were dead after 24, 48, 72 and 96 h, respectively. In the 100 µg/L concentration all 7 fish were dead after 24 h. The 96-h LC_{50} was calculated to be 17 µg/L (95% conf. int.: 12-24 µg/L) based on actual concentrations. The 96-h NOEC was 5.6 µg/L (actually).

Remarks by RMS

Because of the low purity the LC_{50} should be corrected to 14.7 µg/L.
The 96-h LC_{50} of abamectin for *Pimephales promelas* of 0.0147 mg/L (14.7 µg/L) actually can be used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 09**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 07**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/09**	
Title:	Acute toxicity of MK 936 tech. (abamectin) to rainbow trout (*Oncorhynchus mykiss*) in a modified exposure study.	
Project/Report number:	2032520.	
Author(s):	[redacted]	
Date of report:	13/11/2003	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	26 May - 31 July 2003	
GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1.	

Type of study	:	fish, acute toxicity, modified exposure test	Guideline	:	oECD 203
Year of execution	:	2003	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted]			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Oncorhynchus mykiss*	flow-through, modified exposure	13.5	7.7 – 8.1	4 days	LC_{50}	8.7 (nominally)

Description

Methods. The acute toxicity of abamectin (technical, purity 86.2%; batch no.VS094K0) to the rainbow trout *Oncorhynchus mykiss* was tested under GLP according to OECD Guideline 203. The test was carried out under flow-through conditions for 96 h. The mean body length of the fish was 5.2 ± 0.2 cm, the mean body weight was 1.3 ± 0.1 g. After an equilibrium phase of 1 week 7 fish per test concentration were introduced in the flow-through system (60 L aquaria) and exposed to nominal concentrations at the start of 0.64, 1.4, 3.1, 6.8 and 15 µg/L, a solvent control and a water control. The nominal target concentrations were gradually diminished (DT_{50} of 4.9 days to simulate degradation) to 0.46, 1.0, 2.2, 4.9 and 10.9 after 4 days. Dimethylformamid (100 µL/L) was used as the solvent vehicle. Test water: local tap water, hardness 202 mg $CaCO_3$/L. The actual concentrations were determined during the equilibrium phase and on days 0, 1, 2, 3 and 4 of the exposure phase by HPLC with UV detection.
Conditions. Water temperature: 23-24 °C. Photoperiod: 16 h light (50-500 lx), 8 h dark.
Fish were observed for visual abnormalities and mortality after 6, 24, 48, 72 and 96 hours.
Calculations and statistics. The LC_{50} was calculated the geometric mean of the concentrations with 0 and 100% mortality

Results

During the exposure phase the measured concentrations ranged from 126-187% of nominal at day 0, to 34-53% at day 1, 80-103% at day 2, 80-79% of at day 3 and 69-75% at day 4. The pH during the test was 7.7-8.1; DO: 8.5-9.7 mg/L; temperature: 13.2-13.9 °C.
In the controls and in the 0.64-3.1 µg/L nominal (start) concentrations no mortalities and no visual symptoms were observed. In the 6.8 µg/L concentration 3 fish were apathetic after 48 h and 7 fish were apatic or on the bottom after 72 h and 96 h. In the 15 µg/L concentration 2 fish were dead after 24 h, 7 fish were dead after 48 h and all fish were dead after 72 h. The 96-h LC50 was calculated to be 10.1 µg/L based on nominal concentrations. The 96-h NOEC was 3.1 µg/L.

Remarks by RMS

Because of the low purity the LC50 should be corrected to 8.7 µg/L.
Actually measured concentrations were occasionally below 80% of nominal, but the average measured concentrations are > 80%. Therefore, an LC50 based on nominal concentrations can be accepted.
The 96-h LC50 of abamectin for Oncorhynchus mykiss of 0.0087 mg/L (8.7 µg/L) nominally can be used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.1 / 10**	**Acute toxicity to fish**
91/414 Annex Point addressed	**II 8.2.1 / 10**	**Acute toxicity to fish**

		Official use only
Reference point (location) in dossier	**7.4.1.1/10**	
Title:	Acute Toxicity Test of NOA 448112 (Metabolite of MK 936) To Rainbow Trout (*Oncorhynchus mykiss*) Under Semi-Static Conditions	
Project/Report number:	812237.	
Author(s):	[redacted]	
Date of report:	06/07/2001	
Published:	Not published.	
Testing facility:	[redacted]	
Study dates	21 May to 18 June 2001	
GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1.	

Type of study	:	fish, acute toxicity	Guideline	:	OECD 992, US EPA 1992
Year of execution	:	2001	Acceptability	:	acceptable
Test substance	:	8a-hydroxy-avermectin B_{1a} (NOA 448112), batch [redacted], chemical purity [redacted] purity, appearance white-beige powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
8a-hydroxy-avermectin B1a	*Oncorhynchus mykiss*	semi-static	13.4 – 15.1	7.7 – 7.9	96	LC_{50}	520

Description

Methods. Toxicity of 8a-hydroxy-avermectin B_{1a} to rainbow trout was tested under semi-static test conditions. Fish were commercially obtained and acclimated for > 7 days, length 49 mm at start. Nominal concentrations 0.12, 0.27, 0.60, 1.2, 2.7 and 6.0 mg/L, control, solvent control (DMF, 100 µg/L). Dilution with reconstituted water, hardness 250 mg $CaCO_3$/L, pH 7.9, daily renewal. One replicate, 15 L water, seven fish. Daily observations of mortality and abnormal behaviour. *Conditions.* Temperature 13.5 ± 1 °C, 16:8 h L:D (500 lux, with 30 minutes transition period), aeration, no feeding.
Chemical analysis. Analysis of fresh and old solutions by HPLC, LOQ 0.11 mg/L, recovery 98 %.
Calculations and statistics. LC_{50}-values were determined using probit analysis. The LC_{50}-value for 48 h could not be calculated by probit analysis due to a steep concentration-effect relationship. Instead, the LC_{50}-values were determined as the geometric mean value of the two consecutive test concentrations with 0 and 100% mortality and the 95 % CL as the test concentrations with 0 and 100% mortality.

Results

Actual concentrations were 101 - 152 % of nominal in fresh solutions, and 67- 108 % of nominal in old solutions. Mean measured concentrations were 0.12, 0.27, 0.63, 1.3, 2.8 and 6.5 mg/L (99 - 109 % of nominal). No mortality in control, solvent control, and at 0.12 and 0.27 mg /L, 86 % mortality at 0.63 mg/L, 100 % at 1.3 and 2.8 mg/L by day 2, at 6.5 mg/L 100 % mortality after one day. Sunlethal effects at 0.63 mg/L from day 2 onwards. 24-hours LC_{50} 2.5 mg/L (95 % CL 1.7 – 3.7 mg/L), 48-hours LC_{50} 0.90 mg/L (95 % CL 0.63 – 1.3 mg/L), 72-hours LC_{50} 0.61 mg/L (95 % CL 0.48 – 0.77 mg/L), 96-hours LC_{50} 0.52 mg/L (95 % CL 0.29 – 0.93 mg/L, 96-hours NOEC was 0.27 mg/L, all based on mean measured concentrations.

Remarks by RMS

Water quality parameters within accepted limits. Recalculation with Spearman-Kärber yielded similar LC_{50}-values. The result 96-hours LC_{50} 520 µg/L, based on mean measured concentrations, is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 01**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 01**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/01**	
Title:	Acute toxicity of L-676,863-00V50 to the water flea (*Daphnia magna*)	
Project/Report number:	BW-81-6-938	
Author(s):	LeBlanc, G.A. and Surprenant, D.C.	
Date of report:	June 1981	
Published:	Not published.	
Testing facility:	EG & G Bionomics, Massachusetts, USA	
Study dates	25 to 27 June 1981.	
GLP:	Yes.	X
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	Surprenant, D.C. (1981)	GLP statement	:	no
Type of study	:	Daphnia, acute toxicity	Guideline	:	US EPA 1975
Year of execution	:	1981	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Daphnia magna*	static	21	8.0	48	LC_{50}	0.34

Description

Methods. Daphnids (< 24 h old) exposed to abamectin for 48 h in static test systems containing 500 mL solution. Reconstituted deionised water, total hardness 165 mg $CaCO_3$/L, pH 7.9 – 8.3, 400 – 600 µmhos/cm. Nominal concentrations 0.31, 0.48, 0.79, 1.3 and 2.2 µg/L, control, solvent control (acetone, 0.5 mL/L). Two replicates for control, single vessels for test compound, 15 daphnids per test unit.
Conditions. Temperature 21 ± 1°C, no aeration, 16:8 h L:D (540 – 760 lux), no feeding.
Calculations and statistics. EC_{50}-value was calculated using moving average angle analysis.

Results

Control mortality 7% after 48 h, no mortality in solvent control, concentration related mortality of 33 and 93 % at 0.31 and 0.48 µg/L, 100 % at 0.79 µg/L and higher. Nominal 48-hours EC_{50} reported as 0.34 µg/L (95% CL 0.28 – 0.41 µg/L).

Remarks by RMS

Water quality parameters within accepted range. No verification of concentrations. Recalculation of EC_{50} with Spearman-Kärber yielded similar results. The result 48-hours EC_{50} 0.34 µg/L, based on nominal concentrations, is used for risk assessment.

Remarks (Syngenta):
Author identification in DAR is different from originally submitted Doc IIIA.
From the study report: Principal investigator: D.C. Surpenant, study director: G.A. LeBlanc

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*29-10-2007*
Materials and Methods	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 02**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 02**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/02**	
Title:	Acute toxicity of ^{3}H-avermectin B1 to *Daphnia magna*	
Project/Report number:	38094	
Author(s):	Forbis, A.D.	
Date of report:	01/12/1989	
Published:	Not published.	
Testing facility:	Analytical Biochemistry Laboratories Inc., Missouri, USA	
Study dates	29 June to 01 July 1989.	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Forbis, A.D. (1989a)	GLP statement	:	yes
Type of study	:	Daphnia, acute toxicity	Guideline	:	US EPA
Year of execution	:	1989	Acceptability	:	acceptable
Test substance	:	^{3}H-abamectin, batch [redacted], [redacted] chemical purity, ethanol solution			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
^{3}H-abamectin	*Daphnia magna*	static	21	8.0	48	EC_{50}	0.37

Description

Methods. Daphnids (< 24 h old) exposed to ^{3}H-abamectin for 48 h in static test systems, containing 200 mL solution. Mixture of surface impoundment water and soft blended water with total hardness of 174 mg $CaCO_3$/L, pH 8.0, 420 µmhos/cm. Nominal concentrations 0.10, 0.18, 0.32, 0.56 and 1.0 µg/L, control, solvent control (ethanol). Two replicates for controls and test compound, 10 daphnids per vessel.
Conditions. Temperature 21 ± 1°C, no aeration, 16:8 h L:D (540 – 760 lux), no feeding.
Analysis. Determination of test compound concentrations sampled after 0 and 48 h by LSC, LOQ 0.0024 µ/L.
Calculations and statistics. EC_{50}-value was calculated using moving average angle analysis.

Results

Mean measured concentrations 0.058, 0.12, 0.20, 0.36 and 0.65 µg/L (58 – 67% of nominal). No immobilisation in the controls and at 0.058 - 0.20 µg/L, 55 % at 0.36 µg/L and 95 % at 0.65 µg/L. The actual 48-hours EC_{50} reported as 0.37 µg/L (95% CL 0.32 – 0.44 µg/L).

Remarks by RMS

Water quality parameters within accepted range. Recalculation of EC_{50} with Spearman-Kärber yielded similar results. The result 48-hours EC_{50} 0.37 µg/L, based on mean measured concentrations, is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*30-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 03**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 03**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/03**	
Title:	Acute toxicity of soil-bound ^{3}H-avermectin B1 to *Daphnia magna*	
Project/Report number:	38095	
Author(s):	Forbis, A.D.	
Date of report:	01/12/1989	
Published:	Not published.	
Testing facility:	Analytical Biochemistry Laboratories Inc., Missouri, USA	
Study dates	05 to 07 July 1989.	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Forbis, A.D. (1989b)	GLP statement	:	yes
Type of study	:	Daphnia, acute toxicity, spiked soil	Guideline	:	US EPA
Year of execution	:	1989	Acceptability	:	acceptable
Test substance	:	^{3}H-abamectin, batch [redacted] acetone solution			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
^{3}H-abamectin	*Daphnia magna*	static; sediment spiked	21	8.0	48	EC_{50}	0.26

Description

Methods. Daphnids (< 24 h old) exposed to soil bound ^{3}H-abamectin for 48 h in static test systems. Blend of surface impoundment water and soft blended water, total hardness 170 mg $CaCO_3$/L, pH 8.0, 440 µE/cm. Soil spiked with 5.6, 10, 18, 32, 56 and 100 µg/kg dwt, 50 g dw soil and 200 mL solution per test vessel. Control, solvent control (ethanol) and treated soils in duplicate, 10 daphnids per test vessel.
Conditions. Temperature 21°C, 16:8 h L:D, no feeding.
Analysis. ^{3}H-abamectin determined at start and end of test by LSC. Water samples counted directly, 0.0025 µg/L, soil after combustion, total recovery 88 %, LOQ 0.07 µg/kg dwt.
Calculations and statistics. EC_{50}-values were calculated by probit analysis.

Results

Mean measured concentrations 0.043, 0.12, 0.17, 0.26, 0.56 and 0.76 µg/L in the solutions and 6.2, 13, 21, 37, 71 and 110 µg/kg dwt soil (110 – 130% of nominal). After 48 h, no immobilisation in controls, solvent controls, and 6.2 and 13 µg/kg dwt. At 21 µg/kg dwt soil 5% immobilisation and at 37 µg/kg dwt soil 35% immobilisation. Full immobilisation at 71 and 110 µg/kg dwt (0.56 and 0.76 µg/L). EC_{50} reported as 0.26 µg/L (95% CL 0.22 – 0.30 µg/L) and 39 µg/kg dwt (95% CL 34 – 46 µg/kg), based on mean measured concentrations.

Remarks by RMS

Water quality parameters within accepted range. Recalculation of EC_{50} with Spearman-Kärber yielded similar results. The result 48-hours EC_{50} 0.26 µg/L, based on mean measured concentrations, is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*30-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 04**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 04**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/04**	
Title:	*Daphnia magna* 5-day test on immobilization: Effects of MK-936 (Abamectin tech.) on the immobilization of the Cladoceran *Daphnia magna* STRAUS in a semi-static laboratory test under realistic conditions	
Project/Report number:	982569	
Author(s):	Rufli, H.	
Date of report:	21/10/1998	
Published:	Not published.	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland.	
Study dates	22 to 27 April 1998.	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Rufli, H. (1998)	GLP statement	:	yes
Type of study	:	Daphnia, toxicity	Guideline	:	US EPA OECD 202
Year of execution	:	1998	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity, white powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Daphnia magna*	static	20	8.0	48	EC_{50}	0.56

Description

Methods. Daphnids (< 24 h old) exposed to abamectin for 120 h in static test systems, 50 mL test solution per test unit. Nominal initial concentrations 0.19, 0.56, 1.7, 5.0 and 15 µg/L, control, solvent control (DMF). Field exposure simulated by dosing abamectin in one single pulse-dose and diluting the media to reach 87 % reduction of abamectin per day, corresponding with a half-life of 0.34 d. M4 medium, total hardness 260 mg $CaCO_3$/L, pH 8.0, 680 µmhos/cm. Twelve replicates with one daphnid each per treatment.
Conditions. Temperature 20°C, no aeration, 16:8 h L:D (1400 - 1600 lux), daily feeding with 0.04 mg *Scenedesmus* suspension/daphnia.
Chemical analysis. Samples at start, analysis by HPLC, recovery 76 – 107 %, LOQ 0.1 µg/L.
Calculations and statistics. EC_{50}-value calculated using probit model and maximum likelihood analysis.

Results

Measured concentrations of abamectin at test initiation were 0.20, 0.49, 1.4, 3.9 and 12 µg/L (78 - 105 % of nominal).

No immobilisation in controls and solvent controls, 8 % at initial concentration 0.20 µg/L, 100% immobilisation at higher concentrations. Reported 48-hours EC_{50} 0.56 µg/L, 120-hours EC_{50} 0.23 µg/L, based on actual initial concentrations.

Remarks by RMS

Water quality parameters within accepted limits. Aim of the study was determine effect of abamectin pulses to mimic field exposure. Full immobilisation at 3.9 and 12 µg/L reached by day 1, indicating that effect is caused by initial toxic action. The result 48-hours EC_{50} 0.56 µg/L, based on actual initial concentrations, is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*30-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 05**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 05**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/05**	
Title:	Acute toxicity of 8α-hydroxy avermectin B_{1a} to *Daphnia magna*,	
Project/Report number:	33469	
Author(s):	Forbis, A. D. *et al.*	
Date of report:	10/12/1985	
Published:	Not published.	

Testing facility:	Analytical Biochemistry Laboratories Inc., Missouri, USA	
Study dates	1985	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	Forbis, A.D., Georgie, L. and Burgess, D. (1985a)	GLP statement	:	yes
Type of study	:	Daphnia, acute toxicity	Guideline	:	US EPA 1975 and 1983
Year of execution	:	1985	Acceptability	:	acceptable
Test substance	:	8a-hydroxy-avermectin B_{1a} (NOA 448112) batch [redacted] appearance clear liquid			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
8a-hydroxy-avermectin B_{1a}	*Daphnia magna*	static	20	8.5	48	EC_{50}	26

Description

Methods. Acute toxicity of 8a-hydroxy-avermectin B_{1a} (NOA 448112) to *Daphnia magna* (< 24 h old) was tested under static conditions. Nominal concentrations 3.2, 5.6, 10, 18 and 32 µg/L, control, solvent control (ethanol 1.6 mL/L). Dilution with artificial freshwater, hardness 250 mg $CaCO_3$/L, pH 8.5, 200 mL solution per test unit. Duplicate vessels with 10 organisms each.
Conditions. Temperature 20 °C, 16:8 h L:D (50 - 70 lux), no aeration, no feeding.
Calculations and statistics. EC_{50}-value was calculated using the binomial probability.

Results

No immobilisation in any of the tested concentrations, with the exception of 32 µg/L with 90 % immobilisation. EC_{50} reported as 26 µg/L (95 % CL 18 – 32 µg/L), based on nominal concentrations.

Remarks by RMS

Water quality parameters within accepted range. Recalculation with Spearman-Kärber yielded similar results. The result EC_{50} 26 µg/L, based on nominal concentrations, is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*30-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 06**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 06**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/06**	
Title:	Results of *Daphnia* bioassay of MK-0936, Avermectin B_{1a} standard, polar and nonpolar metabolites from a water photolysis reaction of Avermectin B_{1a} standard	
Project/Report number:	Report number unknown	

Author(s):	Naimie, H, Anton, S. and Kaelin, L.	
Date of report:	14/05/1985	
Published:	Not published.	
Testing facility:	Environmental Engineering Laboratory, Merck, Sharp and Dohme, New Jersey, USA	
Study dates	1985	
GLP:	No.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	Naimie, H., Anton, S. and Kaelin L. (1985)	GLP statement	:	no
Type of study	:	daphnids, acute toxicity	Guideline	:	US EPA 1975 and 1983
Year of execution	:	1985	Acceptability	:	partly acceptable
Test substance	:	abamectin technical, batch [redacted] #12101-125C, avermectin B_{1a}, batch [redacted] #12101-132C, batch [redacted] #12101-132E, batch [redacted] #12101-125A, batch [redacted] #12087-234, batch [redacted]			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
abamectin	*Daphnia magna*	static	20	8	48	EC_{50}	0.3
avermectin B_{1a}	*Daphnia magna*	static	20	8	48	EC_{50}	0.63
#12101-132C	*Daphnia magna*	static	20	8	48	EC_{50}	>100
#12101-132E	*Daphnia magna*	static	20	8	48	EC_{50}	6.8
#12101-125A	*Daphnia magna*	static	20	8	48	EC_{50}	27.2
#12087-234	*Daphnia magna*	static	20	8	48	EC_{50}	68.0

Description

Methods. Acute toxicity of abamectin, avermectin B_{1a} and several photoproducts to *Daphnia magna* (< 24 h old) was tested under static conditions. Test compounds and concentration ranges are given in the table below. Metabolites contained all < 1 % avermectin B_{1a}.

Table: Test compounds and concentration ranges

Code	Compound/sample	Test concentrations [µg/L]	Solvent control
	abamectin	0.0125, 0.025, 0.05, 0.1, 0.15, 0.25, 0.5, 1.0	acetone, 1 µL/L
#12101-125C	avermectin B_{1a}	0.05, 0.1, 0.15, 0.25, 0.5, 1.0, 2.0, 4.0	acetone, 20 µL/L
#12101-132C	polar photolysis products of avermectin B_{1a}	0.3, 0.5, 1.0, 5.0, 10, 100	-
#12101-132E	moderately polar photolysis product of avermectin B_{1a}	0.3, 0.5, 1.0, 5.0, 10, 100	-
#12101-125A	non-polar photolysis product of avermectin B_{1a}, 52 % [8,9-Z]-avermectin B_{1a} and 62 % avermectin B_{1a}	0.3, 0.5, 1.0, 5.0, 10, 100	methanol, 10 µL/L
#12087-234	polar photoproducts from thin film dish study with 14C-avermectin B_{1a}	0.3, 0.5, 1.0, 5.0, 10, 100	methanol, 10 µL/L

Artificial freshwater as dilution water, hardness 170 mg $CaCO_3$/L, pH 8, 200 mL solution per test unit. Duplicate vessels with 10 organisms each.
Conditions. Temperature 20 °C, 12:12 h L:D (70 lux), no aeration, no feeding.
Calculations and statistics. EC_{50}-values were calculated using the moving average angle method.

Results

Control mortality was 0 – 10 % in all cases. Concentration related increase in mortality to approximately 100 % for all tested compounds, with the exception of #12101-132C, where mortality increased to 55 % at 100 µg/L. EC_{50} reported as 0.3 µg/L for abamectin, 0.63 µg/L for avermectin B_{1a}, >100 µg/L for #12101-132C/L, 6.8

µg/L for #12101-132E/L, 27.2 µg/L for #12101-125A and 68 µg/L for #121087-234, all based on nominal concentrations.

Remarks by RMS

Metabolite fractions apparently refer to photolysis study summarised in Document IIIA reference point 7.1.1.1.2/02. Water quality parameters within accepted range. No confidence intervals were given.
The results nominal EC_{50} 0.3 µg/L for abamectin and 0.63 µg/L for avermectin B_{1a}, and toxicity of photolysis products less than that of avermectin B_{1a}, are used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*30-10-2007*
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.4.1.2 / 07**	**Acute toxicity to invertebrates**
91/414 Annex Point addressed	**II 8.2.4 / 07**	**Acute toxicity to invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.1.2/07**	
Title:	Acute toxicity test of NOA427011 to *Daphnia magna* in a 48-hour immobilization test	
Project/Report number:	808751	
Author(s):	Peither, A.	
Date of report:	30/05/2001	
Published:	Not published.	
Testing facility:	RCC AG, Itingen, Switzerland	
Study dates	2001	
GLP:	Yes	
Deficiencies:	None	

Reference/notifier	:	Peither, A. (2001b)	GLP statement	:	yes
Type of study	:	Daphnia, acute toxicity	Guideline	:	OECD 202 US EPA FIFRA 72-2
Year of execution	:	2001	Acceptability	:	acceptable
Test substance	:	[8,9-Z]-avermectin B_{1a} (NOA 427011), batch [redacted] checmial purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [h]	Criterion	Value [µg/L]
[8,9-Z]-avermectin B_{1a}	*Daphnia magna*	static	20	8.0	48	EC_{50}	0.082

Description

Methods. Acute toxicity of [8,9-Z]-avermectin B_{1a} (NOA 427011) to *Daphnia magna* (< 24 h old) was tested under static conditions. Test solutions obtained by 22 to 1000 times dilution of supersaturated stock dispersion (100 mg/L nominal), prepared by weighing 60 mg into 600 mL test water, ultrasonic treatment for 15 min. and intense stirring for 96 h. Dilution with artificial freshwater, 250 mg $CaCO_3$/L, pH 8.5, 200 mL solution per test unit. Four replicates with five organisms each.
Conditions. Temperature 20°C, 16:8 h L:D (200 - 1200 lux), no aeration, no feeding.
Chemical analysis. Samples of each concentration at start and termination of test. Analysis by HPLC-UV/VIS, LOQ 0.013 - 0.026 µg/L, recovery 109 %.
Calculations and statistics. EC_{50}-value was calculated using the probit method.

Results

Actual concentrations < LOQ, 0.045, 0.071, 0.20, 0.33 and 0.67 µg/L at start. Concentrations at end < LOQ at 1000 and 460 times dilution, and 0.028, 0.047, 0.12 and 0.21 µg/L at other levels. Average actual concentrations < LOQ, 0.024, 0.045, 0.11, 0.21 and 0.40 µg/L (value of 0.024 µg/L obtained by taking half of LOQ for test end). No immobilisation in control and 1000 times dilution, concentration related immobilisation of 5, 15, 65, 100 and 100 % at 0.024 - 0.40 µg/L. EC_{50} reported as 0.082 µg/L (95 % CL 0.067 – 0.10 µg/L), based on mean measured concentrations.

Remarks by RMS

Water quality parameters within accepted range. The result EC_{50} 0.082 µg/L, based on mean measured concentrations, is used for risk assessment.