At the community level no significant effects are found at 0.005 and 0.015 µg as/L (class 1) and at one time point, 56 days after last treatment for the 0.045, 0.135 and 0.405 µg as/L treatment a significant effect was found and effects are classified as class 2 effects. At the highest treatment, effects are found on two other time points, because full recovery is observed and effects are classified as class 3 effects. The NOEC is set at the lowest concentration without effects: 0.015 µg as/L. Individual species showed some significant effects (class 2-3) in the highest treatments only.

Emergent insects.

At the community level at the three highest treatments (0.135, 0.405 and 1.220 µg as/L) clear effects were found, but the total time span is less than 8 weeks (class 3). In the highest treatment level effects last from day 21 to day 91 with one date without significant effects in between. This effects are classified as class 4 effects.. At lower dosages no consequent effects were found. For the emergent insects the NOEC is set at 0.045 µg as/L. The data for individual species only show some (class 3) effects in the highest treatments.

Macrophytes.

Macrophytes were not monitored during the test period. However, taking the mode of action of the substance into consideration, no great direct effects of the substance are expected.

Below the effects are classified according Brock *et al.* (2000) as recommended in the EU guidance document (see summary of previous study for explanation).

Table: Summary of the effect classes observed for several endpoints in the outdoor microcosm study with A 8612 A

Organism group	Nominal concentration [µg as/L]					
	3 x 0.005	3 x 0.015	3 x 0.045	3 x 0.135	3 x 0.405	3 x 1.220
Phytoplankton	1	3↓	2↑	2↓	3↑	5↑
Zooplankton	2↑↓	2↑	3↓	4↓	5↓	5↓
Copepoda	1	1	2↓	2↓	2↓	2↓
Cyclopoida	2↑	2↑	2↓	3↓	4↓	4↓
Macrozoobenthos	1	1	2↓	2↓	2↓	3↓
Emerging insects	1	1	1	3↓	3↓	3↓

A summary of the endpoints as derived from this study is given below in the table below.

Table: Summary of the several endpoints in the outdoor microcosm study with Vertimec 018 EC. All values based on nominal concentrations.

Organism group	NOEC [µg product/L]	NOEAEC [µg product/L]	NOEC [µg as/L]	NOEAEC [µg as/L]
Phytoplankton	3 x 0.245		3 x 0.005	
Zooplankton	< 3 x 0.736		<3 x 0.015	
Macrozoobenthos	3 x 0.736		3 x 0.015	
Emerging insects	3 x 2.21		<3 x 0.045	
Community	< 3 x 0.736	3 x 2.21	< 3 x 0.015	3 x 0.045

For phytoplankton a NOEC of 3 x 0.005 µg as/L is found. Since however, this is based on indirect effects (appearing among others from the variation in increasing and decreasing of abundance at different concentrations), and no the compound is not specific toxic for algae (see first tier data), this NOEC has not been taken into account for deriving the $NOEC_{community}$.

From the results it can be concluded that the $NOEC_{community}$ is 3 x 0.015 µg as/L (corresponding with 3 x 0.736 µg product/L. The highest treatment in which full recovery of the microcosm community occurred within 8 weeks after the last application was 3 x 0.045 µg as/L. Therefore, the No Observed Ecologically Adverse Effect Concentration (NOEAEC) is considered to be equivalent to a treatment with 3 x 0.045 µg as/L nominal (3 x 0.735 µg/L product). The measured concentrations 6 hours after the last application (t = 14.25, see the first table under Results above) show considerable variation between replicate tanks, indicating that the systems had not reached equilibrium. Preferably, the NOEAEC should therefore be calculated as the sum of the the measured concentration just before the last application and the nominal concentration added with the last application, the latter based on measured concentrations in the application solution. Measurements just before application are not available, however, and this calculation is not possible. Because dissipation of abamectine from the water column is relatively fast and there is no indication that concentrations build up over time, the nominal concentration added with one application is considered to be the NOEAEC. Based on measured concentrations in the

application solution and a water volume of 10000 L, nominal added concentrations are 0.0479, 0.0520 and 0.046 µg as/L for the respective applications. The average nominal NOEAEC of 0.049 µg as/L is used for risk assessment.

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98/8 Doc IIIA section No.	**7.4.3.1 / 01**	**Prolonged toxicity to an appropriate species of fish**
91/414 Annex Point addressed	**II 8.2.2.2 / 01**	**Chronic toxicity test on juvenile fish**

		Official use only
Reference point (location) in dossier	**7.4.3.1/01**	
Title:	Early life stage toxicity of avermectin B_1 (MK-0936) technical to rainbow trout (*Salmo gairdneri*) in a flow through system	
Project/Report number:	33195	
Author(s):	[redacted]	
Date of report:	06/08/1986	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	8 October – 19 December 1985	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	[redacted] (1986)	GLP statement	:	yes
Type of study	:	fish, early life stage toxicity	Guideline	:	ASTM 1983 US EPA 1972
Year of execution	:	1986	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted], chemical purity [redacted] %, appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [µg/L]
abamectin	*Oncorhynchus mykiss*	flow-through	12	8.0	72	NOEC	0.52

Description

Methods. Early life stages of rainbow trout were exposed to abamectin under flow-through conditions. Nominal concentrations 0.125, 0.25, 0.5, 1.0 and 2.0 µg/L, control, solvent (acetone, concentration as in highest treatment). Well water with total hardness 225 – 275 $CaCO_3$ mg/L, conductivity 700 µmhos/cm, pH 8.0 ± 0.5. Commercially obtained trout eggs were incubated in oscillating cups placed in flow-through chambers until hatching, 20 eggs per cup, four replicates per concentration. Flow-through chambers with 18 L test solution and flow-rate of 2.5 L/h. Daily observation of egg mortality until day 12. Survival and growth were determined on days 48 and 72, daily observation of behaviour and appearance.
Conditions. Temperature 12 °C ± 1°C, 16:8 h L:D, aeration. Feeding of sac-fry stage until day 48 with shrimp nauplii and commercial fish food, thereafter only with commercial fish food *ad libitum*.
Chemical analysis. Water samples taken weekly or biweekly. Composite samples of samples from the four replicate chambers were extracted with dichloromethane, dried down and dissolved in imidazole reagent for derivatisation. Chloroform was added as a wash, the samples were dried down again and the residues were brought to volume with methanol before analysis of abamectin by HPLC. Recovery of the method 75 – 126 %.
Calculations and statistics. Survival was arcsin-√ transformed. Tukey's HSD test to determine NOEC-values.

Results

Mean measured concentrations 0.15, 0.28, 0.52, 0.96 and 2.2 µg/L (96 - 125 % of nominal). Hatching was not affected in any of the test concentrations. At termination of the test, mortality was only significantly increased at 2.2 µg/L. Length was decreased at 2.2 µg/L and wet weight at 0.96 and 2.2 µg/L. NOEC for weight 0.52 µg/L, based on mean measured concentrations.

Remarks by RMS

Water quality criteria within accepted limits. The result NOEC 0.52 µg/L, based on mean measured concentrations, is used for risk assessment.

	Evaluation by Competent Authorities
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98/8 Doc IIIA section No.	**7.4.3.1 / 02**	**Prolonged toxicity to an appropriate species of fish**
91/414 Annex Point addressed	**II 8.2.2.1 / 01**	**Chronic toxicity test on juvenile fish**

		Official use only
Reference point (location) in dossier	**7.4.3.1/02**	
Title:	Prolonged toxicity test of MK936 to common carp (*Cyprinus carpio*) under flow through conditions	
Project/Report number:	2002534	

Author(s):	[redacted]	
Date of report:	30/08/2000	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	3 May – 1 June 2000	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	[redacted] (2000)	GLP statement	:	yes
Type of study	:	fish, prolonged toxicity	Guideline	:	OECD 204 1984, draft OECD 215 2000
Year of execution	:	2000	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted], chemical purity [redacted] %,appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [µg/L]
abamectin	*Cyprinus carpio*	flow-through	22 ± 2 °C	8.2 – 8.5	28	NOEC	6.1

Description

Methods. Prolonged toxicity of abamectin to common carp was assessed under flow-through conditions. Fish were commercially obtained and acclimated to test conditions for 70 days, fastened for 24 hours before test. Length 34 - 41 mm at start, weight 0.41 - 0.69 g. Nominal concentrations 3.1, 6.3, 13, 25 and 50 µg/L, control, solvent control (DMF, 98.5 mg/L). Dilution with dechlorinated tap water, hardness 180 mg $CaCO_3$/L, pH 8.2 – 8.5. One replicate with 10 fish, 15 L water per vessel, six volume replacements/d. Daily observations of mortality and behaviour. Fish were individually weighed and measured at start and end of the test.
Conditions. Temperature 22 ± 2 °C, 16:8 h L:D (30 minutes transition period), feeding twice daily 2 % of initial body weight.
Chemical analysis. Samples taken weekly from each test system, analysis by HPLC-UV, LOQ 0.15 µg/L, recovery106 %.
Calculations and statistics. NOECs were determined with the Fisher Exact test for mortality and number of affected fish and with Dunnett's test for growth rate. Bartlett's test was used to test for homogeneity of variance and the t-test to compare control and vehicle control.

Results

Actual concentrations of fresh test media were 78 – 114% of nominal. Mean measured concentrations were 3.5, 6.1, 10, 19 and 41 µg/L (76 - 113 % of nominal). No mortality in control, solvent control and 3.5 µg/L after 28 days, 10 % mortality at 6.1 µg/L and 100 % mortality at 10 µg/L and higher, first deaths at 41 µg/L within one day. Control weight after 28 days increased by 53 % compared to start. Weight was significantly reduced at 10 µg/L. NOEC for mortality, weight and behaviour reported as 6.1 µg/L, based on mean measured concentrations.

Remarks by RMS

Water quality parameters within accepted range. The result 28-days NOEC 6.1 µg/L, based on mean measured concentrations, is used for risk assessment.

	Evaluation by Competent Authorities
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98/8 Doc IIIA section No.	7.4.3.2	Effects on reproduction and growth rate of an appropriate species of fish

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [×] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
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Date Evaluation of applicant's justification	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

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98/8 Doc IIIA section No.	7.4.3.3	Bioaccumulation in an aquatic organism *(headline)*

98/8 Doc IIIA section No.	7.4.3.3. 1 / 01	Bioaccumulation in an appropriate species of fish

JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [×] Technically not feasible [ ] Scientifically unjustified [×] Limited exposure [ ] Other justification [ ]	
Detailed justification: [redacted]	
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98/8 Doc IIIA section No.	7.4.3.3. 2 / 01	Bioaccumulation in an appropriate invertebrate species

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [×] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
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98/8 Doc IIIA section No.	7.4.3.4 / 01	Effects on reproduction and growth rate with an appropriate invertebrate species

91/414 Annex Point addressed	**II 8.2.5 / 01**	**Chronic toxicity to aquatic invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.3.4/01**	
Title:	The chronic toxicity of ^{3}H-avermectin to *Daphnia magna*	
Project/Report number:	BW-83-11-1487	
Author(s):	Surprenant, D.C. and Mastone, J.D.	X
Date of report:	November 1983	
Published:	Not published	
Testing facility:	EG & G Bionomics, Massachusetts, United States	
Study dates	22 June to 13 July 1983	
GLP:	Yes.	
Deficiencies:	No quantitative measurements of adult survivors at test-end, but a qualitative assessment is provided.	
Reliability indicator	1.	X

Reference/notifier	:	Paradice, A.P. (1983)	GLP statement	:	yes
Type of study	:	Daphnia, chronic toxicity	Guideline	:	OECD 211
Year of execution	:	1983	Acceptability	:	acceptable
Test substance	:	5-^{3}H-avermectin B , batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [µg/L]
^{3}H-avermectin-B_{1a}	*Daphnia magna*	flow-through	20	8.0	21	NOEC	0.030

Description

Methods. Chronic toxicity of avermectin B_{1a} to *Daphnia magna* was tested under flow-through conditions. Nominal concentrations 0.021, 0.042, 0.085, 0.17 and 0.34 µg/L, control, solvent control (acetone, 52 µL/L). Dilution water was modified well water with total hardness 160 mg $CaCO_3$/L, pH 8.0, 500 µmhos/cm, 1.75 L per test unit, 4.6 volumes/d. Four replicates with 20 daphnids each. Weekly determination of survival and reproduction.
Conditions. Temperature 20 °C, 16:8 h L:D (200-600 lux). Feeding with yeast and green algae two to three times daily, continuous aeration.
Chemical analysis. Weekly sampling of each vessel to determine radioactivity by LSC, recovery 85 – 104 %, LOQ not reported.
Calculations and statistics. NOEC was determined by ANOVA and Dunnett's posthoc test. Survival data were arcsin-√ transformed.

Results

Mean measured concentrations, mortality and total offspring are summarised in the table below.

Table: Analytical and biological results

Nominal [µg/L]	Actual [µg/L]	Mortality [%]	Reproduction [total # juveniles/female]
control		1	80
solvent control		0	71
0.021	0.030	11	80
0.042	*0.029*	*64*	*71*
0.085	0.093	100	-
0.17	0.19	100	-
0.34	0.38	100	-

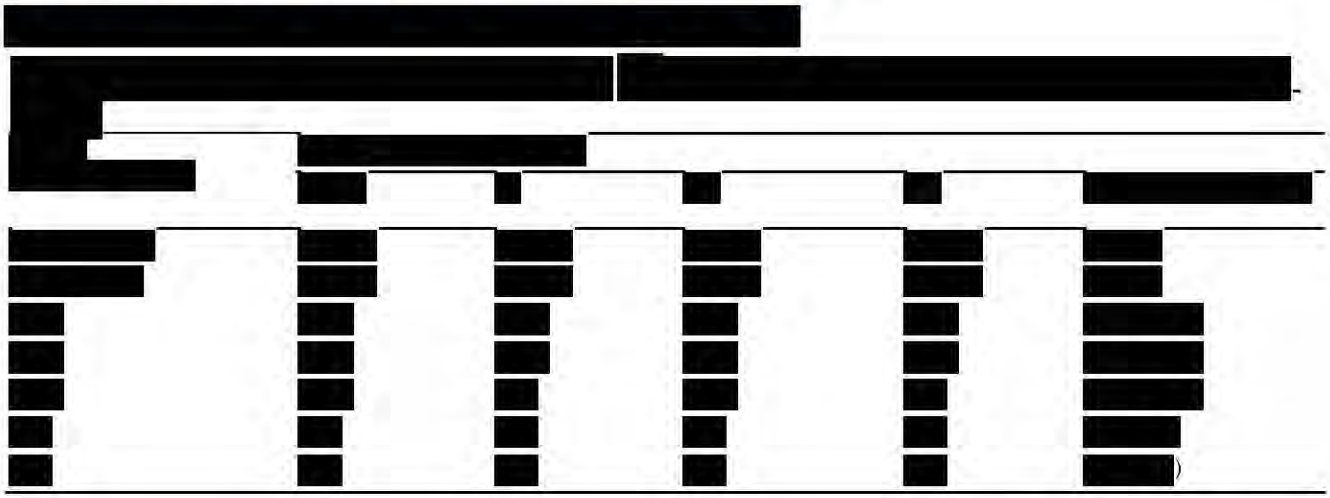
The treatment of 0.042 µg/L nominal was omitted from the dataset, because survival was unexpectedly high in comparison with 0.021 µg/L nominal, although actual concentrations were comparable. NOEC was 0.030 µg/L based on daphnid mortality and expressed on the basis of mean measured concentrations.

Remarks by RMS

Water quality parameters within accepted range. Concentrations not properly chosen, mortality at highest concentrations. The result NOEC 0.030 µg/L, based on mean measured 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: A.P. Paradice, study directors: D.C. Surprenant & J.D. Mastone

Addendum to the RMS remarks after evaluation under the BPD:



$a_n = 2$ [redacted]

[redacted]

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98/8 Doc IIIA section No.	**7.4.3.4 / 02**	**Effects on reproduction and growth rate with an appropriate invertebrate species**
91/414 Annex Point addressed	**II 8.2.5 / 02**	**Chronic toxicity to aquatic invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.3.4/02**	
Title:	Effects of MK936 (Abamectin tech.) on the Reproduction of *Daphnia magna* STRAUS in a Semi-Static Laboratory Test under Realistic Conditions	
Project/Report number:	G63622	
Author(s):	Pfeifle, V	
Date of report:	05/12/2001	
Published:	Not published.	
Testing facility:	Solvias AG, Basel, Switzerland	
Study dates	10 January – 28 July 2001	
GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1.	X

Reference/notifier	:	Pfeifle, V. (2001a)	GLP statement	:	yes
Type of study	:	Daphnia, chronic toxicity	Guideline	:	OECD 211 US EPA FIFRA 72-4
Year of execution	:	2001	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [µg/L]
abamectin	*Daphnia magna*	semi-static	20	8.0	21	NOEC	0.010

Description

Methods. Chronic toxicity of abamectin to *Daphnia magna* (4 - 24 h old) was tested under semi-static conditions. Nominal concentrations 0.005, 0.010, 0.020, 0.040, 0.080 and 0.16 µg/L, control, solvent control (DMF, 0.1 mL/L). Solution water was M4 medium with total hardness 200 mg $CaCO_3$/L, pH 8.0. Three renewals of test medium per week. Twelve replicates with 60 – 80 mL test solution, each with one individual. Daily determination of survival and reproduction. At termination of test, length of surviving adults was measured.

Conditions. Temperature 20 °C, 16:8 h L:D (15 – 20 µE/m^2.sec). Feeding with green algae 6 - 7 times weekly, continuous aeration.

Chemical analysis. Fresh solutions sampled on days 0, 2, 5, 7, 9, 12, 14, 16 and 19, and 2 – 3 d old solutions sampled on days 2, 12 and 21. Analysis by HPLC-MS after SPE, LOQ 0.005 µg/L, recovery 84 %.

Calculations and statistics. Kolmogoroff-Smirnov's and Bartlett's tests were used to test for normality and

homogeneity of variance of reproduction data. NOEC was determined by multiple U-test according to Bonferroni-Holm.

Results

Actual concentrations in the test solutions could not be determined due to analytical problems. Actual concentrations in super-stock solutions corresponded with aimed concentrations. It was assumed that actual concentrations approximated nominal concentrations and results were based on nominal concentrations. Mortality and total offspring are summarised in the table below.

Table: Biological results

Nominal [µg/L]	Mortality [%]	Reproduction [total # juveniles/female]	Body length adults [mm]
Control	0	125	3.0
Solvent control	0	126	3.1
0.005	25	125	3.1
0.01	36	119	3.1
0.02	9	109[1]	3.0
0.04	25	85[1]	2.8[1]
0.08	33	75[1]	2.8[1]
0.16	17	29[1]	2.6[1]

significant different from the controls

NOEC was 0.010 µg/L based on reproduction, and 0.020 µg/L based on adult length, both based on nominal initial concentrations.

Remarks by RMS

Water quality parameters within accepted range. The result NOEC 0.010 µg/L, based on nominal concentrations, is used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

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98/8 Doc IIIA section No.	**7.4.3.4 / 03**	**Effects on reproduction and growth rate with an appropriate invertebrate species**
91/414 Annex Point addressed	**II 8.2.5 / 03**	**Chronic toxicity to aquatic invertebrates**

		Official use only
Reference point (location) in dossier	**7.4.3.4/03**	
Title:	Chronic toxicity of 3H-Avermectin B1 to Mysid shrimp (*Mysidopsis bahia*)	
Project/Report number:	88-4-2706	
Author(s):	Surprenant, D.C.	
Date of report:	07/09/1988	
Published:	Not published.	
Testing facility:	Springborn Life Science Inc., Wareham, United States	

Study dates	19 February – 18 March 1988	
GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1.	

Reference/notifier	:	Surprenant, D.C. (1988c)	GLP statement	:	yes
Type of study	:	mysids, chronic toxicity	Guideline	:	none
Year of execution	:	1988	Acceptability	:	acceptable
Test substance	:	^{3}H-abamectin in methanol 1.11 mg/mL, batch [redacted], 13:1 B_{1a}:B_{1b}, purity [redacted] appearance colourless liquid			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [µg/L]
^{3}H-abamectin	*Mysidopsis bahia*	flow-through	25	7.8	28	NOEC	0.0035

Description

Methods. Chronic toxicity of ^{3}H-abamectin to juvenile *Mysidopsis bahia* (< 24 h old) was tested under flow-through conditions. Nominal concentrations 0.0005, 0.001, 0.002, 0.004 and 0.008 µg/L, control, solvent control (acetone 5.7 µL/L). Dilution with filtered natural seawater, salinity 30 ‰, pH 7.8, seven volume renewals per day. Two aquaria per treatment, each with two retention chamber, 20 mL test solution and 15 mysids per retention chamber. On day 17, when mysids had reached sexual maturity, 10 pairs of male and females per exposure aquarium were transferred to separate glass isolation jars. The remaining mysids were pooled and placed into new retention chambers where they were maintained at appropriate test concentrations. Male mysids from these pools were used to replace dead males. Dead females were not replaced. Daily observation of mortality and after day 17 daily observation of reproduction. At termination of test, individual body weight and offspring per female were determined.
Conditions. Temperature 25 °C, 16:8 h L:D light (323 - 754 lux). Feeding with live brine shrimp nauplii, twice daily and commercial fishfood three times weekly.
Chemical analysis. Test solutions were sampled weekly and analysed by LSC, recovery 103 %.
Calculations and statistics. Survival data were arcsin-√ transformed prior to ANOVA, Kolmogoroff-Smirnov's and Bartlett's tests to test for normality and homogeneity of variance of reproduction data. NOEC was determined by multiple U-test according to Bonferroni-Holm.

Results

Actual concentrations were 31 – 84 % of nominal during the first week and 83 – 138 % of nominal in the period after the first week. Since the diluter system functioned properly, it was assumed that increase in test material concentration was due to adsorption to aquaria walls. Mean actual concentrations were used for derivation of effect concentrations, i.e. 0.00035, 0.00076, 0.0014, 0.0035 and 0.0093 µg/L (70 - 116 % of nominal).
Adult mortality after 28 days was 13 and 10 % in control and solvent control, and 15, 10, 21, 25 and 90 % at 0.00035 - 0.0093 µg/L. Survival, weight and reproduction at 0.0093 µg/L significantly different from controls, other levels not significantly different. NOEC 0.0035 µg/L, based on mean measured concentrations.

Remarks by RMS

Water quality parameters within accepted range. The result NOEC 0.0035 µg/L, based on mean measured concentrations, is used for risk assessment.

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98/8 Doc IIIA section No.	7.4.3.5	Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk *(headline)*

98/8 Doc IIIA section No.	7.4.3.5. 1 / 01	Effects on sediment-dwelling organisms

		Official use only
Reference point (location) in dossier	**7.4.3.5.1/01**	
Title:	Toxicity Test of [14C] NOA 422601([23-14C] Avermectin B1a) on Sediment-Dwelling *Chironomus riparius* (syn. *Chironomus thummi*) under static conditions.	
Project/Report number:	2012613	
Author(s):	Grade, R.	
Date of report:	1 March 2002	
Published:	Not published	
Testing facility:	Syngenta Crop Protection AG, Ecotoxicology Department, CH-4002 Basle, Switzerland	
Study dates	31 August to October 12 2001.	
GLP:	Yes	
Deficiencies:	None	
Reliability indicator	1.	

Reference/notifier	:	Grade, R. (2002)	GLP statement	:	yes
Type of study	:	toxicity sediment dwelling organisms	Guideline	:	OECD proposal 1998 BBA proposal 1995
Year of execution	:	2002	Acceptability	:	acceptable
Test substance	:	^{14}C-avermectin B_{1a}, batch [redacted], 2.486 MBq/mg, radiochemical purity [redacted]			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [µg/kg dwt]
^{14}C-avermectin B_{1a}	*Chironomus riparius*	water/sediment sediment spiked	20	8.0	28	$NOEC_{emergence\ rate}$ $NOEC_{development\ rate}$	3.3[1] 10

1: nominal initial concentration in sediment

Description

Methods. Chronic effects of ^{14}C-avermectin B_{1a} on chironomid larvae were assessed in a water-sediment system under static conditions. Test systems contained 1.5 cm artificial sediment (20 % kaolin clay, 74.5 % industrial sand and 5.5 % peat) and 8 cm M4 test medium, pH 8, hardness 240 mg $CaCO_3$/L and conductivity 640 µS/cm. Sediment was spiked by addition of stock solutions in acetonitrile/acetone to sand

and mixing sand with mixing with aged sediment. Nominal concentrations 0.36, 1.1, 3.3, 10, 30 and 90 µg/kg dwt, control with clean sand and solvent control. Three replicate systems with 20 first instar larvae each, larvae were added 48 hours after system set up. Incubation for 28 days, assessment for mortality, behaviour and emergence on days 3, 5 - 7, 10 - 15, 21, 24 and 26 - 28, sex of emerged individuals determined.
Conditions. Temperature 20 °C, 16:8 h L:D (800 lux), daily feeding with commercial fish food, 1 mg/larvae, constant aeration.
Chemical analysis. Water samples taken on days 0, 3, 7, 14 and 28, analysis by LSC after SPE, LOQ 0.005 µg/L, recovery 101 %. Sediment samples from 30 and 90 µg/kg dwt taken on days 0, 7 and 28. Interstitial water separated by centrifugation and analysed by LSC. Remaining sediment analysed by LSC after extraction with methanol. Analytical method recovery of 95 % for sediments (extracts plus interstitial water), LOQ not reported.
Calculations and statistics. From emergence data, emergence rate, mean development time and development rate were calculated. Gender rate and emergence rate were arcsin-√ transformed prior to statistical analysis. Dunnett's test was used to determine NOEC and probit analysis was used for determination of EC_{50}-value.

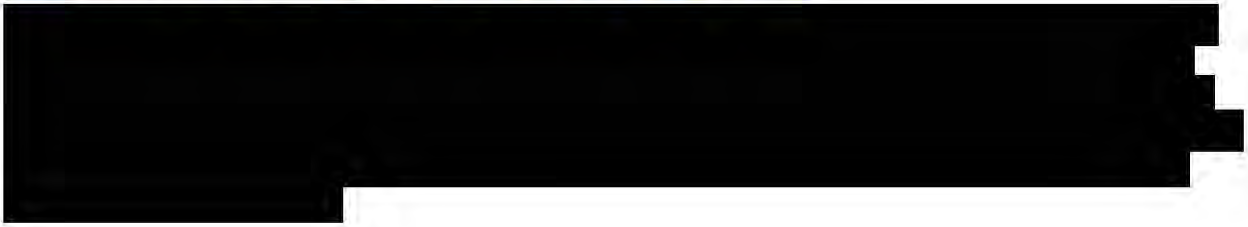
Results

Water pH increased to 9.1 – 9.7 during the exposure period. Actual concentrations in water phase were < LOD in control, solvent control and at 0.36 and 1.1 µg/kg dwt at start and end of the test. Actual concentrations at 3.3 - 90 µg/kg dwt were 0.0085, 0.0276, 0.0847 and 0.216 µg/L at start and 0.0089, 0.0254, 0.089 and 0.175 µg/L at end. Concentrations in water were < 1 % of total applied amount of test substance. Concentrations in sediment (30 and 90 µg/kg dwt) were 83 – 97 % of nominal during the exposure period.
Emergence in controls was > 80 % and no emergence occurred anymore after day 21. Emergence rate was significantly reduced in 10 µg/kg dwt and no emergence occurred at 30 and 90 µg/kg dwt. Gender rate and development rate were not affected by any of the treatments (development rate could not be determined 30 and 90 µg/kg dwt due to no emergence). Calculated EC_{50}-value for emergence rate was 11.3 µg/kg dwt (95 % CL 9.4 – 22.5 µg/kg dwt) based on nominal concentrations. EC_{50} could not be determined for development rate and gender rate. Nominal NOEC 3.3 µg/kg dwt for emergence rate and 10 µg/kg dwt for development rate, both based on nominal initial concentrations in sediment.

Remarks by RMS

The results NOEC 3.3 µg/kg dwt for emergence and 10 µg/kg dwt for development rate, based on nominal initial concentrations in sediment, are used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:



	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*01-11-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
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98/8 Doc IIIA section No.	**7.4.3.5**	**Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk *(headline)***

98/8 Doc IIIA section No.	**7.4.3.5. 1 / 02**	**Effects on sediment-dwelling organisms**
91/414 Annex Point addressed	**II 8.2.7 / 01**	**Effects on sediment dwelling organisms**

		Official use only
Reference point (location) in dossier	**7.4.3.5.1/02**	
Title:	Toxicity test of Abamectin EC 018 (A-8612 A) on sediment dwelling Chironomus riparius (syn. *Chironomus thummi*) under static conditions	
Project/Report number:	982571	
Author(s):	Grade, R.	
Date of report:	11/08/1999	
Published:	Not published.	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	
Study dates	12 January – 13 March 1999	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Grade, R. (1999a)	GLP statement	:	yes
Type of study	:	toxicity sediment dwelling organisms	Guideline	:	OECD proposal 1998 BBA proposal 1995
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	A 8612 A (Vertimec 018 EC), 19.46 g as/L, batch [redacted] appearance yellow liquid			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value product [µg/L]	Value [µg as/L]
Vertimec 018 EC	*Chironomus riparius*	water/sediment	20	8.0	28	NOEC	4[1]	0.081[1]
		water spiked				NOEC	>8[1]	>0.15[1]

[1]: based on nominal initial concentrations in overlying water

Description

Methods. Chronic effects of Vertimec 018 EC on chironomid larvae were assessed in a water-sediment system under static conditions. Test systems contained 1.5 cm artificial sediment (20 % kaolin clay, 74.5 % industrial sand and 5.5 % peat) and 8 cm M4 test medium, pH 8, hardness 240 mg $CaCO_3$/L and conductivity 640 µS/cm. Water was spiked with test solutions 24 hours after introducing the organisms, nominal concentrations 0.5, 1.0, 2.0, 4.0, 8.0, 16 and 32 µg product/L (0.01 - 0.65 µg as/L at product density 0.96 g/mL). Three replicate systems with 20 first instar larvae each. Incubations for 28 day, assessment for mortality, behaviour and emergence on days 1, 3, 6, 8, 10, 13 - 18, 20 - 24, 27, 28, sex of emerged individuals determined.
Conditions. Temperature 20 °C, 16:8 h L:D (800 lux), daily feeding with commercial fish food, 1 mg/larvae, constant aeration.
Chemical analysis. Water samples on days 0, 2, 7, 14 and 28, analysis by reversed-phase HPLC-UV, LOQ 0.3 µg/L, recovery 93.3 %. Method for determination of concentrations in the sediment could not be developed.
Calculations and statistics. From emergence data, emergence rate, mean development time and development rate were calculated. Gender rate and emergence rate were arcsin-√ transformed prior to statistical analysis. Dunnett's test was used to determine NOEC and probit analysis was used for determination of EC_{50}-value.

Results

Actual concentrations at 0.5 - 8 µg product/L were below or at the LOD, concentrations at 16 and 32 µg product/L were 60 – 62 % of nominal at start and 3 – 13% of nominal at end. Emergence in controls was > 80 % and no emergence occurred anymore after day 21. No effect on emergence and no differences in sensitivity between sexes at 0.5 - 4 µg product/L, males and females pooled for statistical analyses. Emergence rate significantly reduced and proportion of males significantly elevated at 8 µg product/L, no emergence at 16 and 32 µg product/L. Development rate was not influenced at the tested concentrations. EC_{50} reported as 8.0 µg product/L (no C.I.) for emergence rate, > 8 µg product/L for development rate, NOEC 4 µg product/L for emergence rate and 8 µg product/L for development rate.

Remarks by RMS

Decline of concentrations in water phase indicates high sorption of test compound. The result NOEC 4 µg product/L for emergence rate (0.081 µg as/L) and >8 µg product/L for development rate (>0.15 µg as/L), based on nominal initial concentrations in the water phase, are used for risk assessment.

Addendum to the RMS remarks after evaluation under the BPD:

[redacted]

	Evaluation by Competent Authorities
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Date	*01-11-2007*
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98/8 Doc IIIA section No.	**7.4.3.5. 2 / 01**	**Aquatic plant toxicity**
91/414 Annex Point addressed	**II 8.2.8 / 01**	**Aquatic plants**

		Official use only
Reference point (location) in dossier	**7.4.3.5.2/01**	
Title:	The effect of avermectin B1 to duckweed *Lemna gibba*	
Project/Report number:	BP-81-7-125	
Author(s):	Hollister, T.A	
Date of report:	23/07/1981	
Published:	Not published	
Testing facility:	EG & G Bionomics Inc., Marine Research Laboratory, Florida, USA	
Study dates	01 to 14 July 1981	
GLP:	Yes.	
Deficiencies:	No analysis to confirm nominal a.s. concentrations and demonstrate stability during exposure.	
Reliability indicator	2.	X

Reference/notifier	:	Hollister, T.A. (1981b)	GLP statement	:	no
Type of study	:	Lemna, growth inhibition	Guideline	:	not reported
Year of execution	:	1981	Acceptability	:	not acceptable
Test substance	:	abamectin technical, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion	Value [mg/L]
abamectin	*Lemna gibba*	static	25		14	NOEC EC_{50}	

Description

Methods. Toxicity of abamectin to *Lemna gibba* was assessed under static conditions by exposure through the water phase. Nominal test concentrations 1.2, 2.5, 5.0, 10 and 20 mg/L, control, solvent control (acetone, 1 mL/L). Test medium was M-type Hoagland's medium, test units contained 100 mL test medium, three replicates. Number of fronds determined on days 1, 2, 3, 4, 7, 8, 9, 10, 11 and 14.
Conditions. Temperature 25°C, continuous light (10300 lux).
Calculations and statistics. Frond counts were used to calculate frond production and inhibition rate. Frond production was analysed with ANOVA followed by Williams' test and with probit analysis.

Results

Doubling time of frond number in the controls was between 2 and 3 days. Mean number of fronds after 14 days was 416 in control and 404 in solvent control, and 384, 329, 50, 40 and 38 1.2, 2.5, 5.0, 10 and 20 µg/L, respectively. Frond number significantly decreased at 2.5 mg/L and higher. EC_{50} reported as 3.9 mg/L (95 % CL) 1.0 – 2.1 mg/L), NOEC 1.2 mg/L, both based on nominal concentrations.

Remarks

Number of initial fronts was not reported, but number of fronds on day 1 was 17 – 20 per replicate among all treatments, indicating an acceptable number of fronds at the start of the experiment (i.e. 9 – 12 fronds per replicate. Water quality parameters were not reported. Method of EC_{50} calculation was not reported. Tested concentrations were all above test compound's solubility and actual concentrations were not determined. 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
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Date	*01-11-2007*
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98/8 Doc IIIA section No.	**7.5**	**Effects on terrestrial organisms *(headline)***

98/8 Doc IIIA section No.	**7.5.1**	**Terrestrial toxicity, initial tests *(headline)***

98/8 Doc IIIA section No.	**7.5.1.1 / 01**	**Inhibition of microbiological activity**
91/414 Annex Point addressed	**II 8.5 / 01**	**Effects on soil non-target micro-organisms**

		Official use only
Reference point (location) in dossier	**7.5.1.1/01**	
Title:	Influence of avermectin B_1 on soil nitrification.	
Project/Report number:	85/03161/1306-13512/DB/LH	
Author(s):	Barug, D. and van Agteren, R.	
Date of report:	08/10/1985	
Published:	Not published	
Testing facility:	TNO, Zeist, The Netherlands	
Study dates	Commenced 19 April 1985	
GLP:	Yes.	
Deficiencies:	Test substance specification incomplete.	
Reliability indicator	2.	X

Reference/notifier	:	Barug, D. and Van Agteren, R. (1985)	GLP statement	:	yes
Type of study	:	soil nitrification	Guideline	:	not specified
Year of execution	:	1985	Acceptability	:	not acceptable
Test substance	:	abamectin, lot [redacted], chemical purity and appearance not given			

Substance	Soil type	Dose [mg/kg]	Duration [d]	pF	OM [%]	pH	T [°C]	Process	Maximal effect [%]	After ... [d]	Effect at end < 25 % ?
abamectin	sand	0.04	42	2.5	4.5	5.4	20	nitrification			
abamectin	sand	0.4	42	2.5	4.5	5.4	20	nitrification			
abamectin	loam	0.04	42	2.5	4.5	5.4	20	nitrification			
abamectin	loam	0.4	42	2.5	4.5	5.4	20	nitrification			

Description

Soils. Sand from Wageningen (NL), FC 13.2 %, loam from Lelystad (NL), FC 24.6 %. Air dried, 2 mm sieved, pre-incubated at 60 % of FC for one week at 20 °C.

Methods. Abamectin was mixed in with 1 % sand, spread evenly over the soil and mixed. Final concentrations 0.04 and 0.4 mg/kg.
Nitrification: Ammonium sulphate solution was added to the soils, final concentration 100 mg NH_4-N/kg, soil moisture content 0.32 bar. Incubation for 42 days at 20 °C in the dark. Duplicate samples were taken after 0, 3, 7, 14, 28 and 42 days and analysed for NH_4-N, NO_2-N and NO_3-N on an autoanalyser after extraction with 2 M KCl.

Results

NO_2-N: levels allways at or below 0.1 mg/kg, except for day 3 when ca. 3 mg/kg was determined in control and abamectin-treated soils. NO_3-N and NH_4-N: No difference between control and treated soil.

Remarks by RMS

Purity given as "> 80 % avermectin B_{1a} and < 20 % avermectin B_{1b}", but purity of abamectin not given. NH_4-N and NO_3-N only given in figures. Some differences between control and treated soils at various time points, but because no raw data are presented it is not possible to determine extent and significance of differences. The study is considered not acceptable for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	**EVALUATION BY RAPPORTEUR MEMBER STATE** *01-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	**COMMENTS FROM ...**

98/8 Doc IIIA section No.	**7.5.1.1 / 02**	**Inhibition of microbiological activity**
91/414 Annex Point addressed	**II 8.5 / 02**	**Effects on soil non-target micro-organisms**

		Official use only
Reference point (location) in dossier	**7.5.1.1/02**	
Title:	The effect of MK 936 A (abamectin tech.) on soil respiration and nitrification	
Project/Report number:	982524	
Author(s):	Grade, R.	
Date of report:	16/02/2000	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	
Study dates	11 October 1999 to 10 February 2000	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Grade, R. (2000)	GLP statement	:	yes
Type of study	:	soil nitrification	Guideline	:	OECD 216 (draft 1999) OECD 217 (draft 1995)
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	abamectin, batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Soil type	Dose [mg/kg]	Duration [d]	pF	OM [%]	pH-KCl	T [°C]	Process	Maximal effect [%]	After ... [d]	Effect at end < 25 % ?
abamectin	loamy sand	0.069	28	2.5	2.4	7.30	20	respiration	+ 9.6	0	Yes
abamectin	loamy sand	0.347	28	2.5	2.4	7.30	20	respiration	+ 9.5	7	Yes
abamectin	loamy sand	0.069	28	2.5	3.4	7.45	20	nitrification	- 5.3	0	Yes
abamectin	loamy sand	0.347	28	2.5	3.4	7.45	20	nitrification	- 6.7	0	Yes

Description

Soil. Loamy sand from Les Barges (CH). Soil had not been treated with pesticides or (in)organic fertilisers for at least three years. Respiration and nitrification with first batch: stored at room temperature, 40 - 50 % of WHC (55.8 % at pF 1) for ca. five weeks. Soils were slightly dried, 2 mm sieved and stored at 20 °C, at 40 – 50 % of WHC until determination of biomass after 7 days, and start of experiments after 9 days. Because control soil did not show nitrogen transformation, nitrification experiment was repeated with second batch (WHC 54.5 % at pF 1) that was stored at 5 °C for three weeks and with amendment of lucerne meal.

Methods. Abamectin stock in acetone was mixed with sand (0.05 – 0.2 mL/g), after evaporation of solvent sand was mixed in with 1 kg test soil. Final concentrations 0.061 and 0.307 mg/kg, solvent control. Reference compound dinoseb acetate, 16.7 mg/kg.
Respiration: Samples incubated in the dark at 20 ± 1 °C. Sampling after 0 – 3 hours, 7, 14 and 28 days. CO_2-production measured for 20 – 28 hours using an IR gas analysed after addition of glucose (10 mg/g).
Nitrification: Addition of 0.5 % lucerne meal after application, incubation in the dark at 20 ± 1 °C. Sampling after 0 – 3 hours, 7, 14 and 28 days. NH_4-N, NO_2-N and NO_3-N analysed with a Flow Injection Analyser after extraction with 1.9 M KCl.
Calculations and statistics. Dunnett's test for comparison of controls treated soils.

Results

Microbial biomass 39 and 27.8 mg C/100 g for first (respiration) and second batch (nitrification). Soil pH 7.3 – 7.5 (KCl).
Respiration. Constant CO_2-production in control between 0.72 and 0.86 mL/h over 28 days (100 g sample). CO_2-production deviated by –2.0 to + 9.6 % at 0.061 mg/kg and by + 4.0 to + 9.5 % at 0.307 mg/kg, differences not significant. Respiration in dinoseb treated soil reduced by 35 % after 28 days.
Nitrification.
NH_4-N in control decreased from 10 mg/kg after 0 – 3 hours to 1.7 mg/kg after 28 days, NO_3-N simultaneously increased from 40.2 to 68.2 mg/kg, total N from 50.7 to 70 mg/kg (NO_2-N allways < 1 mg/kg). Figures for abamectin treatments were similar, total N deviated by –5.3 to + 0.9 % at 0.061 mg/kg and by –6.7 to +2.2 % at 0.307 mg/kg, differences only significant after 0 – 3 hours. In dinoseb treatment, difference in total N increased to 50 % as compared to control, significant after 7, 14 and 28 days.

Remarks by RMS

Corrected for purity of test compound, concentrations are 0.069 and 0.347 mg/kg. The result < 25 % effect on respiration and nitrification at 0.069 and 0.347 mg/kg after 28 days 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	*01-11-2007*
Materials and Methods	
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Conclusion	[redacted]
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98/8 Doc IIIA section No.	**7.5.1.1 / 03**	**Inhibition of microbiological activity**
91/414 Annex Point addressed	**II 8.5 / 03**	**Effects on soil non-target micro-organisms**

		Official use only
Reference point (location) in dossier	**7.5.1.1/03**	
Title:	The effects of NOA 448112 (metabolite of MK 936) on soil respiration and nitrification	
Project/Report number:	2002517	
Author(s):	Seyfried, B.	
Date of report:	10/09/2001	
Published:	Not published.	
Testing facility:	RCC AG, Itingen, Switzerland	
Study dates	03 May – 15 June 2001	

GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Seyfried, B. (2001a)	GLP statement	:	yes
Type of study	:	soil nitrification	Guideline	:	OECD 216 and 217 (2000)
Year of execution	:	2000-2001	Acceptability	:	acceptable
Test substance	:	8a-hydroxy-avermectin B_{1a} (NOA 448112), batch [redacted] chemical purity [redacted] appearance white powder			

Substance	Soil type	Dose [mg/kg]	Duration [d]	pF	OM [%]	pH-$CaCl_2$	T [°C]	Process	Maximal effect [%]	After ..... [d]	Effects at end < 25% ?
NOA 448112	sandy loam	0.26	28	2.5	2.2	6.5	20	respiration	+ 8.2 (n.s.)	14	Yes
NOA 448112	sandy loam	0.66	28	2.5	2.2	6.5	20	respiration	+ 10.1	8	Yes
NOA 448112	sandy loam	0.26	28	2.5	2.2	6.5	20	nitrification	-22.2	14	Yes
NOA 448112	sandy loam	0.66	28	2.5	2.2	6.5	20	nitrification	+57.9	6	Yes

Description

Soil. Sandy loam LUFA/Speyer 2.3 (D). WHC 38 %, bulk density 1260 kg/m^3. Soil had not been treated with pesticides or organic fertilisers for at least four years. Phacelia grown in 2000, inorganic fertilisers in 1996, 1998, 1999 and 2000, soil sampled in March 2001. Soil 2 mm sieved, pre-incubated for one week at just below 40 % of WHC, 20 ± 2 °C.
Methods. Test compound diluted in acetone and mixed with quartz sand (10 mL/ 30 g), after evaporation of solvent 1.5 g sand was mixed in with 150 g test soil, final concentrations 0.24 and 0.61 mg/kg. Triplicate samples for each interval. Water treated control. Reference compound dinoseb acetate, 25 mg/kg.
Respiration: Samples incubated in the dark at 20 ± 1 °C. Sampling after 0 - 3 h, 8, 14 and 28 days. CO_2-production measured for ca. 24 hours using an IR gas analysed after addition of glucose (1.15 mg/g).
Nitrification: Addition of lucerne meal (4.7 g/kg) after application, incubation in the dark at 20 ± 1 °C. Sampling after 0 - 3 h, 6, 14 and 28 days. NO_2-N and NO_3-N analysed with a Flow Injection Analyser after two times extraction with 2 M KCl. LOQ 0.06 mg/kg for NO_2-N and 0.6 mg/kg for NO_3-N.
Calculations and statistics. Dixon's test to detect outliers, Dunnett's test for comparison of controls treated soils.

Results

Microbial biomass 14 mg C/100 g.
Respiration. CO_2-production in control on t = 0 was 5.11 mL/h.kg, production at 0.24 mg/kg was 5.61 mL/h.kg (+ 9.8 %, n.s.) and 5.40 mL/h.kg at 0.61 mg/kg (+ 5.6 %, n.s.). Deviation in CO_2-production at 0.24 mg/kg increased from 6.8 % on day 8 to 7.8 and 8.2 % on day 14 and 28 (difference only significant on t = 14); at 0.61 mg/kg, deviations were + 10.1 % on t = 8 and + 4.5 % on days 14 and 28 (difference significant on t = 8). Respiration in dinoseb treated soil reduced by 41 to 64 % over 28 days, allways significant.
Nitrification.
Untreated, unamended soil contained no NO_2-N and 7.2 mg/kg NO_3-N. NO_2-N remained < 0.1 mg/kg. NO_3-N levels in control dropped to 1.9 mg/kg on t = 6 and thereafter increased to 6.3 and 10.1 mg/kg on t = 14 and 28, respectively. Deviations from control at 0.24 mg/kg were - 2.8, + 21.1, -22.2 and + 1.0 % on

t = 0, 6, 14 and 28, respectively (differences significant on t = 6 and 14). At 0.61 mg/kg these figures were +1.4, + 57.9, - 33.3 and - 9.9 %, respectively (differences significant except for t = 0). In dinoseb treatment, difference in NO_3-N was 63, 43 and 88 % as compared to control after 6, 14 and 28 days (all significant).

Remarks by RMS

Test concentrations equivalent to four and 10 times expected soil concentration based on 15 % formation and highest single application rate of parent of 300 g as/ha. This is > 10 times proposed maximum field rate of 21.6 g as/ha, corrected for purity of test compound, concentrations are 0.26 and 0.66 mg/kg. According to OECD 216, nitrate formation should be expressed as mg nitrate/kg soil.d and formation rates should be compared. Conclusions remain the same. The result < 25 % effect of NOA 448112 on respiration and nitrification after 28 days at 0.26 and 0.66 mg/kg is used for risk assessment.

	Evaluation by Competent Authorities
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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*-01-12-2008*
Materials and Methods	
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Conclusion	[redacted]
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98/8 Doc IIIA section No.	**7.5.1.1 / 04**	**Inhibition of microbiological activity**
91/414 Annex Point addressed	**II 8.5 / 04**	**Effects on soil non-target micro-organisms**

		Official use only
Reference point (location) in dossier	**7.5.1.1/04**	
Title:	The effects of NOA 427011 (isomer of MK 936) on soil respiration and nitrification	
Project/Report number:	2002522	
Author(s):	Seyfried, B.	
Date of report:	10/09/2001	
Published:	Not published.	
Testing facility:	Syngenta Crop Protection AG, Basel, Switzerland RCC AG, Itingen, Switzerland	
Study dates	03 May - 15 June 2001	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Seyfried, B. (2001a)	GLP statement	:	yes
Type of study	:	soil nitrification	Guideline	:	OECD 216 and 217 (2000)
Year of execution	:	2000-2001	Acceptability	:	acceptable
Test substance	:	[8,9-Z]-avermectin B_{1a} (NOA 427011), batch [redacted] purity [redacted]% , appearance white-beige solid			

Substance	Soil type	Dose [mg/kg]	Duration [d]	pF	OM [%]	pH-$CaCl_2$	T [°C]	Process	Maximal effect [%]	After ..... [d]	Effects at end < 25%?
NOA 427011	sandy loam	0.16	28	2.5	2.2	6.5	20	respiration	+11.1	8	Yes
NOA 427011	sandy loam	0.40	28	2.5	2.2	6.5	20	respiration	+10.0	8	Yes
NOA 427011	sandy loam	0.16	28	2.5	2.2	6.5	20	nitrification	+63.2	6	Yes
NOA 427011	sandy loam	0.40	28	2.5	2.2	6.5	20	nitrification	-34.9	14	Yes

Description

Soil. Sandy loam LUFA/Speyer 2.3 (D). WHC 38 %, bulk density 1260 kg/m^3. Soil had not been treated with pesticides or organic fertilisers for at least four years. Phacelia grown in 2000, inorganic fertilisers in 1996, 1998, 1999 and 2000, soil sampled in March 2001. Soil 2 mm sieved, pre-incubated for one week at just below 40 % of WHC, 20 ± 2 °C.

Methods. Test compound diluted in acetone and mixed with quartz sand (10 mL/ 30 g), after evaporation of solvent 1.5 g sand was mixed in with 150 g test soil, final concentrations 0.16 and 0.40 mg/kg. Triplicate samples for each interval. Water control. Reference compound dinoseb acetate, 25 mg/kg. Respiration: Samples incubated in the dark at 20 ± 1 °C. Sampling after 0 - 3 h, 8, 14 and 28 days. CO_2-production measured for ca. 24 hours using an IR gas analysed after addition of glucose (1.15 mg/g).

Nitrification: Addition of lucerne meal (4.7 g/kg) after application, incubation in the dark at 20 ± 1 °C. Sampling after 0 - 3 h, 6, 14 and 28 days. NO_2-N and NO_3-N analysed with a Flow Injection Analyser after two times extraction with 2 M KCl. LOQ 0.06 mg/kg for NO_2-N and 0.6 mg/kg for NO_3-N.
Calculations and statistics. Dixon's test to detect outliers, Dunnett's test for comparison of controls treated soils.

Results

Microbial biomass 14 mg C/100 g.
Respiration. CO_2-production in control on t = 0 was 5.11 mL/h.kg, production at 0.16 mg/kg was 5.65 mL/h.kg (+ 10.5 %, n.s.) and 5.61 mL/h.kg at 0.40 mg/kg (+ 9.6 %, n.s.). Deviations in CO_2-production at 0.16 mg/kg decreased from + 11.1 % on day 8 to + 8.0 % on day 28; at 0.40 mg/kg deviations decreased from + 10.0 on day 8 to + 7.3 % on day 28 (differences significant on t = 8 and 14 at both levels). Respiration in dinoseb treated soil reduced by 41 to 64 % over 28 days, allways significant.
Nitrification.
Untreated, unamended soil contained no NO_2-N and 7.2 mg/kg NO_3-N. NO_2-N remained < 0.1 mg/kg. NO_3-N levels in control dropped to 1.9 mg/kg on t = 6 and thereafter increased to 6.3 and 10.1 mg/kg on t = 14 and 28, respectively. Deviations from control at 0.16 mg/kg were + 5.6, + 63.2, -44.4 and -2.0 % on t = 0, 6, 14 and 28, respectively. At 0.40 mg/kg these figures were - 4.2, - 31.6, - 34.9 and + 1.0 %, respectively (differences significant on t = 6 and 14 for both levels). In dinoseb treatment, difference in NO_3-N was 63, 43 and 88 % as compared to control after 6, 14 and 28 days (all significant).

Remarks by RMS

Control and dinoseb treatment same as in previous study. Test concentrations represent four and 10 times the expected concentration based on 10 % formation and highest single application rate of parent of 300 g as/ha. This is > 10 times proposed maximum field rate of 21.6 g as/ha. According to OECD 216, nitrate formation should be expressed as mg nitrate/kg soil.d and formation rates should be compared. Conclusions remain the same. The result < 25 % effect of NOA 427011 on respiration and nitrification after 28 days at 0.16 and 0.40 mg/kg 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	*-01-12-2008*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
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98/8 Doc IIIA section No.	**7.5.1.2 / 01**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1 / 01**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/01**	
Title:	Earthworm toxicity study of MK-936 (avermectin B_1) in artificial soil	
Project/Report number:	85-E-073 EW	
Author(s):	Cargile, N.L.	
Date of report:	12/02/1987	
Published:	Not published	
Testing facility:	Biospherics Inc., Maryland, USA	
Study dates	13 March to 10 April 1985	
GLP:	Yes.	
Deficiencies:	Test extended to 28 days, mortality assessment but no bodyweight measurements available for day 14, food provided.	
Reliability indicator	2.	

Reference/notifier	:	Cargile, N. (1987)	GLP statement	:	no, QA statement included
Type of study	:	earthworm, toxicity	Guideline	:	in-house protocol
Year of execution	:	1985	Acceptability	:	acceptable
Test substance	:	abamectin, lot no. [redacted]1, chemical purity [redacted] appearance white powder			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Criterion	Value abamectin [mg/kg]
abamectin	*Eisenia fetida*	artificial	10	7.0	25	28	14-d LC_{50}	33

Description

Earthworm toxicity study with abamectin.
Soil. Artificial medium, 70 % sand, 10 % sphagnum peat, 20 % bentonite clay, 1 % $CaCO_3$. Soil moisture content ca. 25 %, pH 7.
Methods. Test substance was applied to the soil mixed in with quartz sand, nominal concentrations 10, 25, 50, 100 and 200 mg/kg. Four replicates per concentrations with 10 mature worms each. Mortality assessed after 7, 14 and 28 days, weight determined at start and end.
Conditions. 25 °C, continuous light. Cow dung (1 %) added weekly.

Calculations and statistics. LC_{50} by probit analysis after correction for control mortality (only day-28; Abbott's formula).

Results

Moisture content was 24.6 - 31.5 % at end.
No mortality in control until day 14, 2.5 % mortality after 28 days. Dose related increase in mortality, full mortality at 200 mg/kg (day 14) and at 100 mg/kg (day 28). 14-days LC_{50} 33 mg/kg (95 % CI 28 - 39 mg/kg), 28-days LC_{50} 28 mg/kg (95 % CI 24 - 32 mg/kg). Body weight of surviving worms decreased by 28 % in control, by 47 % at 10 mg/kg. Reduction was 62 % at 25 mg/kg (n = 2) and 59 % at 50 mg/kg (n = 3).

Remarks by RMS

Actual moisture content at start not measured, pH not determined. Worm weights only reported for one replicate. Deviations from OECD 207: higher temperature and pH, longer test duration, addition of cow dung. Higher temperature and addition of cow dung may have enhanced degradation of abamectin and decreased bioavailability. Although degradation in artificial soil is often much slower than in natural soil, metabolites may have been present. As mortality increased with time, this did not result in decreased toxicity. Delay in burrowing time not reported, this has been consistently shown in other studies (see below). The result 14-days LC_{50} 33 mg/kg 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	*03-11-2007*
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98/8 Doc IIIA section No.	**7.5.1.2 / 02**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1 / 02**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/02**	
Title:	Acute toxicity of abamectin to the earthworm, *Eisenia foetida*	
Project/Report number:	335-ME	
Author(s):	Ward, T.J., Magazu, J.P. and Boeri, R.L.	
Date of report:	29/03/1994	
Published:	Not published	
Testing facility:	T.R. Wilbury Laboratories, Massachusetts. USA	
Study dates	20 December 1993 to 17 January 1994	
GLP:	Yes.	
Deficiencies:	Test extended to 28 days, food provided.	
Reliability indicator	2.	

Reference/notifier	:	Ward, T.J., Magazu, J.P., Boeri, R.L. (1994)	GLP statement	:	yes
Type of study	:	earthworm, toxicity	Guideline	:	in-house protocol
Year of execution	:	1994	Acceptability	:	acceptable
Test substance	:	abamectin, lot no. [redacted] chemical purity [redacted] appearance white powder			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Criterion	Value abamectin [mg/kg]
abamectin	*Eisenia fetida*	artificial	10	5.7- 6.1	25	28	LC_{50}	> 63

Description

Earthworm toxicity study with abamectin.
Soil. Artificial medium, 70 % sand, 10 % sphagnum peat, 20 % kaolin clay, 1 % $CaCO_3$. Soil moisture content ca. 26 %, pH 5.7 - 5.8.
Methods. Test substance was applied to the soil as solution in methanol, nominal concentrations 5.5, 9.1, 14, 23, 36 and 55 mg/kg, methanol control. Methanol was allowed to evaporate for 3 days. Four replicates per concentrations with 10 mature worms each, worms acclimatised 96 h before testing. Mortality and burrowing time assessed after 7, 14, 21 and 28 days, weight determined at start and end. Soil moisture content and pH determined on each assessment day.
Conditions. 20 ± 2 °C, continuous light (600 lux). Cow dung (1 %) added weekly.
Chemical analysis. Extraction with methanol by sonication for 20 min., analysis by HPLC-UV (244 nm).

Calculations and statistics. LC_{50} by binomial or nonlinear interpolation method (Stephan, 1983). Parametric t-test for survival of control and solvent control. Comparison of water control and treatments with Dunnett's test after check for normality and homogeneity of variances; comparison of solvent control and treatments with Kruskal-Wallis' test (data not normally distributed).

Results

Actual concentrations at start were 131 % of nominal at 55 mg/kg and 74 - 80 % of nominal at 5.5 - 36 mg/kg. Concentrations at end were 62 - 72 % of nominal, average measured concentrations were 4.0, 6.5, 10, 16, 27 and 55 mg/kg.
Moisture content was 24 - 26 % at start and 24 - 28 % during test, pH was between 5.7 and 6.1.
Burrowing within 10 min. at 0 - 10 mg/kg, increased burrowing time at 23 mg/kg nominal and higher. Worms at 36 and 55 mg/kg nominal did not burrow on day 14 and 21. Average weight after 28 days increased by 19 - 71 % in control and solvent control, dose-related weight loss in all abamectin treatments. Average mortality is given in the table below.

Table: Average mortality after exposure to abamectin

Nominal	Mean measured	Average mortality [%]			
[mg/kg]	[mg/kg]	Day 7	Day 14	Day 21	Day 28
control		0	2.5	2.5	10
solvent control		0	0	0	0
5.5	4.0	0	2.5	2.5	5
9.1	6.5	0	2.5	5	5
14	10	0	2.5	5	12.5
23	16	0	5	5	7.5
36	27	2.5	10	10	20
55	55	5	17.5	55	67.5

NOEC for weight reported as < 4.0 mg/kg, NOEC for burrowing time 10 mg/kg, 7- and 14-days LC_{50} > 55 mg/kg, 21-days LC_{50} 52 mg/kg, 28-days LC_{50} 43 mg/kg, 28-days NOEC 27 mg/kg, all based on mean measured concentrations.

Remarks by RMS

Long test duration and feeding not in accordance with OECD 207. Test was repeated several times because of mortality in solvent control, longer evaporation time was chosen in final test. High measured concentration at 55 mg/kg nominal on t = 0 might be due to analytical error, as similar recovery is found for all other levels at start and end. Applying mean recovery of other levels to highest test concentration (78 % on t = 0, 66 % on t = 28, average over 28 days 72 %), actual levels would be 43 mg/kg on t = 0 and 36 mg/kg on t = 28, average 39 mg/kg. The lower concentration, together with the lack of burrowing activity, may explain the relative low mortality. Because of uncertainty about the actual initial concentration at the highest test concentration, the LC50 is based on nominal concentrations with correction for purity of the test compound. The result 14-days LC_{50} > 63 mg/kg 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	*03-11-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
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98/8 Doc IIIA section No.	**7.5.1.2 / 03**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1 / 03**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/03**	
Title:	Acute toxicity (14 days) of VERTIMEC 018 EC (A-8612 A) to the earthworm *Eisenia fetida* (Savigny 1826) in artificial soil	
Project/Report number:	4620021	
Author(s):	Gossman, A. & Lührs, U	
Date of report:	12/01/1998	
Published:	Not published	
Testing facility:	IBACON GmbH, Rossdorf, Germany	

Study dates	30 October - 15 December 1998	
GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1	

Reference/notifier	:	Goßmann, A. and Lührs, U. (1999)	GLP statement	:	yes
Type of study	:	earthworm, acute toxicity	Guideline	:	OECD 207; ISO 11268, part 1
Year of execution	:	1998	Acceptability	:	acceptable
Test substance	:	A-8612 A (Vertimec 0.18 EC), batch [redacted], purity 19.46 g abamectin/L, appearance yellow to red liquid			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Criterion	Value product [mg/kg]	Value abamectin [mg/kg]
Vertimec 0.18 EC	*Eisenia fetida*	artificial	10	5.5 - 5.8	20 - 22	14	LC_{50}	> 1000	> 20

Description

Acute toxicity study on earthworms with Vertimec 0.18 EC (19.46 mg abamectin/L).
Soil. Artificial medium, 10 % sphagnum peat, 20 % kaolin clay, ca. 0.2 % $CaCO_3$ and 69.8 % fine quartz sand. Soil moisture content ca. 60 % of WHC, pH 6.
Methods. Test substance was applied to the soil as a solution in water, nominal concentrations 62.5, 125, 250, 500 and 1000 mg product/kg, water control. Four replicates per concentrations with 10 worms each. Worms: 10 months old, 300 - 600 mg, acclimatised for one day. Mortality assessed after 7 and 14 days, weight determined at start and end.
Conditions. 20 - 22 °C, continuous light (416 - 710 lux).
Calculations and statistics. Difference between control and treatment with Dunnett's test (weight) and Student's t-test (mortality) after testing for normality and homogeniety of variance.

Results

Moisture content was 57.4 - 61.6 % of WHC at start and 55.2 - 59.0 % of WHC at end, pH 5.8 at start and 5.5 - 5.6 at end.
No mortality in control and concentrations 62.5 - 500 mg product/kg after 14 days, 32.5 % mortality at 1000 mg product/kg (significant). Dose-related reduction in body weight, significantly different from control at 500 and 1000 mg product/kg. LC_{50} reported as > 1000 mg product/kg, NOEC for weight 250 mg product/kg.

Remarks by RMS

With reported specific gravity 0.968 g/mL and abamectin content 19.46 g/L, 1000 mg product corresponds to 20 mg abamectin. The result LC_{50} > 1000 mg product/kg (> 20 mg abamectin/kg) is used for risk assessment.

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	**EVALUATION BY RAPPORTEUR MEMBER STATE** *03-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	**COMMENTS FROM ...**

98/8 Doc IIIA section No.	**7.5.1.2 / 04**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1 / 03**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/04**	
Title:	Acute Toxicity of NOA448112 (Metabolite of MK936) to the Earthworm, *Eisenia fetida*	
Project/Report number:	2002516	
Author(s):	Pfeifle, V	
Date of report:	09/07/2001	
Published:	Not published	
Testing facility:	Solvias AG, GLP Testing Facility Solvias, CH-4002 Basel, Switzerland	
Study dates	19 April to 04 May 2001	

GLP:	Yes.	
Deficiencies:	None	
Reliability indicator	1	

Reference/notifier	:	Pfeifle, V. (2001b)	GLP statement	:	yes
Type of study	:	earthworm, acute toxicity	Guideline	:	OECD 207
Year of execution	:	2001	Acceptability	:	acceptable
Test substance	:	8a-hydroxy-avermectin B_{1a} (NOA 448112), batch [redacted], purity [redacted], appearance beige solid			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Criterion	Value [mg/kg]
NOA 448112	Eisenia fetida	artificial	10	5.7 – 6.0	20.5 – 22.0	14	LC50	321

Description

Soil. Artificial medium, 10 % sphagnum peat, 20 % kaolin clay, ca. 1 % $CaCO_3$ and 69 % fine quartz sand. Soil moisture content ca. 40 %, pH 6.
Methods. Test substance was applied to the soil mixed in with quartz sand, nominal concentrations 95, 171, 309, 556 and 1000 mg /kg. Four replicates per concentrations with 10 worms each. Worms: 13 months old, 357 - 409 mg, acclimatised for one day. Mortality assessed after 7 and 14 days, weight determined at start and end.
Conditions. 20.5 – 22.0 °C, continuous light (400 - 550 lux).
Calculations and statistics. LC_{50} by probit analysis, NOEC for weight by Bonferroni-Holm U-test.

Results

Moisture content was 39 - 41 % at start and 32 - 35 % at end, pH at start ranged from 5.7 to 6.0.
At start of test, all worms burrowed within 15 min., after 7 days burrowing was delayed at 171 mg/kg and higher, some worms did not burrow within 2 hours. No mortality in control and concentrations 95 and 171 mg/kg after 14 days, 40 % mortality at 309 mg/kg and 100 % mortality at 556 and 1000 mg /kg. Sublethal effects (flaccidity and open wounds) were observed at 309 mg/kg and higher. Some worms died on the surface. Slight weight loss in control (7 %), significant weight loss at 95 - 309 mg/kg (17 - 39 %). LC_{50} reported as 321 mg/kg (95 % CI 296 - 348 mg/kg), NOEC for weight < 95 mg/kg.

Remarks by RMS

The result LC_{50} 321 mg/kg is used for risk assessment.

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	**EVALUATION BY RAPPORTEUR MEMBER STATE** *03-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	**COMMENTS FROM ...**

98/8 Doc IIIA section No.	**7.5.1.2 / 05**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1 / 03**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/05**	
Title:	Acute Toxicity of NOA427011 (Metabolite of MK936) to the Earthworm, *Eisenia fetida*	
Project/Report number:	2002521	
Author(s):	Pfeifle, V	
Date of report:	26/07/2001	
Published:	Not published	
Testing facility:	Solvias AG, GLP Testing Facility Solvias, CH-4002 Basel, Switzerland	
Study dates	24 April to 26 June 2001	
GLP:	Yes.	

Deficiencies:	None	
Reliability indicator	1	

Reference/notifier	:	Pfeifle, V. (2001c)	GLP statement	:	yes
Type of study	:	earthworm, acute toxicity	Guideline	:	OECD 207
Year of execution	:	2001	Acceptability	:	acceptable
Test substance	:	[8,9-Z]-avermectin B_{1a} (NOA 427011), batch [redacted] purity [redacted], appearance white-beige solid			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Criterion	Value [mg/kg]
NOA 427011	*Eisenia fetida*	artificial	10	6.1 - 6.5	19	14	LC_{50}	50

Description

Acute toxicity study on earthworms with NOA 427011 ([8,9-Z]-isomer of avermectin B_{1a}).
Soil. Artificial medium, 10 % sphagnum peat, 20 % kaolin clay, ca. 1 % $CaCO_3$ and 69 % fine quartz sand. Soil moisture content ca. 40 %, pH 6.
Methods. Test substance was applied to the soil mixed in with quartz sand, nominal concentrations 12, 21, 37, 67 and 120 mg /kg. Four replicates per concentrations with 10 worms each. Worms: 3 months old, 303 - 376 mg, acclimatised for one day. Mortality assessed after 7 and 14 days, weight determined at start and end.
Conditions. 19 °C, continuous light (450 - 520 lux).
Calculations and statistics. LC_{50} by binomial distribution, NOEC for weight by Bonferroni-Holm U-test.

Results

Moisture content was 45 - 46 % at start and 42 - 43 % at end, pH at start ranged from 6.1 to 6.5.
At start of test, all worms burrowed within 15 min., after 7 days burrowing was delayed at 12 mg/kg and at higher levels some worms did not burrow within 2 hours. No mortality in control and concentrations 12 - 37 mg/kg after 14 days, 100 % mortality at 67 and 120 mg /kg, some died on the surface. Slight weight loss in control (7 %), significant weight loss at 12 - 37 mg/kg (27 - 32 %). LC_{50} reported as 50 mg/kg (95 % CI 37 - 67 mg/kg), NOEC for weight < 12 mg/kg.

Remarks by RMS

The result LC_{50} 50 mg/kg is used for risk assessment.

Evaluation by Competent Authorities

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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*03-11-2007*
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98/8 Doc IIIA section No.	**7.5.1.2 / 06**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 Annex Point addressed	**II 8.4.1 / 03**	**Effects on earthworms: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.1.2/06**	
Title:	MK936 (abamectin): Sublethal toxicity of an 18 g/L EC formulation (A8612A) to the earthworm (*Eisenia fetida*)	
Project/Report number:	2002547	
Author(s):	Friedrich, S	
Date of report:	23/9/2002	
Published:	Not published	
Testing facility:	BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, D-04827 Gerichshain, Germany	
Study dates	15 May – 17 July 2002	
GLP:	Yes.	

Deficiencies:	None	
Reliability indicator	1	

Reference/notifier	:	Friedrich, S. (2002)	GLP statement	:	yes
Type of study	:	earthworm, sublethal toxicity	Guideline	:	ISO 11268-2
Year of execution	:	2002	Acceptability	:	acceptable
Test substance	:	A-8612 A (Vertimec 0.18 EC), batch [redacted], purity 19.5 g abamectin/L, appearance yellow to red brown liquid			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Criterion	Value product [mg/kg]	Value abamectin [mg/kg]
Vertimec 0.18 EC	*Eisenia fetida*	artificial	10	5.6 - 5.7	18 - 22	56	NOEC	≥ 35	≥ 0.72

Description

Sublethal toxicity study on earthworms with Vertimec 0.18 EC (19.5 g abamectin/L).
Soil. Artificial medium, 10 % sphagnum peat, 20 % kaolin clay, 0.5 % $CaCO_3$ and 69.5 % industrial quartz sand. Soil moisture content 60 % of WHC, pH 6.
Methods. Test substance was applied to the soil as a dispersion in water, nominal concentrations 0.072, 0.18, 0.36 and 0.72 mg as/kg (3.5, 8.6, 17.3 and 35 mg product/kg), water control. Four replicates per concentrations with 10 worms each. Worms, 4 months old, 370 - 483 mg, acclimatised for one day. Mortality and body weight assessed after 28 days, and adults removed. Counting of juveniles and cocoons after incubation for additional 28 days.
Conditions. 18 - 22 °C, 16:8 h L:D (500 lux), weekly feeding with 5 g horse manure during first phase, 5 g horse manure mixed in with soil for second phase.
Calculations and statistics. Difference between control and treatment with Dunnett's or Bonferroni-- U-test.

Results

Moisture content 59 % of WHC at start, 58 – 58 % of WHC at end, pH 5.5 – 5.8.
Weight increase after 28 days was 32 % in control and 31 – 35 % in Vertimec treatments, differences not significant. No mortality in any group. Average number of juveniles 225 ± 24 in control and 240 ± 29, 205 ± 28, 198 ± 7.8 and 197 ± 43 at respective dose levels, differences not significant. NOEC reported as 0.72 mg as/kg.

Remarks by RMS

Validity criteria met. The result NOEC ≥ 0.72 mg as/kg (35 mg product/kg) 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	*03-11-2007*
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98/8 Doc IIIA section No.	7.5.1.3	Acute toxicity to plants
91/414 Annex Point addressed	II 8.6 / 01	Effects on terrestrial plants

		Official use only
Reference point (location) in dossier	**7.5.1.3/01**	
Title:	Herbicide profiling test to evaluate the phytotoxicity of MK 936 018 EC (A-8612 A) to terrestrial non-target higher plants	
Project/Report number:	34	
Author(s):	Wälder, L.	
Date of report:	12/04/2000	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Stein, Switzerland	
Study dates	15 February to 23 March 2000	
GLP:	No	
Deficiencies:	None.	
Reliability indicator	2.	X

Reference/notifier	:	Wälder, L. (2000)	GLP statement	:	no
Type of study	:	herbicide profiling test	Guideline	:	in-house protocols
Year of execution	:	2000	Acceptability	:	acceptable
Test substance	:	A-8612 A (Vertimec 0.18 EC), batch [redacted], chemical purity 18 g abamectin/L			

Substance	Species	Soil type	OM [%]	pH	T [°C]	Duration [d]	Parameter	Result	at [g as/ha]
Vertimec 0.18 EC	*Zea mays*	clay loam	2.6	7.5	18/25	21	emergence	no effect	50.6
						14	vegetative vigour	no effect	50.6
Vertimec 0.18 EC	*Avena fatua*	clay loam	2.6	7.5	18/25	21	emergence	no effect	50.6
						14	vegetative vigour	no effect	50.6
Vertimec 0.18 EC	*Allium cepa*	clay loam	2.6	7.5	15/20	21	emergence	no effect	50.6
						14	vegetative vigour	no effect	50.6
Vertimec 0.18 EC	*Beta vulgaris*	clay loam	2.6	7.5	15/20	21	emergence	no effect	50.6
						14	vegetative vigour	no effect	50.6
Vertimec 0.18 EC	*Brassica napus*	clay loam	2.6	7.5	15/20	21	emergence	no effect	50.6
						14	vegetative vigour	no effect	50.6
Vertimec 0.18 EC	*Glycine max*	clay loam	2.6	7.5	15/20	21	emergence	no effect	50.6
						14	vegetative vigour	slight effect	25.3

Description

Test to determine effects of Vertimec 0.18 on seedling emergence and vegatative vigour of maize (*Zea mays*), wild oat (*Avena fatua*), onion (*Allium cepa*), sugar beet (*Beta vulgaris*), oilseed rape (*Brassica napus*) and soybean (*Glycine max*).
Soil. Clay loam from local origin.
Methods.
Seedling emergence. Seeds were sown in plastic trays with 10 cm soil. Test item was sprayed on the soil surface within 24 hours, application rates 78.13, 156.25, 312.5, 625, 1250 and 2500 g product/ha at 500 L/ha (equivalent to 1.6, 3.2, 6.3, 12.7, 25.3 and 50.6 g as/ha, based on specific gravity 0.963 g/mL and analysed content of 19.5 g as/L). Trays incubated under greenhouse conditions, 15 - 17/20 - 22 °C (night/day) for cold season species; 18 - 20/25 - 27 °C for warm season species, RH 40 - 60 %, additional lighting to maintain 14:8 h L:D at > 10000 lux. Visual rating of emergence after 21 days, scale 1 (complete destruction or no emergence) to 9 (no effect, similar to untreated).
Vegetative vigour. Sowing as described above. Application of test compound 14 or 17 days after emergence, visual rating 14 days after application.

Results

Seedling emergence. No effect on any species.
Vegetative vigour. No effects, except for *Glycine max* with rating 8.5 and 8 at 1250 and 2500 g product/ha.

Remarks by RMS

No information on control, but assumed to be included. The following results are used for risk assessment:
- no effects on seedling emergence of maize, wild oat, onion, sugar beet, oilseed rape and soybean at 2500 g product/ha (50.6 g as/ha).
- no effect on vegetative vigour of maize, wild oat, onion, sugar beet and oilseed rape at 2500 g product/ha (50.6 g as/ha).
- slight effect on vegetative vigour of soybean at 1250 and 2500 g product/ha (25.3 and 50.6 g as/ha).

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*03-11-2007*
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Conclusion	[redacted]
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98/8 Doc IIIA section No.	7.5.2	Terrestrial long-term tests *(headline)*

98/8 Doc IIIA section No.	7.5.2.1 / 01	Reproduction study with other soil non-target macro-organisms
91/414 Annex Point addressed	II 8.4.2 / 01	Sublethal effects on earthworms

	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 [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE *21-07-2008* *No justification is given* [redacted]	
Date Evaluation of applicant's justification Conclusion Remarks	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

98/8 Doc IIIA section No.	7.5.2.2	Long-term test with terrestrial plants
91/414 Annex Point addressed		

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE *03-11-2007* [redacted]	
Date Evaluation of applicant's justification Conclusion Remarks	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

98/8 Doc IIIA section No.	**7.5.3**	**Effects on birds *(headline)***

98/8 Doc IIIA section No.	**7.5.3.1. 1/ 01**	**Acute oral toxicity**
91/414 Annex Point addressed	**II 8.1.1 / 01**	**Effects on birds - Acute oral toxicity**

		Official use only
Reference point (location) in dossier	**7.5.3.1.1/01**	
Title:	An acute oral toxicity study in bobwhite quail with MK-936	
Project/Report number:	105-132	
Author(s):	[redacted]	
Date of report:	10/06/1983	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	10 to 24 May 1983	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	[redacted] (1983a)	GLP statement	:	no
Type of study	:	birds, acute oral toxicity	Guideline	:	not specified
Year of execution	:	1983	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] purity [redacted] appearance white powder			

Substance	Species	Route	Recovery period [d]	Criterion	Value [mg/kg bw]
abamectin	*Colinus viginianus*	oral intubation	14	LD_{50}	> 2000

Description

Acute oral toxicity study with bobwhite quail.
Methods. Test substance was administered to birds in a single oral dose by intubation with corn oil as vehicle. Nominal doses 62.5, 125, 250, 500, 1000 and 2000 mg abamectin/kg bw (corrected for purity of the test compound), control with corn oil only. Birds 12 months old (186 - 274 g), fastened 15 hours prior to dosing. Ten birds per dose level (5 males, 5 females). Daily observations for mortality and/or signs of toxicity, individual body weight determined at start, group weight on days 3, 7 and 14. Food consumption recorded for days 0 - 3, 4 - 8 and 8 - 14.

Conditions. Group housing, 22 ± 2 °C, 86 % RH, 17:7 h L:D (ca. 129 lux), food and water *ad libitum*.

Results

No mortalities in control and at 62.5 and 125 mg/kg bw, 10 % mortality at 250 and 1000 mg/kg bw, 40 % at 500 and 2000 mg/kg bw. Signs of toxicity at all doses, first signs within two hours after dosing at 500 mg/kg bw and higher. Feed consumption reduced at all doses, dose related between days 4 and 7. Weight loss at all dose levels during days 0 - 3, weight gain observed from day 3 - 7 at 62.5 - 500 mg/kg bw. Weight loss > 10 % at 1000 and 2000 mg/kg bw, at these levels weight gain observed as from day 7, but final weight decreased as compared to start (3 and 9 %). LD_{50} reported as > 2000 mg/kg bw.

Remarks by RMS

Although the resulting LD_{50} value is higher than the highest dose tested, there was no clear dose effect relationship. The result LD_{50} > 2000 mg/kg bw, expressed as pure abamectin, is used for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
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Date	*07-11-2007*
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98/8 Doc IIIA section No.	**7.5.3.1. 1/ 02**	**Acute oral toxicity**
91/414 Annex Point addressed	**II 8.1.1 / 02**	**Effects on birds - Acute oral toxicity**

		Official use only
Reference point (location) in dossier	**7.5.3.1.1/02**	
Title:	Acute oral LD_{50} - mallard duck L-676,863-00V50	
Project/Report number:	105-129	
Author(s):	[redacted]	
Date of report:	19/08/1981	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	02 to 16 June 1981	
GLP:	Yes.	
Deficiencies:	No necropsy of birds that died during the test or of survivors at test-end.	X
Reliability indicator	2.	X

Reference/notifier	:	[redacted] (19881)	GLP statement	:	yes
Type of study	:	birds, acute oral toxicity	Guideline	:	not specified
Year of execution	:	1981	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] purity [redacted] appearance white powder			

Substance	Species	Route	Recovery period [d]	Criterion	Value [mg/kg bw]
abamectin	*Anas platyrhynchos*	oral intubation	14	LD_{50}	77

Description

Acute oral toxicity study with mallard duck.
Methods. Test substance was administered to birds in a single oral dose in water by intubation. Nominal doses 10, 17.8, 31.6, 56.2 and 100 mg/kg bw (not corrected for purity of the test compound), control with water only. Birds five months old (897 - 1142 g), fastened for 15 hours prior to dosing. Ten birds per dose level (5 males, 5 females). Daily observations for mortality and/or signs of toxicity, individual body weight determined at start and on days 3, 7 and 14. Food consumption recorded for days 0 - 7 and 8 - 14.
Conditions. Individual housing, 18 - 24 °C, 30 - 80 % RH, 14:10 h L:D, food and water *ad libitum*.

Results

No mortalities in control and 10, 17.8 and 31.6 mg/kg bw, 10 % mortality at 56.2 mg/kg bw and 70 % at 100 mg/kg bw. Vomiting at all doses immediately after dosing. Signs of toxicity at all doses, all surviving birds appeared normal by day 3. Decrease in weight during days 0 - 3 at 56.2 and 100 mg/kg bw, weight gain observed from day 7 onwards. LD_{50} calculated by probit analysis as 85 mg/kg bw (95 % CI 67 - 120 mg/kg bw).

Remarks by RMS

Purity of test compound < 95 %, LD_{50} corrected for purity is 77 mg abamectin/kg bw. Vomiting may have reduced actual dosage, actual LD_{50} may thus be lower. The result $LD_{50} \leq 77$ mg/kg bw, expressed as pure abamectin, is used for preliminary risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	EVALUATION BY RAPPORTEUR MEMBER STATE *07-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	COMMENTS FROM ...

98/8 Doc IIIA section No.	**7.5.3.1. 2 / 01**	**Short term toxicity**
91/414 Annex Point addressed	**II 8.1.2 / 01**	**Effects on birds - Short-term dietary toxicity**

		Official use only
Reference point (location) in dossier	**7.5.3.1.2/01**	
Title:	An eight-day dietary LC_{50} in bobwhite quail with MK-936,	
Project/Report number:	105-130	

Author(s):	[redacted]	
Date of report:	26/05/1983, revised 15/07/1983	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	05 to 13 May 1983	
GLP:	Yes.	
Deficiencies:	No necropsy of birds that died during the test or of survivors at test-end.	X
Reliability indicator	2.	

Reference/notifier	:	[redacted] (1983b)	GLP statement	:	no
Type of study	:	birds, short-term dietary toxicity	Guideline	:	ASTM E857-81; US-EPA FIFRA Subdivision E § 71-2
Year of execution	:	1983	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] purity [redacted] appearance white powder			

Substance	Species	Route	Exposure Duration [d]	Recovery period [d]	Criterion	Value [mg/kg fd]	Value [mg/kg bw·d]
abamectin	*Colinus virginianus*	oral diet	5	3	LC_{50}	3102	560 (indicative)

Description

Short-term dietary toxicity study with bobwhite quail.
Methods. Test substance was added to the diet in acetone, nominal doses 288, 511, 910, 1620, 2876 and 5114 mg abamectin/kg fd (corrected for purity of the test compound), control with 1.7 % v/w acetone. Birds 14 days old, average body weight 30 - 32 g. Ten birds per dose level, five replicate control groups. Daily observations for mortality and/or signs of toxicity, group body weight determined at start and on days 5 and 8. Food consumption recorded for days 0 - 5 and 6 - 8.
Conditions. Group housing, 38 °C, 14:10 h L:D, food and water *ad libitum*.

Results

No mortality in the control and at 288, 511 and 910 mg/kg fd, 10 % mortality at 1620 mg/kg fd, 50 % at 2876 mg/kg fd, 80 % at 5114 mg/kg fd. At two highest dose levels, number of mortalities increases with time, and maximum mortality is reached by 5 and 6 days. Signs of toxicity at all concentrations, recovery time of surviving birds was related to dose, ranging from three days at 288 mg/kg fd to eight days at 2876 and 5114 mg/kg fd. Reduction in food consumption during days 0 - 5 at 511, 2876 and 5114 mg/kg fd. Marked increase in measured consumption at 910 and 1620 mg/kg fd, according to authors due to wastage. Food consumption returned to normal level during days 6 - 8. Body weight gain at 511 and 910 mg/kg fd lower than control during exposure period, decrease in body weight during exposure at 1620 mg/kg fd and higher. Body weight gain during recovery period at all concentrations similar to or higher than control. LC_{50} reported as 3102 mg/kg fd (95 % CI 2338 - 4393 mg/kg fd).

Remarks by RMS

According to the Guidance Document on risk assessment for birds and mammals, recalculation of the daily dose should be based on NOEL when the LC_{50} is below the top concentration and food avoidance has

occurred. Notifier therefore used the highest level without mortality (910 mg/kg fd) to calculate the NOEL as 520 mg/kg bw.d, but at this level food consumption was markedly increased due to wastage and the daily dose is considered not reliable. The daily dose at the LC_{50}-level of 3102 mg/kg fd is therefore estimated by RMS by linear interpolation between the log-transformed daily doses at 2876 and 5114 mg/kg fd (533 and 772 mg/kg bw.d), resulting LD_{50} is 560 mg/kg bw.d. Because the daily doses at 2876 and 5114 mg/kg fd are based on a low number of survivors and food consumption may have changed from day to day during exposure, this value is indicative. Furthermore, increasing mortality with time indicates that effect may also be due to starvation. Therefore, the results LC_{50} 3102 mg/kg fd, corresponding to 560 mg/kg bw.d, should be considered as indicative and are used as such for risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
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98/8 Doc IIIA section No.	**7.5.3.1. 2 / 02**	**Short term toxicity**
91/414 Annex Point addressed	**II 8.1.2 / 02**	**Effects on birds - Short-term dietary toxicity**

		Official use only
Reference point (location) in dossier	**7.5.3.1.2/02**	
Title:	An eight-day dietary LC_{50} in mallard ducks with MK-936	
Project/Report number:	105-131	
Author(s):	[redacted]	
Date of report:	26/05/1983, revised 15/07/1983	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	25 March to 02 April 1983	
GLP:	Yes.	
Deficiencies:	No necropsy of birds that died during the test or of survivors at test-end.	
Reliability indicator	2.	

Reference/notifier	:	[redacted] (1983c)	GLP statement	:	no
Type of study	:	birds, short-term dietary toxicity	Guideline	:	ASTM E857-81; US-EPA FIFRA Subdivision E § 71-2
Year of execution	:	1983	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] purity [redacted] appearance white powder			

Substance	Species	Route	Exposure Duration [d]	Recovery period [d]	Criterion	Value [mg/kg fd]	Value [mg/kg bw·d]
abamectin	*Anas platyrhynchos*	oral diet	5	3	LC_{50}	383	48.6

Description

Short-term dietary toxicity study with mallard ducks.
Methods. Test substance was added to the diet in acetone, nominal doses 162, 288, 511, 910, and 1620 mg abamectin/kg fd (corrected for purity of the test compound), control with 1.7 % v/w acetone. Birds 10 days old, average body weight 154 - 173 g. Ten birds per dose level, five replicate control groups. Daily observations for mortality and/or signs of toxicity, group body weight determined at start and on days 5 and 8. Food consumption recorded for days 0 - 5 and 6 - 8.
Conditions. Group housing, 38 °C, 14:10 h L:D, food and water *ad libitum*.

Results

No mortality in the control and at 162 mg/kg fd, 20 % mortality at 288 mg/kg fd, 80 % at 511 mg/kg fd, 100 % at 910 and 1620 mg/kg fd. All mortalities had occurred by day 1, except for 511 mg/kg fd, where 7 birds had died on day 1 and one additional bird died on day 6. Signs of toxicity at all concentrations, surviving birds recovered by day 6 to 8. Reduction in food consumption during days 0 - 5 at all concentrations, consumption at 162 mg/kg fd only 41 % of control, at other levels < 29 % of control. Decrease in consumption remained during observation period. Body weight loss at all exposure levels, weight gain at 162 mg/kg fd similar to control during observation period, weight gain depressed at 288

mg/kg fd by 14 % as compared to the control and by 60 % at 511 mg/kg fd (two birds). LC_{50} reported as 383 mg/kg fd (95 % CI 302 - 487 mg/kg fd).

Remarks by RMS

According to the Guidance Document on risk assessment for birds and mammals, recalculation of the daily dose should be based on NOEL when the LC_{50} is below the top concentration and food avoidance has occurred. However, because almost all mortalities had occurred by day 1, mortality was clearly caused by the test substance and the estimation of body weight and food consumption is considered accurate. Calculated daily doses are 24.5, 32.5, 72.4, 98.5 and 135 mg/kg bw.d. Fitting a dose-response curve to these data gives an LD_{50} of 48.6 mg/kg bw.d. The result LC_{50} 383 mg/kg fd, corresponding to 48.6 mg/kg bw.d is used for risk assessment.

	Evaluation by Competent Authorities
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98/8 Doc IIIA section No.	**7.5.3.1. 3 / 01**	**Effects on reproduction**
91/414 Annex Point addressed	**II 8.1.3 / 01**	**Effects on birds - Subchronic toxicity and reproduction**

		Official use only
Reference point (location) in dossier	**7.5.3.1.3/01**	
Title:	Abamectin technical: A one-generation reproduction study with the mallard (*Anas platyrhynchos*)	
Project/Report number:	105-135A	
Author(s):	[redacted]	
Date of report:	26/02/1987	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	1987	
GLP:	Yes.	
Deficiencies:	none	
Reliability indicator	1	

Reference/notifier	:	[redacted] 1987)	GLP statement	:	yes
Type of study	:	birds, reproduction	Guideline	:	US-EPA, FIFRA Subdivision E, 71-4
Year of execution	:	1985-1987	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted], purity [redacted] appearance white powder			

Substance	Species	Route	Exposure Duration [w]	Criterion	Value [mg/kg fd]	Value [mg/kg bw·d]]	
abamectin	*Anas platyrhynchos*	oral diet	18	NOEC	12	1.33 1.49	(males) (females)

Description

Reproduction study with mallard ducks.
Methods. Adult birds were acclimatised for 4 weeks and then exposed to the test substance in the diet for at least 18 weeks. Birds were 19 weeks old at test initiation, mean body weight 1184 g (males) and 1031 g (females), and approaching their first breeding season. Pre-mixes of test substance were prepared in corn-oil and acetone and mixed with diet, nominal concentrations 3, 6 and 12 mg/kg fd (corrected for purity) and a control (corn-oil, acetone). Sixteen replicate groups per concentration with one male and one female each. Birds were observed daily for mortality and signs of toxicity. Body weight of adults was determined biweekly until week 8 and at study termination, food consumption measured once a week. Reproductive

parameters (egg production, number of eggs cracked or broken, eggshell thickness, embryo viability, hatchability) were determined as from week 10 over an eight-weeks egg-laying period, and survival and weight of hatchlings were recorded. Freshly prepared food was sampled for analysis each week, and stability samples were taken at the end of the first week (analysis method not described).
Conditions. Housing in pairs, 19.7 ± 2.5 °C, 65 % RH, 8:16 h L:D (129 lux), increased to 16:8 h L:D as from week 9 and 17:7 h L:D as from week 11. Hatchlings at 38 °C until 7 days after hatching, thereafter 20 °C, 16:8 h L:D. Food and water *ad libitum.*
Statistics. Dunnett's test to compare treatments with controls, percentages arc-sin transformed.

Results

Freshly prepared food contained 97.3 - 114.5 % of nominal, old food 97.0 - 109.7 % of nominal. Overall average measured concentrations in fresh food were 3.2, 6.3 and 12.7 mg/kg fd.
One mortality at 6 mg/kg fd, death preceeded by weight loss. One or two birds in each group (nine in total) displayed abnormal behaviour (limb weakness, bumblefoot), not considered related to the test substance according to authors. Gross necropsy at test termination revealed no treatment related lesions.
Body weight at test termination was slightly lower in the abamectin treatments as compared to the control, but differences were small (maximum - 4.8 % as compared to the control) and not statistically significant.
Food consumption was variable and significantly different from the control in some cases (week 12: 3 and 12 mg/kg fd; week 16: 3 and 6 mg/kg fd; week 19: all levels). From week 11 to 19 (except for week 18), consumption in the control was higher than in the treatment groups, difference was mainly caused by five groups that showed high consumption throughout the whole study.
Total number of eggs in the control was 575, total number per hen between 20 and 51, one non-breeder with 9 eggs. Egg laying in abamectin treatments not significantly different, total number at 12 mg/kg fd higher than in control. No significant difference in cracked eggs, eggshell thickness, embryo viability and 14-day old survivors. Hatchability as percentage of live 3-week embryo's was slightly reduced at 12 mg/kg fd as compared to the control (69 vs. 76 %; difference not significant). Difference was caused by three replicates with < 50 % hatchability (27, 37 and 41 %). Control and 6 mg/kg fd had one replicate each with low hatchability (33 and 43 %). No difference in body weight of hatchlings and 14-day old survivors.

Remarks by RMS

Analysis method not described. Pilot study included ([redacted] 1987): Adult birds exposed for 6 weeks to 1, 8 and 64 mg/kg fd, five groups with two birds each. At 64 mg/kg fd, a decrease was found in number of eggs laid, hatching success, number of hatchlings and 14-day old survivors. The result NOEC 12 mg/kg fd, corresponding to 1.33 mg/kg bw.d (males) and 1.49 mg/kg bw.d (females), is used for risk assessment.

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
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Date	*07-11-2007*
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98/8 Doc IIIA section No.	**7.5.3.1. 3 / 02**	**Effects on reproduction**
91/414 Annex Point addressed	**II 8.1.3 / 02**	**Effects on birds - Subchronic toxicity and reproduction**

		Official use only
Reference point (location) in dossier	**7.5.3.1.3/02**	
Title:	MK-936: A reproduction study with the northern bobwhite	
Project/Report number:	108-400	
Author(s):	[redacted]	
Date of report:	11/01/2000	
Published:	Not published	
Testing facility:	[redacted]	
Study dates	2000	
GLP:	Yes.	

Deficiencies:	No	
Reliability indicator	1	

Reference/notifier	:	[redacted] (2000)	GLP statement	:	yes
Type of study	:	birds, reproduction	Guideline	:	US-EPA, FIFRA Subdivision E, 71-4; OECD 206
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	abamectin technical, batch [redacted] purity [redacted] appearance powder			

Substance	Species	Route	Exposure Duration [w]	Criterion	Value [mg/kg fd]	Value [mg/kg bw·d]]	
abamectin	*Colinus virginianus*	oral diet	20	NOEC	≥ 20	≥ 2.0	(males/females)

Description

Reproduction study with bobwhite quail.
Methods. Adult birds were acclimatised for 5 weeks and then exposed to the test substance in the diet for about 20 weeks. Birds were 35 weeks old at test initiation, body weight 179 - 219 g (mean 199 g for males and 197 g for females), and approaching their first breeding season. Test substance was mixed with diet, nominal concentrations 5, 10 and 20 mg/kg fd (corrected for purity) and a control. Sixteen replicate groups with one male and one female each. Birds were observed daily for mortality and signs of toxicity Body weight of adults was determined biweekly until week 8, food consumption measured once a week. Reproductive parameters (egg production, number of eggs cracked or broken, eggshell thickness, embryo viability, hatchability) were determined as from week 11 over a nine-weeks egg-laying period, and survival and weight of hatchlings were recorded. Freshly prepared food was sampled for analysis each week, and stability samples were taken at the end of the first week (analysis method not described).
Conditions. housing in pairs, 19.9 ± 1.5 °C, 62 ± 14 % RH, 8:16 h L:D (262 lux), increased to 17:7 h L:D as from week 8. Hatchlings at 38 °C until 7 days after hatching, thereafter 28 °C, 59 % RH, 16:8 h L:D. Food and water *ad libitum.*
Chemical analysis. Freshly prepared food samples in week 4, 8, 12, 16 and 20. Homogeneity checked at start, stability samples taken on day 7 of first week. Extraction with acetonitrile by shaking for 60 min., aliquot of extracts diluted with acetonitrile:water (50:50 v/v) and analysed by HPLC-UV (245 nm). Average recovery 92.3 - 103 %. LOQ 2 mg/kg fd.
Statistics. Dunnett's test to compare treatments with controls, percentages arc-sin transformed.

Results

Freshly prepared food contained 98.4 - 101 % of nominal, overall average measured concentrations in fresh food were 5.1, 9.8 and 20.0 mg/kg fd. Homogeneity and stability confirmed.
One mortality at 20 mg/kg fd within the first week, death preceeded by leg fracture, bird replaced. No signs of toxicity, incidental clinical observations related to injuries and penwear.
No treatment related effects on body weight. Slight decrease in food consumption during week 6 at 5 mg/kg fd (-11 % as compared to control; significant); significant decrease in consumption during various weeks at 10 and 20 mg/kg fd, difference 13 - 19 % as compared to control. Authors state that reduction may have been caused by avoidance.
Total number of eggs in the control was 668, total number per hen between 16 and 61. Total numbers at 5, 10 and 20 mg/kg fd were 697, 577 and 569, respectively. Reduction at 10 and 20 mg/kg fd not significant and caused by non-breeders: one hen with 6 eggs at 10 mg/kg fd, two hens with 9 and 0 eggs at 20 mg/kg fd; two hens showed evidence of pen-mate agression. When corrected for non-breeders, average number of

eggs/hen was 42 in the control and 44, 38 and 40 at 5, 10 and 20 mg/kg fd, respectively. No significant difference in cracked eggs, eggshell thickness, embryo viability and hatchability. Number of 14-day old survivors as percentage of hatchlings at 20 mg/kg fd lower than control (86 vs. 94 %), caused by one pen with two hatchlings that died during the rearing period. No difference in body weight of hatchlings and 14-day old survivors. NOEC reported as 20 mg/kg fd.

Remarks by RMS

The result NOEC ≥ 20 mg/kg fd, corresponding to ≥ 2.0 mg/kg bw.d (males and females) 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	*07-11-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
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Acceptability	
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98/8 Doc IIIA section No.	**7.5.4**	**Effects on honey beess** ***(headline)***

98/8 Doc IIIA section No.	**7.5.4.1 / 01**	**Acute toxicity to honey bees and other beneficial arthropods, for example predators**
91/414 Annex Point addressed	**II 8.3.1.1 / 01**	**Bees: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.4.1/01**	
Title:	Report on a laboratory investigation into the toxicity of abamectin to honey bees (*Apis mellifera*)	
Project/Report number:	Not stated.	
Author(s):	Davies L.G., Carlile, W.R. and Bratby, P.	
Date of report:	September 1985	
Published:	Not published	
Testing facility:	Department of Life Sciences, Trent Polytechnic, Nottingham, UK	
Study dates	Not stated.	
GLP:	No.	
Deficiencies:	None.	X
Reliability indicator	2.	X

Reference/notifier	:	Davies, L.G., Carlile, W.R. and Bratby P. (1985)	GLP statement	:	no
Type of study	:	Acute toxicity bees	Guideline	:	Pesticide safety precaution scheme working document D3. Laboratory testing for toxicity to honey bees
Year of execution	:	1985	Acceptability	:	acceptable (contact)
Test substance	:	abamectin technical lot [redacted] chemical purity [redacted]			

Substance	Species	Method	Duration [h]	Criterion	Value [µg/bee]
abamectin	*Apis mellifera*	contact	24	LD_{50}	0.0022
		oral	24	LD_{50}	-

Description

Bees were exposed to abamectin dissolved in acetone by topical application or via feeding solution. Azinphos methyl was used as a toxic standard. Five doses, two replicates of ten bees per treatment. Doses for feed test ranged from 0.0005 - 0.05 µg/bee, dose for contact test ranged from 0.00005 - 0.005 µg/bee. Mortality was recorded after 24 h. The LD_{50} was calculated using a Probit Analysis (Glim, 1977 Royal Statistical Society, London).

Results

For the feed test the author calculated a LD_{50} of 0.0094 µg/bee. For the contact test the calculated LD_{50} value was 0.0022 µg/bee.

Remarks by RMS

Mortality in the oral test exceeded 50 % at 0.001 µg/bee and was 40 % at 0.005 µg/bee, the LD_{50} value could therefore not be determined accurately. The results of the oral test will not be used for the risk assessment. The result contact LD_{50} 0.0022 µg/bee 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	*07-11-2007*
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Remarks	

98/8 Doc IIIA section No.	7.5.4.1 / 02	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.2	Other arthropods: Acute toxicity

		Official use only
Reference point (location) in dossier	**7.5.4.1/02**	
Title:	Toxicity of MK 936 EC 018 (A-8612 A) to the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Aphidiidae) under extended laboratory conditions	
Project/Report number:	982614	
Author(s):	Grimm, C.	
Date of report:	02/12/1999	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	
Study dates	4 – 22 March 1999	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Grimm, C. (1999)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods, extended lab.	Guideline	:	IOBC (1992), ESCORT (1994) and Mead-Briggs (1997)
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	A-8612 A, abamectin 0.18 EC (19,46 g/L), batch [redacted], light yellow liquid			

Substance	Species	Method	Dose [L/ha]	Dose [g as/ha]	Duration [d]	Parameter	Reduction [%]	After ... [d]
A-8612 A	*Aphidius rhopalosiphi*	residue on plants	0.06	0.58	2	survival	93.3	2
A-8612 A	*Aphidius rhopalosiphi*	residue on plants	0.3	5.84	2	survival	100.0	2
A-8612 A	*Aphidius rhopalosiphi*	residue on plants	1.5	29.2	2	survival	100.0	2
A-8612 A	*Aphidius rhopalosiphi*	residue on plants	3	58.4	2	survival	100.0	2

Description

The effect of A-8612 A on survival and fecundity of *Aphidius rhopalosiphi* was determined under extended laboratory conditions. Perfekthion (407 g dimethoate/L) was used as a toxic reference. The exposure test

units consisted of potted barley plants (9-15 plants per pot). The pots were enclosed in clear acrylic cylinders and sealed at the top with nylon netting. Wasps were exposed for 48 hours, after the test item had dried on the plants. Six replicate exposure units each containing five female wasps for each treatment group. Plants were pre-treated with a fructose solution, using a hand sprayer, prior to the application. All treatments were applied with a calibrated sprayer. Treatment levels: 0.58 L/ha, 5.84 L /ha, 29.2 L/ha, and 58.4 g as/ha. The temperature ranged from 18.0-21.0 °C, relative humidity from 60-77%, light intensity ranged from 1134-1661 lux.

Results

With rising test item concentration, an increasing number of wasps was found on the sand. Mortality is reported in the following table.

Table: Percentage mortality of *Aphidius rhopalosiphi* following treatment with A-8612 A

Interval	Percent cumulative mortality (mean ± SD)					
	control	0.06 L/ha	0.3 L/ha	1.5 L/ha	3 L/ha	toxic standard
2 h	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	10.0 ± 16.7	66.7 ± 16.3*	0.0 ± 0.0
24 h	0.0 ± 0.0	36.7 ± 23.4*	53.3 ± 20.7*	90.0 ± 16.7*	96.7 ± 8.2*	100.0 ± 0.0*
48 h	0.0 ± 0.0	93.3 ± 10.3*	100.0 ± 0.0*	100.0 ± 0.0*	100.0 ± 0.0*	100.0 ± 0.0*

*statistically significant difference between treatment level and the control

No reproduction phase was carried out with the test item treatments and the toxic standard, since only two wasps survived the exposure phase.

Remarks by RMS

The result > 50 % effect on survival at 0.58 g as/ha and higher, is used for the risk assessment.

Remark (Syngenta) for evaluation under the BPD

It seems that there is some confusion in the text above (from DAR) with respect to the units of the treatment levels (i.e. L/ha vs g as/ha). The information given under Description is not consistent with the tables. The corresponding information of the tables is the same as in the Doc IIIA originally submitted, however the lowest rate of 0.06 L/ha (first table) does correspond to 1.17 g as/ha instead of 0.58 g as/ha.

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*07-11-2007*
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.	**7.5.4.1 / 03**	**Acute toxicity to honey bees and other beneficial arthropods, for example predators**
91/414 Annex Point addressed	**II 8.3.2**	**Other arthropods: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.4.1/03**	
Title:	Toxicity of MK 936 EC 018 (A-8612 A) to the predacious mite *Typhlodromus Pyri* Scheuten (Acari: Phytoseiidae) under extended laboratory conditions	
Project/Report number:	982613	
Author(s):	Grimm, C.	
Date of report:	14/04/2000	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	

Study dates	16 to 30 March 1999	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Grimm, C. (2000)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods, extended lab.	Guideline	:	IOBC (Overmeer, 1988 and Oomen, 1988)
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	A-8612 A, 19.46 g/L, batch [redacted] light yellow liquid			

Substance	Species	Method	Dose [L/ha]	Dose [g as/ha]	Duration [d]	Parameter	Reduction after 7 days	Maximal reduction [%]	After ... [d]
A-8612 A	*Typhlodromus pyri*	sprayed on leaves	0.06	1.17	14	survival	73.7	88.2	14
						reproduction		100.0	14
A-8612 A	*Typhlodromus pyri*	residues on leaves	0.3	5.84	14	survival	97.9	100.0	14
						reproduction			
A-8612 A	*Typhlodromus pyri*	residues on leaves	1.5	29.2	14	survival	100.0	100.0	14
						reproduction			
A-8612 A	*Typhlodromus pyri*	residues on leaves	3	58.4	14	survival	100.0	100.0	14
						reproduction			

Description

The effect of A-8612 A on the survival and reproduction of *Typhlodromus pyri* was determined under extended laboratory conditions. The test consisted of six treatments: control, four test item concentrations and a toxic standard (Perfekthion, dimethoate 400 g/L). The test item was applied at the following rates: 0.06, 0.3, 1.5 and 3 L/ha, corresponding to 1.17, 5.84, 29.2, and 58.4 g as/ha. Ten replicates per treatment, 10 protonymphs per replicate. Test units consisted of a bean leaf disc placed on top of wet cotton in a petridish. Protonymphs were introduced after spraying of the leaves. Food (walnut and apple pollen) was supplied before and at the experimental start and replenished each time the mites were counted. Environmental conditions: T25 ± 2 °C, RH 75 ± 15%, photoperiod 16 h, ± 2000 lux. On test days 3 and 7, the test units were examined individually for mite mortality. The number of eggs, surviving females and males, dead and missing mites were recorded on days 7, 10 and 14. Calculation of the total mortality was performed by adding dead and missing organisms, assuming that missing organisms were dead. Mortality was analysed by using Fisher exact test if the total number of dead and survivors was smaller or equal to 50, and a χ^2 – square approximation with continuity correction was used if the total number of dead and survivors exceeded 50. The number of eggs was tested for normality using the Shapiro and Wilk's test and for homoscedasticity using Bartlett's test. If assumptions were met, Dunnett's test was used to analyse for significant differences between control and treatment effects. If the data were not normally distributed or heteroscedastic, the Mann-Whitney U-test was used to compare the control to each treatment. In the event that the control was being compared to one treatment level and the data were normally distributed, the t-test was used to analyse the data. Homoscedasticity was tested with the F-test, and the Welch test was calculated for heteroscedastic data. If the data were not normally distributed, the Mann-Whitney U-test was used to compare the control to one treatment (Zar, 1984). The corrected mortality-escape rate M, after 7 days of exposure, was calculated according to Abbott (1925).

Results

Mortality and reproduction data are summarised in the two tables below.

Table: Mean percentage mortality and average number of eggs produced per female per day.

Interval	Treatment [L/ha]	Cumulative mean mortality [%]	SD	Corrected mortality [%]	Eggs/female/ day	SD
3	0	0	0.0			
	0.06	21.0	12.9	21.0		
	0.3	90.0	6.7	90.0		
	1.5	100.0	0.0	100.0		
	3	99.0	3.2	99.0		
	toxic reference	77.0	18.3	77.0		
7	0	5.0	7.1	0	4.00	0.86
	0.06	75.0	14.3	73.7	0*	0.00
	0.3	98.0	4.2	97.9	n.a.[b]	-
	1.5	100.0	0.0	100.0	n.a.[c]	-
	3	100.0	0.0	100.0	n.a.[c]	-
	toxic reference	87.0	87.0	86.3	0*	n.a.[c]
10	0	13.0	8.2		1.78	0.20
	0.06	85.0	10.8	82.8	0*	0.00
	0.3	100.0	0.0	100.0	n.a.[c]	-
	1.5	100.0	0.0	100.0	n.a.[c]	-
	3	100.0	0.0	100.0	n.a.[c]	-
	toxic reference	89.0	8.8	87.4	0*	0.00
14	0	15.0	8.5		1.63	0.15
	0.06	90.0	10.5	88.2	0*	0.00
	0.3	100.0	0.0	100.0	n.a.[c]	-
	1.5	100.0	0.0	100.0	n.a.[c]	-
	3	100.0	0.0	100.0	n.a.[c]	-
	toxic reference	90.0	6.7	88.2	0*	0.00

[b] not applicable as the mites had not developed to adults
[c] not applicable as there were no surviving females.
* statistically significant difference between treatment level and the control

Table: The calculated M- and R-value for A-8612 A.

Treatment [L/ha]	Mortality [%]	Effect on reproduction [%]
0	0.0	1.00
0.06	73.7	0.00
0.3	97.9	n.a.
1.5	100.0	n.a.
3	100.0	n.a.
toxic reference	86.3	0.00

n.a.: not applicable as no female adults developed

Remarks by RMS

The cumulative mean number of eggs per female from day 7 to day 14 is not reported and no raw data are available. Only the average number of eggs per female per day is reported. Since the mean mortality rate in the test item treatment has already triggered higher tier tests (lethal effect > 50%), reproduction assessments are not necessary. The result > 50 % effect on survival and reproduction at 1.17 g as/ha and higher is used for the risk assessment.

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	EVALUATION BY RAPPORTEUR MEMBER STATE *07-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	COMMENTS FROM ...

98/8 Doc IIIA section No.	**7.5.4.1 / 04**	**Acute toxicity to honey bees and other beneficial arthropods, for example predators**
91/414 Annex Point addressed	**II 8.3.2**	**Other arthropods: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.4.1/04**	
Title:	Acute toxicity of MK 936 EC 018 (A-8612 A) to the predatory ground beetle *Poecilus cupreus* L. (Coleoptera: Carabidae)	
Project/Report number:	982611	
Author(s):	Reber, B.	
Date of report:	02/11/1999	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	
Study dates	3 – 20 April 1999	
GLP:	Yes.	

Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Reber, B. (1999a)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods	Guideline	:	IOBC (Heimbach, 1992)
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	A-8612 A, abamectin EC (19.46 g/L), batch [redacted] liquid.			

Substance	Species	Method	Dose [L/ha]	Dose [kg as/ha]	Duration [d]	Parameter	Reduction [%]
A-8612 A	*Poecilus cupreus*	sprayed on beetles, food and sand	0.06	0.0012	14	survival	0
						food consumption	0
A-8612 A	*Poecilus cupreus*	sprayed on beetles, food and sand	0.3	0.0058	14	survival	0
						food consumption	0
A-8612 A	*Poecilus cupreus*	sprayed on beetles, food and sand	1.5	0.029	14	survival	0
						food consumption	0
A-8612 A	*Poecilus cupreus*	sprayed on beetles, food and sand	3	0.058	14	survival	0
						food consumption	0

Description

The effect of A-8612 A on the survival and food consumption of male and female *Poecilus cupreus* (2-3 weeks old) was determined under laboratory conditions. Application took place by spraying with a calibrated sprayer on beetles, food and sand (quartz). Treatment levels: 3 L /ha (58 g as/ha), 1.5 L/ha (29 g as/ha), 0.3 L/ha (5.8 g as/ha) and 0.06 L/ha (1.2 g as/ha). Toxic standard: Afugan 30 EC (pyrazophos 30.3%), applied at a rate of 1 L/ga. Five replicates with 6 *P. cupreus* (3 males, and 3 females) per treatment group. Feeding: one *Calliphora* sp. per living beetle on days 0, 2, 4, 7, and 10. Biological observations: mortality, behaviour and food consumption. Temperature: 20 ± 2 °C. Humidity 75 ± 15%. Photoperiod: 16:8 (L:D), range 500-1500 lux. Statistics: Mortality analysed by Fisher exact test or one way χ^2 test. Food consumption data were tested for normality using Shapiro and Wilk test and for homogeneity using Bartlett's test. If assumption were met Dunnett's test was used to analyse for significant differences between control and treatment effects. If the data were not normally distributed of heteroscedastic, the Mann-Whitney U-test was used. Corrected mortality according to Abbott (1925).

Results

Environmental parameters were within accepted limits.
No mortality in any of the treatments except for the toxic standard treatment; 56.7% after 24 hours and 100% by day 2. No abnormal behaviour of the beetles was observed only in the toxic standard treatment. The food consumption for each assessment interval ranged from 0.33-0.47, 0.33-0.57, 0.40-0.57, 0.37-0.53, and 0.37-0.60 fly pupae/beetle in the control, 0.0012 kg as/ha, 0.0058 kg as/ha, 0.029 kg as/ha treatment and for 0.058 kg as/ha treatment, respectively. In all four test item treatments, differences were not significant.

Remarks by RMS

The result of no effect on mortality and food consumption at application rates up to 3 L/ha, corresponding to 0.058 kg as/ha is used for the risk assessment.

Evaluation by Competent Authorities

	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	EVALUATION BY RAPPORTEUR MEMBER STATE *07-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	COMMENTS FROM ...

98/8 Doc IIIA section No.	**7.5.4.1 / 05**	**Acute toxicity to honey bees and other beneficial arthropods, for example predators**
91/414 Annex Point addressed	**II 8.3.2**	**Other arthropods: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.4.1/05**	
Title:	VERTIMEC EC 0.18 (A-8612 A): Combination of a semi-field and an extended laboratory study (field aged residue) to evaluate the effects on the ground beetle, *Poecilus cupreus* L. (Coleoptera: Carabidae)	
Project/Report number:	same as previous	
Author(s):	Kühner, C.	
Date of report:	23/10/1998	
Published:	Not published	
Testing facility:	GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Öschelbronn, Germany	

Study dates	16 June - 24 July 1998	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Kühner, C. (1998)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods, semi-field and extended lab.	Guideline	:	Escort 1994, Heimbach 1992, Dohmen et al. 1996
Year of execution	:	1998	Acceptability	:	acceptable
Test substance	:	Vertimec 0.18 EC (19.46 g abamectin/L analysed), batch [redacted], appearance straw to rust/liquid Adjuvant Para Sommer (75%), appearance liquid			

Substance	Species	Method	Dose [L/ha]	Dose [g as/ha]	Duration [d]	Parameter	Reduction [%]
Vertimec 0.18 EC	*Poecilus cupreus*	sprayed on beetles 2x, on soil and fly pupae 1x	0.3 2x	5.8	14	survival food consumption	-3.4 0
Vertimec 0.18 EC	*Poecilus cupreus*	sprayed on fly pupae 1x	0.3 2x	5.8	14	survival food consumption	3.3 6.1
Vertimec 0.18 EC	*Poecilus cupreus*	sprayed on soil	0.3 2x	5.8	14	survival food consumption	-3.4 -2.8
Vertimec 0.18 EC	*Poecilus cupreus*	sprayed on beetles 2x, on soil and fly pupae 1x	1.5 2x	29.2	14	survival food consumption	10.3 0
Vertimec 0.18 EC	*Poecilus cupreus*	sprayed on fly pupae 1x	1.5 2x	29.2	14	survival food consumption	0 0
Vertimec 0.18 EC	*Poecilus cupreus*	sprayed on soil	1.5 2x	29.2	14	survival food consumption	-3.4 -5.6
Vertimec 0.18 EC + Para Sommer	*Poecilus cupreus*	sprayed on beetles 2x, on soil and fly pupae 1x	0.3 2x	5.8	14	survival food consumption	0 -3.0
Vertimec 0.18 EC + Para Sommer	*Poecilus cupreus*	sprayed on fly pupae 1x	0.3 2x	5.8	14	survival food consumption	0 15.2
Vertimec 0.18 EC + Para Sommer	*Poecilus cupreus*	sprayed on soil	0.3 2x	5.8	14	survival food consumption	-3.4 5.6
Vertimec 0.18 EC + Para Sommer	*Poecilus cupreus*	sprayed on beetles 2x, on soil and fly pupae 1x	1.5 2x	29.2	14	survival food consumption	6.9 9.1
Vertimec 0.18 EC + Para Sommer	*Poecilus cupreus*	sprayed on fly pupae 1x	1.5 2x	29.2	14	survival food consumption	0 -6.1
Vertimec 0.18 EC + Para Sommer	*Poecilus cupreus*	sprayed on soil	1.5 2x	29.2	14	survival food consumption	0 -2.8

Description

Effects of Vertimec EC 0.18 (19.46 g abamectin/L) and Vertimec 0.18 EC + adjuvant (para sommer) on the carabid beetle *Poecilus cupreus* L. were determined under worst-case exposure conditions. The study was a combination of semi-field and extended laboratory tests. Application 2 times at intervals of 7 days to a standard soil, type Lufa 2.1 in plastic containers. Test substance was tested at 29.2 g as/ha (variant 1), at 5.8 g as/ha (20% drift rate, variant 2) , at 29.2 g as/ha + adjuvant (variant 3) and at 5.8 g as/ha + adjuvant (variant 4). Hostathion (420 g triazofos/L) was used as a toxic standard. The treated test containers were transferred to the outdoor area of the testing facility. They were exposed to field environment until use for the exposure test, but protected from rain. Adult beetles, six beetles (2-3 weeks old) per replicate, five replicates per variant, were exposed. Exposure variant one: beetles introduced before 1st application, beetles received two treatments (0 and 7 d) and the fly pupae received one treatment (0 d), boxes kept under semi-field conditions. Exposure variant two: beetles introduced immediately after the 2nd application (not treated), fly pupae received one treatment (+7d). Exposure variant three: beetles and pupae introduced fourteen days after the 2nd application), beetles and fly pupae were not treated. The beetles were fed one *Musca* pupae per living beetle on day 0, 2, 4, 7 and 11 of the test. Exposure variant 1 was under semi-field conditions and exposure variants 2 and 3 were conducted under laboratory conditions. Semi-field conditions: average minimum temperature 14.3 °C, average maximum temperature 33.5 °C, humidity average minimum 51.0%, average maximum 94.2%. Experimental conditions of the laboratory phase: 20 ± 2 °C, relative humidity 70 ± 15%, 16 hrs light/ 8 hrs darkness, light intensity 500-1500 lux. Mortality was determined at 2, 4, and 6 hours after the start of the exposure and again on day 2, 4, 7, 11 and 14 after application. The number of eaten pupae per beetle per day was calculated for each replicate. The reduction in feeding rate and the total mortality was calculated using the formula of Abbott (1925). Mortality data were analysed using Fisher's Exact test. Feeding rate was analysed using Shapiro-Wilk's test and residual analysis (Zar, 1984), ANOVA followed by Tukey's Multiple Comparison.

Results

Mortality and feeding data are summarised in the two tables below.

Table: Mortality of *Poecilus cupreus* after exposure to soil treated with Vertimec, Vertimec and adjuvant, triazophos and control.

Mortality [%]		control	Vertimec		Vertimec + adjuvant		Toxic standard
			max.	20% drift	max.	20% drift	
1st exposure	M [%]	3.33	13.33	0.00	10.00	3.33	86.67
	M corr. [%]	-	10.3	-3.4	6.9	0.0	86.2
2nd exposure	M [%]	0.00	0.00	3.30	0.00	0.00	100.00
	M corr. [%]	-	0.0	3.3	0.0	0.0	100.0
3rd exposure	M [%]	3.33	0.00	0.00	3.33	0.00	36.67
	M corr. [%]	-	-3.4	-3.4	0.0	-3.4	34.5

Table: Feeding capacity of *Poecilus cupreus* after exposure to soil treated with Vertimec, Vertimec and adjuvant, triazophos and control.

Feeding capacity [%]		control	Vertimec		Vertimec + adjuvant		Toxic standard
			max.	20% drift	max.	20% drift	
1st exposure	F	0.33	0.33	0.33	0.30	0.34	0.29
	R [%]	-	0.00	0.00	9.09	-3.03	12.12
2nd exposure	F	0.33	0.33	0.31	0.35	0.28	0.25
	R [%]	-	0.00	6.06	-6.06	15.15	24.24
3rd exposure	F	0.36	0.38	0.37	0.37	0.34	0.34
	R [%]	-	-5.56	-2.78	-2.78	5.56	5.56

F: mean number of eaten pupae per beetle per day
R: reduction in feeding capacity

Remarks by RMS

In the control group of the first exposure group, the beetles did not eat at all during the first observation period (0-2 days) which was compensated by a high consumption during days 2-4. In the treatment groups the average number of fly pupae per beetle per day ranged from 0.40-0.50. The consumption in the control

group in the second observation period (0-4 days) is very high (0.83) compared to the consumption in the treatment groups (range 0.30-0.40). Because the difference between the control and treatment are due to the irregular feeding pattern in the control, these are not used and results in the header are based on average consumption and mortality over 14 days.
The result that Vertimec 0.18 EC and Vertimec 0.18 EC + adjuvant have no effect on mortality and feeding capacity when sprayed at 0.3 and 1.5 L/ha (corresponding to 5.8 and 29.2 g abamectin/L), is used for the risk assessment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	EVALUATION BY RAPPORTEUR MEMBER STATE *07-11-2007* [redacted]
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	COMMENTS FROM ...

98/8 Doc IIIA section No.	**7.5.4.1 / 06**	**Acute toxicity to honey bees and other beneficial arthropods, for example predators**
91/414 Annex Point addressed	**II 8.3.2**	**Other arthropods: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.4.1/06**	
Title:	Toxicity of MK 936 EC 018 (A-8612 A) to the predator	

	Orius laevigatus Fieber (Heteroptera: Anthocoridae) under extended laboratory conditions	
Project/Report number:	982612	
Author(s):	Reber, B.	
Date of report:	25/11/1999	
Published:	Not published	
Testing facility:	Novartis Crop Protection AG, Basel, Switzerland	
Study dates	24 March - 3 May 1999	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Reber, B. (1999b)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods, extended lab.	Guideline	:	IOBC (Hassan, 1992), ESCORT (Barrett *et al.*, 1994), Candolfi & Vickus, 1995
Year of execution	:	1999	Acceptability	:	acceptable
Test substance	:	A-8612 A, abamectin EC (19.46 g/L), batch [redacted] appearance clear, yellow liquid			

Substance	Species	Method	Dose [L/ha]	Dose [kg as/ha]	Duration [d]	Parameter	Reduction [%]
A-8612 A	*Orius laevigatus*	residue on plants	0.060	0.0012	20[1]	survival	63.22
						reproduction	8.3
A-8612 A	*Orius laevigatus*	residue on plants	0.300	0.0058	20[1]	survival	90.80
A-8612 A	*Orius laevigatus*	residue on plants	1.500	0.0292	20[1]	survival	97.70
A-8612 A	*Orius laevigatus*	residue on plants	3.000	0.0584	20[1]	survival	100.00

1: 10 days exposure, 10 days reproduction phase

Description

Effects of A-8612 A on the survival and reproduction of the predator *Orius laevigatus* Fiber were determined under extended laboratory conditions. During the exposure phase *Orius laevigatus* nymphs (second nymphal stage) were confined to treated potted plants that had been sprayed before introduction of the insects, at the following rates: 60 mL/ha, 300 mL /ha, 1500 mL /ha, and 3000 mL /ha, corresponding to 0.0012, 0.0058, 0.0292 and 0.0584 kg as/ha. Ethyl Parathion (200 g/L EC) was used as a toxic standard. In the exposure phase, 10 replicate units with 10 nymphs each, were used for each treatment group. During testing, the insects were fed *ad libitum* with *Ephestia sp.* eggs. Fresh food was added every 2-4 days. At termination of the exposure phase, all the insects had a chance to mate. In the reproduction phase of the test, 15 replicates per treatment group (or less, if no survivors were available) each containing one *O. laevigatus* female were set up. The test units consisted of small plastic petridishes covered with a lid. A bean leaf disc was fixed inside the bottom of the unit on a thin layer of agar. The insects stayed in the same unit for a period of 2 to 3 days, food was added. At the end of each interval, the insects were transferred to new untreated reproduction phase test units and the number of eggs laid was counted. The test was terminated after the fourth assessment on reproduction day 10. T 25 ± 2 °C, RH 75 ± 15%, photoperiod

16L:8D (2500-3000 lux). Total mortality was defined as the sum of dead and missing organisms and calculated according to Abbott (1925).

Results

After 10 days of exposure total mortality was 13.0%, 68.0%, 92.0%, 98.0%, 100.0% and 98.0% for the control, 0.0012 kg as/ha, 0.0058 kg as/ha, 0.0292 kg as/ha, 0.0584 kg as/ha and the toxic standard treatment, respectively. The total mortality was statistically significant higher in all treatments as compared to the control. The reproduction phase was performed with the 1.2 and 5.8 g as/ha and the control. The calculations of the reproduction were done with 14 individuals for the control, 12 individuals for the 1.2 g as/ha and 3 individuals for the 5.8 g as/ha, respectively. Mean daily oviposition over the whole reproduction phase of the study was 10.08, 9.86, and 10.49 eggs/female/day in the control, the 1.2 g as/ha and the 5.8 g as/ha treatment, respectively. No statistically significant effects on mean daily oviposition over the entire duration of the reproduction phase were recorded, with exception of a significantly lower rate of egg-laying recorded in the 1.2 g as/ha treatment during the period from reproduction test day 3 to 5 (Mann-Whitney U-test). The reported corrected mortality values were 63.22%, 90.80%, 97.70% and 100.00% for the 1.2, 5.8, 29.2 and 58.4 g as/ha treatments, respectively.

Remarks by RMS

Validity criteria are met except for the fecundity part of the study. The fecundity assessment was carried out with 14, 12 and 3 replicates which is less than the minimum number of 15 females required according to the guideline (Bakker et al., 2000). The result of a significantly lower rate of egg-laying (temporary on day 3-5) at the 1.2 g as/ha treatment level can therefore only be used as an indicative value. The result > 50 % effect on survival at 1.2 g as/ha and higher, is used for the 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	*07-11-2007*
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	
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Remarks	
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Materials and Methods	
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Reliability	
Acceptability	
Remarks	

98/8 Doc IIIA section No.	**7.5.4.1 / 07**	**Acute toxicity to honey bees and other beneficial arthropods, for example predators**
91/414 Annex Point addressed	**II 8.3.2**	**Other arthropods: Acute toxicity**

		Official use only
Reference point (location) in dossier	**7.5.4.1/07**	
Title:	Testing toxicity to beneficial arthropods. Predatory bug-*Orius laevigatus* (FIEBER)/semi-field following a proposal of a semi-field method (Sechser, 1990)	
Project/Report number:	98 10 48 068	
Author(s):	Kleiner, R	
Date of report:	22/12/1998	
Published:	Not published	
Testing facility:	Biochem agrar, Cunnersdorf, Germany	
Study dates	4 August – 8 September 1998	
GLP:	Yes.	

Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Kleiner, R. (1998)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods, semi-field	Guideline	:	proposal of semi-field method
Year of execution	:	1998	Acceptability	:	partly acceptable
Test substance	:	Vertimec 0.18 EC (A-8612 A)(19.46 g abamectin/L), batch [redacted]			

Substance	Species	Method	Days after last application	Dose[1] [L/ha]	Dose[1] [g as/ha]	Duration [d]	Parameter	Reduction [%]
Vertimec 0.18 EC	*Orius laevigatus*	semi-field	0	0.15	2.9	35	survival	49.2
Vertimec 0.18 EC	*Orius laevigatus*	semi-field	2	0.15	2.9	35	survival	16.9
Vertimec 0.18 EC	*Orius laevigatus*	semi-field	7	0.15	2.9	35	survival	13.2
Vertimec 0.18 EC	*Orius laevigatus*	semi-field	0	0.75	14.6	35	survival	58.7
Vertimec 0.18 EC	*Orius laevigatus*	semi-field	2	0.75	14.6	35	survival	45.8
Vertimec 0.18 EC	*Orius laevigatus*	semi-field	7	0.75	14.6	35	survival	26.5
Vertimec 0.18 EC + paraffin oil	*Orius laevigatus*	semi-field	0	0.15 +1.25	2.9	35	survival	38.1
Vertimec 0.18 EC + paraffin oil	*Orius laevigatus*	semi-field	2	0.15 +1.25	2.9	35	survival	8.5
Vertimec 0.18 EC + paraffin oil	*Orius laevigatus*	semi-field	7	0.15 +1.25	2.9	35	survival	8.8
Vertimec 0.18 EC + paraffin oil	*Orius laevigatus*	semi-field	0	0.75 +1.25	14.6	35	survival	63.5
Vertimec 0.18 EC + paraffin oil	*Orius laevigatus*	semi-field	2	0.75 +1.25	14.6	35	survival	49.2
Vertimec 0.18 EC + paraffin oil	*Orius laevigatus*	semi-field	7	0.75 +1.25	14.6	35	survival	35.3
paraffin oil	*Orius laevigatus*	semi-field	0	1.25	2.9	35	survival	7.9
paraffin oil	*Orius laevigatus*	semi-field	2	1.25	2.9	35	survival	-13.6
paraffin oil	*Orius laevigatus*	semi-field	7	1.25	2.9	35	survival	16.2

1: application 2x, interval 7 days

Description

The effect of residues of Vertimec 0.18 EC (19.46 g abamectin/L) and Vertimec 0.18 EC + paraffin oil on the survival and reproduction of *Orius laevigatus* nymphs was determined under semi-field conditions. Vine plants grown in flowerpots were sprayed using a plot sprayer.

Treatment 1: deionised water, 500 L/ha
Treatment 2: dimethoate EC 400, (399.16 g dimethoate/L) 0.85 L in 500 L water/ha, 2 x 339 g as/ha.
Treatment 3: 0.75 L product in 500 L water/ha, 2 x 14.6 g as/ha
Treatment 4: 0.15 L product in 500 L water/ha, 2 x 2.9 g as/ha
Treatment 5: 0.75 L product + 1.25 L Paraffin oil in 500 L water/ha,
Treatment 6: 0.15 L product + 1.25 L Paraffin oil in 500 L water/ha,
Treatment 7: 1.25 L Paraffin oil in 500 L water/ha
After spraying and air-drying, metal-racks were put over the plants and covered with gauze. Twenty nymphs (age 3-4 days old) per test cage with 5 replicates per treatment were introduced at three different points in time: on the day of the final application, two and seven days after the final application. Feeding (with *Sitotroga cereallela eggs*) during the exposure phase took place 3 and 6 days after exposure on plants. Exposure took place under outdoor conditions for 8 days. Survivors from all replicates of one treatment were counted and divided into two oviposition cages. Fresh green bean pods were placed into each cage as a substrate for oviposition. Feeding during the fecundity test took place at each assessment

day. The fecundity phase was conducted in the laboratory. After 2-3 days the bean pods were removed and replaced with fresh ones.
Mortality was assessed on day 8 after exposure and every second or third day over a 9-day period (during the fecundity phase). Fecundity was assessed 10, 12 (13), 14 (15), 16 (17), 18 (19), and 20 (21) days after exposure (incl. 4 days to determine the hatching rate of the eggs laid at the last evaluation date). Corrected mortality (Abbott, 1925), oviposition ability (R_r), hatching rate (H_r) and the reduction of the beneficial capacity (E), were determined. All data were analysed by ANOVA to test the significance of differences between treatment means.

Results

Mortality and fecundity data and effects on benefecial capacity are summarised in the four tables below.

Table: Mean percentage mortality and corrected mortality of *O. laevigatus* observed at the end of exposure to Vertimec 0.18 EC

treatment	Absolute mortality [%]			Corrected mortality [%]		
days after final application	0	2	7	0	2	7
1: control	37	41	32	-	-	-
2: toxic reference	100[a]	91[a]	87[a]	100	84.7	80.9
3: 14.6 g as/ha	74[a]	68[a]	50	58.7	45.8	26.5
4: 2.9 g as/ha	68[a]	51	41	49.2	16.9	13.2
5: 14.6 g as/ha + paraffin oil	77[a]	70[a]	56[a]	63.5	49.2	35.3
6: 2.9 g as/ha + paraffin oil	61[a]	46	38	38.1	8.5	8.8
7: paraffin oil	42	33	43	7.9	-13.6	16.2

[a]statistically significant as compared to the control

Table: Mean number of eggs oviposited per female per day by *O. laevigatus* following exposure to Vertimec 0.18 EC

treatment	Mean number of eggs per female per day			Reduction in oviposition ability compared to control 100-R_r (%)		
days after final application	0	2	7	0	2	7
1: control	2.7	2.6	2.9	-	-	-
2: toxic reference	0[a]	0[a]	0.15[a]	100	100	94.83
3: 14.6 g as/ha	2.3	2.05	2.25	14.81	21.15	22.41
4: 2.9 g as/ha	1.0[a]	1.25[a]	2.60	62.96	51.92	10.34
5: 14.6 g as/ha + paraffin oil	0.3[a]	1.90	2.80	88.89	26.92	3.45
6: 2.9 g as/ha + paraffin oil	1.95	2.55	3.10	27.78	1.92	-6.9
7: paraffin oil	1.45	2.75	3.10	46.30	-5.77	-6.9

[a]statistically significant as compared to the control

Table: Mean number of succesfully hatching nymphs per egg oviposited by *O. laevigatus* following exposure to Vertimec EC 0.18

treatment	Mean number of successfully emerging nymphs/eggs			Reduction in the number of successfully hatching nymphs/eggs compared to the control.100-R_r (%)		
days after final application	0	2	7	0	2	7
1: control	0.83	0.85	0.87	-	-	-
2: toxic reference	0[a]	0[a]	0.5[a]	100	100	42.5
3: 14.6 g as/ha	0.82	0.83	0.86	1.2	2.4	1.1
4: 2.9 g as/ha	0.89	0.85	0.85	-7.2	0	2.3
5: 14.6 g as/ha + paraffin oil	0.85	0.76[a]	0.83	-2.4	10.6	4.6
6: 2.9 g as/ha + paraffin oil	0.82	0.84	0.89	1.2	1.2	-2.3
7: paraffin oil	0.85	0.83	0.86	-2.4	2.4	1.1

[a]statistically significant as compared to the control

Table: Reduction in beneficial capacity of *O. laevigatus* after treatment with Vertimec 0.18 EC and Vertimec 0.18 EC + paraffin oil

treatment	E (%)* (reduction in beneficial capacity)		
days after final application	0	2	7
1: control	-	-	-
2: toxic reference	100	100	99.4
3: 14.6 g as/ha	65.2	58.3	43.6
4: 2.9 g as/ha	79.8	60.0	24.0
5: 14.6 g as/ha + paraffin oil	95.8	66.8	40.4
6: 2.9 g as/ha + paraffin oil	55.8	11.3	0.3
7: paraffin oil	49.3	-17.3	11.5

*negative values indicate an increase in performance as compared to the control

Remarks by RMS

The fecundity assessment was carried out with 12, 11, 14, and 14 replicates, for treatments 3, 4, 5, and 6, respectively. This is less than the minimum number of 15 females required according to the guideline (Bakker et al., 2000) and mortality in the control of the fecundity test ranged from 54.8 to 61.8 %. The results of the fecundity part of the study are therefore not used for the risk assessment. A significant effect on mortality (> 50 %) was found at all treatment levels on day 0 (fresh residue), with the exception of the paraffin oil treatment and the 20 % application rate + paraffin oil treatment. On day 7 after application, only the mortality in the 100 % application + paraffin treatment, differed significantly from the control. However, since the mean mortality in the control during the exposure phase ranged from 32 to 41%, the effects are likely to be underestimated. The results for mortality in the first part of the study, with the note that the results could be underestimated, together with no consistent effect of paraffin addition, are used for the 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	*20-11-2007*
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.	7.5.4.1 / 08	Acute toxicity to honey bees and other beneficial arthropods, for example predators
91/414 Annex Point addressed	II 8.3.2	Other arthropods: Acute toxicity

		Official use only
Reference point (location) in dossier	**7.5.4.1/08**	
Title:	A semi-field test to determine the effects of MK 936 EC 018 (A-8612 A) on the parasitic wasp *Aphidius colemani*	
Project/Report number:	992669/ NOV-99-16	
Author(s):	Vinall, S.	
Date of report:	29/03/2000	
Published:	Not published	
Testing facility:	Agrochemical Evaluation Unit, Southampton University, England	
Study dates	Not stated.	
GLP:	Yes.	
Deficiencies:	None.	
Reliability indicator	1.	

Reference/notifier	:	Vinall, S. (2000)	GLP statement	:	yes
Type of study	:	toxicity non-target arthropods, semi-field	Guideline	:	Barrett et al. (1994)
Year of execution	:	2000	Acceptability	:	acceptable
Test substance	:	A-8612 A, abamectin EC (19.46 g/L), batch [redacted]			

Substance	Species	Method	Dose [g as/ha]	Age of residue [d]	Number of applications	Duration [d]	Parameter	Reduction [%]
A-8612 A	*Aphidius colemani*	semi-field	0.20-0.73	0	1	15	survival	67
							reproduction	62
A-8612 A	*Aphidius colemani*	semi-field	2.48-9.11	0	1	15	survival	77
							reproduction	80
A-8612 A	*Aphidius colemani*	semi-field	0.20-0.73	0	2	15	survival	13
							reproduction	39
A-8612 A	*Aphidius colemani*	semi-field	2.48-9.11	0	2	15	survival	86
							reproduction	54
A-8612 A	*Aphidius colemani*	semi-field	0.20-0.73	0	4	15	survival	34
							reproduction	0
A-8612 A	*Aphidius colemani*	semi-field	2.48-9.11	0	4	15	survival	84
							reproduction	26
A-8612 A	*Aphidius colemani*	semi-field	0.20-0.73	3	4	15	survival	29
							reproduction	-9
A-8612 A	*Aphidius colemani*	semi-field	2.48-9.11	3	4	15	survival	32
							reproduction	-34
A-8612 A	*Aphidius colemani*	semi-field	0.20-0.73	7	4	15	survival	-40
							reproduction	6
A-8612 A	*Aphidius colemani*	semi-field	2.48-9.11	7	4	15	survival	3
							reproduction	-11

Description

The effect of A-8612 A on the survival and reproduction of *Aphidius colemani* was determined under semi-field conditions. Four applications, with an application interval of 7 days, were conducted at two different concentrations, using a calibrated sprayer. Tomato plants were treated to the point of run-off. Concentrations equivalent to 0.973 g and 0.078 g as/hL (50 mL and 4 mL product/hL). The spray volumes applied to the test plants on each occasion were recorded. A water treated control and a toxic reference (dimethoate) were included. Applications were made on four occasions at weekly intervals (times T1, T2, T3, and T4). Bioassays were carried out at T1, T2, T4, T4+3 days, and T4 + 7 days. The day before the bioassays T1, T2 and T4 were initiated, the plants were lightly sprayed with a fructose solution. The plants used in the persistence bioassays (T4+3 days and T4 + 7 days) were not treated with fructose solution prior to the release of wasps. Wasp-proof cages were placed over eight individual tomato plants from each treatment. Approximately 1 h after treatment, fifty wasps (less then 48 h old) were released into each cage. Two separate bioassay types were carried out, one to assess the survival/activity of the wasps and one to assess the reproductive capacity, each using four of the eight caged replicates available per treatment. To assess the survival/activity of wasps (in four replicate cages per treatment) yellow sticky traps were placed in each cage between 1 and 3 days after the wasps were first introduced. The number of *A. colemani* caught on the traps was recorded.
For the reproductive capacity untreated aphid-infested radish plants were placed into the cages ca. 4 h after the wasps had been released. The radish plants were removed the following day. Additional fecundity plants were placed in the cages and removed daily up to 3 days after the wasps had first been introduced. The radish plants were transferred to a controlled environment room and the numbers of parasitised aphids that developed on them was assessed 8-12 days later.

Results

Planting density for tomatoes in commercial crops range from 17000-26000 bushes per ha. At the lowest densities, 8 bushes would nominally occupy 4.7 m^2 and the estimated volume application rates are calculated on the basis of this area. The spray volumes applied to the test plants were estimated to be equivalent to between 255 and 936 L/ha. This corresponds to application rates ranging from 2.48-9.11 g as/ha for the 0.973 g as/hL treatment and from 0.20-0.73 g as/ha for the 0.078 g as/hL treatment. Activity measurements and fecundity assessments are summarised in the two tables below.

Table: Mean number of wasps caught on sticky traps during the period 1-3 days after the wasps were introduced.

Treatment [g as/hL]	Treatment [g as/ha]	number of applications	age of residue [d]	Mean number of wasps per sticky trap[1]		% change relative to the control
control		1	0	16.3	a	-
0.078	0.20-0.73			5.3	b	-67
0.973	2.48-9.11			3.8	b	-77
dimethoate	102-374			1.0	b	-94
control		2	0	17.3	a	-
0.078	0.20-0.73			15.0	a	-13
0.973	2.48-9.11			2.5	b	-86
dimethoate	102-374			0.0	[2]	-100
control		4	0	22.5	a	-
0.078	0.20-0.73			14.8	ab	-34
0.973	2.48-9.11			3.5	bc	-84
dimethoate	102-374			0.8	c	-96
control		4	3	18.7	a	-
0.078	0.20-0.73			13.3	a	-29
0.973	2.48-9.11			12.7	a	-32
dimethoate	102-374			0.0	[2]	-100
control		4	7	14.3	a	-
0.078	0.20-0.73			20.0	a	40
0.973	2.48-9.11			13.8	a	-3
dimethoate	102-374			0.3	b	-98

1: Treatments that did not differ significantly are indicated with the same letter
2: Treatment excluded from analyses, due to absence of variance

Table: Mean number of aphid mummies that developed on three sets of aphid-infested fecundity plants present in the cage for three days

Treatment [g as/hL]	Treatment [g as/ha]	number of applications	age of residue [d]	Mean number of mummies per replicate[1]		% change relative to the control
control		1	0	423.5	a	-
0.078	0.20-0.73			159.0	b	-62
0.973	2.48-9.11			86.8	b	-80
dimethoate	102-374			69.3	b	-84
control		2	0	260.3	a	-
0.078	0.20-0.73			158.8	ab	-39
0.973	2.48-9.11			120.0	ab	-54
dimethoate	102-374			29.3	b	-89
control		4	0	234.0	a	-
0.078	0.20-0.73			234.0	a	0
0.973	2.48-9.11			173.8	ab	-26
dimethoate	102-374			136.8	b	-42
control		4	3	266.0	ab	-
0.078	0.20-0.73			289.7	ab	+9
0.973	2.48-9.11			356.3	a	+34
dimethoate	102-374			198.0	b	-26
control		4	7	62.8	a	-
0.078	0.20-0.73			59.0	a	-6
0.973	2.48-9.11			69.8	a	+11
dimethoate	102-374			17.0	b	-73

1: Treatments that did not differ significantly are indicated with the same letter

Only in the T1 bioassay the reductions in fecundity of the A-8612 A treatments, differed significantly from the control.

Remarks by RMS

In the T2 fecundity assessment bioassay, the plants introduced for the period 2-3 days did not survive in good condition to allow assessments of the number of parasitised aphids 10 days later. Therefore, the figures for the mean parasitisation per replicate for all treatments in this bioassay are based on just two sets of plants, and not three. This is considered not to have an adverse influence on the assessment or interpretation of treatments in this bioassay. Despite low trapping efficiency in the control (29-45%),

significant effects on activity were found at the highest treatment level without ageing. Effect disappeared when the wasps were exposed to 3 day old residue. At the lowest treatment level the effect of repeated applications was not clear. The results presented in the header are used for the 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	*20-11-2007*
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.	7.5.5	Bioconcentration, terrestrial

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE *20-11-2007* [redacted]	
Date Evaluation of applicant's justification Conclusion Remarks	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

98/8 Doc IIIA section No.	7.5.5.1	Bioconcentration, further studies

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE *20-11-2007* [redacted]	
Date Evaluation of applicant's justification Conclusion Remarks	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

98/8 Doc IIIA section No.	7.5.6	Effects on other terrestrial non-target organisms

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [×] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	EVALUATION BY RAPPORTEUR MEMBER STATE *20-11-2007* [redacted]	
Date Evaluation of applicant's justification Conclusion Remarks	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

98/8 Doc IIIA section No.	7.5.7	Effects on mammals *(headline)*

98/8 Doc IIIA section No.	7.5.7.1	For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment *(headline)*

98/8 Doc IIIA section No.	7.5.7.1. 1	Acute oral toxicity

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [×] 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	*20-11-2007*	
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.	**7.5.7.1. 2**	**Short-term toxicity**

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [×] **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	*20-11-2007*	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		

Evaluation of applicant's justification Conclusion Remarks