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Document Title

Summary of the ecotoxicological studies

Thiacloprid OD 240 (240 g/L)

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013
Document MCP
Section 10: Ecotoxicological studies

According to the guidance document, SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance

Date

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Bayer CropScience

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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Introduction

The representative formulation submitted in the first Annex I listing process is no longer considered as a representative formulation for the renewal of thiacloprid. One of the representative formulations used for the submission of the renewal of the approval of thiacloprid is the spray formulation Thiacloprid OD 240. The summaries of formulation studies and the risk assessment will be presented in this Dossier.

Ecotoxicological endpoints used in the following risk assessment were derived from studies with the formulated product Thiacloprid OD 240, the active substance thiacloprid and the metabolites listed in the residue definition for risk assessment.

In this Dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for thiacloprid and its metabolites please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the Annex I inclusion process, the previously evaluated information is written in grey letters.

Use pattern considered in this risk assessment

Table CP 10- 1: Intended application pattern

Crop	F G or I (b)	Application				Application rate per treatment			Remarks:
		method kind (f-h)	growth stage & season (i)	number min max (k)	interval between applications (min)	g a.s./hl min max	water L/ha min max	g a.s./ha min max	(m)
Oil Seed Rape	F	Foliar spray	BBCH 30-59	1-2	10	24-72	100-300	72	Product label rate: Max. 0.3 L/ha

Definition of the residue for risk assessment for thiacloprid

Due to changes in triggers for metabolites to be further assessed as well as new studies on the route of degradation in various environmental compartments, additional metabolites are proposed to be included in the residue definition for the risk assessment. Accordingly, studies have been prepared to describe the ecotoxicological profile of these metabolites in the relevant environmental compartments. The residue definition is included in Table CP 10- 2.

Table CP 10- 2: Definition of the residue for risk assessment*

Compartment	Residue Definition for Risk Assessment
Soil	Thiacloprid, Thiacloprid amide, Thiacloprid sulfonic acid, Thiacloprid des-cyano
Groundwater	Thiacloprid, Thiacloprid amide, Thiacloprid sulfonic acid, Thiacloprid des-cyano, Thiacloprid sulfonic acid amide, Thiacloprid thiadiazine
Surface water	Thiacloprid, Thiacloprid amide, Thiacloprid sulfonic acid, Thiacloprid des-cyano
Sediment	Thiacloprid
Air	Thiacloprid

*Justification for the residue definition for risk assessment is provided in MCA Sec.7, Point 7.4.1 and MCA Sec. 6, Point 6.7.1.

A list of metabolites, which contains the structures, the synonyms and code numbers attributed to the compound thiacloprid, is presented in Document N3 of this dossier.

CP 10.1 Effects on birds and other terrestrial vertebrates

The risk assessment has been performed according to "European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438), referred to in the following as "EFSA GD 2009".

CP 10.1.1 Effects on birds

Table CP 10.1.1- 1: Endpoints used in Tier 1 risk assessment

Test substance	Exposure	Species	Endpoint	Reference
Thiacloprid	Acute risk assessment endpoint	Geomean LD_{50} from 4 species	**LD_{50} 311 mg a.s./kg bw** [1)]	See Table CA8.1-1
	Reproductive risk assessment endpoint	*Anas platyrhynchos* (Mallard duck)	NOEC 140 mg a.s./kg diet [2)] ≡ **NOEL 11.0 mg a.s./kg bw/d**	[redacted] 1997 M-002265-01-1 KCA 8.1.1.3 /03

[1] the previous EU endpoint (49 mg/kg bw) was based on LD_{50} in Japanese quail; used endpoint representing the geomean of 4 LD_{50} values generated on thiacloprid (acc. to EFSA GD 2009)
[2] previous EU endpoint (60 ppm) based on effects on adult bodyweight and nominal concentrations; used endpoint (140 ppm) is based on effects on offspring and measured concentrations according to EFSA GD 2009 (see also, [redacted]; A.; 2005; M-256668-02-1, KCA 8.1.1.3/4)

Table CP 10.1.1- 2: Relevant generic avian focal species for risk assessment on Tier 1 level according to EFSA GD (2009)

Crop scenario	Scenario	Generic focal species	Representative species	Short cut values for reproductive RA based on	
				RUD_{90}	RUD_m
OSR 2 × 0.072 kg/ha BBCH 30-59 10d interval	late – late (with seeds) (BBCH 30- 99)	Small insectivorous bird "dunnock"	Dunnock (*Prunella modularis*)	**7.4**	**2.7**
	BBCH 30 - 39	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	**7.2**	**3.3**
	BBCH ≥ 40	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	6.0	2.7
	BBCH 30 - 39	Medium herbivorous/granivorous bird "pigeon"	Wood pigeon (*Columba palumbus*)	**2.4**	**1.1**
	BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	Wood pigeon (*Columba palumbus*)	2.0	0.9

Bold: Species considered in risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.1- 3: Tier 1 acute risk assessment for birds

Crop scenario	Generic focal species	DDD			DDD	LD_{50} [mg a.s./kg bw]	TER_A	Trigger
		Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}				
Thiacloprid								
OSR late – late (with seeds) (BBCH 30- 99)	Small insectivorous bird "dunnock"	0.072	7.4	1.3	0.7	311	449	10
OSR BBCH 30 - 39	Small omnivorous bird "lark"		7.2		0.7		461	
OSR BBCH 30 - 39	Medium herbivorous/granivorous bird "pigeon"		2.4		0.2		1384	

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

Acute risk assessment for birds drinking contaminated water from pools in leaf whorls

In the EFSA GD (2009), section 5.5, step 1 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mammals:
Leaf scenario: Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.
Puddle scenario. Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.
For the crop under assessment in this evaluation (oilseed rape) the leaf scenario is not considered relevant. The risk for birds from drinking water in puddles is addressed in Table CP 10.1.1- 5.

LONG-TERM REPRODUCTIVE ASSESSMENT

Table CP 10.1.1- 4: Tier 1 reproductive risk assessment for birds

Crop	Generic focal species	DDD				DDD	NOEL [mg a.s./ kg bw/d]	TER_{LT}	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Thiacloprid									
OSR late – late (with seeds) (BBCH 30- 99)	Small insectivorous bird "dunnock"	0.072	2.7	1.5	0.53	0.2	11	71.2	5
OSR BBCH 30 - 39	Small omnivorous bird "lark"		3.3			0.2		58.2	
OSR BBCH 30 - 39	Medium herbivorous/granivorous bird "pigeon"		1.1			0.1		174.7	

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, the risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

Long-term risk assessment for birds drinking contaminated water in puddles

Table CP 10.1.1- 5: Evaluation of potential concern for exposure of birds drinking water (escape clause)

Crop	Koc [L/kg]	Application rate * MAF [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Thiacloprid						
OSR	615	1.5 * 72	11	9.8	≤ 3000	No concern

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds feeding on contaminated prey like fish or earthworms. For organic chemicals, a log P_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.
Thiacloprid, however, has a log P_{OW} of 1.4 indicating a very low risk of bioaccumulation and, hence, secondary poisoning. A risk assessment is not deemed necessary.

CP 10.1.1.1 Acute oral toxicity

No additional studies are available or required as the toxicity can be derived from the studies on the active substance.

CP 10.1.1.2 Higher tier data on birds

The risk assessment indicates no risk at Tier 1; hence no higher tier studies are triggered. However additional data is presented to support the shorter half-life of thiacloprid on plant matrices following spray treatment. During the Annex I inclusion a half-life of 5.8 days was concluded based on a study

on alfalfa foliage, and this data was used for refinement of the bird risk assessment, the following studies broaden the database for the half-life determination and show that the half-life is lower than previously concluded. This data has previously been used for national registrations for refinement of the risk assessment and is also used for refinement of the non-target arthropod risk assessment and may be required for additional crops.

Report:	[redacted]8; [redacted]; 2012; M-416527-02-1
Title:	Statement on residues of thiacloprid in leafy vegetables: kinetic evaluation
Report No.:	MEF-11/835
Document No.:	M-416527-02-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Objective:
This statement provides kinetic evaluation of the residues of thiacloprid in leafy vegetables as available from various plant residue studies.

Methods:
Kinetic evaluation was conducted using SFO kinetics. The best fitting values of the kinetic parameters were determined by a numerical optimization process. Using non-linear least square fitting algorithms the parameter values leading to the smallest deviations between observed and calculated residues were determined. Apart from the kinetic rates k also the initial amount was fitted. Dissipation half-lives (DT_{50}) were calculated from the dissipation rates k, as $DT_{50} = ln(2) / k$.
The model fit was evaluated by visual inspection. A statistical measure of the quality of a fit was given by a χ^2–test. A t-test was employed to identify the probability that a parameter is not significantly different from zero

Results:
In cases where the original residue data contained the value of <0.01, the following procedure was employed. In the first occurrence the value was replaced by 0.01. In the second occurrence, the value was replaced by 0.005. All subsequent occurrences were replaced by the value of zero.

Findings:

Table CP 10.1.1.2- 1: DT_{50} values for thiacloprid and results of the statistical analysis - scaled error (ε) and significance of the dissipation rate (t-prob) for single first-order kinetic model

Trial code[#]	Trial Study number - Country	Crop	DT_{50} [days]	ε [%]	t-prob.	Study reference
R01	RA-2036/03 Germany	Round cabbage	8.04	7.74	0.0178	M-091154-01-1
R02	RA-2036/03 France	Red cabbage	2.13	8.46	0.0099	M-091154-01-1
R03	RA-2506/04 France	Red cabbage	3.76	4.61	0.0033	M-262857-01-1
R04	RA-2506/04 Germany	Round cabbage	0.88	5.97	0.0089	M-262857-01-1
R05	RA-2507/04 Germany	Curly kale	1.21	10.78	0.0203	M-262958-01-1
R06	RA-2560/05 France	Lettuce head	4.03	8.92	0.0119	M-273640-01-1
R07	RA-2560/05 UK	Lettuce head	1.05	8.77	0.0268	M-273640-01-1
R08	RA-2560/05 Germany	Lettuce head	5.21	2.51	0.0291	M-273640-01-1
R09	RA-2560/05 Belgium	Lettuce head	0.70	2.93	0.0353	M-273640-01-1
R10	RA-2038/03 Germany	Curly kale	3.46	13.96	0.0249	M-241697-01-1
R11	RA-2515/04 Germany	Head cabbage	0.97	6.36	0.0085	M-257513-01-1
R12	RA-2515/04 Germany	Head cabbage	1.02	2.75	0.0014	M-257513-01-1
R13	RA-2554/05 Portugal	Red cabbage	1.95	10.31	0.0335	M-284299-01-1
R14	RA-2554/05 Italy	Round cabbage	4.20	5.61	0.0421	M-284299-01-1
R15	RA-2535/06 France	Red cabbage	7.00	0.00	<0.0001	M-289566-01-1
R16	RA-2535/06 Spain	Round cabbage	4.10	5.58	0.0032	M-289566-01-1
R17	RA-2561/05 France	Lettuce	2.96	9.27	0.0100	M-277957-01-1
R18	RA-2561/05 Italy	Lettuce	1.55	4.47	0.0027	M-277957-01-1
R19	RA-2555/05 Italy	Chinese cabbage	1.57	3.03	0.0051	M-284167-01-1
R20	RA-2555/05 Italy	Chinese cabbage	4.77	4.63	0.0349	M-284167-01-1
		Minimum	0.70			
		Maximum	8.04			
		Average	3.04			
		Median	2.55			
[#] Code used in the kinetic evaluation statement						

Conclusion:

The mean DT_{50} is 3.02 days, the median 2.63 days.

Report:	[redacted]; [redacted]; [redacted]; 2013; M-453083-01-1
Title:	Statement on residue dissipation of thiacloprid in treated foliage of winter cereals: kinetic evaluation
Report No.:	EnSa-13-0275
Document No.:	M-453083-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Objective:

This statement provides kinetic evaluation of the residues of thiacloprid in green parts of monocotyledonous plants (wheat, barley).

Material and Methods:

Residue decline data were evaluated using the following kinetic models: Single First-Order (SFO), and Dual First Order in Parallel (DFOP).

The best fitting values of the kinetic parameters in the equations were determined by a numerical optimization process. Using non-linear least square fitting algorithms the parameter values leading to the smallest deviations between observed and calculated residues were determined. Apart from the kinetic rates k also the initial amount was fitted.
Degradation half-lives (DT_{50}) were calculated from the degradation rates k, as $DT_{50} = \ln(2) / k$

In cases where the original residue data contained the value of <0.01, the following procedure was employed. In the first occurrence the value was replaced by 0.01. In the second occurrence, the value was replaced by 0.005. All subsequent occurrences were replaced by the value of zero

The model fit was evaluated by visual inspection. A statistical measure of the quality of a fit was given by a χ^2–test. A t-test was employed to identify the probability that a parameter is not significantly different from zero

Results:
Evaluation of biphasic kinetic models was either not deemed necessary or lead to insignificant degradation rates. Results are presented below

Table CP 10.1.1.2- 2: DT_{50} values for thiacloprid and results of the statistical analysis - scaled error (ε) and significance of the dissipation rate (t-prob) for single first-order kinetic model

Trial code	Trial description	Crop	DT_{50} [days]	ε [%]	t-prob.	Study reference
R01	11-2957-01	wheat green plant	1.95	20.9	0.007	
R02	11-2957-02	wheat green plant	3.32	10.31	0.001	
R03	11-2957-03	barley green plant	4.84	8.697	0.001	
R04	11-2957-04	barley green plant	2.25	10.06	< 0.001	
		geometric mean	2.90			

Conclusion
The geometric mean DT_{50} is 2.90 days

Plant residue studies referred to in M-416527-02-1 and M-453083-01-1

The kinetic evaluation considered data from a number of plant residue trials which are summarised below, only data included in the kinetic evaluation is summarised.

The following residue studies are used for the determination of the half-life of thiacloprid as described above. As the studies do not concern the representative use they are not included in the residue chapter of this supplemental dossier, hence brief summaries of the data relevant for the half-life determination of thiacloprid are presented here.

Report:	[redacted]:;[redacted];[redacted]; 2004; M-091154-01-1
Title:	Determination of the residues of thiacloprid in/on round cabbage and red cabbage after spraying of Calypso (240 OD) in the field in northern France and Germany
Report No.:	RA-2036/03
Document No.:	M-091154-01-1
Guidelines:	**Not available**
GLP/GEP:	**yes**

Objective:

The purpose of the presented study was to determine the magnitude of residues of thiacloprid in/on round cabbage and red cabbage harvested after spray application with Calypso (240 OD) to round cabbage and red cabbage in Northern France and Germany.

Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and methods:

For spray application the formulation Calypso (240 OD) was used. Calypso (240 OD) is an oil-based dispersion concentrate, containing 240 g/L thiacloprid. The product was used twice with an application rate of 0.4 L/ha and 400 – 600 L water per ha, corresponding to a spray concentration of 0.067 – 0.1% and 0.096 kg/ha active substance (a.s.) thiacloprid. The applications were carried out at growth stages 44 to 49 (corresponding to intervals of 10 days).

For residue analysis, samples were taken from the treated and the control plots. In order to obtain representative samples of the raw commodity, head samples were taken at random from various parts of the treated and the control plot.

In the trials R 2003 0285/1 and R 2003 0288/6 heads were sampled before the last spray application and on day 0, day 3, day 7 and day 14 after the last spray application.

Residues of thiacloprid in/on round cabbage (head) and red cabbage (head) were determined according to method 00548/E004. The Limit of Quantitation (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg for thiacloprid in/on round cabbage (head) and red cabbage (head).

Results:

The single recovery values range from 91 to 100% and the overall recoveries are 98 (round cabbage) and 92% with relative standard deviations of 2.2 and 1.2% (n = 6). All results of the method validation are in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.

No residues of thiacloprid above the LOQ of 0.01 mg/kg were found in any of the control samples.

On day 0 after the last application the residues of thiacloprid in/on round and red cabbage (head) are in the range from 0.03 to 0.22 mg/kg and declined to < 0.01 to 0.05 mg/kg after 14 days.

Table CP 10.1.1.2- 3: Residue values determined following spray application of Thiacloprid 240OD on cabbage in study RA-2036/03

Trial No.	DALT[#]	Sample Material	Residues of Thiacloprid Rounded Values [mg/kg]
R 2003 0285/1 Germany (Round Cabbage)	0*	Head	0.04
	0	Head	0.22
	3	Head	0.19
	7	Head	0.14
	14	Head	0.05
R 2003 0288/6 France (Red Cabbage)	0*	Head	0.01
	0	Head	0.03
	3	Head	< 0.01
	7	Head	< 0.01
	14	Head	0.01

DALT: days after last treatment, *: Before the last treatment

Report: [redacted]; 2005; M-262857-01-1

Title: Determination of the residues of YRC 2894 in/on red cabbage and round cabbage after spraying of Calypso (240 OD) in the field in Germany and Northern-France

Report No.: RA-2506/04

Document No.: M-262857-01-1

Guidelines: **EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; not specified**

GLP/GEP: **yes**

Objective:

The purpose of the presented study was to determine the magnitude of residues of YRC 2894 in/on heads harvested after two spray applications with Calypso (240 OD) on red cabbage and round cabbage in Northern Europe (*Germany* and Northern France).

Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and methods:

The first application at 0.4 L/ha and 400 - 600 L water per ha about 17 days before the expected harvest, the second application at 0.4 L/ha and 400 - 600 L water per ha about 7 days before the expected harvest (desired waiting period). Samples were taken before the second applications and at 0, 3, 7 and 14 days after the second application.

YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and dilution of the extract, the residues were quantified by reversed phase HPLC with Electrospray and MS/MS-detection. The quantification was done using YRC 2894-D2 as stable-labelled internal standard.

The Limit of Quantification (LOQ) for YRC 2894 (thiacloprid), defined as the lowest validated fortification level was 0.01 mg/kg for red cabbage and round cabbage (head).

Results:

Table CP 10.1.1.2- 4: Application and Residue Summary in Red cabbage in Region Northern Europe, (Study RA-2506/04)

Country Trial No.	Portion Analysed	DALT	Residues [mg/kg] YRC 2894 (Thiacloprid)
Northern	head	0*	0.03
France	head	0	0.16
R 2004 0223/6	head	3	0.10
	head	7	0.04
	head	14	0.01
Germany	head	0*	< 0.01
R 2004 0224/4	head	0	0.11
	head	3	0.01
	head	7	< 0.01
	head	14	< 0.01

* = Before the last treatment, DALT = Days After Last Treatment, a.s. = Active Substance

The mean of the concurrent recoveries were for all matrices and for all fortification levels, within the acceptable range of 70 – 110%. Consequently, all the results are considered as valid.

Report: [redacted]S; [redacted]; [redacted]; [redacted]; 2005; M-262958-01-1

Title: Determination of the residues of YRC 2894 in/on curly kale after spraying of Calypso (240 OD) in the field in Germany

Report No.: RA-2507/04

Document No.: M-262958-01-1

Guidelines: **EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; not specified**

GLP/GEP: **yes**

Objective:

The purpose of this study was to determine the magnitude of residues of YRC 2894 in/on curly kale harvested after two spray applications with Calypso (240 OD) : the first and second applications at 0.4 L/ha and 600 L water per ha about 17 days and 7 days (desired waiting period) before the expected date of harvest.

The study comprises one field trial in Northern Europe (Germany).

Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and Methods:

One field trial was conducted with Calypso (240 OD). For spray application the formulation Calypso (240 OD) was used, an oil-based dispersion concentrate formulation, containing 240 g/L of active substance (a.s.) YRC 2894. The product was used two times with an application rate of 0.4 L/ha and 600 L water per ha, corresponding to a spray concentration of 0.067% and 0.096 kg/ha of active substance (a.s.) YRC 2894.

The applications were carried out at growth stages 46 - 47 (corresponding to interval of about 10 days) with the last application 7 days prior to the expected date of harvest (desired waiting period).

For residue analysis, samples were taken from the treated and the control plots. In order to obtain representative samples of the raw commodity, samples were taken at random from various parts of the treated and the control plot.
Samples were taken from the treated plot on day 0 before the last application and on days 0, 3, 7 and 14 after the last spray application, only treated samples were taken.
Residues of YRC 2894 (thiacloprid) were determined by LC-MS/MS according to method 00548/M001.
YRC 2894 (thiacloprid) residues were extracted from 5 g sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and dilution of the extract, the residues are quantified by reversed phase HPLC with Electrospray and MS/MS-detection. The quantification was done using YRC 2894-D2 as stable-labelled internal standard.

Results:
The Limit of Quantification (LOQ) for YRC 2894 (thiacloprid), defined as the lowest validated fortification level, was 0.01 mg/kg in/on curly kale (whole plant without roots).
The obtained recovery values show the validity of the methods used.
Residues of YRC 2894 in/on curly kale were 1.3 mg/kg on day 0 after the last application. The residues decreased then to 0.12 mg/kg at the proposed date of harvest, 7 days after the last application.
Residues of YRC 2894 in the control samples were below the LOQ.

Table CP 10.1.1.2- 5: Analytical Results of Treated Samples for YRC 2894 (thiacloprid)

Trial No.	DALT	Sample Material	Residues of YRC 2894 (thiacloprid) [mg/kg]
R 2004 0227/9 Germany, V6-09	0*	whole plant without roots	0.05
	0	whole plant without roots	1.3
	3	whole plant without roots	0.21
	7	whole plant without roots	0.12
	14	whole plant without roots	0.05

DALT: days after last treatment.
0* : 0 day before the last treatment

Report: [redacted]; 2006; M-273640-01-1
Title: Determination of the residues of YRC 2894 and Deltamethrin in/on lettuce after spraying of Proteus (110 OD) in the field in Northern France, Germany, United Kingdom and Belgium
Report No.: RA-2560/05
Document No.: M-273640-01-1
Guidelines: **EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; not specified**
GLP/GEP: **yes**

Objective:
The purpose of the presented study was to determine the magnitude of residues of thiacloprid (YRC 2894) and deltamethrin (RE F032640) in/on lettuce harvested after three spray applications with Proteus (110 OD). The study was comprised of four field residue trials carried out in Northern Europe (Northern France, Germany, United Kingdom, and Belgium).
Only data relevant for the calculation of the DT_{50} for thiacloprid is summarised below.

Material and methods:

Three applications were scheduled to be done 21, 14, and 7 days prior to the expected date of harvest, each with a product application rate of 0.75 L/ha and a water rate of 600 L/ha. Samples were taken at 0,3 and 7 days after the last treatment at all sites as well as before last treatment and 14 days after treatment in France and the UK.

Residues of YRC 2894 (thiacloprid) were determined by HPLC-MS/MS according to method 00548/M001/E006.

YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After filtration and adding of the internal standard by dilution of the sample, the residues were quantified by reversed phase HPLC on a TURBO ODS-3 GOLD column, with Electrospray and MS/MS-detection (Applied Biosystems API 4000 Triple Quadruple Mass Spectrometer). The quantification was done using YRC 2894-D2 as stable-labelled internal standard.

The Limit of Quantification (LOQ), defined as the lowest validated fortification level was set at 0.01 mg/kg for thiacloprid in lettuce (head).

The Limit of Quantification (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg in/on lettuce (head).

Results:

The mean of the concurrent recoveries were for all matrices and for all fortification levels, within the acceptable range of 70 – 110%. Consequently, all the results are considered as valid.

Table CP 10.1.1.2- 6: Application and residue summary in lettuce in Northern Europe

Country	Portion Analysed	DALT	Residues [mg/kg]
Trial No.			Thiacloprid (YRC 2894)
France	head	0*	0.44
R 2005 0391/1	head	0	2.0
Lettuce	head	3	1.4
	head	7	0.50
	head	14	0.14
United Kingdom	head	0*	0.15
R 2005 0948/0	head	0	3.0
Lettuce	head	3	0.38
	head	7	0.21
	head	14	0.07
Germany	head	0	2.5
R 2005 0393/8	head	3	1.8
Lettuce	head	7	1.0
Belgium	head	0	1.4
R 2005 0949/9	head	3	0.07
Lettuce	head	7	0.03

DALT = Days After Last Treatment * = Before the Last Treatment

Report:	[redacted],;[redacted];[redacted]; 2004; M-241697-01-1
Title:	Determination of the residues of thiacloprid in/on Chinese cabbage and curly kale after spraying of Calypso (240 OD) in the field in Great Britain and Germany
Report No.:	RA-2038/03
Document No.:	M-241697-01-1
Guidelines:	**Not available**
GLP/GEP:	**yes**

Objective:
The purpose of the presented study was to determine the magnitude of residues of thiacloprid in/on Chinese cabbage and curly kale after spraying of Calypso (240 OD) to Chinese cabbage and curly kale plants in Great Britain and Germany.
Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables (curly kale) is summarised.

Material and methods:
For spray application the formulation Calypso (240 OD) was used. Calypso (240 OD) is an oil-based dispersion concentrate, containing 240 g/L thiacloprid. The product was used twice with an application rate of 0.4 L/ha and 600 L water per ha, corresponding to a spray concentration of 0.067% and 0.096 kg/ha active substance (a.s.) thiacloprid. The applications were carried out at growth stages 44 to 47 (corresponding to intervals of 10 days) with the last application 7 days prior to the expected date of harvest (desired waiting period).
For residue analysis, samples were taken from the treated and the control plots. In order to obtain representative samples of the raw commodity with Chinese cabbage and curly kale samples were taken at random from various parts of the treated and the control plot.
In the trial R 2003 0290 8 curly kale, whole plant without roots was sampled before the last spray application and on the days 0, 3, 7 and 14 after the last spray application.
Residues of thiacloprid were determined according to method 00548/E004.

Results:
The individual recovery values range from 86 to 100% and the overall recovery is 95% with a relative standard deviation of 5.5% (n = 7). All results of the method validation are in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.
The Limit of Quantitation (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg for thiacloprid in/on Chinese cabbage and curly kale.

No residues of thiacloprid in/on curly kale (whole plant without roots) at or above the LOQ of 0.01 mg/kg were found in any of the control samples.
On day 0 after the last treatment the residues of thiacloprid in/on curly kale 1.4 mg/kg and declined to 0.1 mg/kg after 14 days.

Table CP 10.1.1.2- 7: Residue values determined following spray application of Thiacloprid 240OD on curly kale in study RA-2038/03

Trial No.	DALT	Sample Material	Sample Weight [g]	Residues of Thiacloprid Rounded Values [mg/kg]
R 2003 0290/8 Germany	0	Whole Plant without Roots	5	1.4
	3	Whole Plant without Roots	5	0.95
	7	Whole Plant without Roots	5	0.20
	14	Whole Plant without Roots	5	0.10

Report: [redacted]:[redacted]:2005; M-257513-01-1
Title: Determination of the residues of YRC 2894 (Thiacloprid) and Deltamethrin in on lettuce after spraying of Proteus (110 OD) in the field in Germany, United Kingdom and Northern France
Report No.: RA-2515/04
Document No.: M-257513-01-1
Guidelines: **Council Directive 91/414/EEC, Annex II, part A, section 6 and Annex III, part A, section 8; Not specified**
GLP/GEP: **yes**

Objective:

The purpose of the presented study was to determine the magnitude of residues of YRC 2894 (thiacloprid) and deltamethrin in/on lettuce heads harvested after three spray applications with Proteus (110 OD) in Northern Europe, more specifically in Germany, United Kingdom and Northern France. Four field trials were conducted with Proteus (110 OD).
Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and methods:

For spray application the formulation Proteus (110 OD) was used, an oil-based dispersion concentrate formulation, containing 100 g/L of YRC 2894 and 10 g/L of deltamethrin. The product was used three times with an application rate of 0.75 L/ha and 600 L water per ha, corresponding to a spray concentration of 0.125% and 0.075 kg/ha of active substance (a.s.) YRC 2894 and 0.008 kg/ha of active substance (a.s.) deltamethrin. The applications were carried out at growth stages between 16 - 43, 43 - 46 and 46 - 48 (corresponding to intervals of about 7 days) with the last application 7 days prior to the expected date of harvest (desired waiting period).
For residue analysis, samples were taken from the treated and the control plots. In order to obtain representative samples of the raw commodity, lettuce head samples were taken at random from various parts of the treated and the control plot.
For trials R 2004 0096/9 and R 2004 0268/6 lettuce head samples were taken from the treated and the control plot before the last treatment) and on day 0, 3, 7 and 13 or 14 after the last spray application.
Residues of YRC 2894 (thiacloprid) were determined by LC-MS/MS according to method 00548/M001/E006.
YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30). After centrifugation and dilution of the sample material, the residues are quantified by reversed phase HPLC with Electrospray and MS/MS-detection. The quantification was done using YRC 2894-D2 as stable-labelled internal standard.

The Limit of Quantification (LOQ) for YRC 2894 (thiacloprid), defined as the lowest validated fortification level, was 0.01 mg/kg in/on lettuce (head).

Results:
Residues of YRC 2894 (thiacloprid) on day 0 after the last application were between 0.98 and 1.5 mg/kg in/on lettuce samples.
No residues of YRC 2894 (thiacloprid) and deltamethrin at or above the respective LOQ were found in any of the control samples.

Table CP 10.1.1.2- 8: Analytical results of treated samples for YRC 2894 (thiacloprid) in lettuce

Trial No.	DALT	Sample Material	Residues of YRC 2894 (thiacloprid) [mg/kg]
R 2004 0096/9 Germany, VG08 Lettuce	0 *	head	0.05
	0	head	0.98
	3	head	0.11
	7	head	0.05
	13	head	< 0.01
R 2004 0268/6 Germany, VG09 Lettuce	0 *	head	0.15
	0	head	1.5
	3	head	0.19
	7	head	0.04
	14	head	0.01
DALT: days after last treatment, *: before the last treatment			

Report: [redacted]; [redacted]; 2007; M-284299-01-1
Title: Determination of the residues of YRC 2894 and deltamethrin in/on red cabbage and round cabbage after spraying of Proteus (110 OD) with additive biopower (026.6 SL) in the field in Portugal and Italy
Report No.: RA-2554/05
Document No.: M-284299-01-1
Guidelines: **ED-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 residues in or on treated products, food and feed; not specified**
GLP/GEP: **yes**

Objective:
The purpose of the presented study was to determine the magnitude of residues of YRC 2894 and deltamethrin in/on red and round cabbage harvested after two spray applications with Proteus (110 OD) with the additive Biopower (026.6 SL). The study was comprised of two field trials carried out in Portugal and Italy.
Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and methods:
Two applications were scheduled to be done 28 and 14 days prior to the expected date of harvest, each with a product application rate of 1 L/ha containing 0.1% of the additive Biopower and a water rate of 800 L/ha.
Samples were taken before the last treatment and at 0, 7 and 14 days after least treatment for both trials and at 21days after last treatment only in Portugal.
YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and dilution of the sample material, the residues were quantified by reversed phase HPLC on a TURBO-ODS-3 GOLD column, with Electrospray and MS/MS-detection (Applied Biosystems API 4000 Triple Quadruple Mass Spectrometer). The quantification was done using YRC 2894-D2 as stable-labelled internal standard.
The Limit of Quantification (LOQ), defined as the lowest validated fortification level , was 0.01 mg/kg in/on red and round cabbage (head).

Results:
The mean of the concurrent recoveries were for all matrices and for all fortification levels, within the acceptable range of 70 – 110%. Consequently, all the results are considered as valid.

Table CP 10.1.1.2- 9: Application and residue summary in red cabbage.

Country	Formulation Type	Portion Analysed	DALT	Residues [mg/kg]
Trial No.				**YRC 2894**
Portugal R 2005 0378/4 Red cabbage	110 OD	head*	-0	0.02
		head	0	0.14
		head	7	0.01
		head	14	0.01
		head	21	< 0.01
Italy R 2005 0379/2 Round cabbage	110 OD	head*	0	0.07
		head	7	0.02
		head	14	0.01

DALT = Days After Last Treatment, "* "= Before Last Treatment

Report: KCP 10.1.1.2.10 [redacted]; [redacted] 2007; M-289566-01-1
Title: Determination of the residues of YRC 2894 and deltamethrin in/on red cabbage and round cabbage after spraying of Proteus (110 OD) in the field in Southern France, Spain and Italy
Report No.: RA-2535/06
Document No.: M-289566-01-1
Guidelines: **EU-Ref; Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; not specified**
GLP/GEP: **yes**

Objective:
The purpose of the presented study was to determine the magnitude of residues of YRC 2894 and Deltamethrin in/on red cabbage and round cabbage harvested after two spray applications with Proteus (110 OD) on red cabbage and round cabbage in Southern Europe.

Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and methods:

Two applications were scheduled to be done between BBCH 41 and 47 with 14 day interval. The final application was scheduled to be 14 days before the anticipated harvest date.
In the red cabbage trial (France) and one of the round cabbage trials (Spain) samples were taken before the last treatment and at 0, 7 (8), 14 and 20 days after least treatment. In the Italian trial samples were taken at 0 and 14 days after the last treatment.
Residues of YRC 2894 (thiacloprid) were determined by HPLC-MS/MS according to method 00548/M001.
YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and dilution of the sample material, the residues were quantified by reversed phase HPLC on a TURBO ODS-3 GOLD column, with Electrospray and MS/MS-detection (Applied Biosystems API 3000 Triple Quadruple Mass Spectrometer). The quantification was done using YRC 2894-D2 as stable-labelled internal standard.
The Limit of Quantification (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg in/on red cabbage and round cabbage (head).

Results

The recoveries were, for all matrices and for all fortification levels, within the acceptable range of 69 – 117%.

Table CP 10.1.1.2- 10: Residue summary in red and round cabbage in Southern Europe

Country	Portion Analysed	DALT	Residues [mg/kg]
Trial No.			YRC 2894
Southern France R 2006 0174/3 Red cabbage	head	-0*	0.01
	head	0	0.04
	head	7	0.02
	head	14	< 0.01
	head	21	< 0.01
Spain R 2006 0175/1 Round cabbage	head	-0*	< 0.01
	head	0	0.04
	head	8	< 0.01
	head	14	< 0.01
	head	20	< 0.01

DALT = Days After Last Treatment, * = Days Before Last Treatment

Report:	KCP 10.1.1.2/11 [redacted],; [redacted]; 2006; M-277957-01-1
Title:	Determination of the residues of YRC 2894 and Deltamethrin in/on lettuce after spraying of Proteus (82.5 OD) in the field in Southern France and Italy
Report No.:	RA-2561/05
Document No.:	M-277957-01-1
Guidelines:	**EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; not specified**
GLP/GEP:	**yes**

Objective:
The purpose of the presented study was to determine the magnitude of residues of YRC 2894 and Deltamethrin in/on lettuce (head) in the field harvested after two spray applications of Proteus (82.5 OD) on lettuce, done in Southern Europe (Southern France and Italy).
Only data relevant for the determination of the DT_{50} of thiacloprid is summarised.

Material and methods
Two applications were scheduled to be done at 1.33 L/ha and 600 L water per ha with intervals of 7 days with the last application, 7 days prior to the expected date of harvest.
Samples in all trials were taken 0, 3 and 7 days after last treatment, additionally in one trial in France (R 2005 0394/6) and one trail in Italy (R 2005 0950/2) samples were taken before the last treatment and at 14 days after the last treatment.
Residues of YRC 2894 (thiacloprid) were determined by HPLC-MS/MS according to method 00548/M001/E006.
YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and adding of the internal standard by dilution of the sample, the residues were quantified by reversed phase HPLC on a PURBO ODS-3 GOLD column, with Electrospray and MS/MS-detection (Applied Biosystems API 4000 Triple Quadruple Mass Spectrometer). The quantification was done using YRC 2894-D2 as stable-labelled internal standard.
The Limit of Quantification (LOQ), defined as the lowest validated fortification level was set at 0.01 mg/kg for thiacloprid in/on lettuce (head).

Results:
The mean of the concurrent recoveries were for all matrices and for all fortification levels, within the acceptable range of 70 - 110%. Consequently, all the results are considered as valid.

Table CP 10.1.1.2- 11: Residue summary in lettuce in Southern Europe

Country	Portion Analysed	DALT	Residues [mg/kg]
Trial No.			Thiacloprid (YRC 2894)
France R 2005 0394/6 Lettuce	head	0*	0.06
	head	0	2.8
	head	3	1.6
	head	7	0.39
	head	14	0.01
Italy R 2005 0950/2 Lettuce	head	0*	< 0.01
	head	0	3.0
	head	3	0.74
	head	7	0.23
	head	14	0.02

DALT = Days After Last Treatment *= Before the Last Treatment

Report:	KCP 10.1.1.2/12[redacted],; 2007; M-284167-01-1
Title:	Determination of the residues of YRC 2894 and deltamethrin in/on Chinese cabbage after spraying of Proteus (110 OD) in the field in Italy
Report No.:	RA-2555/05
Document No.:	M-284167-01-1
Guidelines:	**EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8 Residues in or on Treated Products, Food and Feed; not specified**
GLP/GEP:	**yes**

Objective:

The purpose of the presented study was to determine the magnitude of residues of YRC 2894 and deltamethrin in/on Chinese cabbage harvested after two spray applications with Proteus (110 OD) and the additive Biopower (026.6 SL). The study was comprised of two field trials carried out in Italy. Only the residue data relevant for the determination of the half-life of thiacloprid on leafy vegetables is summarised.

Material and methods:

Two applications were scheduled to be done 28 and 14 days prior to the expected date of harvest, each with a product application rate of 1 L/ha and a water rate of 800 L/ha.
Sampling in trial R 2005 0380/06 was at 0 days before last treatment, and 0, 7, 14 and 21 days after last treatment. In trial R 2005/0381/4 sampling was at 0, 7 and 14 days after last treatment.
Residues of YRC 2894 (thiacloprid) were determined by HPLC-MS/MS according to method 00548/M001.
YRC 2894 (thiacloprid) residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and dilution of the sample material, the residues were quantified by reversed phase HPLC on a TURBO ODS-3 GOLD column, with Electrospray and MS/MS-detection (Applied Biosystems API 4000 Triple Quadruple Mass Spectrometer). The quantification was done using YRC 2894-D2 as stable-labelled internal standard.
The Limit of Quantification (LOQ), defined as the lowest validated fortification level , was 0.01 mg/kg in/on Chinese cabbage (head).

Results:

Table CP 10.1.1.2- 12: Application and residue summary in Chinese cabbage

Country / Trial No.	Portion Analysed	DALT	Residues [mg/kg] Thiacloprid YRC 2894
Italy R 2005 0380/6	head	-0*	0.02
	head	0	0.23
	head	7	< 0.01
	head	14	< 0.01
	head	21	< 0.01
Italy R 2005 0381/4	head	0	0.03
	head	7	< 0.01
	head	14	< 0.01

DALT = Days After Last Treatment, *= Days Before Last Treatment

Report:	KCP 10.1.1.2/13 [redacted],; 2012; M-439731-01-1
Title:	Determination of the residues of thiacloprid in/on barley and wheat after spray application of Thiacloprid OD 240 in Germany, southern France and the Netherlands
Report No.:	01/11/2957
Document No.:	M-439731-01-1
Guidelines:	**EU-Ref: Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, section 6 and Annex III, part A, section 8; Residues in or on Treated Products, Food and Feed; EC guidance working document 7029/VI/95 rev. 5 (1997-07-22) US EPA OCSPP Guideline No. 860.1500.SUPP; not specified**
GLP/GEP:	**yes**

Objective:

The purpose of the study 11-2957 was to determine the magnitude of the relevant residues of thiacloprid in/on wheat or barley (green material) after one spraying application with Thiacloprid OD 240 an OD formulation containing 240 g/L thiacloprid.
The study included four supervised residue trials conducted in northern Europe (Netherlands and Germany) and southern Europe (southern France) during the 2011 season.

Material and methods:

The actual application data are presented in the following table. This data reflects the intended application scheme, or, if minor deviations occurred, these were within the acceptable range.

Table CP 10.1.1.2- 13: Application summary

		Application						
Trial no. Country	**Formulation**	**Appl. mode**	**No. of appl.**	**Growth stage (BBCH code)**	**Test item rate (L/ha)**	**Water rate (L/ha)**	**a.s.**	**Appl. rate (kg a.s./ha)**
11-2957-01 Germany	Thiacloprid OD 240	SPI	1	29	0.4	300	thiacloprid	0.096
11-2957-02 France	Thiacloprid OD 240	SPI	1	29	0.4	300	thiacloprid	0.096
11-2957-03 Netherlands	Thiacloprid OD 240	SPI	1	29	0.4	300	thiacloprid	0.096
11-2957-04 Germany	Thiacloprid OD 240	SPI	1	29	0.4	300	thiacloprid	0.096

a.s.: Active substance, Appl.: Application, SPI: Spraying

Sampling was performed at 0, 1, 3, 5 7 and 10 days after last treatment.
Residues of Thiacloprid were determined by HPLC-MS/MS according to method 00548/M001. Thiacloprid residues were extracted from 5 g of sample material with a mixture of acetonitrile/water (70/30, v/v). After centrifugation and dilution of the sample material, the residues were quantified by reversed phase HPLC on an Uptisphere ODB C18, (150 x 2.0 mm, 3 µm) column, with Electrospray and MS/MS-detection. The quantification was done using stable-labelled internal standard of thiacloprid.
The Limit of Quantification (LOQ), defined as the lowest validated fortification level, was 0.01 mg/kg.

Results:

The average recoveries were within the acceptable range of 70 – 110%.

The level of residues of thiacloprid in the treated samples are summarised in the table below. No residues above the LOQ were found in the control samples. Results were not corrected for concurrent recoveries.

Table CP 10.1.1.2- 14: Residue summary in/on wheat or barley

Trial No. / Country	Crop / Sample material	DALT	Residues [mg/kg] thiacloprid
11-2957-01 Germany Wheat	Wheat / green material	0	2.6
	Wheat / green material	1	2.6
	Wheat / green material	3	0.74
	Wheat / green material	5	0.37
	Wheat / green material	7	0.18
	Wheat / green material	10	0.080
11-2957-02 France Wheat	Wheat / green material	0	3.3
	Wheat / green material	1	2.3
	Wheat / green material	3	1.3
	Wheat / green material	6	0.94
	Wheat / green material	7	0.7
	Wheat / green material	10	0.64
11-2957-03 Netherlands Barley	Barley / green material	0	4.2
	Barley / green material	1	4.2
	Barley / green material	3	2.6
	Barley / green material	5	1.8
	Barley / green material	7	1.6
	Barley / green material	10	1.4
11-2957-04 Germany Barley	Barley / green material	0	3.3
	Barley / green material	1	2.6
	Barley / green material	3	1.6
	Barley / green material	5	0.42
	Barley / green material	7	0.31
	Barley / green material	10	0.23

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Table CP 10.1.2- 1: Endpoints used in risk assessment

Test substance		species/origin	Endpoint		Reference
Thiacloprid	Acute risk assessment	Rat	$LD_{50\ (female)}$	315 mg a.s./kg bw	See MCA Table CA 8.1.2-1 M-495876-01-1
	Long-term risk assessment	Rat	NOEC NO(A)EL	300 ppm ≡ 21 mg a.s./kg bw/d	See MCA Table CA 8.1.2-1 M-495876-01-1

Table CP 10.1.2- 2: Relevant generic focal species for Tier 1 risk assessment

Crop	Scenario	Generic focal species	Representative species	Shortcut value	
				Long-term RA based on RUD_m	acute RA based on RUD_{90}
OSR	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole (*Microtus arvalis*)	**18.1**	**34.1**
	All season	Large herbivorous mammal “lagomorph”	Rabbit (*Oryctolagus cuniculus*)	**14.3**	**35.1**
	BBCH 30 - 39	Small omnivorous mammal “mouse”	Wood mouse (*Apodemus sylvaticus*)	**2.3**	**5.2**
	BBCH ≥ 40	Small omnivorous mammal “mouse”	Wood mouse (*Apodemus sylvaticus*)	1.9	4.3

Bold: Species considered in Tier 1 risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.2- 3: Tier 1 acute DDD and TER calculation for mammals

Crop	Generic focal species	DDD			DDD	LD_{50} [mg/kg bw]	TER_A	Trigger
		Appl. rate [kg/ha]	SV_{90}	MAF_{90}				
OSR BBCH ≥ 40	Small herbivorous mammal "vole"	0.072	34.1	1.3	3.2	315	99	10
OSR All season	Large herbivorous mammal “lagomorph”		35.1		3.3	315	96	10
OSR BBCH 30 - 39	Small omnivorous mammal “mouse”		5.2		0.5	315	647	10

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the a-priori acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

LONG-TERM REPRODUCTIVE ASSESSMENT

Table CP 10.1.2- 4: Tier 1 long-term DDD and TER calculation for mammals

Crop	Generic focal species	DDD				DDD	NO(A)EL [mg kg/bw/d]	TER_{LT}	Trigger
		Appl. rate [kg/ha	SV_m	MAF_m	f_{twa}				
OSR BBCH ≥ 40	Small herbivorous mammal "vole"	0.072	18.1	1.5	0.53	1.0	21	20	5
OSR All season	Large herbivorous mammal “lagomorph”		14.3			0.8	21	26	5
OSR BBCH 30 - 39	Small omnivorous mammal “mouse”		2.3			0.1	21	160	5

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, the risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

Long-term risk assessment for mammals drinking contaminated water

The puddle scenario is relevant for the long-term risk assessment.

Table CP 10.1.2- 5: Evaluation of potential concern for exposure of mammals drinking water

Crop	Koc [L/kg]	Application rate * MAF [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Thiacloprid						
OSR	615	1.5 * 72	21	5.1	**≤ 3000**	No concern

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a $\log_{POW} > 3$ is used to trigger an in depth evaluation of the potential for bioaccumulation. Thiacloprid, however, has a $\log_{POW}$ of 1.4 indicating a very low risk of bioaccumulation and, hence, secondary poisoning. A risk assessment is not deemed necessary.

CP 10.1.2.1 Acute oral toxicity to mammals

The acute oral toxicity of the Thiacloprid OD 240 in rat was studied by Krötlinger (2002), M-064983-01-1, the study is summarised in the MCA 5 document (toxicology). Observed mortalities were 0%, 0% and 100% at 200, 500 and 2000 mg product/kg bw, respectively. According to OECD guideline 423 this corresponds to $LD_{50} > 500 < 1000$ mg pr/kg bw.
LD_{50} estimation by non-linear interpolation yields a point estimate of 1043 mg pr/kg bw.

CP 10.1.2.2 Higher tier data on mammals

No additional studies are available or required, the risk assessment indicates no risk at Tier 1.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies are available or required under the data requirements of EC 1107/2009.

CP 10.2 Effects on aquatic organisms

The risk assessment has been performed according to "Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC" (Sanco/3268/2001 rev.4 (final) 17 October 2002).

Ecotoxicological endpoints used in risk assessment

Table CP 10.2- 1: Endpoints relevant for risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid	Marine fish, acute *Cyprinodon variegatus* (sheepshead minnow)	LC_{50}	19.7 mg a.s./L	[redacted] (1998) M-001198-01-1 KCA 8.2.1/2
	Fish, chronic *Pimephales promelas* (fathead minnow)	NOEC	0.17 mg a.s./L	[redacted] (1999) M-009649-01-1 KCA 8.2.2.1/1
	Invertebrate, acute *Daphnia magna* (cladoceran)	EC_{50}	≥ 85.1 mg a.s./L	[redacted] (1995) M-000738-01-1 KCA 8.2.4.1/1
	Invertebrate, acute *Ecdyonurus* sp. Larvae (mayfly)	EC_{50}	0.0077 mg a.s./L	[redacted] (2002) M-059087-01-1 KCA 8.2.4.2/6
	Sediment dweller, acute *Chironomus riparius* (chironomid)	EC_{50}	0.00108 mg a.s./L	[redacted] (2014) M-491257-01-1 KCA 8.2.4.2/7
	Invertebrate, chronic *Daphnia magna* (cladoceran)	NOEC	0.58 mg a.s./L	[redacted] (1996) M-000652-01-2 KCA 8.2.5.1/1
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	NOEC	0.00056 mg a.s./L	[redacted] (2014) M-493340-01-1 KCA 8.2.5.3/1
	Desmodesmus subspicatus (*Scenedesmus subspicatus*, green algae)	E_bC_{50} E_rC_{50}	44.7 mg a.s./L 96.7 mg a.s./L	[redacted] (1995) M-000731-01-1 KCA 8.2.6.1/1
	Lentic freshwater community- mesocosm	NOEAEC	0.00157 mg a.s./L	[redacted] (1997) M-001191-02-1 KCP 8.2.8/1
Thiacloprid-amide	Fish, acute *Lepomis macrochirus* (bluegill sunfish)	LC_{50}	> 78.6 mg p.m./L	[redacted] (1997) M-003825-01-1 KCA 8.2.1 /3
	Invertebrate, acute *Daphnia magna* (cladoceran)	EC_{50}	> 103 mg p.m./L	[redacted] (1998) M-002382-01-1 KCA 8.2.4.1/2
	Invertebrate, acute *Hyalella azteca* (amphipod)	LC_{50}	47.6 mg p.m./L	[redacted] (1997) M-000997-02-1 KCA 8.2.4.2/8
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	EC_{15}	≥ 0.1 mg p.m./L	[redacted] (1997) M-000999-01-1 KCA 8.2.5.3/3
	Pseudokirchneriella subcapitata (green algae)	E_bC_{50} E_rC_{50}	> 100 mg p.m./L > 100 mg p.m./L	[redacted] (1998) M-004001-01-1 KCA 8.2.6.1/2
Thiacloprid sulfonic acid	Fish, acute *Oncorhynchus mykiss* (rainbow trout)	LC_{50}	> 90.1 mg p.m./L	[redacted] (1995) M-001013-01-1 KCA 8.2.1/4
	Invertebrate, acute *Daphnia magna* (cladoceran)	EC_{50}	> 96.1 mg p.m./L	[redacted] (1995) M-001002-01-1 KCA 8.2.4.1/3
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	EC_{15}	> 100 mg p.m./L	[redacted] & [redacted] (2002), M-051861-01-1 KCA 8.2.5.3/4

Test substance	Test species	Endpoint		Reference
	Desmodesmus subspicatus (*Scenedesmus subspicatus*, green algae	E_bC_{50} E_rC_{50}	> 100 mg p.m./L > 100 mg p.m./L	[redacted] (1996) M-001011-01-1 KCA 8.2.6.1/3
Thiacloprid-descyano	Sediment dweller, chronic *Chironomus riparius* (chironomid)	NOEC	0.00625 mg p.m./L	[redacted] (2011) M-419277-01-1 KCA 8.2.5.3/5
Thiacloprid OD 240	Sediment dweller, chronic Chironomus riparius (chironomid)	EC15	0.0080 mg prod/L (~0.0019 mg a.s./L)	[redacted] (2003) M-111299-01-1 KCP 10.2.2/2

Selection of endpoints for risk assessment

Invertebrates

Endpoint used in risk assessment (Invertebrates)

Based on findings on biological effects and fate of thiacloprid in an outdoor mesocosm study a NOEAEC of 1.57 µg a.s./L (measured peak concentration after 2 applications with target concentration 1 µg a.s./L) could be derived for the community, particularly for invertebrates as the most sensitive group ([redacted], F.; 2001; M-001191-02-1, KCP 8.2.8/1). The value was further supported by expert statements reviewed in the Monograph and the endpoint was agreed.

As recommended by the expert, four acute toxicity studies (including Ephemeroptera) were performed on indigenous insects *(Sericostoma personatum*, *Ecdyonurus sp.*) and macro-crustaceans *(Asellus aquaticus*, *Gammarus pulex*) to enhance the database and to dispel the only reservation mentioned in the expert statement regarding an EAC of 1.57 µg a.s./L. The studies were submitted during the Annex I process. The results of these studies as summarised in the MCA document and they indicate that macro-crustaceans (represented by *Asellus aquaticus* and *Gammarus pulex*) as well as Trichoptera *(Sericostoma personatum*) are less sensitive than the other tested aquatic invertebrate species. Chironomids appear to be similarly sensitive as Ephemeroptera. Thus, in agreement with the expert statement (Brock, 2002), the final conclusions drawn from the outdoor mesocosm study are confirmed and a concentration of 1.57 µg a.s./L was regarded as a peak concentration EAC in water. This conclusion was supported in the Monograph and subsequent amendments.
Because transient effects on some few species were observed at that concentration, it is justified *in sensu* HARAP (Guidance Document on Higher-tier Aquatic Risk Assessment for Pesticides)[1] to use the NOEAEC of 1.57 µg thiacloprid/L determined in the outdoor mesocosm study with an assessment factor of three.

Predicted environmental concentrations used in risk assessment

Full details of the predicted environmental concentrations are given in MCP 9.2.5, M-492014-01-1 and M-491773-01-1

[1] [redacted], P.J., [redacted], D.J.S., [redacted], T.C.M., [redacted], N.J., [redacted], W., [redacted], F., [redacted], S.J., [redacted], M. 1999. Guidance Document on Higher-tier Aquatic Risk Assessment for Pesticides (HARAP). SETAC-Europe publication, 179 pp

Table CP 10.2- 2: Initial max PEC_{sw} values – FOCUS Step 1, 2

Compound	FOCUS Scenario	Oilseed rape (spring, winter) 2 × 72 g a.s./ha
		$PEC_{sw, max}$ [µg/L]
Thiacloprid	STEP 1	27.70
	STEP 2 - North	1.127
	STEP 2 - South	**1.732**
Thiacloprid-amide	STEP 1	3.304
	STEP 2 - North	2.304
	STEP 2 - South	**3.964**
Thiacloprid sulfonic acid	STEP 1	12.44
	STEP 2 - North	0.654
	STEP 2 - South	**1.159**
Thiacloprid-descyano	STEP 1	9.607
	STEP 2 - North	0.552
	STEP 2 - South	**1.103**

Bold values considered in risk assessment

Table CP 10.2- 3: Initial max PEC_{sw} values – FOCUS Step 3

Compound	FOCUS Scenario	Oilseed rape (Spring) 2× 72 g a.s/ha	Oilseed rape (winter) 2× 72 g a.s/ha
		$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]
Thiacloprid	D1 (ditch, 1st)	0.625	-
	D1 (stream, 1st)	0.404	-
	D2 (ditch, 1st)	-	0.462
	D2 (stream, 1st)	-	0.411
	D3 (ditch, 1st)	0.454	0.457
	D4 (pond, 1st)	0.020	0.021
	D4 (stream, 1st)	0.394	0.392
	D5 (pond, 1st)	0.020	0.020
	D5 (stream, 1st)	0.388	0.406
	R1 (pond, 1st)	0.049	0.047
	R1 (stream, 1st)	0.426	0.501
	R3 (stream, 1st)	-	0.424
Thiacloprid-descyano	D1 (ditch, 1st)	0.144	-
	D1 (stream, 1st)	0.090	-
	D2 (ditch, 1st)	-	0.251
	D2 (stream, 1st)	-	0.157
	D3 (ditch, 1st)	< 0.001	< 0.001
	D4 (pond, 1st)	0.027	0.022
	D4 (stream, 1st)	0.045	0.044
	D5 (pond, 1st)	0.019	0.010
	D5 (stream, 1st)	0.033	0.019
	R1 (pond, 1st)	0.019	0.019
	R1 (stream, 1st)	0.125	0.102
	R3 (stream, 1st)	-	0.144

Table CP 10.2- 4: Initial max PEC_{sw} values for thiacloprid – use in spring oilseed rape FOCUS Step 4

Buffer	Scenario	Thiacloprid PECsw [µg/L]

		Drift Reduction							
		0%		50%		75%		90%	
5 m SD*	D1 (ditch, 1st)	M	0.161	M	0.080	M	0.040	M	0.016
	D1 (stream, 1st)	S	0.147	S	0.074	S	0.037	S	0.015
	D3 (ditch, 1st)	S	0.124	S	0.062	S	0.031	S	0.013
	D4 (pond, 1st)	M	0.017	M	0.009	M	0.004	M	0.002
	D4 (stream, 1st)	S	0.144	S	0.072	S	0.036	S	0.014
	D5 (pond, 1st)	M	0.017	M	0.009	M	0.004	M	0.002
	D5 (stream, 1st)	S	0.141	S	0.071	S	0.035	S	0.014
	R1 (pond, 1st)	M	0.048	M	0.042	M	0.039	M	0.037
	R1 (stream, 1st)	M	0.426	M	0.426	M	0.426	M	0.426

S and M denote whether single or multiple application lead to the maximum value * SD denote spray drift buffer

Acute Risk Assessment For Aquatic Organisms

Table CP 10.2- 5: TER_A calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER_A	Trigger
OSR (spring, winter)					
Thiacloprid	Fish, acute *Cyprinodon variegatus*	LC_{50} 19 700	1.732	11 374	100
	Invertebrate, acute *Daphnia magna*	EC_{50} > 85 100	1.732	49 134	100
	Invertebrate, acute *Ecdyonurus* sp.	EC_{50} 7	1.732	**4.4**	100
	Sediment dweller, acute *Chironomus riparius*	EC_{50} 10.8	1.732	**6.2**	100
Thiacloprid-amide	Fish, acute *Lepomis macrochirus*	LC_{50} > 78 600	3.964	> 19 828	100
	Invertebrate, acute *Daphnia magna*	EC_{50} > 103 000	3.964	> 25 984	100
	Invertebrate, acute *Hyalella azteca*	LC_{50} 47 600	3.964	12 008	100
Thiacloprid sulfonic acid	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 90 100	1.159	> 77 739	100
	Invertebrate, acute *Daphnia magna*	EC_{50} > 96 100	1.159	> 82 916	100

Bold values do not meet the trigger

The TER trigger was exceeded for all organisms for the metabolites thiacloprid-amide and thiacloprid-sulfonic acid. For Thiacloprid the trigger was exceeded for all organisms except the aquatic invertebrates *Ecdyonurus sp.* and *Chironomus riparius.* For these species a refined risk assessment is required, this is presented below considering the more realistic Step 3 FOCUS simulations.

Table CP 10.2- 6: TER_A for spring oilseed rape calculations based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
Thiacloprid, spring OSR					
Invertebrate, acute *Ecdyonurus* sp.	EC_{50} 7.7	0.625	D1 (ditch, 1st)	**12.32**	100
		0.404	D1 (stream, 1st)	**19.06**	100
		0.457	D3 (ditch, 1st)	**16.85**	100
		0.020	D4 (pond, 1st)	385	100
		0.394	D4 (stream, 1st)	**19.54**	100
		0.020	D5 (pond, 1st)	385	100
		0.388	D5 (stream, 1st)	**19.85**	100
		0.049	R1 (pond, 1st)	157	100
		0.426	R1 (stream, 1st)	**18.08**	100
Sediment dweller, acute *Chironomus riparius*	EC_{50} 10.8	0.625	D1 (ditch, 1st)	**17.3**	100
		0.404	D1 (stream, 1st)	**26.7**	100
		0.457	D3 (ditch, 1st)	**23.6**	100
		0.020	D4 (pond, 1st)	540.0	100
		0.394	D4 (stream, 1st)	**27.4**	100
		0.020	D5 (pond, 1st)	540.0	100
		0.388	D5 (stream, 1st)	**27.8**	100
		0.049	R1 (pond, 1st)	220.4	100
		0.426	R1 (stream, 1st)	**25.4**	100

Bold values do not meet the trigger

Table CP 10.2- 7: TER_A for winter oilseed rape calculations based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
Thiacloprid, winter OSR					
Invertebrate, acute *Ecdyonurus* sp.	EC_{50} 7.7	0.462	D2 (ditch, 1st)	**16.67**	100
		0.411	D2 (stream, 1st)	**18.73**	100
		0.457	D3 (ditch, 1st)	**16.85**	100
		0.021	D4 (pond, 1st)	367	100
		0.392	D4 (stream, 1st)	**19.64**	100
		0.020	D5 (pond, 1st)	385	100
		0.406	D5 (stream, 1st)	**18.97**	100
		0.047	R1 (pond, 1st)	164	100
		0.501	R1 (stream, 1st)	**15.37**	100
		0.424	R3 (stream, 1st)	**18.16**	100
Sediment dweller, acute *Chironomus riparius*	EC_{50} 19.8	0.462	D2 (ditch, 1st)	**23.4**	100
		0.411	D2 (stream, 1st)	**26.3**	100
		0.457	D3 (ditch, 1st)	**23.6**	100
		0.021	D4 (pond, 1st)	514.3	100
		0.392	D4 (stream, 1st)	**27.6**	100
		0.020	D5 (pond, 1st)	540.0	100
		0.406	D5 (stream, 1st)	**26.6**	100
		0.047	R1 (pond, 1st)	229.8	100
		0.501	R1 (stream, 1st)	**21.6**	100
		0.424	R3 (stream, 1st)	**25.5**	100

Bold values do not meet the trigger

Some of the evaluated scenarios do not meet the required trigger. Thus, a refined risk assessment is presented at the end of the section for the long-term risk assessment for aquatic organisms.

CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 8: TER_{LT} calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
Thiacloprid, (spring, winter) OSR					
Thiacloprid	Fish, chronic	NOEC 170	1.732	98	10
	Invertebrate, chronic	NOEC 580	1.732	335	10
	Sediment dweller, chronic	NOEC 0.56	1.732	**0.32**	10
	Green algae, chronic	E_bC_{50} 44 700	1.732	25 808	10
Thiacloprid-amide	Sediment dweller, chronic	EC_{20} > 100	3.964	> 25	10
	Green algae, chronic	E_bC_{50} > 100 000 E_rC_{50} > 100 000	3.964	> 25 227	10
Thiacloprid sulfonic acid	Sediment dweller, chronic	EC_{15} >100 000	1.159	> 86 281	10
	Green algae, chronic	E_bC_{50} > 100 000 E_rC_{50} > 100 000	1.159	> 86 281	10
Thiacloprid-descyano	Sediment dweller, chronic	NOEC 6.25	1.103	**5.67**	10

Bold values do not meet the trigger

For thiacloprid and thiacloprid-descyano the trigger was not met for sediment dwellers and a refined risk assessment is therefore required. The consideration of the more realistic FOCUS Step 3 surface water concentrations is presented below.

Table CP 10.2- 9: TER_{LT} for spring oilseed rape calculations based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Thiacloprid, spring OSR					
Sediment dweller, chronic	NOEC 0.56	0.625	D1 (ditch, 1st)	**0.90**	10
		0.404	D1 (stream, 1st)	**1.39**	10
		0.457	D3 (ditch, 1st)	**1.23**	10
		0.020	D4 (pond, 1st)	28.00	10
		0.394	D4 (stream, 1st)	**1.42**	10
		0.020	D5 (pond, 1st)	28.00	10
		0.388	D5 (stream, 1st)	**1.44**	10
		0.049	R1 (pond, 1st)	11.43	10
		0.426	R1 (stream, 1st)	**1.31**	10
Thiacloprid-descyano, spring OSR					
Sediment dweller, chronic	NOEC 6.25	0.144	D1 (ditch, 1st)	43.40	10
		0.090	D1 (stream, 1st)	69.44	10
		0.001	D3 (ditch, 1st)	6250	10
		0.027	D4 (pond, 1st)	231	10
		0.045	D4 (stream, 1st)	139	10
		0.019	D5 (pond, 1st)	329	10
		0.033	D5 (stream, 1st)	189	10
		0.019	R1 (pond, 1st)	329	10
		0.125	R1 (stream, 1st)	50.00	10

Bold values do not meet the trigger

Table CP 10.2- 10: TER_{LT} for winter oilseed rape calculations based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Thiacloprid, winter OSR					
Sediment dweller, chronic	NOEC 0.56	0.462	D2 (ditch, 1st)	**1.21**	10
		0.411	D2 (stream, 1st)	**1.36**	10
		0.457	D3 (ditch, 1st)	**1.23**	10
		0.021	D4 (pond, 1st)	26.67	10
		0.392	D4 (stream, 1st)	**1.43**	10
		0.020	D5 (pond, 1st)	28.00	10
		0.406	D5 (stream, 1st)	**1.38**	10
		0.047	R1 (pond, 1st)	11.91	10
		0.504	R1 (stream, 1st)	**1.12**	10
		0.424	R3 (stream, 1st)	**1.32**	10
Thiacloprid-descyano, winter OSR					
Sediment dweller, chronic	NOEC 6.25	0.251	D2 (ditch, 1st)	24.90	10
		0.157	D2 (stream, 1st)	39.81	10
		< 0.001	D3 (ditch, 1st)	> 6250	10
		0.022	D4 (pond, 1st)	284	10
		0.044	D4 (stream, 1st)	142	10
		0.010	D5 (pond, 1st)	625	10
		0.019	D5 (stream, 1st)	329	10
		0.019	R1 (pond, 1st)	329	10
		0.102	R1 (stream, 1st)	61.27	10
		0.144	R3 (stream, 1st)	43.40	10

Bold values do not meet the trigger

The trigger is exceeded for all scenarios considering the metabolite thiacloprid-descyano. For thiacloprid, the trigger is not exceeded for some of the scenarios. Thus, a refined risk assessment for these scenarios is presented below.

Refined Risk Assessment of aquatic invertebrates/insects exposed to thiacloprid

As discussed under "Selection of endpoints for risk assessment" the end-point for the refined risk assessment for aquatic invertebrate communities is 1.57 µg/L with a TER trigger of three.

Table CP 10.2- 11: TER_{LT} calculations for spring oilseed rape for aquatic invertebrates based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Thiacloprid, spring OSR					
Aquatic invertebrate population	NOEAC 1.57	0.625	D1 (ditch, 1st)	**2.51**	3
		0.404	D1 (stream, 1st)	3.89	3
		0.457	D3 (ditch, 1st)	3.44	3
		0.394	D4 (stream, 1st)	3.98	3
		0.388	D5 (stream, 1st)	4.05	3
		0.426	R1 (stream, 1st)	3.69	3

Bold values do not meet the trigger

Table CP 10.2- 12: TER_{LT} calculations for winter oilseed rape for aquatic invertebrates based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Thiacloprid, winter OSR					
Aquatic invertebrate population	NOEAC 1.57	0.462	D2 (ditch, 1st)	3.40	3
		0.411	D2 (stream, 1st)	3.82	3
		0.457	D3 (ditch, 1st)	3.44	3
		0.392	D4 (stream, 1st)	4.01	3
		0.406	D5 (stream, 1st)	3.87	3
		0.501	R1 (stream, 1st)	3.13	3
		0.424	R3 (stream, 1st)	3.70	3

The trigger is meet for all evaluated scenarios and crops, except for the D1 (ditch) scenario for the use in spring oilseed rape. A risk assessment for this crop and scenario based on FOCUS Step 4 calculations considering a 5 m buffer zone is presented below

Table CP 10.2- 13: TER_{LT} calculations for aquatic invertebrate based on FOCUS Step 4:

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Thiacloprid, OSR, 5 m buffer zone, 0% drift reduction					
Aquatic invertebrate population	NOEAC 1.57	0.161	D1 (ditch, 1st)	9.75	3

The TER trigger is exceeded considering a 5 m buffer with no drift reduction.

Hence for winter oil-seed rape no mitigation would be required, while for spring sown oilseed rape a small non-sprayed buffer zone of 5m is indicated.

CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and

macrophytes

No additional acute toxicity studies are available or required. Of the standard species tested Chironomus species are clearly most sensitive to thiacloprid, hence testing in fish, algae and daphnia is not required. The testing of Chironomus species has been covered by chronic toxicity testing with the formulation.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Report:	[redacted]d; [redacted]; 2003; M-111299-01-1
Title:	Chironomus riparius 28-day chronic toxicity text with Thiacloprid 240 OD in a water-sediment system using spiked water
Report No.:	DOM 23040
Document No.:	M-111299-01-1
Guidelines:	**Proposal for a new OECD Guideline 219, December 2002; nine**
GLP/GEP:	**yes**

Objective:
The aim of the study was to determine the influence of the test item on emergence and development of *Chironomus riparius* for 28 days in a static water-sediment-system, expressed as NOEC, LOEC and EC_x for emergence ratio and development rate.

Material and methods:
Test item: Thiacloprid 240 OD; Batch no.: 07690/0086(0082); TOX-No.: 06171-01; Development no.: 3000266399; Content of a.s.: 244.18 g/L.
Larvae of *Chironomus riparius* (1st instars <2-3 days old, 4 beakers per test concentration and control with 20 animals each) were exposed for 28 days in a static test system to concentrations of 4.29, 7.72, 13.7, 24.0 and 42.9 µg formulation/L (nominal initial) in the overlying water of a water-sediment system (spiked water).
Dissolved oxygen concentrations ranged from 7.0 to 8.8 mg O_2/L (7.0 mg O2/L= 78% O_2 - saturation), the pH values ranged from 8.4 to 8.7 and the water temperature ranged from 19.7°C to 20.0°C measured from parallel beakers of each test concentration over the whole period of testing.
Recoveries of Thiacloprid 240 OD were measured three times during the study: 1 hour, 7 days and 28 days after application of one additional test container of each nominal initial test concentrations of 4.92, 13.70 and 42.9 µg form./L and control (only on day 0) of the overlying water and the pore water of the sediment.

Findings:
Validity criteria:
Test conditions met all validity criteria, given by the mentioned guidelines.

Analytical findings:
Since the measured amount of a.s. of the test concentrations 4.29, 13.7 and 42.9 µg form./L on day 0 were only 61 to 67% (on average 63.5%), all five nominal concentrations of 4.29, 7.72, 13.7, 24.0 and 42.9 µg formulation/L were related to mean (63.5% of nominal) initial measured concentrations of i.e. 2.72, 4.90, 8.70, 15.2 and 27.2 µg formulation/L corresponding to 0.635, 1.14, 2.03, 3.56 and 6.35 µg

a.s./L. These calculated concentrations were used for statistical calculations and for the reported results.

Table CP 10.2.2- 1: Analytical results for the nominal test concentrations of 4.29, 13.70 and 42.9 µg formulation/L in the overlying water on average% over the test duration.

	% of nominal on average		
	day 0	day 7	day 28
overlying water	63.5	18.1	5.8
pore water	0.2	0.4	0.2

Biological findings:

Start of emergence was on day 14 for the control and the test levels from 2.72 to 8.7 µg form./L. The start of emergence was postponed for 7 days at the test concentration of 15.2 µg form./L. At the test level of 27.2 µg form./L no midges emerged, 80% of the inserted larvae maturated to adults in the control after 28 days, fulfilling the guideline requirements.

Table CP 10.2.2-2: Influence on the emergence and development after 28 days (based on mean initial measured concentrations of the formulation in the overlying water)

Concentration	Emergence of inserted larvae			Development			
				pooled sex		male	female
mean initial measured µg form./L	total (%)	male (%)	female (%)	Time (d)	Rate (1/d)	Rate (1/d)	Rate (1/d)
Control	80.0	35.0	45.0	17.11	0.058	0.064	0.056
2.72	80.0	30.0	50.0	17.17	0.059	0.064	0.057
4.90	83.8	35.0	48.8	16.40	0.061	0.066	0.057
8.70	61.3	27.5	33.8	17.46	0.058	0.062	0.055
15.2	6.3	2.5	3.8	23.50	0.043	n.c.	n.c.
27.2	0	-	-	-	-	-	-

n.c.: not calculable

Some dead larvae/pupae or midges which failed to emerge could be observed at test levels of 4.90 and 8.70 µg formulation/L.

Conclusion:

Mean initial measured µg formulation/L	NOEC	LOEC	EC_5	EC_{10}	EC_{15}	EC_{20}	EC_{50}
emergence ratio (pooled sex)	4.90	8.70	6.9	7.5	8.0	8.4	10.5
95% c.l.	-	-	5.8 – 8.1	6.5 – 8.7	7.0 – 9.1	7.5 – 9.5	9.7 – 11.4
development rate (pooled sex)	8.70	15.2	9.4	11.2	12.7	14.0	21.3
95% c.l.	-	-	n.c.	n.c.	n.c.	n.c.	n.c.
development rate (male)	8.70	15.2	8.6	10.6	12.2	13.6	22.1
95% c.l.	-	-	n.c.	n.c.	n.c.	n.c.	n.c.
development rate (female)	8.70	15.2	10.4	12.1	13.4	14.5	20.4
95% c.l.	-	-	9.8 – 11.0	11.5 – 12.8	12.6 – 14.3	13.6 – 15.7	18.4 – 23.5

c.l.: confidence limits; n.c.: not calculable

The emergence ratio was a more sensitive endpoint than the development rate.

CP 10.2.3 Further testing on aquatic organisms

No further testing of the formulation is available or required.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

The risk assessment has been performed according to the existing guidance in force at the time of the preparation and submission of this dossier namely the EU Guidance Document on Terrestrial Ecotoxicology (SANCO/ 10329/2002 rev 2) and EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees.

Commission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, to be conducted. Consequently in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided.

- Acute oral and contact toxicity of thiacloprid-amide (metabolite of thiacloprid)
- Acute contact toxicity of thiacloprid to adult bumble bees (*Bombus terrestris*)
- Chronic 10 day toxicity to adult bees under laboratory conditions of thiacloprid
- Chronic 10 day toxicity to adult bees under laboratory conditions of thiacloprid-amide (metabolite of thiacloprid)
- Acute toxicity to larval bees under laboratory conditions of thiacloprid
- Tunnel test according to the guidance document EPPO 170. In this test honey bee colonies were exposed to 73.91 g a.s./ha as spray application on a flowering bee-attractive crop (*Brassica napus*, oil-seed rape).
- Tunnel test to OECD guidance document 75. This test exposed honey bee colonies to a spray application of 72 g a.s./ha on a flowering, bee attractive crop (*Phacelia tanacetifolium*).
- Field test with honey bee colonies exposed to three sequential foliar spray applications on *Phacelia tanacetifolium* with a nominal application rate of 96 g a.s./ha.
- Field test with honey bee colonies exposed to two sequential foliar spray applications on oil-seed rape (*Brassica napus*) with a nominal application rate of 72 g a.s./ha.

Details of the honey bee testing with thiacloprid and ecotoxicological endpoints are presented in MCA, Section 8, Point 8.3.1, as well as within the existing Review Report for thiacloprid (SANCO/4347/2000 – Final, 2004). Furthermore, data on the contact toxicity of Thiacloprid OD 240 indicated that based on laboratory toxicity data there is no evidence to suggest that non-*Apis* bees were at greater risk consequently the risk assessment for honey bees was considered to protect other bees.

The tests conducted with the formulation Thiacloprid OD 240 are presented in this MCP document.

A summary of the critical endpoints thiacloprid, thiacloprid-amide and formulated product Thiacloprid OD 240 are provided in the following tables. Endpoints shown in bold are considered relevant for risk assessment.

Table CP 10.3.1- 1: Critical endpoints for thiacloprid – acute toxicity to adult bees

Test substance	Test species	Endpoint		Reference
Thiacloprid	Honey Bee (oral 48 h)	**LD_{50}**	**17.32 µg a.s./bee**	[redacted] (1995) M-000856-01-1 KCA 8.3.1.1/1
	Honey Bee (contact 48 h)	**LD_{50}**	**38.82 µg a.s./bee**	
Thiacloprid-amide	Honey Bee (oral 48 h)	LD_{50}	**> 108.1 µg p.m./bee**	[redacted] (2009) M-360293-01-1 KCA 8.3.1.1.2/2
	Honey Bee (contact 48 h)	LD_{50}	> 100 µg p.m./bee	
Thiacloprid OD 240	Honey Bee (oral 48 h)	**LD_{50}**	**6.01 µg a.s./bee**	[redacted] (2003) M-103506-01-1 KCP 10.3.1.1.1/2
	Honey Bee (contact 48 h)	**LD_{50}**	**5.92 µg a.s./bee**	[redacted] (2002) M-059157-01-1 KCP 10.3.1.1.2/1
	Bumble bee (contact 48 h) (Bombus terrestris)	LD_{50}	**> 100 µg a.s./bumblebee**	[redacted] (2014) M-480628-01-1 KCA 8.3.1.1.2/1

a.s. = active substance; p.m. = pure metabolite **Bold values used in risk assessment**

Table CP 10.3.1- 2: Critical endpoints for thiacloprid – chronic toxicity to adult bees

Test substance	Test species	Endpoint		Reference
Thiacloprid	Honey bee Laboratory chronic (10 d) (adults)	NOEC	8130 µg p.m./kg	[redacted] (2010) M-397536-01-1 KCA 8.3.1.2/1
Thiacloprid	Honey bee Laboratory chronic (10 d) (adults)	LC_{50} NOEC LDD_{50}	50 900 µg a.s./kg 29 000 µg a.s./kg 3.0 µg a.s./bee/day	[redacted] et al. (2013) M-475374-01-1 KCA 8.3.1.2/2
Thiacloprid-amide	Honey bee Laboratory chronic (10 d) (adults)	NOEC	8130 µg p.m./kg	[redacted] (2012) M-438963-01-1 KCA 8.3.1.2/3

a.s. = active substance; p.m. = pure metabolite; LDD_{50} = median lethal dietary dose

Table CP 10.3.1- 3: Critical endpoints for thiacloprid – toxicity to larvae

Test substance	Test species	Endpoint	Reference
Thiacloprid	Honey bee Laboratory *in vitro*, single exposure test design (larvae)	LD_{50} > 5.34 µg a.s./larva NOED 1.78 µg a.s./larva	[redacted] et al. (2013) M-472283-01-1 KCA 8.3.1.3/1

Table CP 10.3.1- 4: Critical endpoints for thiacloprid – forced exposure conditions (tunnel tests)

Test substance	Test species	Endpoint	Reference
Thiacloprid OD 240	Honey bee Semi-field study (EPPO 170) (colonies)	No adverse effects at 73.19 g a.s./ha except for a slight repellent effect	[redacted] (2002) M-054090-01-1 KCP 10.3.1.5/1
	Honey bee Semi-field study (OECD 75) (colonies)	No adverse effects at 72 g a.s./ha except for a slight repellent effect	[redacted] (2012) M-442217-01-1 KCP 10.3.1.5/2
	Honey bee Semi-field study (EPPO 170) with overwintering	No adverse effects at 2 x 72 g a.s./ha No adverse effects on bee disease and virus status No adverse effects on overwintering performance	[redacted] et al (2014) M-495895-01-1 KCP 10.3.1.5/3,

Table CP 10.3.1- 5: Critical endpoints for thiacloprid –field studies

Test substance	Test species	Endpoint	Reference
Thiacloprid OD 240	Field study (EPPO 170) (colonies)	No adverse effects at 3 x 96 g a.s./ha except short-term effect on bee behaviour	[redacted] (2014) M-492155-01-1 KCP 10.3.1.6/2
	Field study (EPPO 170) (colonies)	No adverse effects at 2 x 72 g a.s./ha except short-term effect on bee behaviour No adverse effects on bee disease and virus status No adverse effects on overwintering performance	[redacted] (2014) M-492158-01-1 KCP 10.3.1.6/3
Thiacloprid SC 480	Bumble bees greenhouse (colonies)	No adverse effects	[redacted] (2000) M-036544-01-2 KCP 10.3.1.6/1

Risk assessment for bees

The risk assessment for bees is based on the maximum single application rate of thiacloprid 72 g a.s./ha for application in oil-seed rape.

Hazard Quotients

The risk assessment is based on Hazard Quotient approach (Q_H) by calculating the ratio between the application rate (expressed in g a.s./ha or in g total substance/ha) and the laboratory contact and oral LD_{50} (expressed in µg a.s./bee or in µg total substance/bee).

Q_H values can be calculated using data from the studies performed with the active substance and with the formulation. Q_H values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral:
$$Q_{HO} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

Hazard Quotient, contact:
$$Q_{HC} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{contact}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

Table CP 10.3.1- 6: Hazard quotients for bees – oral exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Thiacloprid OD 240	OSR	6.01	72	12	50
Thiacloprid	OSR	17.32	72	4.2	50
Thiacloprid-amide	OSR	> 108.1	72	0.7	50

The hazard quotient for oral exposure is below the validated trigger value for higher tier testing (i.e. $Q_{HO} < 50$).

Table CP 10.3.1- 7: Hazard quotients for bees – contact exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Thiacloprid OD 240	OSR	5.92	72	12	50
Thiacloprid	OSR	38.82	72	1.8	50
Thiacloprid-amide	OSR	> 100	72	1.4	50

The hazard quotient for contact exposure is below the validated trigger value for higher tier testing (i.e. $Q_{HC} < 50$).

Toxicology summary and further considerations regarding the risk to bees

According to the finding of the risk assessment (above) applications of Thiacloprid OD 240 at 72 g a.s./ha to flowering crops of oil seed rape (OSR) are not expected to pose a risk to honey bees. Even if the application rate were doubled (144 g a.s./ha to cover both sprays) the resulting HQ values would be still well below the Annex VI trigger of 50 indicating low risk to bees.

The active substance thiacloprid either as technical material or formulated product (Thiacloprid OD 240) is of moderate toxicity to bees. The formulated product was of slightly higher toxicity compared to the technical material and the plant metabolite (thiacloprid-amide) was virtually non-toxic. A new study on the acute contact toxicity of thiacloprid to a non-Apis species (*Bombus terrestris*) has been conducted and indicated that this species is at least an order of magnitude (i.e. 10x) less sensitive than the honey bee to thiacloprid. The resulting HQ calculation for an application rate of 72 or 144 g a.s./ha for bumble bees gives value of 0.72 and 1.44 which are far lower than the current Annex VI trigger of 50.

When fed chronically to adult honey bees via *ad libitum* feeding of 10000 µg a.s./kg sugar solution there were no signs of intoxication or mortality for bees exposed to either thiacloprid or thiacloprid-amide.

A further chronic laboratory feeding study with thiacloprid was undertaken using higher concentrations in order to derive an LC_{50} (lethal concentration) and the corresponding LDD_{50} (median lethal dietary dose). A LDD_{50} of 3.0 µg a.s/bee/day was observed indicating that bees could consume 30 µg a.s/bee over a 10 day feeding period which is approximately 2 – 5x higher than the acute oral LD_{50} values for technical and formulated thiacloprid. As such, there is no indication of delayed or chronic effects in honey bees. Moreover, a comparison of the chronic laboratory toxicity study with thiacloprid-amide with the corresponding acute toxicity study gives no indication that thiacloprid-amide is of any higher toxicity regarding potentially delayed or chronic effects and is less toxic compared to the parent compound.

[redacted] in-vitro honey bee larvae study was conducted according to the provisions of the OECD Draft Test Guideline on Honey Bee (*Apis mellifera*) Larval Toxicity Test, Single Exposure (Version of 21 February 2013) and the current draft version of the Post-WNT25 Approved Larval Honey Bee Test, dated April 2013, which complies with the requirements of the later finalised OECD 237 test guideline. In the study an acute LD_{50} of 1.78 µg a.s./larva was measured. Given that larvae are smaller in size than their adult counterparts at the time of dosing there is no evidence to suggest that larvae are any more sensitivity than adult bees. In addition the exposure levels for foraging adult bees is far higher than that of larvae fed by nurse bees within the hive.

Further toxicity testing on the effects of thiacloprid at the colony level and to further investigate effects on colonies and larvae (brood) has been conducted under semi-field (tunnel) conditions. Two independent semi-field (gauze tunnel) studies have been conducted using Thiacloprid OD 240 as the test material applied to the highly bee attractive surrogate crop *Phacelia tanacetifolia* during bee flight. One test followed the provisions of the EPPO 170 guideline and the other those of OECD 75 guidance document with specific investigation of the development of eggs, young and old larvae by employing digital photo imaging technology. The studies were conducted at applications rates of 73.19 and 72 g a.s./ha for the EPPO 170 and OECD 75 compliant studies respectively. Results showed for both studies that for foliar applications to a full-flowering crop, applied while honey bees were actively foraging on the crop, no adverse effects on mortality, foraging activity, behaviour and brood development as well as on overall hive vitality were observed. Furthermore; detailed assessment of brood undertaken in the OECD 75 compliant study did not detect any adverse effects on brood development when exposed to the test item.

A third and more extensive semi-field test was conducted which also followed EPPO 170 which included an assessment of overwintering success, bee health factors such as disease and virus status. The critical GAP of 2 x 72 g a.s./ha made during bloom and honey bee activity. Exposure of honey bee colonies placed in the tunnels to 2 application at 72 g a.s./ha not experience any adverse impact on mortality, foraging rate, colony strength, brood or food stored compared to the control. No effects the viability of the colonies or on any bee health factors such as disease and virus status were observed. The exposed colonies were also maintained so that overwintering performance could be measured. No difference between overwintering success of control or Thiacloprid OD 240 exposed colonies was observed.

Two field studies (compliant with the provision of EPPO 170) are also available which confirm the finding of the two semi-field studies.
The first one covers the critical GAP of 2 x 72 g a.s./ha made during bloom and honey bee activity. Exposure of honey bee colonies placed at the edge of fields where 2 application at 72 g a.s./ha were made did not result in any adverse effects other than a short-term effect on behaviour observed as

lower foraging rate at one treated field site. This did not have any impact on the mortality, overall foraging rate, colony strength, brood or food stored were noted compared to the control or on the viability of the colonies or on any bee health factors such as disease and virus status. The exposed colonies were also maintained so that overwintering performance could be measured. No difference between overwintering success of control or Thiacloprid OD 240 exposed colonies was observed. These finding support those of a semi-field test conducted in a similar way measuring the same parameters.

The second study investigated a higher use rate and pattern of 3 x 96 g a.s/ha, with 2 of the applications made during bloom. Except for a short-term effect on bee behaviour (i.e. a transient reduction in foraging and a small number of bees cramping bees observed on the days of application) no adverse effects were noted on mortality, overall foraging rate, colony strength, brood or food stored were noted compared to the control.

Overall conclusions for bees

The calculated Hazard Quotients for both technical and formulated thiacloprid are well below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be expected. This conclusion is confirmed by the results of a range of additional tests (adult chronic feeding study, larval toxicity test, tunnel tests (EPPO 170, OECD 75) as well as field studies).

Overall, it can be concluded that thiacloprid, when applied at the maximum application rate of 72 g a.s./ha even during the flowering period of potentially bee-attractive crop and weeds does not pose an unacceptable risk to honey bees and honey bee colonies. Additionally there is no evidence to suggest that non-*Apis* bees were at greater risk.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

Report:	[redacted]; 2002; M-059157-01-1
Title:	Assessment of side effects of Thiacloprid OD 240 to the honey bee, Apis mellifera L. in the laboratory
Report No.:	20021218/01-BLEU
Document No.:	M-059157-01-1
Guidelines:	**OECD Guideline No. 213 and No. 214**
GLP/GEP:	**yes**

Materials and Methods:

Test substance: Thiacloprid OD 240 (YRC 2894 240 OD); Article No.:00-05683696; Batch: 07690/0086(0082); Tox-No.: TOX06069-00; purity: YRC 2894 (thiacloprid): 243.95 g/L (240 g/L nominal).

The oral and contact toxicity of Thiacloprid OD 240 to the honey bee (*Apis mellifera* L.) was determined in a dose-response test according to the OECD guideline No. 213 and No. 214 (1998). In the laboratory, the bees were exposed to the following doses of Thiacloprid OD 240 by feeding and topical application (in brackets: actual intake of Thiacloprid OD 240 in the oral toxicity test):

Oral toxicity test (actual intake)		Contact toxicity test
1.7 mg a.s./10 g honey	(2.16 µg a.s./bee)	6.25 µg a.s. per bee
3.7 mg a.s./10 g honey	(2.61 µg a.s./bee)	12.50 µg a.s. per bee
8.1 mg a.s./10 g honey	(3.35 µg a.s./bee)	25.00 µg a.s. per bee
17.7 mg a.s./10 g honey	(5.70 µg a.s./bee)	50.00 µg a.s. per bee
39.0 mg a.s./10 g honey	(7.41 µg a.s./bee)	100.00 µg a.s. per bee
85.8 mg a.s./10 g honey	(11.84 µg a.s./bee)	

Because in previous tests the test substance precipitated after the stock solution was diluted with sugar solution, the final feeding solution was prepared by mixing the stock solution with pure honey. The intake of test substance solution containing Thiacloprid OD 240 was low and at the maximum concentration level of 85.8 mg a.s./10 g honey an actual intake of only 11.84 µg a.s./bee was observed. At this dose a mortality of 60.0% was observed after 48 hours. At the highest dose of 100.00 µg a.s./bee which was tested in the contact toxicity test with Thiacloprid OD 240 a mortality of 100.0% was observed after 48 hours. In the control group of the oral toxicity test (fed with pure honey) a mortality of 4.0% occurred after 48 hours. The control group fed with 50% (w/v) sugar solution showed no mortality after 48 hours. No mortality was observed in the control group of the contact toxicity test until test termination.

Findings and conclusions:

In both, oral and contact toxicity test, the bees showed symptoms of poisoning at all dose levels immediately after start of feeding or topical application, respectively.

Table CP 10.3.1.1.1- 1: LD_{50} values in the toxicity test of Thiacloprid OD 240.

Thiacloprid OD 240	LD_{50}/24h	LD_{50}/48h
	[µg a.s./bee]	
Oral toxicity test*	7.81	6.98
Contact toxicity test	7.04	5.92

*the mortality which occurred in the control group was not included in the calculation of the LD50 values

Table CP 10.3.1.1.1- 2: LD_{50} values in the oral and contact toxicity test of the toxic standard (dimethoate).

Perfekthion	LD_{50}/24h	LD_{50}/48h
	[µg a.s./bee]	
Oral test	0.14	0.12
Contact test	0.19	0.17

Report:	[redacted]1; [redacted]; 2003; M-103506-01-1
Title:	Acute toxicity of thiacloprid OD 240 to the honeybee Apis mellifera L under laboratory conditions
Report No.:	03 10 48 043
Document No.:	M-103506-01-1
Guidelines:	**OECD 213 (1998), OECD 214 (1998)**
GLP/GEP:	**yes**

Materials and Methods:

Test item: Thiacloprid OD 240 (Thiacloprid (YRC 2894); Article No.: 00 05683696; Development no.: 30-00266399; Batch: 07690/0131(0082); TOX no.: 6311-00; Density: 1.046 g/L; Analysed content: 240.58 g a.s./L.

The insecticide Thiacloprid OD 240 was tested under laboratory conditions on the honeybee *A. mellifera* after oral and contact exposure. Endpoints were mortality and behaviour of the bees compared to control up to 48 h after application. Mortality values were used to provide a regression line and calculate the median lethal dose value (LD_{50}) expressed in µg of active substance or product per bee.

Application rates for contact and oral toxicity test (values in brackets based on the actual consumed amount of sucrose solution) were as follows:

Contact toxicity		Oral toxicity	
µg product/bee	**µg a.s./bee**	**µg product/bee**	**µg a.s./bee**
174	40	174 (126.5)	40 (29.1)
87	20	87 (57.0)	20 (13.1)
43.5	10	43.5 (27.9)	10 (6.4)
21.7	5	21.7 (15.0)	5 (3.5)
10.9	2.5	10.9 (6.9)	2.5 (1.6)

Toxic standard Dimethoate EC 400 was applied at the following doses.

Contact toxicity		Oral toxicity	
µg product/bee	**µg a.s./bee**	**µg product/bee**	**µg a.s./bee**
0.663	0.250	0.663	0.250
0.332	0.125	0.332	0.125
0.166	0.062	0.166	0.062
0.083	0.031	0.083	0.031

Findings:

No statistically significant effects of the test item Thiacloprid OD 240 on survival were observed at the doses of 10.9, 21.7 and 43.5 µg product per bee in the contact toxicity test (0, 3.3 and 6.7% mortality, respectively) during 48 hours. For the tested doses of 87.0 and 174.0 µg product per bee statistically significant effects of the test item on survival were observed (43.3 and 100% mortality, respectively) during 48 hours. The calculated LD_{50} (48 h) was 82.7 µg product per bee in the contact toxicity test.

In the oral toxicity test statistically significant effects on survival were observed at consumed doses of 6.9, 15.0, 28.0, 57.0 and 126.5 µg product per bee in the oral toxicity test (16.7, 26.7, 46.7, 70.0 and 100% mortality, respectively) during 48 hours. Therefore, the calculated LD_{50} (48 h) was 26.2 µg product per bee in the oral toxicity test.

Before bees died in the test item treatments, apathy and immobility were observed shortly after application until the 24 hour assessment.

The LD_{50} of the reference item Dimethoate EC 400 was 0.233 µg a.s. per bee in the contact toxicity test after 24 hours. The LD_{50} of the reference item Dimethoate EC 400 was 0.139 µg a.s. per bee in the oral toxicity test after 24 hours.
All validity criteria according to the guideline were accomplished: the mortality in the control was ≤ 10% (being 0% in the contact and oral toxicity tests after 48 hours), the LD_{50} values of the reference item after 24 h were in the range of 0.10-0.30 µg a.s./bee (contact test) and between 0.10-0.35 µg a.s./bee (oral test).

Table CP 10.3.1.1.1-3: Oral and contact toxicity LD_{50} values of bees treated with Thiacloprid OD 240.

Test item	**Thiacloprid OD 240**						
Test object	**Honeybee *Apis mellifera* L.**						
Exposure	**contact / oral**						
Treatment	**LD_{50}**						
Test item	time	contact toxicity test			oral toxicity test		
		µg product/ bee	slope b	µg a.s./ bee	µg product/ bee	slope b	µg a.s./ bee
Thiacloprid OD 240	24 h 95%-cl lower upper	85.392 72.563 100.488	4.395	-	29.119 25.146 36.634	2.405	-
	48 h 95%-cl lower upper	82.717 70.775 96.675	4.723	-	26.202 20.451 33.571	2.166	-
Reference item Dimethoate EC 400	24 h 95%-cl lower upper	-	-	0.233 0.212 0.256	-	-	0.139 0.116 0.166
	48 h 95%-cl lower upper	-	-	0.171 0.146 0.201	-	-	0.135 0.113 0.162

cl: confidence limits

Observations:

The observed behaviour of the test item exposed bees was different to those in the control, with bees observed as inactive and lethargic up to 24 hours after exposure, depending on the dose applied.
In the reference treatment apathy, uncoordinated movements and immobility were observed before bees died.

Conclusion:

The 48-hour LD_{50} value was 82.7 µg product/bee (corresponding to 18.98 µg a.s./bee) in the contact toxicity test. The 48-hour LD_{50} value was 26.2 µg product/bee (corresponding to 6.01 µg a.s./bee) in the oral toxicity test.

CP 10.3.1.1.2 Acute contact toxicity to bees

The acute contact toxicity studies on honey bees with the product are summarised in Point 10.3.1.1.1, therefore only the results are summarised below.

Report:	[redacted]h; [redacted]; 2002; M-059157-01-1
Title:	Assessment of side effects of Thiacloprid OD 240 to the honey bee, Apis mellifera L. in the laboratory
Report No.:	20021218/01-BLEU
Document No.:	M-059157-01-1
Guidelines:	**OECD Guideline No. 213 and No. 214**
GLP/GEP:	**yes**

Table CP 10.3.1.1.2- 1: LD_{50} values in the toxicity test of Thiacloprid OD 240.

Thiacloprid OD 240	LD_{50}/24h	LD_{50}/48h
	[µg a.s./bee]	
Contact toxicity test	7.04	5.92

*the mortality which occurred in the control group was not included in the calculation of the LD50 values

Report:	[redacted]g[redacted]; 2003; M-103506-01-1
Title:	Acute toxicity of thiacloprid OD 240 to the honeybee Apis mellifera L under laboratory conditions
Report No.:	03 10 48 043
Document No.:	M-103506-01-1
Guidelines:	**OECD 213 (1998), OECD 214 (1998)**
GLP/GEP:	**yes**

Table CP 10.3.1.1.2-2: contact toxicity LD_{50} values of bees treated with Thiacloprid OD 240

Thiacloprid OD 240	LD_{50}/24h	LD_{50}/48h
	[µg product bee]	
Contact toxicity test	85.392	82.717

CP 10.3.1.2 Chronic toxicity to bees

A study with formulated product is not required. See Point CA 8.3.1.2 where studies on the chronic toxicity of technical thiacloprid and thiacloprid-amide are presented.

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A study with formulated product is not required. See Point CA 8.3.1.3 where a study on the toxicity of technical thiacloprid to honey bee larvae is presented.

CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideline to assess “sub-lethal effects” in honey bees. However, in each laboratory study as well as in any higher-tier study, sub-lethal effects, if occurring, are described and reported.

Two publications are summarised at Point CP 8.3.1.4 which describe the well know initial and short term repellence (foraging reduction) and influence on homing behaviour. In both cases these short term effects, (when they occur) are not biologically significant in terms of pollination or for the colony as demonstrated under GLP and test guideline semi-field and field conditions (see; Thiacloprid OD 240 [redacted]°; [redacted]; 2002; M-054090-01-1, [redacted]; [redacted]; 2012; M-442217-01-1, [redacted]; [redacted]; 2014; M-492158-01-1and [redacted]; [redacted]

[redacted]; 2014; M-492155-01-1) as well as Thiacloprid FS 400 KCP 10.3.1.5/1 [redacted], S.; 2010; M-385049-01-1, and KCP 10.3.1.6/1 [redacted], H.U.; 2010; M-373436-01-1

CP 10.3.1.5 Cage and tunnel tests

This section includes a number of tunnel studies. The studies include a highly detailed tunnel test which investigates the cumulative effect of two sequential applications of Thiacloprid OD 240 applied during full-blood to honey bee colonies under tunnel test conditions. Mortality, foraging, behaviour, colony strength, brood and food stores and colony health (disease and Varroa status) were monitored. Following exposure the colonies were followed through to the following year to assess over wintering success [redacted],; 2014; M-492155-01-1.

Report:	[redacted]0;[redacted]; 2002; M-054090-01-1
Title:	Assessment of side effects of Thiacloprid OD 240 on the honey bee (Apis mellifera L.) in the semi-field
Report No.:	20021218/01-BZEU
Document No.:	M-054090-01-1
Guidelines:	**OEPP/EPPO Guideline No. 170(3)**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240 (YRC 2894 240 OD); Article No.:00-05683696; Batch: 07690/0086(0082); Tox-No.: TOX06069-00; Analysed purity: 243.95 g a.s./L (240 g/L nominal).

The effects of Thiacloprid OD 240 were tested on the honey bee (*Apis mellifera* L.) under semi-field conditions following the OEPP/EPPO guideline No. 170(3) (OEPP/EPPO, 2001): Guideline for the efficacy evaluation of plant protection products – Side effects on honey bees.
This study included three treatment groups with three replicates each. The test substance was applied during full flowering of the oil-seed spring-rape (*Brassica napus*) at a rate equivalent to 0.3 L/ha (73.19 g a.s./ha) in 300 L water/ha. A second group treated with tap water served as control. As toxic standard "Perfekthion" (dimethoate) was applied at a concentration of 650 g product/ha (251.97 g a.s./ha) in 300 L water/ha. All applications were conducted during the morning while bees were actively foraging in the blooming crop. The effect of the test substance was examined on small bee colonies containing approx. 4000 to 6000 bees in tunnel tents placed over the plots with flowering oil-seed spring-rape (*Brassica napus*). Mortality, behaviour, foraging activity, condition of the colonies and the development of the bee brood was assessed before and after treatment.
The influence of the test substance was evaluated by comparing the bees in the tents of the test substance treatments to the control bees treated with water and those treated with the toxic standard. The following points were assessed:

- Mortality at the edge of the treated area and in the bee traps.
- Foraging activity (number of foraging bees/m^2 flowering oil-seed spring-rape crop)
- Development of the bee brood

Findings:

Effect on honey bee mortality

No increase of the mortality was observed in the Thiacloprid OD 240 treatment group on day DAA 0 after application. A low mean number of 3.7 dead bees/replicate was found directly after the application in the test substance treated tents. A significant increase of mortality was observed after application in the toxic standard with an average of 317.3 dead bees/replicate on the day of application compared to the control group (2.6 dead bees/replicate).
Almost all values of mortality per replicate and day which were calculated in the test substance treatment during the post-application period remained clearly below the values of the pre-application period and did not exceed 6 dead bees/replicate/day. In the toxic standard treatment the mortality was significantly higher during the post-application period compared to the control on almost all assessment days.

Effects on honey bee flight intensity
After the application the flight intensity in the test substance treatment group decreased slightly and remained with a mean of 6.1 bees/m^2 below the values of the assessment directly before application (7.7 bees/m^2) and below the values observed in the control group (14.0 bees/m^2). On the following four observation days (until DAA 4) the mean flight intensity in the test substance treatment group remained statistically significantly below the mean flight intensity observed in the control group and a repellent effect caused by the test substance on the first four days after application can be assumed. No remarkable differences could be observed regarding the flight intensity between the control and the Thiacloprid OD 240 treatment on the last three assessment days (DAA 5 to 7). The mean flight intensity in the toxic standard treatment was statistically significantly lower compared to the control group during the entire post-application period.

Effects on honey bee brood development
Regarding the colony strength and the bee brood development no differences attributable to the influence of the test substance were observed between the test substance groups and the control.

Effects on honey bee behaviour
Directly after application of Thiacloprid OD 240 and during the post-application assessments no behavioural differences were observed in the Thiacloprid OD 240 treatment group compared to the control group and the bees continued with foraging on the treated oil-seed spring rape flowers.

Table CP 10.3.1.5- 1: Toxicity to honey bees, semi-field test

Test substance		**Thiacloprid OD 240**		
Test object		***Apis mellifera***		
Exposure		**Spray treatment during foraging activity in flowering oil-seed spring-rape**		
Treatment group		**Test substance (Thiacloprid OD 240)**	**Control (water)**	**Toxic standard (Perfekthion)**
Code		**TS**	**C**	**R**
Application rate [in 300 L water/ha]		**0.3 L (73.19 g a.s.)**		**650 g (251.97 g a.s.)**
Average Mortality rate [dead bees/ hive/day]	pre:	6.6	8.8	8.3
	post [0]:	3.6	2.6	317.3
	post [0-7]	2.9	4.4	84.3
	$Q_{M(average)}$:	0.4	0.5	10.2
Average Flight intensity [foraging bees/ m²/day]	pre:	7.7	9.8	7.9
	post [0]:	6.1	14.0	0.6
	post [1-7]:	7.7	11.6	0.9

pre = average values for day -2 to 0 days before application;
post [0] = day of application after application;
post [1-7] = average value for days 1 – 7 after application;
$Q_{M(average)}$ =Average mortality per day before application divided by average mortality per day after application

Conclusion:

Thiacloprid OD 240 had no effect on the mortality when applied to the bee-attractive flowering crop oil-seed spring-rape at an application rate of 0.3 L/ha in 300 L water /ha. A slight repellent effect was observed at this test rate, indicated by a reduced flight intensity during the first four days after application. No impact of Thiacloprid OD 240 on the brood development of honey bees was noticed.

Report: [redacted]b; [redacted]; 2012; M-442217-01-1
Title: Determination of side-effects of thiacloprid OD 240 on honey bee (Apis mellifera L.) brood under confined semi-field conditions
Report No.: S10-03823
Document No.: M-442217-01-1
Guidelines: **OECD Guidance Document No. 75 (2007); not specified**
GLP/GEP: **yes**

Objective:

The objective of the study was to determine the effects of Thiacloprid OD 240 on the honey bee, *Apis mellifera* under semi-field conditions in *Phacelia tanacetifolia*.

Material and methods:

Test item: Thiacloprid OD 240B G; Batch ID: EDE5100633; Material no.: 79674910; Specification no.: 102000021774-01; Analysed content: 234.8 g a.s./L (22.6% w/w).

This study included three exposure groups with three replicates (tunnels) each: one control group (C), one test-item group (T) and one reference item group (R). In all exposure groups, the crop was sprayed 5 days after set-up of the hives in the tunnels at BBCH 64/65 during honey bee foraging activity on the crop under confined conditions. The target application rate of the test item Thiacloprid OD 240

corresponded to 72 g a.s./ha, tap water was applied in the control group and Insegar 25 WG was applied at a target rate of 600 g product/ha in the reference item group (corresponding to 150 g fenoxycarb per ha). The spray volume was 200 L/ha for all groups. The colony size at set-up was in the range of 5188 – 8875 bees. The honey bees remained 12 days in the tunnels.
The first colony assessment was performed before set-up of the colonies in the tunnel tents. Subsequently, six further colony assessments were conducted. The development of the bee brood in individual marked brood cells (BFD = Brood Area Fixing Day) was assessed in parallel with the colony assessments with the exception of the last one where only a colony assessment was done. Overall, the colonies were assessed once before, twice during and four times after the end of the confined exposure phase at the monitoring side. Mortality assessments (in bee trap and on the linen sheets) started 4 days before the applications and continued on a daily basis for 7 days after the applications. Further mortality assessments were conducted at the monitoring site, after the end of the confinement period until the 28th day after application (in the dead bee traps only). Flight intensity assessments started 4 days before the applications and continued on a daily basis until the 7th day after the applications.
The influence of the test item was evaluated by comparing the results obtained in the test item treatment group to those of the control and the reference item group.
The following endpoints were assessed:

- Total and mean number of dead bees on the linen sheets in tunnel tents and in the dead bee traps before as well as after the applications
- Flight intensity
- Behaviour of the bees in the crop and around the hive;
- Condition of the colonies and development of the bee
- Development of the bee brood assessed in individual brood cells.

Findings:

Biological findings:
Mortality:
No treatment-related adverse effects on mortality were found. Observations are presented in the table below.

Table CP 10.3.1.5-2: Mortality of honey bees, semi-field test under confined exposure conditions

Treatment group	Control (C)	Test Item (T)	Reference item (R)
Application rate	--	72 g thiacloprid a.s./ha at BBCH 64/65	150 g fenoxycarb a.s./ha at BBCH 64/65
Mean mortality DAA-4 to 0ba [dead bees/day]	37.9	42.2	42.4
Mean mortality DAA0ba [dead bees/day]	55.7	71.7	52.7
Mean mortality DAA0aa [dead bees/day]	59.0	62.7	43.3
Mean mortality DAA0aa to 7 [dead bees/day]	68.2	71.1	58.7
Mean mortality DAA0aa to 28 [dead bees/day]	42.9	59.9	33.5

DAA = Days after application
ba = before application
aa = after application

Flight intensity

Flight intensity of the test item treatment group T was statistically significantly (t-test, method pooled, one-sided, α = 0.05) reduced in comparison to the control C on DAA0aa, 1, 6 and during DAA0aa to DAA7 (mean). Although being statistically significantly different from control the values of 15.8, 10.5, 7.0 and 7.9 (mean) forager bees/m^2 in T are not biologically relevant, since foraging activity was overall on a still high level. Overall, although a slight repellent effect of the test item cannot be excluded, the slightly reduced flight intensity after test item application in T when compared to C, is well in line to the slightly reduced flight intensity in T when compared to C before the test item treatment, and could as such also originate from the lower colony strength at set up in T when compared to C. In any case, the application of thiacloprid did not result in an adverse effect on foraging activity.

Table CP 10.3.1.5- 3: Flight intensity of honey bees, semi-field test under confined exposure conditions

Treatment group	Control (C)	Test Item (T)	Reference item (R)
Application rate	**--**	**72 g thiacloprid a.s./ha at BBCH 64/65**	**150 g fenoxycarb a.s./ha at BBCH 64/65**
Daily mean flight intensity DAA-4 to 0ba [bees/m^2/min]	13.5	10.9	12.6
Daily mean flight intensity DAA0aa [bees/m^2/min]	21.5	15.8	19.3
Daily mean flight intensity DAA1 [bees/m^2/min]	14.4	10.5	11.5
Daily mean flight intensity DAA0aa to 7 [bees/m^2/min]	11.2	7.9	10.1

DAA = Days after application
ba = before application
aa = after application

Behaviour

Except for DAA0aa (a few bees were observed with intoxication symptoms (cramping, locomotion problems), moreover, fanning bees at the hive entrance, motionless bees on flowers and in the trap, intensive flying over the crop coupled with an infrequent landing on the crop could be observed.) and DAA9 (some motionless bees were observed in the bee trap), honey bee behaviour in test item treatment T was comparable to the control treatment throughout the entire assessment period. In any case, the application of thiacloprid did not result in adverse behavioural effects.

Development of honey bee brood in individual cells (digital image analysis)

The control (C) and test item treatment (T) colonies showed a successful development, with rising brood indices throughout the entire assessment period, except for the assessment on BFD16, where stable values (due to the long development time of the sealed brood) compared to the previous assessment on BFD10 were observed in both, C and T, respectively. While no treatment-related adverse effects on honey bee brood development were caused by the test item, the exposure to the reference item caused negative effects on the brood development typical for the used substance (fenoxycarb). Detailed observations are provided in the table below.

Table CP 10.3.1.5- 4: Summary of the brood indices, compensation indices and termination rates in the control (C), test item treatment (T) and reference item (R) group

Replicate	Brood / Compensation indices at x days after brood area fixing day (BFD)					Termination rate (BFD+22)
	0	+4	+10	+16	+22	[%]
Ca	1.00 / 1.00	1.73 / 1.85	3.14 / 3.56	3.11 / 3.59	3.89 / 4.32	22.13
Cb	1.00 / 1.00	2.00 / 2.01	3.71 / 3.73	3.71 / 3.73	4.64 / 4.70	7.14
Cc	1.00 / 1.00	1.88 / 1.94	3.48 / 3.67	3.47 / 3.67	4.33 / 4.48	13.33
Mean Ca – Cc	1.00 / 1.00	1.87 / 1.93	3.44 / 3.65	3.43 / 3.66	4.29 / 4.50	14.20
STD	0.00 / 0.00	0.14 / 0.08	0.29 / 0.09	0.30 / 0.07	0.38 / 0.19	7.53
Ta	1.00 / 1.00	1.69 / 1.79	3.30 / 3.42	3.30 / 3.42	4.13 / 4.13	17.50
Tb	1.00 / 1.00	1.61 / 1.64	3.14 / 3.35	3.14 / 3.35	3.92 / 4.07	21.58
Tc	1.00 / 1.00	2.03 / 2.06	3.70 / 3.73	3.70 / 3.73	4.63 / 4.76	7.47
Mean Ta – Tc	1.00 / 1.00	1.78 / 1.83	3.38 / 3.50	3.38 / 3.50	4.23 / 4.32	15.52
STD	0.00 / 0.00	0.22 / 0.21	0.29 / 0.20	0.29 / 0.20	0.36 / 0.38	7.49
Ra	1.00 / 1.00	0.74 / 1.00	1.34 / 2.44	1.32 / 2.71	1.65 / 3.12	66.95
Rb	1.00 / 1.00	0.80 / 1.28	0.62 / 1.42	0.62 / 1.07	0.77 / 1.81	84.55
Rc	1.00 / 1.00	1.04 / 1.06	1.47 / 1.75	0.74 / 1.07	0.93 / 2.22	81.40
Mean Ra – Rc	1.00 / 1.00	0.86 / 1.11	1.14 / 1.87	0.89 / 1.62	1.12 / 2.38	77.63
STD	0.00 / 0.00	0.16 / 0.15	0.46 / 0.52	0.37 / 0.95	0.47 / 0.67	9.39

BFD: Brood area Fixing Day, STD: Standard Deviation

Strength of the colonies

The development of colony strength was comparable between C and T throughout the study period and showed the fluctuations which are typical of this endpoint. As such, no test-item related adverse effects on colony strength were observed.

Development of brood area

Except for the colony Ta (no eggs on the fifth colony assessment and no eggs and larvae on the sixth and seventh colony assessment), the fluctuations of all brood stages were within the range of natural variation and typical for this kind of study.

Development of the food storage area

The observed de- and increase in food stores in both, treatment and control, during confinement and thereafter can be considered as typical for this type of study.

Conclusion:

Overall, the employed application scenario did not cause treatment-related adverse effects on mortality, on flight intensity, on honey bee behaviour, on brood- and food development as well as on colony vitality under forced exposure conditions.

A slight repellent effect of the test item might be indicated by reduced flight intensity on the day of the test item application as well as on some further days during the confined exposure period.

Report:	[redacted]; 2014; M-495895-01-1
Title:	Semi-field tunnel study in Phacelia tanacetifolia, evaluating the effects of repeated foliar applications of thiacloprid on honey bees Apis mellifera L. (Hymenoptera, Apidae) under confined conditions, followed by a post-exposure field observation period
Report No.:	E 319 4375-2
Document No.:	M-495895-01-1
Guidelines:	**OEPP/EPPO Guideline No. 170 (4), 2010 (modified); No major deviations**
GLP/GEP:	**yes**

Objective:

This study was designed to evaluate the acute, short-term and long-term effects of repeated foliar applications of Thiacloprid OD 240 during full-bloom of the highly bee-attractive surrogate crop *Phacelia tanacetifolia*, on honey bees *Apis mellifera* L. (Hymenoptera, Apidae) under semi-field conditions.

Material and methods:

Test item: Thiacloprid (tech.); Specification No.: 102000021774 - 01; Material No.: 79674910; TOX No.: 09597-00; Batch-code: ECE7100937.

Small honey bee colonies were exposed to two subsequent foliar applications during actively foraging on the full-flowering crop under confined exposure conditions in gauze tunnels. During the confinement period, lasting in total 16 days, mortality, foraging activity, behaviour, colony-, brood- and food development were assessed regularly. Thereafter, the honey bee colonies were released from confinement and allowed to forage freely under ambient field conditions; during this period, the colonies were maintained as typical for Good Apicultural Practice and the development of the colonies and their overall health status was assessed in regular intervals until overwintering. The study lasted until the overwintering performance had been assessed in the following spring.
The first part of the study was conducted as a semi-field tunnel experiment, set-up in a full-factorial randomised block design, with five blocks (one block = 1 tunnel harbouring one honey bee colony) and three exposure groups. The exposure groups consisted of control (C) - treated with tap water, reference item (R) - treated with 400 g dimethoate/ha and test item treatment (T) - treated with 2 × 72 g thiacloprid/ha. Apparently healthy, queen-right honey bee colonies, equalised for adult worker bees, brood- and food stores as reasonably possible were used for the purpose of this study.
In order to expose the honey bee colonies in the test item treatment group to two subsequent foliar test item applications during full bloom of a highly bee-attractive flowering crop under forced (confined) exposure conditions, Phacelia-seeds were sown during springtime in a staggered manner, i.e. in strips located directly adjacent to one another, with a time period of 10 days in-between the respective seed sowing.
The tunnels that were placed over theses strips were separated in the middle by a gauze barrier; honey bee colonies were placed first in the part that was flowering earlier and where the first application was conducted (during full-bloom), thereafter, once the Phacelia was at full-bloom on the second, later flowering part, the colonies were moved and the second application was conducted (during full-bloom) on this later flowering part. Colonies exposed to the reference item dimethoate were not moved, but replaced by new colonies. After the confined exposure period, the colonies in the control and in the test item treatment group were further regularly inspected and assessed under field conditions until the end of the season and for a last time after overwintering during springtime in the

following year. Colonies in the reference item group were discarded at the latest at the end of the confined exposure period.

The following assessments and observations were made during the study:
Honey bee mortality – during the confinement period was assessed by means of dead bee traps, and on a piece of polyethylene-mesh (50 x 50 cm) laid out in front of each hive. Furthermore, dead worker bees and drones (as well as larvae and pupae, if any) were collected and counted on water-permeable polyethylene-mesh-sheets (width approximately 30 - 50 cm), which were installed along the walls of every gauze tunnel.
Flight intensity/flower visits – throughout the confinement period was assessed twice a day during one-minute lasting observation periods in an arbitrarily selected area of 1 m² at two different locations per tunnel. Additionally, the number of honey bees present on the gauze tunnel roof and walls were counted in order to detect possible repellent/disorientation effects.
Colony condition and the development of colony strength and bee brood was checked repeatedly throughout the entire duration of the study.
At each assessment, the comb area containing adult honey bees and cells with nectar (honey), pollen (bee bread), eggs, larvae and capped cells was assessed. During each assessment, the colonies were inspected for bee diseases according to standard beekeeping practices.
Varroa infestation - each colony was monitored throughout the study by the repeated installation of a board under the mesh-floor of each hive.

To investigate the health status of each colony samples of adult bees were collected for assessments of potential infections (e.g. *Nosema* spp), bee virus analysis and the analysis for European foulbrood (EFB). For American foulbrood (AFB), several tablespoons of nectar/fresh honey were scratched from each colony. Samples were collected before confinement, after confinement, before overwintering and after overwintering.

Results:

Honey bee mortality in front of the hive and at the tunnel walls during confinement
For the colonies exposed to the test item as well as the control, mortality was low throughout the entire confinement period. The colonies treated with the reference item (dimethoate) showed a biologically and statistically significant increase of worker bees and demonstrated that the honey bee colonies and that test system was adequate to detect effects on honey bee survival. The treatment with the test item did not result in any detectable effects on mortality. Statistical analysis revealed no significant differences between the control and the test item group for any of the assessed mortality parameters. Overall, it can be concluded that sequential foliar spray applications of 2 × 72 g thiacloprid a.s./ha did not cause any adverse effects on worker bee, drone or larval/pupal mortality. Findings from the assessments of dead worker bees found in front of the hives are presented in the following figure.

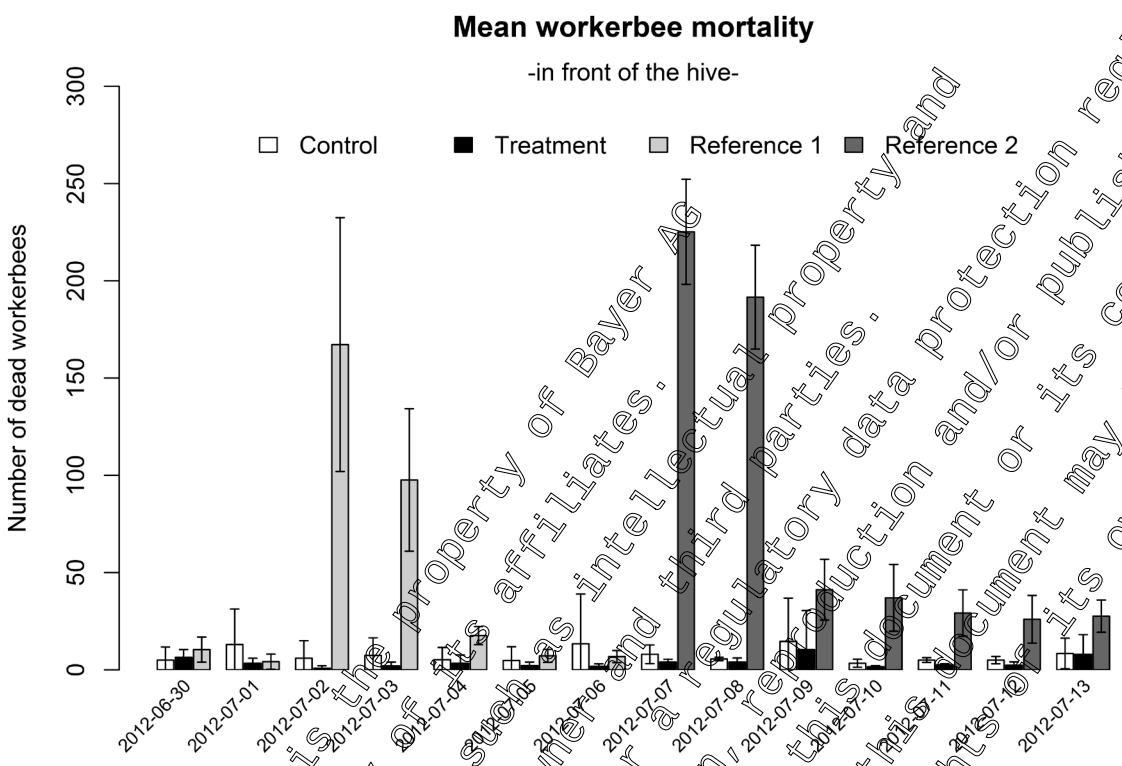

Figure CP 10.3.1.5- 1: Average daily number of dead worker bees in front of the hive per treatment group, throughout the confinement period (± SD). Applications were made on 2012-07-02 and 2012-07-07.

Foraging activity

Prior to the first application, foraging activity for all treatment groups was very homogenous and no statistically significant differences were detected between the groups. Application of the test item had a negative effect on foraging. Colonies exposed to the test item showed a tendency for slightly lower foraging activities on the day of the application but no statistically significant difference in comparison to the control could be detected. In parallel to the assessments of foraging activity, the number of bees sitting at the tunnel walls was also recorded in order to detect any repellent or disorientating effect caused by the test item; no statistically significant differences were found between the colonies in the test item treatment and those in the control group on any day throughout the confined exposure period. Findings from the assessments of foraging worker bees are presented in the following figure.

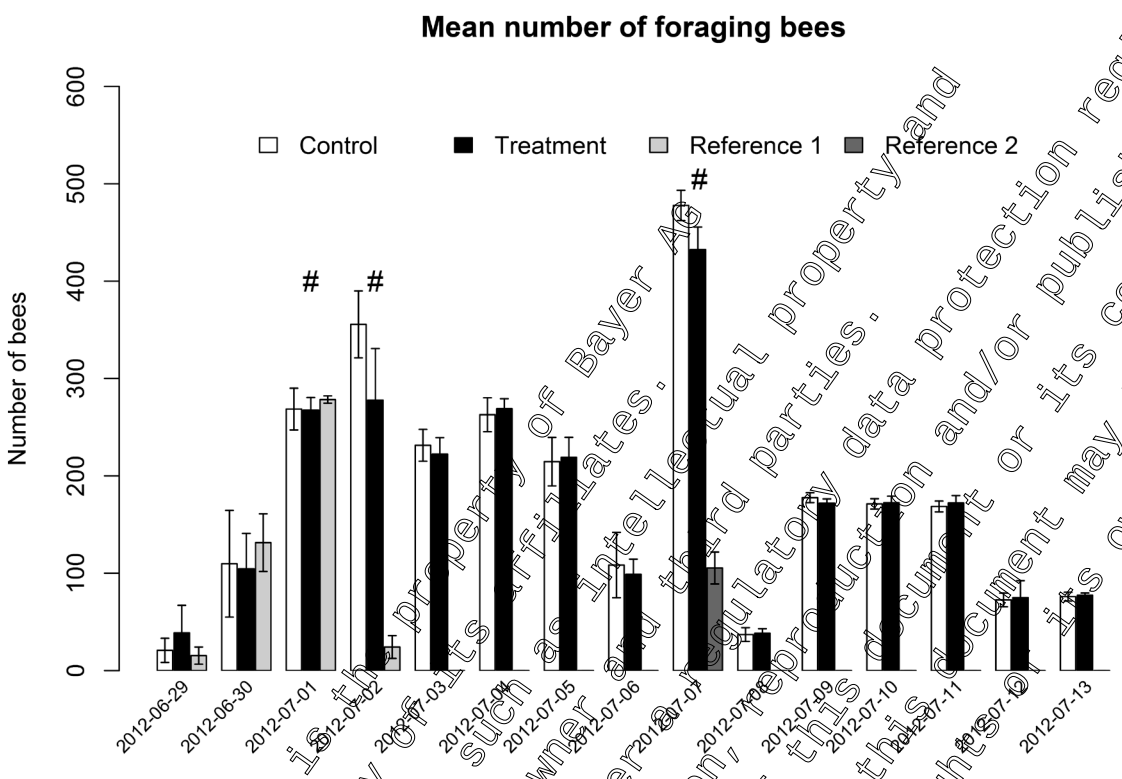

Figure CP 10.3.1.5- 2: Average daily number of foraging bees per treatment group, throughout the confinement period (± SD). Applications were made on 2012-07-02 and 2012-07-07.
Averages presented here are based on the sum of foraging bees found over the whole day, which may lead to an overestimation of the average number of foragers (occasions with more than one assessment per day are marked by # in the graph).

Colony strength

The development of the colonies throughout the entire experiment, in terms of the number of adult worker bees, was very homogenous for the test item and control group. No adverse effects of the two sequential thiacloprid applications were observed. After the release of the control- and the test item colonies from their respective tunnels, the numbers of worker bees increased and colonies exposed to the test item showed a tendency of slightly higher numbers of worker bees. The results show that after the release from the tunnels, colony development in both, control and test item treatment continued as normal. Although colonies in the test item group had a tendency to have slightly more worker bees there were no statistically significant differences between test item treatment and control. After overwintering, one colony each in the test item treatment and control was lost/non-vital. This observation is not treatment related. Findings from the colony strength assessments are presented in the following figure.

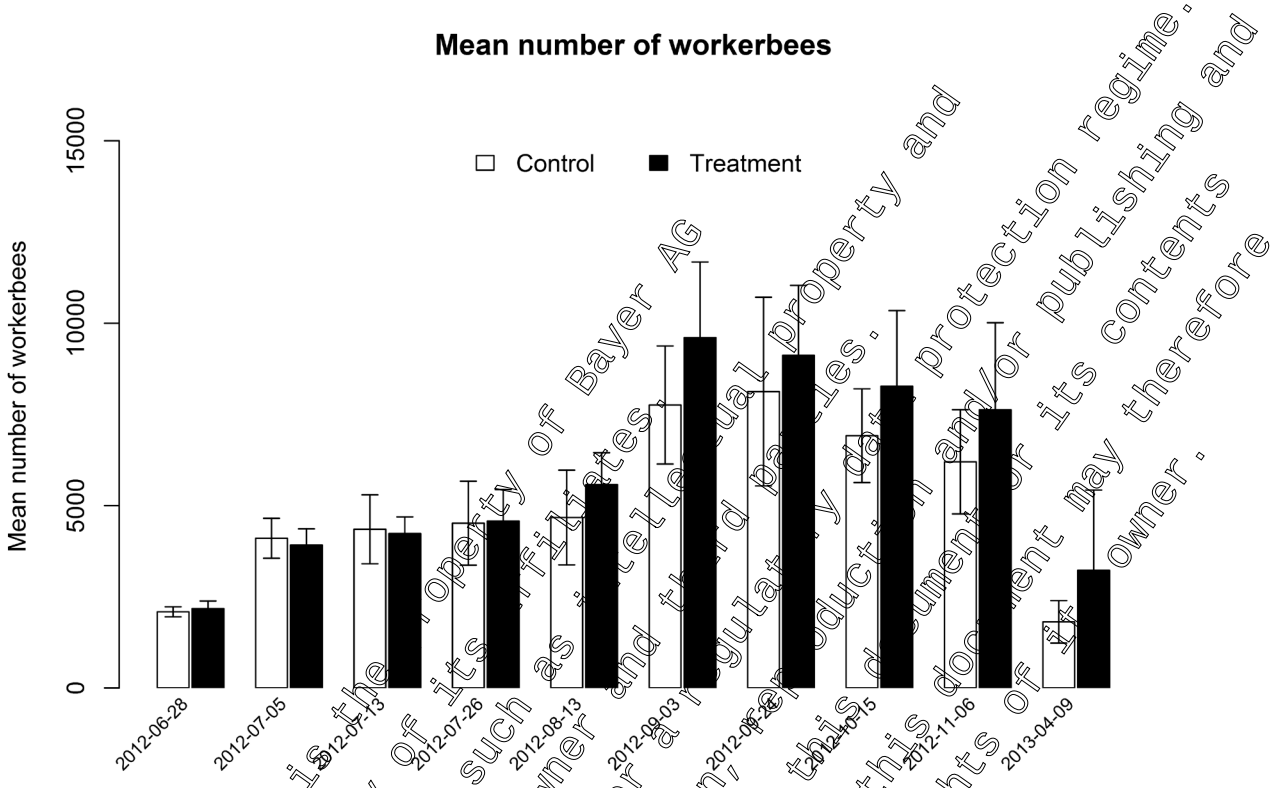

Figure CP 10.3.1.5- 3: Colony strength determined as the average number of worker bees ± SD for the control and treatment group evaluated during each colony assessment throughout the course of the study.

Colony brood status/brood development

Brood development was very homogenous for the colonies in the control as well as in the test item treatment group. The data reflected very well the typical seasonality of brood development in honey bee colonies. No adverse effects of the sequential test item applications were recorded in terms of the average number of total brood cells (eggs+larvae+pupae) present in the colonies. The number of total brood cells was generally slightly higher in the test item treatment group compared to the control group. The same tendency becomes visible when individual brood stages, i.e. eggs, larvae and pupae were assessed separately. For some instances, statistically significantly higher average numbers of total brood cells, eggs or larvae were found in test item treated colonies in comparison to control. These findings were, however, incidental and can be attributed to stochastical effects based on natural variability. Findings from the total assessments are presented in the following figure.

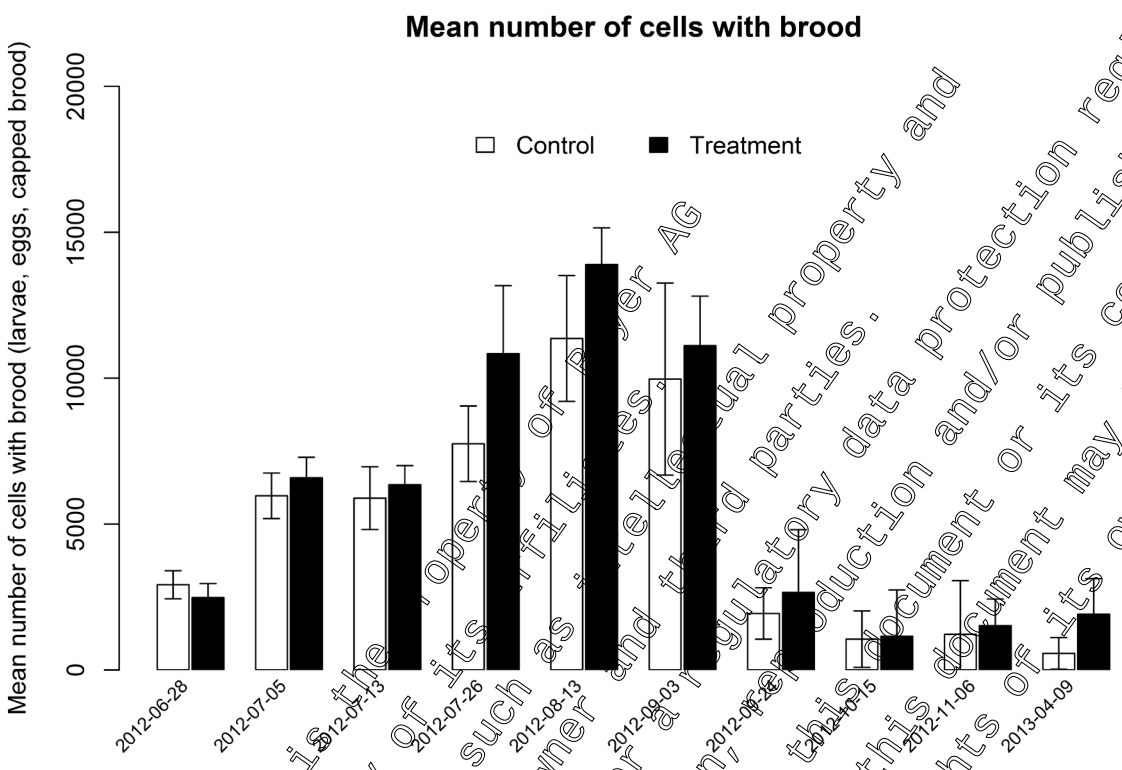

Figure CP 10.3.1.5- 4: Total brood determined as the average number of brood-containing cells per exposure group ± SD evaluated during each colony assessment throughout the course of the study.

Food stores (nectar, honey and pollen)
Storage of nectar/honey was unaffected by the test item treatment. The development of nectar/honey stores for the colonies in the control and in the test item group was influenced by the environmental conditions and the change of seasons. The colonies were fed with supplemental syrup according to Good Apicultural Practice during late summer and autumn in preparation for overwintering. While the storage of pollen showed a certain heterogeneity between the individual colonies, colonies in test item group showed a tendency to slightly exceed the average number of cells filled with pollen as compared to the control colonies (statistically significantly different on one instance).

Honey bee disease and virus analysis and Varroa
When assessing and comparing the colonies in the control and in the test item treatment group in terms of the presence (or absence) of diseases and viruses, the colonies showed typical infestation levels and no distinct differences at any point in time. There were no statistically significant differences in the number of mites dropped per day between the control and test item group, indicating that the exposure to the test item did not lead to a higher susceptibility to *Varroa* infestation.

Behaviour of the bees
There was no evidence that the test item treatments resulted in adverse effects on behaviour. Neither symptoms of poisoning (e.g. twitching or cramping), nor aggressive behaviour, change in the cleaning behaviour or any other form of behavioural change of the bees were observed after the respective application of the test item and thereafter.

Conclusion:

In a full-factorial randomised block design, honey bee colonies were exposed in the test item treatment group to two sequential foliar applications, corresponding to 72 g thiacloprid/ha, respectively, and applied under confined conditions - due to the special set-up of the study - two times during full bloom of the highly bee-attractive surrogate crop *Phacelia tanacetifolia*. After the confined semi-field exposure period, the colonies in the control and in the test item treatment were released from confinement to be repeatedly monitored under field conditions for the remainder of the season until overwintering, and were assessed for a final time after overwintering in the next spring.
The exposure of honey bee colonies to two repeated thiacloprid applications during full bloom did not result in adverse acute, short-term and long-term effects on mortality, colony strength and -development, brood development, food storage, honey bee behaviour, overall hive vitality and colony health, as well as on overwintering performance.

CP 10.3.1.6 Field tests with honeybees

Report:	[redacted]; [redacted]; 2000; M-036544-01-2
Title:	Effect of the application of Calypso 480 SC and BSN 2060 240 SC on pollinating bumblebees (Bombus terrestris) on greenhouse tomatoes
Report No.:	REG02-0010
Document No.:	M-036544-01-2
Guidelines:	**Not stated**
GLP/GEP:	**No**

Objective:

The objective was to determine whether the application of Calypso 480 SC as foliar spray of tomato crops grown in greenhouses has any influence on the activity of pollinating bumblebees *(Bombus terrestris)* and/or on the life and development of the colony.

Material and methods:

Test item: Calypso 480 SC

Tomato plants grown in greenhouses in Spain at different locations were used as crop. Four blocks consisting of control and treatment were established. Bumblebee hives were acquired from a commercial supplier and selected with a number of worker bees according to the plot size and a homogeneous hive stage. The hives were placed into the crop at flowering. Calypso 480 SC was sprayed twice with a spraying interval of 10 days, starting 5 days after the introduction of the bumblebee colonies. The spray solution consisted of 0.03% of the product and a volume of 800 L per ha was applied. In all plots the hives were closed on late afternoon of the day preceding the insecticide application and opened the morning following application. During the trial, crop management was carried out with pesticides compatible with bumblebees.
Pollinating efficiency was checked weekly on a total of 40 plants from the day before application until 4 weeks after application, accounting 5 evaluations. Evaluations of pollination were made based upon the averaged percentage of fruits, aborted flowers, closed or non-marked flowers, and marked flowers from all flowers as well as the averaged percentage of the open marked flowers over the opened

flowers. Flight frequencies as assessed from the number of workers flying out and coming back to the hives with or without pollen were counted for 30 minutes on a weekly basis. Laboratory assessments on the final hive status were performed at study end, evaluating queen survival, number of larvae, new queens, drones, number of workers, larvae and pupae (alive and dead).
Pollinating activity and parameters determined for hive status evaluation (e.g. mortality of worker bees, larvae and pupae, the number of laid eggs and number of cells with food stores, weight of honey storage) were subjected to statistical analysis for variance (95% confidence level)

Findings:

Three out of four plots were included in the final statistical evaluation. Tomato plants in the third plot were not equally developed, presenting only a small number of flowers and thus, preventing the bumblebees from getting established under these crop conditions. The general results of this plot were assessed and reported to equal those of the three remaining blocks. Therefore, exclusion from statistical analysis did not impact the validity of the conclusions made from this trial.

<u>Biological findings:</u>
Pollinating activity
No statistically significant differences were found for pollinating activity. Bumblebee activity was high during the whole period maintaining a high percentage of pollinated flowers (80% at study end). Pollination success as determined by pollinated flowers was similar in all blocks and during the overall course of the trial. Also, the extent of aborted flowers, marked flowers from all flowers or open flowers only, and unmarked flowers/closed flowers did not show differences in the treatments when compared to the untreated control. Furthermore, flight intensity was not adversely affected by the test item.

Colony assessment
As can be expected for these uses under confinement, hives in general showed a significant larval mortality ranging from 21% - 97%, the latter value reported for an untreated plot. Worker and pupal mortality was low. No treatment-related effect was seen in any of the parameters examined. The queen was alive in all hives.

Conclusion:

No treatment-related effect on the pollination activity of bumblebees could be observed in the trial. Furthermore, there were no statistically significant differences between treatment and control for the parameters recorded in the final colony assessment. The queen was alive in all colonies.

Report:	[redacted]; [redacted]; 2014; M-492158-01-1
Title:	Assessment of side effects on the honeybee (Apis mellifera L.), exposed to Phacelia tanacetifolia, sprayed sequentially with thiacloprid OD 240B G once before and two times during flowering in a long-term field study in Alsace, France 2012 and 2013
Report No.:	S12-00040
Document No.:	M-492158-01-1
Guidelines:	**OEPP/EPPO Guideline No. 170 (4) (2010); none specified**
GLP/GEP:	**yes**

Objective:

The objective of the study was to determine the effects of sequential spray applications of Thiacloprid OD 240 on the honey bee, *Apis mellifera* under field conditions.

Material and methods:

Test item: Thiacloprid OD 240B G; Batch ID: ECE7101227; Material no.: 79674910; Specification no.: 102000021774-01; Analysed content: 239.2 g a.s./L.

This study included two treatment groups: The test item group (T) and the untreated control (C). Each group consisted of six commercial honey bee colonies placed at two test fields (distance 4 km) near Saint Pierre and Stotzheim, both located in Alsace, France. The crop used for this field study was *Phacelia tanacetifolia*. Three sequential foliar spray applications (once at imminent pre-bloom and two times during full-flowering) of the test item (target application rate: 96 g a.s./ha) were conducted. All applications were carried out with a spray volume of 300 L/ha (target).
Seven days after the 1st foliar spray application and eight days before the 2nd foliar spray application, the colonies were placed at the field sites in the early morning at beginning of flowering (crop stage mainly in the range of BBCH 60-63 in T, and mainly in the range of BBCH 61-63 in C), one day after the 1st colony assessment. The honey bee colonies in the test item treatment group T were exposed for a time period of in total 25 days to the treated crop. At the end of the flowering period at BBCH 69, the honey bee colonies were relocated to the monitoring site without agricultural crops attractive to bees, where the colony health and strength was assessed (via colony assessment).
Samples of bee hive products from the colonies and of *Phacelia tanacetifolia* flowers from the test fields were collected on several dates for residue analysis of thiacloprid.
The conditions of the colonies (including bee disease analysis) were assessed once before and regularly after the applications until start of overwintering and once after overwintering of the colonies. In order to assess colony health, samples for bee disease and bee virus analysis were collected on four occasions during the study.
The influence of Thiacloprid OD 240B G was evaluated by comparing the data of the assessments of the test item group to the control, and under consideration of the results of:
Total and mean numbers of dead bees on the linen sheets and in the dead bee traps
Flight intensity (mean number of forager bees / m²)
Behaviour of the bees in the crop and around the hive
Condition of the colonies (number of bees (colony strength), total values of the different brood stages per colony and assessment date)
Bee disease and bee virus analysis
Overwintering performance

Findings:

Biological findings:

Mortality:

The total daily mean mortalities during the entire exposure phase from set-up at the field sites until relocation to the monitoring site (at BBCH 69) were calculated to be 17.0 dead bees/colony/day in the control and 15.8 dead bees/colony/day in T, respectively. These values can be considered as typical for colonies of the employed size and are well within the natural range of typical daily mortality.

Table CP 10.3.1.6- 1: Mortality

Assessment timing	Daily mean mortality (dead bees/colony) ± STD	
	Control (C)	Test Item (T)
Pre-application 2 (8DBA2 – 0DBA2)	27.7 ± 37.6	14.3 ± 12.4
Post-application 2 (0DAA2 – 0DBA3)	14.3 ± 8.8	20.8 ± 12.5
Post-application 3 (0DAA3 – 9DAA3)	9.7 ± 6.7	13.2 ± 6.2
Post-application total (8DBA2 – 9DAA3)	17.0 ± 23.8	15.8 ± 11.0

STD = Standard deviation

Flight intensity:

The flight intensity of the honey bees in the crop was determined over a period of 25 days (8DBA2 (= 7DAA1) to 9DAA3). (DAA = Days after application, DBA = Days before application)

During the first (8DBA2 (= 7DAA1) to 0DBA2) and the second (0DAA2 to 0DBA3) phase of flight intensity assessments, the mean flight intensity in control was slightly higher than in the test item group. However, the lower mean flight intensity values in T can still be considered to be within the range of natural variability. During the third phase (0DAA3 to 9DAA3), no notable differences were observed between the two treatment groups.

Table CP 10.3.1.6- 2: Flight intensity

Assessment timing	Daily mean flight intensity (bees/m) ± STD	
	Control (C)	Test Item (T)
Pre-application 2 (8DBA2 – 0DBA2)	10.5 ± 8.5	5.3 ± 4.0
Post-application 2 (0DAA2 – 0DBA3)	17.6 ± 9.9	8.9 ± 3.9
Post-application 3 (0DAA3 – 9DAA3)	8.3 ± 6.3	6.4 ± 5.2
Post-application total (8DBA2 – 9DAA3)	11.8 ± 9.1	6.8 ± 4.9

Behaviour:

Around the hives, behavioural differences (cramping, locomotion problems, trembling, intensive cleaning, motionless bees) of the bees in the test item treatment group compared to the bees in the control group were observed in a small fraction of honey bees on the days of the 2nd (0DAA2) and 3rd foliar spray application (0DAA3). During the assessment period following the 3rd foliar spray application, a small number of cramping bees (maximum: 4 bees) were observed daily from 1DAA3 to 6DAA3. On 2DAA3, one trembling bee was noticed. However, cramping and motionless bees were also observed during the same time period in the control group at the same level.

On all other days during the exposure period, no relevant differences in behaviour were observed between the test item treatment group and the control.

Strength of the colonies
The colony strengths of both, control group C and test item treatment group T, followed the natural course of colony strength development, with a decreasing tendency from summer to autumn and spring of the following year. Throughout the entire observation period, the mean colony strength in the test item treatment group T was on the same level as in the control group C (see Figure 10.3.1.6-1).

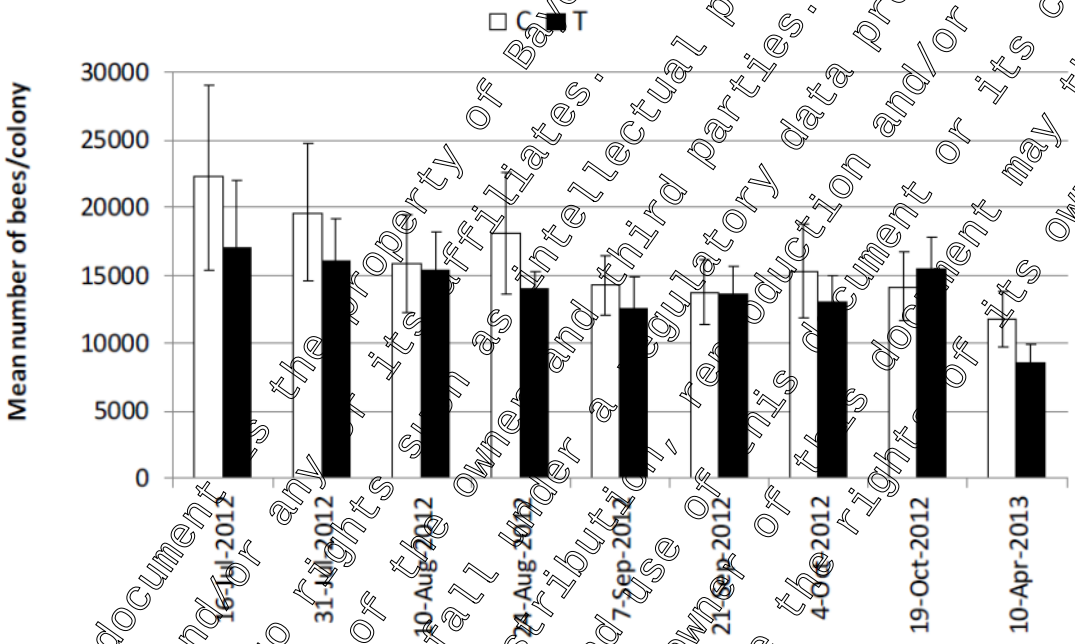

Figure CP 10.3.1.6- 1: Colony strength: Mean number of bees per colony in the control and test item treatment colonies.

Brood Stages and overwintering success
Honey bee brood development and colony conditions in the test item treatment T were comparable to control during the entire assessment period. No test-item related adverse effects on brood development were observed (see Figure CP 10.3.1.6-2).

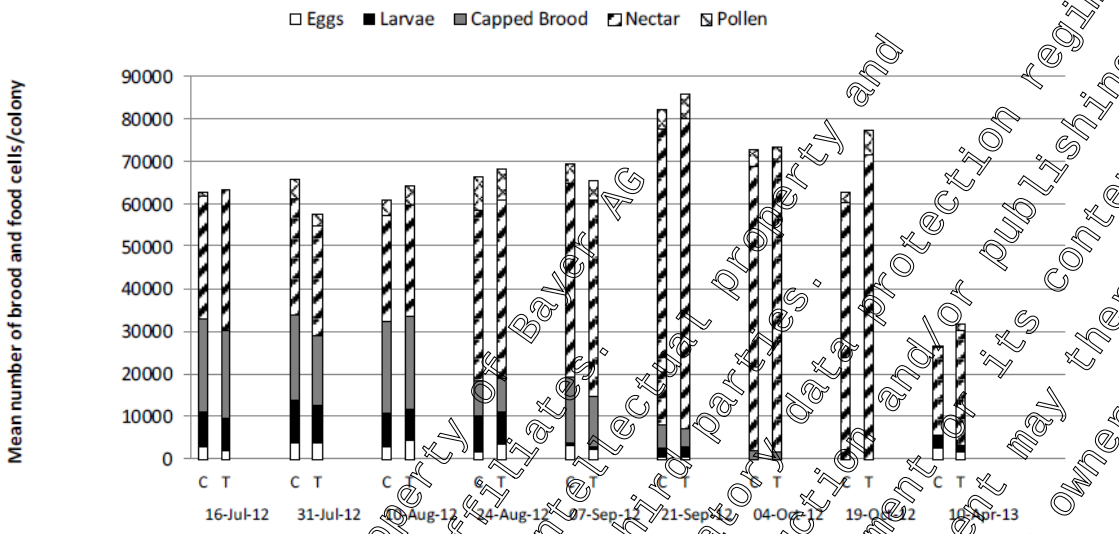

Figure CP 10.3.1.6- 2: Brood stages and food storage: Mean number of brood and food cells of the control and test item treatment colonies.

Food storage
In the colonies of the control group C and the test item treatment group T, respectively, the natural and typical changes and fluctuations in the relative amount of nectar and pollen storage cells occurred during the observation period. All colonies of the study showed approximately equal numbers of pollen and nectar storage cells in C and T, respectively, throughout the entire observation period (see Figure 10.3.1.6-2).

Bee diseases / Viruses
No differences in the bee health status could be observed between the control and the test item treatment colonies in terms of infection with the pathogens *Nosema sp.*, *Malpighamoeba mellificae*, *Varroa destructor* and *Paenibacillus larvae*.
Furthermore, the following bee viruses in bee samples collected at different time points of the year were determined: DWV (deformed wing virus), SBV (sacbrood virus), ABPV (acute bee paralysis virus), CBPV (chronic bee paralysis virus), KBV (Kashmir bee virus), IAPV (Israeli acute paralysis virus), and BQCV (black queen cell virus).
In this study the viruses ABPV, CBPV, KBV and IAPV were not detected in any of the samples taken at any time point. DWV and SBV were detected at the time point 'end of exposure' in 2012 in the sample of one colony of the control group. A higher infestation BQCV level in samples taken from colonies of the test item group was only a temporary phenomenon and of no notable consequences for the affected colonies.

Conclusion:

Overall, it can be concluded that exposure of honey bee colonies to *Phacelia tanacetifolia*, sequentially sprayed with Thiacloprid OD 240B G at a target rate of 96 g a.s./ha (once at imminent pre-bloom and two times during full-flowering, respectively), did neither cause acute, short-term nor long-term adverse effects on mortality, flight intensity, colony strength, colony health and vitality, brood and food development and overwintering performance in the exposed colonies.

Behavioural observations indicated a possible short-term correlation between the application of the test item during bee flight activity and the occurrence of cramping and motionless honey bees as well as honey bees with locomotion problems. However, these symptoms were transient and only observed in a small number of honey bees.

Report:	[redacted]; [redacted]; 2014; M-492155-01-1
Title:	Assessment of side effects on the honeybee (Apis mellifera L.) exposed to winter oilseed rape after two applications of thiacloprid OD 240B G during flowering in southern Germany 2012
Report No.:	S12-00042
Document No.:	M-492155-01-1
Guidelines:	**OEPP/EPPO Guideline No. 170 (4) (2010), SANCO/3029/99 rev. 4; not specified**
GLP/GEP:	**yes**

Objective:

The objective of the study was to determine the effects of two sequential spray applications of Thiacloprid OD 240 on the honey bee, *Apis mellifera* under field conditions.

Material and methods:

Test item: Thiacloprid OD 240B G; Batch ID: ECE7100937; TOX-no.: TOX09597-00; Material no.: 79674910; Specification no.: 102000021774-01; Analysed content: 242.2 g a.s./L.

This study included two treatment groups: The test item group (T) and the untreated control (C). Each group consisted of two fields; four commercial honey bee colonies were placed at each field. The crop used for this field study was winter oilseed rape. The study was conducted near Tübingen, Germany. Two applications of the test item (target application rate: 2 x 72 g a.s./ha) were conducted. The applications were performed during flowering and after set-up of the honey bee colonies at the test fields with 7 days between the 1^{st} and 2^{nd} application. The applications were carried out during honey bee flight. Mortality, flight intensity and behaviour of the bees were assessed 3 days before the 1^{st} application until 12 days after the 2^{nd} application. The conditions of the colonies were assessed seven days before the 1^{st} application, one day before the 2^{nd} application and regularly after the applications. The influence of the test item was evaluated by comparing the results in the test item treatment group to the control group, and under consideration of the results of:
Total and mean number of dead honey bees on the linen sheets and in the dead bee traps,
Flight intensity (mean number of forager bees/m^2/10 to 15 seconds),
Behaviour of the bees in the crop and around the hives,
Condition of the colonies (number of bees (colony strength), mean values of the different brood stages per colony and assessment date)

Findings:

<u>Biological findings:</u>
Mortality:
The mean daily mortality per colony during the entire post application phase (0DAA1 to 12DAA2) was on the same level in the control groups compared to the test item groups (mean value: 11.6 (C1), 11.9 (C2), 10.8 (T1), 10.9 (T2) dead bees/colony/day). No notable differences between the control and the test item group were observed. Only one dead bee (in T1 on 5DAA2) was found throughout the

entire observation period on the three linen sheets within the crop area in the test item group and the control group, respectively. No test item-related adverse effects on mortality were observed. Results for the different phases (pre- and post-application) are presented in the table below.

Table CP 10.3.1.6- 3: Effects on honey bee mortality during the exposure phase of the study.

Treatment group		C1	C2	T1	T2
Daily mean mortality (dead bees/colony) ± STD	Pre-application 1 (3DBA1-0DBA1)	8.9 ± 5.7	18.8 ± 27.2	8.9 ± 7.1	11.9 ± 9.1
	Post-application 1 (0DAA1-0DBA2)	8.4 ± 9.1	6.6 ± 5.7	7.4 ± 6.4	7.8 ± 9.5
	Post-application 2 (0DAA2-12DAA2)	13.5 ± 10.8	15.1 ± 15.9	12.8 ± 12.4	12.8 ± 10.4
	Post-application total (0DAA1-12DAA2)	11.6 ± 10.4	11.9 ± 13.0	10.8 ± 10.8	10.9 ± 10.3

DBA: days before application; DAA: days after application; STD = standard deviation

Flight intensity

The flight intensity of the honey bees in the crop was determined over a period of 23 days (3DBA1 until 12DAA2). The total daily mean flight intensity during the entire post application phase (0DAA1 to 12DAA2) was calculated to be 0.8 bees/m^2/day in C1, 1.9 bees/m^2/day in C2 and 2.3 bees/m^2/day in T1, 2.5 bees/m^2/day in T2 respectively. No test-item related adverse effects on flight intensity were observed. Results for the different phases (pre- and post-application) are presented in the table below.

Table CP 10.3.1.6- 4: Effects on honey bee flight intensity during the exposure phase of the study.

Treatment group		C1	C2	T1	T2
Daily mean flight intensity (bees/m^2) ± STD	Pre-application 1 (3DBA1-0DBA1)	0.6 ± 0.8	0.9 ± 1.1	2.3 ± 1.8	1.9 ± 1.9
	Post-application 1 (0DAA1-0DBA2)	0.7 ± 0.7	2.4 ± 1.6	3.2 ± 2.0	3.7 ± 2.4
	Post-application 2 (0DAA2-12DAA2)	0.8 ± 1.1	1.7 ± 2.6	1.8 ± 1.8	1.8 ± 1.9
	Post-application total (0DAA1-12DAA2)	0.8 ± 1.0	1.9 ± 2.3	2.3 ± 2.0	2.5 ± 2.3

DBA: days before application; DAA: days after application; STD = standard deviation

Behaviour

In the marked assessment areas and in front of the hives, slight differences in behaviour in the test item group compared to the control group were observed on 0DAA1 and 0DAA2 in a small fraction of bees. In T1, honey bees with locomotion problems were observed on 0DAA1 (altogether 13 to 24 bees) and 0DAA2 (altogether 8 to 32 bees). In T2, a few honey bees showing behaviour like cramping, locomotion problems or intensive cleaning and a few motionless bees were observed on 0DAA1. In addition, approximately 40 to 200 honey bees of one colony (T2d) were found to be clustering in the dead bee trap on this day. On 0DAA2, a few cramping bees and a cluster of bees in the dead bee trap of colony T2a were observed.

On all other days during the exposure period, no notable difference in behaviour was observed in the test item treatment group compared to the control group (except for aggressive behaviour in colony T2d before the first application of the test item on 1DBA1).

Strength of the colonies

The colony strengths of both, control group and test item treatment group, followed the natural course of colony strength development, with an increasing tendency from spring to mid-summer. Throughout the entire observation period (except on 1DBA2, T2 where a reduction in colony strength in comparison to the previous assessment was noticed), the mean colony strengths in the test item treatment groups were not notably different from the control colonies.

No test-item related adverse effects on colony strength were observed during the course of the study.

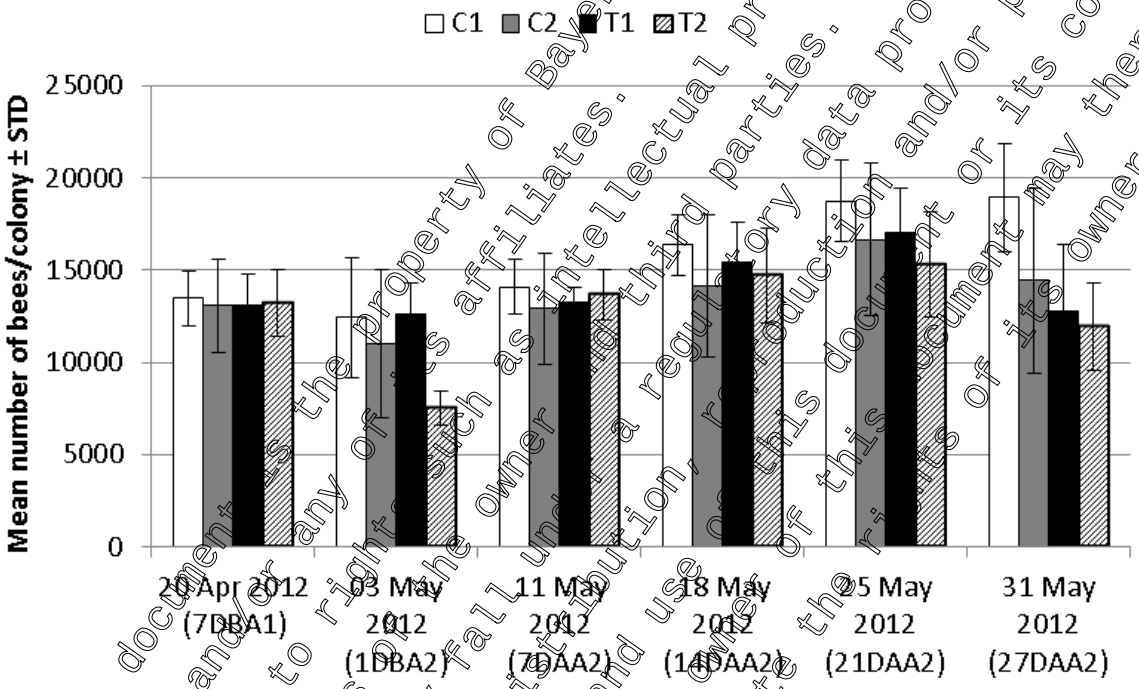

Figure CP 10.3.1.6- 3: Colony strength: Mean number of bees per colony in the control and test item treatment colonies (STD = standard deviation)

Brood Stages

In the colonies of the control groups C (C1, C2) and the test item treatment group T (T1, T2), respectively, the natural and typical changes and fluctuations in the relative amount of the different pre-imaginal stages, i.e. egg stage, larval and pupal stage, occurred during the observation period. No missing brood stages were observed in the test item treatment colonies. No notable differences between the test item treatment group and the control were observed.

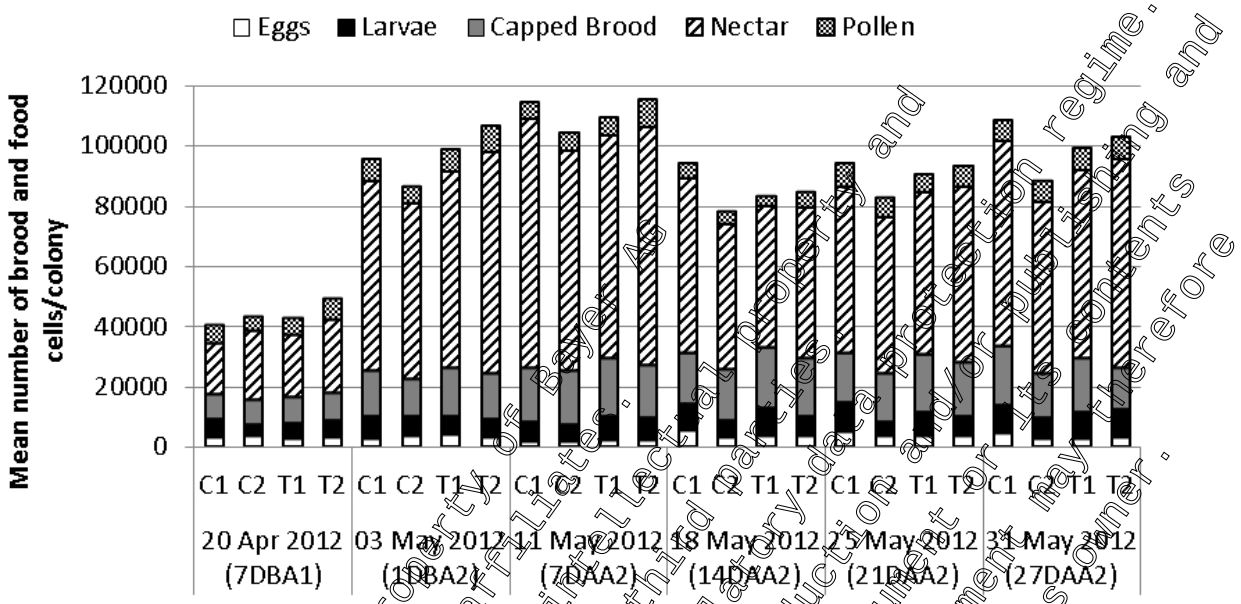

Figure CP 10.3.1.6- 4: Brood stages and food storage: Mean number of brood and food cells of the control and test item treatment colonies.

Food Storage
In the colonies of the control group C (C1, C2) and the test item treatment group T (T1, T2), respectively, the natural and typical changes and fluctuations in the relative amount of nectar and pollen storage cells occurred during the observation period. All colonies of the study showed approximately equal numbers of pollen and nectar storage cells throughout the entire observation period in C and T, respectively.

Conclusion:

Overall, it can be concluded that exposure of honey bee colonies to winter oilseed rape, sequentially sprayed two times with Thiacloprid OD 240B G at a target rate of 72 g a.s./ha during flowering, did neither cause acute, short-term nor long-term adverse effects on mortality, flight intensity, colony strength as well as brood and food development.
Behavioural observations indicated a possible short-term correlation between the application of the test item during bee flight activity and an intensified cleaning behaviour together with some motionless honey bees as well as some intoxication symptoms (cramping or locomotion problems). However, these observations were made only in a very small fraction of the honey bees in the test item treatment group.

CP 10.3.2 Effects on non-target arthropods other than bees

Toxicity tests on non-target arthropods have been performed with Thiacloprid OD 240 on the species *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Coccinella septempunctata*, and *Chrysoperla carnea*. Furthermore, two full-fauna off-crop field studies were conducted. A short summary of the study results is provided in the table below.

Table CP 10.3.2- 1: Thiacloprid OD 240: Ecotoxicological endpoints for arthropods other than bees

Test species, Reference Dossier-file-No.	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Aphidius rhopalosiphi [redacted] (2013) M-451718-01-1 KCA 8.3.2.1 /03	Thiacloprid OD 240 Laboratory, glass plate	LR_{50} < 0.4 g a.s./ha
		Corr. Mortality [%]
	0.4 g a.s./ha	80
	0.8 g a.s./ha	90
	1.8 g a.s./ha	100
	3.8 g a.s./ha	100
	8.0 g a.s./ha	100
Typhlodromus pyri [redacted] (2013) M-451645-01-1 KCA 8.3.2.2 /02	Thiacloprid OD 240 Laboratory, glass plate	LR_{50} = 0.331 g a.s./ha
		Corr. Mortality [%]
	0.2 g a.s./ha	18.7
	0.4 g a.s./ha	70.3
	0.9 g a.s./ha	84.6
	1.9 g a.s./ha	100
	4.0 g a.s./ha	98.9
Aphidius rhopalosiphi [redacted] (2002) M-066016-01-1	Thiacloprid OD 240 Extended Lab., exposure on detached apple leaves (2D application)	LR_{50} = 4.33 g a.s./ha ; ER_{50} > 0.95 g a.s./ha
		Corr. Mortality [%] Effect on Reproduction [%]
	0.30 g a.s./ha	0.0 28.0
	0.95 g a.s./ha	7.0 26.0
	3.00 g a.s./ha	53.0 n.a.
	9.49 g a.s./ha	80.0 n.a.
	30.00 g a.s./ha	83.0 n.a.
Typhlodromus pyri [redacted] (2012) M-436801-01-1	Thiacloprid OD 240 Extended Lab., exposure on detached maize leaves	LR_{50} = 2.49 g a.s./ha ; ER_{50} = 2 g a.s./ha
		Corr. Mortality [%] Effect on Reproduction [%]
	2 g a.s./ha	28.3 6
	4 g a.s./ha	85.9 n.a.
	7 g a.s./ha	96.7 n.a.
	12 g a.s./ha	98.9 n.a.
	22 g a.s./ha	98.9 n.a.
Coccinella septempunctata [redacted] (2005) M-247129-01-1	Thiacloprid OD 240 Extended Lab., exposure on detached apple leaves	LR_{50} = 10.222 g a.s./ha; No impact on reproduction at 3.125 g a.s./ha
		Corr. Mortality [%] Fertile eggs/Female/Day
	Control	- 8.3
	3.125 g a.s./ha	17.9 3.7
	6.25 g a.s./ha	15.4 0.9
	12.50 g a.s./ha	71.8 n.a.
	25.00 g a.s./ha	74.4 n.a.
	50.00 g a.s./ha	100.0 n.a.
Chrysoperla carnea [redacted] (2011) M-419295-01-1	Thiacloprid OD 240 Extended Lab., exposure on detached maize leaves	LR_{50} = 144.8 g a.s./ha; No impact on reproduction up to and including 124.3 g a.s./ha
		Corr. Mortality [%] Eggs/Female/Day Hatching [%]
	Control	- 32.3 87.3
	22.1 g a.s./ha	33.3 33.6 87.5
	39.3 g a.s./ha	10.6 29.5 85.0
	69.9 g a.s./ha	20.5 36.0 85.7
	124.3 g a.s./ha	46.2 38.4 90.8
	221.0 g a.s./ha	84.6 n.a. n.a.

Test species, Reference Dossier-file-No.	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Aphidius rhopalosiphi [redacted] (2012) M-442296-01-1	Thiacloprid OD 240 Aged residue, spray deposits on maize plants, 3 appl. (1st and 2nd appl.: 96 g a.s./ha, 3rd appl.: 110 g a.s./ha), interval 10 days	Corr. Mortality [%] / Effect on Reproduction [%] / Repellency rel. to control [%] Residues aged for 0 days: 100 / n.a. / 97 [B] Residues aged for 14 days: 50.0 / -6.0 [A] / 38.6 Residues aged for 28 days: 3.3 / 2.9 / 1.5
Typhlodromus pyri [redacted] (2013) M-446548-01-1	Thiacloprid OD 240 Aged residue, spray deposits on maize plants, 3 appl. (1st and 2nd appl.: 96 g a.s./ha, 3rd appl.: 110 g a.s./ha), interval 10 days	Corr. Mortality [%] / Effect on Reproduction [%] Residues aged for 0 days: 84.3 / n.a. Residues aged for 14 days: 7.8 / 5.8 Residues aged for 28 days: -2.2 [A] / -4.7 [A]
Coccinella septempunctata [redacted] (2013) M-446545-01-1	Thiacloprid OD 240 Aged residue, spray deposits on maize plants, 3 appl. (1st and 2nd appl.: 96 g a.s./ha, 3rd appl.: 110 g a.s./ha), interval 10 days	Corr. Mortality [%] / Fertile eggs/female/day Residues aged for 0 days: 100 / n.a. Residues aged for 14 days: 0.0 / 11.6 Residues aged for 28 days: 25.9 [C] / 17.6 Residues aged for 42 days: -12.1 [C] / 9.7
NTA off-crop field study (Netherlands) [redacted] & [redacted] (2013) M-462228-01-1	Thiacloprid OD 240 NTA full fauna off-crop field study. Spray application rates: 0.56, 1.2, 4.7, 10.2, 27 g a.s./ha	Community level NOER = 4.7 g a.s./ha Community level NOEAER = 10.2 g a.s./ha Population level NOER = 1.2 g a.s./ha Population level NOEAER = 10.2 g a.s./ha NOER: No Observed Effect Rate NOEAER: No Observed Ecologically Adverse Effect Rate
NTA off-crop field study (South-West France) [redacted] & [redacted] (2013) M-462231-01-1	Thiacloprid OD 240 NTA full fauna off-crop field study. Spray application rates: 0.56, 1.2, 4.7, 10.2, 27 g a.s./ha	Community level NOER = 0.56 g a.s./ha Community level NOEAER = 27 g a.s./ha Population level NOER = <0.56 g a.s./ha Population level NOEAER = 27 g a.s./ha NOER: No Observed Effect Rate NOEAER: No Observed Ecologically Adverse Effect Rate
Joint evaluation of the NTA off-crop field studies in The Netherlands & South-West France in this dossier	Thiacloprid OD 240 NTA full fauna off-crop field study. Spray application rates: 0.56 - 27 g a.s./ha	Regulatory Acceptable Rate (RAR) = 10.2 g a.s./ha

[A]: A negative value indicates a higher reproduction rate in the treatment than in the control
[B]: A negative value indicates a higher percentage of wasps found on plants in the treatment than in the control
[C]: A negative value indicates a lower mortality in the treatment than in the control
n.a.: not assessed

The tier 1 laboratory data and the tier 2 extended laboratory data indicate a high sensitivity of *A. rhopalosiphi*, *T. pyri*, *C. septempunctata* whereas the toxicity to *C. carnea* was significant lower (LR_{50} = 144.8 g a.s./ha). Therefore, aged residue studies were conducted with the 3 species *A. rhopalosiphi*, *T. pyri*, *C. septempunctata* for the refinement of the in-field risk assessment.

Tier 1 risk assessment

In-field hazard quotient (HQ)

The following equation was used to calculate the hazard quotient (HQ) for the in-field scenario:

In field-HQ = max. single application rate * MAF / LR_{50}

The risk is considered acceptable if the calculated HQ is < 2.

Thiacloprid OD 240 is intended to be applied in OSR the field with an application rate of 2 x 72 g a.s./ha. Therefore, the multiple application factor (MAF) was set at 1.7 (generic value for 2 applications according to ESCORT 2).
Resulting HQ values are presented in Table CP 10.3.2- 2.

Table CP 10.3.2- 2: HQ for terrestrial non-target arthropods for the in-field scenario

Crop (field uses)	Species	Appl. rate [g a.s./ha]	MAF	LR_{50} [g a.s./ha]	HQ	Trigger	Refined risk assessment required
OSR	*A. rhopalosiphi*	72	1.7	<0.4	>306	2	yes
OSR	*T. pyri*	72	1.7	0.331	370	2	yes

Conclusion: For the standard species, the in-field HQ values are above the trigger of concern, indicating a need for refinement.

Off-field hazard quotient (HQ)

The following equation was used to calculate the hazard quotient (HQ) for the off-field scenario:

Off-field HQ = max. single application rate * MAF * (drift factor/VDF)*correction factor / LR_{50}

- Max. single application rate = 72 g a.s./ha (OSR)
- MAF (multiple application factor) = 1.7 (generic value for 2 applications according to ESCORT 2)
- Drift factor = 2.38% (field crops, 1m distance, 2 applications; ESCORT2)
- VDF (vegetation distribution factor) = 10 (default value as recommended by the Terrestrial Guidance Document, to take into account the 3-dimensional structure of the off-field vegetation)
- Correction factor = 10 (uncertainty factor for the extrapolation from indicator species to all off-field non-target arthropods; default value for tier 1 risk assessment according to the Terrestrial Guidance Document)

The risk is considered acceptable if the calculated HQ is < 2.

Table CP 10.3.2- 3: HQ for terrestrial non-target arthropods for the off-field scenario

Crop	Species	Appl. rate [g a.s./ha]	MAF	Drift [%]	VDF	Corr. factor	LR_{50} [g a.s./ha]	HQ	Trigger
OSR	*A. rhopalosiphi*	72	1.7	2.38	10	10	<0.4	>7.4	2
OSR	*T. pyri*	72	1.7	2.38	10	10	0.331	8.8	2

Conclusion: The HQ values for *T. pyri* and *A. rhopalosiphi* are above the trigger of concern for the intended uses in OSR, indicating a need for refinement.

Tier 2 risk assessment

Potential exposure
The exposure scenario is based on the intended use of 72 g a.s./ha in OSR.

According to ESCORT2 and the Terrestrial Guidance Document the exposure is calculated as:
In-field: Application rate * MAF
Off-field: Application rate * MAF * (drift factor / VDF) * correction factor

Application rates: 2 x 72 g a.s./ha (OSR)
Drift factor: 2.77% (field crops, 1 m distance, 1 application, 90th percentile, ESCORT2)
MAF (multiple application factor): The Tier 1 risk assessment has been based on the generic MAF value for 2 applications (1.7). These values can be refined based on measured DT_{50} values on leaves. Evaluations have been conducted for residues on leafy vegetables (DT_{50} 2.55 days, [redacted], 2012, M-416527-02-1) and on winter cereals (DT_{50} 2.9 days, [redacted] & [redacted], 2013, M-453081-01-1). Based on the DT_{50} value of 2.9 days and the application interval of 10 days a MAF of 1.1 can be calculated.
VDF (vegetation distribution factor) = 10 (default value as recommended by the Terrestrial Guidance Document, to take into account the 3-dimensional structure of the off-field vegetation; in can only be applied in the context of 2D test systems)
Correction factor = 5 (uncertainty factor for the extrapolation from indicator species to all off-field non-target arthropods, default value for tier 2 risk assessment according to the Terrestrial Guidance Document)

Table CP 10.3.2- 4: Exposure calculation for in-field assessment

Crop / no. of applications	Appl. rate [g a.s./ha]	MAF	in-field PEC_{max}. [g a.s./ha]
OSR / 2	72	1.1	79.2

Table CP 10.3.2- 5: Corrected exposure for off-field risk assessment

Appl. rate [g a.s./ha]	MAF	Drift [%]	Veg. distr. factor	Correction factor	off-field PEC_{max}. [g/ha]	Remark
72	1*	2.77*	-	5	10.0	in case of 3-D study design
72	1*	2.77*	10	5	1.0	in case of 2-D study design

* The values for the off-field PEC_{max} based on two applications with a refined MAF of 1.1 (due to the rapid degradation of the active substance) and a drift rate of 2.38% [82nd percentile] are below the value for a single

application (MAF = 1.0, drift rate 2.77% [90th percentile]). To provide a realistic worst case, the higher drift values based on a MAF of 1.0 and a drift rate of 2.77% are considered relevant for the off-field risk assessment.

Tier 2 in-field risk assessment

Table CP 10.3.2- 6: In-field risk assessment based on study results from extended laboratory studies

Test Species	in-field PEC$_{max.}$, [g a.s./ha]	LR$_{50}$; ER$_{50}$ [g a.s./ha]	Trigger	Refined assessment required?
Use in OSR, 2 x 72 g a.s./ha				
Aphidius rhopalosiphi	79.2	>0.95	Effects are < 50%	**yes**
Typhlodromus pyri	79.2	>2	Effects are < 50%	**yes**
Coccinella septempunctata	79.2	>3.125	Effects are < 50%	**yes**
Chrysoperla carnea	79.2	>124.3	Effects are < 50%	no

The higher tier in-field risk assessment for and *C. carnea* indicates that no unacceptable adverse effects are to be expected in the in-field area for arthropod species with a similar sensitivity as this species. However, the in-field risk assessment for *A. rhopalosiphi, T. pyri*, and *C. septempunctata* indicates that initial effects in the in-field area cannot be excluded. Therefore, further refinement is needed.

Refined in-field risk assessment

The results of the tier 2 risk assessment indicated that initial effects on species with a similar sensitivity as *A. rhopalosiphi* (M-442296-01-1), *T. pyri* (M-446548-01-1), and *C. septempunctata* (M-446545-01-1) cannot be excluded. According to the Terrestrial Guidance Document the potential for recovery needs to be demonstrated in such cases. As a consequence, aged residue studies were performed with all 3 species to demonstrate the potential for recovery. The test item was applied three times on potted maize plants; at the first and second application it was applied with 96 g a.s./ha and at the third application it was applied with 110 g a.s./ha. The application interval was 10 days between the three applications. Aging of the spray deposits of the test item on the potted maize plants took place under semi-field conditions with UV permeable rain protection during the first four weeks of the study. Three bioassays were performed, the first started on the day of the last application of the test item, the second 2 weeks after the last application and the third one four weeks after the last application. All three species indicated clear mortality in the bioassay that was started on the day of the last application (84.3 – 100%). The second bioassay that was started 14 days later resulted in 50% mortality of *A. rhopalosiphi*, 7.8% mortality of *T. pyri*, and 0% mortality of *C. septempunctata*. In this second bioassay the reproduction assessment indicated no adverse effects. In the third bioassay that started 28 days after the last application no adverse effects on mortality (<4%) and no adverse effects on reproduction were observed. The study results indicate that even after 3 repeated applications with higher rates (96 and 110 g a.s./ha) the potential for recovery is given within 2 weeks after the last application.
It can be concluded that no unacceptable adverse effects on non-target arthropods in the infield area are to be expected from the use of Thiacloprid OD 240 according to the proposed use pattern.

Tier 2 off-field risk assessment

Table CP 10.3.2- 7: Off-field risk assessment based on study results from extended laboratory studies

Test Species	off-field $PEC_{max.}$, [g a.s./ha]	LR_{50}; ER_{50} [g a.s./ha]	Trigger	Refined assessment required?
Use in OSR, 2 x 72 g a.s./ha				
Aphidius rhopalosiphi	1.0	>0.95	Effects are < 50%	**yes**
Typhlodromus pyri	1.0	>2	Effects are < 50%	no
Coccinella septempunctata	1.0	>3.125	Effects are < 50%	no
Chrysoperla carnea	1.0	>124.3	Effects are < 50%	no

The maximum PEC off-field for the use in OSR is calculated to be 1.0 g a.s./ha for 2D-test systems. For *T. pyri*, *C. septempunctata*, *C. carnea* no effects > 50% neither on mortality nor on reproduction were observed in extended laboratory studies on natural substrate at a rate of 2 g a.s./ha (*T. pyri*), 3.125 g a.s./ha (*C. septempunctata*) and 124.3 g a.s./ha (*C. carnea*) (see Table CP 10.3.2- 1). However, for *A. rhopalosiphi*, initial effects cannot be excluded, indicating a need for further refinement.

Refined off-field risk assessment

The impact of simulated drift events on arthropod populations and communities typical of grassy field margins in two studies (Netherlands and Southern France, M-462231-01-1 (KCP 10.3.2.4/2) and M-462228-01-1(KCP 10.3.2.4/1)) was evaluated for thiacloprid OD 240 (240 g/L) at exposures equivalent to 0.56, 1.2, 4.7, 10.2, and 27 g a.s./ha. A water treated control and toxic reference (Karate Zeon, lambda-cyhalothrin 100 g/L CS at 40 g a.s./ha) treatment were also included. The arthropod community was sampled using pitfall trapping, weed/Berlese and suction sampling techniques which ensured that the whole range non-target arthropod taxa were adequately sampled. Samples were taken shortly before application and 1 to 8 weeks thereafter. Key metrics and endpoints reported by the authors are summarised in the following table:

Table CP 10.3.2- 8 Comparison of Thiacloprid OD 240 non-target arthropod grassland habitat (off-field) studies

Value reported by Author	Netherlands	Southern France
No. arthropods counted	Approx. 1,000,000	> 2,000,000
No. taxa identified	207	312
No. taxa included in community level analyses	137	215
No. taxa included in population level analyses	54	95
Community NOEAER	10.2 g/ha	27 g/ha
Community NOER	4.7 g/ha	0.56 g/ha
Population NOEAER	10.2 g/ha	27 g/ha
Population NOER	1.2 g/ha	Not given

A difference related to geographical gradient is observed where a greater number of individual arthropods (approximately twice as many) were sampled in the study conducted in southern France compared with the Netherlands location. This also leads to a higher number of taxa identified and consequently more taxa included in the various community and population level analyses. Consequently the Netherland site is more likely to be dominated by a certain number of taxa whereas in southern France the community is more likely to be more diverse and less dominated. Therefore; given similar levels of population sensitivity to the test item one would expect at least twice as many affected taxa in the southern France location compared to the Netherlands. In terms of recovery or

resilience to effect populations and communities in the more southerly location would be expected to be more tolerant. These considerations and observations are important as they represent two major trends in arthropod communities in agro-ecosystems which are often related to a North-South gradient.

Choice of endpoints for risk assessment
As data from two studies are available is necessary to review the findings in detail to define a robust Regulatory Acceptable Rate (RAR) to be used in risk assessment for the off-field environment and not to simply take the lowest value from the reports without full consideration of type of effects and the biological characteristics of the affected organism. For the reasons above careful consideration is necessary before concluding on the most appropriate endpoint to use.

Due temporal variations in populations (e.g. density, activity and availability) and sampling error, which is present in all experimental studies, it is necessary to determine the background levels of variation present. This gives the chances of seeing an effect greater than 50% in the absence of treatment (a kind of type I error). Figures A8-1 of both study reports show the proportion of taxa where effects are above 50% in the toxic reference treatment as a measure of study performance as calculated by the equations given in appendix 7 of the study reports (Abbott calculations). It can be seen in both figures that even for the pre-treatment samples there is a proportion of taxa which show a deviation by chance of at least 50% compared to the control (14.6% and 5.3% respectively in the Netherland and southern France studies). Although not presented in the reports it is estimated from the values in Appendix 8 (Abbott values and P-values) in both study reports that for all plots compared to the control prior to treatment the proportion of taxa with Abbott values above 50% is approximately 6% for the study conducted in the Netherlands (i.e. 3 out of 54 taxa) and 8% of the study conducted in France (i.e. 8 out of 95 taxa). Consequently there is a given proportion of taxa which by chance present at a given time point as showing Abbott values above 50% which is independent of treatment effects. However, such chance effects must be considered in light of additional information such as population trends in the treatment and the control performance.

Consideration of arthropod biology and ecological function
As with other areas of ecological risk assessment the effect and impact on certain taxa is not always of equal importance. For example an impact on a highly mobile, dispersive species will have less of a consequence than an impact on a sedentary species. Likewise species with a high capacity for reproduction (i.e. r-strategists) can tolerate different impacts than those whose reproduction life history strategy is to produce very few offspring (i.e. k-strategists). The former may be well adapted to tolerate such stresses whereas the latter may not. In the studies these factors have not been considered by the author when concluding on the endpoints. Consequently when selecting the most appropriate RAR transient effects on certain taxa may not be biologically significant and recovery may be considered for these taxa when considering the selection of an endpoint.

Another important consideration is the ecological function provided by the arthropods of a community. In ESCORT 3 (Alix et al. 2012)[2] the following functions are listed:

- Parasitiods
- Predators
- Herbivores

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[2] [redacted], A.; [redacted], F.; [redacted], K.; [redacted], C. A.; [redacted], M.; [redacted], S.; [redacted]en, J. P.; [redacted], P.; [redacted], G.; [redacted], P.; [redacted], D.; [redacted], P. 2012. ESCORT 3 - Linking non-target arthropod testing and risk assessment with protection goals. SETAC, Pensacola, ISBN 978-1-880611-98-2

- Detritivores
- Coprophages
- Pollinators
- Food species for vertebrates

It is important that ecological function is protected when selecting a suitable endpoint. The non-target arthropods sampled in the studies fulfil these functions and there are often a collection of species which fulfil the function and there is a certain level of functional redundancy. In some cases a species can fulfil more than one function for example certain coleoptera have predatory larvae but an herbivorous adult stage.

Population level impacts and their relevance to the regulatory acceptable rate (RAR).
To assist in the derivation of a RAR from the two studies it is necessary to consider the taxa present in the studies, their biology, function and effects observed. Tables 2 to 10 compare and summarised the taxa present in the two studies and the impacts observed using the effect classes described by De Jong *et al.* (2010)[3]. In these tables a blank white square indicates that the taxa were present and unaffected by treatment throughout the study, *i.e.* class 1. A "2" (class 2) indicates that a statistically significant deviation from the control of greater than 50% was observed on a single occasion. Where the number "3a" or "3b" is present this indicates that a pronounced treatment related effect was observed but was of short duration and recovery occurred within the study period. For arthropods of low mobility and high reproductive capacity class 2 and 3 effects are considered acceptable when considering the RAR. Where the effect is classified as 8 this means that pronounced effects were observed and recovery was not apparent during the 8 week duration of the study. As mentioned above 6 – 8% of effects above 50% is expected to be observed by chance and may be not treatment related which particular applies to class 2 effects. A grey cell in the table indicates that the taxon was absent at one of the locations.

Population level impacts on mites
Table CP 10.3.2- 9 summarises the taxa present and the impact of the test item. In the Netherlands the mite community was dominated by tarsonemid mites whereas 8 mite taxa were identified in southern France.

Table CP 10.3.2- 9: Summary population level impacts (mites)

Sample method	Order	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
W	Acari	Gamasida female										
W		Gamasida other stages										
W		Tarsonemidae										
W		Tydeoidea										
W		Acaridida										
W		Oribatidae (ad)										
W		Oribatidae (juv)										
S		Oribatidae										

Mites are known to fulfil many ecological functions such as predators, herbivores, fungivores (detritus consumers) and are also prey for other arthropods. Due to their small size, high reproductive capacity

[3] Jong, F. De, F.M.W., F.M. [redacted], K. Brown, C.J.T.J. Jilesen, C.J.A.M. Posthuma-Doodeman, C.E. Smit, J.J.M. van der Steen, G.M.A van Eekelen. 2010. A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies. RIVM report number 601712006/2010, ISBN/EAN: 978-90-6960-245-5

effects up to class 3 could be tolerated. However, none of the mite taxa sampled was adversely affected by any treatment rate up 27 g a.s./ha. Consequently for mites the RAR is 27 g a.s./ha.

Population level impacts on spiders
Spiders are divided in Table CP 10.3.2- 10 into two groups; hunting spiders and web spiders. Spiders are all predatory and tend to have (relative to other arthropods) long reproduction cycles. Due to this effect classes 1 and 2 would be considered to be most appropriate and conservative.

Table CP 10.3.2- 10: Summary population level impacts (spiders)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
P	Hunting spiders	*Zelotes*										
P		Gnaphosidae others										
P		*Pardosa* (juv)										
P		*Pardosa* (ad)										
P		Lycosidae others										
P		Thomisidae										3b
S		Thomisidae (juv)										
S	Web spiders	*Pachygnatha* (juv)										
P		*Pachygnatha*										
P		*Erigone* (ad)/Erigoninae (ad)					8					
S		Erigoninae (ad)										
S		*Lepthyphantes tenuis* (juv)										
S		*Lepthyphantes tenuis* (ad)										
P		*Lepthyphantes tenuis*										
P		*Meioneta*										
P		*Oedothorax* (ad)										
P		*Bathyphantes* (ad)										
S		Liniphiinae (ad)										
S		Linyphiidae (juv)										
P		Linyphiidae (juv)										
S		Araneidae (juv)										2
P		Araneoidea other										

Representatives hunting and web spiders were present at both sites with the greater diversity observed in southern France. Out of the 22 spider taxa present 19 were unaffected by treatment up to 27 g a.s./ha (class 1). However at the highest rate of 27 g a.s./ha, adult *Erigone* spp. (small linyphiid spider) were affected in the Netherlands (class 8) and crab spiders (Thomisidae) were affected in France (class 3b). Web spider juveniles (Araneidae) were slightly affected at the same rate (class 2). Consequently the RAR for spiders is 10.2 g a.s./ha.

Population level impacts on beetles
As would be expected a wide range of beetle (coleopteran) taxa were present and identified (Tables CP 10.3.2-8 and CP 10.3.2-9). A total of 30 beetle taxa (8 in the Netherlands and 26 in southern France) were present at numbers suitable for a population level evaluation. Coleoptera represent a diverse group in terms of ecological function and the life history strategy. Consequently different types of beetle can tolerate differing levels of disturbance or effects. Fourteen different beetle families were identified with the greater diversity found in southern France.

Table CP 10.3.2- 11: Summary population level impacts (beetles; Carabidae, Staphylinidae and Coccinellidae)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
P	Carabidae	*Bembidion* spp.										
P		*Loricera pilicornis*					3b					
P		*Poecilus cupreus*										
P		Harpalinae/*Harpalus* other										
P		*Harpalaus xanthopus*										
P		*Amara aenea*										
P		*Microlestes minitulus*										
P		Carabidae other (ad)										
P	Staphylinidae	Staphylinidae (juv)					3a				3b	2
P		Staphylinidae					8					2
P		Aloecharine										
P		Omaliinae										
P		Oxytelinae										
P		Staphylininae										
P	Coccinellidae	Coccinellini (juv)										
P		Coccinellidae (ad)								2	2	2

Out of the 8 carabid taxa (ground beetles) 4 were located in the Netherlands and 5 in southern France, with overlap of one taxon (Harpalinae). Most carabids are predatory and have 1 to 3 generations per year and typically breed in spring or autumn avoiding the hot summer months. Consequently in this study effect classes 1 and 2 are considered acceptable. All carabid taxa were unaffected by treatment up to 27 g a.s./ha with the exception of *Loricera pilicornis* where effects class 3b was observed at 27 g a.s./ha. Consequently for carabids the RAR is 10.2 g a.s./ha.
Six staphylinid taxa were identified. These rove beetles are usually predatory and some are parasitoids of other insects. Like carabids they tend toward the k-strategy end of the reproductive spectrum and generally effect classes of 1 and 2 are considered acceptable. In the Netherlands Staphlyinindae were unaffected up and including the second highest treatment rate of 10.2 g a.s./ha. In southern France the Aleocharine, Omaliinae, Oxytelinae and Staphylininae were unaffected by all treatments up to 27 g a.s./ha. However, Staphlyinindae juveniles were affected but recovered before the end of the study (class 3b) in plots treated with 10.2 g a.s./ha but only transient effects were noted for both juveniles and adults (class 2) at the highest rate of 27 g a.s./ha. As the effect on Staphlyinindae juveniles was not consistent with a rate related response the 27 g a.s./ha was considered to be acceptable. Overall the RAR for staphylind beetles is considered to be 10.2 g a.s./ha.
Coccinellidae (ladybird beetles) were present at both sites with larvae and adults both present in southern France and only larvae in the Netherlands. The adults are highly mobile and move quite frequently to different locations in order to find food for their voracious larvae and were unaffected (class 1) by all treatment rates up to 27 g a.s./ha in the Netherlands but transient effects (class 2) were observed at rates of 4.7, 10.2 and 27 g a.s./ha in southern France. The larvae are not very mobile and were unaffected by treatment. The overall RAR for ladybird beetles is considered to be 27 g a.s./ha.

Table CP 10.3.2- 12: Summary population level impacts (beetles; other families)

Sample method	Order/Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
P	Hydrophilidae	Hydrophilidae										
P	Corylophidae	Corylophidae										
P	Lathridiidae	Lathridiidae										
P	Silvanidae	Episthemus										
P	Nitidulidae	Nitidulidae										2
P	Histeridae	Histeridae										
P	Byrrhidae	Byrrhidae										
P	Chrysomelidae	Alticinae								2	2	2
S		Alticinae										
S	Curculionidae	Apion								2	2	3
S		Curculionidae others										
P		Curculionidae										3a
P	Dermestidae	Dermestidae										
P	Elateridae	Elateridae										

The remaining beetle families (Table CP 10.3.2-9) were restricted to the southern France study with the exception of the Hydrophilidae which were only found in the Netherlands study. Hydrophilidae, or water scavenger beetles which have predatory larval and herbivorous adult stages were unaffected by all treatment rates (class 1). In southern France effects did not exceed class 2 for any beetle family (Corylophidae, Lathridiidae, Silvanidae, Nitidulidae, Hesteridae, Byrrhidae, Chrysomelidae, , Dermestidae and Elateridae) except for the Curculionidae (weevils) where a class 3a effect was noted at 27 g a.s./ha. These families represent a wide range of ecological functions such as fungivores, detritivores, scavengers, predators and also herbivores. Several families such as Chrysomelidae, Elateridae and Curculionidae contain species which are important pests of crops plants. Overall for this group of beetles the RAR is considered to be 10.2 g a.s./ha.

Population level impacts on Hymenoptera

The majority of Hymenopteran taxa in Table CP 10.3.2- 13 (17 out of 18) were parasitic species belonging to a wide range of groups parasitizing different insect life history stages (e.g. egg and larval parasites). The remaining taxon was a social insect (Formicidae, ants) which is also predatory and were found at both locations.

Table CP 10.3.2- 13. Summary population level impacts (hymenoptera)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
S	Hymenoptera	Icheneumonidae										
S		Aphidiinae										
S		Alysiinae										
S		Eulophidae										
S		Mymaridae										
S		Pteromalidae										2
S		Chalcidoidea other										
S		Platygastridae										
S		Sceliondae										
S		Proctotrupoidea										
S		Cynipoidea										
S		Braconidae other										
S		Aphelinidae										
S		Trichogrammatidae										
S		Diapriidae										
S		Ceraphronidae										
P		wingless micro-hymenoptera										
S		Formicidae										

Eleven and 15 parasitic Hymenopteran taxa were identified at the Netherlands and southern France studies respectively. These arthropods are typically small in size and some are wingless. Of these only the Pteromalidae exhibited effects greater than class 1 (class 2) which are of minor importance to this group of arthropods. Consequently the RAR for Hymenoptera is 27 g a.s./ha.

Population level impacts on Homoptera and Heteroptera
These 7 taxa were all collected by suction sampling (Table CP 10.3.2- 14). These taxa are all phytophagous and contain many important pest species.

Table CP 10.3.2- 14 Summary population level impacts (homoptera and heteroptera)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
S	Homoptera	Aphidoidea										
S		Cicadellidae (juv)					3b					
S		Cicadellidae (ad)										
S		Delphacidae (juv)										
S	Heteroptera	Delphacidae (ad)										
S		Mirridae (ad)										
S		Cynidae										

Cicadellid juveniles in the Netherlands were the most sensitive with an effect class 3b at 27 g a.s./ha. Overall the RAR for *Homoptera and Heteroptera* is 10.2 g a.s./ha.

Population level impacts on Diptera
Effects on Dipteran taxa are presented in Table CP 10.3.2- 15 although many true flies are strong flyers some such as the Drophophilidae (fruit flies) tend to remain in one place where there is a good supply of food.

Table CP 10.3.2- 15 Summary population level impacts (diptera)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
S	Diptera	Cecidomyiidae										
S		Chironmidae										
S		Sciaridae										
S		Lonchopteridae					8					
S		Phoridae										
S		Chloropidae										
S		Drosophilidae			2	2	3a					
S		Sphaeroceridae										
S		Acalyptrata										
S		Empididae										
S		Agromyzidae										
S		Ephydridae										
S		Diptera (juv)										

Out of a total of 13 taxa representing a wide range of ecological functions (e.g. predators, herbivores, frugivores, parasites) only two responded to treatment. Effects with no recovery within the study period was noted at 27 g a.s./ha for Lonchopteridae (spear-winged flies). For the Drophophilidae a transient effect (i.e. class 2) was noted at rates of 4.7 g a.s./ha above. As this is of minor importance to a fly with a high intrinsic reproductive rate and many generations per year the RAR for Diptera is 10.2 g a.s./ha.

Population level impacts on Collembola

Table CP 10.3.2- 16 summarises the taxa present and the impact of the test item. Collembolans are omnivorous, free-living organisms that prefer moist conditions. They contribute towards decomposition through the fragmentation of organic matter and are possibly the most abundant terrestrial macro-organism group on the planet.

Table CP 10.3.2- 16: Summary population level impacts (Collembola)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
S	Collembola	Sminthuridae			3a	3a	8	2	2	3a	2	3b
P		Sminthuridae				3a	3a					
P		Symphypleona							2	3a	3a	3b
P		Entomobryidae										
P		Isotomidae					3a					3a

In the two studies Collembola were among the most sensitive taxa to the test item and were found living on or in the top few cm of soil and related habitat (e.g. leaf litter) and on foliage in the experimental plots. This is indicated by the sample methods which collected collembola specimens; pitfall (active at or near soil surface) and suction (on soil and on plant surfaces). Pitfall samples collect collembolan due to the activity (movement) of the animal and suction samples remove them directly from their location. Due to their small size, high reproductive capacity and low mobility effects up to class 3a could be tolerated when considering an appropriate and ecologically relevant RAR. In the two studies class 3a means that effects would be seen at the two sample points following application, i.e. during the first 4 weeks. After that there will be two consecutive sample points where population recovery had occurred.

In the two studies sminthurid collembola (globular springtails) were more associated with suction sampling indicating that they are not very mobile and prefer the dwell on foliage and are hence highly exposed to treatment. In fact compared with sminthurid numbers in pitfall traps approximately 10x more were caught by suction sampling in the Netherlands study. Sminthurid responses were similar at both sites. None or only transient effects were noted at treatment rates of 0.56 and 1.2 g a.s./ha. At both locations test rates of 4.7 g a.s./ha the response was placed into class 3a (temporary effects with full recovery), however at the next rate of 10.2 g a.s./ha the responses were class 3a and class 2 in the Netherlands and southern France respectively. At the highest treatment rate (27 g a.s./ha) sminthurid populations failed to recover after 8 weeks in the Netherlands, whereas in France recovery was noted only at the final sample point. As collembola are of low mobility the recovery of populations must have come from the existing pool of eggs and young indicating that exposure up to 10.2 g a.s/ha had no ecologically relevant effect on the population. The taxon named Symphypleona (which is the order to which the family Smithuridae belong) presented a similar response to the Sminthuridae in southern France but were unaffected in the Netherlands. The highly active Entomobryidae (or slender springtails) were unaffected by all treatments, perhaps because they are more associated with the surface of the soil and hence less exposed compared to the Sminthuridae. Isotomidae (another Entomobryomorphic taxon also more associated with the soil than foliage) were unaffected by treatments up to 10.2 g a.s./ha at both study locations. At the highest rate (27 g a.s./ha) impacts with full recovery was observed for the Isotomidae. Overall, taking into account the sensitivity, biology and ecology of the collembola present in the two studies the RAR is 10.2 g a.s./ha.

Population level impacts on miscellaneous taxa

A range of taxa including insect and non-insect species is presented in Table CP 10.3.2- 17. These include isopods (crustaceans), chilopods (centipedes), Gillidae (crickets), Phalangia (harvest man) and Thysanoptera (Thrips).

Table CP 10.3.2- 17 Summary population level impacts (miscellaneous taxa)

Sample method	Order/ Group	Taxon	Netherlands					France				
			0.56	1.2	4.7	10.2	27	0.56	1.2	4.7	10.2	27
P	Isopoda	Isopoda (all)										
P	Chilopoda	Chilopoda (all)										
S	Thysanoptera	Thysanoptera (juv)										
S		Thysanoptera (ad)									2	2
P	Orthoptera	Grillidae										
P	Arachnida	Phalangida										

Out these only slight and transient effects (class 2) were noted on adult thrips which is not considered to be biologically significant for these insects. Consequently the RAR for this artificial assemblage of arthropods is 27 g a.s./ha.

Conclusion concerning the Regulatory Acceptable Rate (RAR)

The impact of simulated drift events on arthropod populations and communities typical of grassy field margins was investigate in two studies located in the Netherlands and in Southern France was evaluated for Thiacloprid OD 240 at exposures equivalent to 0.56, 1.2, 4.7, 10.2 and 27 g a.s./ha.

At the community level no consistent rate related response was noted and the $NOEAER_{community}$ (No Observed Ecologically Adverse Effect Rate) was the highest rate test of 27 g a.s./ha. However, when considering the responses the individual taxa in relation to their biology a RAR (Regulatory

Acceptable Rate) suitable for an off-field risk assessment based on the findings of both studies was concluded to be 10.2 g a.s./ha.

Off-field risk assessment based on the off-field non-target arthropod field studies
The evaluation of the two available off-crop field studies indicates that the regulatory acceptable off-field concentration of thiacloprid is 10.2 g a.s./ha. The corresponding off-field exposure is calculated based on the in-field use rate of 72 g a.s./ha and the drift rate for field crops of 2.77% (1 m distance, 90th percentile[4]; ESCORT2). These values result in an off-field exposure rate of 2.0 g a.s./ha. Since this exposure values is below the Regulatory Acceptable Rate of 10.2 g a.s./ha it can be concluded that no unacceptable adverse effects are to be expected from the use of Thiacloprid OD 240 according to the intended use pattern.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Tier 1 laboratory studies on *Aphidius rhopalosiphi* and *Typhlodromus pyri* have been conducted and summaries are provided in the MCA document under KCA 8.3.2.1/1 (M-451718-01-1) and KCA 8.3.2.2/1 (M-451718-01-1), respectively.

Supplemental information from the literature
In addition to the studies performed by BCS in accordance with the requirement a literature search has been performed in accordance with the requirements. From the papers identified during the literature search the following were identified as being potentially relevant for risk assessment. After further evaluation the literature data is considered to provide supplemental information and does not influence the risk assessment.

Report: [redacted]; 2012; M-468146-01-1
Title: Mortality of the leaf roller parasitoid Dolichogenidea tasmanica (Hym: Braconidae) exposed to orchard pesticide residues
Report No.: M-468146-01-1
Document No.: M-468146-01-1
Guidelines: not applicable; not applicable
GLP/GEP: no

Executive summary:

Laboratory bioassay was performed to investigate effects of residues from 10 pesticides including thiacloprid on mortality of the *Dolichogenidea tasmanica* (Cameron) (Hymenoptera: Braconidae) over 7-days. Material and methods as well as results are summarised for thiacloprid only. A laboratory culture of *D. tasmanica* was established from parasitoids that emerged from leaf rollers field-collected collected in Hawke's Bay, and maintained on host larvae of *E. postvittana*. Experimental replicates of thiacloprid used Calypso 480SC mixed with water at 288g a.s./ha (calculated based on 2000 L/ha). The

[4] The values for the off-field PEC_{max} based on two applications with a refined MAF of 1.1 (due to the rapid degradation of the active substance) and a drift rate of 2.38% [82nd percentile] are below the value for a single application (MAF = 1.0, drift rate 2.77% [90th percentile]). To provide a realistic worst case, the higher drift values based on a MAF of 1.0 and a drift rate of 2.77% are considered relevant for the off-field risk assessment.

base and lid (inner facing surfaces) of 85 mm diameter Petri-dishes were sprayed in a Potter tower at 103kPa using 2 ml solution with settling period of 12 seconds. These were dried (15-20 minutes). Controls used water. After drying, 15 randomly selected *D. tasmanica* adults added to each petri-dish with transfer by sable-brush at cooled 8-12ºC to reduce mobility. Petri-dishes were then held at 20ºC for 7 days, and mortality assessed at 24 h intervals. Cotton wick with 1.7ml of 50:50 honey water was placed as a food source and replaced as necessary. Counts of mortality were adjusted using Abott correction where insects that did not respond to probing with a sable brush were considered dead. Toxicity levels were assigned using standard criteria of the International Organization for Biological and Integrated Control of Noxious Animals and Plans (IOBC). Testing was carried out on four separate occasions when sufficient newly emerged parasitoids were available. Residues of thiacloprid were considered harmless (< 30% mortality) by IOBC criteria.

Material and methods:

A. Material

1. Test material

Test item:	Calypso 48 SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	Water
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Dolichogenidea tasmanica* (Hymenoptera: Braconidae).
Cultivar:	-
Source of test species:	Hawke's bay, New Zealand
Age of test organisms at study initiation:	Adults
Crop growth stage at treatment:	-
Holding conditions prior to test:	-
Acclimatisation:	-
Host:	*Epiphyas postvittana* (Lepidoptera: Tortricidae)

B. Study design and methods

1. Test procedure

Test system (study type):	Dried residues on petri-dish (direct contact with adult wasps)
Duration of study:	7 days
Treatments:	Contact with dried residue
Test concentrations:	288g a.s./ha
Number of replicates:	4 per product, controls included but number of controls not stated
Individuals per replicate:	15 adult wasps
Test units (type and size):	Petri dishes
Application / device / nozzles:	Potter tower at 103kPa using 2 ml solution with settling period of 12 seconds
Water volume:	2000 L/ha
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Petri-dishes
Temperature / relative humidity:	20°C
Photoperiod:	-
Lighting	-

3. Observations and measurements:

Analytical parameters measured:	
Biological parameters measured:	Mortality
Measurement frequency:	Every 24h
Statistical analyses:	Abott correction

Results:

Validity criteria:
No validity criteria were stated.

Biological findings:
Residues of thiacloprid were harmless (< 30% corrected mortality) to *D. tasmanica* in the 7 days after treatment. Actual mortality after 7 days 0% as in the control.

Comment by the notifier:
The author refers gives the target application rate with a value of 288 g a.s./ha and refers to an application rate of 2000 L/ha. It seems at least questionable that an application rate of 2000 L/ha was applied with the Potter tower to petri-dishes. The study results indicate a low toxicity of thiacloprid to the parasitoid *Dolichogenidea tasmanica* (Hymenoptera: Braconidae). The data do not influence the outcome of the non-target arthropod risk assessment since A. rhopalosiphi proved to be clearly more sensitive under tier 1 laboratory test conditions. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted],;[redacted];[redacted]; 2012; M-465942-01-1
Title:	Insecticide selectivity tests on spider mite destroyer (Stethorus punctillum) (Weise) (Coleoptera: Coccinellidae) in laboratory conditions.
Report No.:	M-465942-01-1
Document No.:	M-465942-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

Laboratory investigation assessed the selectivity of several insecticides and acaricides including thiacloprid; from direct spray on the adult ladybird *Stethorus punctillum* (Weise) (Coleoptera: Coccinellidae). Thiacloprid was applied by Potter spray tower, and effects on ladybird mortality recorded. Material and methods plus results are summarised for thiacloprid only.
A laboratory colony of *Stethorus punctillum* was established with specimens from orchards in North and Central Poland. Collected adults were kept in 6 isolators (110 x 85 x 85 cm) and fed Two-spotted mite *Tetranychus urticae* established on Broad beans (*Vicia faba*) reared in flowerpots. At 2 weeks, beans inoculated with *T. urticae* were moved into isolators, then covered with nylon gauze and placed in a glasshouse (24 ± 5°C, 60 ± 5% RH and 16:8 (L:D) photoperiod.
Thiacloprid was applied at 96 g a.s./ha from commercial formula Calypso 480 SC. Distilled water was used as control treatment.
Twenty-four hours before bioassays, *S. punctillum* adult were kept in jars in a rearing chamber (Sanyo MLR 350) for acclimatization (24 °C, 60% RH and photoperiod of 16:8 (L:D). For bioassays, adult ladybirds were collected by paintbrush, and placed in jars with *T.urticae* established on 10 broad bean leaves. Jar tops were covered by gauze. After 24 h adaptation, *S. punctillum* adults were transferred to petri dishes (8 cm diameter, 1.5 cm height). Each had 5 adult ladybirds in the dish bottom, sprayed with the insecticide in a Potter tower. Control was sprayed with water, and each treatment had four replicates. After application, adult ladybirds were fed with *T.urticae* on one Broad bean leaf, and Petri dish cages (8 cm diameter, 1.5 cm height) were closed by addition of lid (10 cm diameter, 1.5 cm height, with a central 2.5 cm hole covered with a scrap of gauze) and sides banded by parafilm (10 cm x 2.5cm). Mortality was assessed after 24, 48 and 72 h, and percentages corrected according to Abott formula.
Control mortality was 0% throughout. Thiacloprid caused 20% mortality after 24 hours (h), 25% after 48 h and 35% after 72 h. This equates to the slightly harmful (mortality 25-50%) category according to the IOBC evaluation criteria.

Material and methods:

A. Material

1. Test material

Test item:	Calypso 480 SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	Distilled water
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Stethorus punctillum* (Weise) (Coleoptera: Coccinellidae)
Cultivar:	-
Source of test species:	Orchards in North and Central Poland
Age of test organisms at study initiation / Crop growth stage at treatment:	Adult
Holding conditions prior to test:	24 h before experiments placed in a rearing chamber (Sanyo MLR 350) for acclimatization, plus food mites *Turticide* established on broad bean leaves.
Acclimatisation:	At same climatic conditions - 24 °C; 60% RH; 16:8 (L:D)

B. Study design and methods

1. Test procedure

Test system (study type):	Direct contact (spray on adults)
Duration of study:	72 h
Treatments:	*Test:* 2 ml direct spray of test solution; *Control:* 2 ml direct spray of water
Test concentrations	96 g a.s./ha
Number of replicates:	4
Individuals per replicate:	5
Test units (type and size):	Petri dish base 8 cm diameter, 1.5 cm height
Application / device / nozzles:	Potter spray tower
Water volume:	-
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Petri dish
Temperature / relative humidity:	24 °C / 60% RH
Photoperiod:	16:8 (L:D)
Lighting	-

3. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Mortality
Measurement frequency:	After 24, 48 and 72 h
Statistical analyses:	Corrected by Abbott formula

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.1- 1: Toxicity of control versus thiacloprid on adults of *Stethorus punctillum* (Coleoptera: Coccinellidae)

	% mortality of adult *S. punctillum*		
	after 24 h	after 48 h	after 72 h
Control	0	0	0
Calypso 480 SC (Thiacloprid)	20	25	35

Control mortality was 0% throughout. Thiacloprid caused 20% mortality after 24 hours (h), 25% after 48 h and 35% after 72 h. This equates to the slightly harmful (mortality 25-50%) category according to the IOBC evaluation criteria.

Comment by the notifier:

Thiacloprid caused under laboratory conditions at 96 g a.s./ha a mortality of 35% of the ladybird *Stethorus punctillum* (adults). These findings indicate a lower sensitivity compared to larvae of *Coccinella septempunctata* that was tested for the regulatory data package. The information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report: [redacted]; 2012; M-471259-01-1
Title: Side effects of pesticides on the larvae of the hoverfly Episyrphus balteatus in the laboratory.
Report No.: M-471259-01-1
Document No.: M-471259-01-1
Guidelines: not applicable; not applicable
GLP/GEP: no

Executive summary:

The toxicity of dry residues of several insecticides (including thiacloprid) was evaluated on hoverfly larvae *Episyrphus balteatus* (De Geer) held in Drum-cells. Reproductive performance of adults then assessed sub-lethal effects in Perspex rearing cages. Material and methods as well as results are summarised for thiacloprid only.
Single dose of thiacloprid (Calypso, 480 g/L SC, Bayer CropScience) was used on glass plates of Drum-cells. These consisted of two glass plates (90 mm diameter [dia] and 2 mm height) and a Plexiglas cylinder (90 mm dia and 12 mm height) with eight ventilation holes (5 mm dia) covered with nylon gauze. In test replicates, glass plates were treated with Calypso (96 g a.s./ha) using a Cornelis spray tower giving homogeneous coverage of 1.58 ± 0.06 mg per cm^2. For controls, the plates were sprayed with distilled water. Two hours after spraying, five *E. balteatus* larvae (2–3-day-old) from laboratory culture were confined in each drum cell and offered pea aphids *ad libitum*. Drum cells were incubated at 23 ± 1°C, 60 ± 10% RH and 16 h: 8 h light:dark photoperiod. Eight replicate with 5 larvae were used for each test product (so total 40 larvae), plus controls. Survival was monitored daily until adult emergence, and pupae failing to emerge after 9 days considered dead. Surviving pupae of the same treatment group were transferred to the same perspex adult rearing cage (60 × 60 × 60 cm), with two nylon mesh sides and front opening (25 × 25cm) covered with nylon gauze. Each was placed into an environmentally controlled chamber at 23 ± 2°C and 70 ± 20% RH with neon lighting of ca 8,000 lux with a 16h : 8h light:dark photoperiod. Each had two plastic petri dish lids

(diameter 90 mm, height 15 mm) containing bee-collected pollen and cotton wool soaked with honey-water (20% honey) offered *ad libitum* and replaced twice weekly. Sex was determined after emergence. 8-10 days after adult emergence, six pots of 15-20cm broad beans (*Vicia faba* L.) infested with pea aphids (*Acyrthosiphon pisum* Harris) were introduced as oviposition sites. These were replaced three times a week. Egg collecting occurred 14 times over 6 weeks, at every count 90 eggs were collected at placed into petri dishes (90 cm dia × 15 mm height) to assess hatching, and aphids added daily to prevent cannibalism.
Larval and pupal mortality were transformed by arcsine square root, analysed by one-way ANOVA. Means separated by LSD multiple range test, (P=0.05) or by a Tamhane's T2 test when variances were not homogeneous (P=0.05). For pupal mortality, a non-parametric Mann–Whitney U test was performed when assumptions of normality were violated. Preimaginal mortality was corrected according to Abott formula. Total effect of an insecticide was assessed by calculating the reduction in beneficial capacity as Overmeer and Vanzon.
Thiacloprid did not affect hoverfly larvae significantly; with no significant sub-lethal effects revealed, and a reduction of only 24.9% in beneficial capacity of *E. balteatus* (IOBC category 1, harmless).

Material and methods:

A. Material

1. Test material

Test item:	Calypso®, 480 g/L, SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	Bayer CropScience N.V/S.A.
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	-
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Episyrphus balteatus* (De Geer)
Cultivar:	-
Source of test species:	Laboratory culture from stock collected in 2008, at Sint-Katelijne-Waver, Belgium
Age of test organisms at study initiation /	2-3 day larvae
Crop growth stage at treatment:	
Holding conditions prior to test:	Rearing cages with bean plants infested with pea aphids and bee-collected pollen and 20% honey-water
Acclimatisation:	-

B. Study design and methods

1. Test procedure

Test system (study type):	Residue on Drum-cells (Contact toxicity of larvae and reproductive performance of adults)
Duration of study:	8 weeks
Treatments:	Thiacloprid, control (distilled water)
Test concentrations	96g a.s./ha
Number of replicates:	8 drum-cells [for each product] and (8 further) water control
Individuals per replicate:	5 larval hoverflies per treatment
Test conditions:	23 ± 1°C, 60 ± 10% RH and 16 h: 8 h (L:D)
Test units (type and size):	*For larvae:* Drum-cells cages Perspex tubes 90 mm diameter by 12mm height) with two glass plates (90 mm dia, 2 mm height); *For adults:* rearing cages
Application / device / nozzles:	Cornelis spray tower (1 bar pressure)
Water volume:	1,58 mg/cm²
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	*For larvae:* Perspex tube (drum cell) glass plates; *For adults:* Perspex cages (60 × 60 × 60 cm) with nylon sides and front (25 × 25 cm)
Temperature / relative humidity:	*For larvae:* Incubator at 23 ± 1°C / 60 ± 10% RH; *For adults:* Controlled chamber at 23 ± 2°C / 70 ± 20% RH
Photoperiod:	16 h : 8 h (L:D)
Lighting	*For larvae:* not specified; *For adults:* Neon light providing ca 8,000 lux

3. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Mortality, fecundity, hatching proportion of eggs
Measurement frequency:	Daily
Statistical analyses:	Abott correction, One-way ANOVA, LSD or Tamhane's T2 mean separation, Mann–Whitney U test

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.1- 2: Effect of insecticides on *Episyrphus balteatus*: Preimaginal mortality, reproductive performance and final evaluation according to the IOBC standard (all treatments were started with 40 larvae).

	Preimaginal mortality (%)			Reproductive performance			Final evaluation	
Active ingredient	**Larval mortality (± SE))**	**Pupal mortality (± SE))**	**M (Abott Corrected)**	**Eggs per female (± SE))**	**Egg hatch (%) (± SE)**	**Viable eggs per female (± SE))**	**Reduction in beneficial capacity E (%)**	**IOBC class**
Control	15.0 ± 5.0 [a]	2.5 ± 2.5 [b]	-	86.1 ± 7.9 [a]	48.7 ± 3.4 [a]	43.3 ± 4.5	-	-
Thiacloprid	5.0 ± 3.3 [a]	2.5 ± 2.5 [b]	−12.1	66.9 ± 4.0 [a]	44.1 ± 5.1 [a]	29.0 ± 3.6	25.0	1 [c]

[a] Do not differ significantly (ANOVA, $P>0.05$, LSD or Tamhane's T2 mean separation.
[b] Do not differ significantly (Mann–Whitney U, $P>0.05$).
[c] Category 1, not affected.

The percentage mortality of larvae exposed to residues of thiacloprid (5.0%) was similar to the control group, and not significantly different. Fertility of adults treated as larvae with thiacloprid was not affected, although both number of eggs per female and egg hatching was lower than control, again did not differ significantly. Reduction of beneficial capacity in 1st instar larvae of *E. balteatus* was only 24.9% (IOBC category 1).

Comment by the notifier:

The observed effects of the thiacloprid at an application rate equivalent to 96 g a.s./ha on hoverfly larvae (*Episyrphus balteatus*) indicate a low sensitivity compared to some of the non-target arthropods as tested for the regulatory data package. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]; 2011; M-465998-01-1
Title:	Susceptibility of cocooned pupae and adults of the parasitoid Microplitis mediator to selected insecticides
Report No.:	M-465998-01-1
Document No.:	M-465998-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

This study examined the lethal and sub-lethal effects from contact exposure to dry residues of several insecticides (including thiacloprid) the parasitoid *Microplitis mediator*. Material and methods as well as results are summarised for thiacloprid only. *M. mediator* were cultured in the laboratory from stock collected on Brassica fields in Belgium, using host larvae *M. brassicae* (3-4 first-instar) for culture. For stock, 4-mated females of *M. mediator* (1-4 day-old) larvae were placed in a petri-dish (90 mm diameter × 15 mm height), each containing 20-x host larvae. After 4h contact, *M. brassicae* larvae were transferred to rearing cages (9 diameter × 10 cm high) with ventilated lids, where fed artificial diet *ad libitum* until parasitoid wasp cocoons formed. One-day-old cocoons were transferred to larger 'Bugdorm-1' (30 × 30 × 30cm) adult rearing cages (MegaView Science Education Services Co., Taiwan), each with a plastic cup (3 cm dia) filled with cotton wool soaked with honey-water (20% honey in tap water). Cultures were maintained and experiments conducted at 23 ± 1°C, 60 ± 10% RH with a 16:8h light:dark (L:D) photoperiod. Thiacloprid assay used a single dose fresh solution of Calypso 480 SC prepared at 96 g a.s./ha, and sprayed on two glass plates (90 mm dia) yielding a homogeneous spray coverage of 1.58 ± 0.06 mg aqueous solution deposit per cm^2, which then dried for 1 day. For controls, the glass plates were sprayed with distilled water and similarly dried. Glass-plates were then joined to a Plexiglas cylinder (90 mm dia × 12 mm height) with seven ventilation holes (5 mm dia) covered with nylon gauze to form Drum cells. A plastic tube with cotton wool connected to water reservoir led through the cylinder provided drinking water, and a honey droplet on the nylon gauze as food (changed weekly). One virgin female and one adult male were confined to each drum-cell, with 12 replicates for each product and control. Adult mortality was recorded after 24h exposure. To oviposit, surviving females were each placed for 4h in a petri-dish containing 20 *M. brassicae* (first-instar) larvae, and the number of stings by the female parasitoids (parasitisation activity) in the 1st hour was recorded, before wasps were returned to Drum-cells and survival (of both sexes) recorded daily and longevity determined. Each group of exposed (and potentially parasitised)

caterpillars and any emerged/ cocooning wasp pupae were cultured as above. For effects on pupae, 1-2 day-old cocoons were stuck onto cardboard (4 × 4 cm^2) using honey-water (50% honey in tap water) and sprayed with product at same concentration as adults (or with distilled water in controls). Cocoons were left to dry 2h then placed in petri-dishes (90 cm dia) until emergence. Sub-lethal (parasitisation activity, parasitism percentage and longevity) and lethal (percent mortality of cocooned pupae) impacts were analysed with the Independent Samples T-test (P=0.05) and means compared with the control. Percentages were transformed by arcsine square root.
Adult survival of both sexes and mortality of cocooned pupae was not affected by direct contact with thiacloprid residue. There were no clear differences in development time of pupae. Thiacloprid did have a slight effect on parasitism activity of surviving (reduced number of stings per female/h). The number of parasitised moth larvae per female wasp was not statistically significantly reduced.
Longevity of female offspring was statistically significantly lower than the control, but not statistically significantly lower longevity for male offspring was observed.

Material and methods:

A. Material

1. Test material

Test item:	Calypso®, 480 g/L SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	Bayer CropScience N.V.
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	-
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Microplitis mediator* (Haliday) (Hymenoptera: Braconidae)
Cultivar:	-
Source of test species:	Collected in *Brassica* fields, Belgium
Age of test organisms at study initiation:	1-4 day-old mated females (*host moth:* 3-4 first-instar)
Crop growth stage at treatment:	-
Holding conditions prior to test:	-
Acclimatisation:	-
Host:	Larvae of Cabbage Moth *Mamestra brassicae* (L.) (Lepidoptera: Noctuidae)

B. Study design and methods

1. Test procedure

Test system (study type):	*Adults:* Residue on Drum-cells (Contact toxicity and reproductive performance of adults). *Cocoons:* Direct spray.
Duration of study:	Approx. 60 days
Treatments:	Thiacloprid, control (distilled water)
Test concentrations	96g a.s./ha
Number of replicates:	12 drum-cells [each product] and water controls.
Individuals per replicate:	1 virgin female and adult male
Test units (type and size):	Two glass plates (90 mm diameter) on 12mm high Drum Cells, or petri-dishes/dish (90 mm diameter × 15 mm height).
Application / device / nozzles:	Cornelis spray tower (1 bar pressure)
Water volume:	-
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	*Adults:* Drum cells with glass plates; *Cocoons:* directly on card.
Temperature / relative humidity:	23 ± 1°C / 60 ± 10% RH
Photoperiod:	16:8h (L:D)
Lighting	-

3. Observations and measurements:

Analytical parameters measured:	Individual counts, time (days)
Biological parameters measured:	Mortality, parasitism activity (sting rate), % parasitism (percentage stung larval yielding wasp cocoons) and longevity of wasps (from treated cocoons).
Measurement frequency:	*For Mortality:* After 24 h – then daily; *For parasitism activity:* over 1 hour; *For parasitism activity:* Not specified; Longevity: up to about 40 days (once emerged)
Statistical analyses:	Independent Samples T-test, percentages arcsine square root transformed.

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.1-3: Effect of on cocooned pupae (% mortality) and adults (% mortality, parasitism activity (number of stings per female per hour), % parasitism and longevity) of the wasp *Microplitis mediator*

Active ingredient	Cocooned pupae	Adults					
	% Mortality (± S.E.)[c]	% Mortality		Parasitism activity (± S.E.)[c]	% Parasitism (± S.E.)[c]	Longevity (days) (± S.E.)[c]	
		♂	♀			♂	♀
Control	5.79 ± 1.83	0	0	13.56 ± 1.19	42.65 ± 3.20	31.38 ± 0.88	37.85 ± 0.88
Thiacloprid	7.50 ± 5.26	0	0	5.42 ± 2.19 [a](*)	32.50 ± 6.61	27.80 ± 2.67	30.80 ± 2.62 [a](*)

[a] (*) Significantly different from the control (Independent Samples T- test, $p < 0.05$)
[b] Percentage of parasitism was calculated as: (Number of parasitoid cocoons formed / number of host larvae exposed)*100
[c] Standard error

Adult survival of both sexes was not affected by direct contact with thiacloprid residue (0% mortality). Mortality of cocooned pupae (7.25% mortality) was also not significantly different from the control. There were no clear differences in development time of pupae, ranging from 4.7-6.3 days in treatments and control. Thiacloprid had a slight but statistically significant (P=0.05) effect on parasitism activity of surviving females with lower average number of stings per female/h from 13.56 in control to 5.42. The number of parasitised moth larvae per female wasp was not statistically significantly reduced compared to control (32.50% compared to 42.65% in the control). Longevity of female offspring was statistically significantly lower than the control (30.80 days in those from parental stock that had direct contact with thiacloprid versus 37.85), but no statistically significantly lower longevity for male offspring was observed.

Comment by the notifier:

The observed effects of the thiacloprid at an application rate equivalent to 96 g a.s./ha on the parasitoid *Microplitis mediator* indicate a low sensitivity compared to *Aphidius rhopalosiphi* as tested for the regulatory data package. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]; 2013; M-470745-01-1
Title:	Acute toxicity and safety evaluation of neonicotinoids and macrocyclic loctones to adult wasps of four Trichogramma species (Hymenoptera:Trichogrammidae)
Report No.:	M-470745-01-1
Document No.:	M-470745-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

This study assessed the side effects of multiple insecticides on beneficial trichogrammatid wasps (*Trichogramma* spp. Hymenoptera; Chalcidoidea). Specifically, the pesticide membrane method was used to assess the acute toxicities of nine insecticides, including thiacloprid for adult *T. japonicum* Ashmead, *T. ostriniae* Pang and [redacted], *T. confusum* Viggiani and *T. evanescens* Westwood. This study employed the dry film residue method under laboratory conditions. Material and methods plus results are summarised for thiacloprid only.
Four *Trichogramma* species (*T. japonicum, T. ostriniae, T. confusum,* and *T. evanescens*) were provided by Guangdong Provincial Insect Research Institute, from stock raised indoors for multiple years, and here raised in an artificial climate box (temperature 25 ±1°C, relative humidity 70-80%, light cycle 16L: 8D) using eggs of *Corcyra cephalonica* Stainton (Lepidoptera; Pyralidae) as the host for reproduction. In the test, adult *Trichogramma* were used at 24-48 h of eclosion from pupa. The host moth *C. cephalonica* were provided by the Nanjing Agricultural University (Ministry of Agriculture Huadong Crop Harmful Organism Integrated Pest Management Key Laboratory), and larvae raised in commercial corn flour using a (20 cm × 15 cm × 6 cm) plastic container (temperature 25 ±1°C, relative humidity 70-80%, and the light cycle was 16L: 8D). All host eggs were irradiated for 30 minutes (min) under a 30W ultraviolet bulb prior to wasp propagation to kill the moth embryos. Thiacloprid was prepared directly with acetone into a fixed concentration stock solution (See Table 1 for the active ingredient quantities, source, and recommended field doses). Here, they used slight

modification of the pesticide membrane method to measure acute toxicity of insecticides to adult *Trichogramma* spp. Pretesting precisely defined the basic effective concentration range and the active agent was mixed with acetone to form 5-7 dilution concentrations at geometric gradients. 0.5mL test solution aspirated into a finger-shaped tube (1.5 cm diameter × 8 cm length, 53.38 cm^2) served as one treatment. The experiment used three repetitions for each treatment, and acetone as control. The tube with the added treatment solution was then rolled horizontally on a table top to form a uniform membrane inside the tube, and acetone volatised. Each tube with residue then was inoculated with 80-100 adult *Trichogramma* spp. at 24-48 h eclosion stage, and wasps allowed to crawl freely over treated internal surfaces (the entrance was likely closed). After 1 hour (1h), wasps were transferred into another clean untreated tube and fed 10% honey water, and a black cloth sealed the opening. This tube was placed into an artificial climate box (temperature 25 ±1°C, relative humidity 70-80%, out of the light). After 24h, tubes were checked and recorded the numbers of dead wasps (defined as did move after body contacted with a small pen) then mortality rate was calculated. If the mortality rate in the control group of *Trichogramma* spp. was < 10% then the test was deemed valid.
Statistics and analysis: Probit analysis was used to calculate 50% lethal concentration (LC_{50}) and 95% confidence interval. Presence or absence of LC_{50} and overlap in the 95% confidence interval between treatments and control was the standard for judging significance. Safety factor = insecticide LR_{50} (mg/m²) to *Trichogramma*/thiacloprid maximum recommended field dose (mg/m²), where LR_{50} was the half-lethal dose (dose causing a 50% mortality rate in *Trichogramma* spp. in these conditions), expressed using the unit area of adhered active ingredient.
Results of safety evaluation here for four beneficial wasps (*Trichogramma* spp.) showed thiacloprid was generally ranked as moderate risk with lowest safety factor of 3.45 for *T. ostriniae* (and lowest LC_{50} of 371.91 mg a.s./L), intermediate but still moderate risk for *T. japonicum* and *T. confusum*, up to high risk with the safety factor 0.16 for *T. evanescens* (highest LC_{50} 17.36 mg a.s./L).

Material and methods:

A. Material

<u>1. Test material</u>	
Test item:	Thiacloprid 97.75 TC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	[redacted]
Lot/Batch number:	-
Purity:	97.75%
Storage conditions:	-
<u>2. Test solutions</u>	
Vehicle/solvent:	Acetone
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-
<u>3. Test organism(s)</u>	
Species:	*T. japonicum, T. ostriniae, T. confusum* and, *T. evanescens* (Hymenoptera; Chalcidoidea)
Cultivar:	-
Source of test species:	[redacted]
Age of test organisms at study initiation / Crop growth stage at treatment:	Adults at 24-48h of eclosion.
Holding conditions prior to test:	Artificial climate box (temperature 25 ±1°C, relative humidity 70-80%, light cycle 16L: 8D) using eggs of *Corcyra cephalonica* Stainton (Lepidoptera; Pyralidae
Acclimatisation:	Each species raised indoors for multiple years

B. Study design and methods

1. Test procedure

Test system (study type):	Pesticide membrane method (dry film residue)
Duration of study:	24 h (plus additional setup time)
Treatments:	Thiacloprid and control (acetone)
Test concentrations	10.08 (See table 1)
Number of replicates:	3 per treatment
Individuals per replicate:	80-100 adult *Trichogramma* spp. at 24-48h eclosion stage
Test units (type and size):	finger-shaped tube (1.5 cm diameter × 8cm length, 53.38cm^2)
Application / device / nozzles:	Aspirator
Water volume:	0.5mL
Calibration of sprayer:	-

2. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Mortality (LC_{50}, LR_{50})
Measurement frequency:	After 24 h
Statistical analyses:	Probit analysis for 50% lethal concentration (LC50) and 95% confidence interval; Safety factor = insecticide LR50 (mg/m²) / maximum recommended field dose (mg/m2)

Results:

Validity criteria:
If the mortality rate in the control group of *Trichogramma* was < 10% then the test was deemed valid.

Biological findings:
Acute toxicity of insecticides to adult of four *Trichogramma* spp. (*T. japonicum, ostriniae, confusum* and *evanescens*) varied widely.
For *T. japonicum,* thiacloprid had a mean LC_{50} of 75.34 mg a.s./L.
For *T. ostriniae*, thiacloprid had a mean LC_{50} of 371.91 mg a.s./L.
For *T. confusum*, thiacloprid had a mean LC_{50} of 175.90 mg a.s./L.
For *T. evanescens*, thiacloprid had a mean LC_{50} of 17.36 mg a.s./L.

Table CP 10.3.2.1.-1: Acute toxicity of thiacloprid to adult *Trichogramma* spp.

LC_{50}	Slope	LR_{50} (mg/m^2)	LC_{50}	Slope	LR_{50} (mg/m^2)	LC_{50}	Slope	LR_{50} (mg/m^2)	LC_{50}	Slope	LR_{50} (mg/m^2)
Trichogramma japonicum			***Trichogramma ostriniae***			***Trichogramma confusum***			***Trichogramma evanescens***		
75.34 (67.30 - 85.13)	1.41 ± 0.08	7.05	371.91 (338.93 – 443.10)	1.92 ± 0.14	34.84	175.90 (156.13 – 208.24)	1.70 ± 0.13	16.51	17.36 (15.39 - 23.11)	1.42 ± 0.07	1.63

[a] Slope is represented as mean ± SE

The safety evaluation of thiacloprid indicated the safety grades were the same for adults of *T. japonicum* and *T. confusum*, as moderate risk (with safety factor 0.70- 1.64). Safely values were considerably lower for adult T. *ostriniae* (3.45) but again considered in same class as moderate risk, however this was one grade lower than their safety to *T. evanescens*, where thiacloprid was considered high risk to adults (the safety factor was 0.16).

Table CP 10.3.2.1- 5: Safety evaluation thiacloprid to adult *Trichogramma* spp.

Safety factor (SF)	Safety grade	Safety factor (SF)	Safety grade	Safety factor (SF)	Safety grade	Safety factor (SF)	Safety grade
Trichogramma japonicum		***Trichogramma ostriniae***		***Trichogramma confusum***		***Trichogramma evanescens***	
0.70	Moderate risk	3.45	Moderate risk	1.64	Moderate risk	0.16	High risk

SF = LR_{50} (mg/m²) / FMRD (mg/m²), where FMRD = Field maximum recommended dose

Results summary:

Results of safety evaluation here for four beneficial wasps (*Trichogramma* spp.) showed thiacloprid was generally ranked as moderate risk with lowest safety factor of 3.45 for *T. ostriniae* (and highest LR_{50} of 34.84 mg a.s./m²), intermediate but still moderate risk for *T. japonicum* and *T. confusum*, up to high risk with the safety factor 0.16 for *T. evanescens* (lowest LR_{50} 1.63 mg a.s./m²).

Comment by the notifier:

The study results indicate clear toxicity of thiacloprid to the tested *Trichogramma* species (lowest LR_{50} 16.3 g a.s./ha). The data do not influence the outcome of the non-target arthropod risk assessment since *A. rhopalosiphi* proved to be clearly more sensitive under tier-1 laboratory test conditions. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report: [redacted]9; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; 2013; M-468828-01-1
Title: Insecticide toxic effects on Trichogramma ostriniae (Hymenoptera: Trichogrammatidae)
Report No.: M-468828-01-1
Document No.: M-468828-01-1
Guidelines: not applicable; not applicable
GLP/GEP: no

Executive summary:

The present study examines the toxic effects of selected insecticides on *T. ostriniae* under laboratory conditions. Material and methods as well as results are summarised for thiacloprid treatments only. The host *Corcyra cephalonica* was obtained from the Guangdong Entomological Institute (Guangzhou, China). *Trichogramma ostriniae* was mass maintained on the eggs of the host, *C. cephalonica*. After the parasitism period (24 h), parasitised eggs were kept in a chamber with 50% honey solution until the emergence of the adults. All insects were maintained at 25 ± 1°C temperature, 70 ±10% RH and 14:10 (L:D) photoperiod. Parasitoid adults at a uniform age of 24–48 h after emergence were used in the experiment.
Thiacloprid (97.75%) was purchased from Tianjing Xingguang Chemical Co., Ltd and used for the dry film residue method. Six concentrations with a twofold increase in geometrical ratio were tested. Therefore, thiacloprid was dissolved with acetone and pure acetone was used as control. 500 µL

solution was introduced into a glass tube (height 8.0 cm; diameter 2.0 cm; Internal surface area 53.38 cm²). After complete evaporation (1 h), 80-100 adult parasitoids were introduced and in each tube a small plastic strip with two honey drops were placed. Then, the tubes were maintained at 25 ± 1 C, 70 ± 10% RH and 14:10 h (L:D) photophase. Three replicates were conducted for each dose. After 1 h of exposure, the wasps were transferred into a clean insecticide-free tube that contained a honey solution. After 24 h, dead parasitoids were counted. Wasps showing no movement when prodded were counted as dead.
The mortality percentage of each insecticide for *T. ostriniae* was corrected using the Abbott's formula. The data were then subjected to probit analysis, as described by Finney.
The LC_{50} value to *T. ostriniae* was 376.3 (308.2-489.1) mg a.s./L.

Material and methods:

A. Material

1. Test material

Test item:	Thiacloprid
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	
Source of test item:	[redacted]
Lot/Batch number:	-
Purity:	97.75%
Storage conditions:	

2. Test solutions

Vehicle/solvent:	Acetone
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Trichogramma ostriniae*
Cultivar:	-
Source of test species:	-
Age of test organisms at study initiation:	24 – 48 h
Crop/growth stage at treatment:	
Holding conditions prior to test:	25 ± 1 C, 70 ± 10% RH and 14 : 10 h (L :D) photoperiod
Acclimatisation:	-

B. Study design and methods

1. Test procedure

Test system (study type):	dry film residue method (contact acute toxicity)
Duration of study:	24 h
Treatments:	Thiacloprid and control
Test concentrations	Six concentrations with a twofold increase in geometrical ratio
Number of replicates:	3 replicates
Individuals per replicate:	80-100 wasps per treatment
Test conditions:	25 ± 1◦ C, 70 ± 10% RH and 14: 10 h (L :D) photoperiod
Test units (type and size):	glass tubes (height 8.0 cm; diameter 2.0 cm; internal surface area 53.38 cm2)
Application / device / nozzles:	500 µl test solution was homogeneous introduced into the glass tubes and dried for 1 h
Water volume:	-
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Glass tube
Temperature / relative humidity:	25 ± 1◦C, 70 ± 10% RH
Photoperiod:	14: 10 h (L :D)
Lighting	-

3. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Mortality
Measurement frequency:	After 24 h
Statistical analyses:	Abbott's formula and Probit analysis

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.1- 6: Median lethal concentration of thiacloprid to *Trichgramma ostriniae*

Treatment	Slope (SE)	LC_{50} (95% FI) mg a.s./L	Df (χ^2)	LC_{95} (95% FI) mg a.s./L
Thiacloprid	2.12 (0.11)	376.3 (308.2–489.1)	4 (14.7)	2240.5 (1429.6–4366.6)

The LC_{50} value to *T. ostriniae* was 376.3 (308.2-489.1) mg a.s./L after 24 h.

Comment by the notifier:

The study results indicate a low toxicity of thiacloprid to *T. ostriniae* (376.3 mg a.s./L, considering 0.5 mL application volume and 53.38 cm² this is equivalent to 352 g a.s./ha). The data do not influence the outcome of the non-target arthropod risk assessment since *A. rhopalosiphi* proved to be more sensitive under tier 1 laboratory test conditions. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]x; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; 2013; M-468834-01-1
Title:	Susceptibility of adult Trichogramma nubilale (Hymenoptera: Trichogrammatidae) to selected insecticides with different modes of action
Report No.:	M-468834-01-1
Document No.:	M-468834-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

The objective of this study was to assess toxicities of several insecticides including thiacloprid with different modes of action to *T. nubilale* and provide pest managers with specific information for implementing compatible biological and chemical controls for corn lepidopteran IPM. Material and methods as well as results are summarised for thiacloprid only.
T. nubilale was maintained in the eggs of the rice moth, *Corcyra cephalonica* Stainton (Lepidoptera: Pyralidae) as host. Parasitised eggs and adults were maintained at 25°C ± 1°C and 70% ± 10% relative humidity with 14:10 h (L:D) photoperiod. Adult wasps that emerged from the hosts were maintained in a glass tube containing a small piece of thick paper that had been previously dipped in a 10% honey solution. Adult wasps, 24-48 h after emergence, were used in the experiments.
Thiacloprid (97.75%,Tianjing Xingguang Chemical Co., Ltd.) was used as test substance.
A modified slightly dry film residue method was used to assess the toxicities of insecticides on *T. nubilale*. Adults were exposed to 6 concentrations with 2-fold increases in geometric ratio. Acetone solutions of insecticides were prepared in glass tubes (height x diameter, 8.0 cm x 2.0 cm; internal surface area, 53.4 cm^2). Pure acetone was used as a control. To obtain a homogeneous deposition, we introduced 500 µl of solution, which completely covered the internal surface of the tube. After complete evaporation, 80-100 parasitoids with 2 honey drops were introduced. they were maintained at 25 °C ± 1 °C and 70% ± 10% relative humidity with a 14:10 h (L:D) photoperiod.
Three replicates were conducted for each dose. After 1 h of exposure, the wasps were transferred into a clean insecticide-free tube that contained a honey solution. After 24 h, dead parasitoids were counted. Wasps, showing no movement after a probing, were counted as dead.
The percentage mortality of each insecticide to *T. nubilale* was corrected using the Abbott's formula. The data were then subjected to probit analysis.
The LC_{50} of thiacloprid to *T. nubilale* was 56.73 (51.32 - 63.27) mg a.s./L..

Material and methods:

A. Material

1. Test material

Test item:	Thiacloprid
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	[redacted]
Lot/Batch number:	-
Purity:	97.75%
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	Acetone
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Trichogramma nubilale*
Cultivar:	-
Source of test species:	-
Age of test organisms at study initiation / Crop growth stage at treatment:	24-48 h
Holding conditions prior to test:	25 ± 1°C, RH 70 ± 10% and 14:10 h (L:D)
Acclimatisation:	-
Host:	*Corcyra cephalonica* Stainton

B. Study design and methods

1. Test procedure

Test system (study type):	Film residue method (contact acute toxicity)
Duration of study:	24 h
Treatments:	Thiacloprid and control (acetone)
Test concentrations	Six concentrations
Number of replicates:	3 replicates
Individuals per replicate:	80-100 wasps
Test conditions:	25 ± 1°C, RH 70 ± 10% and 14:10 h (L:D)
Test units (type and size):	Glass tubes (height: 8.0 cm; diameter: 2.0 cm; internal surface area: 53.4 cm²).
Application / device / nozzles:	500 µl test solution (manually rotated on the palms until no more droplets were seen).
Water volume:	-
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Glass tube
Temperature / relative humidity:	25 ± 1°C, RH 70 ± 10%
Photoperiod:	14:10 h (L:D)
Lighting	-

3. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Mortality
Measurement frequency:	After 24 h
Statistical analyses:	Correction using Abbot formula and Probit analysis as described by Finney.

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.1- 7: Median lethal concn of thiacloprid to *T. japonicum*

Treatment	Slope (SE)	LC_{50} (95% CI) mg a.s./L	Df (χ^2)	LC_{95} (95% CI) mg a.s./L
Thiacloprid	1.81 (0.09)	56.73 (51.32-63.27)	4 (6.24)	461.2 (362.0-616.3)

The LC_{50} of thiacloprid to *T. nubilale* was 56.73 (51.32 - 63.27) mg a.s./L.

Comment by the notifier:

The study results indicate moderate toxicity of thiacloprid to *T. nubilale* (56.73 mg a.s./L, considering 0.5 mL application volume and 53.4 cm² this is equivalent to 53.1 g a.s./ha). The data do not influence the outcome of the non-target arthropod risk assessment since *A. rhopalosiphi* proved to be more sensitive under tier 1 laboratory test conditions. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; 2013; M-462301-01-1
Title:	Susceptibility to Selected Insecticides and Risk Assessment in the Insect Egg Parasitoid Trichogramma confusum (Hymenoptera: Trichogrammatidae)
Report No.:	M-462301-01-1
Document No.:	M-462301-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

Toxicity effect of insecticides to *T. confusum* was evaluated in the current study. The objective was to provide pest managers with specific information for implementing compatible biological and chemical control methods for lepidopterous pests. Material and methods as well as results are summarised for thiacloprid only.

T. confusum was maintained in parasitised eggs of the rice moth, *Corcyra cephalonica* Stainton (Lepidoptera: Pyralidae). Parasitisedd eggs and adult parasitoids were kept at 25 ± 1°C and 70 ± 10% RH with a photoperiod of 14:10 (L:D) h. They were fed with 10% honey solutions. Adult wasps (24-48 h old) were used in the experiments.

Thiacloprid (tech., 97.75%, Tianjing Xingguang Chemical Co., Ltd.) was dissolved with analytical grade acetone to obtain the desired concentrations and was used directly for contact toxicity study. Six different concentrations of each insecticide with two-fold increases in the geometrical ratio were tested. 500 µl acetone solutions were applied to the inner surface of glass tubes (height x diameter, 8.0 cm x 2.0 cm; internal surface area, 53.38 cm^2). Pure acetone was used for the controls. After complete evaporation (1 h), adult parasitoids (80-100) were placed in each tube and two drops of honey were added. In the following, they were maintained at 25 ±1 °C and 70 ± 10% RH with a photoperiod 14:10 (L:D) h. Three replicates were used for each dose. After 1 h of exposure, the wasps were transferred into a clean insecticide-free tube that contained a honey solution. After 24 h, the number and percentage mortality of dead parasitoids in the tubes post exposure to insecticides were counted. Wasps showing no movement on probing were considered dead.

The percentage of mortality for each insecticide to *T. confusum* was corrected by using the Abbott formula. Moreover, the mortality in the controls should not exceed 10% at the end of either test. The data were then subjected to probit analysis using the EPA Probit Analysis Program (version 1.5). The LC_{50} of Thiacloprid to *T. confusum* was 176.5 (157.6-200.4) mg a.s./L.

Material and methods:

A. Material

1. Test material	
Test item:	Thiacloprid
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	[redacted]
Lot/Batch number:	-
Purity:	97.75%
Storage conditions:	-
2. Test solutions	
Vehicle/solvent:	Acetone
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-
3. Test organism(s)	
Species:	*T. confusum*
Cultivar:	-
Source of test species:	-
Age of test organisms at study initiation:	Adults 24-48 h
Crop growth stage at treatment:	-
Holding conditions prior to test:	25 ± 1°C and 70 ± 10% RH with a photoperiod of 14:10 (L:D) h
Acclimatisation:	-
Host:	*Corcyra cephalonica*

B. Study design and methods

1. Test procedure	
Test system (study type):	Acute contact toxicity
Duration of study:	24 h
Treatments:	Thiacloprid and control (acetone)
Test concentrations:	Six concentrations with twofold increases in geometrical mean
Number of replicates:	3 replicates
Individuals per replicate:	80-100 individuals per treatment
Test units (type and size):	Glass tubes (height x diameter, 8.0 cm x 2.0 cm; internal surface area, 53.38 cm²)
Application / device / nozzles:	500 µl test solution (manually rotated on the palms until no more droplets were seen)
Water volume:	-
Calibration of sprayer:	-
2. Environmental conditions	
Test medium:	Glass tubes
Temperature / relative humidity:	25 ± 1°C and 70 ± 10% RH
Photoperiod:	14:10 (L:D) h
Lighting:	-
3. Observations and measurements:	
Analytical parameters measured:	-
Biological parameters measured:	Mortality
Measurement frequency:	After 24 h
Statistical analyses:	-

Results:

1. Validity criteria:
The mortality in the controls should not exceed 10% at the end of either test.

2. Biological findings:
The LC_{50} of Thiacloprid to *T.: confusum* was 176.5 (157.6-200.4) mg a.s./L after 24 h.

Table CP 10.3.2.1- 8: Median lethal concentrations of insecticides to *Trichogramma confusum*

Insecticide	Slope (SE)	LC_{50} (95% CI) mg a.s./L	LC_{95} (95% CI) mg a.s./L
Thiacloprid	1.77 (0.09)	176.5 (157.6 - 200.4)	1,507 (1,144 - 2,106)

Results summary:

The LC_{50} of Thiacloprid to *T. confusum* was 176.5 (157.6-200.4) mg a.s./L after 24 h.

Comment by the notifier:

The study results indicate low toxicity of thiacloprid to *T. confusum* (176.5 mg a.s./L considering 0.5 mL application volume and 53.38 cm² this is equivalent to 165 g a.s./ha). The data do not influence the outcome of the non-target arthropod risk assessment since *T. cephalosiphi* proved to be more sensitive under tier 1 laboratory test conditions. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report: [redacted], 2013, M-468833-01-1
Title: Assessment of toxicity risk of insecticides used in rice ecosystem on Trichogramma japonicum, and egg parasitoid of rice lepidopterans
Report No.: M-468833-01-1
Document No.: M-468833-01-1
Guidelines: not applicable; not applicable
GLP/GEP: no

Executive summary:

This study assessed, the toxicity of insecticides on a biological control agent, *Trichogramma japonicum* Ahmead (an egg parasitoid of rice lepidopterans) by using a dry film residue method. Material and methods as well as results are summarised for Thiacloprid treatments only.
T. japonicum was maintained on eggs of the host, *Corcyra cephalonica* Stainton (Lepidoptera: Pyralidae). Parasitised eggs were and emerged adults were maintained at 25 °C ± 1 °C, RH of 70 ± 10% and 14:10 h (L:D) photoperiod. Age of adult parasitoids was standardised at 24-48 h postemergence for experiments.
Thiacloprid (tech., 97.75%, Tianjing Xingguang Chemical Co., Ltd.) was dissolved with analytical grade acetone to obtain the desired concentrations and was used directly for contact toxicity study. 500 µl Acetone solutions of insecticide were made in glass tubes (height: 8.0 cm; diameter: 2.0 cm; internal surface area: 53.38 cm^2). Six concentrations increasing with a geometrical ratio of two-fold were tested. Pure acetone was used as control. After complete evaporation of acetone (ca. 1 h), adult parasitoids (80-100) were placed in each tube containing a small plastic strip with two drops of honey. The tubes were covered with fine nylon mesh to allow air circulation, and were maintained at 25 ±

1 °C, 70 ± 10% RH, and 14:10 h (L:D) photophase. Three replicates were conducted for each dose and each insecticide. After 1 h of exposure, the wasps were transferred into a clean insecticide- free tube containing honey solution. Parasitoid mortality was determined at 24 h post-treatment. The wasps without any movement when prodded were counted as dead.
The percentage of mortality of thiacloprid to *T. japonicum* was corrected by Abott formula. The data were then subjected to probit analysis as described by Finney.
The LC_{50} of Thiacloprid to *T. japonicum* was 75.26 (65.95-87.50) mg a.s./L.

Material and methods:

A. Material

1. Test material

Test item:	Thiacloprid
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	
Source of test item:	[redacted]
Lot/Batch number:	-
Purity:	97.75%
Storage conditions:	

2. Test solutions

Vehicle/solvent:	Acetone
Source of vehicle/solvent:	
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Trichogramma japonicum*
Cultivar:	-
Source of test species:	
Age of test organisms at study initiation:	24-48 h
Crop growth stage at treatment:	
Holding conditions prior to test:	25 ± 1°C, RH 70 ± 10% and 14:10 h (L:D)
Acclimatisation:	-
Host:	*Corcyra cephalonica* Stainton

B. Study design and methods

1. Test procedure

Test system (study type):	Film residue method (contact acute toxicity)
Duration of study:	24 h
Treatments:	Thiacloprid and control (acetone)
Test concentrations	Six concentrations
Number of replicates:	3 replicates
Individuals per replicate:	80-100 wasps
Test conditions:	25 ± 1°C, RH 70 ± 10% and 14:10 h (L:D)
Test units (type and size):	Glass tubes (height: 8.0 cm; diameter: 2.0 cm; internal surface area: 53.38 cm^2).
Application / device / nozzles:	500 µl test solution (manually rotated on the palms until no more droplets were seen)
Water volume:	-
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Glass tube
Temperature / relative humidity:	25 ± 1°C, RH 70 ± 10%
Photoperiod:	14:10 h (L:D)
Lighting	-

3. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Mortality
Measurement frequency:	After 24 h
Statistical analyses:	Correction using Abbot formula and Probit analysis as described by Finney

Results:

Validity criteria:
No validity criteria were stated.

Biological findings:

Table CP 10.3.2.1- 9: Median lethal concentration of thiacloprid to *T. japonicum*

Treatment	Slope (SE)	LC_{50} (95% CI) mg a.s./L	Df (χ^2)	LC_{95} (95% CI) mg a.s./L
Thiacloprid	1.45 (0.08)	75.26 (65.95-87.50)	4 (6.13)	1034.8 (727.5-1599.5)

Results summary:

The LC_{50} of Thiacloprid to *T. japonicum* was 75.26 (65.95-87.50) mg a.s./L.

Comment by the notifier:

The study results indicate moderate toxicity of thiacloprid to *T. japonicum* (75.26 mg a.s./L, considering 0.5 mL application volume and 53.38 cm² this is equivalent to 70.5 g a.s./ha). The data do not influence the outcome of the non-target arthropod risk assessment since *A. rhopalosiphi* proved to be more sensitive under tier 1 laboratory test conditions. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target

arthropods

Report:	[redacted]1; [redacted]; 2002; M-066016-01-1
Title:	An extended laboratory test to determine the effects of Thiacloprid OD 240 on the parasitic wasp, Aphidius rhopalosiphi
Report No.:	BAY-02-4
Document No.:	M-066016-01-1
Guidelines:	**Mead-Briggs et al. (2000), modified for an extended laboratory test design.**
GLP/GEP:	**yes**

Materials and methods:

Test item: Thiacloprid OD 240; Development no.: 30-00266399; Article no.: 000-05683696; Batch no.: 07690/0086(0082); TOX no.: 06069-00.

The test item was diluted in deionised water (200 L/ha) for application at rates equivalent to 122.98, 38.90, 12.30, 3.89 and 1.23 mL product/ha (i.e. 30.0, 9.49, 3.00, 0.95 and 0.30 g a.s./ha, based on the measured content of a.s.).
A control treatment of deionised water (200 L/ha) and a toxic reference treatment of Perfekthion (nominally 400 g/L dimethoate, applied at a rate equivalent to 0.75 mL product/200 L water/ha) were also included in the experiment. All treatments were applied to the upper (adaxial) surface of excised leaves of apple trees (*Malus domestica* var. Bramley), using a calibrated laboratory sprayer. Prior to treatment application, a stripe of fructose solution was drawn along the centre of each leaf to provide a source of food for the wasps. Following treatment, the leaves were allowed to dry for approximately 1 h. They were then used to line the floor and ceiling of shallow arenas, with their treated surfaces facing inwards. Three replicate arenas were prepared per treatment and 10 adult wasps (including a minimum of five females) were placed in each replicate arena (i.e. a total of 30 wasps per treatment). The wasps were also provided with a supply of tap water to drink. Assessments of treatment effects were made after 2, 24 and 48 h. To assess any sub-lethal effects on the relative fecundity of the insects, surviving females (n = 15 per treatment) were taken from the control and from all treatment rates of the test item that resulted in <50% mortality. These wasps were individually confined over aphid-infested plants (untreated) and removed after a further 24 h. The aphid-infested plants were left for a further 10 days before the numbers of aphid mummies that had developed on them were recorded. The toxic reference treatment resulted in 70% mortality.

Findings and conclusions:

Table CP 10.3.2.2- 1: Results from the ext. laboratory test with *Aphidius rhopalosiphi*

Test item	Thiacloprid OD 240	
Test object	***Aphidius rhopalosiphi***	
Exposure	**Apple leaves**	
	Mortality at 48 h (%)	Mean mummies per surviving female ##
Control	0	13.6
Application rate#	Mortality at 48 h (%)	Reproduction relative to control (%)
30.0 g a.s./ha	83	-
9.49 g a.s./ha	80	-
3.00 g a.s./ha	53	-
0.95 g a.s./ha	7	74
0.30 g a.s./ha	0	72
Observations	No adverse effects on behaviour with any of the test item treatments.	
LR_{50} (95% c.l.)	4.33 g a.s./ha (2.08 & 9.05 g a.s./ha)	

\# Based on the measured content of active ingredient.
\## Results for individual treatments were compared

Conclusions:

The LR_{50} was calculated to be 4.33 g a.s./ha

Report: [redacted]; 2005; M-247129-01-1
Title: Toxicity to the ladybird beetle Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test - Thiacloprid, oil based suspension concentrate
Report No.: CW03/005
Document No.: M-247129-01-1
Guidelines: **IOBC Guideline (Schmuck et al. 2000), modified; none**
GLP/GEP: **yes**

Material and methods:

Test item: Thiacloprid OD 240; Sample description: TOX06264-00; Product code: AE F158944 01 OD23 A101; Batch no.: 07690/0086(0082); Density: 1.046 g/mL; Analysed content: 239.53 g a.s./L.

The test item was applied to apple leaves at rates of 3.125; 6.25; 12.5; 25.0 and 50 g a.s./ha and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 150 mL product/ha, and a water treated control. The pre-imaginal mortality was monitored over the duration of the study. The toxicity of the test item residues to the larvae and pupae are summarised below. The fertility and fecundity of the surviving hatched adults were then evaluated over the period of 14 days. Mortality and reproduction in each of the treatments are summarised below.

Findings:

Table CP 10.3.2.2- 2: Results from the ext. laboratory test with *C. septempunctata*

Test item	Thiacloprid OD 240					
Test object	*Coccinella septempunctata*					
Exposure	Apple leaves					
	Rate	Mortality [%]			Reproduction	
Treatment	[g a.s./ha]	Uncorr.	Schneider-Orelli (corr.)	(*) P-Value	Fertility (hatching rate) [%]	Fertile eggs per female and day
Control (deionised water)	-	2.5	-	-	73.0	8.3
AE F158944 00 OD23 A101	3.125	20.0	17.9	0.057	52.0	3.7
AE F158944 00 OD23 A101	6.25	17.5	15.4	0.057	44.3	0.9
AE F158944 00 OD23 A101	12.5	72.5	71.8	< .0001	n.d.**	n.d.**
AE F158944 00 OD23 A101	25.0	75.0	74.4	< .0001	n.d.**	n.d.**
AE F158944 00 OD23 A101	50.0	100	100	< .0001	n.d.**	n.d.**
Reference item (ml prod./ha)	150	100	100		n.d.**	n.d.**

LR_{50}: 10.222 g a.s./ha ; 95% Confidence Interval: (0.000 – 27.629)
* Fisher`s Exact test, two-sided, p-values are adjusted according to Bonferroni-Holm
** n.d.: not detected

In this extended laboratory study the effects of the test item residues of AE F158944 00 OD23 A101 to larvae of the ladybird beetle *Coccinella septempunctata* were determined. The application was done onto detached leaves of apple trees (*Malus communis*). The dose rates of 3.125 and 6.25 g a.s./ha had little influence on pre-imaginal mortality. At the test rates of 12.5; 25 and 50 g a.s./ha there were significant effects on the preimaginal mortality.

Reproduction was assessed in the two lowest rates of AE F158944 00 OD23 A101, 3.125; and 6.25 g a.s./ha. The mean number of fertile eggs per female and day was 8.3 in the control and 3.7, respectively 0.9, in the 3.125 and 6.25 g a.s./ha rate. Because the reproductive performance was within the historical data base for control beetles (≥ 2 fertile eggs per viable female and day in the glass plate method) at 3.125 g a.s./ha, this parameter is considered as not impacted by this test item rate.

Conclusions:
The LR_{50} was calculated to be 10.222 g a.s./ha.

Report:	[redacted].,; [redacted]; 2011; M-419295-01-1
Title:	Toxicity to the green lacewing Chrysoperla carnea STEPH. (Neuroptera, Chrysopidae) using an extended laboratory test on maize Thiacloprid OD 240 g/L
Report No.:	CW11/060
Document No.:	M-419295-01-1
Guidelines:	**VOGT ET AL. (2000) modified: Use of natural substrate (maize leaves) instead of glass plate; CANDOLFI ET AL. (2001); For the duration of 36 h during the reproduction phase, the temperature was 22 - 25 °C (recommended range: 23 - 27 °C) and the relative humidity was 55 - 73% (recommended range: 60 - 90%). These minor deviations did not affect the results of the study as all validity criteria were met**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240 g/L; Sample description: FAR 01509-00; Specification no.: 102000021774 - 01; Batch ID: ECE5100633; density: 1.039 g/mL; Analysed content: 234.8 g a.s./L.

The test item was applied to detached maize leaves (*Zea mays*) at rates of 22.1, 39.3, 69.9, 124.3 and 221.0 g a.s./ha and the effects on the green lacewing *Chrysoperla carnea* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 24.0 g a.s./ha was included to indicate the relative susceptibility of the test organisms and the test system.
The preimaginal mortality of 40 larvae, 2 days old at study start (per test group), was assessed till the hatch of the imagines (up to 18 days). The fertility and fecundity of the surviving hatched adults were then evaluated over the period of one week.
The climatic test conditions during the study were 23.5 - 26.5 °C temperature and 63 - 74% relative humidity; for the duration of 36 h during the reproduction phase the temperature was 22 - 25 °C and the humidity 55 - 73%. The light / dark cycle was 16:8 h with a light intensity range of 1213 - 3254 Lux during the mortality phase and of 1707 - 2770 Lux during the reproduction phase of the study.

Findings:

At the test item rates of 22.1, 39.3 and 69.9 g a.s./ha, a corrected preimaginal mortality of 33.3%, 10.6% and 20.5% has been observed, respectively. At the highest rates of 124.3 and 221.0 g a.s./ha, a corrected preimaginal mortality of 46.2% and 84.6% was found.

Table CP 10.3.2.2- 3: Summary of the effects on mortality and reproduction for each treatment

Test item:		Thiacloprid OD 240 g/L				
Test organism:		*Chrysoperla carnea*				
Exposure on:		Detached maize leaves				
		Mortality [%]			Reproduction	
Treatment	g a.s./ha	Uncorr.	Corr.	P-Value(*)	Eggs per female and day	Fertility [hatching rate in%]
Control	0	2.5			32.3	87.3
Test item	22.1	35.0	33.3	0.001 sign.	33.6	87.5
Test item	39.3	12.8	10.6	0.095 n.sign.	29.5	85.0
Test item	69.9	22.5	20.5	0.014 sign.	36.0	85.7
Test item	124.3	47.5	46.2	<0.001 sign.	38.4	90.8
Test item	221.0	85.0	84.6	<0.001 sign.	n.a.	n.a.
Reference item	24.0	100.0	100.0		n.a.	n.a.
LR50: 144.8 g a.s./ha (calculated with Probit analysis)						
* Fisher`s Exact test, one-sided, p-values are adjusted according to Bonferroni-Holm						
n.a. not assessed; n.sign. not significant; sign. significant						

Conclusion:

The LR_{50} was calculated to be 144.8 g a.s./ha.

Report:	[redacted]j; [redacted]; 2012; M-436801-01-1
Title:	Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) using an extended laboratory test on maize - Thiacloprid OD 240 g/L - TCP OD 240 g/L
Report No.:	CW11/055
Document No.:	M-436801-01-1
Guidelines:	**EU Directive 91/414/EEC, Regulation (EC) No. 1107/2009, BLÜMEL ET AL. (2000) modified, CANDOLFI ET AL. (2001), US EPA OCSPP Not Applicable; not specified**
GLP/GEP:	**yes**

Materials and methods:

Test item: Thiacloprid OD 240 g/L; Sample description: TOX09597-09; Specification no.: 102000021774 - 01; batch ID: ECE7100937; density: 1.044 g/mL; Analysed content: 242.2 g a.s./L.

The test item was applied onto detached maize leaves (*Zea mays*) at rates of 2.0, 4.0, 7.0, 12.0 and 22.0 g a.s./ha and the effects on the predatory mite *Typhlodromus pyri* were compared to those of a deionised water treated control. A toxic reference (active substance, Dimethoate) applied at 20.0 g a.s./ha was included to indicate the relative susceptibility of the test organisms and the test system.

Mortality of 100 predatory mites, protonymphs at study start (10 replicates with 10 individuals per test group), was assessed 7, 10, 12 and 14 days after exposure by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed. Due to the known repellent effects of the test item, the mortality part of this study was performed in closed but actively ventilated cells (Munger cages). On day 7 after application the surviving mites were transferred on untreated open exposure units (glass plates) and the reproduction rate of surviving mites was then evaluated from day 7 until day 14 after treatment by counting the total number of offspring (eggs and larvae) produced.

The climatic test conditions during the study were 24.0 - 25.5 °C temperature and 62 - 81% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1790 - 2870 Lux.

Findings:

The mortality / escaping rate in the control group up to day 7 after treatment was 8.0%. The mean corrected mortality of the mites, and the mean reproduction rate of the surviving females exposed to the test item and the toxic reference is given below:

Table CP 10.3.2.2- 4: Results from the ext. laboratory test with *T. pyri*

Test item:		Thiacloprid OD 240 g/L					
Test organism:		*Typhlodromus pyri*					
Exposure on:		Detached maize leaves (day 0 to day 7 after application)					
		Mortality after 7 days [%]			Reproduction		
Treatment	g a.s./ha	Uncorr.	Corr.	P-Value(*)	Rate (eggs per female)	Red. rel. to Control [%]	P-Value(#)
Control	0	8.0			6.1		
Test item	2.0	34.0	28.3	<0.001 sign.	5.8	6.0	0.174 n.sign.
Test item	4.0	87.0	85.9	<0.001 sign.	n.a.	n.a.	
Test item	7.0	97.0	96.7	<0.001 sign.	n.a.	n.a.	
Test item	12.0	99.0	98.9	<0.001 sign.	n.a.	n.a.	
Test item	22.0	99.0	98.9	<0.001 sign.	n.a.	n.a.	
Reference item	20.0	98.0	97.8		n.a.	n.a.	

LR_{50}: : 2.49 g as/ha; 95% Confidence Interval: 0.62 - 3.89; calculated with Probit analysis
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
# Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed; n.sign. not significant; sign. significant

Conclusion:
In this extended laboratory test the effects of Thiacloprid OD 240 g/L residues on the survival of the predatory mite *Typhlodromus pyri* were determined at the rates of 2.0, 4.0, 7.0, 12.0 and 22.0 g a.s./ha applied to detached maize leaves (*Zea mays*).
At the test item rate of 2.0 g a.s./ha a corrected mortality of 28.3% has been observed. 85.9% and 96.7% corrected mortality, respectively, occurred in the 4.0 and 7.0 g a.s./ha rate. In the higher rates of 12.0 and 22.0 g a.s./ha the corrected mortality was 98.9% each.
The LR_{50} was calculated to be 2.49 g a.s./ha.
Reproduction was assessed only for the lowest rate of Thiacloprid OD 240 g/L, 2.0 g a.s./ha. The reproduction was reduced by 6.0%.
The figures obtained fulfil the validity criteria of the laboratory method for exposure on glass plates.

Report: [redacted]; 2012; M-442296-01-1
Title: Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DeStephani-Perez) (Hymenoptera: Braconidae) using an extended laboratory test with aged residues on maize - thiacloprid OD 240 g/L - final report
Report No.: CW12/015
Document No.: M-442296-01-1
Guidelines: **MEAD-BRIGGS ET AL. (2000), MEAD-BRIGGS ET AL. (2009), CANDOLFI ET AL. (2001), ; none**
GLP/GEP: **yes**

Material and methods:
Test item: Thiacloprid OD 240 g/L; Sample description: TOX 09597-00; Specification no.: 102000021774-01; batch ID: ECE7100937; Density: 1.044 g/mL; Analysed content: 242.2 g a.s./L.

The test item was applied three times on potted maize plants; at the first and second application it was applied with 96 g a.s./ha each in 400 L deionised water/ha and at the third application it was applied

with 110 g a.s./ha diluted in 400 L deionised water/ha. The application interval was 10 days between all applications. The control was treated with deionised water in the same way as the test item.
A toxic reference (active substance: Dimethoate) was applied at 3 g a.s./ha diluted in 400 L deionised water/ha on the third application day of the test item on potted maize plants as well. For the further exposure dates it was applied directly on detached maize leaves (with 3 g a.s./ha diluted in 400 L deionised water/ha). It was included to indicate the relative susceptibility of the test organisms and the test system.
Aging of the spray deposits of the test item on the potted maize plants took place under semi-field conditions with UV permeable rain protection during the first four weeks of the study. Three bioassays were performed, the first started on the day of the last application of the test item (0DAT3 = 0 days after treatment 3) and the last one four weeks later (28DAT3).
Parasitoid wasps (*Aphidius rhopalosiphi*) were exposed to these residues on the treated leaf surfaces. Mortality of 30 female wasps, not older than 48 h at study start (6 replicates with 5 wasps per test group), was assessed 2, 24 and 48 h after exposure in all bioassays.
Repellency of the test item was assessed during the initial 3 h after the release of the females. Five separate observations were made at 30-minute intervals starting 15 - 30 minutes after the introduction of all wasps.
The reproductive performance was assessed in the bioassays started on day 14 and 28 after the third application of the test item. For this 15 impartially chosen females from the water control and the test item group were each transferred to a cylinder containing untreated barley seedlings infested with *Rhopalosiphum padi* for a period of 24 h. The number of mummies was assessed 12 days later in the second bioassay and 11 days later in the third bioassay.

Findings:

Table CP 10.3.2.2- 5: Results from the ext. laboratory test with *A. rhopalosiphi*

Test item:	Thiacloprid OD 240 g/L		
Application:	2 x 96 g a.s./ha (1st and 2nd application) and 1 x 110 g a.s./ha (3rd application) with an interval of 10 days		
Test organism:	*Aphidius rhopalosiphi*		
Exposure on:	Dried spray deposits on maize leaves (from treated maize plants)		
Start bioassay:	0DAT3[a]	14DAT3[a]	28DAT3[a]
	Mortality (%) after 48 h		
Control:	0.0	0.0	0.0
Test item:	100.0	50.0	3.3
Reference item:	100.0	100.0	100.0
	Corrected Mortality (%)		
Test item:	100.0 (p-value < 0.001, significant[b])	50.0 (p-value < 0.001, significant[b])	3.3 (p-value 0.500 not significant[b])
Reference item:	100.0	100.0	100.0
	Repellency (mean values)		
	% Wasps on plant		
Control:	49.7	51.8	44.0
Test item:	54.5	31.8	43.3
Reference item:	67.3	43.3	41.0
	Reduction rel. to control (%)		
Test item	-9.7 (p-value 0.137, not significant[c])	38.6 (p-value 0.031, significant[c])	1.5 (p-value 0.478, not significant[c])
Reference item:	35.6	16.4	6.8
	Reproduction		
	Number of mummies per female		
Control:	n.a.	19.3	60.7
Test item:	n.a.	20.4	58.9
	Reduction rel. to control (%)		
Test item:	n.a.	-6.0 (p-value 0.366, not significant[d])	2.9 (p-value 0.500, not significant[d])

n.a. = not assessed; a DAT = days after treatment; b Fisher´s Exact test (one-sided); c one-way ANOVA, Williams test (one-sided); d Wilcoxon test (one-sided)

Conclusion:

In this extended laboratory test the effects of Thiacloprid OD 240 g/L residues (aged under semi-field conditions, with rain protection during the first four weeks) on the parasitoid wasp *Aphidius rhopalosiph*i were determined after three applications onto maize plants (*Zea mays*). The first two applications were done with 96 g a.s./ha and the third application with 110 g a.s./ha with an application interval of 10 days.

In this study a corrected mortality of 100% of the test item was found in the first bioassay started at the day of the third application. A second bioassay was started 14 days after the last application and showed 50% corrected mortality in the test item group after 48 h of exposure. In a third bioassay (day 28), the corrected mortality decreased to 3.3%.

No repellent effect of the test item (settling of the wasps on plants <30%) was observed in all bioassays.

In the second bioassay there was no reduction in reproductive success relative to the control (-6.0%). In the third bioassay a reduction of only 2.9% was detected.

The figures obtained fulfil the validity criteria of the extended laboratory method (Mead-Briggs et al., 2009).

Report:	[redacted]; [redacted]; 2013; M-446545-01-1
Title:	Toxicity to the ladybird beetle Coccinella septempunctata (Coleoptera, Coccinellidae) using an extended laboratory test with aged residues on maize - Thiacloprid OD 240 g/L
Report No.:	CW12/016
Document No.:	M-446545-01-1
Guidelines:	**SCHMUCK ET AL. (2000) modified: Use of treated maize plants, ladybird beetle larvae were exposed to freshly applied and under semi-field conditions aged residues on detached leaves.** **CANDOLFI ET AL. (2001); none**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240 g/L; Sample description: TOX 09597-00; Specification no.: 102000021774-01; Batch ID: ECE7100937; Density: 1.044 g/mL; Analysed content: 242.2 g a.s./L.

The test item was applied three times on potted maize plants; at the first and second application it was applied with 96 g a.s./ha each in 400 L deionised water/ha and at the third application it was applied with 110 g a.s./ha diluted in 400 L deionised water/ha. The application interval was 10 days between each application. The control was treated with deionised water in the same way as the test item.
A toxic reference (active substance: Dimethoate) was applied at 10 g a.s./ha diluted in 400 L deionised water/ha on the third application day of the test item on potted maize plants as well. For the second, third and fourth bioassay, the toxic reference was applied directly on detached maize leaves (with 10 g a.s./ha diluted in 200 L deionised water/ha). It was included to indicate the relative susceptibility of the test organisms and the test system.
Aging of the spray deposits of the test item on the potted maize plants took place under semi-field conditions with UV permeable rain protection during the first four weeks of the study. Four bioassays were performed, the first started on the day of the last application of the test item (0DAT3 = 0 days after treatment 3) and the last one six weeks later (42DAT3).
Larvae of the ladybird beetle (*Coccinella septempunctata*) were exposed to these residues on the treated leaf surfaces and the preimaginal mortality was assessed. In the second, third and fourth bioassay the fertility and fecundity of the surviving hatched adults were evaluated as well.

Findings:

Table CP 10.3.2.2- 6: Results from the ext. laboratory test with *C. septempunctata*

Test item:	Thiacloprid OD 240 g/L			
Application:	**2 x 96 g a.s./ha (1st and 2nd application) and 1 x 110 g a.s./ha (3rd application) with an interval of 10 days**			
Test organism:	***Coccinella septempunctata***			
Exposure on:	**Dried spray deposits on maize leaves (from treated maize plants)**			
Start bioassay:	**0DAT3[a]**	**14DAT3[a]**	**28DAT3[a]**	**42DAT3[a]**
	Preimaginal mortality (%)			
Control:	0.0	35.0 [c]	38.5 [c]	17.5
Test item:	100.0	35.0	22.5	7.5
Reference item:	100.0	100.0	100.0	100.0
	Corrected preimaginal mortality (%)			
Test item:	100.0 (all larvae were dead after 2 days of exposure)	0.0 (p-value 0.593, not significant[b])	25.9 (p-value 0.964, not significant[b])	12.1 (p-value 0.956, not significant[b])
Reference item:	100.0	100.0	100.0	100.0
	Reproduction			
	Fertile eggs per female and day			
Control:	n.a.	15.0	13.9	14.3
Test item:	n.a.	11.6	17.6	9.7

n.a. = not assessed
a DAT = days after treatment
b Fisher´s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
c Control mortality exceeded 30% (validity criteria from the glass plate laboratory test guideline)

Conclusion:

In this extended laboratory study the effects of Thiacloprid OD 240 g/L residues (aged under semi-field conditions, with rain protection during the first four weeks) on the ladybird beetle *Coccinella septempunctata* were determined after three applications onto maize plants (*Zea mays*). The first two applications were done with 96 g a.s./ha and the third application with 110 g a.s./ha with an application interval of 10 days.

In this study a corrected mortality of 100 % of the test item was found in the first bioassay started at the day of the third application. A second bioassay was started 14 days after the last application and showed no corrected mortality in the test item group. In a third bioassay (after 28 days) and fourth bioassay (after 42 days) no mortality was found as well.

Reproduction was assessed in the second, third and fourth bioassay. Since the reproductive performance in all bioassays was within the range of the historical data base for control beetles (≥ 2 fertile eggs per female and day, Schmuck et al. 2000) this parameter is considered as not affected.

Report:	[redacted]t;[redacted]; 2013; M-446548-01-1
Title:	Toxicity to the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) using an extended laboratory test with aged residues on maize Thiacloprid OD 240 g/L
Report No.:	CW12/017
Document No.:	M-446548-01-1
Guidelines:	**BLÜMEL ET AL. (2000) modified: Use of treated maize plants; mites exposed to freshly applied and under semi-field conditions aged residues on detached leaves in Munger cages for the mortality assessment; CANDOLFI ET AL. (2001); During the mortality phase in the third bioassay the temperature increased for the duration of 3 hours to 27.2 °C. This had no negative impact on the study results as all validity criteria were met.**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240 g/L; Sample description: TOX 09597-00; Specification no.: 102000021774-01; Batch ID: ECE7100937; Density: 1.044 g/mL; Analysed content: 242.2 g a.s./L.

The test item was applied three times on potted maize plants; at the first and second application it was applied with 96 g a.s./ha each in 400 L deionised water/ha and at the third application it was applied with 110 g a.s./ha diluted in 400 L deionised water/ha. The application interval was 10 days between each application. The control was treated with deionised water in the same way as the test item.
A toxic reference (active substance: Dimethoate) was applied at 15 g a.s./ha diluted in 400 L deionised water/ha on the third application day of the test item on potted maize plants as well. For the second and third bioassay, the toxic reference was applied directly on detached maize leaves (with 20 g a.s./ha diluted in 200 L deionised water/ha). It was included to indicate the relative susceptibility of the test organisms and the test system.
Aging of the spray deposits of the test item on the potted maize plants took place under semi-field conditions with UV permeable rain protection during the first four weeks of the study. Three bioassays were performed, the first started on the day of the last application of the test item (0DAT3 = 0 days after treatment 3) and the last one four weeks later (28DAT3).
Predatory mites (*Typhlodromus pyri*) were exposed to these residues on the treated leaf surfaces. Mortality of 100 predatory mites, protonymphs at study start (10 replicates with 10 individuals per test group), was assessed 7 days in all bioassays and 10, 12 and 14 days after exposure in the second and third bioassay by counting the number of living and dead mites. The number of escaped mites was calculated as the difference from the total number exposed.
Due to the known repellent effects of the test item, the mortality part of the bioassays was performed in closed but actively ventilated cells (Munger cages). On day 7 after application (in the second and third bioassay) the surviving mites were transferred on untreated open exposure units (glass plates) and the reproduction rate of surviving mites was then evaluated from day 7 until day 14 after treatment by counting the total number of offspring (eggs and larvae) produced.
From these data the endpoints mortality (after 7 days) and effects on reproduction were calculated and summarised below.

Findings:

Table CP 10.3.2.2- 7: Results from the ext. laboratory test with *T. pyri*

Test item:	**Thiacloprid OD 240 g/L**		
Application:	**2 x 96 g a.s./ha (1st and 2nd application) and 1 x 110 g a.s./ha (3rd application) with an interval of 10 days**		
Test organism:	***Typhlodromus pyri***		
Exposure on:	**Dried spray deposits on maize leaves (from treated maize plants)**		
Start bioassay:	**0DAT3[a]**	**14DAT3[a]**	**28DAT3[a]**
	Mortality (%) after 7 days		
Control:	11.0	10.0	10.0
Test item:	86.0	17.0	8.0
Reference item:	55.0	86.0	91.0
	Corrected Mortality (%)		
Test item:	84.3 (p-value < 0.001, significant[b])	7.8 (p-value 0.107, not significant[b])	-2.2 (p-value 0.770, not significant[b])
Reference item:	49.4[c]	84.4	90.0
	Reproduction		
	Number of eggs per female		
Control:	n.a.	7.2	6.3
Test item:	n.a.	6.8	6.6
	Reduction rel. to control (%)		
Test item:	n.a.	5.8 (p-value 0.323, not significant[d])	-4.7 (p-value 0.124, not significant[e])

n.a. = not assessed
a DAT = days after treatment
b Fisher´s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
c Corrected mortality of reference item was below 50% (validity criterion from the glass plate laboratory test guideline)
d Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm
e one-way ANOVA, Williams test, one-sided

Conclusion:

In this extended laboratory study the effects of Thiacloprid OD 240 g/L residues (aged under semi-field conditions, with rain protection during the first four weeks) on the survival of the predatory mite *Typhlodromus pyri* were determined after three applications onto maize plants (*Zea mays*). The first two applications were done with 96 g a.s./ha and the third application with 110 g a.s./ha with an application interval of 10 days.

In this study a corrected mortality of 84.3% of the test item was found in the first bioassay started at the day of the third application. A second bioassay was started 14 days after the last application and showed a corrected mortality of 7.8% in the test item group. In a third bioassay (28 days after the last application) no corrected mortality (-2.2%) was found any more.

Reproduction was assessed in the second and third bioassay. In the second bioassay there was a reduction in reproductive success relative to the control of 5.8% and in the third no reduction (-4.7%) occurred at all.

Supplemental information from the literature

In addition to the studies performed by BCS in accordance with the requirement a literature search has been performed in accordance with the requirements. From the papers identified during the literature search the following were identified as being potentially relevant for risk assessment. After further evaluation the literature data is considered to provide supplemental information and does not influence the risk assessment.

Report:	[redacted]; 2009; M-465486-01-1
Title:	Effect of seven new orchard pesticides on Galendromus occidentalis in laboratory studies
Report No.:	M-465486-01-1
Document No.:	M-465486-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

The aim of this study was to test the toxicity of seven pesticides to the predatory mite *Galendromus occidentalis*. The pesticides were tested at a single rate of application corresponding to their recommended label rate (and multiples thereof). The toxicity of these compounds to eggs and adults of *G. occidentalis* by residual contact was investigated. The effects on eggs were recorded after 144 h, mortality and fecundity of adults was recorded 24, 48 and 72 after treatment. Furthermore, the repellence of the products was investigated. In the following, the results for the formulation containing the active substance thiacloprid are summarised. Results showed a corrected mortality of eggs of *G. occidentalis* treated with 0.160 g thiacloprid/L of 5.8%. The mortality of adults at the highest concentration used (0.640 g a.s./L) was 5.8%. There was a statistically significant effect on fecundity of females treated with 0.160 g thiacloprid after 48 h, no statistically significant effect was found after 24 and 72 h. Furthermore, thiacloprid had a statistically significant repellent effect after 48 and 72 h.

Material and methods:

A. Material

1. Test material	
Test item:	Calypso 480 SC
Active substance(s):	Thiacloprid
Source of test item:	Bayer CropScience, Calgary, Alberta
Lot/Batch number:	Not reported
Purity:	Not reported
Storage conditions:	Not reported
2. Test solutions	
Vehicle/solvent:	Not reported
3. Test organism(s)	
Species:	*Galendromus occidentalis*
Source of test species:	Reared in the laboratory, originally collected in orchards wit integrated pest management the Okanagan Valley, British Columbia, Canada.
Age of test organisms at study initiation:	Eggs, 24-h-old adults
Holding conditions prior to test:	65% relative humidity, 27 °C and 16:8h light : dark photoperiod, feeding with *Tetranychus urticae*

B. Study design and methods

1. Test procedure	
Test system (study type):	Laboratory study
Duration of study:	144 h (eggs), 72 h (adults)
Test concentrations	Eggs: water control, 0.160 g a.s./L (600 L/ha) [96 g a.s./ha] Adults: water control, 0.160, 0.320, 0.640 g a.s./L (600 L/ha) [control, 96, 192, 384 g a.s./ha] Reproduction & repellence assessment: water control, 0.1333 g a.s./L (600 L/ha) [80 g a.s./ha]
Number of replicates:	3
Individuals per replicate:	32.2 ± 1.4 (mean, eggs), 52 (adults)
Test units (type and size):	Petri dishes (14.5 cm in diameter) containing leaf discs
Application:	Spraying with a thin-layer chromatography sprayer set at 10.34 kPa
2. Environmental conditions	
Temperature / relative humidity:	24 °C, 70%
Photoperiod:	16 : 8 h light : dark
3. Observations and measurements:	
Analytical parameters measured:	None
Biological parameters measured:	Corrected (Henderson and Tilton) egg and adult mortality, repellence
Measurement frequency:	Eggs: 144 h after exposure, adults: 24, 48 and 72 h after exposure
Statistical analyses:	Percentage mortality estimated according to Henderson and Tilton, ANOVA, Tukey-Kramer test

Results:

Validity criteria:

No validity criteria were stated in this report.

Biological findings:

Thiacloprid (applied at 0.160 g a.s./L) caused a corrected mortality of eggs of 1.9%. Average mortality of eggs in the control was 0.7% (± 0.5). The corrected mortality (Henderson and Tilton) of adults treated with 0.160, 0.320 and 0.640 g a.s./L was 2.8, 2.3 and 5.8%, respectively. For the control it was 5.8% (± 3.4). The average number of eggs per female per day treated at a rate of 0.1333 g a.s./L recorded 24 h, 48 h and 72 h after exposure was 1.64, 1.26 and 1.58 per day, respectively. For the control the numbers were 2.11, 2.15 and 2.23 eggs per female per day 24 h, 48 h and 72 h after

exposure, respectively. Statistical analysis (ANOVA and Tukey-Kramer test, $\alpha = 0.05$) revealed statistically significant differences between treatment and control for the measurement only after 48 h. Repellence of thiacloprid, expressed as the percentage of individuals outside the treated leaf discs, was 12.2, 44.9 and 49.4% after 24, 48 and 72 hours after exposure, respectively. For the control the numbers were 3.6, 5.8 and 16.1% 24 h, 48 h and 72 h after exposure, respectively. There was a statistically significant difference (ANOVA and Tukey-Kramer test, $\alpha = 0.05$) between the control and treatment for the measurements after 48 and 72 h.

Conclusion

The corrected mortality of eggs of *Galendromus occidentalis* treated with 0.160 g thiacloprid/L was 1.9%. The mortality of adults at the highest concentration used (0.640 g a.s./L) was 5.8%. There was a statistically significant effect on fecundity of females treated with 0.1333 g a.s./L thiacloprid after 48 h. Furthermore, thiacloprid had at 0.1333 g a.s./L a statistically significant repellent effect after 48 and 72 h.

Comment by the notifier:

The study results indicate that thiacloprid caused under extended laboratory conditions a low mortality of the predatory mite *Galendromus occidentalis* at application rates up to 384 g a.s./ha. Effects on reproduction at 80 g a.s./ha were in the range of 22-41%. Since the predatory mite *T. pyri*, indicated a significant higher sensitivity under extended laboratory conditions, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]; [redacted]; [redacted]; [redacted]; [redacted]; 2010; M-464112-01-1
Title:	Effects of six selected orchard insecticides on Neoseiulus fallacis (Acari: Phytoseiidae) in the laboratory
Report No.:	M-464112-01-1
Document No.:	M-464112-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

The aim of this study was to test the toxicity of six insecticides to the predatory mite *Neoseiulus fallacis*. The pesticides were tested at a single rate of application corresponding to their maximum recommended label rate. The toxicity of these compounds to eggs and adults of *N. fallacis* by residual contact was investigated. The effects on eggs were recorded after 120 h, mortality and fecundity of adults was recorded 24, 48, 72 and 96 h after treatment. In the following, the results for the formulation containing the active substance thiacloprid are summarised. Results showed a corrected mortality of eggs of *Neoseiulus fallacis* treated with 0.178 g thiacloprid/L of 3.4%. The mortality of adults at the highest concentration used (5.696 g/L) was 33.8%. There was a statistically significant effect on the fecundity of females exposed to 0.178 g/L thiacloprid.

Material and methods:

A. Material

1. Test material	
Test item:	Calypso 480 SC
Active substance(s):	Thiacloprid
Source of test item:	Bayer CropScience, Calgary, Alberta
Lot/Batch number:	Not reported
Purity:	Not reported
Storage conditions:	Not reported
2. Test solutions	
Vehicle/solvent:	None
3. Test organism(s)	
Species:	*Neoseiulus fallacis*
Source of test species:	Reared in the laboratory, originally collected in a research orchard in Frelighsburg, Quebec, Canada.
Age of test organisms at study initiation:	Eggs, 48-h-old adults
Holding conditions prior to test:	Climatic conditions not specified, feeding with *Tetranychus urticae*

B. Study design and methods

1. Test procedure	
Test system (study type):	Laboratory study
Duration of study:	120 h (eggs), 96 h (adults)
Test concentrations	Eggs: (tap) water control, 0.178 g a.s./L [96 g a.s./ha] Adults: (tap) water control, 0.178, 0.356, 0.712, 1.424, 2.848 and 5.696 g a.s./L at 540 L/ha [0.178 g a.s./L => 96 g a.s./ha; 5.696 g a.s./L => 3075 g a.s./ha]
Number of replicates:	3
Individuals per replicate:	41 (eggs), 52 (adults)
Test units (type and size):	Petri dishes (14.5 cm in diameter) containing apple leaf discs (20 mm)
Application:	Spraying with a thin-layer chromatography sprayer set at 10.34 kPa, the amount of residue of the insecticide suspension throughout the disc was 0.002 mL/cm^2
2. Environmental conditions	
Temperature / relative humidity:	21 °C, 82%
Photoperiod:	16 : 8 h light : dark
3. Observations and measurements:	
Analytical parameters measured:	None
Biological parameters measured:	Corrected (Henderson and Tilton) egg and adult mortality
Measurement frequency:	Eggs: 120 h after exposure, adults: 24, 48, 72 and 96 hours after exposure
Statistical analyses:	ANOVA, Tukey-Kramer test

Results:

Validity criteria:

No validity criteria were stated in this report.

Biological findings:

Thiacloprid (applied at 0.178 g a.s./L) caused a corrected mortality of eggs of 3.4%. Average mortality of eggs in the control was stated as 0.9 ± 0.6.

The corrected mortality of adults treated with 0.178, 0.356, 0.712, 1.424, 2.848 and 5.696 g a.s./L thiacloprid was 2.2, 6.6, 11.0, 20.6, 32.4, and 33.8%. The control mortality was 5.6%. The LC_{50} value could not be estimated.

The number average number of eggs of female treated at a rate of 0.178 g a.s./L was 0.48, 0.42, 1.15 and 1.17 as recorded 24 h, 48 h, 72 h and 96 h after exposure, respectively. For the control the

numbers were 1.80, 2.01, 2.57 and 2.50 eggs per female per day 24 h, 48 h, 72 h and 96 h after exposure, respectively. Statistical analysis (ANOVA and Tukey-Kramer test, α = 0.05) revealed statistically significant differences between treatment and control for each point of measurement.

Comment by the notifier:

The study results indicate that thiacloprid caused under extended laboratory conditions a low mortality of the predatory mite *Neoseiulus fallacis* at application rates up to 3075 g a.s./ha. Effects on reproduction at 96 g a.s./ha were in the range of 53-79%. Since the predatory mite *T. pyri*, indicated a significant higher sensitivity under extended laboratory conditions, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	KCP 10.3.2.2/10 [redacted]; [redacted]; [redacted]; [redacted]; [redacted]; 2012; M-465941-01-1
Title:	The response of Neoseiulus fallacis (Garman) and Galendromus occidentalis (Nesbitt) (Acari: Phytoseiidae) to six reduced risk insecticides in Canada
Report No.:	M-465941-01-1
Document No.:	M-465941-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary

This study reports the impact of insecticides to the two closely related predators *Galendromus occidentalis* and *Neoseiulus fallacis*. Material and methods as well as results are summarised for thiacloprid treatment only.
Treatment was made with a thin-layer chromatography sprayer set at 10.34 kPa (1.5 psi). The chemicals were applied to *N. fallacis*, *G. occidentalis*, the prey, *Tetranychus urticae* (Koch) and the leaf discs. Test substance was Calypso® 480 SC.
A 48-h-old adult female predatory mite was placed on the abaxial side of an apple leaf disc (20mm). Each treatment contained 52 discs replicated three times for a total of 156 predators per concentration. Following treatment, the survival of adults and the number of eggs laid were recorded at 72 h post treatment. Specimens were considered dead when they were unable to move a distance of 1 mm when probed with a camel-hair brush.
Adult mortality data were corrected according to Henderson and Tilton.
Average adult female *Galendromus occidentalis* mortality in the laboratory at 0.160 g a.s./L was 2.8%. The average adult female *Neoseiulus fallacis* mortality at 0.178 g a.s./L was 2.2%. Reduction in egg production compared to control was 27% for *Galendromus occidentalis* (0.133 g a.s./L) and 54% for *Neoseiulus fallacis* (0.178 g a.s./L).

Material and methods:

A. Material

1. Test material

Test item:	Calypso® 480 SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	-
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Galendromus occidentalis* and *Neoseiulus fallacis*
Cultivar:	-
Source of test species:	-
Age of test organisms at study initiation:	48 h old adult female
Crop growth stage at treatment:	
Holding conditions prior to test:	-
Acclimatisation:	-

B. Study design and methods

1. Test procedure

Test system (study type):	Acute toxicity test
Duration of study:	72 h
Treatments:	Thiacloprid and control
Test concentrations:	0.16, 0.133 and 0.178 g a.s./L (540 L/ha) [86 g a.s./ha, 72 g a.s./ha and 96 g a.s./ha]
Number of replicates:	3 replicates
Individuals per replicate:	52 per treatment
Test units (type and size):	Apple leaf disc (20 mm)
Application / device / nozzles:	Thin-layer chromatography sprayer (10.34 kPa, 1.5 psi)
Water volume:	
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Apple leaf disc
Temperature / relative humidity:	-
Photoperiod:	-
Lighting:	-
Fertilization:	

3. Observations and measurements

Analytical parameters measured:	-
Biological parameters measured:	Mortality and number of eggs
Measurement frequency:	72 h post treatment
Statistical analyses:	Henderson and Tilton

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Average adult female *Galendromus occidentalis* mortality in the laboratory at 0.160 g a.s./L was 2.8%. The average adult female *Neoseiulus fallacis* mortality at 0.178 g a.s./L was 2.2%. Reduction in egg production compared to control was 27% for *Galendromus occidentalis* (0.133 g a.s./L) and 54% for *Neoseiulus fallacis* (0.178 g a.s./L).

Comment by the notifier:

The study results indicate that thiacloprid caused under extended laboratory conditions a low mortality of the predatory mites *Galendromus occidentalis* and *Neoseiulus fallacis* at application rates of 86 and 96 g a.s./ha, respectively. Effects on reproduction of *Galendromus occidentalis* were 27% at 72 g a.s./ha and of *Neoseiulus fallacis* were 54% at 96 g a.s./ha. Since the predatory mite *T. pyri* indicated a significant higher sensitivity under extended laboratory conditions, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	KCP 10.3.2.2/11 [redacted]; [redacted]; 2012; M-468106-01-1
Title:	Susceptibility of the European earwig, Forficula auricularia, to insecticide residues on apple leaves
Report No.:	M-468106-01-1
Document No.:	M-468106-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

This paper presents results from a laboratory bioassay to determine the residual effects of registered IFP insecticides and a new candidate insecticide (spirotetramat) on European earwigs. Material and methods as well as results are summarised for thiacloprid treatments only.
Thiacloprid (Calypso® 480SC) and water as a control treatment were sprayed at 14.4 g a.s./100 L onto well separated, tagged apple shoots on previously unsprayed apple trees in the field. Treatments were applied on 18-19 January 2010 (with separate water controls on each day) with a small hand pump pressure sprayer (Yates Plassay® Maxi 2) to achieve an even fine spray cover to the point of run-off (water rate equivalent to ~ 2000 litres/ha). After drying, the stems of three individual leaves were inserted directly into moistened floral foam, which was then placed inside a ventilated clear plastic container (100 mm high x 100 mm diameter). This procedure was repeated for five replicates.
Six adult earwigs, collected previously from an unsprayed abandoned orchard, were placed onto treated leaves in each plastic container. The earwigs maintained prolonged contact with the leaves as they provided sheltering sites for the earwigs in the containers. No food was provided in the containers.
Earwigs in the containers were kept in the laboratory and exposed to natural light during the trial (light:dark of ~15:9 h). Temperature during the experiment was maintained at 20°C. Earwigs were assessed for mortality and sublethal effects on four occasions at 1, 3, 7 and 10 days after treatment (DAT). The floral foam was moistened with distilled water during these examinations. In the analysis, dead or moribund individuals were combined together and affected individuals are presented separately.

Sublethal (i.e. 'affected') and mortality data from each assessment time were analysed separately using generalised linear modelling. Results were compared with the control following the Schneider-orelli method[5].
Thiacloprid affected earwigs and caused increased mortality at an exposure rate of 288 g a.s./ha. Almost all (>90%) of the affected earwigs had died by the end of the experiment. Sublethal symptoms of affected earwigs were observed already after 1 day of exposure to residues.

Material and methods:

A. Material

1. Test material

Test item:	Calypso® 50 WG
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	-
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Forficula auricularia*
Cultivar:	-
Source of test species:	unsprayed abandoned orchard
Age of test organisms at study initiation / Crop growth stage at treatment:	-
Holding conditions prior to test:	-
Acclimatisation:	-

[5] Püntener W 1981. Manual for field trials in plant protection, second edition. Agricultural Division, Ciba-Geigy Limited, Basle, Switzerland.

B. Study design and methods

1. Test procedure

Test system (study type):	Residue Contact bioassay
Duration of study:	10 days
Treatments:	Thiacloprid and control (water)
Test concentrations	14.4 g a.s./100 L (2000 L/ha => 288 g a.s./ha]
Number of replicates:	5 replicates
Individuals per replicate:	6 per treatment
Test units (type and size):	Apple shoots in plastic container (100 mm high × 100 mm diameter)
Application / device / nozzles:	Hand pump pressure sprayer
Water volume:	2000 L/ha
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Apple shoots
Temperature / relative humidity:	20°C
Photoperiod:	15:9 h
Lighting	Natural light

3. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured:	Alive, affected, moribund or dead
Measurement frequency:	1, 3, 7 and 10 days after treatment
Statistical analyses:	Generalised linear modelling and Schneider-Orelli method

Results:

Validity criteria:
No validity criteria were stated.

Biological findings:
Thiacloprid affected earwigs and caused increased mortality at an exposure rate of 288 g a.s./ha. Almost all (>90%) of the affected earwigs had died by the end of the experiment. Sublethal symptoms of affected earwigs were observed already after 1 day of exposure to residues.

Comment by the notifier:

The study results indicate that thiacloprid caused under extended laboratory conditions at 288 g a.s./ha clear mortality of the European earwig *Forficula auricularia*. Since other tested non-target arthropods that were tested for the regulatory data package indicated a significant higher sensitivity under extended laboratory conditions, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report: KCP 10.3.2.2/12 [redacted]; 2013; M-468296-01-1
Title: Toxicity of two neonicotinoid insecticides via the food chain for larvae of the two spot ladybird Adalia bipunctata.
Report No.: M-468296-01-1
Document No.: M-468296-01-1
Guidelines: **not applicable; not applicable**
GLP/GEP: **no**

Executive summary:

The toxicity by ingestion of aphids (Hemiptera: Aphididae) contaminated by 2 insecticides including thiacloprid (Calypso) was laboratory assessed for larval two-spot ladybirds *Adalia bipunctata* Linnaeus (Coleoptera: Coccinellidae). Material and methods as well as results are summarised for thiacloprid only. Adult *A. bipunctata* were reared in groups of 15-20 in plastic cages, fed with honey-bee pollen and aphid *Acyrthosiphon pisum* Harris and *Myzus persicae* (Sulzer) harvested from French beans (Fabales: Fabaeae; *Vicia faba* L.) and sweet pepper (Solanales: Solanaceae: *Capsicum annuum* L.) respectively. Synchronised patches of eggs laid on crumpled paper were removed daily. For each experiment, 4 x 10 larvae of *A. bipunctata* were used per product and for control. Three experimental contamination of aphids methods were used. Drinking water was used for the control groups. Calypso was used at 0.25 L/ha (120 g a.s./ha thiacloprid). Toxicity was assessed using 2-3 days old *A. bipunctata* larvae isolated in exposure units of glass plate surrounded by plastic cylinder (height 3 cm, diameter 5 cm) treated with Fluon GPI to prevent escape. Larvae were fed contaminated (or control) aphids until pupation, then pupae isolated in plastic petri dishes and adult emergence recorded. Firstly, in treatment (a) direct spray, aphids in petri dishes were directly treated using a Burgerjon Spray-Tower apparatus at 200 l ± 10% spray mixture, before dried for 1-2 h and part used to feed *A. bipunctata* larvae. Remainder were kept 2-8°C to for 1-2 days. Treatment was repeated every 2-3 days to maintain stock of freshly treated aphids. Secondly in (b) spray on plants, French beans infested with aphids were treated outside using a knapsack 'boom' sprayer connected to a sprayer ramp with Azo 110 flat-fan nozzles at a rate of 400 L spray mixture/ha ± 10%. Plants were left to dry for 1-2 h before aphids were harvested to feed *A. bipunctata* larvae, or kept at 2-8°C to for 1 or 2 days. Again, treatment was repeated every 2-3 days. Thirdly (c) irrigation, aphids were confined to French beans treated by irrigation at 5 different test concentrations. This experiment used 5 containers of 50 x 35 cm plastic trays with 75 bean seeds in vermiculite per concentration and 5 controls. Trays were pierced with holes, and put in larger water filled trays to humidify the substrate. Water was initially added *ad lib* to start germination during first 6 days, then excess water removed and substrate left drying 24 h to then promote absorption of the insecticide added to outer plastic trays in one litre of water. After 24 h, 600 mg aphids were added to each and kept at 20 ± 2°C. After 7 days, aphids were collected and weighted. Aphids used to feed ladybird larvae were produced with same procedure, and new rearing containers were produced every 2-3 days for continuous stock of aphids.
Aphid population growth was reduced by 50%, 75% and 90% compared to the control within one week by adding 3 µL, 12 µL and 25 µL of Calypso (volumes determined by preliminary dose-range trials) to one plant rearing container. Any pupal mortality was combined with larval mortality, and time required to reach adulthood calculated. For each experiment/test conditions, emerged adults of *A. bipunctata* from the same treatment were pooled in rearing cages at least one week after the first egg laying. Then mature female were isolated in plastic petri dishes with aphids as food and transferred every 24 h to new petri dishes. Emergence per day of eggs and numbers laid per day were assessed over 6 successive 24 h periods. Adults were fed untreated food (aphids) only during the pre-fertility and fertility phase. Mean development time was calculated for each replicate. Fertility was assessed on all living adult female ladybirds. Percentages were arcsin transformed, and observed mortalities calculated on the basis living larvae and pupae found, and corrected according to Abott formula.
High mortality of *A. bipunctata* was observed reaching 100% after 4 days of feeding with thiacloprid sprayed aphids (a). Feeding aphids from thiacloprid sprayed plants (b) resulted in 5.5% corrected mortality which was not statistically significant different from the control treatment and no effect on fertility performance was observed. Development time (until adult emergence) was near identical and not statistically significantly different. Fertility (of emerged adults) was also not significantly affected,

neither eggs/female/day nor number of viable eggs. In treatment with irrigation (c), again *A. bipunctata* mortality and fertility was not statistically significantly different compared to the control.

Material and methods:

A. Material

1. Test material

Test item:	Calypso, 480 g/L SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	Bayer
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test area:

Location:	
Field history:	
Pesticides used on fields:	-

3. Test organism(s):

Species:	*Adalia bipunctata* L. (Coleoptera: Coccinellidae).
Cultivar:	
Source of test species:	Laboratory rearing
Age of test organisms at study initiation:	
Crop growth stage at treatment:	2-3 day old larvae
Holding conditions prior to test:	-
Acclimatisation:	-
Host:	*Acyrthosiphon pisum* Harris and *Myzus persicae* (Sulzer) raised on French beans (*Vicia fabae* L.) and sweet pepper (*Capsicum annuum* L.) respectively

B. Study design and methods

1. Test procedure

Test system (study type):	(a) Direct spray on aphid prey; (b) Spray on plants/aphid prey; (c) Plants uptake through Irrigation then prey feeding
Duration of study:	Rearing 18-23 days, breeding ca. 25 days [inferred].
Treatments:	Thiacloprid, control (drinking water)
Application rate:	(a) 120 g a.s./ha (200 L spray mixture/ha); (b) 120 g a.s./ha (400 L spray mixture/ha) (c) thiacloprid was applied via the irrigation water (1 L with 3, 12, 25 µL Calypso/plant rearing container)
Number of replicates:	(a-c) 4 x 10 larvae per product and control (c) 5 planted containers per test concentration and 5 controls, for each of 5* test concentrations (*NB: results of only 3 test concentrations given)
Individuals per replicate:	1 larva
Test conditions:	-
Plot size:	-
Application / device / nozzles:	(a) Burgerjon spray tower; (b) Boom sprayer / Azo 110 flat-fan nozzles (c) 50 x 35 cm trays with 75 seeds in vermiculite placed in larger water-filled trays (with varying concentration of treatment or untreated water as control)
Water volume:	(a) 200 L/ha; (b) 400 L/ha; (c) 1 L
Verification of dispersion:	-
Sampling technique:	-
Sampling frequency:	-
Transport/storage of samples:	-
2. Environmental conditions	
Test medium:	*Treatment:* 'Exposure units' of glass plate surrounded by plastic cylinder (height 3cm, diameter 5cm) treated with Fluon GPI to prevent escape. Pupae were isolated in petri-dishes. *Rearing:* Plastic cages in groups of 15-20 fed with honeybee pollen and aphids offered on cut plants.
Temperature / relative humidity:	(c) 20 ± 2°C. *Rearing:* Controlled chamber at 20 ± 2°C/ 60-90% RH
Photoperiod:	*Rearing:* 16 h : 8 h (L:D)
Lighting	*Rearing:* 7-10,000 lux
3. Observations and measurements:	
Conditional (e.g. weather) parameters:	-
Biological parameters measured:	Larval survival, development time and adult fertility
Measurement frequency:	-
Statistical analyses:	One-way ANOVA with Tukey test for pairs comparison. Arcsin transformation; (c) Linear regression

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.2- 8: Effects of ingestion of aphids contaminated by thiacloprid on *A. bipunctata*. Survival rate, development time to reach adult stage, total and viable egg production by female and number of females assessed (n).

	Mortality (%)		Development time (days) ± sd	Fertility		
	Observed ± sd	Corr-ected[2]		Egg/female/day ±sd	Viable eggs/female/day ± sd	Number of females assessed (n)
Aphids contaminated by direct spray (method a)						
Control	10.0% ± 8.2%	-	21.2 +0.5			
Thiacloprid	100.0% ± 7.5%	100.0%	-	-	-	-
Aphids harvested on sprayed plants (method b)						
Control	17.5% ± 5.0%[a]	-	20.9% ± 0.8%[a]	27.6% ± 6.5%[a]	13.5%[a] ± 6.8%[a]	14
Thiacloprid	22.5% ± 12.6%[a]	5.5%	20.9% ± 0.4%[a]	26.9% ± 7.2%[a]	17.0% ± 8.4%[a]	11

ANOVA (one-way) and Tukey test (P=0.05). Numbers followed by the same letter are not different in a significant way.

Table CP 10.3.2.2- 9: Toxicity of thiacloprid for larvae of *A. bipunctata* by ingestion of aphids reared on plants treated by irrigation (method c). Survival rate, development time to reach adult stage, total and viable egg production by female and number of females assessed (n).

	Mortality (%)		development time (days) ± sd	Fertility		
	Observed (± sd)	Corr ected		Eggs/female/day ± sd	Viable eggs/female/day (± sd)	n
Control	22.5% ± 9.6[a]	-	22.4 ± 0.8[a]	18.1 ± 7.9[a]	8.7 ± 7.1[a]	13
Thiacloprid LD_{50}	27.5% ± 5.0[a]	6.5	21.0 ± 0.7[a]	19.2 ± 9.8[a]	8.2 ± 7.5[a]	11
Thiacloprid LD_{75}	27.5% ± 15.0[a]	6.5	21.7 ± 0.4[a]	17.9 ± 10.1[a]	10.1 ± 7.3[a]	9
Thiacloprid LD_{90}	30.0% ± 8.2[a]	9.7	21.8 ± 0.6[a]	19.6 ± 8.1[a]	10.0 ± 5.6[a]	8

ANOVA and Tukey test (P = 0.05), results followed by the same letter are not statistically different.

High mortality of *A. bipunctata* was observed reaching 100% after 4 days of feeding with thiacloprid sprayed aphids (a). Feeding aphids from thiacloprid sprayed plants (b) resulted in 5.5% corrected mortality which was not statistically significant different from the control treatment and no effect on fertility performance was observed. Development time (until adult emergence) was near identical and not statistically significantly different. Fertility (of emerged adults) was also not significantly affected, neither eggs/female/day nor number of viable eggs. In treatment with irrigation (c), again *A. bipunctata* mortality and fertility was not statistically significantly different compared to the control.

Comment by the notifier:

Exposure to thiacloprid treated aphids (120 g a.s./ha) caused 100% mortality of the ladybird *Adalia bipunctata*. These findings are in line with the effects observed for *Coccinella septempunctata* that was tested for the regulatory data package. The information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	KCP 10.3.2.2/13[redacted]ヌ;[redacted];[redacted]; 2014; M-485102-01-1
Title:	Lethal and behavioural effects of pesticides on the insect predator Macrolophus pygmaeus
Report No.:	M-485102-01-1
Document No.:	M-485102-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

The lethal effects of thiacloprid on *Macrolophus pygmaeus* were evaluated. *M. pygmaeus* nymphs were exposed to the pesticides via the following three combined exposure routes: direct, residual (on leaves) and oral (each treated with 144 mg a.s./L, 2.55 mg/cm²). Thiacloprid caused 100% mortality to *M. pygmaeus*. The behavioural effects were assessed following a combined residual and oral exposure. Residual and oral exposure was derived by spraying tomato seedlings and food separately till run-off (144 mg a.s./L). This exposure scenario caused within 24 h 48% mortality. Furthermore showed *M. pygmaeus* on control plants spent a lower amount of time preening, compared to plants sprayed with thiacloprid. *M. pygmaeus* on control plants spent significantly longer time feeding from the plant than insects on plants sprayed with the pesticide. Total walking time did not differ significantly among treatment and control. The percentage of eggs consumed was significantly higher on control plants than plants treated with thiacloprid.

Material and methods:

A. Material

1. Test material

Test item:	CALYPSO 480 SC®
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	Bayer CropScience
Lot/Batch number:	-
Purity:	
Storage conditions:	

2. Test organism(s)

Species:	*M. pygmaeus* fifth-instar nymphs Food: *Ephestia kuehniella* Zeller (Lepidoptera: Pyralidae) eggs
Source of test species:	Koppert (Netherlands)

B. Study design and methods

1. Test procedure

Test system (study type):	Lethal effects; Behavioural effects
Duration of study:	Lethal effects: 72 h Behavioural effects: 72 h
Treatment:	Lethal effects: *M. pygmaeus* nymphs were exposed to thiacloprid through a combined triple exposure: directly through contact with spray droplets, orally through their food (*Ephestia kuehniella* eggs), and residually through walking on spayed plant leaves. Both sides of the tomato leaflets were sprayed with 144 mg a.s./L (spray volume 2.55 mg/cm²). Nymphs were placed in 9 cm Petri dishes in groups of fifteen and were also sprayed with 144 g a.s./ha. *E. kuehniella* eggs were placed in a 9 cm Petri dish and in the same way. Control treatment was sprayed with distilled water. *M. pygmaeus* nymphs and *E. kuehniella* eggs were allowed to dry, and the predators were transferred individually to the containers containing the leaflets with an abundance of sprayed eggs as prey. Behavioural effects: Nymphs were exposed by combined residual and oral exposure. Tomato seedlings were sprayed till run off with a handheld sprayer with pesticide (144 mg a.s./L) or distilled water for the control. *E. kuehniella* eggs were placed in a 9 cm Petri dish and were also sprayed with pesticide or distilled water till run-off (144 mg a.s./L) using the handheld sprayer. The plants and the eggs were allowed to dry and 2 hours later, 15 sprayed *E. kuehniella* eggs were transferred on the first leaflet of the first true leaf of the tomato plant. A *M. pygmaeus* nymph (not sprayed) was placed at the bottom of the main stem of the plant.
Application rate:	Lethal effects: Potter spray tower; 144 mg a.s./L spray deposit of 2.55 mg/cm² [36.7 g a.s./ha] onto both sites of the leaves distilled water was applied to the control Behavioural effects: Handheld sprayer; 144 mg a.s./L; spraying tomato seedlings till run-off Spraying *E. kuehniella* eggs in a petri dish till run-off (144 mg a.s./L)
Number of replicates:	Lethal effects: 5 replicates Behavioural effects: 21 replicates
Individuals per replicate:	Lethal effects: Insects were kept individually.
Exposure:	Lethal effects: *M. pygmaeus* nymphs were exposed to pesticides through a combined exposure method: directly through contact with spray droplets, orally through their food, and residually through walking on spayed plant leaves. Behavioural effects: The two routes of combined pesticide exposure via walking on treated surfaces and consuming treated egg prey or plant material.

2. Environmental conditions

Test conditions:	Lethal effects: The insects were kept at 25 ± 2 _C, 16:8 L:D and 65% RH. Behavioural effects: The insects were kept at 25 ± 2 _C, 16:8 L:D and 65% RH.

3. Observations and measurements:

Biological parameters measured:	Lethal effects: Mortality Behavioural effects: Mortality; resting, preening, plant feeding and walking

Statistical analyses:	Lethal effects: Comparison of percentage of mortality in controls for day 1 and day 2 using a t-test (R version 2.14.2, R Development Core Team, 2006). One-way analysis of variance (ANOVA) (aov). Post hoc Tukey HSD tests (TukeyHSD) were used for multiple pairwise comparisons. Before analyses, all data were transformed using the arcsine square root transformation to achieve normality and homoscedasticity of variance. Behavioural effects: Behavioural data were expressed as time in seconds allocated to each different activity over the 11 min observation period. An ANOVA model (aov) was used to compare the time allocated to each activity in the different treatments in R 2.14.2. An ANOVA was also used to compare the egg consumption rate at 24 h among treatments. Data on consumption rate were transformed using the arcsine square root transformation to achieve normality and homoscedasticity of variance. Dead individuals were excluded from the egg consumption rate analysis. Post hoc Tukey HSD tests (TukeyHSD) were used for multiple pairwise comparisons.

Results:

Validity criteria:
No validity criteria defined.

Biological findings:
Lethal effects
Thiacloprid caused 100% mortality to *M. pygmaeus* nymphs.

Behavioural effects
Ten out of the 21 insects (48%) in the thiacloprid treatment died after 24 h. No predator deaths were recorded on control plants at 24 h. No additional deaths were recorded at 72 h.
There were no significant differences in walking time of *M. pygmaeus* between treatments. The percentage of *E. kuehniella* eggs consumed by *M. pygmaeus* nymphs was significantly higher on control plants than plants treated with thiacloprid (no predation in thiacloprid treatment).

Comment by the notifier:

The thiacloprid caused under extended laboratory conditions with a combined overspray, residual and oral exposure at 36.7 g a.s./ha 100% mortality of the predatory bug *Macrolophus pygmaeus*. These findings are in line with the effects observed for other non-target arthropods that were tested for the regulatory data, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

CP 10.3.2.3 Semi-field studies with non-target arthropods

Supplemental information from the literature
In addition to the studies performed by BCS in accordance with the requirement a literature search has been performed in accordance with the requirements. From the papers identified during the literature search the following were identified as being potentially relevant for risk assessment. After further evaluation the literature data is considered to provide supplemental information and does not influence the risk assessment.

Report:	[redacted]; [redacted]; 2010; M-466778-01-1
Title:	Effects of four insecticides on the two-spotted ladybird Adalia bipunctata using a microcosm test design
Report No.:	M-466778-01-1
Document No.:	M-466778-01-1
Guidelines:	
GLP/GEP:	**no**

Executive summary:

The effects of four insecticides including thiacloprid were assessed through study of development time, fecundity and fertility of Two-spot ladybirds *Adalia bipunctata* Linnaeus (Coleoptera: Coccinellidae) in an extended-lab test on their larvae fed on Pea aphids *Acyrthosiphon pisum* Harris (Hemiptera: Aphididae). The aim was to adapt the 'microcosm' type semi-field test for the ladybird *A. bipunctata,* combining a realistic exposure mode in 'exposure units' with the simplicity/advantages of laboratory trials for repeatability and interpretation. Material and methods as well as results are summarised for thiacloprid only.
Larvae of *A. bipunctata* (15 individuals, introduced when 2-3 day old) were placed on each replicate of aphid infested French beans (*Vicia faba* L. - Fabales: Fabaceae) in exposure units of 20-25 seedlings, surrounded by a Fluon GP1 treated metal frame 10-12cm height. These larvae were released 48 h after 600 mg of *A. pisum* had been added to the *V. fabae* seedlings (of 2-4 cm height in 35 x 55 cm plastic trays) within each 'exposure unit'. Larvae were allowed to disperse for 2-4 hours before units were transferred outside for application of thiacloprid (120 g a.s./ha) via knapsack sprayer with a flat-fan nozzle (2 m wide sprayer ramp with 4 Teejet flat fan nozzle (XR series, 110, 50 cm spacing). Pressure/ramp was adapted to deliver 400 L/ha ± 10%. Four replicates were made of each object, each tested in two groups in the same time as the water treated control. Units were placed outdoors in a 10 m x 2 m area while treated, then left to dry (under rain protection if needed) for 1-2 h, before kept 8-9 days in the laboratory (randomly distributed in a climatic chamber) without food addition. Replicates were dismantled and larvae and pupae counted in each unit when the first larvae started to pupate in the control. For each replicate, larvae and pupae of *A. bipunctata* were counted and surviving larvae kept individually in petri dished, fed aphids harvested from the same exposure units until pupation. Mortality was calculated on the basis living larvae and pupae, and corrected according to Abott formula. Emerging adults were transferred to breeding containers (15 x 15 x 25 cm) and fed honeybee pollen and aphids from cut French beans. Crumpled paper was added to rearing chambers to stimulate oviposition. Date of first egg-lay was noted. Fertility was assessed in the second week by counting number of eggs individual isolated females (eggs/female/24 h) over 6 successive 24 h periods (each time transferred), plus calculating hatching rate (viable eggs/female/24 h). Those not hatching in 7 days were discarded. To determine food availability in exposure units, 10-12 plants infected with 300 mg of aphids were previously grown and treated to test product and protocol of those units with ladybirds. Living aphids were weighed (and 100 mg subset counted) from 3 sets of 4 replicates per product/control, dismantled 2, 5 and 8 days post treatment. The method combines various aspects of toxicity, direct from spray, contact with treated plants, ingestion of contaminated aphids and starvation by elimination or reduction in food availability. For the ladybird *A. bipunctata,* thiacloprid treatment significantly increased larval mortality (corr. 80%), development time to reach adulthood (+12%), but total egg production/ viability of surviving *A. bipunctata* was not affected compared to a control.

Material and methods:

A. Material

1. Test material

Test item:	Calypso® 480g/L, SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test solutions

Vehicle/solvent:	Water
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Adalia bipunctata* L.
Cultivar:	-
Source of test species:	Laboratory raised
Age of test organisms at study initiation / Crop growth stage at treatment:	2-3 day old *A. bipunctata* / *Vicia faba* seedlings of 2-4cm.
Holding conditions prior to test:	-
Acclimatisation:	
Host:	Food: *Acyrthosiphon pisum* Harris on *Vicia fabae L.*

B. Study design and methods

1. Test procedure

Test system (study type):	Semi-field test / laboratory
Duration of study:	15-20 days
Treatments:	-
Test concentrations:	120 g a.s./ha
Number of replicates:	4
Individuals per replicate:	15 ladybirds
Test units (type and size):	35 x 35 cm tray of 20-25 seedlings with 600 mg aphids
Application / device / nozzles:	Knapsac sprayer 2m ramp, 4 Teejet flat fan nozzle (XR 110).
Water volume:	400 L/ha
Calibration of sprayer:	-

2. Environmental conditions

Test medium:	Planting substrate sand covered
Temperature / relative humidity:	22-25°C, 50-95% RH
Photoperiod:	16/8 day/night
Lighting	Sodium lamp (Son-T Agro) 7000-10000 lux.
pH:	-
Organic matter (C_{org}):	-
$CaCO_3$	-
Cation exchange capacity:	-
Soil textural fractions / extractable micronutrient concentrations [mg per kg soil]:	-
Fertilization:	-

3. Observations and measurements:

Conditional (eg weather) parameters:	-
Biological parameters measured:	Mortality, developmental time, fecundity, hatching rate and proportion of viable eggs.
Measurement frequency:	24 h – 6 days.
Statistical analyses:	Arcsin transformation, One-way Anova (Minitab), and Tukey test multiple comparison

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.3- 1: Effects of thiacloprid on larval *A. bipunctata*.

	Larval Mortality ± sd	Larval Mortality (corrected)	Developmental time to adult stage (days) ± sd	Total egg production ± sd	Hatching rate ± sd	Viable egg production ± sd
Control	16.7% ± 15.3%a	-	22.59 ± 0.46a	22.80 ± 7.04a	63.8% ± 11.9%a	15.04 ± 4.20a
Thiacloprid	83.3% ± 7.5%b	80%	25.33 ±0.76b	19.50 ± 11.81a	65.6% ± 10.6%a	12.17 ± 6.84a

sd = standard deviation
Anova test (one-way) followed by Tukey multiple comparison at P=0.05 level. Arcsin transformation for percentage before analysis.
Numbers followed by the same letter are not different in a significant way.

On day 8 aphid population in the thiacloprid treatment was reduced by 80% compared to the control treatment, staying at the same level as initially added. Thiacloprid increased larval toxicity (corr. 80%) and developmental time to adulthood (+12%) statistically significantly compared to the control. Fecundity and fertility were not affected (measured through egg production, hatching rate, and viable egg production).

Comment by the notifier:

The thiacloprid caused under semi-field conditions with a combined residual and oral exposure at 120 g a.s./ha 80% mortality of the ladybird *Adalia bipunctata*. These findings are in line with the effects observed for *Coccinella septempunctata* that was tested for the regulatory data package, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

CP 10.3.2.4 Field studies with non-target arthropods

Report:	[redacted]; [redacted]; [redacted]; 2013; M-462228-01-1
Title:	A field study to assess the effects of thiacloprid OD 240 (240 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in The Netherlands during spring/summer
Report No.:	B162FFN
Document No.:	M-462228-01-1
Guidelines:	**IOBC (Hassan, 1992), Anonymous (1992), Brown (1998), IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000, 2001), De Jong et al., 2010; US EPA OCSPP Not Applicable; not applicable**
GLP/GEP:	**yes**

Objective:

This field study was designed to assess the potential adverse effects on Non-Target Arthropods (NTA) in off-crop habitats that might occur at various distances from a treated area for current and future use patterns of the test item. By analogy to regulatory studies in e.g. aquatic environments (SANCO 2002) the study was set up to enable an assessment of community- and population level ecotoxicological standards, in particular the NOER (No Observed Effect Rate), the NOEAER and the LOEAER (No and Lowest Observed Ecologically Adverse Effect Rate, respectively).
The study was performed in a true off-crop habitat, i.e. a meadow habitat with little agricultural input in The Netherlands. This approach has the advantage that the observed response would pertain to a representative off-crop NTA community, i.e. a community not previously under selection in an agricultural regime. For this reason the study outcome represents a realistic worst case situation.
The study was designed as a NOER-type ([redacted] and [redacted], 2007 [redacted] et al, 2010). The choice for a NOER approach makes the results applicable to any product use pattern. At the same time the assessment of a NOEAER/LOEAER avoids the caveats of assessing the acceptability of certain effect levels at given drift rates (Bakker, 2012; Miles and Bakker, 2012). The finding that the NOER or NOEAER may be expected to occur at a certain distance from a treated area will be unambiguously interpretable. The approach was fully in line with the ESCORT 3 proposal (Alix et al, 2012).
To enable a refined assessment of NOEAER/LOEAER, sampling was continued until 8 weeks post-application. Recovery within this time frame was considered to be ecologically acceptable, even when initial effects would have occurred.

Material and methods:

Test item: Thiacloprid OD 240B G; Batch ID: ECE7101227; Material no.: 79674910; Specification no.: 102000021774-01; Sample description: TOX09758-00; Density: 1.040 g/mL; Analysed content: 239.2 g a.s./L (23.0% w/w).

Thiacloprid OD 240 was applied once to a grassland meadow on 5 June 2012 at nominal rates of 0.56, 1.2, 4.7, 10.2 and 27 g a.s./ha, equivalent to typical drift values for different use patterns of the test item. Average application rates per treatment deviated 8.5% or less from intended rates. A water control treatment and a toxic reference treatment (lambda-cyhalothrin at a rate of 40 g a.s./ha) were run in parallel. Nominal application volumes were 200 L/ha.
The soil-surface- and plant-dwelling arthropod communities were monitored shortly before and one, two, four and eight weeks after application. A broad spectrum of arthropods was sampled with a combination of sampling methods, viz. pitfall trapping, Berlese-Tullgren extraction from weed samples and suction sampling.
The trial had a randomised complete block design with 4 replicates/treatment. Each block had seven treatment plots of 24 x 24 m. To minimise interference among plots, the trial was laid out in a checkerboard design. During treatment of the second half of the last plot of each treatment (all plots in one block), air was observed to enter the spray liquid, resulting in potentially inaccurate spray rates. These plots were therefore reduced in size. Before the first post-application sample pitfalls were re-installed in the centre of the 12 x 24 m area that did receive the correct spray volume. Additional analyses were performed to confirm that smaller plot size in this block had no influence on recovery rates of arthropod taxa in comparison to recovery rates in large plots.
The effects of Thiacloprid OD 240 were expressed in terms of population and community changes relative to the water control. The No Observed Effect Rate (NOER) was defined at the community level and at the population level as the highest rate at which adverse responses were not significantly different from the water control at any time point. The No Observed Ecologically Adverse Effect Rate (NOEAER) was defined at the community level and at the population level as the highest rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after application. By analogy the LOEAER (for community and population responses) was defined as the lowest test rate at which adverse effects were statistically significantly different from the water control without recovery occurring.
Statistical significances were in principal considered at an alpha level of 5%. Statistical significances at an alpha level of 10% were also indicated as additional information to evaluate potential trends

Findings:

Test performance
Average application rates per treatment deviated 8.5% or less from target rates.
Both univariate and multivariate analyses of pitfall- and suction sample data demonstrated acute and persistent statistically significant adverse effects in plots treated with the reference item, indicating that the test system was sufficiently sensitive and adequate to detect statistically significant and distinctly different responses in case these occurred.
For several taxa no recovery was seen in the reference treatment within the time frame of the study, indicating that test design parameters, such as plot size, were adequate to demonstrate persistent adverse treatment related effects. This was also true for the smaller plots in block 1.
Due to high dominance of one single mite taxon (98% of all mites identified) multivariate analysis of the weed sample dataset was considered of low value for effect evaluations at the community level.

Biological findings:

Biological system

The experimental field was a humid to wet, nutrient rich grassland meadow with high coverage and low plant species diversity. There was a homogeneous vegetation and soil constitution, without structures potentially causing irregular microclimates. *Poa trivialis* (Rough bluegrass), *Lolium perenne* (Perennial Ryegrass), *Alopecurus pratensis* (Meadow foxtail) and *Agrostis stolonifera* (Fiorin Grass) were the most dominant grass species. The coverage of non-graminae plants was lower than 1% on estimation.

The arthropod community sampled in this study was diverse and typical for grassland vegetation, and representative for an off-crop non-target arthropod community. The timing of the experiment was such that a high number of abundant taxa were present during the sampling period. In addition timing coincided with typical use patterns for the test item. Pitfall- and suction data were appropriate for community analyses using ordination techniques. The mite community extracted from weed samples was entirely dominated by one taxon (Tarsonemidae; 98% of all mites identified) and therefore not included in effect evaluations. A total of 54 taxa were sufficiently abundant to be subjected to population level evaluations. A number of evaluations were performed at the family level, but several taxa occurred at sufficiently high numbers to allow for an evaluation at genus or species level.

The taxonomical analysis was performed in great detail. Despite the restrictions caused by the inevitable categorization of specimens at different taxonomic levels, it was felt that the number of taxa together with the choice of taxonomic level used for analysis did provide a sufficiently detailed and valid ecological analysis.

Sampling

The entire arthropod community occurring in the off-crop habitat was monitored using pitfall-, weed/Berlese and suction sampling techniques. In total almost 1 million specimens from 207 taxa were identified, 137 of which were included in community analyses and 54 in univariate analyses. Highly abundant taxa were Collembola, Thysanoptera and the micro-hymenopteran wasp family Mymaridae.

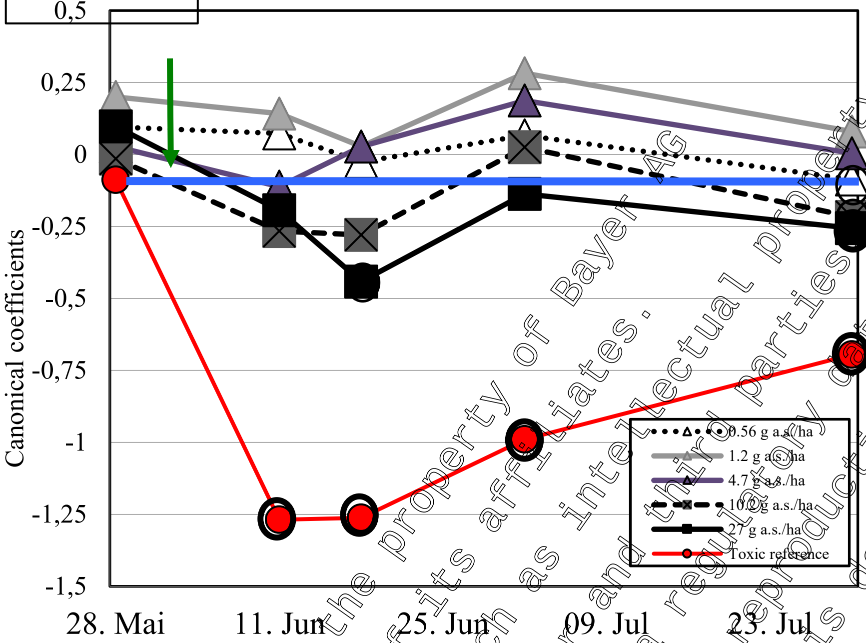
Results test item

Treatment with the insecticide Thiacloprid OD 240 in an off-field grassland habitat in the Netherlands led to statistically significant adverse effects on prevailing arthropod communities for the highest test rates of 10.2 and 27 g a.s./ha. Community analyses of the suction dataset revealed moderate and transient adverse community responses in the two highest test item rates one and two weeks after application. A weak adverse effect in the pitfall dataset was not statistically significant at $\alpha=0.05$ shortly after application, but at the end of the two-week sampling period an adverse response had developed which was statistically significant in the highest test item rate. In the combined dataset, a statistically significant adverse response was observed at the highest test rate of 27 g a.s./ha two weeks after application.

Nine taxa showed statistically significant adverse responses that were considered related to the test item treatment (based on magnitude and duration in relation to dose and timing). At the highest test item rate of 27 g a.s./ha, the collembolan taxon Sminthuridae, the linyphiid web spider *Erigone*, the coleopteran family Staphylinidae and the dipteran taxon Lonchopteridae (Aschiza) were moderately affected and did not recover within the two months study period. *Loricera pilicornis* (Carabidae, Coleoptera), juvenile Cicadellidae (Homoptera), Drosophilidae (Diptera) and another collembolan taxon (Isotomidae) also showed statistically significant adverse effects at the highest test item rate,

with full recovery occurring latest two months after treatment. Transient and moderate but statistically significant adverse effects were observed for Drosophilidae at 10.2 g a.s./ha and for Sminthuridae at 10.2 and 4.7 g a.s./ha of Thiacloprid OD 240. At these rates, recovery occurred within two weeks after treatment for Drosophilidae and one month after treatment for Sminthuridae.
For few other taxa reductions compared to the control occurred incidentally, but differences were not statistically significant at α=0.05, or no consistent trend in time or relation to the dose rate was found.

Summary community level effects



xon	Species weight
inthuridae <500 µm	3.1703
tomidae>500 µm	2.8098
inthuridae >500 µm	2.6961
aphylinidae juveniles	2.2838
tomidae <500 µm	1.748
mphyplema (other) <500 µm	1.4728
ederinae	1.2523
rata (adult)	1.1099
bria brevicollis	1.0923
leocharinae	1.0181
erostichus melanarius	1.0004
igone (adult)	0.9753
alangida (adult)	0.9721
ricera pilicornis	0.9603
eninae	0.9077
kytelinae	0.8904
ydrophilidae	0.8507
igoninae (juv.)	0.8435
ythyphantes (adult)	0.8385
tomobryidae <500 µm	0.8158
mbidion spp.	-1.0913
rdosa (juv.)	-1.34
mara spp.	-1.734
ecilus cupreus	-1.8007

Suction

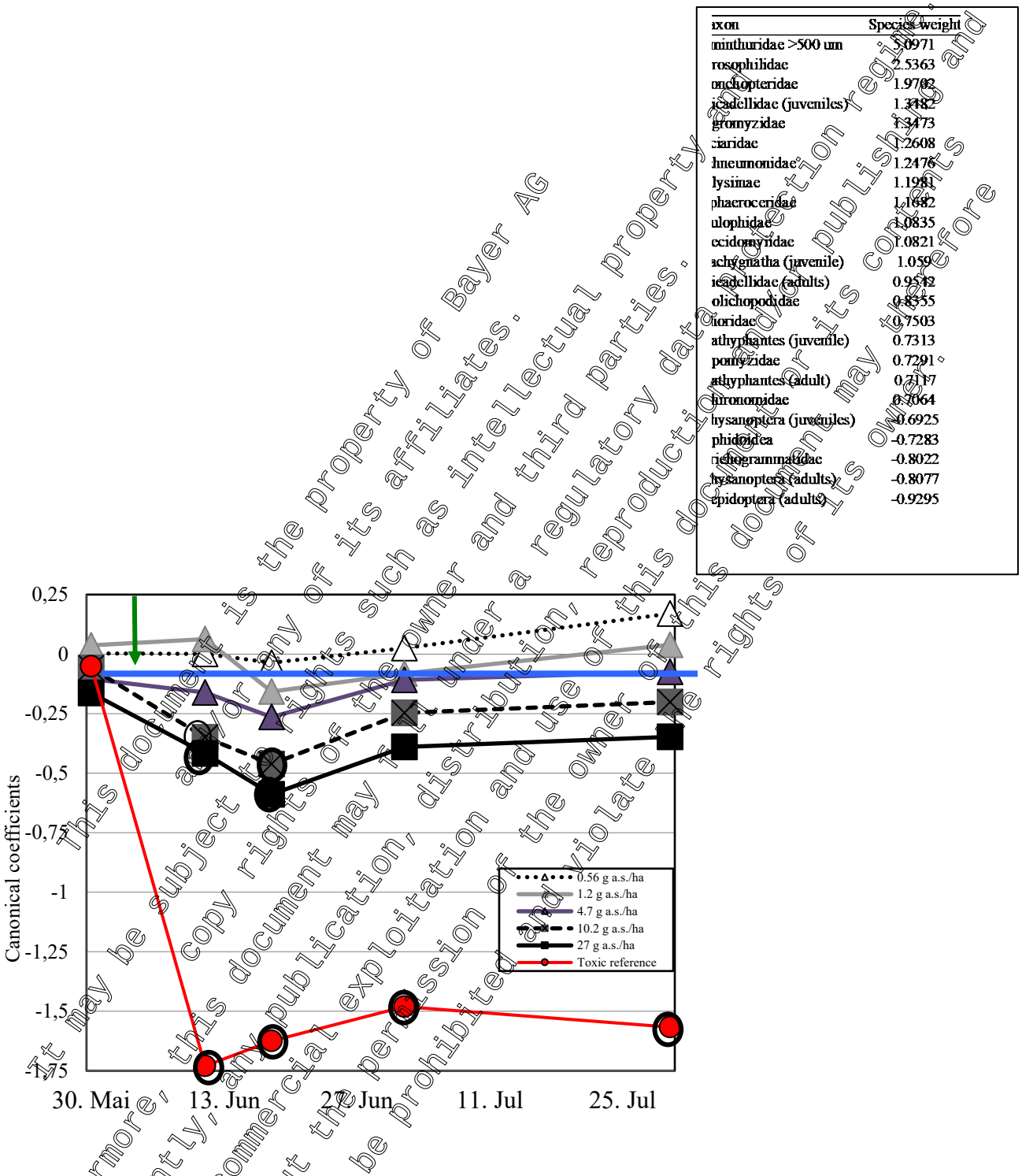
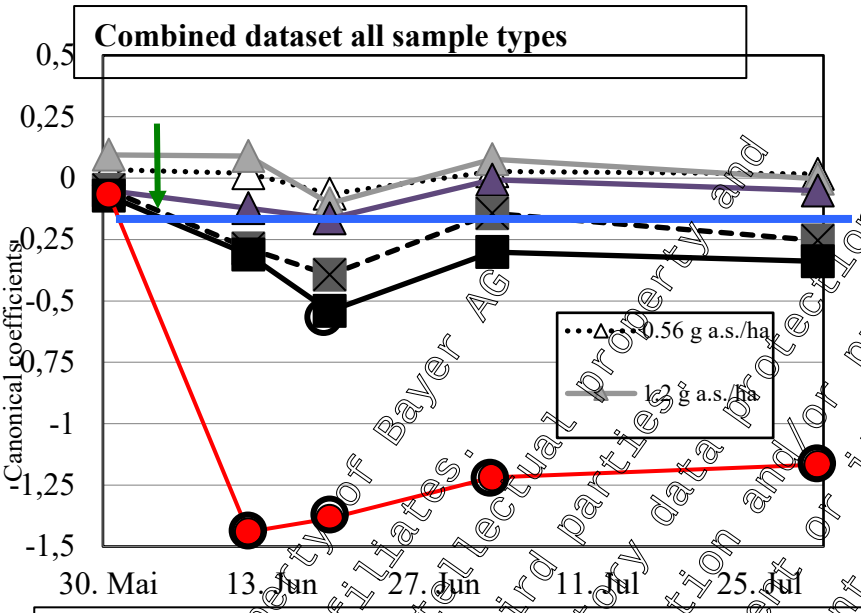


Figure CP 10.3.2.4- 1: Principal Response Curve (first ordination axis).
Test- and toxic reference items were analysed separately but for comparison plotted in one graph. Encircled data points are statistically significant (Monte-Carlo Permutation test, alpha = 0.05 thick circle; alpha = 0.1 thin circle). The 24 largest species scores of the test item treatments are presented (i.e. these species had the largest influence on the shape of the PRC curves of test item treatments). The arrow indicates the application day.



Method	Taxon	Species score
S	Sminthuridae	5.7005
P	Sminthuridae >500 µm	2.9637
S	Drosophilidae	2.7599
S	Lonchopteridae	2.5121
P	Isotomidae >500 µm	2.4671
P	Sminthuridae <500 µm	2.2483
P	Staphylinidae juveniles	2.2172
W	Pygmephoroidea	1.9922
S	Cicadellidae (juveniles)	1.5979
S	Alysiinae	1.5277
S	Ichneumonidae	1.5198
P	Isotomidae <500 µm	1.4272
S	Agromyzidae	1.3849
S	Sphaeroceridae	1.2899
P	Bathyphantes (adult)	1.2871
S	Pachygnatha (juvenile)	1.268
P	Loricera pilicornis	1.2122
P	Paederinae	1.1973
S	Sciaridae	1.1942
S	Cicadellidae (adults)	1.1717
S	Eulophidae	1.1715
P	Stenus	1.1445
S	Cecidomyiidae	1.103
S	Opomyzidae	1.1001
P	Nebria brevicollis	1.0697
P	Erigone (adult)	1.0121
P	Amara spp.	-1.0443
S	Thysanoptera (juveniles)	-1.0675
W	Erionyhoidea	-1.0757
P	Poecilus cupreus	-1.7264

Figure CP 10.3.2.4- 2: Principal Response Curve (first ordination axis)
Test- and toxic reference items were analysed separately but for comparison plotted in one graph. Encircled data points are statistically significant (Monte-Carlo Permutation test, alpha = 0.05 thick circle; alpha = 0.1 thin circle). The 30 largest species scores of the test item treatments are presented (i.e. these species had the largest influence on the shape of the PRC curves of test item treatments). The arrow indicates the application day.
Method: S=suction; P=pitfall; W=weed

Results community analyses

Treatments included in analysis	% Variance accounted for by time	% Variance accounted for by treatment	% Variance explained by treatment regime in ax1	% Variance explained by treatment regime in ax2	P-value ax1	P-value ax2
PITFALL						
all	29.2	27.6	46.8	16.2	0.001	0.001
Test item rates	36.2	13.3	18.2	10.0	0.310	0.983
0.56 g a.s./ha	40.4	7.9	37	26.4	0.627	0.722
1.2 g a.s./ha	39.9	7.2	33.7	21.7	0.901	0.970
4.7 g a.s./ha	40.2	7.5	33.8	24.2	0.810	0.692
10.2 g a.s./ha	41.3	8.8	30.5	27.4	0.691	0.321
27 g a.s./ha	39.4	9.2	39.3	23.1	0.443	0.668
Reference	30.4	35.2	66.4	22.8	0.023	0.023
SUCTION						
all	44.6	27.9	62.3	9.6	0.001	0.001
test item rates	57.6	9.5	23.3	11.4	0.238	0.920
0.56 g a.s./ha	60.3	4.8	42.5	21.3	0.450	0.920
1.2 g a.s./ha	63.0	5.1	30.7	27.1	0.829	0.920
4.7 g a.s./ha	63.9	4.5	40.3	21.0	0.627	0.913
10.2 g a.s./ha	60.0	6.2	44.5	18.3	0.235	0.897
27 g a.s./ha	60.5	7.6	52.6	14.6	0.071	0.670
Reference	39.6	38.3	80.8	10.4	0.023	0.027
COMBINED DATASET						
all	38.4	26.8	53.9	10.8	0.001	0.001
test item rates	48.3	11.0	18.6	9.0	0.199	0.937
0.56 g a.s./ha	51.9	6.0	38.8	23.0	0.485	0.800
1.2 g a.s./ha	52.7	6.0	30.5	24.0	0.882	0.713
4.7 g a.s./ha	53.2	5.6	33.4	20.2	0.806	1.000
10.2 g a.s./ha	51.8	7.4	36.3	20.8	0.303	0.742
27 g a.s./ha	51.3	8.3	46.8	17.6	0.088	0.517
Reference	36.0	35.6	74.5	14.4	0.023	0.027

P-values at individual sampling moments (Monte Carlo Permutation Test-comparison to control)

PITFALL	0.56 g a.s./ha	1.2 g a.s./ha	4.7 g a.s./ha	10.2 g a.s./ha	27 g a.s./ha	Reference
29-May-12	0.899	0.646	0.873	0.772	0.800	0.202
12-Jun-12	0.548	0.969	0.735	0.292	0.807	0.023
19-Jun-12	0.401	0.368	0.426	0.291	0.068	0.030
03-Jul-12	0.938	0.595	0.243	0.466	0.647	0.030
31-Jul-12	0.061	0.887	1.000	0.095	0.038	0.030
SUCTION	**0.56 g a.s./ha**	**1.2 g a.s./ha**	**4.7 g a.s./ha**	**10.2 g a.s./ha**	**27 g a.s./ha**	**Reference**
31-May-12	0.180	0.856	0.657	0.363	0.379	0.922
12-Jun-12	0.588	0.796	0.459	0.096	0.045	0.029
19-Jun-12	0.645	0.819	0.287	0.043	0.024	0.024
03-Jul-12	1.000	0.158	0.972	0.734	0.186	0.024
31-Jul-12	0.412	0.376	0.583	0.630	0.439	0.024
COMBINED	**0.56 g a.s./ha**	**1.2 g a.s./ha**	**4.7 g a.s./ha**	**10.2 g a.s./ha**	**27 g a.s./ha**	**Reference**
31-May-12	0.664	0.756	0.897	0.611	0.751	0.442
12-Jun-12	0.700	0.975	0.692	0.127	0.233	0.022
19-Jun-12	0.546	0.856	0.472	0.152	0.035	0.035
03-Jul-12	1.000	0.433	0.732	0.708	0.369	0.035
31-Jul-12	0.313	0.336	1.000	0.351	0.315	0.035

All	All treatments (test- and reference item) analyzed together
Test item rates	All test item treatments analyzed together
0.56 g, 1.2 g, etc	One test item treatment analyzed separately
Reference	Reference item analyzed separately
(light shading)	Statistically significant at alpha = 0.1 (Monte Carlo permutation test)
(dark shading)	Statistically significant at alpha = 0.05

Summary population level effects

Effect classification (Based on De Jong *et al*, 2010):		Effect class:
one occasion	Clear adverse treatment related effect but observed on one occasion only	2
< 2 months (a)	Advese effect no longer statistically significant on the last two sampling moments	3a
< 2 months (b)	Adverse effect no longer statistically significant on the the last sampling moment	3b
> 2 months	No recovery from adverse effect within the study period (= 2 months)	8

Based on 10% significance level and visual consideration of trends: 2

Based on 5% significance level and visual consideration of trends: 2 (bold frame)

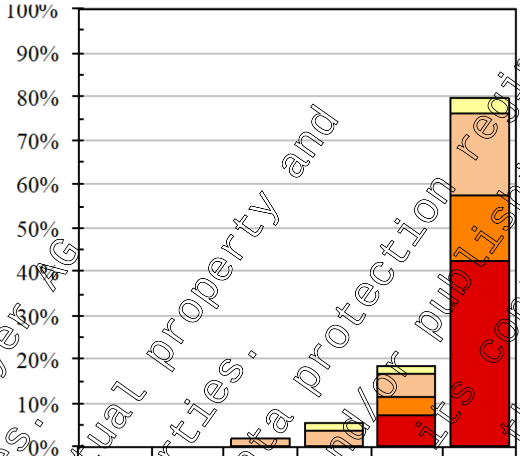
Method: S=suction:P=pitfall; W=weed

method	Order	Thiacloprid OD 240 (g/L)	0.56 g	1.2 g	4.7 g	10.2 g	27 g	Ref
W	ACARI	Tarsonemidae						
P	ARANEAE	Pardosa (juv.)						8
P	ARANEAE	Pardosa (adult)						3b
P	ARANEAE	Lycosidae others						8
S	ARANEAE	Pachygnatha (juvenile)						8
P	ARANEAE	Pachygnatha						8
P	ARANEAE	Erigone (adult)					8	8
P	ARANEAE	Oedothorax (adult)						8
P	ARANEAE	Bathyphantes (adult)						3b
S	ARANEAE	Linyphiidae juvenile						8
P	ARANEAE	Juvenile Linyphiidae						
P	COLEOPTERA	Bembidion spp.						3a
P	COLEOPTERA	Loricera pilicornis					3b	3a
P	COLEOPTERA	Poecilus cupreus						
P	COLEOPTERA	Harpalinae other						3a
P	COLEOPTERA	Staphylinidae juveniles					3a	3a
P	COLEOPTERA	Staphylinidae					8	3a
S	COLEOPTERA	Coccinellini (juveniles)						3b
P	COLEOPTERA	Hydrophilidae						
S	HYMENOPTERA	Ichneumonidae						8
S	HYMENOPTERA	Aphidiinae						8
S	HYMENOPTERA	Alysiinae						3b
S	HYMENOPTERA	Eulophidae						8
S	HYMENOPTERA	Mymaridae						3a
S	HYMENOPTERA	Pteromalidae						8
S	HYMENOPTERA	Chalcidoidea other						8
S	HYMENOPTERA	Platygastridae						8
P	HYMENOPTERA	Scelionidae						2
S	HYMENOPTERA	Proctotrupoidea other						8
S	HYMENOPTERA	Cynipoidea						8
S	HOMOPTERA	Aphidoidea						3b
S	HOMOPTERA	Cicadellidae (juveniles)					3b	8
S	HOMOPTERA	Cicadellidae (adults)						3a
S	HOMOPTERA	Delphacidae (juveniles)						8
S	HOMOPTERA	Delphacidae (adults)						8
S	HETEROPTERA	Miridae (juveniles)						3b
S	DIPTERA	Cecidomyiidae						8
S	DIPTERA	Chironomidae						3a
S	DIPTERA	Sciaridae						3a
S	DIPTERA	Lonchopteridae					8	8
S	DIPTERA	Phoridae						
S	DIPTERA	Chloropidae						8
S	DIPTERA	Drosophilidae				2	2	3a
S	DIPTERA	Sphaeroceridae						3b
S	DIPTERA	Acalyptrata other						3b
S	COLLEMBOLA	Sminthuridae			3a	3a	8	
P	COLLEMBOLA	Sminthuridae				3a	3a	
P	COLLEMBOLA	Symphypleona (other)						
P	COLLEMBOLA	Entomobryidae						
P	COLLEMBOLA	Isotomidae					3a	
P	ISOPODA	Isopoda (all)						2
P	CHILOPODA	Chilopoda (all)						
S	THYSANOPTERA	Thysanoptera (juveniles)						8
S	THYSANOPTERA	Thysanoptera (adults)						8

Graphical presentation of effects table

Summarized are percentages of taxa adversely affected by the different treatments, subdivided in different effect classes (duration of effects), as explained in the header of the previous table.

According to De Jong *et al*. (2010), recovery should be demonstrated on two consecutive sampling moments. Due to the 4 week interval between the last two sampling moments this would result in a very conservative effect classification. Effect class 3 was therefore subdivided in class 3a (no longer statistically significant on the last two sampling moments) and class 3b (no longer statistically significant on the last sampling moment).



	0.56 g	1.2 g	4.7 g	10.2 g	27 g	Ref
one occasion	0.0%	0.0%	0.0%	1.9%	1.9%	3.7%
< 2 months (a)	0.0%	0.0%	1.9%	3.7%	5.6%	18.5%
< 2 months (b)	0.0%	0.0%	0.0%	0.0%	3.7%	14.8%
> 2 months	0.0%	0.0%	0.0%	0.0%	7.4%	42.6%

Summary table effect classifications

Effect classification (Based on De Jong *et al*, 2010):		Effect class:
one occasion	Clear adverse treatment related effect but observed on one occasion only	2
< 2 months (a)	Advese effect no longer statistically significant on the last two sampling moments	3a
< 2 months (b)	Adverse effect no longer statistically significant on the the last sampling moment	3b
> 2 months	No recovery from adverse effect within the study period (= 2 months)	8

Community level effects (PRC/Monte-Carlo; 5% alpha level)	**0.56 g a.s/ha**	**1.2 g a.s/ha**	**4.7 g a.s/ha**	**10.2 g a.s/ha**	**27 g a.s/ha**
			Effect class		
Suction	-	-	-	3a	3a
Pitfall	-	-	-	-	8
Combined dataset (suction, pitfall, weed)	-	-	-	-	2
Conclusion			**Community NOER**	**Community NOEAER**	**Community LOEAER**

			Population level effects (Mann-Whitney U test; 5% alpha level)	**0.56 g a.s/ha**	**1.2 g a.s/ha**	**4.7 g a.s/ha**	**10.2 g a.s/ha**	**27 g a.s/ha**
						Effect class		
P	ARANEAE	*Erigone* (adult)		-	-	-	-	8
P	COLEOPTERA	*Loricera pilicornis*		-	-	-	-	3b
P	COLEOPTERA	Staphylinidae juveniles		-	-	-	-	3a
P	COLEOPTERA	Staphylinidae adults		-	-	-	-	8
S	HOMOPTERA	Cicadellidae juveniles		-	-	-	-	3b
S	DIPTERA	Lonchopteridae		-	-	-	-	8
S	DIPTERA	Drosophilidae		-	-	-	2	2
S	COLLEMBOLA	Sminthuridae		-	-	3a	3a	8
P	COLLEMBOLA	Sminthuridae		-	-	-	3a	3a
P	COLLEMBOLA	Isotomidae		-	-	-	-	3a
Conclusion					**Population NOER**		**Population NOEAER**	**Population LOEAER**

-	No consistent statistically significant effect observed
NOER:	No Observed Effect Rate (highest test rate where no statistically consistent significant differences compared to the control occurred)
NOEAER:	No Observed Ecologically Adverse Effect Rate (highest test rate where at least 1 taxon with effect class 2 or 3, i.e. clear response to treatment occurred, but with recovery within 2 months after application)
LOEAER:	Lowest Observed Ecologically Adverse Effect Rate (lowest test rate for which at least 1 taxon had a statistically significant adverse response to treatment, lasting more than two months)

P=pitfall; S=suction

Conclusion:

It is concluded that Thiacloprid OD 240 applied at a rate of 27 g a.s./ha in an off-crop grassland meadow in The Netherlands is the community LOEAER (Lowest Observed Ecologically Adverse Effect Rate). Moderate adverse effects found in the suction dataset were no longer observed one month after treatment, but a gradually increased adverse effect in the pitfall dataset was statistically significant on the last sampling moment two months after application.
Thiacloprid OD 240 applied at a rate of 10.2 g a.s./ha is the community NOEAER (No Observed Ecologically Adverse Effect Rate). Moderate adverse effects were statistically significant one and two weeks after treatment, but the community as a whole had recovered one month after treatment.
No statistically significant adverse community effects were found in the 4.7 g a.s./ha rate. This rate is classified as the community NOER (No Observed Effect Rate).
At the population level nine taxa were considered adversely affected by treatment with Thiacloprid OD 240 applied at a rate of 27 g a.s./ha, of which four taxa did not recover within the two-month sampling period. This rate is therefore the population LOEAER.
In the 4.7 g and 10.2 g a.s./ha rate of Thiacloprid OD 240 one and two taxa were adversely affected but recovered within one month after treatment. The 10.2 g a.s./ha rate is therefore the population NOEAER.
No statistically significant adverse population effects were found in the 1.2 g a.s./ha rate. This rate is classified as the population NOER.

Report:	[redacted]; [redacted]; [redacted]; 2013; M-462231-01-1
Title:	A field study to assess the effects of thiacloprid OD 240 (240 g/L) on the non-target, surface- and plant-dwelling, arthropod fauna of a grassland habitat (off-crop) in SW France during spring/summer
Report No.:	B163FFN
Document No.:	M-462231-01-1
Guidelines:	**IOBC (Hassan, 1992), Anonymous (1992), Brown (1998), IOBC, BART and EPPO Joint Initiative (Candolfi et al., 2000, 2001), De Jong et al., 2010; US EPA OCSPP**
	Not Applicable; not applicable
GLP/GEP:	**yes**

Objective:
This field study was designed to assess the potential adverse effects on Non-Target Arthropods (NTA) in off-crop habitats that might occur at various distances from a treated area for current and future use patterns of the test item. By analogy to regulatory studies in e.g. aquatic environments (SANCO 2002) the study was set up to enable an assessment of community- and population level ecotoxicological standards, in particular the NOER (No Observed Effect Rate), the NOEAER and the LOEAER (No and Lowest Observed Ecologically Adverse Effect Rate, respectively).
The study was performed in a true off-crop habitat, i.e. a meadow habitat with little agricultural input in the South-West of France. This approach has the advantage that the observed response would pertain to a representative off-crop NTA community, i.e. a community not previously under selection in an agricultural regime. For this reason the study outcome represents a realistic worst case situation.
The study was designed as a NOER-type (Bakker and Miles, 2007; De Jong et al, 2010). The choice for a NOER approach makes the results applicable to any product use pattern. At the same time the assessment of a NOEAER/LOEAER avoids the caveats of assessing the acceptability of certain effect levels at given drift rates (Bakker, 2012; Miles and Bakker, 2012). The finding that the NOER or NOEAER may be expected to occur at a certain distance from a treated area will be unambiguously interpretable. The approach was fully in line with the ESCORT 3 proposal (Alix et al, 2012).
To enable a refined assessment of NOEAER/LOEAER, sampling was continued until 8 weeks post-application. Recovery within this time frame was considered to be ecologically acceptable, even when initial effects would have occurred.

Material and methods:
Test item: Thiacloprid OD 240B G; Batch ID: ECE7101227; Material no.: 79674910; Specification no.: 102000021774-01; Sample description: TOX09758-00; Density: 1.040 g/mL; Analysed content: 239.2 g a.s./L (23.0% w/w).

Thiacloprid OD 240 was applied once to a grassland meadow on 29 May 2012 at nominal rates of 0.56, 1.2, 4.2, 10.2 and 27 g a.s./ha, equivalent to typical drift values for different use patterns of the test item. Average application rates per test item treatment deviated at maximum 1.5% from intended rates. A water control treatment and a toxic reference treatment (lambda-cyhalothrin at a rate of 40 g a.s./ha) were run in parallel. Nominal application volumes were 200 L/ha.
The soil-surface- and plant-dwelling arthropod communities were monitored shortly before and one, two, four and eight weeks after application. A broad spectrum of arthropods was sampled with a combination of sampling methods, viz. pitfall trapping, Berlese-Tullgren extraction from weed samples and suction sampling.

The trial had a randomised complete block design with 4 replicates/treatment. Each block had seven treatment plots of 24 x 24 m. To minimise interference among plots, the trial was laid out in a checkerboard design.
The effects of Thiacloprid OD 240 were expressed in terms of population and community changes relative to the water control. The No Observed Effect Rate (NOER) was defined at the community level and at the population level as the rate at which adverse responses were not significantly different from the water control at any time point. The No Observed Ecologically Adverse Effect Rate (NOEAER) was defined at the community level and at the population level as the highest rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after application. By analogy the LOEAER (for community and population responses) was defined as the lowest test rate at which adverse effects were statistically significantly different from the water control without recovery occurring.
Statistical significances were in principal considered at an alpha level of 5%. Statistical significances at an alpha level of 10% were also indicated as additional information to evaluate potential trends.

Findings:

Test performance

Average application rates per test item treatment deviated 1.5% or less from target rates.
Both univariate and multivariate analyses of pitfall-, suction- and weed sample data demonstrated acute and persistent statistically significant adverse effects in plots treated with the reference item, indicating that the test system was sufficiently sensitive and adequate to detect statistically significant and distinctly different responses in case these occurred.
For several taxa no recovery was seen in the reference treatment within the time frame of the study, indicating that test design parameters, such as plot size, were adequate to demonstrate persistent adverse treatment related effects.

Biological findings:

Biological system

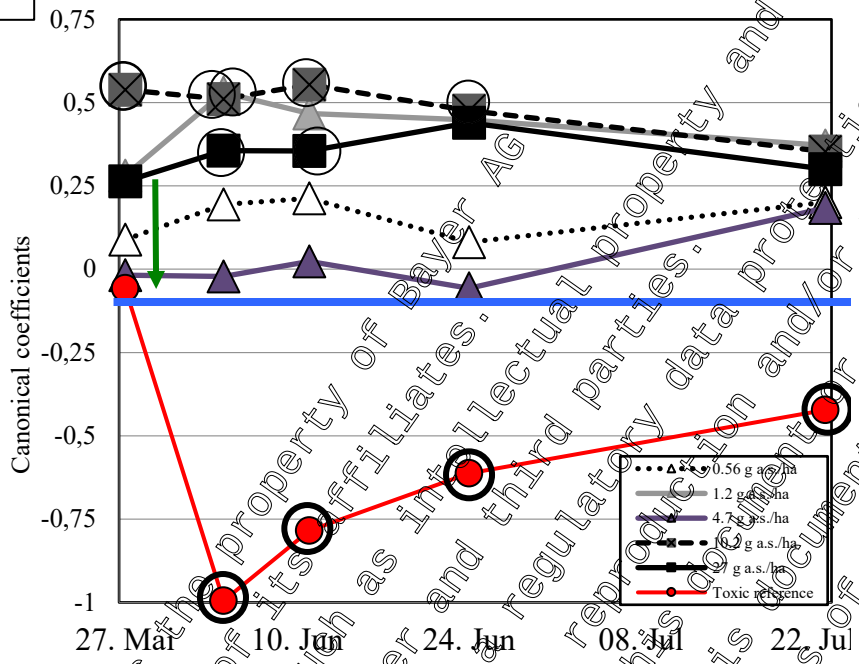
Vegetation structure indicated that the experimental field was a humid, moderately nutrient rich grassland with high coverage and low plant species diversity. There was a homogeneous vegetation and soil constitution, without structures potentially causing irregular microclimates. *Holcus lanatus* (common velvet grass), *Dactilis glomerata* (Cocks foot), and *Festuca pratensis* (Meadow Fescue) were dominant grass species. White clover (*Trifolium repens*) and ribwort plantain (*Plantago lanceolata*) were common plant species.
The arthropod community sampled in this study was diverse and typical for grassland vegetation, and representative for an off-crop non-target arthropod community. The timing of the experiment was such that a high number of abundant taxa were present during the sampling period. In addition timing coincided with typical use patterns for the test item. The entire dataset was appropriate for community analyses using ordination techniques. In addition, a total of 95 taxa were sufficiently abundant to be subjected to population level evaluations. A number of evaluations were performed at the family level, but several taxa occurred at sufficiently high numbers to allow for an evaluation at genus or species level.
The taxonomical analysis was performed in great detail. Despite the restrictions caused by the inevitable categorization of specimens at different taxonomic levels, it was felt that the number of taxa together with the choice of taxonomic level used for analysis did provide a sufficiently detailed and valid ecological.

Sampling
The entire arthropod community occurring in the off-crop habitat was monitored using pitfall-, weed/Berlese and suction sampling techniques. In total more than two million specimens from 312 taxa were identified; 215 of which were included in community analyses and 95 in univariate analyses. Highly abundant taxa were Collembola, Thysanoptera, Oribatida, aphids, cicadellids and mosquitoes of the family Sciaridae.

Results test item
Treatment with the insecticide Thiacloprid OD 240 in an off-field grassland habitat in South-West France led to moderate but statistically significant effects on prevailing arthropod communities for all but the lowest test rate of 0.56 g a.s./ha. Community analyses of the suction dataset revealed transient community responses one week after application only in rates equal to or higher than 1.2 g a.s./ha, and one and two weeks after application in the 27 g a.s./ha rate. Recovery of the community had taken place two weeks after treatment in the rates of 1.2, 4.7 and 10.2 g a.s./ha and one month after treatment in the highest rate of 27 g a.s./ha.
No statistically significant adverse community effects were detected in arthropod communities sampled with pitfalls and with weed extraction methods.
Community analysis of the combined dataset revealed a transient community response one and two weeks after application at the 10.2 g a.s./ha rate, while at the rate of 27 g a.s./ha a statistically significant community response was only observed one week after application.
Fourteen taxa showed statistically significant adverse responses that were considered related to the test item treatment (based on magnitude and duration in relation to dose and timing). Several collembolan and coleopteran taxa, two spider taxa, one hymenopteran taxon and adult Thysanoptera were moderately affected by the highest test item rate of 27 g a.s./ha and in few cases also by lower test item rates, but all populations recovered within two months after treatment. The lowest test rate showing an adverse treatment related response was 0.56 g a.s./ha. At this rate, the collembolan family Sminthuridae, sampled with suction, was adversely affected only one week after application, and had recovered at the next sampling event one week later.
For few other taxa reductions compared to the control occurred incidentally, but differences were not statistically significant at $\alpha = 0.05$, or no consistent trend in time or relation to the dose rate was found.

Summary community level effects

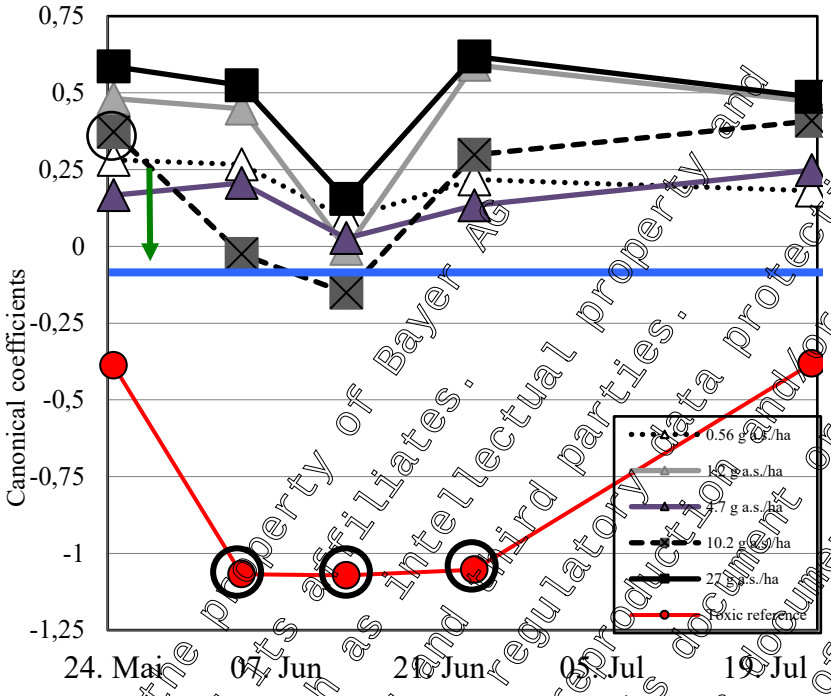
Pitfall



Taxon	Species score	Taxon	Species score
Amara aenea	3.6092	Leiodidae	1.525
Harpalus affinis	3.2423	Elateridae	1.3829
Dermestidae	3.1459	Harpalus other spp.	1.2958
Cydnidae	2.7315	Epicharmus spp.	1.2761
Harpalus distinguendus	2.5884	Brachinus spp.	1.2395
Oxytelinae	2.2492	Harpalus xanthopus	1.2104
Poecilus cupreus	2.2399	Byrrhidae	1.0968
Staphylininae	2.0223	Scarabaeoidea	1.0053
Carabidae (other juveniles)	1.9668	Lygaeidae	1.0036
Rhizophagidae	1.7309	Isopoda (all)	-1.101
Anthicidae	1.6353	Entomobryidae	-1.1238
Bembidion spp.	1.6298	Phaenolithus (adult)	-1.4647

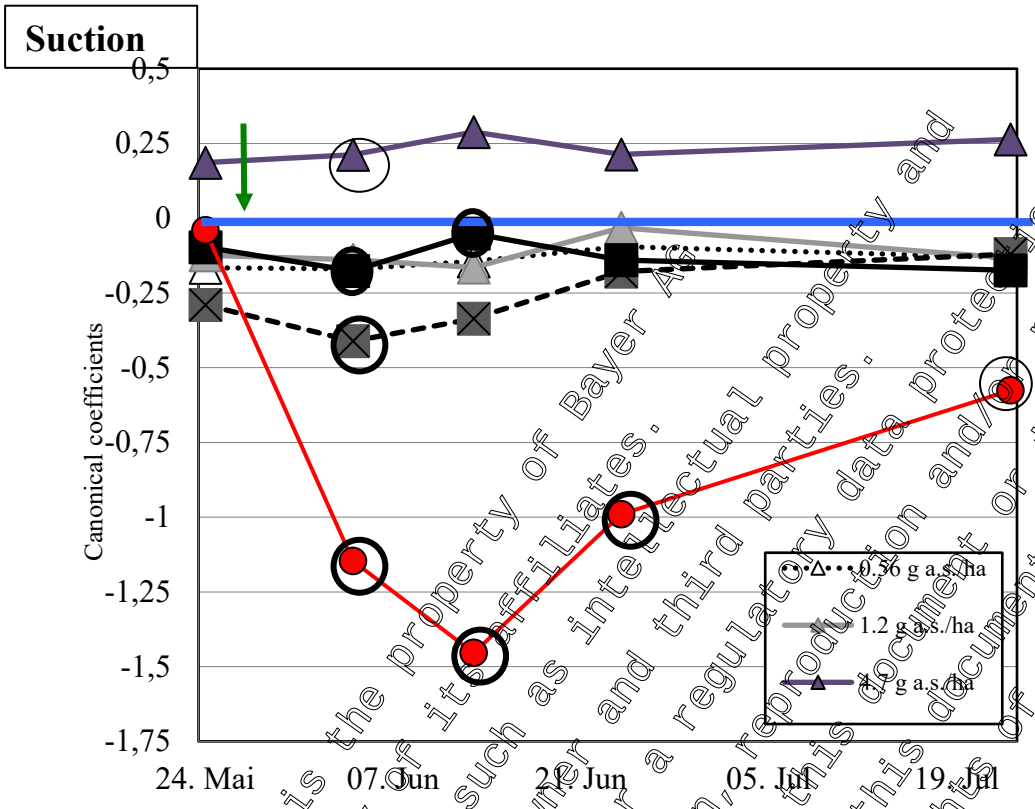
Figure CP 10.3.2.4- 3: Principal Response Curves (first ordination axis)
Test- and toxic reference items were analysed separately but for comparison plotted in one graph. Encircled data points are statistically significant (Monte-Carlo Permutation test, alpha = 0.05 thick circle; alpha = 0.1 thin circle). The 24 largest species scores of the test item treatments are presented (i.e. these species had the largest influence on the shape of the PRC curves of test item treatments). The arrow indicates the application day.

Weed



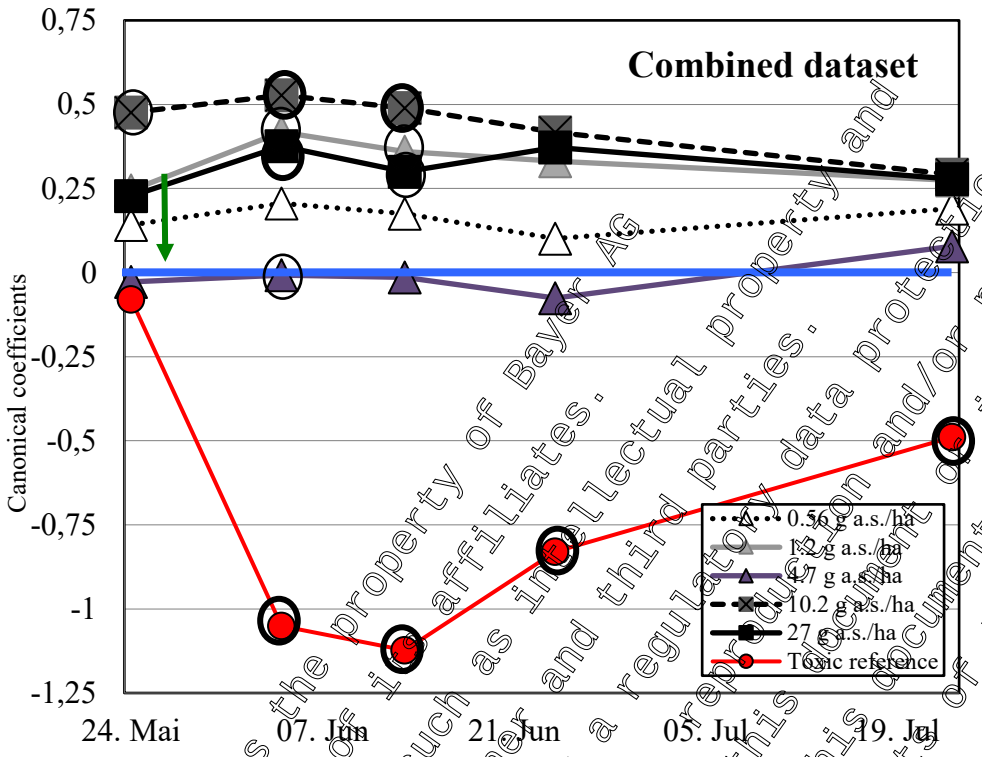
Taxon	Species score	Taxon	Species score
Scheloribates other	3.2561	Phenopelopidae	-0.4873
Pygmephoroidea	0.3401	Tydeoidea	-0.4908
Gamasida Larvae	0.2240	Eriophyoidea	-0.5685
Galumnidae	0.2138	Gamasida Nymph and male	-0.5881
Phytoseiidae (female)	0.106	Zygoribatula undulata	-0.5895
Oribatida Juveniles	-0.034	Tarsonemidae	-0.7192
Bdellidae	-0.2276	Tetranychidae	-0.9147
Scheloribates laevigatus	-0.317	Erythraeoidea	-1.3089
Stigmaeidae	-0.4245	Acaridae	-1.7481
Gamasida other (female)	-0.4708		

Figure CP 10.3.2.4-3: continued



Taxon	Species score	Taxon	Species score
Cicadellidae adults	2.7982	Physanoptera juveniles	-1.0791
Trichogrammatidae	2.5648	Coccoidea juveniles	-1.2637
Mymaridae	2.1586	Ephydridae	-1.3009
Alticinae	1.8305	Chloropidae	-1.3275
Aphelinidae	1.5194	Chironomidae	-1.5893
Lepthyphantes tenuis juveniles	1.3624	Sciaridae	-1.6416
Cicadellidae juveniles	1.3598	Coccinellim juveniles	-1.71
Pachygnatha juvenile	1.3324	Curculionidae others	-1.7959
Miridae juveniles	1.1123	Drosophilidae	-1.8175
Araneidae juvenile	1.0897	Scelionidae	-2.0067
Opomyzidae	0.9708	Ichneumonidae	-2.0721
Calyptrata	0.9963	Sphaeroceridae	-2.6884

Figure CP 10.3.2.4- 4: Principal Response Curves (first ordination axis) Test- and toxic reference items were analysed separately but for comparison plotted in one graph. Encircled data points are statistically significant (Monte-Carlo Permutation test, alpha = 0.05 thick circle, alpha = 0.1 thin circle). The 24 (30 in combined dataset) largest species scores of the test item treatments are presented (i.e. these species had the largest influence on the shape of the PRC curves of test item treatments). The arrow indicates the application day. M=method: P=Pitfall; S=suction; W=weed



M	Taxon	Species score	M	Taxon	Species score
P	Amara aenea	4.0194	S	Delphacidae juveniles	1.6146
P	Harpalus affinis	3.6479	P	Elateridae	1.4351
P	Dermestidae	3.6214	P	Brachinus spp.	1.3957
P	Cydnidae	2.9744	P	Episthemus	1.3712
P	Harpalus distinguendus	2.7628	S	Coccinellini juveniles	1.3668
P	Oxytelinae	2.4525	S	Thysanoptera juveniles	1.3323
S	Sphaeroceridae	2.3942	S	Lepthyphantes tenuis juvenile	-1.3293
P	Carabidae (other juveniles)	2.3836	S	Sminthuridae	-1.3413
P	Staphylininae	2.2456	P	Isopoda (all)	-1.3427
P	Poecilus cupreus	2.21	P	Entomobryidae	-1.4015
S	Scelionidae	2.0686	S	Trichogrammatidae	-1.6501
P	Rhizophagidae	1.9815	S	Mymaridae	-1.8281
P	Leiodidae	1.898	P	Phrurolithus (adult)	-1.8378
P	Anthicidae	1.8273	S	Alticinae	-1.8445
P	Bembidion spp.	1.7168	S	Cicadellidae adults	-2.7282

Figure CP 10.3.2.4-4: continued

Results community analyses

Treatments included in analysis	% Variance accounted for by time	% Variance accounted for by treatment	% Variance (treatment) explained in ax1	% Variance (treatment) explained in ax2	P-value ax1	P-value ax2
PITFALL						
all	28.4	21.3	28.3	16.1	0.010	0.244
Test item rates	30.9	16.2	26.7	12.0	0.218	0.809
0.56 g a.s./ha	35.6	6.8	46.2	18.5	0.793	1.000
1.2 g a.s./ha	36.6	12.2	65.4	12.5	0.056	0.759
4.7 g a.s./ha	33.1	9.8	44.4	20.1	0.529	0.649
10.2 g a.s./ha	34.7	13.5	62.3	15.3	0.089	0.691
27 g a.s./ha	37.6	11.7	53.6	17.7	0.113	0.400
Reference	32.6	19.7	60.9	18.1	0.023	0.023
SUCTION						
all	37.5	21.7	47.8	8.4	0.001	0.693
test item rates	44.1	12.2	18.4	16.4	0.674	0.643
0.56 g a.s./ha	48.8	6.1	43.4	28.9	0.583	0.487
1.2 g a.s./ha	51.8	7.5	44.8	24.8	0.296	0.571
4.7 g a.s./ha	45.8	8.2	54.1	17.2	0.409	0.841
10.2 g a.s./ha	46.2	8.6	56.3	15.7	0.096	0.973
27 g a.s./ha	50	8	52.5	17.6	0.180	0.880
Reference	37.6	23.1	78.5	7.5	0.023	0.735
WEED						
all	27.5	21.0	38.5	19.4	0.001	0.002
test item rates	31.2	14.3	21.2	16.3	0.877	0.875
0.56 g a.s./ha	36.3	8.3	37.0	28.5	0.763	0.222
1.2 g a.s./ha	32.2	11.1	51.9	18.4	0.186	0.232
4.7 g a.s./ha	33.4	6.6	35.2	32.2	0.917	0.222
10.2 g a.s./ha	35.0	10.6	35.4	25.5	0.685	0.248
27 g a.s./ha	32.8	12.4	56	23.4	0.144	0.255
Reference	30.0	20.6	71.7	14.5	0.023	0.238
COMBINED						
all	32.5	21.5	36.5	11.4	0.001	0.311
test item rates	36.9	14.2	20.7	11.2	0.358	0.838
0.56 g a.s./ha	41.8	6.6	42.4	22.2	0.640	0.874
1.2 g a.s./ha	42.8	10.1	55.9	15.3	0.079	0.798
4.7 g a.s./ha	39.1	8.7	46.9	18.1	0.439	0.854
10.2 g a.s./ha	36.6	12.7	22.7	15.1	0.063	0.542
27 g a.s./ha	43	10.0	50.7	17.1	0.120	0.663
Reference	34.7	21.4	70.2	11.9	0.023	0.039

P-values at individual sampling moments (Monte Carlo Permutation/Test-comparison to control)

	PITFALL	0.56 g a.s./ha	1.2 g a.s./ha	4.7 g a.s./ha	10.2 g a.s./ha	27 g a.s./ha	Reference
PITFALL	pre-treatment	0.853	0.122	0.469	0.087	0.248	0.632
	1 week	0.763	0.074	0.195	0.087	0.056	0.027
	2 weeks	0.787	0.102	0.362	0.062	0.056	0.027
	1 month	0.950	0.107	0.398	0.091	0.198	0.027
	2 months	0.936	0.527	0.667	0.449	0.689	0.034
SUCTION	pre-treatment	0.904	0.439	0.656	0.414	0.942	0.839
	1 week	0.176	0.022	0.054	0.022	0.022	0.022
	2 weeks	0.780	0.457	0.214	0.173	0.022	0.022
	1 month	0.883	0.494	0.624	0.332	0.393	0.022
	2 months	0.476	0.549	0.510	0.805	0.764	0.074
WEED	pre-treatment	0.257	0.293	0.846	0.087	0.184	0.257
	1 week	0.874	0.238	0.488	0.708	0.327	0.023
	2 weeks	0.624	0.531	1.000	0.745	0.725	0.023
	1 month	0.677	0.215	0.677	0.504	0.207	0.035
	2 months	0.367	0.540	0.823	0.204	0.168	0.176
COMBINED	pre-treatment	0.881	0.118	0.705	0.087	0.670	0.641
	1 week	0.456	0.067	0.079	0.022	0.022	0.022
	2 weeks	0.808	0.093	0.327	0.022	0.067	0.024
	1 month	1.000	0.201	0.514	0.109	0.147	0.022
	2 months	0.654	0.539	0.707	0.746	0.668	0.028

All	All treatments (test- and reference item) analyzed together
Test item rates	All test item treatments analyzed together
0.56 g, 1.2 g, etc	One test item treatment analyzed separately
Reference	Reference item analyzed separately

Statistically significant at α = 0.1
Statistically significant at α = 0.05
(Monte Carlo permutation test)

Summary population level effects

Effect classification (Based on De Jong *et al*, 2010):		Effect class:
one occasion	Clear adverse treatment related effect but observed on one occasion only	2
< 2 months (a)	Advese effect no longer statistically significant on the last two sampling moments	3a
< 2 months (b)	Adverse effect no longer statistically significant on the the last sampling moment	3b
> 2 months	No recovery from adverse effect within the study period (= 2 months)	8
	Based on visual consideration of trends	2
	Based on 10% significance level and visual consideration of trends	2
	Based on 5% significance level and visual consideration of trends	2

Method: S=suction:P=pitfall: W=weed

method	Order	Thiacloprid OD 240 (g/L)	0.56 g	1.2 g	4.7 g	10.2 g	27 g	Ref
W	ACARI	Gamasida female						3b
W	ACARI	Gamasida other stages						3b
W	ACARI	Tydeoidea						3b
W	ACARI	Oribatida Juveniles						3a
S	ACARI	Oribatida						2
P	ARACHNIDA	Phalangida						3a
P	ARANEAE	Zelotes						2
P	ARANEAE	Gnaphosidae others						2
P	ARANEAE	Thomisidae					3b	3b
S	ARANEAE	Thomisidae juvenile						3a
P	ARANEAE	Pardosa juvenile						3a
P	ARANEAE	Pardosa adult						3b
P	ARANEAE	Lycosidae others						3a
P	ARANEAE	Erigoninae						8
S	ARANEAE	Lepthyphantes tenuis juvenile						3b
P	ARANEAE	Meioneta						3a
S	ARANEAE	Linyphiinae adult						3a
S	ARANEAE	Linyphiidae other juvenile						8
S	ARANEAE	Pachygnatha juvenile						8
S	ARANEAE	Araneidae juvenile					2	3a
P	ARANEAE	Araneoidea other						8
P	COLEOPTERA	Staphylinidae other					2	3a
P	COLEOPTERA	Staphylinidae juveniles				3b	2	3b
S	COLEOPTERA	Coccinellini juveniles						8
P	COLEOPTERA	Coccinellidae adults				2	2	2
P	COLEOPTERA	Corylophidae						3a
P	COLEOPTERA	Lathridiidae						3a
P	COLEOPTERA	Nitidulidae					2	
P	COLEOPTERA	Histeridae						3b
P	COLEOPTERA	Byrrhidae						3b
P	COLEOPTERA	Alticinae			2	2	2	2
S	COLEOPTERA	Alticinae						3b
S	COLEOPTERA	Apion spp.			2	2	2	3a
S	COLEOPTERA	Curculionidae others						3a
P	COLEOPTERA	Curculionidae					3a	3b
P	COLEOPTERA	Elateridae						3b
S	HYMENOPTERA	Ichneumonidae						2
S	HYMENOPTERA	Aphidiinae						3a
S	HYMENOPTERA	Alysiinae						2
S	HYMENOPTERA	Braconidae other						3a
S	HYMENOPTERA	Eulophidae						3b
S	HYMENOPTERA	Mymaridae						3b
S	HYMENOPTERA	Pteromalidae					2	3a
S	HYMENOPTERA	Platygastridae						3a
P	HYMENOPTERA	wingless micro-Hymenoptera						2
S	HOMOPTERA	Aphidoidea						3b
S	HOMOPTERA	Cicadellidae juveniles						3b
S	HOMOPTERA	Cicadellidae adults						2
S	HETEROPTERA	Miridae juveniles						3b
P	HETEROPTERA	Cydnidae						3b
S	DIPTERA	Cecidomyiidae						3b
S	DIPTERA	Lonchopteridae						3b
S	DIPTERA	Agromyzidae						3a
S	DIPTERA	Chloropidae						3a
S	DIPTERA	Ephydridae						3b
S	DIPTERA	Diptera juveniles						8
P	COLLEMBOLA	Isotomidae					3a	
S	COLLEMBOLA	Sminthuridae	2	2	3a	2	3b	
P	COLLEMBOLA	Symphypleona		2	3a	3a	3b	
S	THYSANOPTERA	Thysanoptera juveniles						3b
S	THYSANOPTERA	Thysanoptera adults				2	2	3b
P	ORTHOPTERA	Gryllidae						8

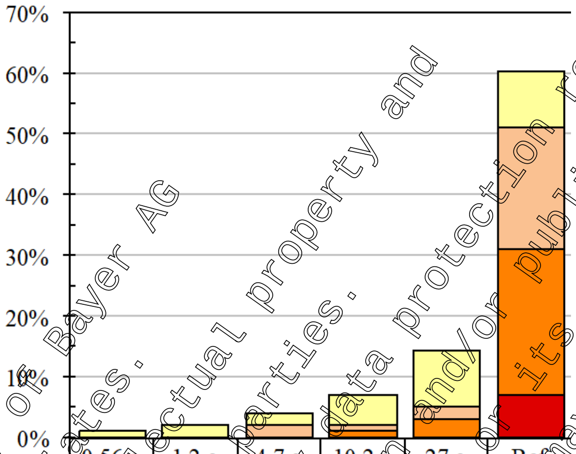
Only taxa with adverse effects in the test- and/or reference item are shown.
See Table 6 for a complete list of taxa examined at the population level

Summary table effect classifications

Graphical presentation of effects

Summarized are percentages of taxa adversely affected by the different treatments, subdivided in different effect classes (duration of effects), as explained in the header of the previous table.

According to De Jong *et al*. (2010), recovery should be demonstrated on two consecutive sampling moments. Due to the 4 week interval between the last two sampling moments this would result in a very conservative effect classification. Effect class 3 was therefore subdivided in class 3a (no longer statistically significant on the last two sampling moments) and class 3b (no longer statistically significant on the last sampling moment).



	0.56 g	1.2 g	4.7 g	10.2 g	27 g	Ref
one occasion	1.0%	2.1%	2.1%	5.2%	9.4%	9.4%
< 2 months (a)	0.0%	0.0%	2.1%	1.0%	2.1%	19.8%
< 2 months (b)	0.0%	0.0%	0.0%	1.0%	3.1%	24.0%
> 2 months	0.0%	0.0%	0.0%	0.0%	0.0%	7.3%

P=pitfall; S=suction

* Mainly of the subfamily Paederinae

Conclusion:

Based on statistical analyses and considerations described in the results chapter, effects of Thiacloprid OD 240 applied to an off-crop grassland arthropod fauna in South-West France are classified as follows: No statistically significant adverse community effects were found at the 0.56 g a.s./ha rate. This rate is classified as the community NOER (No Observed Effect Rate).

Thiacloprid OD 240 applied at the rate of 27 g a.s./ha is the community NOEAER (No Observed Ecologically Adverse Effect Rate). This is the highest rate tested in this study where statistically significant adverse community effects were observed, followed by recovery of the community within one month after treatment. At the test rate of 27 g a.s./ha statistically significant adverse population effects occurred for fourteen taxa, all of which recovered within the two-month sampling period. Therefore, this rate is classified as the population NOEAER.

The community and population LOEAER is higher than 27 g a.s./ha.

Supplemental information from the literature

In addition to the studies performed by BCS in accordance with the requirement a literature search has been performed in accordance with the requirements. From the papers identified during the literature search the following were identified as being potentially relevant for risk assessment. After further evaluation the literature data is considered to provide supplemental information and does not influence the risk assessment.

Report:	[redacted]i; [redacted]; [redacted]; 2006; M-455888-01-2
Title:	Influence of some pesticides on number of predatory mite Typhlodromus pyri (Phytoseiidae). Wpyw wybranych srodkow ochrony roslin na liczebnosc drapiezncgo roztocza dobroczynka gruszowca Typhlodromus pyri (Phytoseiidae).
Report No.:	M-455888-01-2
Document No.:	M-455888-01-2
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

This work presents the results of field tests relating to the impact of plant protection agents on *Typhlodromus pyri*. Material and methods as well as results are summarised for thiacloprid treatments only.
A field experiment was conducted in a 16-year-old orchard, on Ida red apple trees (rootstock M-7, spacing 2.5 × 4). in a random block system. One experimental plot comprised of 4 trees growing in a single row. The plant protection agents used were tested in 4 repetitions. The control trees were sprayed with water. 120 leaves were taken at random from each plot at four times: before the treatment, a week after the treatment and three and five weeks after the treatment. The chemical treatment (Calypso 480 SC, test concentration: 0.2 l/ha) was carried out using a Stihl SR 420 powered backpack mistblower. The number of predatory mites on the leaves was checked in the laboratory using a Nikon SMZ-1 stereoscopic microscope with 7 to 30 times magnification.
The results obtained were subjected to statistical verification using variance analysis and the [redacted]-Keuls test to calculate differences between averages.
Calypso 480 SC had no significant impact on lowering predatory mite numbers on apple tree leaves treated with this product when compared to predator numbers on the control trees.

A. Material

1. Test material

Test item:	Calypso 480 SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	
Storage conditions:	

2. Test area:

Location:	16 year old orchard on Ida red apple trees (root stock M-7, spacing 3 x 4)
Field history:	
Pesticides used on fields:	-

3. Test organism(s)

Species:	*Typhlodromus pyri*
Cultivar:	-
Source of test species:	-
Age of test organisms at study initiation / Crop growth stage at treatment:	-
Holding conditions prior to test:	-
Acclimatisation:	-

B. Study design and methods

1. Test procedure

Test system (study type):	Field experiment
Duration of study:	5 weeks
Treatments:	Control (water) and Calypso 480 SC
Application rate:	0.2 L/ha [96 g a.s./ha]
Number of replicates:	4
Plot size:	4 trees
Application / device / nozzles:	Stihl SR 420 powered backpack mist blower
Water volume:	-
Verification of dispersion:	-
Sampling technique:	120 leaves were taken for each plot
Sampling frequency:	Before application and 1, 3 and 5 weeks after application
Transport/storage of samples:	-

2. Environmental conditions

Soil at study site:	-
pH:	-
Organic matter (C_{org}):	-
$CaCO_3$	-
Cation exchange capacity:	-
Soil textural fractions / extractable micronutrient concentrations [mg per kg soil]:	-
Fertilization:	-

3. Observations and measurements:

Conditional (eg weather) parameters:	-
Biological parameters measured:	Number of *T. pyri*
Measurement frequency:	Before application and 1, 3 and 5 weeks after application
Statistical analyses:	Newman-Keuls test

Results:

Validity criteria:

No validity criteria were stated.

Weather conditions:

No weather conditions were presented.

Biological findings:

Calypso 480 SC had no significant impact on lowering predatory mite numbers on apple tree leaves treated with this product when compared to predator numbers on the control trees.

Table CP 10.3.2.4- 1: Selectivity of thiacloprid to predatory mite *Typhlodromus pyri* – field test

		Number of *T. pyri* / leaf			
Pesticides (active substance)	**Dose (L/ha)**	**Before application**	**One week after application**	**Three weeks after application**	**Five weeks after application**
Control	0.2	0.4 a	0.5 c	0.3 b	0.5 cd
Calypso 480 SC (Thiacloprid)	--	0.4 a	0.5 c	0.6 d	0.6 d

Means in columns followed by the same letter do not differ at 5% level of significance (Newman-Keuls's multiple range test)

Calypso 480 SC had no significant impact on lowering predatory mite numbers on apple tree leaves treated with this product when compared to predator numbers on the control trees.

Comment by the notifier:

The study results indicate a low toxicity of thiacloprid to the predatory mite *Typhlodromus pyri* under field conditions. The information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]1; [redacted]; [redacted]; [redacted]; [redacted]; 2012; M-468254-01-1
Title:	Influence of some insecticides and acaricides on beneficial mites and on Coccinella septempunctata (Coleoptera; Coccinellidae) larvae
Report No.:	M-468254-01-1
Document No.:	M-468254-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Executive summary:

Several experiments have been conducted under laboratory and field conditions to assess the influence of a range of insecticides and acaricides on different predatory mites and on *Coccinella septempunctata*. However, material and methods are summarised here only for thiacloprid treatment, which was only assessed concerning its effects on *Typhlodromus pyri* under field conditions.
The tests were conducted in three apple orchards localised in Central Poland. Experimental plots were fixed for each tested product and for the control. Every plot (replicate) had 3 to 6 trees growing in one row (depending on orchard). Thirty leaves were randomly sampled from each plot and then analysed in the laboratory by Henderson-McBurnie method by counting the numbers of mites present on them. Every tested product was applied in 4-5 replicates, depending on the experiment. Control trees were treated with water. The treatments were accomplished using a knapsack turbine-motor sprayer and a spray volume equivalent to 750 L/ha. Thiacloprid (Calypso 480 SC) was applied with 0.2 L/ha. Mortalities of *Typhlodromus pyri* was assessed 1, 3 and 5 weeks after treatment.
The results of the experiment were analysed by means of ANOVA and Newman-Keuls test. The percentage of mites mortality was calculated from results of the treatments and then corrected according to Abbott.
Thiacloprid revealed low toxicity to predatory mite in comparison to the control trees. After 1, 3, and 5 weeks, the difference in mortality between treatment and control was 0% (IOBC class 1), 50% (IOBC class 2), and 17% (IOBC class 1), respectively. IOBC class 1-2.

Material and methods:

A. Material

1. Test material

Test item:	Calypso 480 SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	-
Storage conditions:	-

2. Test area:

Location:	Apple orchards localised in Central Poland
Field history:	-
Pesticides used on fields:	-

3. Test organism(s)

Species:	*Typhlodermus pyri*
Cultivar:	-
Source of test species:	-
Age of test organisms at study initiation:	-
Crop growth stage at treatment:	-
Holding conditions prior to test:	-
Acclimatisation:	-

B. Study design and methods

1. Test procedure

Test system (study type):	Field test
Duration of study:	5 weeks
Treatments:	Thiacloprid and control (water)
Application rate:	0.2 L/ha [96 g a.s./ha]
Number of replicates:	4-5 replicates
Plot size:	3 to 6 trees
Application / device / nozzles:	Knapsack turbine-motor sprayer
Water volume:	750 L/ha
Verification of dispersion:	-
Sampling technique:	30 leaves randomly sampled
Sampling frequency:	1, 3 and 5 weeks after treatment
Transport/storage of samples:	-

2. Environmental conditions

Soil at study site:	-
pH:	-
Organic matter (C_{org}):	-
$CaCO_3$	
Cation exchange capacity:	-
Soil textural fractions / extractable micronutrient concentrations [mg per kg soil]:	-
Fertilization:	-

3. Observations and measurements:

Conditional (eg weather) parameters:	-
Biological parameters measured:	Number of mites (Mortality)
Measurement frequency:	1, 3 and 5 weeks after treatment
Statistical analyses:	ANOVA, Newman-Keuls, Abbott correction of mortality

Results:

Validity criteria:
No validity criteria were stated

Weather conditions:
No weather conditions were measured.

Conclusion:

Thiacloprid revealed low toxicity to predatory mite in comparison to the control trees. After 1, 3, and 5 weeks, the difference in mortality between treatment and control was 0% (IOBC class 1), 50% (IOBC class 2), and 17% (IOBC class 1), respectively; IOBC class 1-2.

Comment by the notifier:

The study results indicate that thiacloprid caused under field conditions (96 g a.s./ha) a low mortality of the predatory mite *Amblyseius andersoni*. The information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]; 2010; M-466066-01-2
Title:	Impact of neonicotinoid insecticides on beneficial phytoseiid mites
Report No.:	M-466066-01-2
Document No.:	M-466066-01-2
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

The study includes data for several insecticides, only the thiacloprid data is summarised.

Executive summary:

Three insecticides including thiacloprid were tested on their side effects towards phytoseiid mites, specifically *Amblyseius andersoni* (Chant) (Mesostigmata, Phytoseiidae). Material and methods plus results are summarised for thiacloprid only.
Selectivity tests were conducted at the Agrarian Institute of San Michele all'Adige (Fem-Iasma, Trento, Italy in 2006 and 2007) by the same operational methods on both vines and apple trees. Different doses of the reference substance etofenprox were used on vines versus apple trees, while the reference substance flufenoxuron dosage was equal between field experiments, as was thiacloprid. Treatments on both crops used a hand-held nozzle attached to a spray tank, performed when the population of phytoseiid mites was deemed sufficiently high (> 1.5 mobile stages/leaf).
Field tests on vines used plots with the black Pinot variety grafted on Kober 5BB stock, grown on a double "pergola trentina" with layout of 0.80 x 4.2 meters. The vineyard was divided randomly into plots with 4 x 81 m² repeats (24 vines) for each of the chemical treatments/controls with a single exposure for each insecticide on 13-7-2006 for vines. Samples (of phytoseiid *A. andersoni*) were collected one day before treatment (T -1) then T +4, T +7, T +14, T +21, T +28 and T +42 days after treatment. An untreated plot provided a control.
Field tests on apple trees used Red Delicious variety grafted on 6-year-old M9 rootstock. Again, was experimental randomisation, with four repeats of 16 plants for each treatment including an untreated

control. A single exposure event was made on 2-7-2007. Samples (of phytoseiid *A. andersoni*) were collected one day before treatment (T -1), then at day T +7, T +14, T +29 and T +46 afterwards.
For both field experiments, phytoseiid population (of *A. andersoni*) was quantified by microscopic examination of mobile stages, from specimen samples on 25 leaves per repetition (100 leaves/treatment). Values from phytoseiid mites per leaf underwent variance analysis (ANOVA) and Duncan test for $P < 0.05$. Abbott's formula was used for corrected mortality compared with the control. Results were sorted into IOBC field toxicity classes (N = Abbott mortality 0-50% - selective or mildly toxic; M = 51-75% - moderately toxic; T = 76-100% - toxic).
Further laboratory trials adopted published methodology ([redacted] & Ioriatti, 1994) with phytoseiids maintained in a climatic cell and fed mobile stages and eggs of *Tetranychus urticae* Koch (Trombidiformes, Tetranychidae). Female pairs of the same age (10-13 days) of *A. andersoni* were tested with the active substances. Treatments were made by Potter tower, distributing a mixture quantity equivalent to 1.7 ± 0.1 mg per cm^2. Mortality and fertility level (eggs/female) were recorded at T+2 hours, T+1, T+3 and T+7 days with 4 repetitions for each theory (80 females/treatment). An additional water treatment (control) was used. Results were sorted to IOBC laboratory toxicity classes (1 = Abbott mortality 0-30% - selective; 2 = 31-79% - weakly toxic; 3 = 80-99% - toxic; 4 = 99-100% - highly toxic). Toxicity levels were calculated by the Toxicity Index: E (%) = 100 – (100 – M) x 100 (where M = Abbott corrected mortality and R = fertility).
As regards the selectivity of thiacloprid towards phytoseiid mites, the investigations in the apple orchard, in the vineyard and in the laboratory showed that the formulation investigated, did not cause acute toxicity effects of particular severity on the mobile stages of phytoseiids, either as juveniles or as adults. Interference with the fertility of the females and with egg release also proved to be limited. The selectivity levels were statistically comparable to the reference growth regulator substance flufenoxuron and statistically better (with less mortality) than those of the toxic reference etofenprox.

Material and methods:

A. Material

1. Test material

Test item:	Calypso SC
Active substance(s):	Thiacloprid
Adjuvant / Surfactant:	-
Source of test item:	-
Lot/Batch number:	-
Purity:	40.4% a.s.
Storage conditions:	-
Other specifications if stated:	4A Irac Class

2. Test solutions

Vehicle/solvent:	-
Source of vehicle/solvent:	-
Concentration of vehicle/solvent:	-

3. Test organism(s)

Species:	*Amblyseius andersoni* (Chant) (Mesostigmata; Phytoseiidae)
Cultivar:	-
Source of test species:	Agrarian Institute of San Michele all'Adige (Fem-Iasma, Trento, Italy in 2006 and 2007
Age of test organisms at study initiation / Crop growth stage at treatment:	Mobile adults, reproducing
Holding conditions prior to test:	-
Acclimatisation:	-

B. Study design and methods

1. Test procedure

Test system (study type):	*Field vines:* Direct spray application; *Field apple:* Direct spray application; *Lab:* Direct spray application
Duration of study:	*Field vines:* 44 days (T-1 to T+42); *Field apple:* 46 days (T-1 to T+44); *Lab:* 20 days
Treatments:	Thiacloprid, control (untreated) and reference (flufenoxuron, etofenprox)
Test concentrations	Thiacloprid: 25 mL/hL [15 hL/ha =>180 g a.s./ha; 1.7 ± 0.1 mg/cm² => 20.4 g a.s./ha]; flufenoxuron 150 mL/hL; etofenprox: apple 50 mL/hL, vine 100 mL/hL, laboratory 100 mL/hL
Number of replicates:	*Field vines:* 4 repeats with 24 vines; *Field apple:* 4 repeats of 16 trees; *Lab:* 4 repeats (of 20 mites)
Individuals per replicate:	*Field vines:* 25 leaves; *Field apple:* 25 leaves; *Lab:* 20 mite pairs
Test units (type and size):	*Field vines:* Vine plants *in situ; Field apple:* Apple trees; *Lab:* climatic cell and fed mobile forms and eggs of *T. urticae*
Application / device / nozzles:	*Field vines/Field apple:* hand-held nozzle attached to a spray tank, 15 hL/ha; *Lab:* Potter tower 1.7 ± 0.1 mg/cm²
Water volume:	-
Calibration of sprayer:	-

2. Observations and measurements:

Analytical parameters measured:	-
Biological parameters measured	Mortality (% -Abbott corrected); Fertility (%); Toxicity Index: E (%)
Measurement frequency:	*Field vines:* T-1 day, T+4, T+7, T+14, T+21, T+28, T+42 days; *Field apple:* T-1 day, T+7, T+14, T+29, T+46 days; *Lab:* T+2 hours, T+1, T+3 and T+7 days
Statistical analyses:	Variance analysis (ANOVA) and Duncan test; Toxicity Index: E

Results:

Biological findings:

In field trials with vines, thiacloprid interferes weakly with populations of the useful phytoseiid mite within first the two weeks after application (Table CP 10.3.2.4- 2), phasing through class M of moderate toxicity (moderately harmful) around day 7 (T+7) then falling at day 14 (T+14) into class N for non-toxicity and/or weak toxicity (harmless or slightly harmful).

Table CP 10.3.2.4- 2: Mobile stages of *Amblyseius andersoni* found per leaf (on average) on the plants (vines)

	Dates of findings (*)						
	12.7.06 (T – 1 day)	**17.7.06 (T+4 days)**	**20.7.06 (T+7 days)**	**27.7.06 (T+14 days)**	**3.8.06 (T+21 days)**	**10.8.06 (T+28 days)**	**24.8.06 (T+42 days)**
Untreated control	1.75	1.85*a*	3.05*a*	1.85*a*	1.12*a*	0.92*a*	0.63
Thiacloprid	1.77	1.60*a*	1.15*b*	0.93*b*	1.02ab	0.72*a*	0.62
Flufenoxuron [a]	1.77	1.25*a*	1.18*b*	0.93*b*	0.38*bc*	0.75*a*	0.45
Etofenprox [a]	2.05	0.22*b*	0.12*b*	0.15*c*	0.08*c*	0.08*b*	0.25
Significance	0.326	0.007	0.031	0.000	0.017	0.041	0.353

[a] reference substances

Values followed by the same letter (italics) are not significantly different in ANOVA and Duncan Test $P < 0.05$.

Thiacloprid offers selectivity levels comparable to the reference growth regulator substance flufenoxuron and significantly better compared to the known toxic reference substance etofenprox.

Table CP 10.3.2.4- 3: Mobile stages of the phytoseiid mite *A. andersoni* found per leaf (on average) on the apple trees

	Dates of findings (*)				
	30.6.06 (T – 1 day)	**7.7.06 (T+7 days)**	**14.7.06 (T+14 days)**	**31.7.06 (T+29 days)**	**17.8.06 (T+46 days)**
Untreated control	1.13	1.12 a	3.52 a	2.02 a	0.65 a
Thiacloprid	1.38	1.07 a	2.90 a	1.13 b	0.35 b
Flufenoxuron [a]	1.17	0.91 ab	1.90 ab	0.97 b	0.02 c
Etofenprox [a]	1.28	0.13 c	0.42 c	0.83 c	0.17 bc

Note, those values followed by the same letter (italics) are not significantly different in ANOVA and Duncan Test $P < 0.05$.

In field trials with apples, thiacloprid interferes weakly with populations of the phytoseiid mite within first week following the application, falling into class M of moderate toxicity (moderately harmful) around day 7 (T+7), then falling after day 29 (T+29) into class N for non-toxicity and/or weak toxicity (harmless or slightly harmful). Thiacloprid offers levels of selectivity comparable and / or improvements compared to the reference growth regulator Flufenoxuron and statistically more selective (less lethal, less persistent) than the toxic reference substance Etofenprox.

In laboratory trials (Table CP 10.3.2.4- 4), thiacloprid fell into Class 2, and so proved weakly toxic. There was zero mortality with thiacloprid, but fertility was reduced to 36.62% compared to the control. The reproductive suppressant action of the pyrethroid etofenprox was confirmed.

Table CP 10.3.2.4- 4: Laboratory evaluation of the selectivity of the active substance tested

Active substance	Mortality: Abbott (%)	Fertility (%)	Toxicity (%) E	IOBC class [b]
Thiacloprid	0	0.63	36.62	2
Flufenoxuron [a]	5.00	0.74	29.39	1
Etofenprox [a]	100	0	100	4

[a] "reference substances"
[b] IOBC toxicity was: Class 1 = selective (<30%); 2 = slightly harmful (30-79%); 3 = harmful (80-99%); c4 = very harmful (>99%).

Conclusion:

As regards the selectivity of thiacloprid towards phytoseiid mites, the investigations both in the apple orchard and in the vineyard and in the laboratory showed that, of the formulation investigated, was not causing acute toxicity effects of particular severity on the mobile stages of phytoseiids, either as juveniles or as adults. Interference with the fertility of the females and with egg release also proved to be limited. The selectivity levels were statistically comparable to the reference growth regulator substance flufenoxuron and statistically better (with less mortality) than those of the toxic reference etofenprox.

Comment by the notifier:

The study results indicate that thiacloprid caused under field conditions (180 g a.s./ha) a low mortality of the predatory mite *Amblyseius andersoni*. No mortality and moderate effects on reproduction (37%) were observed under extended laboratory conditions (20.4 g a.s./ha). The information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

Report:	[redacted]i; [redacted]; [redacted]; [redacted]; 2012; M-468250-01-1
Title:	Side effects of modern insecticides in fruit growing on the European earwig, Forficula auricularia Einfluss von Insektiziden im Obstbau auf den Ohrwurm Forficula auricularia
Report No.:	M-468250-01-1
Document No.:	M-468250-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

This study includes data on several insecticides, only data relevant to thiacloprid is summarised.

Executive summary:

A field test was carried out in 2008 with four insecticides (including thiacloprid) used in apple production, to study their effects on earwig populations. Material and methods as well as results are summarised for thiacloprid only.
The test was conducted at the JKI-Institute at Dossenheim (Golden Delicious apple variety, M9 rootstock, planting year 1994. Planting system: slender spindle, planting distance: 1.20 x 4 metres). For sampling purposes, bamboo tubes were installed as artificial shelters at the end of May. Once the shelters were clearly occupied by earwigs, and when earwigs were in the 4th instar, the insecticides were applied (4 replicates of 7 trees per plot); Calypso (480 g/l Thiacloprid) was used as test and control plots were left untreated. The numbers of earwigs in the shelters of 5 trees per plot were assessed for up to 10 weeks post-application, by knocking the earwigs out of the tubes, collecting them in a plastic bag and photographing them for later counts from the digital images. Immediately afterwards, the earwigs were released back to the appropriate tree. The effect to the earwig population was calculated according to Henderson & Tilton.
Thiacloprid caused up to 6 weeks after the application a statistical significant reduction in the earwig numbers as compared with the control population. Within two weeks post-application, the earwig number was reduced by 60%. Six week post-application, the effect according to Henderson & Tilton were still about 50% for thiacloprid. After 10 weeks the effect decreased to ~28% and was not anymore statistical significant.

Material and methods:

A. Material

1. Test material

Test item:	Calypso
Active substance(s):	Thiacloprid (480 g/L)
Chemical state and description:	-
Source of test item:	-
Batch number:	-
CAS number:	-
IUPAC name:	-
Purity:	-
Storage conditions:	-
Water solubility:	-

2. Test area:

Location:	IKI-Institute at Dossenheim
Catchment area:	
Amount of agricultural area:	7 trees per plot (4 replicates)
Distance to agricultural area:	-
Cultivated crops:	Apple trees (Golden delicious (M9))
Pesticides used on fields:	-
Buffer zone(s):	-
Run-off or drainage:	-

B. Study design and methods:

1. Test procedure

Test system:	Natural earwig population
Test concentrations	100 mL/m canopy height [equivalent to 144 g a.s./ha for 3 m canopy height]
Application / device / nozzles:	Spray gun attached to the pump of a large sprayer
Water volume:	4.2 L/ treatment group
Calibration of sprayer:	-
Test period:	-
Test principle:	-
Test duration:	10 weeks
Endpoints:	Number of earwigs
Statistics:	Evaluation for significant differences by means of simulation procedures (multiple significance level α = 0.05) using SAS 9.1 (proc mixed). The efficacy rates calculated according to using the method of Henderson & Tilton (1955).

2. Measurements during the test

Water/medium parameters:	-
Biological parameters:	-

3. Sampling

Sampling technique:	bamboo tubes were installed in the trees as artificial shelters
Sampling frequency:	10 days before the application and 7, 14, 28, 42 and 72 days after application
Transport/storage of samples:	Air-tight (bag)

4. Chemical analysis

Guideline/protocol:	-
Method:	-
Pre-treatment of samples:	-
Conduction:	-
Reference item:	-
Recovery:	-
Limit of detection:	-
Limit of quantification:	-

Results:

Validity criteria:

No validity criteria were stated.

Biological findings:

Table CP 10.3.2.4- 5: Effect of insecticides to earwig population. Effect according to Henderson & Tilton (%)

	7 days after treatment	14 days after treatment	28 days after treatment	42 days after treatment	72 days after treatment
Thiacloprid	60.5 (sign.)	51.3 (sign.)	41.8 (sign.)	49.4 (sign.)	~28 (not sign.)

sign. = statistically significant
not sign. = statistically not significant

Thiacloprid caused up to 6 weeks after the application a statistical significant reduction in the earwig numbers as compared with the control population. Within two weeks post-application, the earwig number was reduced by 60%. Six week post-application, the effect according to Henderson & Tilton were still about 50% for thiacloprid. After 10 weeks the effect decreased to ~28% and was not anymore statistical significant.

Comment by the notifier:

The observed effects of the insecticide thiacloprid at an application rate equivalent to 144 g a.s./ha on *Forficula auricularia* (up to 60%) are in line with the results of the available regulatory non-target arthropod data. The information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

CP 10.3.2.5 Other routes of exposure for non-target arthropods

No further studies or risk assessment are presented or required.

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the EU Regulation 1107/2009 and the Guidance Document on Terrestrial Ecotoxicology.

Predicted environmental concentrations used in risk assessment
Predicted environmental concentrations in soil (PEC_{soil}) values were calculated and reported on MCP 9.1.3.

The relevant PEC values considered for TER calculations are summarised in the tables below. Maximum values are used for risk assessments.

Table CP 10.4- 1: max PEC_{soil} values

Compound	Oilseed rape		
	$PEC_{soil, ini}$ [mg/kg]	**$PEC_{soil, accu}$ [mg/kg]**	**$PEC_{soil, max}$ [mg/kg]**
Thiacloprid	0.031	-	**0.031**
Thiacloprid-amide	0.035	0.007[a]	**0.043**
Thiacloprid-sulfonic acid	0.010	-	**0.010**
Thiacloprid-descyano	0.011	0.008[a]	**0.019**

Bold values: worst case considered in risk assessment
[a] PEC_{accu} (mixing depth 20 cm) to account for tillage in arable crops

CP 10.4.1 Earthworms

Table CP 10.4.1- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid OD 240	Earthworm, reproduction	NOEC	0.8 mg prod./kg dws **≙ 0.185 mg a.s./kg dws**	[redacted] (2012) M-426431-01-1 KCP 10.4.1.1/1
Thiacloprid-amide	Earthworm, reproduction	NOEC	**60 mg p.m. /kg dws**	[redacted] (2010) M-362816-01-1 KCA 8.4.1/1
Thiacloprid sulfonic acid	Earthworm, reproduction	NOEC	**≥ 9.49 mg p.m./kg dws**	[redacted] (2010) M-369557-01-1 KCA 8.4.1/2
Thiacloprid-descyano	Earthworm, reproduction	NOEC	**3.1 mg p.m./kg dws**	[redacted] (2013) M-446955-01-1 KCA 8.4.1/3

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment

Risk assessment for earthworms

Based on the endpoints in the table above the TER values are calculated using the following equations:

$TER_{LT} = NOEC / PEC_{soil}$

The risk is considered acceptable if the TER_{LT} is >5.

For lipophilic substances (log P_{OW} > 2) all results from the laboratory studies are corrected by a factor 2 even when the organic matter is less than 10%.
The logP_{OW} does not exceed this trigger (refer to Section 2 of the MCA document, CA 2.7), for any component hence an additional assessment factor is not required.

Table CP 10.4.1- 2: TER calculations for earthworms

Compound	Species	Endpoint [mg/kg]		$PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
OSR						
Thiacloprid OD 240	Earthworm, reproduction	NOEC	0.185	0.031	5.97	5
Thiacloprid-amide	Earthworm, reproduction	NOEC	60	0.043	1395	5
Thiacloprid sulfonic acid	Earthworm, reproduction	NOEC	≥ 9.49	0.010	≥ 949	5
Thiacloprid-descyano	Earthworm, reproduction	NOEC	3.1	0.019	163	5

All TER values calculated with the worst case $PEC_{soil, max}$ values exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

CP 10.4.1.1 Earthworms sub-lethal effects

Report:	[redacted]; [redacted]; 2012; M-426431-01-1
Title:	Thiacloprid OD 240B G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil
Report No.:	KRA-RG-R-107/11
Document No.:	M-426431-01-1
Guidelines:	**ISO 11268-2: 1998 (E) and OECD 222: April 13, 2004; none**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240B G; (Sample description: FAR01509-00; Batch ID: ECE5100633; Material No. 79674910; Specification No. 102000021774 - 01; content: 234.8 g thiacloprid/L; density: 1.039 g/mL).
Principles of the testing procedure: Adult *Eisenia fetida* (approx. 5 months old, 8 x 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in an artificial soil (with 5% peat content) to the nominal test concentrations of 0.2, 0.4, 0.8, 1.6, 3.2 and 6.4 mg test item/kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

Findings:

Validity criteria:

Validity criteria	Recommended	Obtained
Mortality of the adults in the control	≤ 10%	0
Rate of reproduction of juveniles (earthworms per control vessel)	≥ 30	194.9 (160 – 245)
Coefficient of variance of reproduction in the control	≤ 30%	14.0

The validity criteria of the test according to the guideline were fulfilled.

Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days are shown in the following table (values in this table are rounded values).

Table CP 10.4.1-1: Effects on mortality and changes in body weight

Test object	***Eisenia fetida***						
Test item	**Control**	**TCP OD 240B G**					
mg test item/kg dry weight artificial soil	---	0.2	0.4	0.8	1.6	3.2	6.4
Mortality of adult earthworms [%] after 28 days	0	0	0	0	0	0	0
Mean change of body weight of the adults from day 0 to day 28 [%] *	53.87	57.63	56.95	52.59	51.50	55.39	53.75
Standard Deviation	4.75	4.14	5.36	5.34	6.03	2.14	5.50
Mean number of offspring per test vessel after 56 days **	194.9	203.0	173.5	200.5	144.0 **	155.3 **	169.3 **
Standard Deviation	27.4	20.6	20.9	19.5	21.5	24.1	34.6
Coefficient of variance (%)	14.0	10.1	12.1	9.7	14.9	15.6	20.4
% of control	---	104.2	89.0	102.9	73.9	79.7	86,9

* no statistical significance compared to the control (Williams Multiple Sequential t-test, two-sided, α = 0.05)
** statistical significance compared to the control (Williams Multiple Sequential t-test, one-sided smaller, α = 0.05)

The results of the reference test item indicated that the test system was sensitive to the reference test item.

Observations and conclusions:

Mortality
After 28 days of exposure no worms died in the control group and no mortality was observed at any test item concentration.
Effects on growth
Statistically significant different values for the growth relative to the control were not observed at any concentration. EC_{50} could not be calculated.

Therefore, based on biological and statistical significance:
NOEC related to growth: ≥ 6.4 mg test item/kg dry weight artificial soil
LOEC related to growth: > 6.4 mg test item/kg dry weight artificial soil

Effects on reproduction
No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the test concentrations of 0.2, 0.4 and 0.8 mg test item/kg dry weight artificial soil. Statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the three highest test concentration of up to 6.4 mg test item/kg dry weight artificial soil. EC_{50} could not be calculated.

Therefore, based on biological and statistical significance:
NOEC related to reproduction: 0.8 mg test item/kg dry weight artificial soil
LOEC related to reproduction: 1.6 mg test item/kg dry weight artificial soil

Overall conclusions of the study:
Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is 0.8 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be 1.6 mg test item/kg dry weight artificial soil.

CP 10.4.1.2 Earthworms field studies

Not required as the risk to earthworms is acceptable.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Table CP 10.4.2- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid OD 240	*Folsomia candida*	NOEC	14 mg prod./kg dws **≙ 3.2 mg a.s./ kg dws**	[redacted] (2011) M-416014-01-1 KCP 10.4.2.1/1
	Hypoaspis aculeifer	NOEC	316 mg prod./kg dws **≙ 71 mg a.s./ kg dws**	[redacted] (2011) M-417921-01-1 KCP 10.4.2.1/2
Thiacloprid-amide	*Folsomia candida*	NOEC	**10 mg p.m./kg dws**	[redacted] (2001) M-070983-01-1 KCA 8.4.2.1/3
	Hypoaspis aculeifer	NOEC	**≥ 10 mg p.m./kg dws**	[redacted] (2010) M-364270-01-1 KCA 8.4.2.1/3
Thiacloprid sulfonic acid	*Folsomia candida*	NOEC	**≥ 100 mg p.m./kg dws**	[redacted] (2002) M-043981-01-1 KCA 8.4.2.1/4
	Hypoaspis aculeifer	NOEC	**≥ 100 mg p.m./kg dws**	[redacted] (2011) M-420081-01-1 KCA 8.4.2.1/5
Thiacloprid-descyano	*Folsomia candida*	NOEC	**10 mg/kg dws**	[redacted] (2012) M-432536-01-1 KCA 8.4.2.1/7
	Hypoaspis aculeifer	NOEC	**≥ 100 mg p.m./kg dws**	[redacted] (2011) M-419836-01-1 KCA 8.4.2.1/6

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints and PEC_{soil} values used for TER calculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation:

$$TER = NOEC / PEC_{soil}$$

The risk is considered acceptable if the TER is ≥ 5.

Table CP 10.4.2- 2: TER calculations for other non-target soil meso- and macrofauna

Compound	Species	Endpoint [mg/kg]		PEC$_{soil,max}$ [mg/kg]	TER$_{LT}$	Trigger
OSR						
Thiacloprid OD 240	*Folsomia candida*	NOEC	3.2	0.031	103	5
	Hypoaspis aculeifer	NOEC	71	0.031	2290	5
Thiacloprid-amide	*Folsomia candida*	NOEC	10	0.043	232	5
	Hypoaspis aculeifer	NOEC	≥ 10	0.043	≥ 232	5
Thiacloprid sulfonic acid	*Folsomia candida*	NOEC	≥ 1000	0.010	≥ 100 000	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.010	≥ 10 000	5
Thiacloprid-descyano	*Folsomia candida*	NOEC	10	0.019	526	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.019	≥ 5263	5

All TER values calculated with the worst case PEC$_{soil, max}$ values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product.

CP 10.4.2.1 Species level testing

Report:	[redacted]h; [redacted]; 2011; M-416014-01-1
Title:	Thiacloprid OD 240B G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil
Report No.:	FRM-COLL-128/11
Document No.:	M-416014-01-1
Guidelines:	**OECD 232 adopted, September 07, 2009: OECD Guidelines for Testing Chemicals - Collembolan Reproduction Test in Soil; none**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240B G (analytical findings: 22.6% w/w Thiacloprid (YRC 2894) equivalent to 234.8 g/L; density: 1.039 g/mL (20°C), batch ID: ECE5100633, sample description: FAR 01509-00, specification no.: 102000021774 - 01, material no.: 79674910.

10 collembolans (10-12 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 4.4, 7.9, 14.0, 24.9 and 44.3 mg test item/kg artificial soil dry weight (corresponding to 1.0, 1.8, 3.2, 5.6, and 10 mg a.s./kg artificial soil dry weight) at 20 ± 2°C, 400 – 800 lux, 16h light : 8h dark. During the study, they were fed with granulated dry yeast.
Mortality and reproduction were determined after 28 days.

Findings:

Mortality
In the control group 8.8% of the adult *Folsomia candida* died which is below the allowed maximum of ≤ 20% mortality. A LC_{50} could not be calculated due to mathematical reasons. The adult mortality of 50% in the treatment group with 7.9 mg test item/kg artificial soil is not considered test item related.

Reproduction

Concerning the number of juveniles statistical analysis (Williams' test, one-sided smaller, α = 0.05) revealed statistically significant differences between control and the treatment groups with 24.9 and 44.3 mg test item/kg artificial soil dry weight.

Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 14.0 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 24.9 mg test item/kg artificial soil dry weight. The EC_{10}, EC_{20} and EC_{50} values determined by Probit analysis are 15.9, 19.5 and 28.8 mg test item/kg artificial soil dry weight, respectively.

Table CP 10.4.2.1-1: Effects of Thiacloprid OD 240B G on *Folsomia candida*

Test item Test object Exposure	Thiacloprid OD 240B G *Folsomia candida* Artificial soil		
mg test item (mg a.s.)/kg soil dry weight nominal concentration	**Adult mortality (%)**	**Mean number of juveniles±SD**	**Reproduction (% of control)**
Control	8.8	1409.3 ± 116.2	-
4.4 (1.0)	20.0	1284.3 ± 159.6	91.1 n.s.
7.9 (1.8)	50.0	1421.8 ± 180.3	100.9 n.s.
14.0 (3.2)	27.5	1309.5 ± 61.5	92.9 n.s.
24.9 (5.6)	30.0	887.0 ± 137.0	62.9*
44.3 (10.0)	40.0	240.3 ± 44.5	17.0*
		Adult mortality	Reproduction
LC_{10}/EC_{10} (mg test item/kg soil dry weight)		n.d.	15.9 1)
LC_{20}/EC_{20} (mg test item/kg soil dry weight)		n.d.	19.5 1)
$NOEC_{reproduction}$ (mg test item/kg soil dry weight)			14.0
$LOEC_{reproduction}$ (mg test item/kg soil dry weight)			24.9

The calculations were performed with un-rounded values.
1) Probit analysis
n.d. = could not be determined due to mathematical reasons
* = statistically significant (William's-t test one-sided-smaller, α = 0.05)
n.s. = statistically not significant (William's-t test one-sided-smaller, α = 0.05)

Conclusions:

$NOEC_{reproduction}$: 14.0 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$: 24.9 mg test item/kg artificial soil dry weight.

Report:	[redacted]t; [redacted]; 2011; M-417921-01-1
Title:	Thiacloprid OD 240 G: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil
Report No.:	KRA-HR-55/11
Document No.:	M-417921-01-1
Guidelines:	**OECD 226 from October 03, 2008: OECD guideline for the Testing of Chemicals - Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil; yes, 15 days of exposition instead of 14 days**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid OD 240 G; (Batch ID: ECE5100633; Specification No.: 102000021774 - 01; Sample description: FAR01509-00; Material No.: 79674910; content: 234.8 g thiacloprid/L; density 1.039 g/mL)

Ten adult, fertilised, female *Hypoaspis aculeifer* per replicate (8 control replicates and 4 replicates for each test item concentration) were exposed to control and treatments. Concentrations of 100, 178, 316, 562 and 1000 mg test item/kg dry weight artificial soil were tested. In each test vessel 20 g dry weight artificial soil were weighed in. The *Hypoaspis aculeifer* were of a uniform age not differing more than three days (28 days after start of egg laying). During the test, they were fed with cheese mites bred on brewer's yeast. During the study a temperature of 20 ± 2 °C and light regime of 400 – 800 Lux, 16 h light : 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 74.8% fine quartz sand, 5% Sphagnum peat, air dried and finely ground, 20% Kaolin clay and approximately 0.2% Calcium carbonate ($CaCO_3$).
After a period of 15 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution (20% ethylene glycol, 80% deionised water, 2 g detergent/L fixing solution were added). All *Hypoaspis aculeifer* were counted under a binocular.

Findings:

Mortality
In the control group 11.3% of the adult *Hypoaspis aculeifer* died which is below the allowed maximum of ≤ 20% mortality. The LC_{50} for the test item could not be calculated and is considered to be ≥ 1000 mg test item/kg dry weight artificial soil.
Reproduction
Concerning the number of juveniles statistical analysis (Williams t-test, one-sided smaller, $\alpha = 0.05$) revealed significant differences between control and the two highest concentrations of the test item. Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 316 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 562 mg test item/kg dry weight artificial soil. EC_x-values could not be calculated.

Table CP 10.4.2.1-2: Effects of Thiacloprid OD 240B G on *Hypoaspis aculeifer*

Test item Test object Exposure	Thiacloprid OD 240 G *Hypoaspis aculeifer* Artificial Soil		
mg test item/kg dry weight artificial soil	**% mortality (Adults)**	**Mean number of juveniles per test vessel ± standard dev.**	**Reproduction (% of control)**
Control	11.3	224.4 ± 46.5	---
100	5.0	175.3 ± 36.7	78.1
178	22.5	176.5 ± 51.3	78.7
316	2.5	183.0 ± 77.7	81.6
562	0.0	118.3 * ± 18.9	52.7
1000	13.3	191.7 * ± 77.0	85.4
			Reproduction
NOEC (mg test item/kg dry weight artificial soil)			316
LOEC (mg test item/kg dry weight artificial soil)			562

* Statistical significance (Williams t-test, one-sided smaller, $\alpha = 0.05$) was found.

Conclusions:

NOEC: 316 mg test item/kg dry weight artificial soil.
LOEC: 562 mg test item/kg dry weight artificial soil.

CP 10.4.2.2 Higher tier testing

Not required as the risk for other non-target soil meso- and macro-organisms is acceptable.

CP 10.5 Effects on soil nitrogen transformation

Table CP 10.5- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid OD 240	Nitrogen transformation 28 d	No influence	≥ 6.93 mg prod./kg dws **≙ ≥ 1.56 mg a.s./ kg dws**	[redacted] (2013) M-462791-01-1 KCP 10.5/1
Thiacloprid		No influence	**≥ 2.57 mg a.s./kg dws**	[redacted] (1995) M-001022-02-1 KCA 10.5/1
Thiacloprid-amide		No influence	**≥ 16 mg/kg dws**	[redacted] (2008) M-301378-01-1 KCA 10.5/2
Thiacloprid sulfonic acid (Na salt)		No influence	**≥ 4 mg/kg dws**	[redacted] (2008) M-301383-01-1 KCA 10.5/3
Thiacloprid-descyano		No influence	**≥ 5 mg/kg dws**	[redacted] (2012) M-422083-01-1 KCA 10.5/4

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment

Risk assessment for Soil Nitrogen Transformation

Table CP 10.5- 2: Risk Assessment for soil micro-organisms

Compound	Species	Endpoint [mg/kg]	$PEC_{soil,max}$ [mg/kg]	Refinement required
Thiacloprid OD 240	Soil micro-organisms	≥ 1.56 mg a.s./kg dws	0.031	No
Thiacloprid	Soil micro-organisms	≥ 2.57 mg a.s./kg dws	0.031	No
Thiacloprid-amide	Soil micro-organisms	≥ 16 mg/kg dws	0.043	No
Thiacloprid sulfonic acid (Na salt	Soil micro-organisms	≥ 4 mg/kg dws	0.010	No
Thiacloprid-descyano	Soil micro-organisms	≥ 5 mg/kg dws	0.019	No

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a compound/product is ≤ 25% after 100 days.

In no case did deviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This indicates acceptable risk to soil micro-organisms for the intended uses.

Report: [redacted]4; [redacted]; 2013; M-462791-01-1
Title: Thiacloprid OD 240 G: Effects on the activity of soil microflora (nitrogen transformation test)
Report No.: 13 10 48 044 N
Document No.: M-462791-01-1
Guidelines: OECD 216 (2000); none
GLP/GEP: yes

Objective:
The purpose of this study was to determine the effects of the test item on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

Material and methods:
Test item: Thiacloprid OD 240 G; Batch ID: ECE7101227; BCS-code: BCS-AA56362; Specification No.: 102000021374 – 01; Material No.: 79674910; Density (20 °C): 1.040 g/mL; Purity: 23.0% w/w.

A loamy sand soil (DIN 4220) was exposed for 28 days to 0.69 and 6.93 mg test item/kg soil dry weight. Application rates were equivalent to 0.5 and 5.0 L test item/ha. The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 0.5%). NH_4-nitrogen, NO_3- and NO_2-nitrogen were determined by an Autoanalyzer at different sampling intervals (0, 7, 14 and 28 days after treatment).

Findings:

Validity criteria:

The coefficients of variation in the control (NO_3-N) were maximum 5.4% and thus fulfilled the demanded range (≤ 15%).

Reference test:

In a separate study the reference item Dinoterb caused a stimulation of nitrogen transformation of +33.7% and +42.6% at 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, determined 28 days after application.

Biological findings:

Thiacloprid OD 240 G caused a temporary inhibition of the daily nitrate rate at the tested concentration of 0.69 mg/kg dry soil at time interval 7-14 days after application. However, no adverse effects of thiacloprid OD 240 G on nitrogen transformation in soil could be observed at both test concentrations (0.69 mg and 6.93 mg test item/kg dry soil) at the end of the test, 28 days after application (time interval 14-28). Differences from the control of -16.2% (test concentration 0.69 mg/kg dry soil) and -14.4% (test concentration 6.93 mg/kg dry soil) were measured at the end of the 28-day incubation period (time interval 14-28).

Table CP 10.5- 2: Effects on nitrogen transformation in soil after treatment with Thiacloprid OD 240 G

Time Interval (days)	Applications rates [Thiacloprid OD 240 G]											
	Control			0.69 mg test item/kg soil dry weight equivalent to 0.5 L test item/ha				6.93 mg test item/kg soil dry weight equivalent to 5.0 L test item/ha				
	Nitrate-N[1)]			Nitrate-N[1)]			% difference to control	Nitrate-N[1)]			% difference to control	
0-7	3.00	±	0.18	3.16	±	0.17	+5.3 n.s.	3.28	±	0.26	+9.4 n.s.	
7-14	1.88	±	0.26	1.29	±	0.15	-31.2 *s.	1.55	±	0.25	-17.5 n.s.	
14-28	0.91	±	0.11	1.06	±	0.21	+16.2 n.s.	0.78	±	0.10	-14.4 n.s.	

The calculations were performed with unrounded values

1) Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation

n.s. = No statistically significant difference to the control (Student's t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

*s. = statistically significantly different to control (Student's t-test for homogeneous variances, 2-sided, $p \leq 0.05$)

Conclusion:

Thiacloprid OD 240 G caused no adverse effects (difference to control < 25%, OECD 216) on the soil nitrogen transformation (measured as NO_3-N production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 6.93 mg test item/kg soil, which are equivalent to application rates up to 5.0 L test item/ha and equivalent to 1.56 mg a.s./kg dws.

CP 10.6 Effects on terrestrial non-target higher plants

Risk assessment for Terrestrial Non-Target Higher Plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev 2 final, 2002). It is restricted to off-field situations, as non-target plants are defined as non-crop plants located outside the treated area. Spray drift from the treated areas may produce residues of a product in adjacent off-crop areas.

A post-emergence screening test and Tier 1 seedling emergence study have been conducted with the formulation Thiacloprid OD 240. The endpoints relevant for the risk assessment are compiled in the table below.

Table CP 10.6- 1: Endpoints used in risk assessment

Test organism	Study type, tested rate	Max. effects	Most sensitive species	References
Terrestrial non-target plants; 11 species	Post-emergence screening, 17 days, 0.814 L prod./ha	0% phytotoxicity	Not applicable	[redacted] (2002) M-071045-01-1 KCP 10.6.1/1
Terrestrial non-target plants; 10 species	Seedling emergence, Tier 1 single dose, 14 days, 0.4 L prod./ha	11.5% reduction of shoot dry weight	*Allium cepa*	[redacted] (2012) M-440266-01-1 KCP 10.6.2/1

In the case of Thiacloprid OD 240, neither the post-emergence screening test, nor the tier 1 seedling emergence study showed phytotoxic effects >50% at the tested rates of 0.814 and 0.4 L prod./ha, respectively.

To demonstrate the low risk of the formulation to terrestrial non-target plants, TER calculations have been performed for the representative use in oilseed rape. The test rates given in Table 10.6-1 were used as most conservative endpoint estimates (i.e., ER_{50} > 0.814 and > 0.4 L prod./ha, respectively).

Table CP 10.6- 2: Deterministic risk assessment based on the ER_{50} > 0.814 L prod./ha (vegetative vigour)

Crop	Use pattern	Distance from field edge [m]	Drift [%]	PER* [L prod./ha]	TER (Trigger = 5)
Oilseed rape	2 × 0.3 L prod./ha (10 d interval)	1	2.38 [1)]	0.011 [2)]	> 74

* Predicted environmental rate
1) Basic drift value for two applications in field crops
2) Considering MAF = 1.5 from EFSA GD Birds & Mammals (2009)

Table CP 10.6- 3: Deterministic risk assessment based on the ER_{50} > 0.4 L prod./ha (seedling emergence)

Crop	Use pattern	Distance from field edge [m]	Drift [%]	PER* [L prod./ha]	TER (Trigger = 5)
Oilseed rape	2 × 0.3 L prod./ha (10 d interval)	1	2.38 [1)]	0.005 [2) 3)]	> 80

* Predicted environmental rate
1) Basic drift value for two applications in field crops
2) Considering MAF = 1.5 from EFSA GD Birds & Mammals (2009)
3) Considering 50% interception by off-crop vegetation

From the calculations above, it is concluded that effects of the product on non-target terrestrial plants are not to be expected.

CP 10.6.1 Summary of screening data

Report:	[redacted]x; [redacted]; 2002; M-071045-01-1
Title:	Thiacloprid OD 240: Post-emergence screening for herbicidal activity
Report No.:	LKC NTPscr 06/02
Document No.:	M-071045-01-1
Guidelines:	**Not specified**
GLP/GEP:	**no**

Objective:

The purpose of this herbicidal screening test was to evaluate potential phytotoxic effects of Thiacloprid OD 240 on the vegetative vigour of eleven non-target terrestrial plant species following a post-emergence application of the product to the plant foliage.

Materials and methods:

Test item: Thiacloprid OD 240; Batch No.: 07690/0086(0082); Fox No.: 06069-00; Content of a.s.: 243.95 g/L.

A total of eleven species were tested in this post-emergence screening test including six dicotyledonous and five monocotyledonous species representing seven plant families (see table below).

Table CP 10.6.1- 1: Species tested

Test species					
Plant family	**EPPO Code**	**Species**	**Plant family**	**EPPO Code**	**Species**
Dicotyledonae			**Monocotyledonae**		
Malvaceae	ABUTH	*Abutilon theophrasti*	Poaceae	ALOMY	*Alopecurus myosuroides*
Amaranthaceae	AMARE	*Amaranthus retroflexus*	Poaceae	AVEFA	*Avena fatua*
Chenopodiaceae	BEAVA	*Beta vulgaris*	Poaceae	ECHCG	*Echinochloa crus-galli*
Rubiaceae	GALAP	*Galium aparine*	Poaceae	SETVI	*Setaria viridis*
Convolvulaceae	IPHOE	*Ipomoea hederacea*	Poaceae	ZEAMX	*Zea mays*
Brassicaceae	SINAL	*Sinapis alba*			

Seeds of the eleven species were planted in 420 cm^2 greenhouse pots. The pots were filled with a sandy loam soil with an organic matter content of 2.5-3.0%. Ten seeds per species were sown. Plants were grown for a period of about 14 days before application. Test conditions: temperature 22°C during day, 15°C at night; 14 h photoperiod with light intensity of 8 klux; relative humidity 50%.
Spray treatments were applied in an automatic spray chamber for primary screening tests. The spray chamber was adjusted as follows: pressure 3 bar; height of spray boom 45 cm; nozzle type: 8003E; water application rate to the target area 1000 litres/ha. The test item was applied at rates of 400 and 814 mL formulation/ha, equivalent to 96 and 195 g a.s./ha.
The final evaluation was done 17 days after treatment. Assessment of phytotoxicity was done by visual observations using a rating scale of 0 to 100%, where 100% represented complete destruction of above ground parts and 0% represented no visual damage (normal growth) as compared to untreated plants.

Findings:

None of the eleven species showed phytotoxic effects at the two application rates tested. The results of the final assessment are summarised in the table below.

Table CP 10.6.1- 2: Phytotoxic effects of Thiacloprid OD 240 at different application rates

Thiacloprid OD 240 Post-Emergence-Test Phytotoxicity ratings in% at different application rates (17 days after application)		
Species	**400 mL Formulation/ha**	**814 mL Formulation/ha**
Zea mays	0	0
Beta vulgaris	0	0
Alopecurus myosuroides	0	0
Avena fatua	0	0
Echinochloa crus-galli	0	0
Setaria viridis	0	0
Abutilon theophrasti	0	0
Amaranthus retroflexus	0	0
Galium aparine	0	0
Ipomoea hederacea	0	0
Sinapis alba	0	0

Conclusion:

Following a foliar application of Thiacloprid OD 240 at rates up to 0.814 L product/ha to eleven non-target terrestrial plant species, no phytotoxic effects reaching or exceeding the 50% level were observed in this post-emergence screening test.

CP 10.6.2 Testing on non-target plants

Report: [redacted]; 2012; M-440266-01-1
Title: Thiacloprid OD 240B G - Effects on the seedling emergence and growth of ten species of non-target terrestrial plants (Tier 1)
Report No.: SE120003
Document No.: M-440266-01-1
Guidelines: **OECD 208 Guidelines for the testing of chemicals, Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test.; not specified**
GLP/GEP: **yes**

Objective:

The purpose of this specific study was to evaluate potential phytotoxic effects of Thiacloprid OD 240BG G on the seedling emergence and growth of ten non-target terrestrial plant species following a pre-emergence application of the product to the soil surface.

Material and methods:

Test item: Thiacloprid OD 240B G; Batch ID: ECE7100937; Material no.: 79674910; Specification no.: 102000021774-01; Sample description: TOX09597-00; Analysed content: 242.2 g a.s./L (23.2% w/w).

A total of ten species were tested in this seedling emergence and growth test including six dicotyledonous and four monocotyledonous species representing eight plant families. Five seeds of each species were sown in 10.5 cm pots in the glasshouse. The soil surface of the pots was treated with 0.4 L/ha Thiacloprid OD 240B G using a laboratory track sprayer. The water volume rate was 200 L/ha. Each pot (replicate) contained 5 seeds and there were 20 seeds per species treated, i.e. 4 replicates. Control pots were treated with deionised water. Following application, pots were maintained under glasshouse conditions with a temperature control regulated to get 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod. Emergence was assessed daily until 70% emergence of control seedlings was reached. Emergence, survival and visual phytotoxicity were then recorded 7 and 14 days once 70% emergence had been achieved against the deionised water treated controls. The study was terminated 14 days after 70% emergence in the controls of each species. Parameters measured were emergence, survival of the emerged seedlings, visual phytotoxicity, plant growth stage and shoot dry weight.

Findings:

Validity criteria:
This study is valid as the validity criteria of 70% emergence and 90% survival of the emerged seedlings at the end of the test in the untreated controls were achieved for all species.

Analytical findings:
Analysis of thiacloprid in the spray solution yielded 103.3% of nominal.

Biological findings:
A summary of the findings for each species is provided in the following table:

Table CP 10.6.2- 1: Summary of the effects of Thiacloprid OD 240B G on terrestrial plants

Species	Emergence (% inhibition)	Survival (% inhibition)	Phytotoxicity	Shoot Dry Weight (% inhibition)	BBCH (control / treated) min - max
Dicotyledonae					
Beta vulgaris	11.1	6.3	0	-0.4	12-14/12-14
Brassica napus	0	0	0	-2.2	13-14/13-14
Cucumis sativus	0	0	0	2.2	12-13/12-13
Glycine max	5.3	0	0	-3.2	12-13/12-13
Helianthus annuus	-6.3	0	0	3.9	14-16/14-16
Lycopersicon esculentum	5.3	0	0	2.7	13-14/13-14
Monocotyledonae					
Allium cepa	11.1	0	0	11.5	11-12/10-12
Avena sativa	0	0	0	-7.3	12-13/12-13
Triticum aestivum	-5.3	0	0	-5.0	13-21/13-21
Zea mays	0	0	0	-2.5	13-14/13-14

Negative figures indicate that there was an increase compared to the control

Emergence for *Beta vulgaris*, *Glycine max*, *Lycopersicon esculentum* and *Allium cepa* was reduced by 11.1, 5.3, 5.3 and 11.1% compared to the control, respectively. Survival for *Beta vulgaris* was reduced by 6.3% compared to the control. Shoot dry weight for *Cucumis sativus*, *Helianthus annuus*, *Lycopersicon esculentum* and *Allium cepa* was reduced by 2.2, 3.9, 2.7 and 11.5% compared to the control, respectively. None of the shoot dry weight reductions was statistically significant. The study revealed no adverse effects of the test item on growth stage development and the plants exhibited only normal variation in growth. No symptoms of phytotoxicity were observed.

Conclusion:

Following a soil application of Thiacloprid OD 240B G at a rate of 0.4 L product/ha to ten non-target terrestrial plant species, no adverse effects on emergence, seedling survival, visual phytotoxicity, growth and shoot dry weight reaching or exceeding the 50% effect level were observed in this seedling emergence and growth study.

CP 10.6.3 Extended laboratory studies on non-target plants

In view of the results presented above, no further studies are deemed necessary.

CP 10.6.4 Semi-field and field tests on non-target plants

Please refer to Point CP 10.6.3.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

No studies are required.

CP 10.8 Monitoring data

No monitoring data are available.