Bayer CropScience

M-490958-02-5

Document Title

Summary of the ecotoxicological studies
Propineb WG 70 (700g/kg)

- Amendment -

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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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number
2014-07-10	Initial dossier	M-490958-01-1 (Version 1)
2015-03-20	Amended subsection 10.1.2.2, page 28 and 46	M-490958-02-1 (Version 2)

[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

Use pattern considered in this risk assessment

Table10- 1: Intended application pattern

Crop	Timing of application (range)	Number of applications	Application interval [days]	Maximum label rate (range) [kg pr/ha]	Maximum application rate, individual treatment (ranges) [kg a.s./ha] propineb
Orchards (Apple)	BBCH 40-59 BBCH 60-73	1 1	14	2.25	1.575
Grapes I	BBCH 40-59	2	10	1.6	1.12
Grapes II	BBCH > 70	2	10	2.0	1.4
Tomato (greenhouse use)	-	4	7	3.0	2.1

Definition of the residue for risk assessment

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

Table10- 2: Definition of the residue for risk assessment

Compartment	Residue Definition
Soil	Propineb (LH 30/Z) 4-Methyl-imidazoline (BCS-AB78877) Propineb-DIDT (BCS-CU99534) PTU (BCS-AA-66386) PU (BCS-AA17927)
Groundwater	Propineb (LH 30/Z) 4-Methyl-imidazoline (BCS-AB78877) Propineb-DIDT (BCS-CU99534) PTU (BCS-AA-66386) PU (BCS-AA17927)
Surface water	Propineb (LH 30/Z) 4-Methyl-imidazoline (BCS-AB78877) Propineb-DIDT (BCS-CU99534) PTU (BCS-AA-66386) PU (BCS-AA17927)
Sediment	Propineb (LH 30/Z)
Air	Propineb (LH 30/Z)

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), refered to in the following as "EFSA GD 2009".

CP 10.1.1 Effects on birds

Table 10.1.1- 1: Endpoints used in risk assessment

Test substance	Exposure	Species	Endpoint		Reference
Propineb	Acute risk assessment	Japanese quail	LD_{50}	>5000 mg a.s./kg bw	KCA 8.1.1.1/01 LoEP[1] M-017018-01-2
	Reproductive risk assessment	Japanese quail (6 wk)	NOAEL repro (ind.)	472 ppm 59.2 mg a.s./kg bw/d	KCA 8.1.1.3/01 [redacted] (1994) M-017014-01-1
			NOAEL repro (pop.)	2130 ppm 234 mg a.s./kg bw/d	KCA 8.1.1.3/02 Amended report [redacted] (2004) M-017014-02-1
		Japanese quail (13 wk)	NOAEL repro	≥ 550 ppm 64.7 mg a.s./kg bw/d	KCA 8.1.1.3/03 [redacted] (2014) M-487532-01-1

Note:
- studies referring to KCA are filed in the dossier for the active substance
- studies written in grey type are referring to studies in the corresponding Baseline-dossier, whereas studies in black type are studies of the Supplemental dossier

[1] List of Endpoints (2003): EU Review Report for propineb (SANCO/7574/VI/97-final)

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

Crop scenario	Most critical window of relevance for generic focal species scenario	Generic focal species	Representative species	Short cut values for reproductive RA based on RUD90	Short cut values for reproductive RA based on RUDm
Orchards 2 × 1.575 kg/ha BBCH ≥ 40 14d interval	Spring, Summer	Small insectivorous bird "tit"	Blue tit	46.8	18.2
	BBCH ≥ 40	Small insectivorous/worm feeding bird "thrush"	Robin	2.2	0.8
	BBCH ≥ 40	Small granivorous bird "finch"	Serin	8.2	3.8
Grapes I 2 × 1.12 kg/ha BBCH 40 -59 10d interval	BBCH ≥ 20	Small insectivorous bird "redstart"	Black redstart	25.7	9.9
	BBCH ≥ 40	Small granivorous bird "finch"	Linnet	7.4	3.4
	BBCH ≥ 40	Small omnivorous brid "lark"	Wood lark	7.2	3.3
Grapes II 2 × 1.4 kg/ha BBCH >70 10d interval	BBCH ≥ 20	Small insectivorous bird "redstart"	Black redstart	25.7	9.9
	BBCH ≥ 40	Small granivorous bird "finch"	Linnet	7.4	3.4
	BBCH ≥ 40	Small omnivorous brid "lark"	Wood lark	7.2	3.3
	Ripening	Frugivorous bird "thrush/starling"	Song thrush	28.9	14.4

Identical focal species are relevant for the risk assessment in grapes I and grapes II, except for frugivorous birds which occur only in the late growth stages (BBCH >70) in grapes II. Additionally, the application rate in grapes II is higher and covers the use in grapes I. Therefore, only the use in grapes II (besides the use in orchards) is addressed in the risk assessment presented below.

ACUTE DIETARY RISK ASSESSMENT

Table 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}				
Propineb								
Orchards Spring, Summer	Small insectivorous bird "tit"	1.575	46.8	1.2	89	> 5000	>57	10
Orchards BBCH ≥ 40	Small insectivorous/worm feeding bird "thrush"		2.2		4.2		>1203	
Orchards BBCH ≥ 40	Small granivorous bird "finch"		8.2		15.5		>323	
Grapes BBCH ≥ 20	Small insectivorous bird "redstart"	1.4	25.7	1.3	47		>107	
Grapes BBCH ≥ 40	Small granivorous bird "finch"		7.4		13.5		>371	
Grapes BBCH ≥ 40	Small omnivorous bird "lark"		7.2		13.1		>382	
Grapes Ripening	Frugivorous bird "thrush/starling"		28.9		53		>95	

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.

LONG-TERM REPRODUCTIVE ASSESSMENT

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

Crop	Generic focal species	DDD				DDD	NOAEL [mg a.s./ kg bw/d]	TER_{LT}	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Propineb									
Orchards Spring, Summer	Small insectivorous bird "tit"	1.575	18.2	1.4	0.53	21.3	≥64.7	**3.0**	5
Orchards BBCH ≥ 40	Small insectivorous/worm feeding bird "thrush"		0.8			0.93		70	
Orchards BBCH ≥ 40	Small granivorous bird "finch"		3.8			4.4		15	
Grapes BBCH ≥ 20	Small insectivorous bird "redstart"	1.4	9.9	1.5		11.0		5.9	
Grapes BBCH ≥ 40	Small granivorous bird "finch"		3.4			3.8		17	
Grapes BBCH ≥ 40	Small omnivorous bird "lark"		3.3			3.7		18	
Grapes Ripening	Frugivorous bird "thrush/starling"		14.4			16.0		**4.0**	

Bold values do not meet the Tier 1 TER trigger

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level do not exceed the a-priori-acceptability trigger of 5 for the small insectivorous bird scenario in orchards and the frugivorous bird scenario in grapes. Thus, a refined risk assessment for these scenarios is presented below.

Refined risk assessment – small insectivorous birds in orchards

More realistic exposure parameters were considered in the refined risk assessment.

Based on the results of a field trial by [redacted] (KCP 10.1.1.2 /01, [redacted] [redacted].; 2013; M-460299-01) aiming to measure the propineb residue decline on insects, a DT_{50} value of 1.97 days (combined for propineb and PTU) was calculated.

With that DT_{50}, refined MAF_m = 1.01 and 21-d f_{TWA} = 0.26 are calculated with a moving time window calculator, for 2 applications with a 14d interval, which can be used to refine the default values in the reproductive risk assessment for the small insectivorous bird "tit".

TWA Residue Calculator ver. 2

Enter data into the yellow cells only

SFO calculation of residue concentration (PPB + PTU) on foliage dwelling invertebrates in orchards (DT50 = 1.97d)
(2x 1.575 kg as/ha; 14d int, RUD 21)
C(ini) = 1.575 x 21 = 33.08 mg/kg
MAF: 1.007; 21-d f_{TWA}: 0.257
C(max) = 33.08 x 1.007 = 33.31 mg/kg

DT50 Type	SFO		TWA interval (days):	21
DT50 (SFO)	1.97	days		
DT50 (DFOP, slow)	3.405	days		day
g (DFOP)	0.87601		max TWA start:	0
			max TWA end:	21
RUD	21	mg/kg / kg/ha	max residue at:	14

	Effective application rate (kg/ha)	Application interval (days)	Residue increase by (mg/kg)	DAT1 (days)
Application 1	1.575	0	33.075	0
Application 2	1.575	14	33.075	14

Residue ini	33.08	mg/kg
MAF	1.007	
Residue max	33.31	mg/kg
f_{twa}	0.257	
21d TWA C	8.57	mg/kg

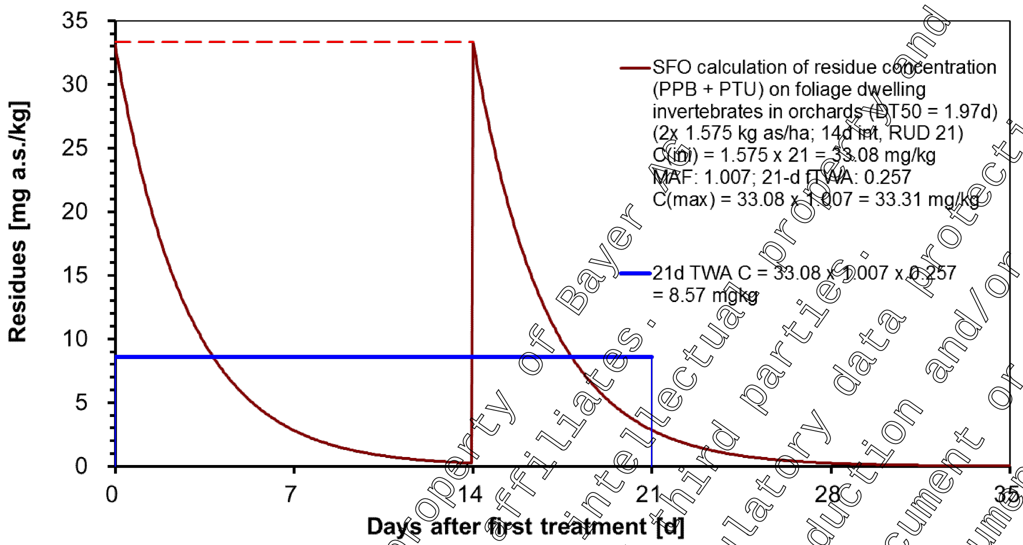

Table 10.1.1- 5: Refined reproductive risk assessment for small insectivorous birds in orchards

Crop	Generic focal species	DDD				DDD	NOAEL [mg a.s./ kg bw/d]	TER$_{LT}$	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Propineb									
Orchards Spring, Summer	Small insectivorous bird "tit"	1.575	18.2	1.007 [a]	0.257 [a]	7.4	≥ 64.7	≥ 8.7	5

[a] with geometric mean field DT_{50} of 1.97 days for propineb and PTU on foliage dwelling insects

Additional refinement potential can be employed by incorporating PT values for the blue tit in orchards as reported by Finch et al. (2006): mean PT = 0.21 for all birds (0.27 for "consumers"), 90[th] percentile PT = 0.55 for all birds (0.58 for "consumers");
A recalculation of the data already evaluated by Finch et al (2006) has been provided in Prosser (2010): 90[th] percentile PT for blue tits in orchards: 0.53 for all birds (0.57 for consumers).

The documents with these PT values are accessible on the internet:

Finch et al: 2006:
http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/P/PTFeb06.pdf

Prosser 2010:
http://randd.defra.gov.uk/Document.aspx?Document=10258_ConsolidationofbirdandmammalPTdataforuseinriskassessment.pdf

For illustration, below the screenshot of Table 3 on page 13 of Prosser 2010, providing highly conservative PT – value recommendations for blue tits in orchards.

Screenshot Table 3 on page 13 of Prosser 2010:

Table 3 PT values for passerine birds in orchards, with modelled 90th and 95th percentiles and their confidence limits. Consumers only.

Season	Species	No. of individuals	90th percentile PT value (95% CLs)	95th percentile PT value (95% CLs)
Summer (April – September)	Blackbird	28	0.73 (0.61 – 0.86)	0.83 (0.71 – 0.93)
	Blue tit	16	0.57 (0.43 – 0.75)	0.66 (0.52 – 0.84)
	Chaffinch	24	0.8 (0.69 – 0.91)	0.87 (0.77 – 0.96)
	Robin	24	0.54 (0.43 – 0.69)	0.65 (0.52 – 0.80)

Refined risk assessment – frugivorous birds in vineyards

For the refined risk assessment for frugivorous birds in grapes, an expert evaluation has been conducted (KCP 10.1.1.2 /02; [redacted], [redacted]; 2014; M-485363-01) primarily based on the egg-laying phase (corresponding to the exposure in the avian reproduction test) in the reproductive season of the bird species considered as focal species for the scenario of frugivorous birds in European vineyards (Song thrush (*Turdus philomelos*), Blackbird (*T. merula*) and Common starling (*Sturnus vulgaris*).

Evaluating the temporal match of the reproductive cycles of these species with the vine berry ripening phase in various European vine growing areas and also the nutritional need profile of the birds over the reproduction phase, it is concluded that exposure of birds before or during egg-laying from residues on vine berries can be considered negligible, because of two fundamental ecological/biological mismatches:

a) the temporal mismatch of egglaying with potential exposure from berry-eating: egglaying is finished before vine berries ripening

b) the nutritional mismatch of egglaying with berry eating: laying birds primarily require protein-rich diet for egg production and chick feeding, which cannot be obtained when eating vine berries.

Therefore reproductive risk for birds from exposure by eating grape berries with residues of propineb can be excluded, without need for a refined reproductive risk TER calculation.

Uncertainty analysis

Refinement of the Tier 1 risk assessments is only triggered for two scenarios in the reproductive risk assessment: small insectivorous birds ("tit") in orchards, and frugivorous birds ("thrush") in vineyards.

For each of these two scenarios, a single refinement element is introduced in the sections above. Therefore it is considered appropriate and acceptable to focus the uncertainty analysis on these two elements instead of a tabular approach as recommended in the EFSA GD (2009).

For the scenario of **small insectivorous birds ("tit") in orchards**, a targeted field study was conducted with residue measurements on foliage dwelling and and flying invertebrates ([redacted]h;[redacted];[redacted];2013;M-460299-01-1) . This study has been conducted in vineyards and thus in a comparable exposure situation (application into the canopy of a high crop). In total, 6 applications have been made with the relevant propineb formulation (3 plots, all with a first application at 1 kg pr/ha and a second application with 2 kg pr/ha. Based on residues measured at various time points after these applications, 6 individual DT_{50} values for foliage dwelling invertebrates have been established. Additionally, 2 DT_{50} values are available for residues on flying insects. All these DT_{50} values are based on combined residues of PPB and PTU.

The risk assessment is conducted with the DT_{50} of 1.97 days as geometric mean of the 6 DT_{50} values for foliage dwelling invertebrates. DT_{50} on flying insects is even lower. Taking into account that geometric mean DT_{50} values are usually considered appropriate in the drinking water assessment for human consumers, it should also be considered as conservative estimation for the residue dissipation of propineb and its metabolite PTU on food items of small insectivorous birds. TER_{LT} calculations with the maximum of the DT_{50} values would still exceed the a-priori acceptability trigger, demonstrating sufficient additional margins of safety even under worst case conditions. However, the exposure assessment presented in Tab. 10.1.1-5 is considered sufficiently conservative even without employing the worst case DT_{50} value, where even higher margins of safety could be demonstrated when employing the PT value from radiotracking blue tits, the representative of the generic focal species in the scenario of concern.

All other elements of the exposure assessment remain unchanged in refined risk assessment. The uncertainty in the sense of overlooking an undue risk for small insectivorous birds in orchards can be considered as low.

For the scenario of **frugivorous birds ("thrush") in vineyards**, an expert evaluation identified the lack of any significant overlap of the critical toxicological phase in the avian reproduction studies (egg-production phase) and the exposure of frugivorous birds to residues of propineb on vine berries. This lack of overlap (mismatch) is due to many constraints of the avian reproduction in the field, first of all the need to forage on protein-rich diet during egg production, and the need to finish chick-rearing well in time before autumn so that the young birds can grow up before winter and/or migration. Since the time window for the critical reproduction phase is before the time window for exposure in the field, there is basically zero exposure from vine berry eating in the TER calculation for fruigvorous birds. Exposure during egg-laying (mainly through foraging for invertebrates) is addressed with the other generic focal species scenarios calculated at the EFSA Tier 1. Though not needed, additional margins of safety could also be provided for insectivorous birds in vineyards by employing the measured residue DT_{50} ([redacted]$;[redacted];[redacted];2013;M-460299-01-1) which has been included and discussed in the risk assessment for small insectivorous birds in orchards.

Exposure of frugivorous birds prior to or during egglaying to residues on vine berries can be considered as negligible. Exposure from ingesting residues on other food items is addressed in the Tier 1 assessment showing low risk for insectivorous, granivorous and omnivorous birds without any refinement. Thus the risk to birds from the use of propineb in vineyards can be considered as low and acceptable without undue uncertainty in the 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 crops under assessment in this evaluation (grapevine, orchards) the leaf scenario is not considered relevant. The risk for birds from drinking water in puddles is addressed in Table 10.1.1- 6.

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

Table 10.1.1- 6: Evaluation of potential concern for exposure of birds drinking water

Crop	K_{oc} [L/kg]	Single application rate × f_{DEP} × MAF [g a.s./ha]	NO(A)EL [mg a.s./ kg bw/d]	Ratio (Application rate × MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Propineb						
Orchards [a]	(> 500 [b])	1575 × 1.4 × 0.3 = 661.5	64.7	661.5/64.7 = 10.2	**≤ 3000**	No concern

[a] the use in orchards (including 70% interception) is considered as worst case and covers the use in grapes
[b] the active substance propineb is practically insoluble and its sorption caracteristics cannot be determined, therefore the threshold of ≤ 3000 is used which applies to all compounds with Koc ≥ 500.

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log K_{ow} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

Table 10.1.1- 7: Log K_{ow} values of propineb and its metabolites

Substance	log K_{ow}	compartment	Reference
Propineb	- [a]	Soil, surface water	MCA, Section 2, point 2.7
PU	-0.26	Soil, surface water	
PTU	< -0.17	Soil, surface water	
4-IM	-3.4 (pH 7)	Soil	
Propineb-DIDT	1.9	Soil, surface water	

[a] not determinable

Propineb is a macro-molecule and not available for bioconcentration. For the degradation products, the log K_{ow} values are below the trigger value of 3, indicating a very low risk of secondary poisoning.

CP 10.1.1.1 Acute oral toxicity

Study already evaluated during the first Annex I inclusion (see Table 10.1.1- 8). No new studies were required.

CP 10.1.1.2 Higher tier data on birds

Report:	[redacted]l;[redacted];[redacted];2013;M-460299-01
Title:	Residue decline of propineb and PTU on arthropods after spray application in vines in the Czech Republic
Report No:	P12017
Document No:	M-460299-01-1
Guidelines:	**No official test guideline available at present type of study. The study was conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009)**
GLP/GEP:	**yes**

Objective:

The purpose of the study was to determine residue decline of propineb and PTU in foliage dwelling and flying arthropods following application with the formulated product Propineb WG 70 (containing 700 g a.s./kg) at the application rate of 1 x 1.0 kg and 1 x 2.0 kg product/ha in vineyards in the Czech Republic.

Materials and Methods:

Study site:

The study was conducted in vineyards in southern Moravia in the Czech Republic. Three vineyards were selected and in each vineyard one plot with a size > 1 ha was established.

Test item and application:

The tested item was propineb, a water dispersible fungicide. Propineb was applied as WG 70 formulation on each plot at a nominal application rate of 700 g active substance = 1.0 kg product per ha with a spray volume of 500 L/ha (first run) and was repeated at nominal 1400 g active substance = 2.0 kg product per ha and 700 L water/ha (second run) according to Good Laboratory Practice and Good Agricultural Practice. Time between first and second run was 13 days on all plots. (The mean actual application rate was 1.008 kg product per ha at the first run and 2.011 kg prod/ha at the second run).

Arthropod sampling:

Foliage dwelling arthropods were collected by inventory spraying and flying insects were collected with Malaise traps. In order to collect foliage dwelling arthropods from the canopy of grapevines, whole plants within the vineyard were sprayed with a 'knock down' insecticide (Aquapy®) at approx. 25 mL product in 1 L water with a motor driven knapsack sprayer from Stihl (SR 430) (NON-GLP application). Malaise traps consisted of a large, tent-like structure. Insects which flew into the tent wall were funneled into a collecting vessel attached to the highest point. One trap per plot was placed between the rows. The trap was emptied approx. after 24 h. Targeted minimum biomass per DAT and plot was 1 g.

Sampling period was 10 days after the first application (1st run). The application was repeated and sampling took place for 21 days after the second application (2nd run). After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis:

All samples were analysed for their content of propineb and metabolite PTU residues via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of Quantification (LOQ) value was 1.0 mg/kg for propineb and 0.05 mg/kg for PTU.

Calculations and statistics:

The residue decline (DT_{50}) of propineb and PTU in leaf dwelling arthropods and flying insects was determined to assess the time course of potential exposure of insectivorous birds. It was assumed that the residue decline followed a first-order kinetic.

Results:

The DT_{50} of propineb on foliage-dwelling arthropods was very consistent over the two runs with 3 replicates each, resulting in a geometric mean DT_{50} of 1.94 days for propineb and 1.97 days for propineb and PTU combined. Although heavy rainfall occurred on different days after applications, no pronounced effect on residue decline was visible. The geometric mean DT_{50} for propineb on flying insects was 1.26 days.

DT_{50} of propineb (PPB) and the sum of propineb + PTU on foliage-dwelling arthropods in vines

SFO kinetics	**DT_{50} PPB [days]**		
	Plot 1	Plot 2	Plot 3
1st run (1 kg prod./ha)	2.2	1.62 [1]	1.55 [2]
2nd run (2 kg prod./ha)	1.37	3.01	1.89
Geomean (n = 6)	**1.94**		
	DT_{50} PPB + PTU [days]		
1st run (1 kg prod./ha)	2.24	1.65 [1]	1.56 [2]
2nd run (2 kg prod./ha)	1.37	3.04	1.93
Geomean (n = 6)	**1.97**		

[1] Simulation conducted excluding an outlier on DAT +2

[2] Simulation performed starting with maximum value on DAT +2

DT_{50} of propineb on flying insects in vines

SFO kinetics	**DT_{50} PPB [days]**
	Plots 1+2+3 [1]
1st run (1 kg prod./ha)	1.80
2nd run (2 kg prod./ha)	0.72
Geomean (n = 2)	1.26

[1] Samples of flying insects were pooled because individual sample weights in Malaise traps were not sufficient for analysis.

Conclusion:
The study provides realistic field data on the time course of residue decline of propineb in foliage-dwelling arthropods. These data provide a reliable basis for use in higher tier risk assessments of insectivorous birds.

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Report:	[redacted]; [redacted]; [redacted];2014;M-485363-01
Title:	Expert statement - Frugivorous birds in vineyards in Europe
Report No:	R14153
Document No:	M-485363-01-1
Guidelines:	**No official test guideline available at present type of study. The study was conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009)**
GLP/GEP:	**n.a.**

The aim of this expert evaluation based on literature and additional data survey is to provide information on the typical duration of the egg-laying period and of the proportion of fruits (especially grapes) within the diet during this period in three frugivorous bird species frequently recorded in European vineyards, the song thrush (*Turdus philomelos*), blackbird (*T. merula*) and common starling (*Sturnus vulgaris*). The main sources used in the compilation of the current survey were literature reports detailing various aspects of the breeding biology and/or diet composition of the relevant species. In addition, the availability and development of grapes in different regions of Europe were investigated.

The main egg-laying periods (95% of clutches found) lie between March and June (song thrush), late March and May (starling) and late March and early July (blackbird) depending on region, initiation of replacement and multiple clutches. The consumption of fruits is of low importance during this period and all three species mainly forage on invertebrates during the breeding season to satisfy their high demand of proteins. The ripening of grapes varies in different regions of Europe depending on climate and time of harvest. Ripening grapes are available from mid-July until early September (Spain), mid-August until mid-October (France) and September until early November (Germany) for three different countries in Central and Southern Europe.

During these ripening periods fruits can form a large portion of the diet. However, the main breeding period, i.e. egg-producing and laying phase, hardly overlaps with the time period of frugivorous food consumption in these species and in particular it does not overlap with the ripening period of grapes as potential fruits taken by these species. In conclusion, reproductive effects to song thrushes, blackbirds or starlings feeding on grapes treated with pesticides are very unlikely.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Reference is made to baseline and supplemental dossier KCA 5.2.1 and KCP 7.1.1

Table 10.1.2- 1: Endpoints used in risk assessment

Test substance	Exposure	Species/Origin	Endpoint		Reference
Propineb	Acute risk assessment	Rat	LD_{50}	> 2000 mg a.s./kg bw	KCA 5.2.1/01; [redacted] 2010; M-370055-01
	Long-term risk assessment	Rat	NOAEL	200 ppm eq. to 16.0 [a] mg a.s./kg bw/d	KCA 5.6.1/01 [redacted]., 1973; M-075529-01-1

[a] dose conversion based on generic factor 0.08 provided in EFSA GD (2009) Table 2
Note:
- studies referring to KCA are filed in the dossier for the active substance
- studies written in grey type are referring to studies in the corresponding Baseline-dossier, whereas studies in black type are studies of the Supplemental dossier

The risk to wild mammals from the animal metabolite PTU is considered to be covered in the studies conducted with the parent substance. Therefore, the residues of PTU are included in the DT_{50} applied in the refined risk assessment.

Table 10.1.2- 2: Relevant generic focal species for risk assessment on Tier 1 level acc. to EFSA GD (2009)

Crop scenario	Most critical window of relevance for generic focal species scenario	Generic focal species	Representative species	Short cut values for reproductive RA based on	
				RUD_{90}	RUD_m
Orchards 2 × 1.575 kg/ha BBCH 40-73 14d interval	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole	40.9	21.7
	BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Rabbit	10.5	4.3
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse	5.2	2.3
Grapes I 2 × 1.12 kg/ha BBCH 40 -59 10d interval	BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Brown hare	8.1	3.3
	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew	5.4	1.9
	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole	40.9	21.7
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse	5.2	2.3
Grapes II 2 × 1.4 kg/ha BBCH >70 10d interval	BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Brown hare	8.1	3.3
	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew	5.4	1.9
	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole	40.9	21.7
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse	5.2	2.3

For the uses grapes I and grapes II identical focal species are relevant for the risk assessment. However, since the application rate in grapes II is higher than in grapes I, only the use in grapes II (besides the use in orchards) is presented below.

ACUTE DIETARY RISK ASSESSMENT

Table 10.1.2- 3: Tier 1 acute risk assessment for wild mammals

Crop	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}				
Propineb								
Orchards BBCH ≥ 40	Small herbivorous mammal "vole"		40.9		77.3		> 25.9	
Orchards BBCH ≥ 40	Large herbivorous mammal "lagomorph"	1.575	10.5	1.2	19.8		> 131	
Orchards BBCH ≥ 40	Small omnivorous mammal "mouse"		5.2		9.8		> 101	
Grapes BBCH ≥ 40	Large herbivorous mammal "lagomorph"		8.1		14.7	> 2000	> 176	10
Grapes BBCH ≥ 20	Small insectivorous mammal "shrew"	1.4	5.4	1.3	9.8		> 204	
Grapes BBCH ≥ 40	Small herbivorous mammal "vole"		40.9		74.4		> 35	
Grapes BBCH ≥ 40	Small omnivorous mammal "mouse"		5.2		9.5		> 136	

Bold values do not meet the trigger

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

LONG-TERM REPRODUCTIVE ASSESSMENT

Table 10.1.2- 4: Tier 1 reproductive risk assessment for wild mammals

Crop	Generic focal species	DDD				DDD	NOAEL [mg a.s./kg bw/d]	TER_{LT}	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Propineb									
Orchards BBCH ≥ 40	Small herbivorous mammal “vole”	1.575	21.7	1.4	0.53	25.4	16.0	**0.6**	5
Orchards BBCH ≥ 40	Large herbivorous mammal “lagomorph”	1.575	4.3	1.4	0.53	5.0	16.0	**3.2**	5
Orchards BBCH ≥ 40	Small omnivorous mammal “mouse”	1.575	2.3	1.4	0.53	2.7	16.0	6.0	5
Grapes BBCH ≥ 40	Large herbivorous mammal “lagomorph”	1.4	3.3	1.5	0.53	3.7	16.0	**4.4**	5
Grapes BBCH ≥ 20	Small insectivorous mammal “shrew”	1.4	1.9	1.5	0.53	2.1	16.0	7.6	5
Grapes BBCH ≥ 40	Small herbivorous mammal “vole”	1.4	21.7	1.5	0.53	24.2	16.0	**0.7**	5
Grapes BBCH ≥ 40	Small omnivorous mammal “mouse”	1.4	2.3	1.5	0.53	2.6	16.0	6.3	5

Bold values do not meet the trigger

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level do not exceed the a-priori-acceptability trigger of 5 for the small herbivorous mammal and the large herbivorous mammals scenario in both crops. Thus, a refined risk assessment for these scenarios is presented below.

Refined risk assessment

Since there is a need for refinement highlighted in the Tier 1 risk assessment, more realistic exposure parameters were considered in the risk assessment.

The geometric mean DT_{50} for the residue decline on foliage is 2.92 days (for the sum of propineb and PTU), according to field trials evaluated by [redacted] & [redacted] (2014) (KCP 10.1.2.2 /01; [redacted]S; [redacted]; 2014; M-486413-01).

This value is used to refine the MAF_m and 21-d f_{TWA} values in the reproductive risk assessment for small and large herbivorous mammals.

The calculation with a moving time window according to the minimum inter-application interval of 14 days in **orchards** is demonstrated below, resulting in MAF = 1.036 and 21-d f_{TWA} = 0.349 which are employed in the refined TER_{LT} calculation in Table 10.1.2.5.

TWA Residue Calculator ver. 2

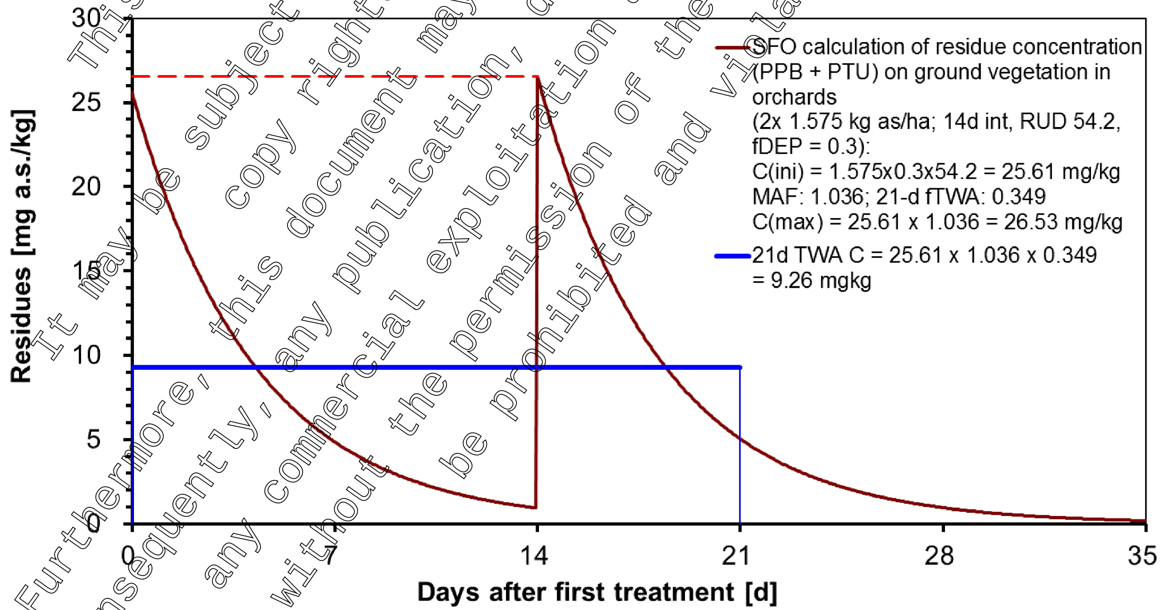
Enter data into the yellow cells only

SFO calculation of residue concentration (PPB + PTU) on ground vegetation in orchards
(2x 1.575 kg as/ha; 14d int, RUD 54.2, fDEP = 0.3):
C(ini) = 1.575x0.3x54.2 = 25.61 mg/kg
MAF: 1.036; 21-d f_{TWA}: 0.349
C(max) = 25.61 x 1.036 = 26.53 mg/kg

DT50 Type	SFO		TWA interval (days):	21
DT50 (SFO)	2.92	days		
DT50 (DFOP, slow)	3.405	days		day
g (DFOP)	0.87601		max TWA start:	0
			max TWA end:	21
RUD	54.2	mg/kg / kg/ha	max residue at:	14

	Effective application rate (kg/ha)	Application interval (days)	Residue increase by (mg/kg)	DAT1 (days)
Application 1	0.4725	0	25.6095	0
Application 2	0.4725	14	25.6095	14

Residue ini	25.61	mg/kg
MAF	1.036	
Residue max	26.53	mg/kg
f_{twa}	0.349	
21d TWA C	9.26	mg/kg



The calculation with a moving time window according to the minimum inter-application interval of 10 days in **vines** is demonstrated below, resulting in MAF = 1.093 and 21-d f_{TWA} = 0.352 which are employed in the refined TER_{LT} calculation in Table 10.1.2.5.

TWA Residue Calculator ver. 2

Enter data into the yellow cells only

SFO calculation of residue concentration (PPB + PTU) on ground vegetation in vineyards
(2x 1.4 kg as/ha; 10d int, RUD 54.2, fDEP = 0.3):
C(ini) = 1.4 x 0.3 x 54.2 = 22.76 mg/kg
MAF: 1.093; 21-d f_{TWA}: 0.352
C(max) = 22.76 x 1.093 = 24.88 mg/kg

DT50 Type	SFO		TWA interval (days):	21
DT50 (SFO)	2.92	days		
DT50 (DFOP, slow)	3.405	days		day
g (DFOP)	0.87601		max TWA start:	0
			max TWA end:	21
RUD	54.2	mg/kg / kg/ha	max residue at:	10

	Effective application rate (kg/ha)	Application interval (days)	Residue increase by (mg/kg)	DAT1 (days)
Application 1	0.42	0	22.764	0
Application 2	0.42	10	22.764	10

Residue ini	22.76	mg/kg
MAF	1.093	
Residue max	24.88	mg/kg
f_{twa}	0.352	
21d TWA C	8.77	mg/kg

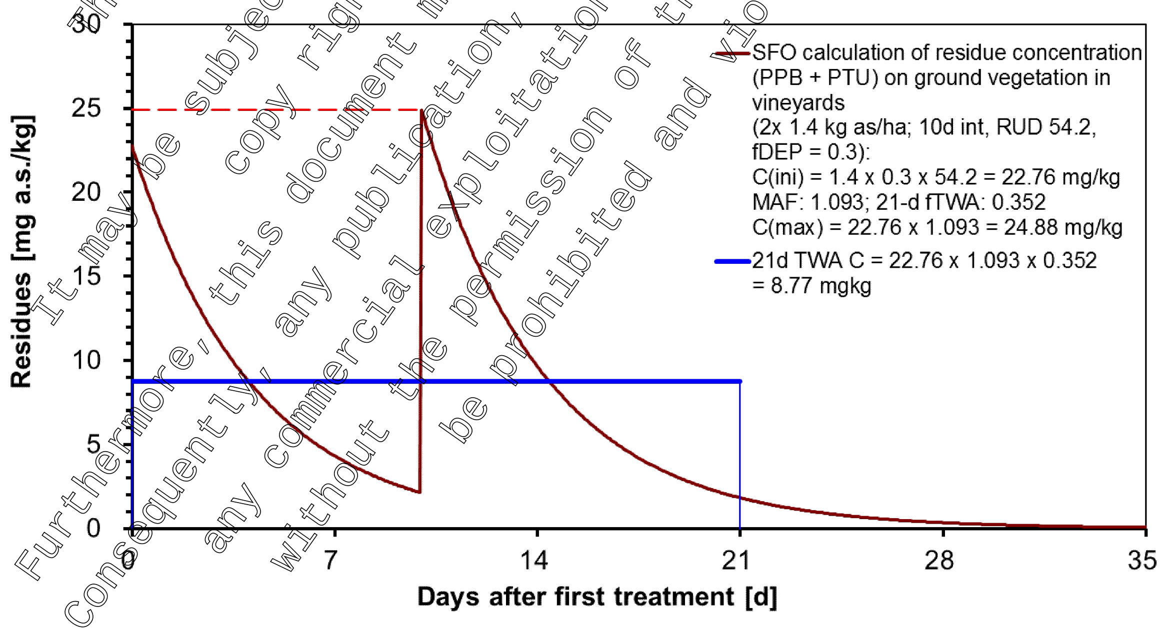


Table 10.1.2- 5: Refined reproductive risk assessment for small and large herbivorous mammals in orchards and grapes

Crop	Generic focal species	DDD				DDD	NOAEL [mg a.s./ kg bw/d]	TER_{LT}	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Propineb									
Orchards BBCH ≥ 40	Small herbivorous mammal "vole"	1.575	21.7	1.036	0.349	12.4	16.0	**1.3**	5
Orchards BBCH ≥ 40	Large herbivorous mammal "lagomorph"		4.3			2.45		6.5	
Grapes BBCH ≥ 40	Small herbivorous mammal "vole"	1.4	21.7	1.093	0.352	11.7	16.0	**1.4**	5
Grapes BBCH ≥ 40	Large herbivorous mammal "lagomorph"		3.3			1.78		9.0	

Bold values do not meet the trigger
[a] recalculation with DT_{50} of 2.92 days for the sum of propineb and PTU on foliage

TER_{LT} are ≥ 5 either already at Tier 1 (small insectivorous mammals "shrew", small omnivorous mammals "mouse") or after refinement with the measured DT_{50} of PPB+PTU on foliage (large hervivorous mammals "lagomorph), indicating low risk without need for a more refined assessment.

However, a further refined evaluation remains triggered for the scenario of "small herbivorous mammals" represented by the Common vole (*Microtus arvalis*).

This further refined assessment is provided with a "weight-of-evidence approach", based on

1) **lower sensitivity of voles determined in targeted toxicity studies with propineb in the Common vole,**
2) **general knowledge of the biology and ecology of Common voles in the agricultural landscape,**
3) **generic field studies in orchards and vineyards, and their evaluation**
4) **non-generic studies on the Common vole**
   4.1) population model
   4.2) field effect study

1) Lower sensitivity of common voles to toxic effects from propineb: The TER_{LT} calculation that resulted in the need for further refinement of the generic focal species scenario "small herbivorous mammal – vole" was based on the NOAEL of 200 ppm in the rat reproduction study by [redacted] et al. (1973) (baseline dossier, KCA 5.6.1 /01; [redacted]; et al.; 1973; M-075529-01). In this study treatment at the LOAEL with 600 ppm provoked severe clinical signs in the females, which were affected by myasthenia of the hind extremities with mobility impairment: the affected animals could hardly reach their feed bowl and feed adequately. As a consequence body weights were decreased and survival was affected during the 70-day premating period.

Of the F0 generation at 600 ppm, only 14/20 female rats were still alive at the first mating and only 13/20 after the second mating. The main consequences of the toxic effects were the reduction of mating success (percent pregnant females) and of live pups per litter at the highest concentration of 600 ppm. Males are much less sensitive than female rats.

The effects on the hind limbs were also observed in other toxicity studies with rat. The lowest treatment level at which this effect was observed was 300 ppm (21.21 mg as/kg bw/d in the females) the 90-d neurotoxicity study in rat (supplementary dossier [redacted];2004;M-066913-01).

In the second reproductive toxicity study (supplementary dossier: KCA 5.6.1 /02; [redacted], D.;2010;M-370252-01) the test concentrations were selected in order to avoid the onset of the clinical signs even after multi-generation exposure, and there were no effects on any of the reproductive parameters and pup development in both sexes in any generation.

Therefore, it can be assumed that reproduction in rat is hindered at concentrations provoking severe systemic toxicity and affecting the possibility of adequately feeding.

Whilst high sensitivity to myopathic effects after exposure to propineb has consistently been reported at moderate treatment levels in rats (> 200 ppm), with females being more susceptible than males, this high sensitivity has not been observed in toxicological studies with other mammals like mice (Brune et al. 1980: baseline dossier KCA 5.5 /06 [redacted] et al.; 1980; M-056652-02) or dogs (Jones 1999: baseline dossier KCA 5.3.2 /04 [redacted].; 1999; M-009667-01).

Also in targeted studies on the focal species common vole, these kinds of effects were not observed up to concentrations of 1050 ppm, equivalent to ca. 100 mg/kg bw/day (supplementary dossier KCA 8.1.1.2.2 /01; [redacted].; 2013; M-476238-01; supplementary dossier KCA 8.1.1.2.2 /02; [redacted].; 2014; M-487560-01-1).

Therefore it is considered appropriate to accept a lower safety factor than 5 for Common voles in reproductive risk assessments when based on the rat endpoint of 200 ppm = 16 mg as/kg bw/d, since Common voles are at least 5x less sensitive to the dominating effect driving the endpoint selection in the rat reproduction studies.

2) General knowledge of the biology and ecology of Common voles in the agricultural landscape:

Additional to the low individual toxicological sensitivity of the representative species behind the EFSA generic focal species scenario “small herbivorous mammals – vole”, the Common vole is also of limited relevance as real focal species since it typically occurs in orchards and vineyards only under particular circumstances.

These particularities of the Common vole scenario is depicted in a recent comprehensive yet targeted expert overview on the role of the Common vole in agriculture in Europe provided by [redacted] et al. (KCP 10.1.2.2 /02 [redacted]; [redacted]; 2013; M-476622-01):

Common voles (*Microtus arvalis*) are common in Central European landscapes. They can be a major rodent pest in European agriculture and at the same time they are also a representative generic focal small herbivorous mammal species used in risk assessment for plant protection products.

Common voles are a component of agroecosystems in many parts of Europe, inhabiting agricultural areas (secondary habitats) when the carrying capacity is exceeded in adjacent prime habitats (grassland, multi-annual leafy crops like alfalfa). Colonisation of secondary habitats therefore typically occurs during multiannual outbreaks, when population sizes can exceed 1000 individuals ha^{-1}. In such cases, in-crop common vole population control management has been practised to avoid significant crop damage. The species' status as a crop pest, high fecundity, resilience to disturbance and intermittent colonisation of crop habitats are important characteristics that should be reflected in risk assessment. Based on the information provided in the scientific literature, it seems justified to modify elements of the current risk assessment scheme for plant protection products, including the use of realistic food intake rates, reduced assessment factors or the use of alternative focal rodent species in particular European regions. Some of these adjustments are already being applied in some EU member states. Therefore, the authors suggest to apply such pragmatic and realistic approaches in risk assessments for plant protection products across the EU.

Particularly the option to consider the high resilience and recovery potential of the Common vole at the population level (by eg accepting a lower margin of safety in this scenario) is of relevance for the evaluation in this dossier.

3) Generic field study results, and their evaluation:

Common vole population dynamics in prime and secondary habitats are investigated in a generic field study conducted in orchards in Germany (KCP 10.1.2.2 /03 [redacted]. von; 2006; M-291201-01), and discussed by [redacted] (2009) (KCP 10.1.2.2 /04 [redacted].; 2009; M-355596-01).

[redacted] (2009) evaluated the study results ([redacted] 2006) as to support the view that modern orchards with managed ground vegetation are only secondary habitats (often "sinks" rather than "source") for the common vole, whilst source populations of the species live in primary habitats characterized by perennial and well developed vegetation cover (eg, natural meadows, alfalfa).

Such secondary habitats like modern orchards may be colonized when the following factors combine: (i) gradation year (every 3 - 5 years), (ii) inconsistent orchard ground vegetation management with resulting periods of high grass, and (iii) proximity of orchards to prime grassland habitats, which all combined for the plots in Thuringia in the study of [redacted] (2006).

Using general ecological knowledge on the common vole and the results of the field study [redacted] (2009) concluded that the common vole long-term population level does not depend on the individuals that may be adversely affected by various kinds of agricultural operations in modern orchards (including ground vegetation management, or intoxication after *eg*. rodenticide use).

Therefore the common vole does not appear as typical 'Focal Species' significantly depending on orchard habitats. In contrary, the species occur only secondary in those modern orchards with rich ground vegetation, with permanent grassland in vicinity that serves as source habitat. Even then, established populations would be expected only in gradation years. In gradation years, Common voles are typically target of active control strategies (like rodenticide use), the effects of which would largely override any hypothetical effect from exposure to propineb.

Therefore, orchards (or vineyards) with appropriate ground vegetation management are not considered as natural habitat for voles (to some extent similar to non-permanent waterbodies in the aquatic area). Only orchards (or vineyards) with well developed and permanent understorey can harbor viable vole populations, which is not typically the case in modern plantations that are protected against diseases with Propineb WG70.

Therefore the risk for Common vole populations is very low in most plantations where Propineb WG70 is used. The relevance of the Common vole scenario would be limited to at most a small subset of plantations (those with well developed and permanent understorey), which are addressed in the following evaluations.

Equivalent conclusions can be drawn from field study work conducted in vineyards in Germany (e.g. **KCP 10.1.2.2 /07** [redacted].; et al.; 2004; M-298157-01): local common vole populations can be expected only in vineyards with well developed and continuous ground vegetation, but only single individuals are observed in vineyards without or with only partial ground vegetation.

4) Non-generic studies on the Common vole

4.1) Population model

For plantations with suffifciently developed ground vegetation to harbor local populations, an evaluation was conducted with a **individual based population model** simulating population dynamics of common voles in the computer (KCP 10.1.2.2/05 [redacted].; 2014; M-488425-01). In this evaluation the virtual voles were forced to "live" in a landscape consisting only of a hypothetical pome fruit orchard, in order to provide a worst case ecological and exposure scenario.

In agreement with the general ecology of the species, and the evidence from the generic field studies, that sustainable vole populations can only persist in habitats with sufficiently well developed permanent ground vegetation, the virtual "model orchard habitat" had to be provided with a continuous grass layer that was only moderately managed over the season. No untreated habitat at all was included in the model, i.e full exposure of all simulated voles, without any refugia or exchange with populations in untreated areas. According to the recommendations from the Modelink-Workshop, the effect assessment was based on the population density during the minimum phase in winter, since this population constitutes each time the founder generation for the following year, and thus for the sustainability of the population which is considered as main protection goal in the long-term assessment.

Over 10 years, the simulated voles in this worst case orchard scenario were exposed to residues from 2 annual applications at 1.575 kg a.s./ha of propineb (interval 14 days). Daily dietary exposure was calculated for each vole according to the Tier 1 settings in the EFSA GD scenarios for "small herbivorous mammals – "vole", with the DT50 of 2.92 days which was also employed in the refined TER_{LT} calculation for herbivorous mammals.

Based on the effect profile obtained from studies with propineb in rat, the following effects were imposed on the voles in the model: The effect of the myasthenia of the hind extremities was simulated assuming immediate mortality (Effect A) under field condition if mobility is reduced.

Additional indirect effects were simulated by reducing the mating success (effect B) and the number of live pups per litter (effect C).

Various effect type combinations (A+B+C, B+C, C) were simulated for application scenarios of 1x, 2x or 5x application rate (2x or 5x application rate are equivalent with a TER of 2 or 5, respectively).

The high sensitivity of female rats for myopathy after treatment with propineb (effect A) has not been observed at much higher doses in female voles, and also effects (B) and (C) are considered secondary to myopathy. Therefore, the effect condition combination B+C, i.e. without the mobility effect, is only slightly more relevant than A+B+C for this species of concern which is simulated in the population model. For B+C, neither the 1x, 2x nor 5x application rate led to significant effects on the local population level of the common vole (max: 5.6% at 5x).

Equally, simulating the effect condition C (reduction of litter size) alone resulted in negligible effects at the 1x, 2x and 5x application rate on the local population level of the common vole (max: 5.1% at 5x). A 5x application rate is equivalent with a TER of 5.

Difference of population density in control vs. treatment simulations (vole population model)

Szenario	Simulated application rate	Max. difference compared to control [1)]
All effects (A, B, C), 1x	1x	1.0%
All effects (A, B, C), 2x	2x	100%
All effects (A, B, C), 5x	5x	100%
Mating & Litter size (B, C), 2x	2x	2.8%
Mating & Litter size (B, C), 5x	5x	5.6%
Litter size (C), 2x	2x	2.0%
Litter size (C), 5x	5x	5.1%

[1)] Measured on 1st of January of each year, in which applications were simulated.

Thus the population model conducted under very worst case ecological conditions, with a hypothetical isolated but permanent vole population in an orchard with continuous and insufficiently managed ground vegetation, indicates that even vole populations with a sensitivity profile fully identical to the worst case species (rat) would not be at risk at the long-term population level when propineb is applied over 10 years at the maximum recommended application rate (1.575 kg/ha) and the minimum recommended application interval (14 days).

Since the Common vole, the representative species behind the EFSA GD scenario "small herbivorous species" are not sensitive to myopathy at much higher dose levels than rat (KCA 8.1.1.2.2 /01; [redacted] 2013; M-476238-01, KCA 8.1.1.2.2 /02, [redacted]; 2014; M-487560-01-1), the effect scenarios with myopathy (A) as the primary driver of the modelled population effect (100% effect at 2x or 5x in all effect senarios with A) are clearly overestimating the risk to Common vole populations.
Also the effects B (successful mating) and C (litter size after successful mating) appear to be directly linked to the poor physiological condition of the females at 600 ppm in [redacted] et al. (baseline dossier: KCA 5.6.1 /01; [redacted].; et al.; 1973; M-075529-01) caused by myopathy and therefore of little if any relevance for the Common vole. Nevertheless, even assuming comparable sensitivity of the Common vole and rat and thus comparably reduced mating success and reduced litter size after long-term treatment with propineb, there were only negligible differences without repercussions on the long-term population sustainability after 10 years of continuous product use at up to 5x the maximum recommended application rate.
Thus, no long-term effects on population level would be expected in common vole populations exposed at the maximum recommended application rate in an orchard scenarios, even if a worst-case exposure scenario and unrealistic worst-case effect scenario (A+B+C) is assumed.
For more realistic worst-case effect scenarios, no long-term effects on the vole population sustainability were predicted even at 5x the maximum recommended application rate.

4.2) Field effect study

A field experiment (**KCP 10.1.2.2 /06,** [redacted].; [redacted]; 2014; M-488499-01) is ongoing in order to further demonstrate under realistic worst case conditions of use the low risk to Common vole populations that is expected based on the considerations above.
The difficulties to conduct this experiment reflect many of the constraints also established in the generic field study ([redacted] 2006) and the evaluation of by [redacted] (2009), as well as encountered in the model simulations:

- vole populations in modern orchards are untypical and unpredictable, so that the study must be conducted in a meadow as surrogate habitat
- vole population development is characterized by large inter-annual variation, so that the study originally initiated for 2013 had to be canceled after crash of the vole populations in the selected area after severe spring weather conditions including flooding.

In order to reduce the risk for another failed study attempt due to population crashes after after heavy rainfalls, the study site for the 2014 work has been re-considered and selected in a more slopy area. ~~This ongoing study is designed to study the effect of propineb application in orchards and vines on the population level of Common voles under realistic worst case field conditions. An~~ The interim report is provided in **KCP 10.1.2.2 /06).**

The final report is ~~scheduled for end of 2014~~ provided in KCP 10.1.2.2/11. The aim of this field study was to investigate the potential long-term effects of spray applications of Antracol WG70 (a.s. propineb) on wild populations of small herbivorous mammals (common voles) living in managed meadows in France.

Managed meadows (4 treated plots, 4x untreated controls) were selected as study fields as surrogate for grassy ground vegetation in arable fields, orchards or vineyards where vole populations might be exposed to propineb after use as agricultural fungicide.

The application scenario was designed to represent realistic worst case exposure of ground vegetation resulting from residue deposition after a canopy spray treatment at 2x 1.575 kg as/ha with 70% interception and a 7-d inter-application interval.

A live trapping campaign was carried out from May to September 2014 in order to assess the occurrence, abundance and population dynamics of common voles in the treated study fields compared to the control fields. A total of eleven trapping sessions in each of the study fields (one trapping session = two consecutive nights of trapping) were carried out. The first and the second trapping session were conducted before mowing and the first application; the third and further eight trapping sessions were conducted after the second of the two applications.

The trapping data were evaluated and presented as abundance values and population parameters as follows:

Abundance values include the following parameters:

- Captures and Trapping efficiency (captures per 100 trap nights)
- Minimum Number Alive (MNA)
- Recapture

Population parameters include the following parameter:

- Body weight
- Reproductive status
- Sex ratio
- Age structure

Neither the abundance values nor the population parameter revealed any evidence for treatment-related differences between populations of the common vole on control or treatment fields.

Uncertainty assessment (refined risk assessment for small herbivorous mammals – "vole")

Sourc of uncertainty	Potential to make true risk lower	Explanation	Potential to make true risk higher	Explanation
Reproductive risk assessment endpoint for voles	---	Critical species voles tested and found not susceptible to myopathy at > 5x the dose used as reproductive risk assessment endpoint; no effect of propineb on reproductive parameter in rat at doses without myopathy		
Exposure assessment: voles assumed to be present in orchard & vineyard	---	In reality orchards and vineyards are only populated by voles in phases of high population density when toxic effects below the magnitude of rodenticides are not likely to impact the population dynamics		
Exposure assessment PT/PD = 1.0	-	Cannot be worse		
Exposure assessment DT50 = 2.92 d	-	Geometric mean estimate with some variability in both directions	+	Geometric mean estimate with some variability in both directions
Population level risk assessment	--	In silico-experiment under several worst case assumptions (consider also specific uncertainty analysis included in the model report)	(+)	Reliability of population model prediction in risk assessment not yet agreed
Effect field study	---	Conducted under worst case conditions	+	Experimental variability

CONCLUSION

Taking into account the elements introduced into the weight of evidence evaluation in the refined risk assessment for small herbivorous mammals (voles), the risk from application of propineb in orchards and vineyards on the population level of voles can be considered as low and acceptable.

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Long-term risk assessment for mammals drinking contaminated water

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

Table 10.1.2- 6: Evaluation of potential concern for exposure of mammals drinking water

Crop	K_{oc} [L/kg]	Application rate * MAF [g a.s./ha]	NO(A)EL [mg a.s./ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL)	"Escape clause" No concern if ratio	Conclusion
Propineb						
Orchards [a]	10000 [b]	1575 × 1.4 x 0.3 = 661.5	16.0	661.5/16 = 41.3	≤ 3000	No concern

[a] the use in orchards is considered as worst case and covers the use in grapes
[b] the active substance propineb is practically insoluble and ist sorption caracteristics cannot be determined, therefore a highly conservative value is used

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 K_{ow} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation.

As presented in Tab. 10.1.1- 7, log K_{ow} values are below the trigger value indicating a very low risk of secondary poisoning.

CP 10.1.2.1 Acute oral toxicity to mammals

Reference is made to supplemental dossier KCP 7.1.1/01.

Test item	Species	TG	Endpoint [mg/kg bw]	Source
Propineb WG70	Rat M+F	OECD 423	LD50 > 2500	KCA 7.1.1./01 [redacted] 2000 M-030439-01

CP 10.1.2.2 Higher tier data on mammals

The residue trial studies mentioned in KCA 10.1.2.2/01 are partly included in this Supplemental Dossier (see KCA 10.1.2.2/10). The other residue trial studies are included in the Baseline Dossier and therefore no study summaries need to be presented here.

Report:	[redacted]t;[redacted];[redacted];2014;M-486413-01
Title:	Statement on residue dissipation of propineb in treated foliage of different plants: kinetic evaluation
Report No:	EnSa-14-0580
Document No:	M-486413-01-1
Guidelines:	**Calculation under consideration of FOCUS guidance for DT50 calculation**
GLP/GEP:	**no**

This statement provides a kinetic evaluation of the residues of propineb (PPB) and its metabolite propylene-thiourea (PTU) in green parts of mono- (barley) and dicotyledonous plants (lettuce, celery) that may represent food items for leaf-eating herbivorous birds or mammals, respectively. The single-first-order (SFO) DT_{50} of propineb derived in this evaluation are summarised below.

SFO- DT_{50} values for propineb and results of the statistical analysis - scaled error percentage (ε) and significance of the dissipation rate (t-prob) for single first-order kinetic model (PPB only)

Trial code	Trial description	Crop	DT_{50} [days]	ε [%]	t-prob.
R01	11-2956-01	barley green plant	2.32	31.65	0.013
R02	11-2956-02	barley green plant	2.47	15.24	0.001
R03	11-2956-03	barley green plant	2.43	19.65	0.005
R04	11-2956-04	barley green plant	2.64	18.85	0.004
R05	M-103315-01-2	lettuce, head	2.79	6.811	0.001
R06	M-103321-01-2	lettuce, head	2.23	10.95	0.007
R07	M-103325-01-2	celery, leaf	2.68	2.390	< 0.001
R08	M-103328-01-2	celery, leaf	2.10	1.556	0.002
R09	M-103330-01-2	celery, leaf	2.41	2.861	0.003
R10	M-103339-01-2	celery, leaf	3.33	0.693	< 0.001
R11	M-103342-01-2	celery, leaf	4.54	4.077	< 0.001
		Geom. mean	2.66		
		Median	2.47		

Only in trials R01 to R04 and R10 to R11, respectively, residue analysis was targeted on both propineb and its metabolite propylene-thiourea and thus a kinetic evaluation of the combined residue data (PPB + PTU) could also be conducted.

SFO-DT_{50} values for propineb and results of the statistical analysis - scaled error (ε) and significance of the dissipation rate (t-prob) for single first-order kinetic model (total residue of PPB and PTU)

Trial code	Trial description	Crop	DT_{50} [days]	ε [%]	t-prob.
R01	11-2956-01	barley green plant	2.33	31.34	0.012
R02	11-2956-02	barley green plant	2.52	15.46	0.001
R03	11-2956-03	barley green plant	2.49	19.58	0.005
R04	11-2956-04	barley green plant	2.81	18.75	0.005
R10	M-103339-01-2	celery, leaf	3.33	0.693	< 0.001
R11	M-103342-01-2	celery, leaf	4.54	4.077	< 0.001
		Geom. mean	2.92		
		Median	2.67		

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Report:	[redacted];2013;M-476622-01
Title:	Common vole (Microtus arvalis) ecology and management: implications for risk assessment of plant protection products
Report No:	M-476622-01-1
Document No:	M-476622-01-1
Guidelines:	**-/-not applicable**
GLP/GEP:	**n.a.**

Abstract:

Common voles (*Microtus arvalis*) are common small mammals in some European landscapes. They can be a major rodent pest in European agriculture and they are also a representative generic focal small herbivorous mammal species used in risk assessment for plant protection products. In this paper, common vole population dynamics, habitat and food preferences, pest potential and use of the common vole as a model small wild mammal species in the risk assessment process are reviewed. Common voles are a component of agroecosystems in many parts of Europe, inhabiting agricultural areas (secondary habitats) when the carrying capacity of primary grassland habitats is exceeded. Colonisation of secondary habitats occurs during multiannual outbreaks, when population sizes can exceed 1000 individuals ha^{-1}. In such cases, in-crop common vole population control management has been practised to avoid significant crop damage. The species' status as a crop pest, high fecundity, resilience to disturbance and intermittent colonisation of crop habitats are important characteristics that should be reflected in risk assessment. Based on the information provided in the scientific literature, it seems justified to modify elements of the current risk assessment scheme for plant protection products, including the use of realistic food intake rates, reduced assessment factors or the use of alternative focal rodent species in particular European regions. Some of these adjustments are already being applied in some EU member states. Therefore, it seems reasonable to apply consistently such pragmatic and realistic approaches in risk assessments for plant protection products across the EU.

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Report:	[redacted]7;[redacted];2006;M-291201-01
Title:	Small mammal monitoring in pome orchards of Baden-Wuerttemberg and Thuringia
Report No:	RC05-021
Document No:	M-291201-01-1
Guidelines:	**Gurnell and Flowerdew (1990)**
GLP/GEP:	**no**

Objective:
Investigation of whether modern pome orchards colonised by small mammals, and determination of the focal small mammal species. Determination of the population dynamics of the focal species during the growing season.

Material and methods:
A capture-mark-recapture study was conducted in two typical pome growing regions in Central Germany (Thuringia) and in Southwest Germany (Baden-Württemberg). For each region three study plots were investigated where the trapping grids were set up. The six study plots consisted of large modern pome fruit orchards directly bordered on at least one side by a traditional meadow, where the meadows were considered 'prime habitats' of common voles. In addition, two control plots consisting of orchards inside or bordered by other orchards, and thus not adjacent to meadows or any other 'prime habitat' for the common vole. The small mammal populations were monitored using the capture - mark - recapture method between March and August 2005. The live-traps were installed every second week for two successive nights, arranged in a 5 x 5 meter grid area, activated in the evening, and checked in the morning. Except for shrews (legal restriction), all captured individuals were individually marked with a passive integrated transponder (PIT).

Results:
The most abundant species in modern pome orchards was found to be the common vole. The two study regions proved to have clearly different common vole population dynamics, covering scenarios with low densities (Baden-Württemberg) and high densities (Thuringia) of common voles.

Marked individuals								
Species	**Baden-Württemberg**				**Thuringia**			
	Study plot 1	**Study plot 2**	**Study plot 3**	**Control plot 4**	**Study plot 5**	**Study plot 6**	**Study plot 8**	**Control plot 7**
Apodemus flavicollis	-	1	13	-	22	12	30	-
Apodemus sylvaticus	5	6	10	1	2	3	2	-
Apodemus agrarius	-	-	-	-	-	2	-	-
Cricetus cricetus	-	-	-	-	-	2	-	-
Clethrionomys glareolus	1	1	9	-	-	1	-	-
Arvicola terrestris	1	-	-	-	-	2	-	-
Microtus arvalis	27	87	55	3	319	331	281	207
Total	34	95	87	4	343	353	313	207

The common vole's colonisation of traditional meadows and modern pome orchards did not seem to depend primarily on the different habitat type but rather on ground vegetation height. Populations decreased when the ground vegetation was mowed, mulched or pastured in both habitat types. In undisturbed traditional meadow habitats recapture rates and the rate of non-adult individuals were in general higher which indicates a stable population and reproduction. High ground vegetation provides shelter and better protection against predators. Therefore, traditional meadows with high ground vegetation were probably preferred when spring reproduction started. Regular mulched modern pome orchards provide less protection against avian predators and consequently less shelter. Therefore, they were probably not very attractive in spring and only used on a small scale. In summer when primary habitats like traditional meadows were well occupied the modern pome orchards were used as secondary habitat to a larger extent – including reproduction.

Captures on study plots in the different habitats									
Baden-Württemberg	**Study plot 1**			**Study plot 2**			**Study plot 3**		
	Captures	**Meadow[%]**	**Orchard [%]**	**Captures**	**Meadow[%]**	**Orchard [%]**	**Captures**	**Meadow [%]**	**Orchard [%]**
Sorex sp.[1]	3	100.0	0.0	2	100.0	0.0	4	50.0	50.0
Apodemus flavicollis	0	-	-	1	100.0	0.0	36	30.6	69.4
Apodemus sylvaticus	9	100.0	0.0	7	100.0	0.0	14	92.9	7.1
Clethrionomys glareolus	1	100.0	0.0	1	100.0	0.0	31	0.0	100.0
Arvicola terrestris	1	0.0	100.0	-	-	-	-	-	-
Microtus arvalis	35	94.3	5.7	266	99.6	0.4	170	58.2	41.8
Total	49	93.9	6.1	277	99.6	0.4	255	49.0	51.0
Thuringia	**Study plot 5**			**Study plot 6**			**Study plot 8**		
	Captures	**Meadow [%]**	**Orchard [%]**	**Captures**	**Meadow [%]**	**Orchard [%]**	**Captures**	**Meadow [%]**	**Orchard [%]**
Sorex sp.[1]	7	100.0	0.0	1	100.0	0.0	-	50.0	50.0
Apodemus flavicollis	43	90.7	9.3	20	95.0	5.0	115	34.8	65.2
Apodemus sylvaticus	3	33.3	66.7	3	100.0	0.0	3	33.3	66.7
Apodemus agrarius	-	-	-	3.0	100.0	0.0	-	-	-
Apodemus sp.	4	100.0	0.0	1	0.0	100.0	5	0.0	100.0
Cricetus cricetus	-	-	-	2	100.0	0.0	-	-	-
Clethrionomys glareolus	1	100.0	0.0	3	100.0	0.0	-	-	-
Arvicola terrestris	-	-	-	2	100.0	0.0	-	-	-
Microtus arvalis	741	71.8	28.2	964	68.3	31.7	640	54.4	45.6
Total	799	73.1	26.9	999	69.2	30.8	763	51.0	49.0

[1]*Sorex sp.* individuals were not individually marked, due to nature conservation requirements.

Population dynamics of the dominant species, the common vole

Common vole (*Microtus arvalis*)									
Investigated parameter	**Habitat**	**Study plot 1**	**Study plot 2**	**Study plot 3**	**Control plot 4**	**Study plot 5**	**Study plot 6**	**Study plot 8**	**Control plot 7**
First capture of common vole	orchard	**July** 27 CW[1] BBCH[2] 74	**June** 25 CW BBCH 72	**June** 25 CW BBCH 72	**June** 23 CW BBCH 72	**April** 14 CW BBCH 54	**April** 14CW BBCH 53	**April** 14 CW BBCH 53	**March** 12 CW BBCH 00
	meadow	**May** 21 CW	**May** 21CW	**May** 21 CW	-	**March** 12 CW	**March** 12 CW	**June** 22 CW	-
Time of population increase	orchard	**no**	**no**	**July** 27 CW BBCH 74	**no**	**July** 30 CW BBCH >74	**July** 30 CW BBCH >74	**July** 30 CW BBCH >74	**July** 30 CW BBCH >74
	meadow	**August** 33 CW	**May** 21 CW	**July** 27 CW	-	**May** 18 CW	**June** 22 CW	**July** 28 CW	-
Maximum density individuals/ha	orchard	**4** July 27CW BBCH 74	**9** June 25 CW BBCH 72	**52** July 27 CW BBCH 74	**4** July 29 CW BBCH >74	**167** August 34 CW BBCH >74	**286** August 34 CW BBCH >74	**270** August 32 CW BBCH >74	**178** August 34 CW BBCH >74
	meadow	**60** August 33 CW	**254** June 23 CW	**75** August 31 CW	-	**258** June 24 CW	**337** August 32 CW	**369** August 34 CW	-
Recapture [%]	orchard	0	0	50	0	36	42	44	40
	meadow	7	46	42		42	52	34	-
Non-adult [%]	orchard	0	0	19	67	18	9	8	11
	meadow	48	7	15	-	33	18	25	-

positive correlation between ground vegetation height and population density					
Spearman rank	**Habitat**	**Baden-Württemberg**		**Thuringia**	
		R	**p**	**R**	**p**
	orchard	0.468	< 0.001	0.6532	<0.001
	meadow	0.379	< 0.05	0.6391	<0.001

[1] CW = calendar week

[2] BBCH = Plant stage codes defined by the **B**iologische **B**undesanstalt für Land- und Forstwirtschaft, **B**undessortenamt und **Ch**emische Industrie.

Conclusion:

Common vole populations require sufficient ground vegetation (cover, height) as feature in permanent primary habitats. Hence, common vole populations in agricultural landscape characterized by modern pome orchards are probably not at risk by plant protection products because the population resources are located mainly in primary habitats like e.g. meadows.

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Report:	[redacted]; [redacted];2009;M-355596-01
Title:	Field study on small herbivorous mammals in modern pome fruit orchards - Evaluation in support of regulatory submissions
Report No:	2009/1100344
Document No:	M-355596-01-1
Guidelines:	**not applicable (expert evaluation)**
GLP/GEP:	**n.a.**

Objective:

This expert evaluation evaluates in detail, and in the context of the general biology and ecology of the species, the results of the field study **KCP 10.1.2.2 /03** [redacted]; 2006; M-291201-01 with regard to common vole trappings in pome fruit orchards and adjacent habitats.

The objective was to evaluate to which extent the study results corroborates the view that orchards with managed ground vegetation are considered as secondary habitats for the common vole, whilst source populations of the species live in primary habitats characterized by perennial vegetation cover.

Prime habitats for the common vole are considered to present a minimum permanent vegetation height of ca. 20 cm. Secondary vole habitats can be occupied during high phase of the population cycles, but populations there regularly decrease or even go extinct after vegetation management (moving, harvest) and during the low phases of the vole population cycles. The prime habitats harbor permanent vole populations and hence are essential strongholds (source habitats) for the survival of common vole populations.

Evaluation:

The field study **KCP 10.1.2.2 /03** [redacted]; 2006; M-291201-01 was performed in a gradation year, and also the secondary habitats were increasingly populated over the season. The spatial/temporal analysis of the trapping data was considered to support the hypothesis that the voles trapped in the orchards were in fact disperser from the surroundings, colonizing the orchards during phases of good ground vegetation cover. Population density, proportion of recapture and the proportion of non-adults are measures for carrying-capacity, stable populations and reproduction. These parameters always scored higher for the meadows than for the orchards, which indicates the relevance of the meadows as 'prime habitat'.

Conclusions:

The population sources of common voles (*Microtus arvalis*) are located in prime habitats like the traditional meadows evaluated in the field (**KCP 10.1.2.2 /03** [redacted]; 2006; M-291201-01). Common voles may occur in modern orchards as secondary habitats during summer when the following factors combine: (i) gradation year (every 3 - 5 years), (ii) inconsistent orchard ground vegetation management with resulting periods of high vegetation, and (iii) proximity of orchards to prime grassland habitats, which all combined for the plots in Thuringia.

Using ecological knowledge on the common vole and the results of the field study it can be concluded that the common vole long-term population level does not depend on the individuals that may be exposed to adverse effects of whatever kind (including also mowing or other kind of vegetation management, intoxictation after rodenticide use), in modern orchards.

Therefore the common vole does not appear as typical 'Focal Species' for orchard uses, because from its ecology it would only occur secondary and only in those modern orchards (sink habitat) where adjacent permanent grassland serves as source habitat, typically expected only in gradation years.

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Report:	[redacted]d;[redacted];2009;M-355944-01
Title:	Letter of Access for Generic Behavioural Ecology Data: Study Report BASF DocID 2006/1039467 and Evaluation Document BASF DocID 2009/1100344 - Grouping: Pome-fruit orchard, foliar stages: - Small mammal monitoring in modern pome fruit orchards of Baden-Wuerttemberg and Thuringia - and - Field study on small herbivorous mammals in modern pome fruit orchards: Evaluation in support of regulatory submissions-
Report No:	M-355944-01-1
Document No:	M-355944-01-1
Guidelines:	**-/-**
GLP/GEP:	**n.a.**

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Report:	[redacted]5;[redacted];2014;M-488425-01
Title:	Propineb: Population-level risk assessment for the common vole - Use in orchards in Europe
Report No:	13068-BCS
Document No:	M-488425-01-1
Guidelines:	**No guideline at the time of study conduct (recommendations in EFSA Opinion on good modelling practice)**
GLP/GEP:	**no**

Objective:

In order to connect the risk assessment on the individual level (TER calculation) to the protection goal for higher tier risk assessment of "no visible mortality and no long-term repercussions for abundance and diversity" (EFSA 2009), a population-level risk assessment has been conducted for the substance propineb with an individual based population model for the Common vole (*Microtus arvalis*).

Material and methods:

Simulations were conducted with the population model for the common vole (*Microtus arvalis*) implemented in the commercial software POLARIS (software version 1.5, common vole model version 2.0, WSC Scientific GmbH). This model is an updated version based on the model described in [redacted] (2013 [2]). In this publication a detailed model description following the ODD protocol (Grimm et al., 2006 [3]) is given together with a description on the calibration and validation process as well as sensitivity analyses.

[2] [redacted] 2013. From home range dynamics to population cycles: validation and realism of a common vole population model for pesticide risk assessment. Integr. Environ. Assess. Manag. 9: 294 – 307

[3] Grimm, V., Berger, U., Bastiansen, F., Eliassen, S., Ginot, V., Giske, J., Goss-Custard, J., Grand T., Heinz, S., Huse, G., et al. 2006. A standard protocol for describing individual-based and agent-based models. Ecol.

Population dynamics of the common vole emerge due to the interaction of the individual voles which each other. The sublethal effect measured on individual level in rats can be directly integrated into the model, so that the individual voles are affected according to their dose calculated according to the standard EFSA approach. Due to the effects on individual level the population dynamics change and effects on population level over time is the outcome of the model. As a simulation end-point population density on 1st of January was used to compare control populations and treatment populations, as recommended in the proceedings of the MODELINK WORKSHOP, case study group "wild mammals" (Schmitt et al. in press [4]).

The population modelling approach was conducted following EFSA "Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products" (EFSA Journal 2014;12(3):3589) and a summary table of the model development, testing and regulatory question is provided with the report as requested.

All simulations were conducted in a very worst-case exposure scenario: only treated orchard without refugia, small landscape size of only 5 ha, no immigration considered. Simulations were conducted for 1x, 2x, or 5x the application rate in pome fruit orchards (2x 1.575 kg a.s./ha; 14 d interval, 70% interception), in order to provide different "margins of safety" in this risk assessment.

Based on the effect profile obtained from studies with propineb in rat, the following effects were imposed on the voles in the model. The effect of the myasthenia of the hind extremities was simulated assuming immediate mortality (Effect A) under field condition if mobility is reduced. Additional indirect effects were simulated by reducing the mating success (effect B) and the number of live pups per litter (effect C). For all these effects a dose-response relationship was established and within the model the three different effects are imposed on the individual voles based on the TWA of the ingested dose.

Expected effects were calculated based exposure from dietary intake, according to appendix G of the EFSA guidance (2009).

Results:

Combining all worst-case effect conditions (A+B+C) no impacts on population dynamics of the common vole were observed for the proposed application rate (1x). Pronounced effects on the population viability under these conditions were observed after application at 2x or 5x the intended application rate, demonstrating the sensitivity of the model when severe toxic effects were imposed.

However, these effects on mobility were not observed in targeted experimental studies with the common vole as the species of concern (KCA 8.1.1.2.2 /01; [redacted]; 2013; M-476238-01, KCA 8.1.1.2.2 /02; [redacted].; 2014; M-487560-01): no effects on mobility (and also no mortality) were observed following 4 weeks of exposure to an average dose of ca. 100 mg/kg bw/d.

Model. 198: 115-126.

[4] [redacted] Population-level effects on small mammals. Case study 2, Modelink workshop, in press.

Therefore the effect condition combination B+C, i.e. without the mobility effect (which is translated into mortality in the model), is clearly more relevant than A+B+C for this species of concern which is simulated in the population model.
However, also effects B or C are considered secondary to the myopathy in the rat studies underlying the effect parametrization. For B+C, neither the 1x, 2x nor 5x application rate led to significant effects on the local population level of the common vole (max: 5.6% at 5x). A 5x application rate is equivalent with a TER of 5.
Equally, simulating the effect condition C (reduction of litter size in rat studies) alone resulted in negligible effects at the 1x, 2x and 5x application rate on the local population level of the common vole (max: 5.1% at 5x). A 5x application rate is equivalent with a TER of 5.

Difference of population density in control vs. treatment simulations

Szenario	Simulated application rate	Max. difference compared to control[1]
All effects (A, B, C), 1x	1x	1.0%
All effects (A, B, C), 2x	2x	100%
All effects (A, B, C), 5x	5x	100%
Mating & Pups (B, C), 2x	2x	2.8%
Mating & Pups (B, C), 5x	5x	5.6%
Pups only (C), 2x	2x	2.0%
Pups only (C), 5x	5x	5.1%

[1] Measured on 1st of January of each year, in which applications were simulated.

Conclusion:
It could be clearly demonstrated that no long-term effects on population level would be expected in common vole populations exposed at the maximum recommended application rate in an orchard scenarios, even if a worst-case exposure scenario and unrealistic worst-case effect scenario (A+B+C) is assumed. For more realistic worst-case effect scenarios, no long-term effects on the vole population level were predicted even at 5x the maximum recommended application rate.

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Report:	[redacted];[redacted];[redacted];[redacted];2014;M-488499-01
Title:	Non-GLP interim report - Preliminary results of field study to monitor the potential effects of a fungicide on small mammal populations in meadows in Central Europe
Report No:	R12238-1
Document No:	M-488499-01-1
Guidelines:	**No guideline at the time of study conduct (recommendations in EFSA GD 2009)**
GLP/GEP:	**Yes** (study is conducted under GLP, however interim-report non GLP)

Objective:
The objective of the study is the evaluation of potential effects of spray applications of Antracol WG70 on Common vole (*Microtus arvalis*) populations based on the comparison of live trapping data from treated plots and untreated control plots in meadows. This interim report provides an overview of

the initial phase of the study, i.e site selection and first application of the test item. The study protocol is included as Appendix to the interim report.

Material and Methods:

Study site

Study site selection was piloted in the federal states Thuringia, Baden-Württemberg, Hesse (in Germany), and the provinces Alsace (France), Ardennes (Luxembourg) and Luxemburg (Belgium). Based on pre-trapping in spring 2013 and 2014, a suitable study site was identified in the Alsace.

Methods

The work included searching for collaborating farmers, live trapping of small mammals to check for local distributions of common voles on several study plots and application for all necessary permissions needed for the realisation of the study (trapping, animal marking, product applications on meadows etc.).

'Ugglan' multiple capture live traps were used for live trapping. Each trap was baited with rolled oats which served as food for captured animals. Between 20 and 80 traps were placed per potential study plot. Traps were activated for trapping in the evening and checked in the morning. Pre-trapping was performed in spring 2013 and spring 2014.

Results:

A total of six study sites were examined for the feasibility of a long-term effect study of Antracol WG70 on populations of the common vole in meadows. The suitability of the study sites comprising different parameters are summarized in the table below.

Suitability of study sites for a common vole long-term effect study with Antracol WG70

Parameter	**Potential study sites investigated for suitablity**					
	Thuringia (Germany)	Baden-Württemberg (Germany)	Hesse (Germany)	**Alsace (France)**	Ardennes (Luxembourg)	Luxemburg (Belgium)
Collaborating farmers in 2013 or 2014	Yes	Yes	Yes	**Yes**	Yes	No
All permissions in place	Yes	Yes	Yes	**Yes**	Yes	Yes
Population size of common voles	Moderate in spring 2013[1]	Low in spring 2014	Low in spring 2014	**High in spring 2014**	Low in spring 2013/14	n.d.
Overall suitability of the study site in 2013 and/or 2014	Not suitable	Not suitable	Not suitable	**Suitable in 2014**	Not suitable	Not suitable

[1] Population collapsed in June 2013 after heavy rain falls throughout Central Europe (Study was cancelled); n.d. = not determined; Belgium was just an option in 2013

The first application of the test item was conducted on 13 June 2014 by the Test Facility in cooperation with local farmers in compliance with GLP in the study site of Alsace (France). The actual application rate was within +/- 5% of the nominal target rate.

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Report:	[redacted];[redacted];[redacted];[redacted];2004;M-298157-01
Title:	Small mammals in vineyards of southern Germany basic data for risk assessment of pesticides
Report No:	M-298157-01-1
Document No:	M-298157-01-1
Guidelines:	**No guideline at the time of study conduct (recommendations in EFSA GD 2009)**
GLP/GEP:	**n.a.**

Objective:

The objective of this poster published presented at the SETAC Europe Annual Meeting in Lille 2005 was to summarise the qualitative and quantitative evaluation of a study (KCP 10.1.2.2/08 [redacted], I.; et al.; 2003; M-237095-01-2; German language) conducted on the small mammal fauna inhabiting vineyards in southwestern Germany with a particular focus on the occurrence of herbivorous species (voles).

Materials and Methods:

A capture-mark-recapture study has been conducted between April and August 2002 by means of live-trapping. Three study sites were selected which differed in ground cover:

(I) a vineyard devoid of any ground cover ([redacted]),

(II) a vineyard characterized by grassy strips alternating with bare soil ([redacted]) and

(III) a completely grass-covered untended vineyard ([redacted]).

Traps were set in an area of 0.25 ha in the centre of the vineyards. A total of 15 trapping series consisting of 9600 trap units was conducted. At every study site traps were set once a month for four days. Trapped small mammals were marked individually at the first catch.

Results:

During the investigation period 53 small mammals were detected belonging to 2 species of 2 different families: common vole (*Microtus arvalis*–Arvicolidae) and wood mouse (*Apodemus sylvaticus*–Muridae). Common voles were only recorded in the vineyard (III) in densities reflecting a local population (28.8 Ind./ha). This vineyard was characterized by an untended grassy ground cover on 100 % of the area.

No voles were caught in the vineyard (I) which did not possess any contiguous soil cover vegetation (0 voles/ha), and only ondividual (0.8 Ind/ha) in the vineyard with grass strips alternating with bare soil.

Wood mice were caught in every vineyard in low numbers of 1 to 4 individuals per site and probably comprised also dispersing individuals since the recapture rates proved low.

Trapping results of common vole and wood mouse at the three study sites (average of 5 trapping series)

Site	**Coverage of ground vegetation**	**Common vole**		**Wood mouse**	
		Individuals [#]	**Population [Ind./ha]**	**Individuals [#]**	**Population [Ind./ha]**
(I)	No area with contiguous soil cover vegetation	0	0	0.8	3.2

[redacted]					
(II) [redacted]	Grassy strips alternating with bare soil	0.2	0.8	0.8	3.2
(III) [redacted]	Full area with untended grass cover	7.2	28.8	1.6	6.4

Conclusion:

Southwestern German vineyards without full area ground vegetation cover represent a suboptimal habitat for common voles since population densities proved well below the densities found in other habitats. The existence of an untended grass cover in vineyards is considered to be crucial for the regular occurrence of small mammal populations, particularly vole populations.

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Report:	*KCP 10.1.2.2 /x8: [redacted], et al.; 2003; M-237095-01-1*
Title:	*Kleinsäugercoenosen südwestdeutscher Weinberge*
Report No:	*n.a. (Carolinea 61: 191-196)*
Document No:	*M-237095-01-1*
Guidelines:	***-/-***
GLP/GEP:	***No***

***Background**:*

This publication provides more detailed information (material, methods, results and discussion) on the study behind the poster submitted as KCP 10.1.2.2/06 ([redacted] et al.; 2004; M-298157-01).

The information relevant for the evaluation in this dossier is included in the summary to KCP 10.1.2.2/06 and therefore not repeated here. The original publication is primarily submitted to permit tracking poster and translation back to the content of the original publication.

For EU review the study translated in Enlish is provided, see study mentioned below. This German original can be provided upon request.

Report:	[redacted];[redacted];[redacted];[redacted];2003;M-237095-01
Title:	Small mammals in vineyards in south-west Germany
Report No:	M-237095-01-2
Document No:	M-237095-01-2
Guidelines:	**-/-**
GLP/GEP:	**no**

Background:

This in-house translation aims to provide access for non-German language readers to the more detailed information (material, methods, results and discussion) on the study behind the poster submitted as KCP 10.1.2.2/07, [redacted]; et al.; 2003; M-237095-01-2.

The information relevant for the evaluation in this dossier is included in the summary to KCP 10.1.2.2/06 [redacted] et al.; 2004; M-298157-01 and therefore not repeated here. The document is primarily submitted in order to permit cross-check of the poster with the original publication (in German language).

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Report:	[redacted]6;[redacted];[redacted];2012;M-443162-01
Title:	Determination of the residues of propineb in/on barley after spray application of antracol in northern France, Germany, Spain and Italy
Report No:	11-2956
Document No(s):	Report includes Trial Nos.: 11-2956-01 11-2956-02 11-2956-03 11-2956-04 M-443162-01-1
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 Guidedance working document 7029/VI/95 rev.5 (1997-07-22) US EPA OCSPP Guideline No. 860.1500.SUPP**
GLP/GEP:	**yes**

Summary:
The purpose of the study 11-2956 was to determine the magnitude of the relevant residues of propineb (propineb (determined via CS_2 and via PDA) and PTU) in/on barley (green material) after one spray application with Antracol (WG 70) a water-dispersible granules formulation containing 70% w/w propineb. The study included four supervised residue trials conducted in Northern Europe (northern France and Germany) and Southern Europe (Spain and Italy) during the 2011 season. The actual application data are presented in the following table. This data reflects the intended application scheme.

Dates of experimental work: February 21 to April 09, 2014

Application summary

Trial no. Country	Formulation	Appl. mode	Treated area/ Reference	Application					
				No. of appl.	Growth stage (BBCH code)	Test item rate (kg/ha)	Water rate (L/ha)	a.s.	Appl. Rate (kg a.s./ha)
11-2956-01 northern France	Antracol	SPI	GF	1	25	2.0	300	propineb	1.4
11-2956-02 Germany	Antracol	SPI	GF	1	29	2.0	300	propineb	1.4
11-2956-03 Spain	Antracol	SPI	GF	1	30	2.0	300	propineb	1.4
11-2956-03 Italy	Antracol	SPI	GF	1	30	2.0	300	propineb	1.4

a.s.: active substance, Appl.: Application, SPI: Spraying, GF: Whole Area

The analysis were conducted according to the following analytical method:

Summary of analytical method criteria to this study

Active substance	Analytes	Method number	Limit of quantification [mg/kg]	Measurement principle
propineb	Propineb (calculated as CS_2)	01099	0.05 [a]	HPLC-MS/MS
	PTU	01099	0.01 [b]	HPLC-MS/MS
	Propineb (via PDA)	01099	0.05 [c]	HPLC-MS/MS

[a] fortified as propineb, determined, calculated and expressed as CS_2
[b] fortified, determined, calculated and expressed as PTU
[c] fortified as PDA, determined as 1,2-dibenzoyl propylene diamine (1,2BisBzPDA), calculated and expressed as propineb

Propineb is determined via PDA (expressed as propineb) and via CS_2 (expressed as CS_2) according to method 01099. The metabolite of propineb PTU is determined as PTU (expressed as PTU) according to method 01099.

The average recoveries were within the acceptable range of 70 - 110%. RSD values are below 20%.

The level of residues of propineb (determined via CS_2 and via PDA) and its metabolite PTU in the treated samples are summarised in the table below. Some recoveries for propineb (determined via CS_2) were corrected for the apparent residues found in the control samples. Results were not corrected for concurrent recoveries.

Residue summary in/on barley

Trial No. Country	Sample material	DALT	Residues a.s. propineb			
			Propineb (via CS_2) determined and expressed as CS_2*	Propineb (via CS_2) determined and expressed as propineb**	PTU determined and expressed as PTU	Propineb (via PDA) determined as 1,2BisBZPDA expressed as propineb
11-2956-01 Northern France	Barley green material	0	24	45	0.21	35
		1	20	38	0.27	33
		2	17	32	0.19	36
		3	3.0	5.7	0.08	7.7
		5	2.5	4.7	0.07	4.4
		7	1.8	3.4	0.08	3.3
		10	0.64	1.2	0.03	1.4
11-2956-02 Germany	Barley green material	0	12	23	0.16	21
		1	12	22	0.20	18
		2	8.7	16	0.26	15
		3	6.4	12	0.19	12
		5	1.3	2.4	0.07	2.3
		7	0.81	1.5	0.06	1.6
		10	0.44	0.83	0.03	0.86
11-2956-03 Spain	Barley green material	0	17	33	0.23	33
		1	7.0	13	0.15	15
		2	5.8	11	0.26	20
		3	5.6	11	0.16	13
		5	3.6	6.9	0.19	8.9
		7	1.8	3.4	0.10	3.4
		10	0.55	1.0	0.03	1.6
11-2956-04 Italy	Barley green material	0	16 [b]	31	0.22	37 [a]
		1	10	20	0.17	17
		2	11	20	0.33	22
		3	8.9	17	0.29	15
		5	4.2	8.1	0.35	9.8
		7	2.3	4.3	0.19	5.2
		10	2.2	4.3	0.26	4.7

DALT= Days after last treatment, a.s.= active substance
* Factor for conversion of CS_2 into propineb: Residue CS_2 x 1.903
[a] Sample evaluated using one point calibration
[b] mean of duplicate analyses (35.9 and 37.2 mg/kg)

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Report:	KCP 10.1.2.2/11 [redacted] 7; [redacted]; 2015; M-513857-01-1
Title:	GLP field study to monitor potential long-term effects of Antracol WG70 on vole populations in meadows in Central Europe
Report No.:	R12238-1a
Document No.:	M-513857-01-1
Guideline(s):	No guideline at the time of study conduct (recommendations in EFSA GD 2009)
Guideline deviation(s):	--
GLP/GEP:	**Yes**

Aim

According to the Regulations (EC) 1107/2009 the possible adverse effects of crop protection products on wild vertebrates have to be assessed. Effects are depending on the inherent toxicity of those products and their exposure to wild vertebrates, as well as on the biology of those species.

The aim of this field study was to investigate the potential long-term effects of spray applications of Antracol WG70 (a.s. propineb) on wild populations of small herbivorous mammals (common voles) living in managed meadows in France.

Managed meadows were selected as study field as surrogate for grassy ground vegetation in arable fields, orchards or vineyards where vole populations might be exposed to propineb after use as agricultural fungicide.

The application scenario was designed to represent realistic worst case exposure of ground vegetation resulting from residue deposition after a canopy spray treatment at 2x 1.575 kg as/ha with 70% interception and a 7-d inter-application interval.

Material and Methods

The study was conducted on eight study fields in the Alsace, France. The meadows were selected based on results from explorative vole trapping sessions conducted in spring 2013 and 2014 (KCP 10.1.2.2 /07).

The size of the study fields ranged from 0.6 to 1.1 ha. Four study fields (treatment) were treated with Antracol WG70 (a.s. propineb) at an application rate of nominal 472.5 g a.s./ha in a spray volume of 200 L/ha according to Good Agricultural Practice (GAP) and in compliance with Good Laboratory Practice (GLP). Applications were conducted twice, the first application on 13 June 2014. The second application was carried out on 20 June 2014. The four remaining study fields served as control and were treated with 200 L/ha of water (control). Control and treatment fields were selected pairwise in vicinity to each other to avoid spatial effects of microclimatic differences, predation, structures of meadows, vegetation, surrounding, etc.

The preparation of all eight study fields used before application was similar in terms of fertilisation and management. The fields have been mowed between 02 and 06 June 2014 before the applications.

A live trapping campaign was carried out from May to September 2014 in order to assess the occurrence, abundance and population dynamics of common voles in the treated study fields compared to the control fields. A total of eleven trapping sessions in each of the study fields (one trapping session = two consecutive nights of trapping) were carried out. The first and the second trapping session were conducted before mowing and the first application; the third and further eight trapping sessions were conducted after the second of the two applications.

A total of 80 Ugglan multiple-capture traps per study field were used to live-trap common voles. The captured voles (≥ 7.0 g) were individually marked with Passive Integrated Transponders (PITs) and released at the site of capture.
The trapping data were evaluated and presented as abundance values and population parameters as follows:

Abundance values include the following parameters:

- Captures and Trapping efficiency (captures per 100 trap nights)
- Minimum Number Alive (MNA)
- Recapture

Population parameters include the following parameters:

- Body weight
- Reproductive status
- Sex ratio
- Age structure

The study endpoint was the evaluation of possible long-term effects on vole populations; therefore the calculation of the "Minimum Number Alive" (MNA) was considered to be a most useful parameter. The MNA is an estimate based on the sum of all individuals known to be alive during a specific trapping session. According to this methodology an individual is known to have been alive during a specific trapping session if it was captured either during that session or both before and thereafter. The MNA can be considered as an enumeration estimate and provides a conservative value for a population size which can be used to describe the dynamics of that population.
To assess whether the treatment with Antracol WG70 had any effect on populations of the common vole, the results of the four treatment fields were compared with those of the four control fields.

Results

Abundance values

Trapping Data (Tab. S1)

The trapping data are presented as captures and trapping efficiency (captures per 100 trap nights) over the Field Phase (1760 trap nights).

Table S1: Trapping data presented as number of captures and as trapping efficiency

	Study field no.								Total	
	1 (T)	2 (C)	3 (T)	4 (C)	5 (T)	6 (C)	7 (T)	8 (C)	Treatment	Control
Captures	383	412	714	728	506	443	471	443	2074	2026
Trapping efficiency	21.8	23.4	40.6	41.4	28.8	25.2	26.8	25.2	29.5	28.9

(T = Treatment; C = Control)

Over the study, a total of 4.100 common vole captures was recorded within the treatment and control fields.

Minimum Number Alive (MNA) (Fig S1)

The Minimum Number Alive (MNA) is presented as minimum and maximum range for control fields (grey shaded) and the arithmetic mean for the control and treatment fields.

Over the trapping period the MNAs show a parallel population development in treatment and control, with the treatment fields starting at a lower level than the controls (slightly outside the control range). This relative difference changed not remarkably during mowing and the two applications. Following trapping session 6 (calendar week 29) until the end of the trapping period the initial difference is compensated and the treatment populations remain within the range of the controls fields. The repeated measures ANOVA reveals no significant differences in population dynamics between the treatment and control fields over the course of the whole trapping period ($F = 0.9$, $p > 0.05$), during trapping session 1 + 2 ($F = 0.9$, $p > 0.05$) and during trapping session 3 – 11 ($F = 3.4$, $p > 0.05$).

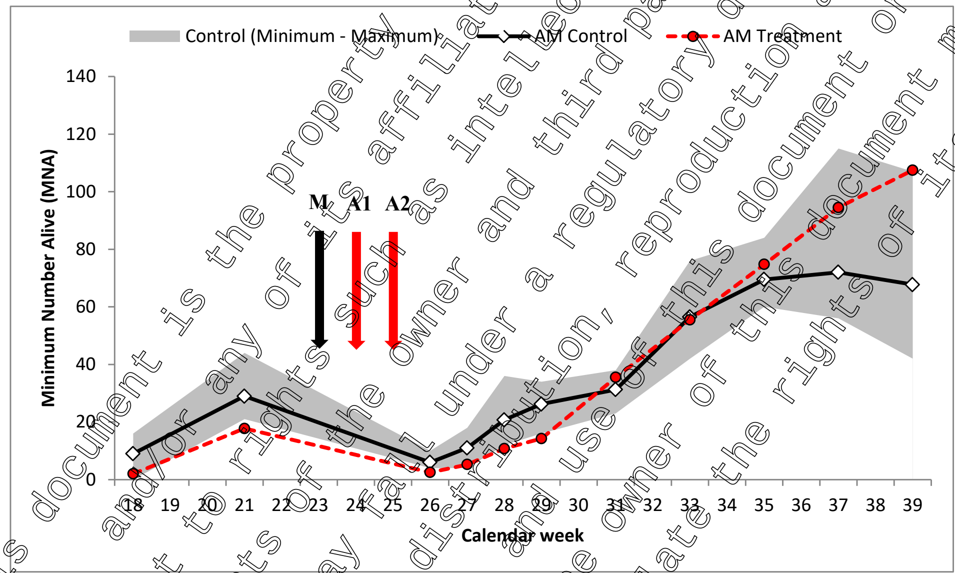

Figure S1: Minimum Number Alive (MNA) during the Field Phase in treatment and control

(AM = Arithmetic mean; M = Mowing; A1 = First Application; A2 = Second Application; Calendar week (CW) 18 = Trapping session (TS) 1; CW 21 = TS 2; CW 26 = TS 3, etc.)

Recapture [%]

The percentage of recaptured males and females are comparable for control and treatment fields (Table S2). In general the percentage of recaptured females is slightly higher than the percentage of recaptured males.

Table S2: Capture and recapture of males and females on the treatment and control fields

Sex	Treatment fields (n = 4)			Control fields (n = 4)		
	Capture [n]	Recapture [n]	Recapture [%]	Capture [n]	Recapture [n]	Recapture [%]
Males	655	230	35.1	623	234	37.6
Females	901	424	47.1	840	406	48.3

Fig. S2 and S3 indicate that the percentage of recaptured males and females is on a similar high level in treatment and control over the study.

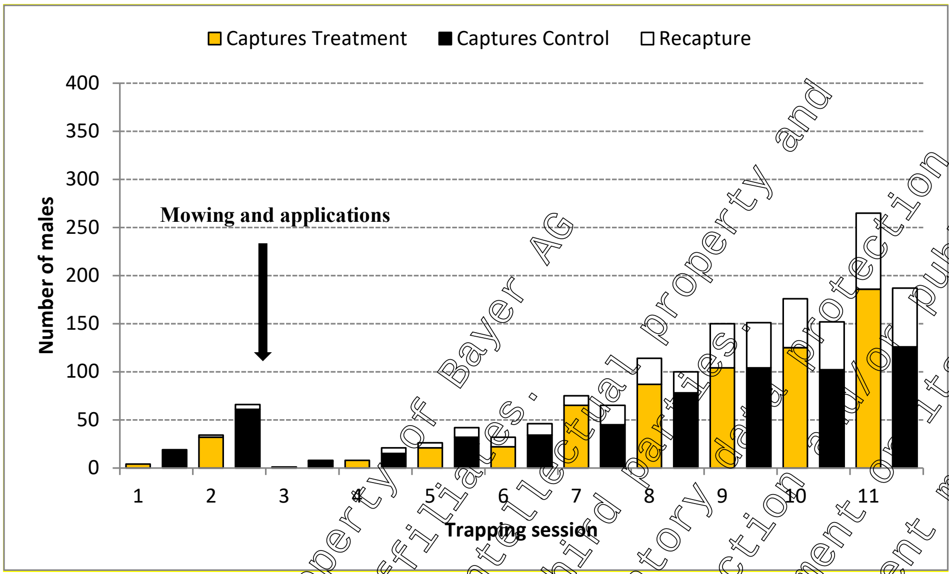

Figure S2: Captures and recaptures of males in treatment and control

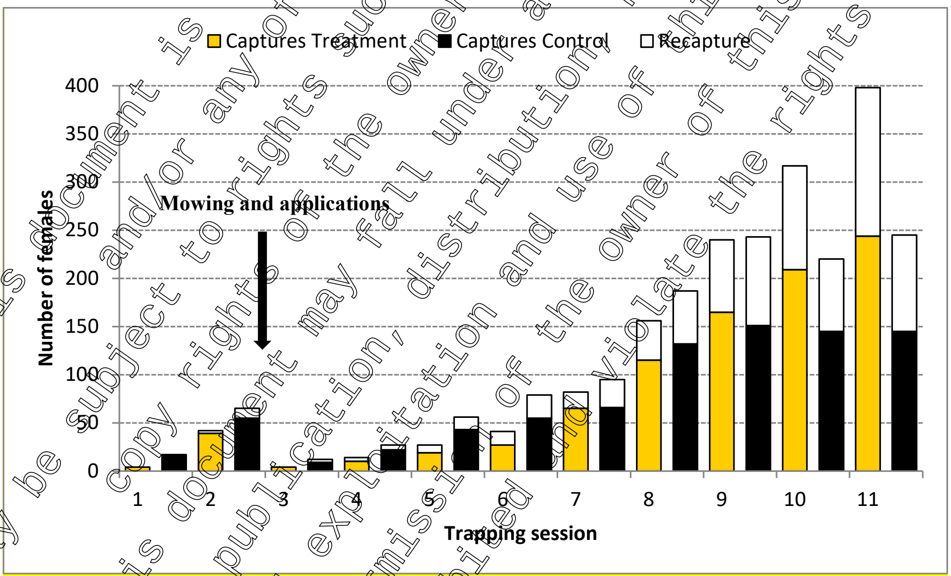

Figure S3: Captures and recaptures of females in treatment and control

The recapture of individual common voles over different phases of the trapping program is shown in Tables S3 to S6.

The percentages of the total recaptures reveal no indication of an adverse effect.

Table S3: Individuals during TS 1 – 2 (period before application) and recapture during TS 3 – 4 (period shortly after application

Sex	Treatment/ Control	Individuals [n] during trapping session 1 – 2	Recaptured individuals [n] during trapping session 3 – 4	Recapture [%]
Males	Treatment	34	0	0.0
	Control	75	2	2.7
Females	Treatment	40	3	7.5
	Control	62	3	4.8
Total	Treatment	74	3	4.1
	Control	137	5	3.6

Table S4: Individuals during TS 1 – 2 (period before application) and recapture during TS 3 – 11 (whole period after application)

Sex	Treatment/ Control	Individuals [n] during trapping session 1 – 2	Recaptured individuals [n] during trapping session 3 – 11	Recapture [%]
Males	Treatment	34	1	2.9
	Control	75	4	5.3
Females	Treatment	40	4	10.0
	Control	62	8	12.9
Total	Treatment	74	5	6.8
	Control	137	12	8.8

Table S5: Individuals during TS 3 – 4 (period shortly after application) and recapture during TS 5 – 11 (period towards the end of the Field Phase)

Sex	Treatment/ Control	Individuals [n] during trapping session 3 – 4	Recaptured individuals [n] during trapping session 5 – 11	Recapture [%]
Males	Treatment	9	4	44.4
	Control	17	11	64.7
Females	Treatment	13	10	76.9
	Control	26	13	50.0
Total	Treatment	22	14	63.6
	Control	43	24	55.8

Table S6: Individuals during TS 3 – 6 (period shortly after application) and recapture during TS 7 – 11 (period towards the end of the Field Phase)

Sex	Treatment/ Control	Individuals [n] during trapping session 3 – 6	Recaptured individuals [n] during trapping session 7 – 11	Recapture [%]
Males	Treatment	38	13	34.2
	Control	61	20	32.8
Females	Treatment	38	26	68.4
	Control	89	37	41.6
Total	Treatment	76	39	51.8
	Control	150	57	38.0

Overall, the abundance values (trapping data, MNAs and recapture rate) did not reveal any evidence for treatment related differences between populations of the common vole on control and treatment fields.

Population parameter

Body weight (Fig S4 & S5)

The body weights of individual adult males and females are presented as minimum and maximum range for control fields (grey shaded) and the arithmetic mean for the control and treatment fields.

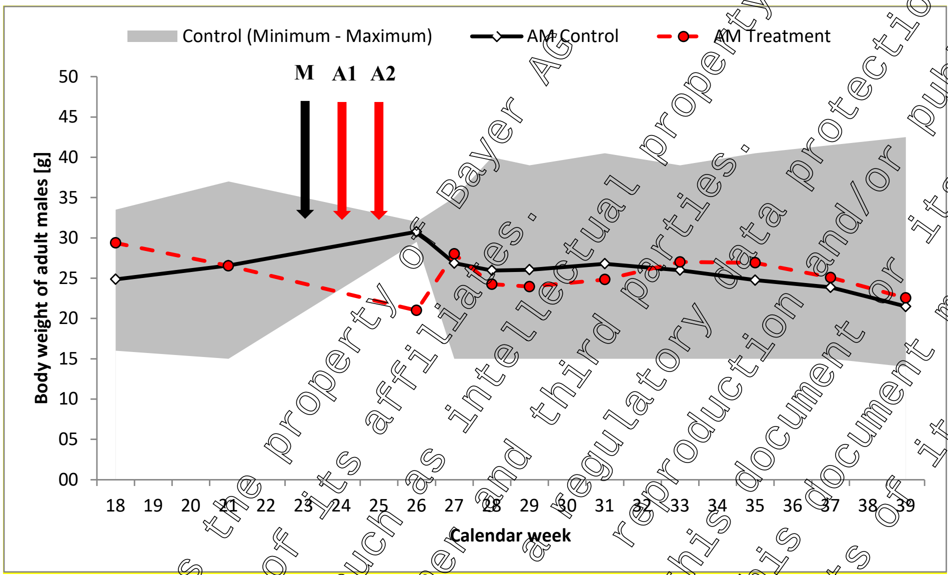

Figure S4: Body weights of adult males in treatment and control

(AM = Arithmetic mean; M = Mowing; A1 = First Application; A2 = Second Application; Calendar week (CW) 18 = Trapping session (TS) 1; CW 21 = TS 2; CW 26 = TS 3; etc.)

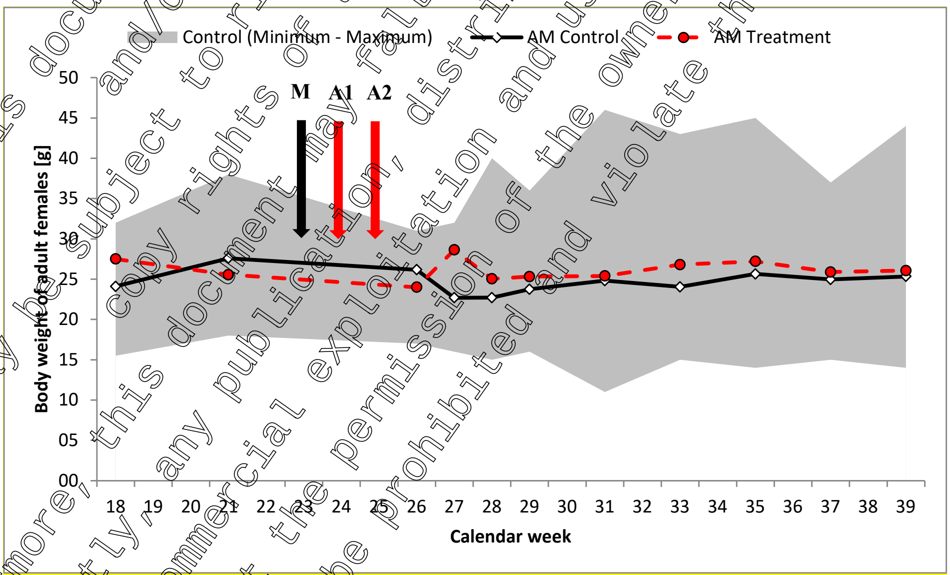

Figure S5: Body weights of adult females in treatment and control

(AM = Arithmetic mean; M = Mowing; A1 = First Application; A2 = Second Application)

The mean body weights in the treatment fields are very similar to those in the control fields. The only instance of a seeming discrepancy between the average body weight of adult males in calendar week 26 (Trapping session 3) is based on a very low number of trapped individuals (Control: two individuals; Treatment: one individual).

Reproductive status (Fig. S6 & S7)

The reproductive status (as percentage of active males and females) is presented as minimum and maximum range for control fields (grey shaded) and as overall values for the control and treatment fields in.

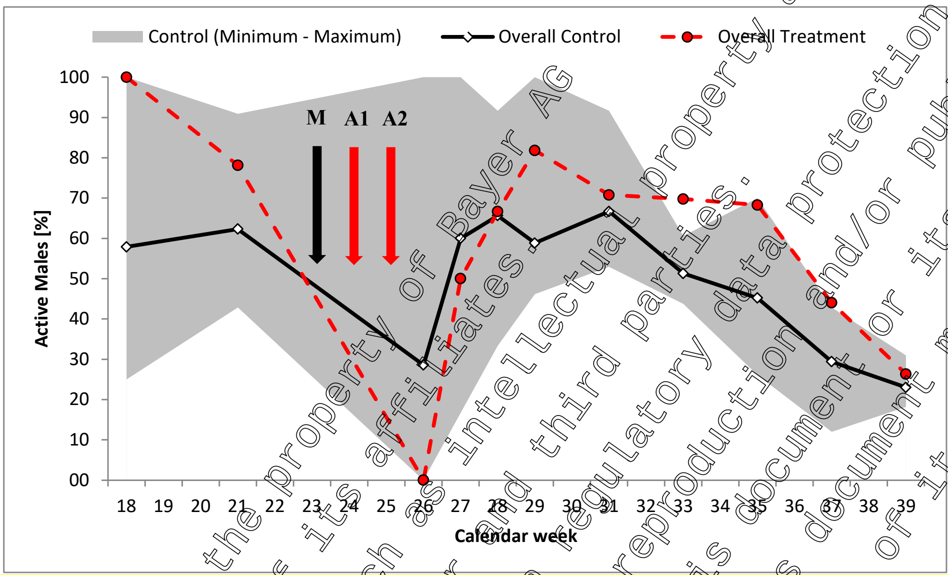

Figure S6: Active males [%] during the Field Phase in treatment and control

(M = Mowing; A1 = First Application; A2 = Second Application; Calendar week (CW) 18 = Trapping session (TS) 1; CW 21 = TS 2; CW 26 = TS 3; etc.)

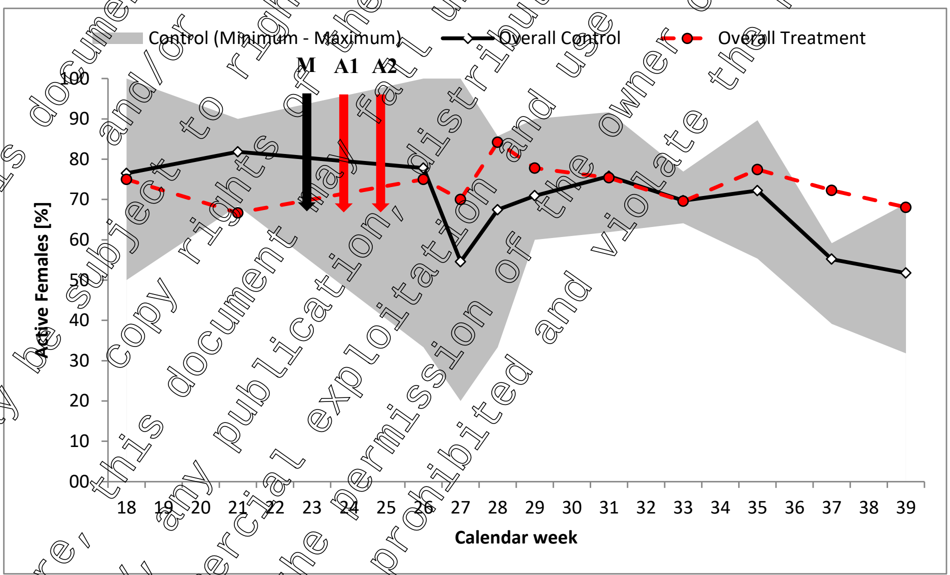

Figure S7: Active females [%] during the Field Phase in treatment and control

(M = Mowing; A1 = First Application; A2 = Second Application)

The percentages of active males and females calculated for the treatment fields is within the range of the minimum and maximum of the control fields (except slightly higher in trapping session 8, CW 33 for males, and in trapping session 10, CW 37 for females).

No significant differences between the percentages of active males and females between treatment and control fields can be detected (repeated measures ANOVA: Male: $F = 2.5$, $p > 0.05$; Female: $F = 1.7$, $p > 0.05$).

Sex ratio (Fig S8)

The percentage of females and males in the treatment and control fields is summarised in Fig S8.

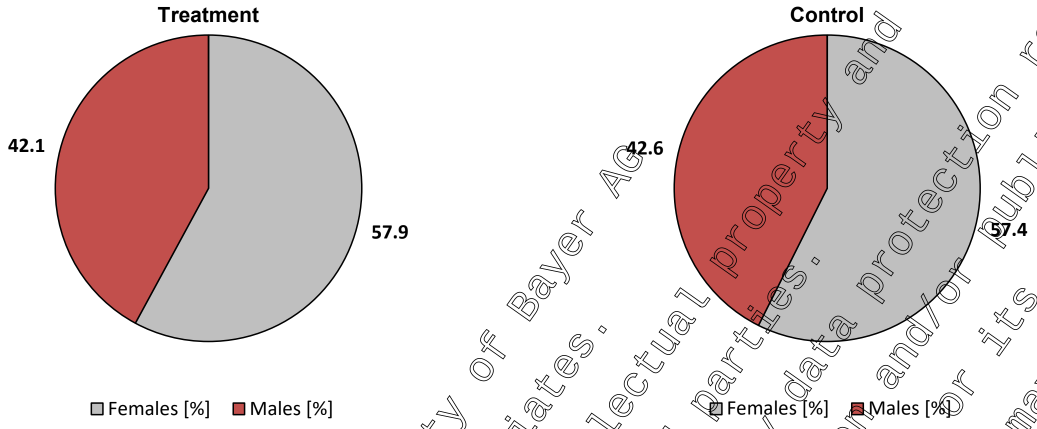

Figure S8: Percentage of females and males on treatment and control

No differences were detected between treatment and control (Mann Whitney U-Test; $p > 0.05$).

Age structure (Fig. S9)

The number of adults and juveniles in the treatment and control fields are summarised in Fig S9. Juveniles were found during the whole study in the treatment fields in comparable numbers to the control fields.

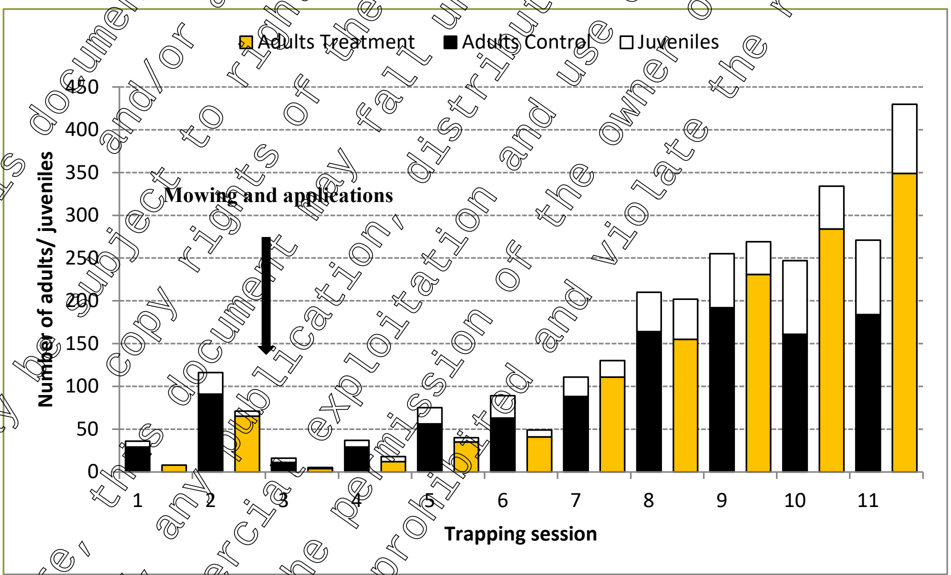

Figure S9: Number of adults and juveniles during the Field Phase in treatment and control

Overall, the population parameters (body weight, reproductive status, sex ratio and age structure) of the current study did not show any evidence for treatment related differences between populations of the common vole on control and treatment fields.

Conclusion

No discernible long-term effect on wild populations of the common vole living in managed fields (as surrogate for grassy ground vegetation in arable fields, orchards or vineyards) in France was found during the Field Phase of the current study, following two spray applications of Antracol WG70 (a.s. propineb) at an application rate of nominal 472.5 g a.s./ha in a spray volume of 200 L/ha according to Good Agricultural Practice (GAP) and in compliance with Good Laboratory Practice (GLP).

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

Information on effects of propineb on reptiles or amphibians is not available. No guidelines for studies with terrestrial amphibian life stages and reptiles are available and no risk assessment schemes are established so far.

CP 10.2 Effects on aquatic organisms

The risk assessment is based on the current Guidance Document on Aquatic Ecotoxicology, SANCO/3268/2001, rev 4 final, 17 October 2002. Some implications of the new Aquatic Guidance Document (EFSA Journal 2013, 11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290), which is not yet notified, have been taken into consideration as well.

Only endpoints used for the risk assessment are presented here. For an overview of all available endpoints on propineb and its metabolites please refer to the respective section of the MCA document.

Risk assessment for aquatic organisms

Ecotoxicological endpoints used in risk assessment

Table 10.2- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Propineb WG 70	Fish, acute , *Oncorhynchus mykiss*	LC_{50}	6.81 mg product/L	KCP 10.2.1 /02 [redacted] (2011) M-401282-01-1
	Invertebrate, acute *Daphnia magna*	EC_{50}	4.10 mg product/L	KCP 10.2.1 /03 [redacted] (2010) M-372880-01-1
	Invertebrate, chronic *Daphnia magna*	NOEC	0.025 mg product/L	KCP 10.2.2 /01 [redacted] (1990) M-016882-01-1
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_rC_{50}	0.239 mg product/L	KCP 10.2.1 /04 [redacted] (2010) M-397379-01-1
	Algae, growth inhibition *Desmodesmus subspicatus*	E_bC_{50} E_rC_{50}	0.67 mg product/L 2.4 mg product/L	KCP 10.2.1 /02 [redacted] (1989) M-016881-01-1
Propineb VM 80	Fish, acute *Oncorhynchus mykiss*	LC_{50}	0.329 mg a.s./L [1]	KCA 8.2.1 /01 LoEP M-016891-01-1
	Fish, chronic *Oncorhynchus mykiss*	NOEC	0.0823 mg a.s./L [1]	KCA 8.2.2 /01 LoEP M-016895-01-1
	Invertebrate, acute *Daphnia magna*	EC_{50}	1.50 mg a.s./L [3]	KCA 8.2.3 /03 [redacted] (2004) M-086995-01-1
	Invertebrate, chronic *Daphnia magna*	NOEC	0.015 mg a.s./L [4]	KCA 8.2.5.1 /01 LoEP M-016899-01-1
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} E_rC_{50}	0.017 mg product/L 0.055 mg product/L	KCA 8.2.6.1 /04 [redacted] (2004) M-088372-01-1
Propineb WP 70	Invertebrate, chronic *Daphnia magna*	NOEC	0.480 mg a.s./L [5]	KCA 8.2.5.1 /04 [redacted] (2005) M-252129-01-1

Test substance	Test species	Endpoint	Reference
	Lentic freshwater microcosm *Oncorhynchus mykiss*	NOEC > 0.6 mg a.s./L [2)]	KCA 8.2.8 /01 [redacted] (2005) M-246864-02-1
	Sediment dweller *Chironomus riparius*	EC_{15} 0.89 mg a.s./L [6)]	KCA 8.2.5.3 /03 [redacted] (2005) M-253817-01-1
Propineb-DIDT	Invertebrate, acute *Daphnia magna*	EC_{50} 0.112 mg pm/L	KCA 8.2.4.1/04 [redacted] (2014) M-481861-01-1
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_rC_{50} 0.114 mg pm/L	KCA 8.2.6.1/05 [redacted] (2014) M-485275-01-1
PTU (propylene thiourea)	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100 mg pm/L	KCA 8.2.1/03 LoEP M-016918-01-1
	Fish, chronic *Oncorhynchus mykiss*	NOEC ≥ 102 mg pm/L	KCA 8.2.2/02 LoEP M-016913-01-1
	Invertebrate, acute *Daphnia magna*	EC_{50} 18.4 mg pm/L	KCA 8.2.4.1/02 LoEP M-016919-01-1
	Invertebrate, chronic *Daphnia magna*	NOEC 3.2 mg pm/L	KCA 8.2.5.1/02 [redacted] (1998) M-016917-01-1
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} > 100 mg pm/L E_rC_{50} > 100 mg pm/L	KCA 8.2.6.1/03 LoEP M-016916-01-1
PU (propylene urea)	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100 mg pm/L	KCA 8.2.1/04 LoEP M-016922-01-1
	Fish, chronic *Oncorhynchus mykiss*	NOEC ≥ 2.0 mg pm/L	KCA 8.2.2.1/01 LoEP M-016921-01-1
	Invertebrate, chronic *Daphnia magna*	EC_{50} > 100 mg pm/L [7)] NOEC > 100 mg pm/L	KCA 8.2.5.1/03 LoEP M-016924-01-1
	Algae, growth inhibition *Scenedesmus subspicatus*	E_bC_{50} > 1000 mg pm/L E_rC_{50} > 1000 mg pm/L	KCA 8.2.6.1/02 LoEP M-016920-01-1
4-MI	Fish, acute	LC_{50} 393 mg pm/L	KCA 8.2.8 /02 [redacted] (2014) M-488533-01-1
	Invertebrate, acute	LC_{50} 7.3 mg pm/L	
	Algae, growth inhibition	EC_{50} 49 mg pm/L	

a.s. = active substance, pm = pure metabolite, prod. = product
[1]) The EU agreed endpoint refers to the tested item Propineb VM 80. The endpoint used in risk assessment is calculated on a basis of 82.3% a.s. content (nominal initial with analysis)
[2]) Endpoint of microcosm study used in the refined risk assessment
[3]) Lower endpoint obtained with a new study ([redacted] 2004, M-086995-01-1)
[4]) The value of 0.026 mg as/L that appears in the EU Review Report for Propineb is mistakenly attributed to the NOEC but is in reality the EC_{50} (see KCA 8.2.5). The NOEC of 0.015 mg as/L is the endpoint used in the risk assessment
[5]) Endpoint of 35 d *Daphnia* population study used in the refined risk assessment
[6]) Endpoint obtained with a new study ([redacted] 2005, M-253817-01-1)
[7]) The EU agreed endpoint refers to the NOEC from the chronic test, and this endpoint is also used for the acute risk assessment.

Note:
- Studies referring to KCA are filed in the dossier for the active substance.
- Studies written in grey type are referring either to studies in the corresponding Baseline-dossier for the active substance or to the dossier for the old representative formulation for Annex I inclusion (which is provided for renewal as well); whereas studies in black type are studies of the Supplemental dossier for the active substance or this present dossier for the new representative formulation.

Selection of algae endpoints for risk assessment

Processes in ecosystems are dominantly rate driven and therefore, the unit development per time (growth rate) appears more suitable to measure effects in algae. Also, growth rates and their inhibition can easily be compared between species, test durations and test conditions, which is not the case for biomass. After numerous discussions, the current test guidelines OECD TG 201, the EU-Method C3, the EC regulation for Classification and Labeling (EC regulation 1272/2008) and the PPR Opinion (EFSA Journal 461, 1-44; 2007) list growth rate as the most suitable endpoint of the algae inhibition test. Therefore, E_rC_{50} values will be taken into account for TER calculations presented in this document.

Predicted environmental concentrations used in risk assessment

Table 10.2- 2: Initial max PEC_{sw} values – FOCUS Steps 1 and 2

Compound	FOCUS Scenario	Orchards [A] 2 × 1.575 kg a.s./ha, 14 d int., BBCH 40-73	Grapes I 2 × 1.12 kg a.s./ha, 10 d int., BBCH 40-59	Grapes II 2 × 1.4 kg a.s./ha, 10 d int., BBCH >70
		$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]
Propineb	STEP 1	189.9	36.12	70.02
	STEP 2 – North [B]	153.3	10.08	37.46
	STEP 2 - South [B]	153.3	10.08	37.46
PTU	STEP 1	171.1	100.6	131.0
	STEP 2 - North [B]	16.35	1.237	4.410
	STEP 2 - South [B]	16.35	1.237	4.410
PU	STEP 1	205.9	112.0	148.6
	STEP 2 - North [B]	50.61	5.648	14.21
	STEP 2 - South [B]	57.17	8.206	15.81
Propineb-DIDT	STEP 1	109.1	54.33	73.75
	STEP 2 - North [B]	36.03	2.369	8.807
	STEP 2 - South [B]	36.03	2.369	8.807
4-MI	STEP 1	40.63	18.77	25.99
	STEP 2 - North [B]	11.89	0.867	2.951
	STEP 2 - South [B]	11.89	1.024	2.951

[A] Worst case values for early application in apples
[B] Worst case values for single or multiple application

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

Compound	FOCUS Scenario	Orchards 2 × 1.575 kg a.s./ha, 14 d int., BBCH 40-73	Grapes I 2 × 1.12 kg a.s./ha, 10 d int., BBCH 40-59	Grapes II 2 × 1.4 kg a.s./ha, 10 d int., BBCH >70
		$PEC_{sw, max}$ [A] [µg/L]	$PEC_{sw, max}$ [A] [µg/L]	$PEC_{sw, max}$ [A] [µg/L]
Propineb	D3 (ditch, 1st)	121.3	-	-
	D4 (pond, 1st)	7.378	-	-
	D4 (stream, 1st)	116.2	-	-
	D5 (pond, 1st)	7.377	-	-
	D5 (stream, 1st)	117.6	-	-
	D6 (ditch, 1st)	-	6.195	23.68
	R1 (pond, 1st)	7.377	0.214	0.849
	R1 (stream, 1st)	98.15	4.581	17.44
	R2 (stream, 1st)	130.0	6.085	23.36
	R3 (stream, 1st)	138.2	6.480	24.65
	R4 (stream, 1st)	98.17	4.579	17.15
Propineb-DIDT	D3 (ditch, 1st)	28.70	-	-
	D4 (pond, 1st)	1.748	-	-
	D4 (stream, 1st)	<0.001	-	-
	D5 (pond, 1st)	1.747	-	-
	D5 (stream, 1st)	<0.001	-	-
	D6 (ditch, 1st)	-	1.470	<0.001
	R1 (pond, 1st)	1.748	0.051	0.018
	R1 (stream, 1st)	0.057	0.062	0.467
	R2 (stream, 1st)	0.070	<0.001	0.465
	R3 (stream, 1st)	28.09	1.535	<0.001
	R4 (stream, 1st)	19.97	0.081	0.321

[A] Worst case values for single or multiple application

Table 10.2- 4: Initial max FOCUS Step 4 PEC_{sw} values for propineb for the use in orchards (early) (2× 1575 g a.s./ha) with mitigation options; SD denotes spray drift buffer

Buffer Width & Type	Scenario	Single application [A]			
		PEC_{sw} [µg/L] Drift Reduction			
		0%	50%	75%	90%
5 m SD	D3 (ditch, 1st)	95.32	47.66	23.83	9.532
	D4 (pond, 1st)	8.306	4.153	2.077	0.831
	D4 (stream, 1st)	99.83	49.92	24.96	9.983
	D5 (pond, 1st)	8.305	4.153	2.076	0.831
	D5 (stream, 1st)	101.0	50.52	25.26	10.10
	R1 (pond, 1st)	8.306	4.153	2.076	0.831
	R1 (stream, 1st)	84.33	42.16	21.08	8.432
	R2 (stream, 1st)	111.7	55.85	27.93	11.17
	R3 (stream, 1st)	118.7	59.36	29.68	11.87
	R4 (stream, 1st)	84.34	42.17	21.09	8.434
10 m SD	D3 (ditch, 1st)	58.54	29.27	14.63	5.854
	D4 (pond, 1st)	4.555	2.277	1.139	0.455
	D4 (stream, 1st)	61.31	30.65	15.33	6.131
	D5 (pond, 1st)	4.554	2.277	1.138	0.455
	D5 (stream, 1st)	62.05	31.02	15.51	6.205
	R1 (pond, 1st)	4.554	2.277	1.139	0.455
	R1 (stream, 1st)	51.78	25.89	12.95	5.178
	R2 (stream, 1st)	68.60	34.30	17.15	6.860
	R3 (stream, 1st)	72.91	36.46	18.23	7.291
	R4 (stream, 1st)	51.80	25.90	12.95	5.180
20 m SD	D3 (ditch, 1st)	13.39	6.692	3.346	1.338
	D4 (pond, 1st)	1.473	0.736	0.368	0.147
	D4 (stream, 1st)	14.02	7.009	3.505	1.402
	D5 (pond, 1st)	1.473	0.736	0.368	0.147
	D5 (stream, 1st)	14.19	7.094	3.547	1.419
	R1 (pond, 1st)	1.473	0.736	0.368	0.147
	R1 (stream, 1st)	11.84	5.920	2.960	1.184
	R2 (stream, 1st)	15.69	7.843	3.922	1.569
	R3 (stream, 1st)	16.67	8.336	4.168	1.667
	R4 (stream, 1st)	11.84	5.922	2.961	1.184
30 m SD	D3 (ditch, 1st)	5.119	2.559	1.280	0.512
	D4 (pond, 1st)	0.713	0.357	0.178	0.071
	D4 (stream, 1st)	5.361	2.681	1.340	0.536
	D5 (pond, 1st)	0.713	0.357	0.178	0.071
	D5 (stream, 1st)	5.426	2.713	1.356	0.543
	R1 (pond, 1st)	0.713	0.357	0.178	0.071
	R1 (stream, 1st)	4.528	2.264	1.132	0.453
	R2 (stream, 1st)	5.999	2.999	1.500	0.600
	R3 (stream, 1st)	6.376	3.188	1.594	0.638
	R4 (stream, 1st)	4.529	2.265	1.132	0.453

[A] Single application values are worst case values and used for risk assessment

Table 10.2- 5: Initial max FOCUS Step 4 PEC_{sw} values for propineb for the use in grapes I (2× 1120 g a.s./ha) with mitigation options; SD denotes spray drift buffer

Buffer Width & Type	Scenario	Single application [A] PEC$_{sw}$ [µg/L] Drift Reduction 0%	50%	75%	90%
0 m SD	D6 (ditch, 1st)	6.195	3.098	1.540	0.620
	R1 (pond, 1st)	0.214	0.107	0.054	0.022
	R1 (stream, 1st)	4.581	2.290	1.145	0.458
	R2 (stream, 1st)	6.085	3.043	1.522	0.609
	R3 (stream, 1st)	6.480	3.240	1.620	0.648
	R4 (stream, 1st)	4.579	2.290	1.145	0.458
5 m SD	D6 (ditch, 1st)	3.693	1.846	0.923	0.369
	R1 (pond, 1st)	0.250	0.125	0.063	0.025
	R1 (stream, 1st)	3.307	1.654	0.827	0.331
	R2 (stream, 1st)	4.394	2.197	1.098	0.439
	R3 (stream, 1st)	4.679	2.339	1.170	0.468
	R4 (stream, 1st)	3.306	1.653	0.827	0.331
10 m SD	D6 (ditch, 1st)	1.300	0.650	0.325	0.130
	R1 (pond, 1st)	0.135	0.067	0.034	0.014
	R1 (stream, 1st)	1.164	0.582	0.291	0.116
	R2 (stream, 1st)	1.547	0.774	0.387	0.155
	R3 (stream, 1st)	1.647	0.824	0.412	0.165
	R4 (stream, 1st)	1.164	0.582	0.291	0.116

[A] Single application values are worst case values and used for risk assessment

Table 10.2- 6: Initial max FOCUS Step 4 PEC_{sw} values for propineb for the use in grapes II (2× 1400 g a.s./ha) with mitigation options; SD denotes spray drift buffer

Buffer Width & Type	Scenario	Single application [A] PEC$_{sw}$ [µg/L] Drift Reduction 0%	50%	75%	90%
0 m SD	D6 (ditch, 1st)	23.68	11.84	5.921	2.368
	R1 (pond, 1st)	0.839	0.424	0.212	0.085
	R1 (stream, 1st)	17.44	8.718	4.359	1.744
	R2 (stream, 1st)	23.36	11.68	5.839	2.336
	R3 (stream, 1st)	24.65	12.32	6.162	2.465
	R4 (stream, 1st)	17.15	8.575	4.288	1.715
5 m SD	D6 (ditch, 1st)	14.32	7.160	3.580	1.432
	R1 (pond, 1st)	0.985	0.493	0.246	0.099
	R1 (stream, 1st)	12.70	6.352	3.176	1.270
	R2 (stream, 1st)	17.02	8.509	4.255	1.702
	R3 (stream, 1st)	17.96	8.979	4.490	1.796
	R4 (stream, 1st)	12.50	6.248	3.124	1.250
10 m SD	D6 (ditch, 1st)	5.187	2.593	1.297	0.519
	R1 (pond, 1st)	0.543	0.271	0.136	0.054
	R1 (stream, 1st)	4.601	2.301	1.150	0.460
	R2 (stream, 1st)	6.164	3.082	1.541	0.616
	R3 (stream, 1st)	6.505	3.252	1.626	0.650
	R4 (stream, 1st)	4.526	6.263	1.131	0.453
15 m SD	D6 (ditch, 1st)	2.818	1.409	0.704	0.282
	R1 (pond, 1st)	0.368	0.184	0.092	0.037
	R1 (stream, 1st)	2.500	1.250	0.625	0.250
	R2 (stream, 1st)	3.349	1.674	0.837	0.335
	R3 (stream, 1st)	3.534	1.767	0.883	0.353
	R4 (stream, 1st)	2.459	1.229	0.615	0.246

[A] Single application values are worst case values and used for risk assessment

Table 10.2- 7: Initial max FOCUS Step 4 PEC$_{sw}$ values for propineb-DIDT for the use in orchards (early) with mitigation options; S and M denote whether single or multiple application lead to the maximum value; SD denotes spray drift buffer

Buffer Width & Type	Scenario	PEC$_{sw}$ [µg/L] Drift Reduction 0%		50%		75%		90%	
5m SD	D3 (ditch, 1st)	S	22.55	S	11.28	S	5.638	S	2.255
	D4 (pond, 1st)	S	1.968	S	0.984	S	0.492	S	0.197
	D4 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	D5 (pond, 1st)	S	1.967	S	0.984	S	0.492	S	0.197
	D5 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R1 (pond, 1st)	S	1.968	S	0.984	S	0.492	S	0.197
	R1 (stream, 1st)	M	0.057	M	0.057	M	0.057	M	0.057
	R2 (stream, 1st)	M	0.070	M	0.070	M	0.070	M	0.070
	R3 (stream, 1st)	M	0.357	M	0.357	M	0.357	M	0.357
	R4 (stream, 1st)	M	0.319	M	0.319	M	0.319	M	0.319
10m SD	D3 (ditch, 1st)	S	13.85	S	6.925	S	3.463	S	1.385
	D4 (pond, 1st)	S	1.079	S	0.539	S	0.270	S	0.108
	D4 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	D5 (pond, 1st)	S	1.079	S	0.539	S	0.270	S	0.108
	D5 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R1 (pond, 1st)	S	1.079	S	0.539	S	0.270	S	0.108
	R1 (stream, 1st)	M	0.057	M	0.057	M	0.057	M	0.057
	R2 (stream, 1st)	M	0.070	M	0.070	M	0.070	M	0.070
	R3 (stream, 1st)	M	0.357	M	0.357	M	0.357	M	0.357
	R4 (stream, 1st)	M	0.319	M	0.319	M	0.319	M	0.319
20m SD	D3 (ditch, 1st)	S	3.167	S	1.583	S	0.792	S	0.317
	D4 (pond, 1st)	S	0.349	S	0.174	S	0.087	S	0.035
	D4 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	D5 (pond, 1st)	S	0.349	S	0.174	S	0.087	S	0.035
	D5 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R1 (pond, 1st)	S	0.349	S	0.174	S	0.087	S	0.035
	R1 (stream, 1st)	M	0.057	M	0.057	M	0.057	M	0.057
	R2 (stream, 1st)	M	0.070	M	0.070	M	0.070	M	0.070
	R3 (stream, 1st)	M	0.357	M	0.357	M	0.357	M	0.357
	R4 (stream, 1st)	M	0.319	M	0.319	M	0.319	M	0.319
30m SD	D3 (ditch, 1st)	S	1.211	S	0.606	S	0.303	S	0.121
	D4 (pond, 1st)	S	0.169	S	0.085	S	0.042	S	0.017
	D4 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	D5 (pond, 1st)	S	0.169	S	0.085	S	0.042	S	0.017
	D5 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R1 (pond, 1st)	S	0.169	S	0.085	S	0.042	S	0.017
	R1 (stream, 1st)	M	0.057	M	0.057	M	0.057	M	0.057
	R2 (stream, 1st)	M	0.070	M	0.070	M	0.070	M	0.070
	R3 (stream, 1st)	M	0.357	M	0.357	M	0.357	M	0.357
	R4 (stream, 1st)	M	0.319	M	0.319	M	0.319	M	0.319

Table 10.2- 8: Initial max FOCUS Step 4 PEC_{sw} values for propineb-DIDT for the use in grapes I (2 × 1120 g a.s./ha) with mitigation options; S and M denote whether single or multiple application lead to the maximum value; SD denotes spray drift buffer

Buffer Width & Type	Scenario	PEC_{sw} [µg/L] Drift Reduction							
		0%		50%		75%		90%	
0 m SD	D6 (ditch, 1st)	S	1.470	S	0.736	S	0.369	S	0.149
	R1 (pond, 1st)	S	0.051	S	0.025	S	0.013	S	0.005
	R1 (stream, 1st)	M	0.062	M	0.062	M	0.062	M	0.062
	R2 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R3 (stream, 1st)	S	1.535	S	0.768	S	0.384	M	0.336
	R4 (stream, 1st)	M	0.990	M	0.495	M	0.248	M	0.099
5 m SD	D6 (ditch, 1st)	S	0.877	S	0.440	S	0.221	S	0.090
	R1 (pond, 1st)	S	0.059	S	0.030	S	0.015	S	0.006
	R1 (stream, 1st)	M	0.062	M	0.062	M	0.062	M	0.062
	R2 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R3 (stream, 1st)	S	1.108	S	0.554	M	0.336	M	0.336
	R4 (stream, 1st)	M	0.708	M	0.354	M	0.177	M	0.081
10 m SD	D6 (ditch, 1st)	S	0.310	S	0.156	S	0.079	S	0.033
	R1 (pond, 1st)	S	0.032	S	0.016	S	0.008	S	0.003
	R1 (stream, 1st)	M	0.062	M	0.062	M	0.062	M	0.062
	R2 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R3 (stream, 1st)	S	0.390	M	0.336	M	0.336	M	0.336
	R4 (stream, 1st)	M	0.241	M	0.120	M	0.081	M	0.081
15 m SD	D6 (ditch, 1st)	S	0.167	S	0.085	S	0.044	S	0.019
	R1 (pond, 1st)	S	0.021	S	0.011	S	0.005	S	0.002
	R1 (stream, 1st)	M	0.062	M	0.062	M	0.062	M	0.062
	R2 (stream, 1st)	M	<0.001	M	<0.001	M	<0.001	M	<0.001
	R3 (stream, 1st)	M	0.336	M	0.336	M	0.336	M	0.336
	R4 (stream, 1st)	M	0.126	M	0.081	M	0.081	M	0.081

Table 10.2- 9: Initial max FOCUS Step 4 PEC_{sw} values for propineb-DIDT for the use in grapes II (2 × 1400 g a.s./ha) with mitigation options; S and M denote whether single or multiple application lead to the maximum value; SD denotes spray drift buffer

Buffer Width & Type	Scenario	PEC_{sw} [µg/L] Drift Reduction 0%		50%		75%		90%	
0 m SD	D6 (ditch, 1st)	S	5.610	S	2.805	S	1.403	S	0.561
	R1 (pond, 1st)	S	0.201	S	0.101	S	0.050	S	0.020
	R1 (stream, 1st)	S	4.130	S	2.065	S	1.033	M	0.467
	R2 (stream, 1st)	M	0.465	M	0.465	M	0.465	M	0.465
	R3 (stream, 1st)	S	5.839	S	2.920	S	1.460	S	0.584
	R4 (stream, 1st)	S	4.063	S	2.031	S	1.016	S	0.406
5 m SD	D6 (ditch, 1st)	S	3.392	S	1.696	S	0.848	S	0.339
	R1 (pond, 1st)	S	0.233	S	0.117	S	0.058	S	0.023
	R1 (stream, 1st)	S	3.009	S	1.505	S	0.752	M	0.467
	R2 (stream, 1st)	M	0.465	M	0.465	M	0.465	M	0.465
	R3 (stream, 1st)	S	4.254	S	2.127	S	1.064	S	0.425
	R4 (stream, 1st)	S	2.960	S	1.480	S	0.740	M	0.321
10 m SD	D6 (ditch, 1st)	S	1.229	S	0.614	S	0.307	S	0.123
	R1 (pond, 1st)	S	0.129	S	0.064	S	0.032	S	0.018
	R1 (stream, 1st)	S	1.090	S	0.545	M	0.467	M	0.467
	R2 (stream, 1st)	M	0.465	M	0.465	M	0.465	M	0.465
	R3 (stream, 1st)	S	1.541	S	0.770	S	0.385	S	0.154
	R4 (stream, 1st)	S	1.072	S	0.536	M	0.321	M	0.321
15 m SD	D6 (ditch, 1st)	S	0.668	S	0.334	S	0.167	S	0.067
	R1 (pond, 1st)	S	0.087	S	0.044	S	0.022	S	0.018
	R1 (stream, 1st)	S	0.592	M	0.467	M	0.467	M	0.467
	R2 (stream, 1st)	M	0.465	M	0.465	M	0.465	M	0.465
	R3 (stream, 1st)	S	0.837	S	0.419	S	0.209	S	0.084
	R4 (stream, 1st)	S	0.583	M	0.321	M	0.321	M	0.321

Risk assessment for aquatic organisms

ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table 10.2- 10: TER_A calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_A	Trigger
Orchards						
Propineb	Fish, acute	LC_{50}	329	153.3	**2.1**	100
	Invertebrate, acute	EC_{50}	1500		**9.8**	
PTU	Fish, acute	LC_{50}	> 100000	16.35	> 6116	
	Invertebrate, acute	EC_{50}	18400		1125	
PU	Fish, acute	LC_{50}	> 100000	57.17	> 1749	
	Invertebrate, acute	EC_{50}	> 100000	57.17	> 1749	
Propineb-DIDT	Invertebrate, acute	EC_{50}	> 112	36.03	**> 3.1**	
4-MI	Fish, acute	LC_{50}	393000	11.89	33053	
	Invertebrate, acute	EC_{50}	7300		614	
Grapes I						
Propineb	Fish, acute	LC_{50}	329	10.08	**33**	100
	Invertebrate, acute	EC_{50}	1500		149	
PTU	Fish, acute	LC_{50}	> 100000	1.237	> 80841	
	Invertebrate, acute	EC_{50}	18400		14875	
PU	Fish, acute	LC_{50}	> 100000	8.206	> 12186	
	Invertebrate, acute	EC_{50}	> 100000	8.206	> 12186	
Propineb-DIDT	Invertebrate, acute	EC_{50}	> 112	2.369	**> 47**	
4-MI	Fish, acute	LC_{50}	393000	1.024	383789	
	Invertebrate, acute	EC_{50}	7300		7129	
Grapes II						
Propineb	Fish, acute	LC_{50}	329	37.46	**8.8**	100
	Invertebrate, acute	EC_{50}	1500		**40**	
PTU	Fish, acute	LC_{50}	> 100000	4.410	> 22676	
	Invertebrate, acute	EC_{50}	18400		4172	
PU	Fish, acute	LC_{50}	> 100000	15.81	> 6325	
	Invertebrate, acute	EC_{50}	> 100000	15.81	> 6325	
Propineb-DIDT	Invertebrate, acute	EC_{50}	> 112	8.807	**> 13**	
4-MI	Fish, acute	LC_{50}	393000	2.951	133175	
	Invertebrate, acute	EC_{50}	7300		2473	

Bold values do not pass the risk assessment

CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table 10.2- 11: TER_{LT} calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw.max}$ [µg/L]	TER_{LT}	Trigger
Orchards					
Propineb	Fish, chronic	NOEC 82.3	153.3	**0.5**	10
	Invertebrate, chronic	NOEC 15		**0.1**	
	Sediment dweller	EC_{15} 890		**5.8**	
	Green algae, chronic	E_rC_{50} 55		**0.4**	
Propineb-DIDT	Green algae, chronic	EC_{50} 114	36.03	**3.2**	
PTU	Fish, chronic	NOEC ≥ 102000	16.35	≥ 6239	
	Invertebrate, chronic	NOEC 3200		196	
	Sediment dweller	NOEC ≥100		**≥ 6.1**	
	Green algae, chronic	E_rC_{50} > 100000		> 6116	
PU	Fish, chronic	NOEC ≥ 2000	57.17	≥ 35	
	Invertebrate, chronic	NOEC ≥ 100000		≥ 1749	
	Sediment dweller	NOEC ≥100		**≥ 1.8**	
	Green algae, chronic	E_rC_{50} > 100000		> 1749	
4-MI	Green algae, chronic	E_rC_{50} 49000	11.89	4121	
Grapes I					
Propineb	Fish, chronic	NOEC 82.3	10.08	**8.2**	10
	Invertebrate, chronic	NOEC 15		**1.5**	
	Sediment dweller	EC_{15} 890		88	
	Green algae, chronic	E_rC_{50} 55		**5.5**	
Propineb-DIDT	Green algae, chronic	EC_{50} 114	2.369	48	
PTU	Fish, chronic	NOEC ≥ 102000	1.237	≥ 82458	
	Invertebrate, chronic	NOEC 3200		2587	
	Sediment dweller	NOEC ≥100		≥ 81	
	Green algae, chronic	E_rC_{50} > 100000		> 80841	
PU	Fish, chronic	NOEC ≥ 2000	8.206	≥ 244	
	Invertebrate, chronic	NOEC ≥ 100000		≥ 12186	
	Sediment dweller	NOEC ≥100		≥ 12	
	Green algae, chronic	E_rC_{50} > 100000		> 12186	
4-MI	Green algae, chronic	E_rC_{50} 49000	1.024	47852	
Grapes II					
Propineb	Fish, chronic	NOEC 82.3	37.46	**2.2**	10
	Invertebrate, chronic	NOEC 15		**0.4**	
	Sediment dweller	EC_{15} 890		24	
	Green algae, chronic	E_rC_{50} 55		**1.5**	
Propineb-DIDT	Green algae, chronic	EC_{50} 114	8.807	13	
PTU	Fish, chronic	NOEC ≥ 102000	4.410	≥ 23129	
	Invertebrate, chronic	NOEC 3200		726	
	Sediment dweller	NOEC ≥100		≥ 23	

Compound	Species	Endpoint [µg/L]		PEC$_{sw.max}$ [µg/L]	TER$_{LT}$	Trigger
	Green algae, chronic	E_rC_{50}	> 100000		> 22676	
PU	Fish, chronic	NOEC	≥ 2000	15.81	≥ 127	
	Invertebrate, chronic	NOEC	≥ 100000		≥ 6325	
	Sediment dweller	NOEC	≥100		**≥ 6.3**	
	Green algae, chronic	E_rC_{50}	> 100000		> 6325	
4-MI	Green algae, chronic	E_rC_{50}	49000	2.951	16605	

Bold values do not pass the risk assessment

The TER$_A$ values for fish and invertebrates and the TER$_{LT}$ values for fish, invertebrates, sediment dweller and green algae do not meet the respective trigger values and further assessment is necessary.

Refined risk assessment for the acute and long-term risk to fish exposed to propineb

Since the TER-values in the tier 1 risk assessment for the active substance propineb considering the use in grapes and orchards do not meet the trigger values, a refinement is necessary. For that purpose, a 28-day higher tier study with rainbow trout in a microcosm enclosure had been performed (for details see KCA 8.2.8 /01; [redacted].; 2005; M-246864-02). This chronic study with a NOEC greater than 600 µg a.s./L under natural field and exposure conditions including multiple applications demonstrates that the chronic exposure does not increase the toxicity of propineb.

An acute laboratory study with Propineb VM 80 resulted in a LC_{50} endpoint of 329 µg a.s./L and a NOEC of 125 µg a.s./L.

This acute/chronic-ratio also underlines that the toxicity observed in the acute study does not increase in studies with prolonged exposure. Thus the 28-day outdoor enclosure study covers both exposures, chronic and acute. Since it has not been shown that the rainbow trout is the most sensitive fish species to propineb, the uncertainty of species sensitivity still remains and an assessment factor of 1-3 is not justified. However, the chronic assessment factor of 10 can be used for the final risk assessment for fish based on the 28-day microcosm enclosure.

The refined risk assessment is presented in Table 10. 2-8 below.

Refined long-term risk assessment for *Daphnia* exposed to propineb

The aquatic invertebrate *Daphnia magna* is the most sensitive aquatic organism to propineb. A comparison of chronic endpoints demonstrates that *Daphnia magna* (NOEC = 0.015 mg a.s./L) is almost 100 times more sensitive than *Chironomus riparius* (EC_{15} = 0.89 mg a.s./L).

To further address the long-term risk for the most sensitive species, a 35-day *Daphnia* population study in a water-sediment system was performed in order to achieve a better simulation of field and exposure conditions (for details see KCA 8.2.5.1 /04; [redacted].;2005;M-252129-01-1). The study included 4 applications within the first 21 days of the exposure period and resulted in a NOEC of 480 µg a.s./L based on nominal initial treatment levels. At the highest concentration of 960 µg/L effects were observed but obviously recovery was possible at this concentration as well.

This chronic study with a NOEC of 480 µg a.s./L including multiple applications demonstrates that toxicity of propineb is not increased by chronic exposure.

This is further supported by the low acute-chronic ratio compared to an acute laboratory study with Propineb VM 80 that resulted in an EC_{50}-endpoint of 1500 µg a.s./L, and 0% immobilisation of daphnids at 500 µg a.s./L after 48 h.
Thus the 35-day *Daphnia* population study covers both exposures, chronic and acute. A chronic assessment factor of 10 can be used for the final risk assessment for aquatic invertebrates based on the 35-day *Daphnia* population study.

Table 10.2- 12: Refined TER calculations using endpoints derived from higher tier studies based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
Propineb	Microcosm (fish, chronic)	NOEC	> 600	153.3	**> 3.9**	10
	D. magna (pop. study)	NOEC	> 480	153.3	**> 3.1**	
Grapes I						
Propineb	Microcosm (fish, chronic)	NOEC	> 600	10.08	> 60	10
	D. magna (pop. study)	NOEC	> 480	10.08	> 48	
Grapes II						
Propineb	Microcosm (fish, chronic)	NOEC	> 600	37.46	> 16	10
	D. magna (pop. study)	NOEC	> 480	37.46	> 13	

Bold values do not pass the risk assessment

The TER values for the uses in grapes (I and II) meet the trigger value based on FOCUS Step 2 PEC_{sw} values. Therefore, an unacceptable risk to aquatic organisms is not to be expected following the application of the product in this crop.
For the uses in orchards further refinement using FOCUS Step 3 values in necessary. It is presented below.

Table 10.2- 13: Refined TER calculations for propineb using endpoints derived from higher tier studies based on FOCUS Step 3

Compound	Species	Endpoint [µg/L]	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
Propineb	Fish, chronic (microcosm)	NOEC > 600	D3 (ditch, 1st)	121.3	**> 4.9**	10
			D4 (pond, 1st)	7.378	> 81	
			D4 (stream, 1st)	116.2	**> 5.2**	
			D5 (pond, 1st)	7.377	> 81	
			D5 (stream, 1st)	117.6	**> 5.1**	
			R1 (pond, 1st)	7.377	> 81	
			R1 (stream, 1st)	98.15	**> 6.1**	
			R2 (stream, 1st)	130.0	**> 4.6**	
			R3 (stream, 1st)	138.2	**> 4.3**	
			R4 (stream, 1st)	98.17	**> 6.1**	
	D. magna, chronic (pop. study)	NOEC > 480	D3 (ditch, 1st)	121.3	**> 4.0**	10
			D4 (pond, 1st)	7.378	> 65	
			D4 (stream, 1st)	116.2	**> 4.1**	
			D5 (pond, 1st)	7.377	> 65	
			D5 (stream, 1st)	117.6	**> 4.1**	
			R1 (pond, 1st)	7.377	> 65	
			R1 (stream, 1st)	98.15	**> 4.9**	
			R2 (stream, 1st)	130.0	**> 3.7**	
			R3 (stream, 1st)	138.2	**> 3.5**	
			R4 (stream, 1st)	98.17	**> 4.9**	

Bold values do not pass the risk assessment

Further refinement using FOCUS Step 4 values in necessary and presented below.

Table 10.2- 14: Refined TER calculations for propineb using endpoints derived from higher tier studies based on FOCUS Step 4 including mitigation measures

Species	Endpoint [µg/L]	Mitigation	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
Fish, chronic (microcosm)	NOEC > 600	5 m buffer and 50% drift reduction	D3 (ditch)	47.66	> 13	10
			D4 (stream)	49.92	> 12	
			D5 (stream)	50.52	> 12	
			R1 (stream)	42.16	> 14	
			R2 (stream)	55.85	> 11	
			R3 (stream)	59.36	> 10	
			R4 (stream)	42.17	> 14	
Fish, chronic (microcosm)	NOEC > 600	20 m drift buffer	D3 (ditch)	13.39	> 45	10
			D4 (stream)	14.02	> 43	
			D5 (stream)	14.19	> 42	
			R1 (stream)	11.84	> 51	
			R2 (stream)	15.69	> 38	
			R3 (stream)	16.67	> 36	
			R4 (stream)	11.84	> 51	
D. magna, chronic (pop. study)	NOEC > 480	5 m buffer and 75% drift reduction	D3 (ditch)	23.83	> 20	10
			D4 (stream)	24.96	> 19	
			D5 (stream)	25.26	> 19	
			R1 (stream)	21.08	> 23	
			R2 (stream)	27.93	> 17	
			R3 (stream)	29.68	> 16	
			R4 (stream)	21.09	> 23	
D. magna, chronic (pop. study)	NOEC > 480	10 m buffer and 50% drift reduction	D3 (ditch)	29.27	> 16	10
			D4 (stream)	30.65	> 16	
			D5 (stream)	31.02	> 15	
			R1 (stream)	25.89	> 19	
			R2 (stream)	34.3	> 14	
			R3 (stream)	36.46	> 13	
			R4 (stream)	25.9	> 19	
D. magna, chronic (pop. study)	NOEC > 480	20 m drift buffer	D3 (ditch)	13.39	> 36	10
			D4 (stream)	14.02	> 34	
			D5 (stream)	14.19	> 34	
			R1 (stream)	11.84	> 41	
			R2 (stream)	15.69	> 31	
			R3 (stream)	16.67	> 29	
			R4 (stream)	11.84	> 41	

According to the presented risk assessment based on FOCUS Step 4 calculations, the risk to aquatic organisms from the use of the product in orchards is unlikely if
- 5 m buffer and 75% drift reduction,
- 10 m buffer and 50% drift reduction or
- 20 m drift buffer

are maintained during application of the product.

Refined assessment for algae exposed to propineb

As the TER_{LT} values for algae do not meet the respective trigger value a refined risk assessment for propineb based on FOCUS Step 3 values is presented below.

Table 10.2- 15: TER calculations for algae exposed to propineb based on FOCUS Step 3

Compound	Species	Endpoint [µg/L]	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
Propineb	*P. subcapitata*	E_rC_{50} 55	D3 (ditch)	121.3	**0.5**	10
			D4 (pond)	7.378	**7.5**	
			D4 (stream)	116.2	**0.5**	
			D5 (pond)	7.377	**7.5**	
			D5 (stream)	117.6	**0.5**	
			R1 (pond)	7.377	**7.5**	
			R1 (stream)	98.15	**0.6**	
			R2 (stream)	130.0	**0.4**	
			R3 (stream)	138.2	**0.4**	
			R4 (stream)	98.17	**0.6**	
Grapes I						
Propineb	*P. subcapitata*	E_rC_{50} 55	D3 (ditch)	6.195	**8.9**	10
			D4 (pond)	0.214	257	
			D4 (stream)	4.581	12	
			D5 (pond)	6.085	**9.0**	
			D5 (stream)	6.480	**8.5**	
			R1 (pond)	4.579	12.0	
Grapes II						
Propineb	*P. subcapitata*	E_rC_{50} 55	D3 (ditch)	23.68	**2.3**	10
			D4 (pond)	0.849	65	
			D4 (stream)	17.44	**3.2**	
			D5 (pond)	23.36	**2.2**	
			D5 (stream)	24.65	**2.2**	
			R1 (pond)	17.15	**3.2**	

Further refinement using FOCUS Step 4 values in necessary and presented below.

Table 10.2- 16: Refined TER calculations for propineb based on FOCUS Step 4 including mitigation measures

Species	Endpoint [µg/L]	Mitigation	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
P. subcapitata	E_rC_{50} 55	20 m drift buffer and 75% drift reduction	D3 (ditch)	3.346	16.4	10
			D4 (pond)	0.368	150	
			D4 (stream)	3.505	15.7	
			D5 (pond)	0.368	150	
			D5 (stream)	3.547	15.5	
			R1 (pond)	0.368	150	
			R1 (stream)	2.960	18.6	
			R2 (stream)	3.922	14.0	
			R3 (stream)	4.168	13.2	
			R4 (stream)	2.961	18.6	
P. subcapitata	E_rC_{50} 55	30 m drift buffer and 50% drift reduction	D3 (ditch)	2.559	21.5	10
			D4 (pond)	0.357	154	
			D4 (stream)	2.681	20.5	
			D5 (pond)	0.357	154	
			D5 (stream)	2.713	20.3	
			R1 (pond)	0.357	154	
			R1 (stream)	2.264	24.3	
			R2 (stream)	2.999	18.3	
			R3 (stream)	3.188	17.3	
			R4 (stream)	2.265	24.3	
Grapes I						
P. subcapitata	E_rC_{50} 55	50% drift reduction	D6 (ditch)	3.098	17.8	10
			R1 (pond)	0.107	514	
			R1 (stream)	2.290	24.0	
			R2 (stream)	3.043	18.1	
			R3 (stream)	3.240	17.0	
			R4 (stream)	2.290	24.0	
P. subcapitata	E_rC_{50} 55	5 m buffer zone	D6 (ditch)	3.693	14.9	10
			R1 (pond)	0.250	220	
			R1 (stream)	3.307	16.6	
			R2 (stream)	4.394	12.5	
			R3 (stream)	4.679	11.8	
			R4 (stream)	3.306	16.6	
Grapes II						
P. subcapitata	E_rC_{50} 55	90% drift reduction	D6 (ditch)	2.368	23.2	10
			R1 (pond)	0.085	647	
			R1 (stream)	1.744	32	
			R2 (stream)	2.336	23.5	
			R3 (stream)	2.465	22.3	

Species	Endpoint [µg/L]	Mitigation	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
			R4 (stream)	1.715	32.1	
P. subcapitata	E_rC_{50} 55	5 m buffer zone and 75% drift reduction	D6 (ditch)	3.580	15.4	10
			R1 (pond)	0.246	224	
			R1 (stream)	3.176	17.3	
			R2 (stream)	4.255	12.9	
			R3 (stream)	4.490	12.2	
			R4 (stream)	3.124	17.6	
P. subcapitata	E_rC_{50} 55	15 m buffer zone	D6 (ditch)	2.818	19.5	10
			R1 (pond)	0.368	150	
			R1 (stream)	2.500	22.0	
			R2 (stream)	3.349	16.4	
			R3 (stream)	3.534	15.6	
			R4 (stream)	2.459	22.4	

According to the presented risk assessment based on FOCUS Step 4 calculations, the risk to aquatic organisms is unlikely if

use in orchards:
- 20 m buffer and 75% drift reduction, or
- 30 m buffer and 50% drift reduction

use in grapes I:
- 50% drift reduction, or
- 5 m buffer zone

use in grapes II:
- 90% drift reduction,
- 5 m buffer zone and 75% drift reduction, or
- 15 m buffer zone

are maintained during application of the product.

Refined assessment for *Daphnia* and algae exposed to propineb-DIDT

As the TER_A values for daphnids and the TER_{LT} values for algae both do not meet the respective trigger value a refined risk assessment for the metabolite propineb-DIDT based on FOCUS Step 3 values is presented below.

Table 10.2- 17: Refined TER calculations for propineb-DIDT using PEC_{sw} values based on FOCUS Step 3

Compound	Species	Endpoint [µg/L]	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
Propineb-DIDT	Invertebrate, acute	EC_{50} > 112	D3 (ditch, 1st)	28.70	**3.9**	100
			D4 (pond, 1st)	1.748	**64**	
			D4 (stream, 1st)	<0.001	>112000	
			D5 (pond, 1st)	1.747	**64**	
			D5 (stream, 1st)	<0.001	>112000	
			R1 (pond, 1st)	1.748	**64**	
			R1 (stream, 1st)	0.057	1965	
			R2 (stream, 1st)	0.070	1600	
			R3 (stream, 1st)	28.09	**4.0**	
			R4 (stream, 1st)	19.97	**5.6**	
	Green algae, chronic	EC_{50} 114	D3 (ditch, 1st)	28.70	**3.9**	10
			D4 (pond, 1st)	1.748	64	
			D4 (stream, 1st)	<0.001	>112000	
			D5 (pond, 1st)	1.747	64	
			D5 (stream, 1st)	<0.001	>112000	
			R1 (pond, 1st)	1.748	64	
			R1 (stream, 1st)	0.057	1965	
			R2 (stream, 1st)	0.070	1600	
			R3 (stream, 1st)	28.09	**4.0**	
			R4 (stream, 1st)	19.97	**5.6**	
Grapes I						
Propineb-DIDT	Invertebrate, acute	EC_{50} > 112	D6 (ditch, 1st)	1.470	**76**	100
			R1 (pond, 1st)	0.051	2196	
			R1 (stream, 1st)	0.062	1807	
			R2 (stream, 1st)	<0.001	>112000	
			R3 (stream, 1st)	1.535	**73**	
			R4 (stream, 1st)	0.081	1383	
Grapes II						
Propineb-DIDT	Invertebrate, acute	EC_{50} > 112	D6 (ditch, 1st)	<0.001	>112000	100
			R1 (pond, 1st)	0.018	6222	
			R1 (stream, 1st)	0.467	240	
			R2 (stream, 1st)	0.465	241	
			R3 (stream, 1st)	<0.001	>112000	
			R4 (stream, 1st)	0.321	349	

Bold values do not pass the risk assessment

For the use in Grapes II, all TER values meet the required trigger of 100. For the uses in orchards and grapes I further refinement using FOCUS Step 4 values in necessary and presented below.

Table 10.2- 18: Refined TER calculations for propineb-DIDT based on FOCUS Step 4 including mitigation measures

Species	Endpoint [µg/L]	Mitigation	FOCUS scenario	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards						
Invertebrate, acute	EC_{50} > 112	20 m buffer and 75% drift reduction	D3 (ditch, 1st)	0.792	>141	100
			D4 (pond, 1st)	0.087	>1287	
			D4 (stream, 1st)	<0.001	>112000	
			D5 (pond, 1st)	0.087	>1287	
			D5 (stream, 1st)	<0.001	>112000	
			R1 (pond, 1st)	0.087	>1287	
			R1 (stream, 1st)	0.057	>1965	
			R2 (stream, 1st)	0.070	>1600	
			R3 (stream, 1st)	0.357	>314	
			R4 (stream, 1st)	0.319	>351	
Green algae, chronic	EC_{50} 114	5 m buffer and 50% drift reduction	D3 (ditch, 1st)	11.28	10.1	10
			D4 (pond, 1st)	0.984	116	
			D4 (stream, 1st)	<0.001	114000	
			D5 (pond, 1st)	0.984	116	
			D5 (stream, 1st)	<0.001	114000	
			R1 (pond, 1st)	0.984	116	
			R1 (stream, 1st)	0.057	2000	
			R2 (stream, 1st)	0.070	1629	
			R3 (stream, 1st)	0.357	319	
			R4 (stream, 1st)	0.319	357	
Grapes I						
Invertebrate, acute	EC_{50} > 112	50% drift reduction	D6 (ditch, 1st)	0.736	>152	100
			R1 (pond, 1st)	0.025	>4480	
			R1 (stream, 1st)	0.062	>1806	
			R2 (stream, 1st)	<0.001	>112000	
			R3 (stream, 1st)	0.768	>146	
			R4 (stream, 1st)	0.495	>226	
Invertebrate, acute	EC_{50} > 112	5 m buffer	D6 (ditch, 1st)	0.877	>128	100
			R1 (pond, 1st)	0.059	>1898	
			R1 (stream, 1st)	0.062	>1806	
			R2 (stream, 1st)	<0.001	>112000	
			R3 (stream, 1st)	1.108	>101	
			R4 (stream, 1st)	0.708	>158	

According to the presented risk assessment for propineb-DIDT based on FOCUS Step 4 calculations, the risk to aquatic organisms from the use of the product is unlikely if a 20 m buffer zone and 75% drift reduction in orchards and a 5 m buffer zone or 50% drift reduction in grapes I are maintained during application of the product.

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

Report:	[redacted] §; [redacted] ;2011;M-401282-01
Title:	Acute toxicity of propineb WG 70A W to fish (Oncorhynchus mykiss) under static - renewal conditions
Report No:	EBLHL011
Document No:	M-401282-01-1
Guidelines:	**EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985)** **OPPTS 850.1075 (Public Draft, 1996)** **Directive 92/69/EEC, C.1 (1992)** **OECD No. 203 (rev.1992)** **JMAFF, 12 Nousan No. 8147 (2000)1;none**
GLP/GEP:	**yes**

Objective:

The aim of the study was to determine the acute toxicity of the test item to Rainbow trout (*Oncorhynchus mykiss*), expressed as 96h-LC_{50}.

Materials and Methods:

Test item: propineb WG 70A W, analyzed content of active substance: 69.5 % w/w, specified by batch ID: EM20004026, specification no.: 102000004026, tox no.: 08654-00.

Test organism: Rainbow trout (*Oncorhynchus mykiss*), mean body length 3.8 cm, mean body weight 0.5 g. The biomass loading for this test was 0.125 g fish / L test medium.

Ten fish in each test level were exposed for 96 h under static - renewal conditions to nominal concentrations of 0.358 (0.198), 1.14 (0.468), 3.66 (1.72), 11.7 (4.92), 37.5 (14.8) and 120 (52.7) mg test item (mean measured mg a.s. / L) / L against control.

During the test, fish were examined after four hours and then daily for mortalities and signs of poisoning. Within the study dissolved oxygen, water temperature and pH values were determined daily in each aquarium, water temperature was additionally measured in the control aquarium and recorded hourly with a data logger. Dissolved oxygen concentrations ranged from 90% to 101% oxygen saturation, the pH values ranged from 6.9 to 7.1 and the water temperature ranged from 10.9°C to 11.7°C in all aquaria over the whole testing period. The photoperiod was 16 hours of light and 8 hours dark.

After 4, 24, 48, 72 and 96 hours of exposure the fish were inspected for the number of deaths, toxic symptoms or abnormalities. The mortality (%) after 4, 24, 48, 72 and 96 hours of exposure was calculated in each treatment group. Propineb was analyzed in all test levels after 0 h, on day 2 (old and new media) and on day 4 of the exposure period to confirm nominal concentrations.

Dates of experimental work: October 18, 2010 to October 22, 2010

Results:

Validity criteria:

Validity Criteria	Recommended	Obtained
Mortality in the control	≤ 10%	0%
Constant water quality and environmental conditions during the test	Yes	Yes
Concentration of dissolved oxygen	≥ 60%	78 - 88%

All validity criteria for the study were met.

Analytical results:
Mean measured concentrations for the different test levels ranged between 56.7 % and 79.5 % of nominal values for propineb. Therefore, all results are based on mean measured concentrations.

Biological results:
In the test level 0.468 mg a.s./L (mean measured) behavioural changes were observed during the entire exposure period. After 96 h of exposure towards the concentration of 0.468 mg a.s. / L (mean measured) the fish showed the following behavioural symptoms:

- fish remained for unusually long periods on the bottom of the aquarium

In the controls no mortalities or sub-lethal findings were observed.

LC_{50} values for rainbow trout exposed to Propineb WG 70A W based on nominal and mean measured concentrations

Test substance:	Propineb WG 70A W
Test object:	Rainbow trout (*Oncorhynchus mykiss*)
Exposure:	96 hours, static test design (limit)
LC_{50} 96 h (95% C.I.):	**4.73 (2.84-7.90) mg (mean measured) test item / L**

Conclusions:

The LC_{50} (96h) of propineb to Rainbow trout (*Oncorhynchus mykiss*) in a static 96-hour-test was determined to be 4.73 mg test item / L.
The no-observed-effect-concentration (NOEC) after 96 h is 0.198 mg test item / L.

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Report:	[redacted]8;[redacted];2010;M-372880-01
Title:	Acute toxicity of propineb WG 70A W to the waterflea Daphnia magna in a static laboratory test system
Report No:	EBLHL010
Document No:	M-372880-01-1
Guidelines:	**OECD guideline 202,(2004); EEC Directive 92/69/EEC, part C.2 (1992); U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72-2 (1982); OPPTS Guideline 850.1010 public draft 1996 (modified); JMAFF 12 Nousan No. 8147 (2000)**
GLP/GEP:	**yes**

Objective:

The study was performed, to detect possible effects of the test item on mobility of *Daphnia magna* caused by 48 hours of exposure in a static laboratory test system, expressed as EC_{50} for immobilisation.

Materials and methods:

Test item: Propineb WG 70A W, batch no.: EM200004026, specification No. 102000006516-02, content: 49.5% w/w propineb (TOX 08654-00).

Daphnia magna (1^{st} instars < 24 h old, 6 x 5 animals per concentration) were exposed in a static test system for 48 hours to nominal concentrations of 0, 0.63, 1.25, 2.50, 5.00 and 10.00 mg form./L without feeding.

The content of propineb in exposure media was measured for verification of the test item concentrations at start and end of the exposure period.

After 24 and 48 hours, the behaviour of the water fleas was visually evaluated by counting mobile daphnids, defined as animals with swimming movements within approx. 15 seconds after gentle agitation of the test vessel. Additionally, all visible features of the test item in water as well as possible signs on sublethal affected daphnids had to be recorded.

For verification of the prepared exposure concentrations, the a.s. component Propineb was analytically determined and quantified as propylenethiourea (PTU) which is the hydrolysis product of propineb. Before measurement, Propineb residues were completely transferred into PTU by heating up to 65°C for 24 hours.

Dates of experimental work: October 05, 2009 to March 03, 2010

Results:

Analytical findings:

The accompanying chemical analysis of propineb in freshly prepared test solutions revealed measured concentrations between 87% and 102% (mean: 95%) of nominal.

The corresponding concentrations in the aged test solutions at the end of the 48 hours exposure period ranged between 74% and 86% (mean: 81%) of nominal.

Due to the limited water solubility of propineb under test conditions, the corresponding concentrations of the aged test solutions at the end of exposure were dose-dependingly reduced. While concentrations up to 1.74 mg a.s./L revealed sufficient recovery rates (less than - 20% of nominal), the recovery rates for higher test concentrations fell below 80% of nominal. As the toxicity has to be attributed to the

tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.
Nevertheless, since the discontinuous dose-response relation for the highest test concentration of 10 mg form./L may be affected by reduced bioavailability due to strong precipitation of the test item in the test vessels, this treatment group was excluded from 48h EC_{50} calculation to approximate EC_{50} to a "worst case" principle.

No contaminations of propineb were detected in samples from untreated water control.

<u>Biological findings:</u>
No immobilities or other effects on behaviour occurred in the untreated control within 48 hours of exposure.

Toxicity of propineb WG 70A W to *Daphnia magna* (based on nominal concentrations):

Nominal test concentration (mg p.m./L)	Exposed daphnids (=100%)	Immobilised daphnids			
		24 h.		48 h.	
		n	%	n	%
Control	30	0	0	0	0
0.63	30	0	0	0	0
1.25	30	0	0	2	6.7
2.50	30	1	3.3	6	20.0
5.00	30	5	16.7	19	63.3
10.00	30	8	26.7	**19**	**63.3**[*1]

[*1] excluded from EC_{50} calculation

Conclusions:

No immobilities or other effects on behaviour occurred in untreated control within 48 hours of exposure.
Based on mean-measured concentrations of Propineb WG 70A W, the following EC_{50} values for immobilisation after 24 and 48 hours of static exposure were assessed:

Statistical results of probit analysis conducted for determination of EC_{50} values:

Probit analysis for data obtained after	**EC_{50}** mg pure metabolite / L (mean measured)	lower 95% cl mg pure metabolite / L (mean measured)	upper 95% cl mg pure metabolite / L (mean measured)
24 hours	**20.4**	7.25	57.4
48 hours	**4.10**	3.18	5.28

highest test concentration excluded from EC_{50} calculation

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Report:	[redacted]o;[redacted];2010;M-397379-01
Title:	Pseudokirchneriella subcapitata growth inhibition test with propineb WG 70A W
Report No:	EBLHL009
Document No:	M-397379-01-1
Guidelines:	**OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006)**
GLP/GEP:	**yes**

Objectives:

The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and ECx for growth rate of algal biomass (cells per volume).

Materials and Methods:

Test material: Propineb WG 70A W (analysed purity: 69.5 % w/w was tested; specified by batch ID: EM200004026, sample description: TOX08654-00 and specification no.: 102000006516-02).
Pseudokirchneriella subcapitata were exposed in a chronic multi-generation test for 3 days under static exposure conditions to the geometric mean measured concentration of 9.54, 30.5, 97.7, 313 and 1000 µg formulation/L in comparison to a control. The test system consisted of three replicate vessels per test level and six replicate vessels per control. The initial cell number was 10,000 cells/mL.
The test system consisted of three replicate vessels per test level and six replicate vessels per control level. The initial cell number was 10,000 cells/mL.
Growth inhibition was calculated using algae biomass per volume. The surrogate for biomass was cell density (used as response parameter).
The pH values ranged from 7.7 to 8.2 in the controls and the incubation temperature ranged from 21.8°C to 22.0°C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 7233 lux.
Quantitative amounts of Propineb were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Dates of experimental work: November 06 2009 to May 20 2010

Results:

Validity of the study:

Validity Criteria:	**Obtained in this study:**
Increase of biomass:	Biomass increased in the control by more than 16-fold within the evaluation period.
Sectional control rates:	Mean percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35%
Control replicate rates:	Percent coefficient of variation of the average growth rate in each control replicate did not exceed 7%

In conclusion, it can be stated that the test conditions met all validity criteria given by the mentioned guideline.

Strain material of defined sensitivity was used, as shown by reference substance testing with 3,5-dichlorophenol or potassium dichromate. Reference tests are conducted event driven *(i.e. in case of receiving new strains, introduction of new test conditions, apparatus, etc.)*. These tests are documented and archived together with strain protocols.

Analytical results:
Propineb WG 70A W could not be directly determined due to the low solubility and low hydrolytic stability in water. The hydrolysis product propineb propylenethiourea (PTU) was analysed and the amount of propineb was recalculated. Recoveries of PTU were measured twice during the study, day 0 and 3.
The chemical analysis of propineb in the treatment levels resulted in 46.7 % to 95.1 % of nominal (average 57.4 %) on day 0. On day 3 39.8 % to 83.0 % of nominal (average 47.4 %) were found. Taking into account the physico-chemical properties of propineb under test conditions, nominal concentrations of the formulation are used for reporting and evaluation of results.

Biological results:

Effect of Propineb WG 70A W on Freshwater Algae (*Pseudokirchneriella subcapitata*) in a 72 h growth inhibition test

Geom. mean measured concentration [µg form./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]
Control	844 000	1.478	--
9.54	826 000	1.471	0.5
30.5	780 000	1.452	1.8
97.7	156 000	0.915	38.1
313	58 000	0.588	60.2
1000	34 000	0.409	72.3

test initiation with 10,000 cells/mL

No morphological change in algae was observed in any test concentration.

Conclusions:

The (0 - 72h)-E_rC_{50} for Propineb WG 70A W is 239 µg form./L and the (0 - 72h)-NOE_rC is 9.54 µg form./L.

CP 10.2.2 Add. long-term and chronic tox. studies on fish, aquatic invert., sediment dwelling org.

No new studies were necessary based on the current data requirements. See the respective MCA document.

CP 10.2.3 Further testing on aquatic organisms

No studies were necessary based on the current data requirements. See the respective MCA document.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

The risk assessment has been performed according to the exisiting 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:

- Chronic 10 day toxicity to adult bees under laboratory conditions
- Acute toxicity to larval bees under laboratory conditions
- Colony feeding studies (Oomen et al 2008). This is only triggered when the acute oral LD50 for adult bees is less than 100 µg a.s./bee which is not the situation for propineb. However a study has been conducted using a realsitic worse case spray solution concentration and covers exposure for effects on brood (eggs, young and old larvae) and their development, nurse bee on-going behaviour in brood care and colony strenght.
- Tunnel test to OECD guidance document 75 (with methodological improvements). This test exposed honey bee colonies to a spray application of 1575 g a.s./ha (maximum use rate) on a flowering, bee attractive crop (*Phacelia tanacetifolia*).

Details of the honey bee testing with propineb and ecotoxicological endpoints are presented in MCA, Section 6, Point 8.3.1, as well as within the existing Review Report for propineb (SANCO/7574/VI/97-Final, 2003). The tunnel test with Propineb WG 70 to OECD 75 is presented in this document (MCP Point 10.3.1).

Table 10.3.1- 1: Acute toxicity of propineb (a.s.) to bees

Test substance	Test species/study design	Endpoint	Reference
Propineb TK 83	Honey bee 48 h	LD_{50} – oral > 164.6 µg a.s./bee LD_{50} – contact > 164.6 µg a.s./bee	KCA 8.3.1.1.1/01 KCA 8.3.1.1.2/01 [redacted] (1998) M-017002-01-1
Propineb TK 83	Honey bee, 48h	**LD_{50} – oral > 107.9 µg a.s./bee** **LD_{50} – contact > 100 µg a.s./bee**	KCA 8.3.1.1.1/07 KCA 8.3.1.1.2/07 [redacted] (2012) EBLHN001 M-442120-01-1

Table 10.3.1- 2: Honey bee toxicity data generated with Propineb WG 70

Test substance	Test species/study design	Endpoint	Reference
Acute oral and contact toxicity (laboratory)			
Propineb WG 70	Honey bee, 48 h	LD_{50} – oral >100 µg a.s./bee	KCP 10.3.1.1/01 [redacted] (1987) M-017013-01-2
Propineb WG 70A W	Honey bee, 48h	LD_{50} – oral >112.3 µg a.s./bee LD_{50} – contact **>100 µg a.s./bee**	KCP 10.3.1.1/02 [redacted] (2009) EBLHL007 M-352507-01-1
Effects on larvae (laboratory)			
Propineb WG 70A W	Honey bee brood (in vitro) *Apis mellifera*	NOED >6.25 µg a.s./larva LD50 11.1 µg a.s./larva	KCA 8.3.1.2 /03 [redacted] (2014) S13-01495 M-488422-01-1
Bee brood feeding test			
Propineb WG 70A W	Honey bee brood feeding (Oomen *et al.*, 1992)	Although a small but statistically significant effect on egg termination rate was observed, Propineb WG 70A W fed at a concentration of 2.10 g a.s./L (typical for high volume spray) did not adversely affect overall honey bee brood development or success and did not increase the overall mortality rate of the colonies compared to the control.	KCA 8.3.1.3/01 [redacted] (2013) EBLHL033 M-454682-01-1
Semi-field (tunnel) test conducted to OECD 75			
Propineb WG 70A W	OECD Guidance document 75 with current recommendations of the AG Bienenschutz and ICPPR (2010)	No adverse effects on mortality, foraging, bee brood development (eggs, young larvae, old larvae, pupae) and colony development due exposure to sprayed test item onto a flowering crop under tunnel conditions at 1575 g a.s./ha.	KCP 10.3.1.5/01 [redacted], (2014) EBLHN023 M-488039-01-1

Note:
- Studies referring to KCA are filed in the dossier for the active substance.
- Studies written in grey type are referring either to studies in the corresponding Baseline-dossier for the active substance or to the dossier for the old representative formulation for Annex I inclusion (which is provided for renewal as well); whereas studies in black type are studies of the Supplemental dossier for the active substance or this present dossier for the new representative formulation.

Chronic toxicity of propineb to adult honey bees

There is currently no harmonised and ring tested test guideline available in Europe to assess the chronic risk to adult honey bees. Nonetheless, there is to date some experience within the European honey bee testing community on conducting chronic studies in adult honey bees, by exposing honey bees orally to a treated 50% (w/v) sugar solution as an exclusive food source for a period of 10 consecutive days by continuous and *ad libitum* feeding. Due to the very low water solubility of technical propineb, the study was conducted with the representative formulation Propineb WG 70A W.

Table 10.3.1- 3: Chronic toxicity of propineb to adult honey bees

Test substance	Test species/study design	Endpoint	Reference
Propineb WG 70A W	10 d chronic adult feeding study	NOEC > 120 mg a.s./kg sucrose LC_{50} > 120 mg a.s./kg sucrose	KCA 8.3.1.2/01 [redacted] (2014) M-487104-01-1

Risk assessment for bees

The risk assessment for bee is based on the maximum label rate of propineb 1575 g a.s./ha for applications in orchards which covers all uses and GAPs using the critical endpoints (LD_{50} values) in bold in the preceding tables for Propineb TK 83 of >107.5 and >100 µg a.s./bee for oral and contact toxicity respectively.

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:
$$Q_{HO} = \frac{\text{maximum application rate}}{LD_{50}\text{ oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or }\mu\text{g total substance/bee}]}$$

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

Table 10.3.1- 4: Hazard quotients for bees – oral exposure

Compound	Oral LD_{50} [µg a.s./bee]	Max. application rate [g a.s./ha]	Hazard quotient Q_{HO}	Trigger	*A-priori* acceptable risk for adult bees
Propineb	>107.9	1575 [a]	<14.6	50	yes

[a] maximum application rate in orchards covers all other intended uses

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

Table 10.3.1- 5: Hazard quotients for bees – contact exposure

Compound	Contact LD_{50} [µg a.s./bee]	Max. application rate [g a.s./ha]	Hazard quotient Q_{HC}	Trigger	*A-priori* acceptable risk for adult bees
Propineb	>100	1575 [a]	<15.8	50	yes

[a] maximum application rate in orchards covers all other intended uses

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

The active substance propineb either as technical material or formulated product (Propineb WG 70A W) is of low toxicity to bees. Both technical material and formulation exhibit acute LD_{50} values for adult bees in excess of 100 µg a.s./bee for oral and contact routes of administration with HQ values considerably lower than the levels regarded to indicate a risk to bees.

When fed chronically to adult bees via *ad libitum* feeding of 120 mg a.s./kg sugar solution there were no signs of intoxication or mortality indicating that propineb does not cause adverse effects or is more toxic when administered chronically. This chronic study was designed as a limit test by exposing adult honey bees for 10 consecutive days to a concentration of nominally 120 mg propineb a.s./kg in aqueous sugar solution. As propineb is practically insoluble in water (>0.01 mg/L at 20 °C), the test was conducted by using the formulated product Propineb WG 70. The nominal test concentration as such equals about 12× the water solubility of propineb. When fed chronically to adult bees via *ad libitum* feeding of 120 mg a.s./kg sugar solution there were no signs of intoxication or mortality indicating that propineb does not cause adverse effects or is more toxic when administered chronically. No adverse lethal-, sub-lethal, behavioural or delayed effects were found by exposing adult honey bees for ten consecutive days exclusively to sugar solution, containing 120 ppm propineb (nominal).

In a laboratory study, honey bee larvae were sensitive to propineb with an acute LD_{50} of 11.1 µg a.s./larva. The methodology for testing larval and adult bees differs in that larval exposure is both by dermal and oral (dietary) routes of exposure, whereas in the standard adult bee toxicity tests the two routes are investigated separately. Larval bees are also smaller than their adult counterparts when dosed in the studies if compared on a weight by weight basis. Consequently although the larvae appear to be more sensitive numerically than the adult bees the two test methods are not directly comparable. 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 propineb at the colony level and to further investigate effects on larvae has been conducted under colony feeding and semi-field conditions.

A bee brood feeding study has been conducted by following the provisions/method of Oomen P.A., de Ruijter, A. & van der Steen, J. (OEPP/EPPO Bulletin 22:613-616 (1992), which require, amongst other parameters to "*...use formulated products only... products are fed at a concentration recommended for high-volume use...*". The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the hive with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, young and old larvae by employing digital photo imaging technology. In this study fed with formulated Propineb WG 70A W at a concentration of 2.10 g a.s./L (typical for high volume spray, see table below) experienced a small but statistically significant effect on egg termination rate compared to the control (fed on syrup only). However, there were no adverse effects due to exposure to propineb as the overall honey bee brood development and success mortality rates of the colonies showed better performance compared to the control even under the unlikely worse case conditions of direct consumption of spray solution.

Table 10.3.1- 6: Intended application patterns relevant to bees and spray tank concentrations

Crop	Timing of application (range)	Maximum label rate (range) [kg pr/ha]	Water volume (min – max) [L/ga]	Concentration of spray solution (min – max) [g a.s./L]	Maximum application rate, [g a.s./ha] propineb
Orchards (Apple)	BBCH 40-59 BBCH 60-73	2.25	800 – 1500	1.05 – 1.97	1575
Grapes I	BBCH 40-59	1.6	600 – 800	1.4 – 1.87	1120
Grapes II	BBCH > 70	2.0	600 – 800	1.75 – 2.33	1400

In a semi-field (tunnel) test conducted to OECD guidance document 75 (with recent methodological improvement) colonies exposed to propineb at 1575 g a.s./ha applied directly as a spray and as residues on flowers (nectar and pollen) exhibited equivalent performance in terms of mortality, foraging rate, behaviour, brood development, colony strength and food stores compared to colonies exposed to only water. Overall, under worse case condition of use exposure to propineb at the maximum application rate of 1575 g a.s./ha produced no deleterious effects on honey bees or honey bee colonies.

Overall conclusions for bees

The calculated Hazard Quotients for both technical and formulated propineb 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, bee brood feeding study and tunnel test to OECD 75).

Overall, it can be concluded that propineb, when applied at the maximum application rate of 1575 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.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

Report:	[redacted];[redacted];[redacted];2009;M-352507-01
Title:	Effects of propineb WG 70A W (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No:	50021035
Document No:	M-352507-01-1
Guidelines:	**OECD 213 and 214 (1998)**
GLP/GEP:	**yes**

Objective:

The purpose of this study was to determine the acute contact and oral toxicity of Propineb WG 70A W to the honey bee (*Apis mellifera* L.). Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

Materials and Methods:

Test item: Propineb WG 70A W (Batch ID.: EM200004026, Sample Description: TOX08654-00, Specification No.: 102000006516-02, purity: 69.5 % w/w analytical)
Test organism: Honey bee (*Apis mellifera* L.), female worker bees, obtained from a healthy and queen-right colony, bred by IBACON, collected on the morning of use.
Under laboratory conditions 30 worker bees (*Apis mellifera*) per treatment were exposed for 48 hours to doses of 100.0, 50.0, 25.0, 12.5 and 6.3 µg a.s. per bee for topical application (contact) and 112.3, 51.9, 27.5,13.5 and 6.8 µg a.s. per bee for feeding (oral, value based on the actual intake of the test item).

Oral toxicity study

Aqueous stock solutions of the test item and reference item were prepared in such a way that they had the respective target concentration of the test item once they were subsequently mixed with sugar syrup at a ratio of 1 + 1. After mixing of these test solutions with ready-to-use sugar syrup (composition of the sugar component: 30 % saccharose, 31 % glucose, 39 % fructose) the final concentration of sugar syrup in the test item solution offered to the bees was 50 %. For the controls water and sugar syrup was used at the same ratio (1 + 1). The treated food was offered in syringes, which were weighed before and after introduction into the cages (duration of uptake ranged from 1.25 to 1.5 hour for the test item treatments). After a maximum of 1.5 hour, the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.
The target dose levels (*e.g.* 100 µg a.s./bee nominal) would have been obtained if 20 mg/bee of the treated food was ingested. In practice, higher dose levels were obtained as the bees had a higher uptake of the test solutions than the nominal 20 mg/bee. The test was conducted in darkness, temperature was 24-25°C and humidity between 37 and 87%. Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing. Results are based on measured concentrations of the a.s. per bee.

Contact toxicity study

A single 5 µL droplet of Propineb WG 70A W in an appropriate carrier (acetone) was placed on the dorsal bee thorax.
For the control, one 5 µL droplet of tap water containing 0.5% Adhäsit was used. The reference item was also applied in 5 µL tap water (dimethoate made up in acetone). The reference item was also applied in 5 µL tap water (dimethoate made up in tap water containing 0.5 % Adhäsit).
A 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item.
The test was conducted in darkness, temperature was 24-25°C and humidity between 37 and 87%.
Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application. Results are based on nominal concentrations of the product per bee.

Dates of experimental work: June 29, 2009 – July 3, 2009

Results:

The results can be considered as valid, as all validity criteria of the test were met: control mortality is < 10% in the oral and in the contact test, LD_{50} (24 h) of the toxic standard in the oral test equals 0.12 µg a.s./bee, the LD_{50} (24 h) of the toxic standard in the contact test equals 0.16 µg/bee.
A summary of effects of the test item on mortality and behavioural abnormalities of the bees is given below for both tests:

Mortality and behavioural abnormalities of the bees in the contact toxicity test

	after 4 hours		after 24 hours		after 48 hours	
dosage [µg a.s./bee]	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %
test item						
100.0	0.0	0.0	3.3	0.0	6.7	0.0
50	0.0	0.0	0.0	0.0	10.0	0.0
25	0.0	0.0	0.0	3.3	3.3	0.0
12.5	0.0	0.0	3.3	0.0	3.3	0.0
6.3	0.0	0.0	0.0	0.0	3.3	0.0
water	0.0	0.0	0.0	0.0	6.7	0.0
reference item						
0.30	13.3	6.7	90.0	0.0	96.7	0.0
0.20	0.0	6.7	70.0	0.0	76.7	0.0
0.15	0.0	3.3	50.0	0.0	53.3	0.0
0.10	0.0	0.0	6.7	0.0	30.0	0.0

results are averages from three replicates (ten bees each) per dosage / control
water = CO_2/water-treated control

Mortality and behavioural abnormalities of the bees in the oral toxicity test

	after 4 hours		after 24 hours		after 48 hours	
ingested [µg a.s./bee]	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %
test item						
112.3	0.0	0.0	0.0	0.0	0.0	0.0
51.0	0.0	0.0	0.0	0.0	0.0	0.0
27.5	0.0	0.0	0.0	0.0	6.7	0.0
13.5	0.0	0.0	0.0	0.0	3.3	0.0
6.8	0.0	0.0	0.0	0.0	6.7	0.0
water	0.0	0.0	0.0	0.0	0.0	0.0
reference item						
0.29	90.0	10.0	100.0	0.0	100.0	0.0
0.17	23.3	26.7	100.0	0.0	100.0	0.0
0.08	0.0	0.0	13.3	0.0	16.7	0.0
0.06	0.0	0.0	0.0	0.0	0.0	0.0

results are averages from three replicates (ten bees each) per dosage / control
water = water-treated control

Observations:

Contact Test:

Dose levels of 100.0, 50.0, 25.0, 12.5 and 6.3 µg a.s./bee led to mortality of 6.7, 10.0, 3.3, 3.3 and 3.3 % at the end of the test (48 hours), respectively. 6.7 % mortality occurred in the control (water + 0.5 % Adhäsit). Only one single bee showed behavioural abnormalities (e.g. movement coordination problems) at the 24 hours assessment. At the 48 hours assessment no behavioural abnormalities were found any more.

Oral Test:

Mortality occurred in the three dose levels (27.5, 13.5 and 6.8 µg a.s./bee). Oral doses of 27.5, 13.5 and 6.8 µg a.s./bee resulted in mortality ranging from 3.3 % to 6.7 % at the end of the test (48 hours after application). There was no mortality in the control group. No behavioural abnormalities were observed in any of the dose treatment groups at any time.

Conclusions:

Toxicity to Honey Bees; laboratory tests

Test Item	Propineb WG 70A W	
Test object	*Apis mellifera*	
Application rate (µg a.s./bee)	100.0, 50.0, 25.0, 12.5 and 6.3	112.3, 51.9, 27.5, 13.5 and 6.8
Exposure	contact (solution in Adhäsit (0,5%)/water)	oral (sugar solution)
LD_{50} µg product/bee	> 100.0	> 112.3

The LD_{50} (48 h) values of Propineb WG 70A W was > 100.0 µg a.s./bee in the contact toxicity test. The LD_{50} (48 h) values of Propineb WG 70A W was > 112.3 µg a.s./bee in the oral toxicity test.

CP 10.3.1.1.2 Acute contact toxicity to bees

Please refer to Point 10.3.1.1.1.

CP 10.3.1.2 Chronic toxicity to bees

A 10 day chronic oral toxicity study was conducted with Propineb WG 70, the corresponding summary is filed under KCA, point 8.3.1.2/01 (see MCA document, [redacted]; 2014; M-487404-01).

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

A honey bee brood feeding study accoding to the method of Oomen *et al.* 1998 ([redacted], 2013, M-454682-01-1) and an *in vitro* honey bee larval toxicity test ([redacted], 2014 M-488422-01-1) have been conducted with the Propineb WG 70-formulation and and are included in the MCA document under points MCA 8.3.1.3/01 and MCA 8.3.1.3/03 respectively.

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.

CP 10.3.1.5 Cage and tunnel tests

Although this study was not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies a semi-field (tunnel) test conducted to OECD guidance document 75 incorporating the methodological improvements recommended the AG Bienenschutz and ICPPR (2010). The findings of this study indicate that honey bee colonies exposed to direct spray and residues via nectar, pollen and foliar routes of exposure, applications of Propineb WG 70A W pose no unaacpetble risk to bees.

Report:	[redacted];§[redacted];2014;M-488039-01
Title:	Assessment of side effects of Propineb WG 70A W on the honeybee (Apis mellifera L.) in the semi-field after one application on Phacelia tanacetifolia in Germany 2013
Report No:	S13-00137
Document No(s):	Report includes Trial Nos.: S13-00137-01 M-488039-01-1
Guidelines:	**OECD Guidance Document No. 75 (2007) and current recommendations of the AG Bienenschutz (PISTORIUS et al., 2012), OEPP/EPPO Guideline No. 170(4) (2010);No major deviations**
GLP/GEP:	**yes**

Objective:
The aim of the study was to evaluate potential side effects of a spray application of Probineb WG 70A W on the honeybee (*Apis mellifera* L.) under confined semi-field conditions.

Materials and Methods:
Test item: Propineb WG 70A W (Batch ID: EM20004026, Content of active ingredient (a.s.): 68.3 % w/w (683 g/kg) (analysed).

The study included three treatment groups with four replicates (tunnels) each: one tap-water treated control group (C), one test-item group (T) and one reference item group (R). The crop used was full-flowering *Phacelia tanacetifolia*, the study was conducted in the [redacted] region of Germany. Applications were made at full-flowering (BBCH 65) with honeybees actively foraging on the crop. The application rate of the test item Probineb WG 70A W was 1575 g a.s./ha. Tap water was applied in the control group and Insegar 25 WG was applied at 1200 g product/ha in the reference item group (corresponding to 300 g fenoxycarb per ha). The spray volume was 300 L/ha in all treatment groups.
The initial mean colony sizes per treatment group were in the range of 5657 to 6126 bees. The honeybees remained in the tunnels for 12 days and colonies were assessed before set-up, during and four times after the end of the confined phase.

The following endpoints were assessed:

- Total and mean number of dead bees on the linen sheets in tunnels and in the dead bee traps before as well as after the start of exposure in T and the application in C and R, respectively
- Flight intensity (mean number of forager bees/m2 and treatment group on *Phacelia tanacetifolia* before as well as after the start of exposure in T and the application in C and R, respectively
- Behaviour of the bees in the crop and around the hive
- Condition of the colonies (colony strength and area of the different brood stages and food storage per colony and assessment date)
- Development of the bee brood assessed in individual brood cells. For this particular assessment, between 265 and 365 individually marked cells per colony were selected

Dates of experimental work: 11 August 2013 – 11 September 2013

Results:

Mortality: Findings are summarized in the table below.

Treatment group		Control (C)	Test item (T)	Reference Item (R)
Daily mean mortality (dead bees/colony) ± STD	4DBA to 0DBA	16.3 ± 7.2	13.1 ± 6.0	11.5 ± 3.8#
	0DAA	20.5 ± 18.5	15.3 ± 9.7	20.8 ± 6.9
	0DAA to 7DAA	26.4 ± 14.5	18.3 ± 8.6	25.5 ± 5.9
	0DAA to 27DAA	33.8 ± 11.8	36.1 ± 17.1	34.2 ± 5.7
Mean sum of dead pupae and larvae (0DAA to 27DAA)		1.5 ± 1.7	1.3 ± 2.5	17.0 ± 14.9

DAA: days after application; DBA: days before application; STD: standard deviation
#: statistically significantly higher than control group
*: statistically significantly lower than control group

Throughout the study, (before and following exposure), mortality across all treatments was similar indicating no effect on the test item. Some daily fluctuations occurred where mortality was significantly higher in the test item colonies on three occasions (19DAA, 20DAA and 26DAA Student´s t-Test, method pooled, one-sided, $\alpha = 0.05$). However these were minor in nature and not considered to be treatment related. During the entire period after the applications (0DAA to 27DAA), the average sum of dead pupae and larvae per colony recorded during the mortality assessments was 1.5, 1.3 and 16.5 for C, T, and R, respectively. Effects on pupae of the reference substance are a well-known effect.

Flight Intensity:

Findings are summarized in the table below.

Treatment group		Control (C)	Test item (T)	Reference Item (R)
Daily mean flight intensity (bees/m^2) ± STD	4DBA to 0DBA	11.1 ± 0.8	9.6 ± 3.5	13.9 ± 0.8
	0DAA	21.7 ± 1.1	17.2 ± 1.1*	19.8 ± 3.0
	0DAA to 7DAA	22.6 ± 5.2	20.2 ± 2.0	18.1 ± 2.5

DAA: days after application; DBA: days before application; STD: standard deviation
#: statistically significantly higher than control group
*: statistically significantly lower than control group

As observed for the mortality assessment, foraging rates were similar across all treatments throughout the study before and following exposure up to the end of the conferment phase (7DAA). Thus, no test-item related adverse effects on flight intensity were observed.

Behaviour of the Bees
The behaviour of the bees across all tunnels and treatments was similar and no test item-related effects were observed.

Development of Honeybee Brood in Individual Cells
Findings are summarized in the table below.

Summary of the brood and compensation indices and termination rates

Treatment	Brood / Compensation indices at x days after brood area fixing day (BFD)					Termination rate (BFD+22)
	0	+6	+10	+15	+22	[%]
Control C	1.00 / 1.00	2.41 / 2.49	2.85 / 3.06	2.86 / 3.28	3.55 / 4.45	29.08
Test item T	1.00 / 1.00	2.82 / 2.85	3.60 / 3.61	3.55 / 3.59	4.40 / 4.57	11.92
Ref item R	1.00 / 1.00	0.25* / 0.43*	0.28* / 0.39*	0.17* / 0.42*	0.20* / 1.16*	96.08*

BFD: Brood area fixing day; STD: Standard deviation
*: Mean value statistically significantly lower (brood and compensation indices) or higher (termination rate) compared to the control

In the control group C, successful development was observed in the majority of the marked brood cells indicating a healthy development of brood. The mean termination rate was acceptable at 29.08%. In the reference item treatment group R, the post treatment mean values of the brood and compensation indices were clearly lower than those observed in the control indicating a strong adverse effect. The mean brood and compensation indices as well as the mean termination rates in R were statistically significantly different from the respective values in the control for all post treatment assessments (t-test, method pooled, one-sided, $\alpha = 0.05$). The mean termination rate was 96.08 %. In the test item treatment group T the brood development and mean termination rates showed better performance than the control. The mean brood and compensation indices as well as the mean termination rate in T on all BFD dates were not statistically significantly different from the respective values in the control (t-test, method pooled, one-sided, $\alpha = 0.05$).

Overall, the quantitative assessments of brood development in individually marked cells revealed that Probineb WG 70A W , applied to full-flowering *Phacelia tanacetifolia* at a rate of 1575 g a.s./ha, did not cause a treatment-related adverse effect on honeybee brood development.

Strength of the Colonies

The overall development of colony strength of all treatment groups showed fluctuations which can be considered to be in a typical and normal range. The colony strength values of the test item group were on approximately the same level or even higher during the entire study than the corresponding values of the control group. Therefore, no test-item related adverse effects on colony strength were observed.

Development of the Brood Area

The mean abundance of brood in the colonies (sum of cells containing eggs, larvae, and pupae) was assessed. Overall, honeybee brood development in the test item treatment group T was not affected when compared to the control.

Development of the Food Storage Area

The mean extent of food stores in the colonies (sum of cells containing nectar and pollen) was assessed.
Except for the last colony assessment (due to a seasonal decline in the availability of nectar and pollen) the majority of the colonies were well provided during the course of the study. Thus, no test-item related adverse effects on the development of the food storage area were observed.

Conclusion:

Probineb WG 70A W was applied at a target rate corresponding to 1575 g a.s./ha at full-flowering *Phacelia tanacetifolia* during actively foraging honeybee colonies. The effects on honeybee colonies under confined conditions considering mortality, flight intensity, behaviour, colony strength and brood development were evaluated.
No test-item related adverse effects on mortality or flight intensity were observed.
The quantitative assessments of brood development in individually marked cells performed in this study revealed that Probineb WG 70A W did not caused a treatment-related adverse effect on honeybee brood development.
The overall honeybee brood development in the test item treatment group T, measured as mean number of cells covered with the different types of brood per colony cells, was not affected when compared to the control.
No test-item related adverse effects on colony strength or on the development of the food storage area were observed.
Overall, Propineb WG 70A W applied at 1575 g a.s./ha to a flowering crop in presence of honey bees did not cause any unacceptable effects on mortality, flight intensity, behaviour, colony strength and brood development.

CP 10.3.1.6 Field tests with honeybees

Not necessary when considering the outcome of the risk assessment and the results of the lower-tiered studies.

CP 10.3.2 Effects on non-target arthropods other than bees

The risk assessment was performed according to Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2, Candolfi et al. 2000[5]).

Table 10.3.2- 1: Propineb WG 70 (current representative formulation)

Test species, Dossier-file-No. Reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Aphidius rhopalosiphi M-103548-01-1 Rep.No: 20031369/01-NLAp [redacted] 2003 KCP 10.3.2.1 /04	PPB WG 70 Laboratory, glass plates 179.2 g a.s./ha 448.0 g a.s./ha 1120.0 g a.s./ha 2800.0 g a.s./ha 7000.0 g a.s./ha	LR_{50} > 7000 g a.s./ha; ER_{50} > 7000 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 7.5 / -8.1[A] 10.0 / 25.0 15.0 / -37.8[A] 35.6 / 11.9 12.5 / -16.8[A]
Typhlodromus pyri M-103529-01-1 Rep.No: B124TPL [redacted], 2003 KCP 10.3.2.1 /05	PPB WG 70 Laboratory, glass plates 1.4 g a.s./ha 3.6 g a.s./ha 7.1 g a.s./ha 14.2 g a.s./ha 28.5 g a.s./ha	LR_{50} 5.6 g a.s./ha; ER_{50} > 1.4 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 11 / 12 21 / 78 64 / n.a. 86 / n.a. 97 / n.a.
Typhlodromus pyri M-105196-01-1 Rep.No: B123TPE [redacted], 2003 KCP 10.3.2.2 /02	PPB WG 70 Extended Lab., exposure on detached cow pea leaves 28.5 g a.s./ha 89.7 g a.s./ha 285 g a.s./ha 901 g a.s./ha 2848 g a.s./ha	LR_{50} 247 g a.s./ha; ER_{50} > 89.7 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 10 / 13 18 / 47 51 / n.a. 91 / n.a. 96 / n.a.
Typhlodromus pyri M-095484-01-1 Rep.No: CW04/076 [redacted], 2004 KCP 10.3.2.2 /03	PPB WP 70 Extended Lab., exposure on detached bean leaves 80 g a.s./ha 200 g a.s./ha 502 g a.s./ha 1257 g a.s./ha 3150 g a.s./ha	LR_{50} 347.0 g a.s./ha; ER_{50} > 80 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 7.8 / 28.4 27.3 / 73.9 62.3 / n.a. 94.8 / n.a. 100 / n.a.
Typhlodromus pyri M-073476-01-1 Rep.No: 20021339/02-NETp [redacted], 2002 KCP 10.3.2.2/01	PPB WP 70 Aged residues spray deposits on potted apple trees, 1 appl. of 2370 g a.s./ha Residues aged for 0 d: Residues aged for 14 d:	Corr. Mortality [%] / Effect on Reproduction [%] 48.9 / 60.7 14.8 / 8.0

[5] Candolfi et al.: Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), Wageningen, NL, March 21-23, 2000, SETAC Europe; SETAC publication August 2001

Test species, Dossier-file-No. Reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Typhlodromus pyri M-017106-01-1 Rep.No: BAY01 [redacted] 1993 KCP 10.3.2.4 /01	PPB WG 70 Field study, spray application in vines with two pre-flowering applications (interval 14 days) Control 549 + 824 g a.s./ha	Average Number of predatory mites on 25 leaves Pre-evaluation 7DAT2 28DAT2 440 223 179 505 242 188
Typhlodromus pyri M-017093-01-2 Rep.No: 93 01 BAY 1 [redacted], 1993 KCP 10.3.2.4 /02	PPB WG 70 Field study, spray application in vines, 2 applications (interval 15 days) Control Treatment	Average Number of predatory mites on 25 leaves Pre-evaluation 7DAT2 28DAT2 225 240 223 210 100 197
Chrysoperla carnea M-424149 -01-1 Rep.No: 69281047 [redacted], 2012 KCP 10.3.2.2 /04	PPB WG 70 Extended laboratory, exposure on detached bean leaves Control 590 g a.s./ha 1039 g a.s./ha 1829 g a.s./ha 3220 g a.s./ha 5670 g a.s./ha	LR_{50} > 5670 g a.s./ha; no effect on reproduction Corr. Mortality [%] Eggs/Female/Day Hatching [%] - 35.5 91.7 2.6 37.6 89.9 0.0 34.0 92.6 -2.6 [B] 27.9 89.2 0.0 33.1 92.6 12.8 31.7 89.3
Coccinella septempunctata M-017081-01-1 Rep.No: 92020/01-CS [redacted], 1992 KCP 10.3.2.1 /02	PPB WG 70 Laboratory, glass plates Control 2632 g a.s./ha	LR_{50} > 2632 g a.s./ha; no effect on reproduction Corr. Mortality [%] Eggs/Female [over 8 weeks] Hatching [%] 409 50 33.2 755 40
Coccinella septempunctata M-457265-01-1 Rep.No: CW13/029 [redacted], 2013 KCP 10.3.2.2 /05	PPB WG 70 Extended lab., exposure on detached grape vine leaves Control 590 g a.s./ha 1039 g a.s./ha 1829 g a.s./ha 3220 g a.s./ha 5670 g a.s./ha	LR_{50} > 5670 g a.s./ha; no effect on reproduction Corr. Mortality [%] Fertile eggs/female/day - 13.5 7.1 12.5 0 9.1 0 11.4 10.7 13.9 3.6 13.0
Coccinella septempunctata M-017109-01-1 Rep.Nr: SXR/CS 04 [redacted], 1994 KCP 10.3.2.3/01	PPB WG 70 Semi-field, spray deposits on bean seedlings, 2 applications: at larval stage and at the adult stage (during fecundity assay) 1st run: Control 2 x 2560 g a.s./ha 2nd run: Control 2 x 2560 g a.s./ha	Mortality [%] Eggs/Female Hatching [%] 54 338 66 46 382 60 64 718 68 49 341 69

Test species, Dossier-file-No. Reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Poecilus cupreus M-017076-01-1 Rep.No: HBF/CA 18 [redacted] 1990 KCP 10.3.2.1 /03	PPB WG 70 Laboratory, spray deposits on sand 1328 g a.s./ha	ER_{50} > 1328 g a.s./ha Corr. Mortality [%]: 0.0 Effect on Feeding Rate [%]: 5
Trichogramma cacoeciae M-017078-01-1 Rep.No.: 271405 [redacted], 1992 KCP 10.3.2.1 /01	PPB WG 70 Laboratory, spray deposits on glass plates & dipping of parasitized host eggs. 4386 g a.s./ha	Adult wasps - Effect on Reproduction [%]: 28 Pupae - Effect on Reproduction [%]: -57 [C]

A: A negative value indicates a higher reproduction rate in the treatment than in the control.
B: A negative value indicates a lower mortality rate in the treatment than in the control.
C: A negative value indicates a higher hatching rate in the treatment than in the control.
n.a. = not assessed
Note:
- Studies referring to KCA are filed in the dossier for the active substance.
- Studies written in grey type are referring either to studies in the corresponding Baseline-dossier for the active substance or to the dossier for the old representative formulation for Annex I inclusion (which is provided for renewal as well); whereas studies in black type are studies of the Supplemental dossier for the active substance or this present dossier for the new representative formulation.

Natural populations of arthropods other than bees are not expected in glasshouses. Thus non-target arthropods are not at risk from the application of Propineb WG 70 in glasshouses and consequently a risk assessment is not considered necessary.

Tier 1 in-field risk assessment for other non-target arthropods

Table 10.3.2- 2: Tier 1 in-field risk assessment for non-target arthropods

Crop	Species	Appl. rate [g a.s./ha]	MAF	LR_{50} [g a.s./ha]	HQ	Trigger
Orchards (late)	*T. pyri*	1575	1.7	5.6	478	2
	A. rhopalosiphi	1575	1.7	> 7000	< 0.38	2
Grapes (late) [a]	*T. pyri*	1400	1.7	5.6	425	2
	A. rhopalosiphi	1400	1.7	> 7000	< 0.34	2

[a] due to the higher application rate the use grapes II covers the use grapes I

Table 10.3.2- 3: Tier 1 off-field risk assessment for non-target arthropods

Crop	Species	Appl. rate [g a.s./ha]	MAF	Drift [%]	VDF	Correction factor	LR_{50} [g a.s./ha]	HQ	Trigger
Orchards (late)	*T. pyri*	1575	1.7	12.13	10	10	5.6	58	2
	A. rhopalosiphi	1575	1.7	12.13	10	10	> 7000	< 0.05	2
Grapes (late) [a]	*T. pyri*	1400	1.7	7.23	10	10	5.6	31	2
	A. rhopalosiphi	1400	1.7	7.23	10	10	> 7000	< 0.02	2

[a] due to the higher application rate the use grapes II covers the use grapes I

For *A. rhopalosiphi* the calculated HQ values for the in-field and off-field scenario are below the trigger of concern. For *T. pyri* the HQ values indicate that a Tier 2 risk assessment is needed in the in-field as well as for off-field scenario. Therefore, two additional species are considered in the Tier 2 risk assessment.

Tier 2 in-field risk assessment for non-target arthropods

The tier 1 risk assessment for *Aphidius rhopalosiphi* indicated an acceptable risk for non-target arthropods in the in-field and the off-field area, whereas the tier 1 risk assessment for *Typhlodromus pyri* indicated the need for a tier 2 risk assessment for this species and for 2 additional species. This tier 2 risk assessment based on extended laboratory studies for *T. pyri*, *C. septempunctata*, and *C. carnea* is provided below.

Propineb WG 70 is intended to be applied up to 2 times in orchards and grapes. For the tier 1 risk assessment a generic multiple application factor (MAF) of 1.7 for 2 applications has been considered. This value can be refined based on measured DT_{50} values on leaves. [redacted] (M-486413-01-1) evaluated the residue studies in barley, lettuce, and celery and derived single 1[st] order dissipation half-live values (DT_{50}) in the range of 2.10 to 4.54 d with a geometric mean of 2.92 d. Based on the intended minimum application intervals of 14 d in orchards a refined MAF value of 1.1 can be used for the refined exposure assessment as indicated in Appendix V of ESCORT 2 under the assumption of a 1:4 ratio between the DT_{50} and the application interval. Based on the intended minimum application intervals of 10 d in grapes a refined MAF value of 1.2 can be used for the refined exposure assessment under the assumption of a 1:3 ratio between the DT_{50} and the application interval.

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

Crop / no. of applications	Appl. rate [g a.s./ha]	MAF	in-field $PEC_{max.}$ [g a.s./ha]
Orchards (late) / 2	1575	1.1	1733
Grapes (late) [a] / 2	1400	1.2	1680

[a] due to the higher application rate the use grapes II covers the use grapes I

According to ESCORT 2 Appendix VI, 90[th] percentiles for drift values are used for 1 application, 82[nd] percentiles for 2 applications. As the DT_{50} for propineb on leaves is short (2.92 d) the product of MAF for the use in orchards and drift values based on 82[nd] percentile is lower than the drift values derived for single application. In this case, as a worst-case assumption, the drift value of 90[th] percentile is applied for the off-field PEC calculation, while the MAF is set to 1.

Table 10.3.2- 5: Exposure assessment for off-field assessment

Crop	Application rate [g a.s./ha]	MAF	Drift [%]	Veg. distr. factor	Correction factor	off-field PEC_{max} [g a.s./ha]	Remark
Orchards (late)	1575	1	15.73	10	5	124	in case of 2-D study design
Grapes (late) [a]	1400	1.2	7.23	10	5	60.7	in case of 2-D study design

[a] due to the higher application rate the use grapes II covers the use grapes I

Table 10.3.2- 6: Tier 2 risk assessment for terrestrial non-target arthropods for the in-field scenario

Crop	Species	In-field PEC_{max} [g a.s./ha]	LR_{50}; ER_{50} [g a.s./ha]	Risk acceptable if	Refined risk assessment required
Orchards (late)	*T. pyri*	1733	>89.7	Effects are < 50%	Yes
	C. carnea		>5670	Effects are < 50%	No
	C. septempunctata		>5670	Effects are < 50%	No
Grapes (late) [a]	*T. pyri*	1680	>89.7	Effects are < 50%	Yes
	C. carnea		>5670	Effects are < 50%	No
	C. septempunctata		>5670	Effects are < 50%	No

[a] due to the higher application rate the use grapes II covers the use grapes I

Table 10.3.2- 7: Tier 2 risk assessment for terrestrial non-target arthropods for the off-field scenario

Crop	Species	off-field PEC_{max} [g a.s./ha]	LR_{50} [g a.s./ha]	Risk acceptable if	Refined risk assessment required
Orchards (late)	*T. pyri*	124	>89.7	Effects are < 50%	Yes
	C. carnea		>5670	Effects are < 50%	No
	C. septempunctata		>5670	Effects are < 50%	No
Grapes (late) [a]	*T. pyri*	60.7	>89.7	Effects are < 50%	No
	C. carnea		>5670	Effects are < 50%	No
	C. septempunctata		>5670	Effects are < 50%	No

[a] due to the higher application rate the use grapes II covers the use grapes I

The results of the Tier 2 in-field risk assessments indicate no concern for non-target arthropod species *Chrysoperla* and *Coccinella*. However, the in-field assessment for both crops and the off-field assessment for orchards show that effects on non-target arthropod cannot be excluded. Therefore, a further evaluation is required.

Refined off-field risk assessment for *T. pyri*

To reduce the estimated off-crop exposure from 124 g a.s./ha below 89.7 g a.s./ha a drift reduction of 28% is required. Therefore, applying the product in orchards with a 5 m buffer zone (drift value 8.81 %) will lower the off-crop exposure to 72.9 g a.s./ha or applying the product with 50% drift reducing spray nozzles will lower the off-crop exposure to 68.1 g a.s./ha. Under consideration of such mitigation measures for the use in orchards no unacceptable risk is expected for non-target arthropods in the off-crop area from the use of Propineb WG 70 according to the proposed use pattern.

The available additional data on the species, *Trichogramma cacoeciae* and *Poecilus cupreus* confirm the results of the risk assessment as provided above.

Tier 3 in-field risk assessment for *T. pyri*

The in-field tier 2 risk assessment indicated that initial effects on predatory mites cannot be excluded in the in-field area therefore a further refined risk assessment is presented below.

According to the Guidance Document on Terrestrial Ecotoxicology (SANCO/3268/2001) the potential for recovery needs to be demonstrated in case that initial effects cannot be excluded. This potential for recovery has been demonstrated by an aged residue study on *T. pyri* (M-073476-01-1). The bioassay that started on the day of the application (2370 g a.s./ha) resulted in 48.9% mortality and an effect of 60.7% on reproduction. Within 14 days the residues declined to a level that resulted in only 14.8% mortality and a reduction of the reproduction performance of 8%.

It can be concluded that no unacceptable adverse in-field effects are to be expected from the use of Propineb WG 70 according to the proposed use pattern. Furthermore, these conclusions are supported by the results of the available field studies.

<u>Field studies with predatory mites</u>

A field study on the effects of Propineb WG 70 to predatory mites in vine has been conducted according to GLP regulations by the [redacted], Germany. As a result no effects on predatory mite populations as compared to the control were observed 7 days and 4 weeks after the last of two applications. In this field study, Propineb WG 70 was applied two times at an application rate of 549 g a.s./ha and 824 g a.s./ha 14 days later.

A number of additional field studies have been conducted on the effects of propineb to predatory mites in vine. Although these field studies were not conducted according to GLP regulations, they provide additional data on the effects of propineb to predatory mites. The results are depicted in Table 10.3.2-8. These field studies have been conducted according to the BBA guideline for mite field studies.

Repeated applications of propineb are known to be harmful to predatory mites ([redacted] *et al.* 2000). Propineb was tested in 10 field trials for its effect on field populations of predatory mites according to the BBA guideline 23-2.3.4. The field trials have been performed by official test laboratories [redacted], [redacted], LLVA [redacted], FA [redacted], LLVA [redacted]. Additional data published in the IOBC/WPRS publication ([redacted] *et al.* 2000) were included. The field studies cover a broad geographical range and a range of at least 5 different laboratories. Taking the normal variability of natural mite populations and the respective variability of field studies into consideration a reliable assessment on the effect of propineb on predatory mites can be set up. The study design of the field studies comprised up to seven applications with an application rate of in total 2000 g Propineb WG 70 per hectare. From the results of the studies it was obvious that after two applications the effects rarely exceeded 40% one week and four weeks after the last applications. Of five studies conducted with two applications, only one revealed effects exceeding 40% 7 days after the last application and 4 weeks after the last application. From the results of the field studies it can be concluded that 2 applications of propineb will not result in unacceptable effects on predatory mites.

Table 10.3.2- 8: Overview on the impact of Propineb WG 70 on predatory mites in field studies in vine

Application concentration	Number of applications	Effects 7 d after last appl. [% Abbott]	Effects ~ 28 d after last appl. [% Abbott]	Reference and document No.
0.2%	2	-8.5	-5.0	[redacted] 1993, M-017106-01-1
0.2%	2	58.4	11.4	[redacted] 1993, M-017093-01-2
0.2%	2	10.3	23.8	[redacted] 1992, M-036083-01-1
0.2%	2	-11.3	28.9	[redacted] 1992, M-036090-01-1
0.2%	2	-79.4	66.7	[redacted] 1992, M-036105-01-1
0.2%	7	100	98.8	[redacted] 1988, M-036476-01-1
0.2%	6	85.9	92.5	[redacted] 1988, M-036484-01-1
0.2%	6	95.5	96.1	[redacted] 1988, M-036515-01-1
0.2%	6	67.4	83.0	[redacted] 1986, M-036523-01-1
0.2%	6	51.6	66.8	[redacted] 1986, M-036547-01-1
n.s.	5	85.7	97.1	[redacted] al. 2000 [a]
n.s.	5	91.1	95.8	[redacted] al. 2000 [a]
n.s.	5	89.3	52.6	[redacted] et al. 2000 [a]
n.s.	5	60.0	39.0	[redacted] et al. 2000 [a]
n.s.	5	89.7	37.8	[redacted] et al. 2000 [a]

[a] Candolfi, M.P, S. Blümel, R. Förster (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC, BART and EPPO Joint Initiative

Study trials including 5 to 7 applications of Propineb are commonly characterized by more severe effects on predatory mites mostly exceeding 40% (see Figure 10.3.2- 1).

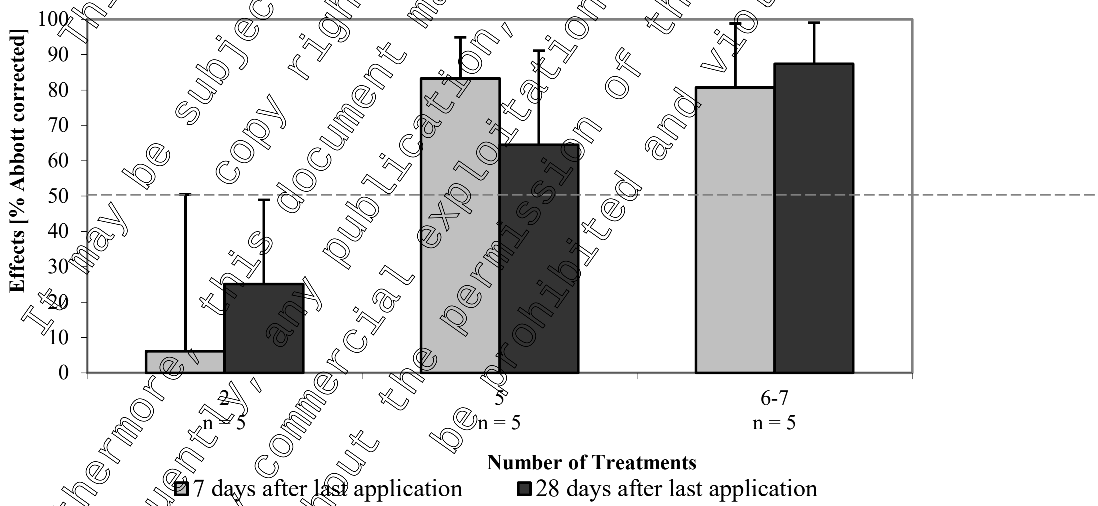

Figure 10.3.2- 1: Mean values of Abbott corrected effects to predatory mites of multiple spray applications of Propineb WP 70 in vine (Standard deviation is indicated as whisker)

Conclusions

In-field environment

Initial effects on non-target arthropods with a sensitivity similar to predatory mites cannot be excluded, but the potential for recovery can be expected within a few weeks. Hence, the in-field risk from the use of Propineb WG 70 according to the proposed use pattern for non-target arthropods is considered acceptable.

Off-field environment

The off-field risk assessment indicted that no unacceptable adverse effects are to be expected from the use of Propineb WG 70 on off-field non-target arthropod populations. Only for the use on orchards appropriate risk mitigation measures, i.e. 50% drift reducing nozzles or a 5 m buffer zone need to be considered.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Report:	[redacted]t;[redacted];2003;M-103548-01
Title:	Antracol WG 70, Code: AE F074263 00 WG70 A101: Acute toxicity to the aphid parasitoid, Aphidius rhopalosiphi De Stefani Perez (Hymenoptera, Braconidae) in the laboratory
Report No:	20031369/01-NLAp
Document No:	M-103548-01-1
Guidelines:	**ESCORT II Guidance Document (Candolfi et al. 2001) and IOBC (Mead-briggs et al. 2000);no major deviations**
GLP/GEP:	**yes**

Objective:
The objectives of the study were to determine the effects of AE F074263 00 WG70 A101 on mortality and reproduction of the parasitoid *Aphidius rhopalosiphi* under worst-case exposure conditions and to establish the rate producing 50 % mortality (LR_{50}), where possible.

Materials and Methods:
Test item: Anthracol WG 70, Code: AE F074263 00 WG70 A101 (Batch No. PF 90042868, purity: 71.2 % LH 30/Z, analyzed).
The test item was applied to glass plates at rates equivalent to 179.2, 448.0, 1120, 2800 and 7000 g a.s./ha and the effects were compared to a water treated control. A toxic reference (a.s.: dimethoate) applied at 0.3 mL product in 200 L water/ha was included to indicate the relative susceptibility of the test organisms and the test system.
Aphidius rhopalosiphi (5 females and 5 males) were exposed in groups of 10 per unit to glass plates treated with the test item within 48 hours after application. There were four exposure units for the control and for each Anthracol WG 70 treatment and 4 units for the toxic reference. The parasitoids were confined for 48 h and their condition was assessed after approx. 30 min, 2, 24 and 48 h. After 48 h the surviving females were removed from the cages and the parasitic capacity per female was assessed in a fertility test. The fertility test was conducted with females from all test groups.
The females were offered aphids for oviposition for 24 hours. Counting of parasitised aphids was carried out 11 days after the start of the fertility test.

Dates of experimental work: November 04 to November 17, 2003

Results:

Validity Criteria	Recommended by the guideline	Obtained in this study
Mortality in water control	≤ 13%	0.0%
Mortality in reference item	≥ 50%	100.0%
Mean reproduction in water control	≥ 4	6.4
minimum control parasitisation rate (mean) [aphid mummies per surviving female]	> 5	11.47
Number of females in control group failed to produced mummies	≤ 2	1

All validity criteria for the study were met.

Mortality and reproduction of *Aphidius rhopalosiphi* after exposure to Anthracol WG 70

Test item	**Anthracol WG 70**			
Test organism	***Aphidius rhopalosiphi***			
Exposure	**Glass plates**			
Nominal application volume	**200 L/ha**			
	Mortality after 48 h [%]		**Fecundity (mummies/female)**	
control	**0.00**		**11.47**	
Treatment [g a.s./ha]	**Mortality after 48 h [%]**	**Corrected Mortality(2) after 48 h [%]**	**Mummies/ female**	**Reproduction relative to control [%]**
179.2	7.50	7.50	12.40	108.1
448.0	10.0	10.00	8.60	75.0
1120	15.00*	15.00	15.80	137.8
2800	35.00*	35.00	10.10	88.1
7000	12.50*	12.50	13.40	116.8
LR_{50}	**> 7000 g a.s./ha**			

(1) Based on the number of moribund and dead organisms
(2) Corrected mortality according to SCHNEIDER-ORELLI (1947)
* statistically significantly different from the control (Fisher's Exact-Test (one-sided), $p < 0.05$)

The results of the control group indicate that the test organisms were in a good condition (mortality: 0.0 %, 11.47 mummies per female were produced in the reproduction test). The results of the reference item group indicates that the test system was sensitive to harmful substances (mortality: 100.0 %) and that potential adverse effects of exposure to test item residues could be detected with the set-up used in this experiment. In all application rates of AE F074263 00 WG70 A101 no statistically significant differences to the reproduction data of the control group could be detected. It can be concluded that there was no treatment effect on reproduction of *A. rhopalosiphi*.

Conclusion:

The LR_{50} was estimated to be > 7000 g a.s./ha.

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Report:	[redacted]h;[redacted];2003;M-103529-01
Title:	A laboratory dose-response study to evaluate the effects of Propineb WG 70 on survival and reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae)
Report No:	B124TPL
Document No:	M-103529-01-1
Guidelines:	**Laboratory test with the predatory mite Typhlodromus pyri Scheuten for regulatory testing of plant protection (Blümel et al. 2000); Guidance document on testing and risk assessment procedures for protection products with arthropods(Candolfi et al. 2001); there were no deviations from the guideline**
GLP/GEP:	**yes**

Objective:

This study is designed to evaluate the effects of Propineb WG70 on survival and reproduction of the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae), in a laboratory bioassay, using ventilated glass and inert PTFE units (Cofin cells).

Materials and Methods:

Test item: Propineb WG70 (active ingredient LH30/Z, content: 71.2%, TOX no.: 6364-00, Art. no: 0005468906, Batch no.: PF 90042868 was tested.

The fungicide was applied to mortality units ('coffin cells') consisting of glass and inert PTFE and glass reproduction units at four nominal rates, viz. 2, 5, 10, 20 and 40 g product/ha, at a spray application volume of approximately 200 L/ha. The control was treated with deionised water. Dimethoate at a rate of 0.26 mL product/ha (0.026% of the highest recommended field rate) was used as a toxic reference.

Typhlodromus pyri Scheuten was exposed in groups of 20 per unit to dry residues within 1.5 hours after application. There were 5 units for the deionised water control, 4 units for each Propineb WG 70 treatment and 3 units for the toxic reference.

Mortality was assessed after a 7-day exposure period. The toxic reference treatment was stopped after mortality assessments.

All surviving individuals of the deionised water control group and the Propineb WG70 rates equivalent to 2 and 5 g product/ha were transferred to treated (on day 0) open glass arenas on the day of the mortality assessment, because corrected mortality in these rates was ≤ 50%. Reproduction for these treatments was determined during 7- days in total (3 consecutive assessments at 2-3 day intervals).

Dates of experimental work: October 31, 2003 to November 14, 2003

Results:

Validity Criteria	Recommended by the guideline	Obtained in this study
Mortality in water control	≤ 20%	5%
Corrected mortality reference item	50% - 100%	100%
Mean reproduction in deionised water control (eggs/female/7 days)	≥ 4	9.9

All validity criteria for the study were met.

Mortality and reproduction of predatory mites

Test item	**Propineb WG70**			
Test organism	*Typhlodromus pyri*			
Exposure	7 days on on glass and inert PTFE mortality units (Coffin cells) and 7 days on glass reproduction units (total period: 14 days)			
Nominal application volume	200 l/ha			
	Mortality after 7 days [%]		Reproduction [eggs/female/7 days]	
Deionised water control	5		9.9	
Application rates of Propineb WG70 [g a.s./ha]	Corrected mortality after 7 days [%]		Reproduction in eggs/female/7 days (reduction relative to control in%)	
2	11	P = 0.038*	8.7 (%)	P = 0.417
5	21	P <0.001*	2.2 (78%)	P <0.001*
10	64	P <0.001*	Not assessed	
20	86	P < 0.001*	Not assessed	
40	97	P < 0.001*	Not assessed	
Toxic reference	100	P <0.001*	Not assessed	
LR_{50}	**7.9 g product/ ha** **The 95% confidence limits were 6.8 and 9.2 g product/ha**			
Other observations	**A delay in development was observed at increasing test rates.**			

* Statistically significantly different from deionised water control. Statistical analysis: mortality data with Fisher's Exact Test and reproduction data with ANOVA/Fisher's Least Significant Difference Test

Low control mortality and high reproductive performance in the control treatment indicated that test animals were in good condition. Mortality in the toxic reference, showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test item residues could be detected with the set-up used in this experiment.

After 7 days of exposure to Propineb WG 70 at rates equivalent to 2, 5, 10, 20 and 40 g product/ha, survival of *Typhlodromus pyri* was statistically significantly reduced compared to the water control.

Reproduction of *T. pyri* on untreated glass plates treated with Propineb WG 70 at a rate equivalent to 5 g product/ha was statistically significantly reduced compared to reproduction in the water control. Exposure to rates equivalent to 2 g product/ha had no significant effect on reproduction.

Conclusion:
The LR_{50} was calculated as 7.9 g product/ha with 95% confidence limits of 6.8 and 9.2 g product/ha.

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

Report:	[redacted]:;[redacted];2003;M-105196-01
Title:	An extended laboratory dose-response study to evaluate the effects of propineb WG 70 on survival and reproduction of the predaceous mite Typhlodromus pyri Scheuten (Acari: Phytoseiidae) on cow pea leaves
Report No:	B123TPE
Document No:	M-105196-01-1
Guidelines:	**Laboratory residual contact test with the predatory mite Typhlodromus pyri Scheuten for regulatory testing of plant protection products (Blümel et al., 2000); Guidance document on regulatory testing and reisk ass. procedures (Candolfi et al 2001);There were no deviations from the guideline**
GLP/GEP:	**yes**

Objective:
This extended laboratory study is designed to evaluate the effects of Propineb WG70, applied to the underside of detached cowpea leaves, on survival and reproduction of the predaceous mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae).

Materials and Methods:
Test item: Propineb WG 70 (active ingredient LH30/Z, content: 71.2%, TOX no.: 6364-00, Art. no: 0005468906, Batch no.: PF 90042868) was tested.
The fungicide was applied to the underside of cowpea leaves at four nominal rates of 40, 126, 400, 1265 and 4000 g product/ha, at a spray application volume of approximately 200 L/ha. The control was treated with deionised water. Dimethoate at a rate of 4.8 mL product/ha (0.48% of the highest recommended field rate) was used as a toxic reference.
Typhlodromus pyri Scheuten was exposed in groups of 10 per unit to dry residues within 1.5 hours after application. There were 5 units for the deionised water control, 8 units for each Propineb WG 70 treatment and 6 units for the toxic reference.
Mortality was assessed after a 7-day exposure period. The toxic reference treatment was stopped after mortality assessments.
All surviving individuals of the deionised water control group and the Propineb WG 70 rates equivalent to 40 and 126 g product/ha were transferred to untreated open glass arenas on the day of the mortality assessment, because corrected mortality in these rates was >50%. Reproduction for these treatments was determined during 7- days in total (3 consecutive assessments at 2-3 day intervals).

Dates of experimental work: November 19, 2003 to December 03, 2003

Results:

Validity Criteria	Recommended by the guideline	Obtained in this study
Mortality in water control	≤ 20%	13%
Corrected mortality reference item	50% - 100%	85%
Mean reproduction in water control	≥ 4	10.8

All validity criteria for the study were met.

Mortality and reproduction of predatory mites

Test item	**Propineb WG70**			
Test organism	*Typhlodromus pyri*			
Exposure	7 days on the underside of cowpea leaves in glass/plexiglass mortality units			
Nominal application volume	200 L/ha			
	Mortality after 7 days [%]		Reproduction [eggs/female/7 days]	
Deionised water control	13		10.8	
Application rates of Propineb WG70 [g a.s./ha]	Corrected mortality after 7 days [%]		Reproduction in eggs/female/7 days (reduction relative to control in%)	
40	10	P = 0.256	9.4 (13%)	P = 0.690
126	18	P = 0.037*	5.7 (47%)	P = 0.006*
400	51	P <0.001*	Not assessed	
1265	91	P < 0.001*	Not assessed	
4000	96	P < 0.001*	Not assessed	
Toxic reference	85	P <0.001*	Not assessed	
LR_{50}	**347 g product/ ha** **The 95% confidence limits were 268 and 448 g product/ha**			
Other observations	**A delay in development was observed at increasing test rates.**			

* Statistically significantly different from deionised water control. Statistical analysis: mortality data with Fisher's Exact Test and reproduction data with ANOVA/Fisher's Least Significant Difference Test

Low control mortality and high reproductive performance in the control treatment indicated that test animals were in good condition. Mortality in the toxic reference, showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test item residues could be detected with the set-up used in this experiment.

After 7 days of exposure to Propineb WG 70 at rates equivalent to 126, 400, 1265 and 4000 g product/ha, survival of *Typhlodromus pyri* was statistically significantly reduced compared to the water control. Exposure to a rate equivalent to the 40 g product/ha had no significant effect on survival.

Reproduction of *T. pyri* on untreated glass plates treated with Propineb WG 70 at a rate equivalent to 126 g product/ha was statistically significantly reduced compared to reproduction in the water control. Exposure to rates equivalent to 40 g product/ha had no significant effect on reproduction.

Conclusion:

The LR_{50} was calculated as 347 g product/ha with 95% confidence limits of 268 and 448 g product/ha.

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Report:	[redacted]x;[redacted];2004;M-095484-01
Title:	Toxicity to the predatory mite Typhlodromus pyri Scheuten (Acari, Phytoseiidae) using an extended laboraotry test - Propine-wettable powder
Report No:	CW04/076
Document No:	M-095484-01-1
Guidelines:	**IOBC (Blümel et al. 2000)**
GLP/GEP:	**yes**

Objective:

The aim of the study was to determine the toxicity of freshly dried residues applied onto leaves of *Phaseolus vulgaris* var. nanus, to the predatory mite *Typhlodromus pyri*.

Materials and Methods:

Test item: A wettable powder formulation was tested, specified by batch no. PF31112692; TOX6763-00 and product code: AE F074263 00 WP70 A201 [content of active ingredient: 71,1%].

The test item was applied at rates of 80; 200; 502; 1257 and 3150 g a.s./ha and the effects were compared to a toxic reference (a.s.: dimethoate) applied at 40 g a.s./ha, and a water treated control.

Mortality of 80 protonymphs was assessed 1, 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. The reproduction rate of surviving mites was then evaluated over the period of 7-14 days after treatment by counting the total number of offspring (eggs and larvae) produced.

Dates of experimental work: September 14 to September 28, 2004

Results:

Validity Criteria	**Recommended by the guideline**	**Obtained in this study**
Mortality in water control	≤ 20%	3.8%
Corrected mortality reference item	50% - 100%	100%
Mean reproduction in water control	> 4	7.8

All validity criteria for the study were met.

Summary of effects of AE F074263 00 WP70 A201 on mortality and reproduction of *Typhlodromus pyri* exposed on *Phaseolus vulgaris* leaves

		Mortality [%]			Reproduction		
Treatment	**g a.s./ha**	**Uncorr.**	**Abbot**	**P-Value (*)**	**Rate**	**Rel. to Control [%]**	**P-Value(#)**
Control (deionised water)	-	3.8	0.0		7.8	0	
Test item	80	11.3	7.8	0.131	5.6	28.4	0.029
Test item	200	30.0	27.3	<.001	2	73.9	<.001
Test item	502	63.8	62.3	<.001	n.d.**	n.d.**	
Test item	1257	95.0	94.8	<.001	n.d.**	n.d.**	
Test item	3150	100	100	<.001	n.d.**	n.d.**	
Reference item	40	100	100	<.001	n.d.**	n.d.**	

LD50: 346.993 g a.s./ha; 95% Confidence Interval: (275.902 – 417.486)
* Fisher´s Exact test, two-sided, p-values are adjusted according to Bonferroni- Holm
# one-way ANOVA, p-values are adjusted according to Dunnett
** : not detected

In the highest dose rate of 3150 g a.s./ha of the test item there was 100% corr. mortality. At the lower rates of 1257; 502; 200 and 80 g a.s./ha 94.8; 62.3; 27.3 and 7.8% corr. Mortality were found and the reduction of reproduction was at the rates of 200 and 80 g a.s./ha 73.9 and 28.4% rel. to the control.

Conclusion:

The LD_{50} was calculated to be 346.99 g a.s./ha.

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Report:	[redacted]5;[redacted];2012;M-424149-01
Title:	Effects of Propineb WG 70% w/w on the lacewing Chrysoperla carnea, extended laboratory study - dose response test -
Report No:	69281047
Document No:	M-424149-01-1
Guidelines:	**Vogt et al. 2000; this guideline was modified for exposure of Chrysoperla carnea on natural substrate**
GLP/GEP:	**yes**

Objective:

The purpose of this study was to produce a concentration-response curve for mortality effects on the green lacewing (*Chrysoperla carnea*). From these the LR_{50} value was estimated.

Materials and Methods:

Test item: Propineb WG 70% w/w (water dispersible granules formulation), specified by sample description: TOX08654-01; Specification No.: 102000006516-02; Batch ID: EM20004026, content of a.s.: 68.5% w/w propineb (LH 30/Z).

Under extended laboratory conditions 2 - 3 day old larvae of the lacewing *Chrysoperla carnea* were exposed to dried spray deposits of 590, 1039, 1829, 3220 and 5670 g a.s./ha (diluted in 200 L deionised water/ha) on treated bean leaves (40 replicates each containing 1 larva per treatment group). Deionised water was used as a control treatment and Perfekthion (100 mL product/ha diluted in 200 L deionised water/ha) as a reference treatment. Exposure time lasted until pupae were transferred to the reproduction units for development of adults. Mortality checks were carried out regularly until eclosion of adult lacewings (up to 21 days after test start). In addition, for the control and the test item treatment groups where the corrected mortality was < 50% the reproduction performance, *i.e.* egg deposition and larval hatching rate, was determined (2 checks/week, 24 hours period each check).
The climatic test conditions during the study were 24.0 - 26.0 °C temperature and 70 - 83% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1030 - 2610 Lux during the study.

Dates of experimental work: October 12, 2011 – November 18, 2011

Results:

	Validity criteria	Finding
Control Mortality	≤ 20%	2.5%
Reference item Mortality	50% (preferably <100%) corrected	87.2%
Fecundity in the Control Group (mean number of eggs per female per day)	≥ 15	35.5
Fertility in the Control Group (mean larval hatching rate)	≥ 70%	91.7%

All validity criteria for the study were met.

Pre- imaginal mortality and reproduction of *Chrysoperla carnea*

Treatment	Rate[1] [g a.s./ha]	Mortality[2] [%]	Mortality Corr.[3] [%]	Reproduction [eggs/female/day]	Hatching rate [%]
Control	-	2.5	-	35.5	91.7
Test item	590	5.0 n.s.	2.6	37.6	89.9
Test item	1039	2.5 n.s.	0.0	34.0	92.6
Test item	1829	0.0 n.s.	-2.6	27.9	89.2
Test item	3220	2.5 n.s.	0.0	33.1	92.6
Test item	5670	15.0 n.s.	12.8	31.7	89.3
Reference item	100ml product/ha	87.5 *	87.2	-	-
LR_{50}: > 5670 g a.s./ha					

[1] Application rate in 200 L deionised water/ha
[2] Pre-imaginal mortality after exposure to spray residue on leaf surfaces (Fisher´s Exact Test, α = 0.05: n.s. not significant, * significant
[3] Corrected pre- imaginal mortality according to Abbott and improvements by Schneider-Orelli; negative values indicate better survivorship compared to control

The corrected mortality for all test item rates was below 13%. Reproduction was > 15 eggs per female per day and the mean hatching rate was > 70% at all tested test item rates. This indicates that there was no negative effect of the test item on reproductive performance of *C. carnea* up to and including 5670 g a.s./ha.

Conclusion:

The LR_{50} is estimated to be greater than 5670 g a.s./ha in 200 L water/ha.

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Report:	[redacted]ü;[redacted];2013;M-457265-01
Title:	Toxicity to the ladybird beetle Coccinella septempunctata L. (Coleoptera, Coccinellidae) in an extended laboratory test on grape vine Propineb WG 70 percent w/w
Report No:	CW13/029
Document No:	M-457265-01-1
Guidelines:	**EU Directive 91/414/EEC** **Regulation (EC) No. 1107/2009** **US EPA OCSPP Not Applicable**
GLP/GEP:	**yes**

Objective:

The objective of this study was to investigate the lethal and sublethal toxicity of Propineb WG 70% w/w to the ladybird beetle *Coccinella septempunctata* when exposed to treated leaf surfaces.

Materials and Methods:

Test item: Propineb WG 70% w/w (water dispersible granules formulation), specified by sample description: TOX 09448-00; specification no.: 102000006516-02; batch ID: EDFL009304 [analysed content of active ingredient: Propineb 69.6% w/w].

The test item was applied to detached grape vine leaves (*Vitis vinifera*) at rates of 590, 1039, 1829, 3220 and 5670 g a.s./ha and the effects on the ladybird beetle *Coccinella septempunctata* were compared to those of a deionised water treated control. A toxic reference (active substance: Dimethoate) applied at 21 g a.s./ha was included to indicate the relative susceptibility of the test organisms and the test system.

Coccinella septempunctata was exposed in groups of 40 per unit to dry residues within 1.5 hours after application. There were 1 unit for the water control, 5 units for the test item Propineb WG 70% w/w and 1 unit for the toxic reference. The preimaginal mortality of the 4 days old larvae at study start (per test group), was assessed till the hatch of the imagines (up to 16 days).

All exposure units were assessed daily and the condition of the ladybird larvae was recorded. The larvae were fed daily with fresh aphids (*A. pisum*) ad libitum. At every feeding session dead aphids and exuviae from earlier feeding sessions were removed. Once the larvae had pupated and the pupae hatched, the emerged beetles were transferred to glass jars per test group. The reproduction phase of the study started 7 days after the first eggs. The fertility and fecundity of the surviving hatched adults were then evaluated over the period of 17 days.

The climatic test conditions during the study were 23.0 - 27.0°C temperature and 60 - 77% relative humidity. The light / dark cycle was 16:8 h with a light intensity range of 1329 - 5230 Lux during the study.

Dates of experimental work: March 12, 2013 – April 22, 2013

Results:

	Validity criteria	Finding
Preimaginal mortality in water control	≤ 30%	30%
Preimaginal mortality reference item	≥ 40%	100%
Mean number of fertile eggs per female and day in water control	≥ 2	13.5

All validity criteria for the study were met.

Mortality and reproduction of *Coccinella septempunctata* after exposure to Propineb WG 70 % w/w

Test item:		Propineb WG 70 % w/w			
Test organism:		*Coccinella septempunctata*			
Exposure on:		Detached grape vine leaves			
		Preimaginal mortality [%]			Reproduction
Treatment	**g a.s./ha**	**Uncorr.**	**Corr.**	**P-Value (*)**	**Fertile eggs per female and day**
Control	0	30.0			13.5
Test item	590	35.0	7.1	1.000 n.sign.	12.5
Test item	1039	30.0	0.0	1.000 n.sign.	9.1
Test item	1829	30.0	0.0	1.000 n.sign.	11.4
Test item	3220	37.5	10.7	1.000 n.sign.	13.9
Test item	5670	32.5	3.6	1.000 n.sign.	13.0
Reference item	21	100.0	100.0		n.a.

LR_{50}: > 5670 g a.s./ha;
* Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm
n.a. not assessed
n.sign. not significant

Low control mortality and high reproductive performance in the control treatment indicated that test animals were in good condition. Mortality in the toxic reference, showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test item residues could be detected with the set-up used in this experiment.

Preimaginal mortality:
In the control 29 larvae pupated of which 28 pupae developed successfully into adult beetles.

In the test item rates of 590 and 1039 g a.s./ha, 27 and 30 larvae pupated, respectively. From these pupae 26 and 28 developed into adults, respectively. At the rates of 1829, 3220 and 5670 g a.s./ha, 29, 28 and 31 larvae pupated, respectively. From these pupae 28, 25 and 27, respectively, hatched successfully. In the reference item no larvae survived.
At all test item rates no statistically significant different corrected preimaginal mortality compared to the control group was found.
In the lowest rate of 590 g a.s./ha, the corrected mortality was 7.1%. At the rates of 1039 and 1829 g a.s./ha, no corrected mortality occurred. At the highest rates of 3220 and 5670 g a.s./ha, a corrected mortality of 10.7% and 3.6%, respectively, was detected.

Reproduction:
The mean number of fertile eggs per female and day for the control during the test period was 13.5.
The mean number of fertile eggs per female and day for the 590 g a.s./ha rate was 12.5. For the rates of 1039 and 1829 g a.s./ha, the mean number of fertile eggs per female and day was 9.1 and 11.4, respectively. For the highest rates of 3220 and 5670 g a.s./ha, the mean number of fertile eggs per female and day was 13.9 and 13.0, respectively. Reproduction is considered as not affected at all test item rates.

Conclusion:
The LR_{50} was estimated to be > 5670 g a.s./ha.

CP 10.3.2.3 Semi-field studies with non-target arthropods

In view of the results presented above, no semi-field studies were deemed necessary.

CP 10.3.2.4 Field studies with non-target arthropods

In view of the results presented above, no additional field studies were deemed necessary.

CP 10.3.2.5 Other routes of exposure for non-target arthropods

No relevant exposure of non-target arthropods is expected by other routes of exposure.

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the Council Directive 91/414/EEC (Annex III), Council Directive 97/57/EC (Annex VI) and the Guidance Document on Terrestrial Ecotoxicology.

Exposure in greenhouses

Cultivation of vegetables or fruits in greenhouses is mostly conducted in natural soils or soil substrates. In both cases, only a semi-natural soil community with low species variety and stimulation of opportunistic, ubiquitous species is to be expected due to the highly artificial environment with respect to microclimate, pest management (e.g. sterilisation or fumigation of soil) and high input of soil fertilisers. Since these species have no ecologically or economically important function (soil fumigation) it is not deemed necessary to conduct a risk assessment for the time during cultivation in the greenhouse as it is required for wildlife associated with outdoor agriculture.

Despite above mentioned restrictions, TER calculations were performed for the greenhouse use on tomatoes in order to highlight the hazard potential for earthworms and other soil non-target macro-organisms. In this tier 1 approach, ecotoxicological endpoints were related to maximum PEC_{soil} values calculated for greenhouse soils.

Predicted environmental concentrations used in risk assessment

The PEC_{soil} values below are taken from MCP Sec.9, Point 9.1.3.

Table 10.4- 1: Initial max PEC_{soil} values (bold values were used in the tier 1 risk assessment)

Compound	Orchards	Grapes [a]	Tomato [b]
	$PEC_{soil, max}$ [mg/kg]	$PEC_{soil, max}$ [mg/kg]	$PEC_{soil, max}$ [mg/kg]
Propineb WG 70 [c]	1.95 [d]	2.13 [e]	**4.80 [f]**
Propineb	0.852	1.064	**1.609**
PTU	0.099	0.116	**0.189**
PU	0.180	0.204	**0.407**
4-MI	0.037	0.041	**0.071**
Propineb-DIDT	0.125	0.127	**0.237**

bold values are worst-case
[a] worst-case use in grapes (1.4 kg a.s./ha at BBCH stages 40 - 59)
[b] greenhouse use only
[c] calculated for a soil depth of 5 cm, a soil density of 1.5 g/mL and the use pattern for
[d] apples: 2 × 2.25 kg product/ha and 65% + 70% interception
[e] vines: 2 × 2.0 kg product/ha, 60% interception for both applications
[f] tomatoes: 4 × 3.0 kg product/ha and 50% + 70% + 80%+ 80% interception

The tier 1 risk assessments are based on the worst case PEC_{soil} values for the application in tomatoes. Since the PEC_{soil} values for all other uses are distinctly lower than those for tomates the risk assessment for the uses in orchards and grapes are covered by the risk assessment for tomatoes.

CP 10.4.1 Earthworms

Table 10.4.1- 1: Endpoints used in risk assessment

Test item	Test species, test design	Ecotoxicological endpoint		Reference
Propineb WG 70	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**56 mg product/kg dws** **38.7 mg a.s./kg dws**	KCA 8.4.1/04 [redacted] (2014) EBLHN035 M-476355-01-1
PTU	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**178 mg pm/kg dws**	KCA 8.4.1/05 [redacted] (2014) EBLHN040 M-478183-01-1
PU	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥ 1000 mg pm/kg dws**	KCA 8.4.1/06 [redacted] (2000) MPE/RG 329 M-033580-01-1
4-MI	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**90 mg pm/kg dws**	KCA 8.4.1/07 [redacted] (2013) Kra/Rg-R-118/12 M-449101-01-1
Propineb-DIDT	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**32 mg pm/kg dws**	KCA 8.4.1/08 [redacted] (2014) EBLHN051 M-486083-01-1

dws = dry weight soil; a.s. = active substance; pm = pure metabolite
Bold values: endpoints used for risk assessment

Risk assessment for earthworms

Table 10.4.1- 2: TER calculations for earthworms

Compound	Species, study type	Endpoint [mg/kg]		worst case $PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
Propineb WG 70	Earthworm, reproduction	NOEC	56	4.80	11.7	5
Propineb (tech.)	Earthworm, reproduction	NOEC	39.1 [a]	1.609	24	5
PTU	Earthworm, reproduction	NOEC	178	0.189	942	5
PU	Earthworm, reproduction	NOEC	>1000	0.407	>2457	5
4-MI	Earthworm, reproduction	NOEC	90	0.071	1268	5
Propineb-DIDT	Earthworm, reproduction	NOEC	32	0.237	135	5

[a] The NOEC of PPB tech. given in mg a.s./kg soil was recalculated from the PPB WG 70 study

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 earthworms are to be expected from the intended uses of Propineb WG 70.

CP 10.4.1.1 Earthworms - sub-lethal effects

Studies are provided in KCA 8.4.2.1.

CP 10.4.1.2 Earthworms - field studies

In view of the results presented above, no field studies were necessary.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Table 10.4.2- 1: Endpoints used in risk assessment

Test item	Test species, test design	Ecotoxicological endpoint		Reference
Collembola, reproduction				
Propineb WG 70	*Folsomia candida* reproduction 28 d, mixed	NOEC	56 mg prod./kg dws **39.1 mg a.s./kg dws**	KCA 8.4.2.1/01 [redacted] (2011) EBLHL016 M-416315-01-1
PU	*Folsomia candida* reproduction 28 d, mixed	NOEC	**90 mg pm/kg dws**	KCA 8.4.2.1/03 [redacted] (2011) FRM-Coll-130/11 M-420414-01-1
PTU	*Folsomia candida* reproduction 28 d, mixed	NOEC	**9.0 mg pm/kg dws**	KCA 8.4.2.1/05 [redacted] (2014) FRM-Coll-169/14 M-484500-01-1
4-MI	*Folsomia candida* reproduction 28 d, mixed	NOEC	**≥100 mg pm/kg dws**	KCA 8.4.2.1/07 [redacted] (2013) FRM-Coll-168/13 M-473843-01-1
Propineb-DIDT	*Folsomia candida* reproduction 28 d, mixed	NOEC	**≥100 mg pm/kg dws**	KCA 8.4.2.1/09 [redacted] (2014) 14 10 48 093 S M-481886-01-1
Soil mites, reproduction				
Propineb WG 70	*Hypoaspis aculeifer* reproduction 14 d, mixed	NOEC	56 mg prod./kg dws **39.1 mg a.s./kg dws**	KCA 8.4.2.1/02 [redacted] (2011) EBLHL017 M-421441-01-1
PTU	*Hypoaspis aculeifer* reproduction 14 d, mixed	NOEC	**≥100 mg pm/kg dws**	KCA 8.4.2.1/04 [redacted] (2014) 14 10 48 096 S M-484793-01-1
PU	*Hypoaspis aculeifer* reproduction 14 d, mixed	NOEC	**≥100 mg pm/kg dws**	KCA 8.4.2.1/06 [redacted] (2011) kra-HR-56/11 M-415889-01-1
4-MI	*Hypoaspis aculeifer* reproduction 14 d, mixed	NOEC	**≥100 mg pm/kg dws**	KCA 8.4.2.1/08 [redacted] 2014) EBLHN054 M-487109-01-1
Propineb-DIDT	*Hypoaspis aculeifer* reproduction 14 d, mixed	NOEC	**32 mg pm/kg dws**	KCA 8.4.2.1/10 [redacted] (2014) EBLHN049 M-487493-01-1

dws = dry weight soil; a.s. = active substance; pm = pure metabolite
Bold values: endpoints used for risk assessment

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Table 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
Propineb WG 70	*Folsomia candida*	NOEC	56	4.80[b]	11.7	5
	Hypoaspis aculeifer	NOEC	56		11.7	
Propineb tech.	*Folsomia candida*	NOEC	39.1 [a]	1.609	24.3	
	Hypoaspis aculeifer	NOEC	39.1 [a]		24.3	
PTU	*Folsomia candida*	NOEC	9.0	0.189	47.6	
	Hypoaspis aculeifer	NOEC	≥ 100		≥ 529	
PU	*Folsomia candida*	NOEC	90	0.407	221	
	Hypoaspis aculeifer	NOEC	≥ 100		≥ 246	
4-MI	*Folsomia candida*	NOEC	≥ 100	0.071	≥ 1408	
	Hypoaspis aculeifer	NOEC	≥ 100		≥ 1408	
Propineb-DIDT	*Folsomia candida*	NOEC	≥ 100	0.237	≥ 422	
	Hypoaspis aculeifer	NOEC	32		135	

[a] The NOEC of PPB tech. given in mg a.s./kg soil was recalculated from the PPB WG 70 study
[b] worst-case use in grapes (1.4 kg a.s./ha at BBCH stages 40 - 59)

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 Propineb WG 70.

CP 10.4.2.1 Species level testing

Studies are provided in KCA 8.4.2.1.

CP 10.4.2.2 Higher tier testing

In view of the results presented above, no further testing is necessary.

CP 10.5 Effects on soil nitrogen transformation

Table 10.5- 1: Endpoints used in risk assessment

Test item	Test design	Endpoint		Reference
N-transformation				
Propineb WG 70A W	Study duration 70 d	no unacceptable effects	≥30 kg prod./ha **≥40 mg prod./kg dws**	KCA 8.5 /05 [redacted] (2012) M-422074-01-1
PTU	Study duration 28 d	no unacceptable effects	≥ 8.48 kg /ha **≥11.31 mg/kg dws**	KCA 8.5 /06 [redacted] (2014) M-4802253-01-1
PU	Study duration 56 d	no unacceptable effects	≥7.26 kg/ha **≥9.68 mg/kg dws**	KCA 8.5 /07 [redacted] (2013) M-472711-01-1
4-MI	Study duration 28 d	no unacceptable effects	≥6.1 kg/ha **≥8.13 mg/kg dws**	KCA 8.5 /08 [redacted] (2013) M-472708-01-1
Propineb-DIDT	Study duration 42 d	no unacceptable effects	≥13.87 kg/ha **≥18.49 mg/kg dws**	KCA 8.5 /09 [redacted] (2014) M-485360-01-1

Bold values are used in the risk assessment

Studies are provided in KCA 8.5.

Risk assessment for Soil Nitrogen Transformation

Table 10.5- 2: Risk Assessment for soil micro-organisms

Compound	Species	Endpoint [mg/kg]	$PEC_{soil,max}$ [mg/kg]	Refinement required
Propineb WG 70	Soil micro-organisms	40	4.80	No
Propineb tech.	Soil micro-organisms	27.9 [a]	1.609	No
PTU	Soil micro-organisms	11.31	0.189	No
PU	Soil micro-organisms	9.68	0.407	No
4-MI	Soil micro-organisms	8.13	0.071	No
Propineb-DIDT	Soil micro-organisms	18.49	0.237	No

[a] The endpoint of this PPB WG 70 study is given in mg a.s./kg soil

According to regulatory requirements the risk is acceptable, if the effect on nitrogen transformation at the maximum PEC_{soil} values is < 25% after 100 days. In no case, deviations from the control exceeded 25% after 28 up to 70 days, indicating low risk to soil micro-organisms.

CP 10.6 Effects on terrestrial non-target higher plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 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.

Risk assessment for Terrestrial Non-Target Higher Plants

Tier 1 limit tests have been conducted with the formulation Propineb WG 70.

Table 10.6- 1: Endpoints used in risk assessment

Test organism	Study type	Max. effects	Most sensitive species	References
Maximum application rate: 4.62 kg a.s./ha				
Terrestrial non-target plants; 10 species	Seedling emergence; Tier 1 single dose 14 days	14.0% reduction of shoot dry weight	sorghum	KCP 10.6.2 /01 [redacted] (2011) Rep. No.: SE 11/035 M-412289-01-1
Terrestrial non-target plants; 10 species	Vegetative vigour; Tier 1 single dose 21 days	22.7% reduction of shoot dry weight	onion	KCP 10.6.2 /03 [redacted] (2011) Rep. No.: VV 11/034 M-412277-01-1
Maximum application rate: 1.75 kg a.s./ha				
Terrestrial non-target plants; 6 species	Seedling emergence; Tier 1 single dose 21 days	22% reduction of shoot dry weight	cucumber	KCP 10.6.2 /02 [redacted] (2004) Rep. No.: VV03/29 M-105257-01-1
Terrestrial non-target plants; 6 species	Vegetative vigour; Tier 1 single dose 21 days	31% inhibition of germination	sunflower	KCP 10.6.2 /[redacted] (2004) Rep. No.: SE 03/29 M-105248-01-1

In the case of Propineb WG 70, neither the tier 1 seedling emergence nor the vegetative vigour studies showed phytotoxic effects ≥50% at the tested rates of 1.75 and 4.62 kg a.s./ha, respectively.

To demonstrate the low risk of the formulation to terrestrial non-target plants, TER calculations have been performed for the representative uses given in Table 10-1 (excl. tomato greenhouse use). The test rate of 4.62 kg a.s./ha was used as a most conservative endpoint estimate (i.e., ER_{50} > 4.62 kg a.s./ha).

Table 10.6- 2: Deterministic risk assessment based on the ER_{50} > 4.62 kg a.s./ha

Crop	Use pattern	Distance from field edge [m]	Drift [%]	PER [kg a.s./ha]	TER (Trigger = 5)
Orchards (late)	2 × 1.575 kg a.s./ha (14 d interval)	3	12.13 [1)]	0.27 [2)]	> 17.1
Grapes (late)	2 × 1.4 kg a.s./ha (10 d interval)	3	7.23 [3)]	0.15 [4)]	> 30.8

[1)] Basic drift value for two applications in orchards late
[2)] Considering MAF = 1.4 from EFSA GD Birds & Mammals (2009)
[3)] Basic drift value for two applications in grapes late
[4)] Considering MAF = 1.5 from EFSA GD Birds & Mammals (2009)

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

Not necessary as guideline studies for terrestrial non-target plants are available.

CP 10.6.2 Testing on non-target plants

Report:	[redacted]us[redacted];2011;M-412289-01
Title:	Propineb WG 70A W - Effects on the seedling emergence and growth of ten species of non-target terrestrial plants (Tier 1)
Report No:	SE 11/035
Document No:	M-412289-01-1
Guidelines:	**OECD Guideline for the testing of Chemicals, Terrestrial Plant Test OECD 208: Seedling emergence and seedling growth Test, July 2006**
GLP/GEP:	**no**

Objective:

The purpose of this specific study was to evaluate potential phytotoxic effects of Propineb WG 70A W on the seedling emergence and growth of ten non-target terrestrial plant species following a pre-emergence application of 4.62 kg a.s./ha onto the soil surface.

Materials and Methods:

Test item: Propineb WG 70A W (purity 69.5 %; specification No.: 102000006516-02; Batch ID: EM20004026).

Ten species of terrestrial non-target plants (4 monocots and 6 dicots) were treated with 4.62 kg a.s./ha. The species tested were *Beta vulgaris* (Sugar beet), *Brassica napus* (Oilseed rape), *Cucumis sativus* (Cucumber), *Glycine max* (Soybean), *Helianthus annuus* (Sunflower), *Lycopersicon esculentum* (Tomato), *Allium cepa* (Onion), *Lolium perenne* (Ryegrass), *Sorghum sudanense* (Sorghum) and *Zea mays* (Corn). The seeds were introduced manually into the soil. The test continued for 14 days following the emergence of 70% of the control seedlings which occurred 4 to 10 days after sowing.

The soil surface of the pots were treated with 4.62 kg a.s./ha Propineb WG 70A W using a laboratory track sprayer and a water volume rate of 200 L/ha. Each pot (replicate) contained 5 seeds and there were 20 seeds treated i.e. 4 replicates. Control pots were treated with deionised water. 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 water treated controls. The parameters measured were emergence, survival of the emerged seedlings, visual phytotoxicity, plant growth stage and shoot dry weight.

Pots were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8ºC during day and 18 ± 8ºC at night with a 16 h photoperiod.

Dates of experimental work: May 10 to June 01, 2011

Results:

In general this study revealed a very low level of phytotoxicity as a result of a soil application of 4.62 kg a.s. Propineb WG 70A W/ha.

Emergence was not affected in *Brassica napus* (Oilseed rape), *Cucumis sativus* (Cucumber), and *Zea mays* (Corn). Emergence was increased in *Glycine max* (Soybean), *Helianthus annuus* (Sunflower), *Lycopersicon esculentum* (Tomato), *Allium cepa* (Onion), *Lolium perenne* (Ryegrass), and *Sorghum sudanense* (Sorghum) by 5.3, 11.1, 5.3, 5.6, 20.0 and 11.1%, respectively. Emergence was reduced in *Beta vulgaris* (Sugar beet) by 11.1%.

Survival was not affected in nine of the tested species. Survival was reduced in *Allium cepa* (Onion) by 5.3%.

There were no observed phytotoxic symptoms in any of the tested plant species.

Shoot dry weight was increased in *Beta vulgaris* (Sugar beet), *Brassica napus* (Oilseed rape), *Cucumis sativus* (Cucumber), *Allium cepa* (Onion), *Lolium perenne* (Ryegrass) and *Zea mays* (Corn) by 6.7, 0.2, 4.4, 60.2, 24.6 and 8.2%, respectively.

Shoot dry weight was reduced in *Glycine max* (Soybean), *Helianthus annuus* (Sunflower), *Lycopersicon esculentum* (Tomato) and *Sorghum sudanense* (Sorghum) by 0.9, 1.0, 6.3 and 14.0%, respectively.

There were no statistically significant effects in any of the tested plant species.

The findings from a single application of 4.62 kg a.s./ha to the 10 plant species tested are summarised in the following table.

Summary of effects of Propineb WG 70A W at test termination in the seedling emergence and seedling growth Test (Tier 1)

	Seedling emergence and seedling growth Test			
Plant Species	Emergence (% inhibition)	Survival* (% inhibition)	Phytotoxicity **	Shoot Dry Weight*** (% inhibiton)
Beta vulgaris	11.1	0	0	-6.7
Brassica napus	0	0	0	-0.2
Cucumis sativus	0	0	0	-4.4
Glycine max	-5.5	0	0	0.9
Helianthus annuus	-11.1	0	0	1.0
Lycopersicon esculentum	-5.3	0	0	6.3
Allium cepa	-5.6	5.3	0	-60.2
Lolium perenne	-20.0	0	0	-24.6
Sorghum sudanense	-11.1	0	0	14.0
Zea mays	0	0	0	-8.2

* survival is a measure of treated plants that survived at the end of the study and is expressed as an inhibition compared to the untreated control
** see materials and methods for a desription of the phytotoxicity rating
*** inhibition or reduction is expressed on a per plant basis
- negative values indicate that there was an increase when compared to the untreated control
Bold figures for shoot dry weight are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller; $p \leq 0.05$).

Conclusion:

Following a soil surface application of Propineb WG 70A W at 4.62 kg a.s./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 seedling growth study.

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Report:	[redacted];[redacted];[redacted];2004;M-105248-01
Title:	Non-target terrestrial plants: An evaluation of the effects of Propineb WG 70 in the seedling emergence and growth test (Tier 1)
Report No:	SE03/29
Document No:	M-105248-01-1
Guidelines:	**OECD 208 A (July 2000, draft): seedling emergence and growth test (Tier 1);no major deviation**
GLP/GEP:	**no**

Objective:

The purpose of the study was to evaluate the phytotoxic effects of Propineb WG 70 on six species representing non-target terrestrial plant species during the seedling emergence and growth following a pre-emergence application of the product.

Materials and Methods:

Test item: Propineb WG 70 (Product: Antracol WG70; active ingredient: LH 30/Z; purity 71.2 %; Batch No.: PF 90042868; content 71.2%)

Six species of terrestrial non-target plants (2 monocots and 4 dicots) were treated with the highest nominal product application rate for Propineb WG 70 of 1.75 kg a.s./ha. The species tested were oilseed rape (*Brassica napus*), sunflower (*Helianthus annuus*), sugar beet (*Beta vulgaris*), cucumber (*Cucumis sativus*), oats (*Avena sativa*), and corn (*Zea mays*). The seeds were introduced manually into the soil. All seeds were planted on the day of application and test duration was 21 days after 50% emergence of the seedlings in the controls for each species.

The application of the spray solution was done by spraying two times 200 L/ha to reach the target amount of 400 L/ha. Control pots were sprayed with deionized water. Four replicates with five seeds per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse. Plants were assessed for emergence, survival and rated for phytotoxicity on days 7, 14 and 21. At study termination, biomass endpoint determinations were performed for plant dry weights. The plants of one pot represent one replicate.

Pots were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 5°C during day and 18 ± 5°C at night with a 16 h photoperiod.

Dates of experimental work: October 22 to November 19, 2003

Results:

The effects of Propineb WG 70A W applied at a rate of 1.75 kg a.s./ha on the six species tested are summarized in the table below.

Summary of effects of Propineb WG 70A W at test termination in the seedling emergence and growth test

Seedling emergence and growth test				
Plant Species	Germination (% inhibition)	Mortality* (% of control)	Phytotoxicity (% of control)	Dry Weight** (% growth inhibiton)
Oil seed rape	-20	+6	0	+43
Sunflower	-31	0	0	-27
Sugar beet	-5	0	0	-4
Cucumber	-17	0	0	+14
Oats	+5	0	0	-7
Corn	+5	0	0	+2

"+" means an increase of the evaluated endpoint compared to control
"-" means a decrease of the evaluated endpoint compared to control
* Mortality is a measure of the number of those plants that germinated but failed to survive and effect of the treatment is presented as a percentage of the survival in the control.
** on a per plant basis

Conclusion:

The highest nominal product application rate of 1.75 kg a.s./ha for Propineb WG 70 showed no significant adverse effect (i.e. greater than 50%) to representative non-target crops in the seedling emergence and growth test.

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Report:	[redacted]1;[redacted];2011;M-412277-01
Title:	Propineb WG 70A W - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 1)
Report No:	VV 11/034
Document No:	M-412277-01-1
Guidelines:	**OECD 227 (July 2006): Guideline for the testing of chemicals, Terrestrial Plant Test: Vegetative vigour test; Deviation not specified**
GLP/GEP:	**no**

Objective:

The purpose of this specific study was to evaluate potential phytotoxic effects of Propineb WG 70A W on the vegetative vigour of ten non-target terrestrial plant species following a postemergence application of 4.62 kg a.s.//ha onto the foliage of plants at the 2-4 leaf stage.

Materials and Methods:

Test item: Propineb WG 70A W (purity 69.5 %; specification No.: 102000006516-02; Batch ID: EM20004026)

Ten species of terrestrial non-target plants (4 monocots and 6 dicots) were treated with 4.62 kg a.s./ha. The species tested were *Beta vulgaris* (Sugar beet), *Brassica napus* (Oilseed rape), *Cucumis sativus* (Cucumber), *Glycine max* (Soybean), *Helianthus annuus* (Sunflower), *Lycopersicon esculentum* (Tomato), *Allium cepa* (Onion), *Lolium perenne* (Ryegrass), *Sorghum sudanense* (Sorghum) and *Zea mays* (Corn). The seeds were introduced manually into the soil. To reach the 2 to 4 leaf stage for application, sowing was started prior to testing. At application the species had to be in 2 to 4 leaf stage and test duration was 21 days following application of the test substance.

At the 2-4 leaf stage plants were treated with 4.62 kg a.s./ha Propineb WG 70A W using a laboratory track sprayer and a water volume rate of 200 L/ha. Each pot (replicate) contained 4 plants and there were 20 plants treated i.e. 5 replicates. Control pots were sprayed with deionized water.

Survival and visual phytotoxicity were recorded 7, 14 and 21 days after application and assessments were made against the water treated controls. The study was terminated 21 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight.

Pots were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8ºC during day and 18 ± 8ºC at night with a 16 h photoperiod.

Dates of experimental work: May 10 to May 31, 2011

Results:

In general this study revealed a very low level of phytotoxicity as a result of a foliar application of 4.62 kg a.s. Propineb WG 70A W/ha.

There were no effects on survival at any of the tested species.

Slight phytotoxic symptoms were observed as chlorosis, necrosis or stunting in *Glycine max* (Soybean) and *Allium cepa* (Onion) only in a single pot in the two plant species. Shoot dry weight was increased in *Beta vulgaris* (Sugar beet), *Glycine max* (Soybean), *Helianthus annus* (Sunflower), *Lolium perenne* (Ryegrass) and *Sorghum sudanense* (Sorghum) by 16.9, 19.7, 10.4, 16.6 and 71.1%,

respectively. Shoot dry weight was reduced in *Brassica napus* (Oilseed rape), *Cucumis sativus* (Cucumber), *Lycopersicon esculentum* (Tomato), *Allium cepa* (Onion) and *Zea mays* (Corn) by 3.9, 10.6, 8.3, 22.7 and 6.7%, respectively.
There were no statistically significant effects in any of the tested plant species.

The findings from a single application of 4.62 kg a.s./ha to the 10 plant species tested are summarised in the following table.

Summary of effects of Propineb WG 70A W at test termination in the vegetative vigour test (Tier I)

Vegetative vigour test			
Plant Species	Survival* (% inhibition)	Phytotoxicity**	Shoot Dry Weight*** (% inhibiton)
Beta vulgaris	0	0	-16.9
Brassica napus	0	0	3.9
Cucumis sativus	0	0	10.6
Glycine max	0	0-A[ab]	-19.7
Helianthus annuus	0	0	-10.4
Lycopersicon esculentum	0	0	8.3
Allium cepa	0	0-A[af]	22.7
Lolium perenne	0	0	-16.6
Sorghum sudanense	0	0	-71.1
Zea mays	0	0	6.7

* survival is a measure of treated plants that survived at the end of the study and is expressed as an inhibition compared to the untreated control
** see materials and methods for a desription of the phytotoxicity rating
*** inhibition or reduction is expressed on a per plant basis
\- negative values indicate that there was an increase when compared to the untreated control
Bold figures for shoot dry weight are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller; $p \leq 0.05$).

Conclusion:

Following a foliar application of Propineb WG 70A W at 4.62 kg a.s./ha to ten non-target terrestrial plant species at the 2 to 4 leaf stage, no adverse effects on survival, visual phytotoxicity, growth and shoot dry weight reaching or exceeding the 50% effect level were observed in this vegetative vigour study.

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Report:	[redacted]8;[redacted];[redacted];2004;M-105257-01
Title:	Non-target terrestrial plants: An evaluation of the effects of Propineb WG 70 in the vegetative vigour test (Tier 1)
Report No:	VV03/29
Document No:	M-105257-01-1
Guidelines:	**OECD 208 B (July 1.750, draft): vegetative vigour test (Tier 1); no major deviation**
GLP/GEP:	**no**

Objective:

The purpose of the study was to evaluate the phytotoxic effects of Propineb WG 70 on six species representing non-target terrestrial plant species during vegetative vigour test following a post emergence application of the product onto the foliage of plants at the 2 to 4 -leaf growth stage.

Materials and Methods:

Test item: Propineb WG 70 (Product: Antracol WG70; active ingredient: LH 30/Z; purity 71.2 %; Batch No.: PF 90042868; content 71.2%)

Six species of terrestrial non-target plants (2 monocots and 4 dicots) were treated with the highest nominal product application rate for Propineb WG 70 of 1.75 kg a.s./ha. The species tested were oil seed rape (*Brassica napus*), lettuce (*Lactuca sativa*), soybean (*Glycine max*), cucumber (*Cucumis sativus*), corn (*Zea mays*) and oats (*Avena sativa*). Plants were treated at the 2-4-leaf stage with foliar spray application.

Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of 400 litres/ha. Control pots were sprayed with deionized water. Four replicates with five seeds per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse. Plants were assessed for mortality and phytotoxicity on days 7, 14 and 21. At study termination, endpoint determinations were performed for plant dry weights. The plants of one pot represent one replicate.

Pots were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 5ºC during day and 18 ± 5ºC at night with a 16 h photoperiod.

Dates of experimental work: October 29 to November 19, 2003

Results:

The effects of Propineb WG 70A W applied at a rate of 1.75 kg a.s./ha on the six species tested are summarized in the table below.

Summary of effects of Propineb WG 70A W at test termination in the vegetative vigour test (Tier 1)

Vegetative vigour test			
Plant Species	Mortality* (% of control)	Phytotoxicity (% of control)	Dry Weight** (% growth inhibiton)
Oil seed rape	0	0	+12
Lettuce	0	0	+7
Soybean	0	0	-2
Cucumber	0	0	-22
Oats	0	0	+8
Corn	0	0	+1

"+" means an increase of the evaluated endpoint compared to control
"-" means a decrease of the evaluated endpoint compared to control
* Mortality is a measure of the number of those plants that germinated but failed to survive and effect of the treatment is presented as a percentage of the survival in the control.
** on a per plant basis

Conclusion:

The highest nominal product application rate of 1.75 kg a.s./ha for Propineb WG 70 showed no significant adverse effect (i.e. greater than 50%) to representative non-target crops in the vegetative vigour test.

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 10.6.2.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

No studies are required based on current data requirements.

CP 10.8 Monitoring data

No monitoring data are available and are not triggered by current data requirements.