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Document Title

Summary of the ecotoxicological studies Trifloxystrobin WG 50

Data Requirements

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

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

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[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/ha]	Maximum application rate, individual treatment (ranges) [g a.s./ha] trifloxystrobin
Apple/Pear/ Quince (early)	BBCH 31 - 89	3	10	0.15	75
Apple/Pear/ Quince (late)	BBCH 55 - 87	3	10	0.225	112,5
Strawberries	BBCH 55 - 89	2	7	0.30	150
Strawberries	BBCH 10 - 92	2	7	0.25	125
Grapes	BBCH 12 -89	3	10	0.25	125

Definition of the residue for risk assessment

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

Table10- 2: Definition of the residue for risk assessment

Compartment	Residue Definition
Soil	trifloxystrobin, CGA 357261, CGA 321113, CGA 373466, CGA 381318, NOA 413161, NOA 413163, CGA 357276, NOA 409480
Groundwater	same as soil
Surface water	same as soil plus CGA 357262, CGA 107170, 2-hydroxymethylbenzonitrile
Sediment	trifloxystrobin, CGA 321113
Air	trifloxystrobin, CGA 107170

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).

CP 10.1.1 Effects on birds

Table 10.1.1- 1: Endpoints used in risk assessment

Test substance	Exposure	Species	Endpoint		Reference
Trifloxystrobin	Acute risk assessment	Bobwhite quail	LD_{50}	>2000 mg a.s./kg bw	LoEP[1] M-032008-01-1 KCA 8.1.1.1/01
	Reproductive risk assessment	Bobwhite quail	NOEL	≥32 mg a.s./kg bw/d	LoEP [2] M-032013-01-1 KCA 8.1.1.3/01

Table 10.1.1- 2: Relevant indicator species for risk assessment on screening level acc. to EFSA GD (2009)

Crop	Indicator species	Shortcut value	
		Acute risk assessment	Reproductive risk assessment
Orchards	Small insectivorous bird	46.8	18.2
Strawberries	Small omnivorous bird	158.8	64.8
Grapes	Small omnivorous bird	95.3	38.9

[1] List of Endpoints: EU Review Report for trifloxystrobin (SANCO/4339/2000-Final)
[2] NOEC listed as 320 ppm, converted to 32 mg/kg bw/d with default conversion factor from EFSA GD 2009

ACUTE DIETARY RISK ASSESSMENT

Table 10.1.1- 3: Screening level acute risk assessment for birds

Crop	Indicator species	DDD			DDD	LD_{50} [mg a.s./kg bw]	TER_A	Trigger
		Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}				
Trifloxystrobin								
Orchards 3x 75 g/ha, 10d int. BBCH 31-89	Small insectivorous bird	0.075	46.8	1.47	5.16	> 2000	> 388	10
Orchards 3x 112.5 g/ha, 10d int. BBCH 55-87		0.1125	46.8	1.47	7.74		> 258	
Strawberries 2x 150 g/ha, 7d int. BBCH 55-89	Small omnivorous bird	0.150	158.8	1.38	32.9		> 61	
Strawberries 2x 125 g/ha, 7d int. BBCH 10-92		0.125	158.8	1.38	27.4		> 73	
Grapes 3x 125 g/ha, 10d int. BBCH 12-89	Small omnivorous bird	0.125	95.3	1.47	17.5		> 114	

The TER_A values calculated in the screening level acute risk assessment for birds 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.

Table 10.1.1- 4: Screening level reproductive risk assessment for birds

Crop	Indicator 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}				
Trifloxystrobin									
Orchards 3x 75 g/ha, 10d int. BBCH 31-89	Small insectivorous bird	0.075	18.2	1.75	0.53	1.27	≥ 32	≥ 25	5
Orchards 3x 112.5 g/ha, 10d int. BBCH 55-87		0.1125	18.2	1.75	0.53	2.07		≥ 17	
Strawberries 2x 150 g/ha, 7d int. BBCH 55-89	Small omnivorous bird	0.150	64.8	1.62	0.53	8.32		≥ 3.8	
Strawberries 2x 125 g/ha, 7d int. BBCH 10-92		0.125	64.8	1.62	0.53	6.94		≥ 4.6	
Grapes 3x 125 g/ha, 10d int. BBCH 12-89	Small omnivorous bird	0.125	38.9	1.50	0.53	3.87		≥ 8.3	

The TER_{LT} values calculated in the screening level reproductive risk assessment for birds exceed the a-priori-acceptability trigger of 5 for the scenarios in grapes and orchards. Thus, the reproductive risk to birds from the use in grapes and orchards can be considered as low and acceptable without need for further, more realistic risk assessment.

The TER_{LT} values calculated in the screening level reproductive risk assessment for birds do not reach the a-priori-acceptability trigger of 5 for the scenarios in strawberries.
Thus, the reproductive risk to birds from the use in strawberries has to be evaluated at the Tier 1 level based on the generic focal species scenarios.

Table 10.1.1- 5: Relevant generic avian focal species scenarios for Tier 1 risk assessment in strawberries

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_m
Strawberries 2x 150 g/ha BBCH 55-89 7d int.	BBCH ≥ 40	Small omnivorous bird "lark"	Woodlark	4.4
	BBCH 61-89	Frugivorous bird "starling"	Starling	13.4
	BBCH ≥ 20	Small insectivorous bird "wagtail"	Yellow wagtail	9.7
Strawberries 2x 125 g/ha BBCH 10-92 7d int.	BBCH 10-39	Small omnivorous bird "lark"	Woodlark	10.9
	BBCH 61-89	Frugivorous bird "starling"	Starling	13.4
	BBCH 10-19	Small insectivorous bird "wagtail"	Yellow wagtail	11.3

Table 10.1.1- 6: Tier 1 reproductive risk assessment for birds (use in strawberries)

Compound / 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}				
Trifloxystrobin									
Strawberries 2x 150 g/ha BBCH 55-89 7d int.	Small omnivorous bird "lark"	0.150	4.4	1.62	0.53	0.57	≥ 32	≥ 57	5
	Frugivorous bird "starling"		13.4			1.72		≥ 19	
	Small insectivorous bird "wagtail"		9.7			1.25		≥ 26	
Strawberries 2x 125 g/ha BBCH 10-92 7d int.	Small omnivorous bird "lark"	0.125	10.9	1.62	0.53	1.17	≥ 32	≥ 27	5
	Frugivorous bird "starling"		13.4			1.43		≥ 22	
	Small insectivorous bird "wagtail"		11.3			1.21		≥ 26	

The TER_{LT} values calculated in the Tier 1 reproductive risk assessment for birds exceed the a-priori-acceptability trigger of 5 for the scenarios in strawberries. Thus, the reproductive risk to birds from all uses in grapes, orchards and strawberries can be considered as low and acceptable without need for further, more realistic risk assessment.

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

In the EFSA GD (2009), section 5.5, step 1 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mammals:
- Leaf scenario: Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.
- Puddle scenario. Birds and mammals taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil.

For the crops under assessment in this evaluation (grapevine, pome fruit orchards, strawberries) the leaf scenario is not considered relevant. Risk for birds from drinking water in puddles is addressed in Table 10.1.1- 7

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

Table 10.1.1- 7: Evaluation of potential concern for exposure of birds 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
Trifloxystrobin						
Strawberries	2377	150 × 1.62	≥ 32	≤ 7.6	**≤ 3000**	No concern

RISK ASSESSMENT OF SECONDARY POISONING

Table 10.1.1- 8: Log P_{ow} values of trifloxystrobin and its metabolites [a)]

Substance	log P_{ow}	compartment	Reference
Trifloxystrobin	4.5	Soil, surface water	MCA, Section 2, point 2.7
CGA 357261	3.86 (pH 7)	Soil, surface water	
CGA 357262	5.39 (pH7)	Surface water	
CGA 357276	4.7	Soil, surface water	
NOA 409480	4.2	Soil, surface water	

[a)] only compounds with log P_{ow} > 3 mentioned

In the risk assessment for secondary poisoning, the NOAEL obtained for the parent trifloxystrobin is also used as surrogate endpoint for the metabolites under assessment (CGA 357261, CGA 357262, CGA 357276 and NOA 409480). This approach is considered appropriate since the available data suggest in fact lower toxicity of the metabolites than the parent [3]. Furthermore, there are additional margins of safety that can account for any remaining uncertainty.

[3] Comparative toxicity data in MCA 5.8.1 (mammals); and MCA 8.2 in Tab. 8.2.1-1 and -2 (fish); Tab. 8.2.4.1-1 and -2 (Daphnia); Tab. 8.2.8-1 and -2 (algae)

Table 10.1.1- 9: Avian generic focal species for the Tier 1 risk assessment of secondary poisoning

Generic avian indicator species	Body weight [g]	FIR [g]	FIR/bw
Earthworm eater	100	104.6	1.05
Fish eater	1000	159	0.159

Table 10.1.1- 10: BCF calculation for earthworms

parameter	Trifloxystrobin	CGA 357261	CGA 357276	NOA 409480
K_{OW}	32000	7244	50119	15849
K_{OC} [mL/g]	2377	487	8170	2356
f_{OC}	0.02	0.02	0.02	0.02
BCF_{worm}	$BCF_{worm} = (0.84 + 0.012\ K_{ow}) / f_{oc} * K_{oc}$			
	8.10	9.0	3.7	4.1

Long-term DDD and TER calculation for earthworm-eating birds

Table 10.1.1- 11: Tier 1 long-term DDD and TER calculation for earthworm-eating birds (Trifloxystrobin)

	Orchards	Grapes	Strawberries
Trifloxystrobin			
BCF_{worm}	8.10	8.10	8.10
PEC_{soil} (twa, 21 d) [mg/kg] [a]	0.005	0.007	0.012
PEC_{worm} [mg/kg]	0.04	0.06	0.10
FIR/bw	1.05	1.05	1.05
DDD [mg/kg bw/d]	0.04	0.06	0.10
NO(A)EL [mg/kg bw/d]	≥ 32	≥ 32	≥ 32
TER_{LT}	≥ 753	≥ 539	≥ 314
Trigger	5	5	5

[a] Worst-case PEC_{soil} twa 21 d value per crop, see chapter 9.1.3 of this document

Table 10.1.1- 12: Tier 1 long-term DDD and TER estimation for earthworm-eating birds (metabolites)

	CGA 357261	CGA 357276	NOA 409480
BCF_{worm}	9.0	3.7	4.1
PEC_{soil} (twa, 21 d)[mg/kg] [a)]	0.024	0.004	0.014
PEC_{worm} [mg/kg]	0.22	0.01	0.06
FIR/bw	1.05	1.05	1.05
DDD [mg/kg bw/d]	0.23	0.02	0.06
NO(A)EL [mg/kg bw/d] [b)]	≥ 32	≥ 32	≥ 32
TER_{LT}	≥ 141	≥ 2067	≥ 537
Trigger	5	5	5

[a)] worst-case PEC_{soil} twa 21 d value (use in strawberries 2x 75 g/ha) , see chapter 9.1.3 of this document
[b)] endpoint of parent used in estimation

Long-term DDD and TER calculation for fish-eating birds

Table 10.1.1- 13: Tier 1 long-term DDD and TER calculation for fish-eating birds

	Orchards	Grapes	Strawberries
Trifloxystrobin			
BCF_{fish}	431	431	431
PEC_{SW} (twa, 21 d)[mg/L] [a)]	0.00025	0.000142	0.0000586
PEC_{fish} [mg/kg]	0.108	0.061	0.025
FIR/bw	0.159	0.159	0.159
DDD [mg/kg bw/d]	0.02	0.01	0.004
NO(A)EL [mg/kg bw/d]	≥ 32	≥ 32	≥ 32
TER_{LT}	≥1866	≥3103	≥7969
Trigger	5	5	5

[a)] Worst-case PEC_{sw} twa 21 d value, see chapter 9.2.5 of this document

No specific secondary poisoning risk assessment is performed for the metabolites under assessment (CGA 357261, CGA 357262, CGA 357276 and NOA 409480). This approach is considered appropriate since the available data suggest lower toxicity of the metabolites than the parent. The large additional margins of safety in the calculation on the parent can account for any remaining uncertainty.

CP 10.1.1.1 Acute oral toxicity

No new studies were required.

CP 10.1.1.2 Higher tier data on birds

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

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Table 10.1.2- 1: Endpoints used in risk assessment

Test substance	Exposure	Species/Origin	Endpoint		Reference
Trifloxystrobin	Acute risk assessment	Rat	LD_{50}	>5000 mg a.s./kg bw	LoEP M-039034-01-1 KCA 5.2.1/01
	Long-term risk assessment	EFSA GD Screening level	ADI NOAEL	9.8 mg a.s./kg bw/d	LoEP
		EFSA GD Tier 1 level	NOAEL 2-gen repro	2.3 mg a.s./kg bw/d	LoEP
		EFSA GD Tier 2 level	BMD_5 pup weight	38.3 mg a.s./kg bw/d	KCA 8.1.2.2 /01

Table 10.1.2- 2: Relevant indicator species for risk assessment on screening level acc. to EFSA GD (2009)

Crop	Indicator species	Shortcut value	
		Acute risk assessment	Reproductive risk assessment
Orchards	Small herbivorous mammal	136.4	72.3
Strawberries	Small herbivorous mammal	118.4	48.3
Grapes	Small herbivorous mammal	136.4	72.3

ACUTE DIETARY RISK ASSESSMENT

Table 10.1.2- 3: Screening level acute risk assessment for wild mammals

Crop	Indicator species	DDD			DDD	LD_{50} [mg a.s./kg bw]	TER_A	Trigger
		Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}				
Trifloxystrobin								
Orchards 3x 75 g/ha, 10d int. BBCH 31-89	Small herbivorous mammal	0.075	136.4	1.47	15.0	>5000	> 322	10
Orchards 3x 112.5 g/ha, 10d int. BBCH 55-87		0.1125	136.4	1.47	22.6		> 222	
Strawberries 2x 150 g/ha, 7d int. BBCH 55-89		0.150	118.4	1.57	24.5		> 204	
Strawberries 2x 125 g/ha, 7d int. BBCH 10-92		0.125	118.4	1.38	20.4		> 245	
Grapes 3x 125 g/ha, 10d int. BBCH 12-89		0.125	136.4	1.47	25.1		> 199	

The TER_A values calculated in the screening level acute risk assessment 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

The reproductive risk assessment for wild mammals in the frame of the Annex 1 Renewal of trifloxystrobin is conducted according to the stepwise approach recommended in the EFSA GD (2009).

This stepwise approach includes a stepwise identification/selection of the endpoint to be used at the different stages of the reproductive risk assessment (screening level – Tier 1 – higher Tier), which are recommended in the EFSA GD (2009), of the wild mammal reproductive risk assessment.

Simple reference to the list of endpoints established for the Annex I listing of trifloxystrobin (SANCO/4339/2000-Final, 2003) is not considered appropriate, since this list contains two entries ("*2-gen. repro NOEC > 1500 ppm*" and "*short-term oral toxicity to mammals 90-day rat: 100 ppm (6.4 mg/kg bw/day*"), and because the rationale behind the inclusion of these two values cannot be unequivocally traced back in the relevant documents.

Therefore it is necessary to re-initiate the evaluation for the wild mammal reproductive risk assessment endpoint, starting with the tiered approach recommended in the EFSA GD (2009) for that purpose:

Tier 0 (screening level assessment)
"*The screening assessment may be useful to identify quickly those substances that pose very low reproductive risk, for which more detailed assessment is unnecessary*"

Step 1: "*determine if breeding mammals could be exposed ... if not, no further assessment is required*"
- ⇨ Applications are made in the field during spring and summer: assessment is required.

Step 2: "*if exposure is possible, then the same endpoint as in the human risk assessment shall be used (without the assessment factor applied in the human risk assessment)*"
- ⇨ In the current LoE: "*ADI = 0.1 mg/kg bw/d; 2-year rat study; safety factor 100)*"
- ⇨ NOAEL currently used in human risk assessment: 9.8 mg/kg bw/d

Step 3: "*identify the appropriate indicator species and short-cut value for the crop under assessment. ... Calculate the daily dietary dose (DDD) = application rate x shortcut value x TWA x MAFm*"
- ⇨ Table 10.1.2-4 with TER_{LT} calculated for representative uses according to Table 12 of the EFSA GD (2009), with MAF calculate according to App. H of EFSA GD (2009) and with the default 21-d f_{TWA} = 0.53.

Table 10.1.2- 4: Screening level reproductive risk assessment for wild mammals

Crop	Indicator 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}				
Trifloxystrobin									
Orchards 3x 75 g/ha, 10d int. BBCH 31-89	Small herbivorous mammal	0.075	72.3	1.75	0.53	5.03	9.8	1.9	5
Orchards 3x 112.5 g/ha, 10d int. BBCH 55-87		0.1125	72.3	1.75	0.53	7.54		1.3	
Strawberries 2x 150 g/ha, 7d int. BBCH 55-89		0.150	48.3	1.62	0.53	6.20		1.6	
Strawberries 2x 125 g/ha, 7d int. BBCH 10-92		0.125	48.3	1.62	0.53	5.17		1.9	
Grapes 3x 125 g/ha, 10d int. BBCH 12-89		0.125	72.3	1.75	0.53	8.38		1.2	

Step 4: "*calculate the toxicity exposure ratio and compare the TER to the respective trigger values*"
- ⇨ TER are below the trigger value of 5: "*go to Tier 1 (step 5)*"

The TER_{LT} values calculated in the screening level reproductive risk assessment for wild mammals do not reach the a-priori-acceptability trigger of 5 for the scenarios in orchards, strawberries or grapes. Thus, the reproductive risk to wild mammals from the uses in in orchards, strawberries and grapes has to be evaluated at the Tier 1 level based on the generic focal species scenarios and the guidance given for Tier 1 endpoint selection in the EFSA GD (2009).

Tier 1 risk assessment)

Step 5: "*identify the endpoint from the developmental study that is used in the human risk assessment. Check if the developmental study contained lower endpoints that were considered rodent specific, and if so take the lowest of these instead of the endpoint used for human risk assessment … Identify the lowest NOAEL from the 2-generation rat study. … Use the lowest of these endpoints and proceed to step 6.*
… The lowest endpoint is taken to avoid the need for detailed re-evaluation of the mammalian toxicity studies in Tier 1 of the ecotoxicological assessment. The relevance of the endpoints for wild mammals may be reconsidered as a refinement option (step 9)"

- ⇨ Lowest relevant reproductive NOAEL: 50 ppm (2.3 mg/kg bw/d) ("decreased bodyweight gain of pups and delayed eye opening at parental toxic doses")

Step 6: "*identify the appropriate crop and generic focal mammal species in the Appendix. … Where there are more than one generic focal species in terms of timing etc., Tier 1 risk assessments (and refined risk assessments, if necessary) should be carried out for all the relevant generic focal species.*"

- ⇨ All relevant generic focal species scenarios are included in Table 10.1.2- 5

Step 7: "*for each relevant generic focal species scenarios, calculate the daily dietary dose DDD = application rate x shortcut value x TWA x MAFm*"

- ⇨ Table 10.1.2- 6 with TER calculated for representative uses according to Table 12 of the EFSA GD (2009); MAF calculated according to App. H of EFSA GD (2009) and with the default 21-d f_{TWA} = 0.53.

Table 10.1.2- 5: Relevant generic wild mammal focal species scenarios for Tier 1 risk assessment

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_m
Orchard 3x 75 g/ha BBCH 31-89 10d int.	BBCH 20-40	Small herbivorous mammal "vole"	Common vole	43.4
	BBCH 20-40	Large herbivorous mammal "lagomorph"	Rabbit	8.6
	BBCH 20-40	Small omnivorous mammal "mouse"	Wood mouse	4.7
Orchard 3x 112.5 g/ha BBCH 55-87 10d int.	BBCH ≥ 40	Small herbivorous mammal "vole	Common vole	21.7
	BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Rabbit	4.3
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse	2.3
Strawberries 2x 150 g/ha BBCH 55-89 7d int.	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew	1.9
	BBCH ≥ 40	Small herbivorous mammal "vole	Common vole	28.9
	BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Rabbit	5.7
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse	3.1
Strawberries 2x 125 g/ha BBCH 10-92 7d int.	BBCH 10-19	Small insectivorous mammal "shrew"	Common shrew	4.2
	BBCH ≥ 40	Small herbivorous mammal "vole	Common vole	28.9
	BBCH 10-39	Large herbivorous mammal "lagomorph"	Rabbit	14.3
	BBCH 10-39	Small omnivorous mammal "mouse"	Wood mouse	7.8
Grapes 3x 125 g/ha BBCH 12-89 10d int.	BBCH 10-19	Large herbivorous mammal "lagomorph"	Brown hare	6.7
	BBCH 10-19	Small insectivorous mammal "shrew"	Common shrew	4.2
	BBCH 10-19	Small herbivorous mammal "vole	Common vole	43.4
	BBCH 10-19	Small omnivorous mammal "mouse"	Wood mouse	4.7

Step 8: "*for each relevant generic focal species, calculate the toxicity exposure ratio and compare the TER to the respective trigger values*"

⇨ If TER < 5: "*refined assessment required for this generic focal species - go to step 9*"

Table 10.1.2- 6: Tier 1 reproductive risk assessment for wild mammals

Compound / 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}				
Trifloxystrobin									
Orchard 3x 75 g/ha BBCH 31-89 10d int.	Small herbivorous mammal "vole	0.075	43.4	1.75	0.53	3.02	2.3	0.8	5
	Large herbivorous mammal "lagomorph"		8.6			0.60		3.8	
	Small omnivorous mammal "mouse"		4.7			0.33		7.0	
Orchard 3x 112.5 g/ha BBCH 55-87 10d int.	Small herbivorous mammal "vole	0.1125	21.7	1.75	0.53	2.26	2.3	1.0	5
	Large herbivorous mammal "lagomorph"		4.3			0.45		5.1	
	Small omnivorous mammal "mouse"		2.3			0.24		10	
Strawberries 2x 150 g/ha BBCH 55-89 7d int.	Small insectivorous mammal "shrew"	0.150	1.9	1.62	0.53	0.15	2.3	15.2	5
	Small herbivorous mammal "vole		28.9			3.71		0.6	
	Large herbivorous mammal "lagomorph"		5.7			0.73		3.1	
	Small omnivorous mammal "mouse"		3.1			0.40		5.8	
Strawberries 2x 125 g/ha BBCH 10-92 7d int.	Small insectivorous mammal "shrew"	0.125	4.2	1.62	0.53	0.45	2.3	5.1	5
	Small herbivorous mammal "vole		28.9			3.09		0.7	
	Large herbivorous mammal "lagomorph"		14.3			1.53		1.5	
	Small omnivorous mammal "mouse"		7.8			0.83		2.8	
Grapes 3x 125 g/ha BBCH 12-89 10d int.	Large herbivorous mammal "lagomorph"	0.125	6.7	1.75	0.53	0.78	2.3	3.0	5
	Small insectivorous mammal "shrew"		4.2			0.49		4.7	
	Small herbivorous mammal "vole		43.4			5.03		0.5	
	Small omnivorous mammal "mouse"		4.7			0.54		4.2	

The TER_{LT} values calculated in the Tier 1 level reproductive risk assessment for wild mammals do not all reach the a-priori-acceptability trigger of 5 for the generic focal scenarios in orchards, strawberries or grapes.

Thus, the reproductive risk to wild mammals from the uses in orchards, strawberries and grapes has to be evaluated in a refined risk assessment, according to the guidance given in step 9 of that section in the EFSA GD (2009).

Step 9: Refinement options

"*Refined assessments should be carried out for all generic focal species that have a TER < 5 at Step 8. Re-examination of the relevance of mammalian toxicity endpoints for wild mammals. - Evaluate the 2-generation (or if absent, extended 1-generation) rat study/studies in detail, and determine for each study (or merged dataset, where it is appropriate to merge studies, see section 2.4.3) the endpoints that are considered relevant for reproductive performance, as listed below:*

- *NOAEL for body weight change (included as an indicator of parental effects with potential to disrupt reproduction), behavioural effects and systemic toxicity;*
- *NOAEL for indices of gestation, litter size, pup and litter weight (any effects in foetal body weight should be evaluated in the context of all pertinent data including other developmental effects as well as maternal toxicity)*
- *NOAEL for indices of viability, pre- and post-implantation loss*
- *NOAEL for embryo/foetal toxicity including teratological effects*
- *NOAEL for number aborting and number delivering early*
- *NOAEL for systemic toxicity and effects on adult body weight*
- *NOAEL for indices of post-natal growth, indices of lactation and data on physical landmarks*
- *NOAEL for survival and general toxicity up to sexual maturity*

Effects on other endpoints are considered not relevant for reproductive performance and may be disregarded.

Note that slight delays, e.g. 1 day, in obtaining a particular endpoint or developmental milestone can be ignored. However, longer delays could be considered as adverse effect. This is based on the frequency of measuring and hence is a pragmatic approach. Note that a 1-d delay may be of importance for certain substances. It should be checked that this is not treatment related before discounting it. Further discussion of the ecological relevance of test endpoints for wild mammals may be found in Appendix J and EFSA (2006).

Examination of additional mammalian toxicity studies. – The Tier 1 assessment concentrates on endpoints from the 2-generation rat study and the developmental study. In refined assessments it is desirable also to examine other mammalian toxicity studies to check whether they contain lower NOAELs for relevant endpoints. The lowest relevant NOAEL should be used for assessment.

Re-assessment of the exposure period relevant to the toxicity endpoints. – The screening and Tier 1 assessments use time-weighted averages over 21 days, except where there is specific evidence that the effects could be caused by short-term exposures. The default periods of 21 days for long-term effects and 1 day for short-term effects are arbitrary choices without specific scientific justification. In refined assessments the evidence for the exposure period relevant to each endpoint should be reviewed in more detail, in consultation with a mammalian toxicologist. See Appendix J for more information."

Since there is a need for refinement highlighted in the Tier 1 risk assessment, the guidance given at step 9 for refined endpoint selection has been applied to the specific case of trifloxystrobin. The evaluation is provided in by Hartmann, Ebeling & Diesing (2013 MCA section CA 8.1.2.2/01), concluding with the proposal to employ the BMD_5 = 38.3 mg/kg bw/d as the reproductive risk assessment endpoint in the TER_{LT} calculation.

Table 10.1.2- 1: Refined reproductive risk assessment for wild mammals

Compound / Crop	Generic focal species	DDD Appl. rate [kg a.s./ha]	DDD SV_m	DDD MAF_m	DDD f_{twa}	DDD	NOAEL [mg a.s./kg bw/d]	TER_{LT}	Trigger
Trifloxystrobin									
Orchard 3x 75 g/ha BBCH 31-89 10d int.	Small herbivorous mammal "vole	0.075	43.4	1.75	0.53	3.02	38.3	12.7	5
	Large herbivorous mammal "lagomorph"		8.6			0.60		64.0	
	Small omnivorous mammal "mouse"		4.7			0.33		117.1	
Orchard 3x 112.5 g/ha BBCH 55-87 10d int.	Small herbivorous mammal "vole	0.1125	21.7	1.75	0.53	2.26	38.3	16.9	5
	Large herbivorous mammal "lagomorph"		4.3			0.45		85.4	
	Small omnivorous mammal "mouse"		2.3			0.24		159.6	
Strawberries 2x 150 g/ha BBCH 55-89 7d int.	Small insectivorous mammal "shrew"	0.150	1.9	1.62	0.53	0.15	38.3	253.6	5
	Small herbivorous mammal "vole		28.9			3.71		10.3	
	Large herbivorous mammal "lagomorph"		5.7			0.73		52.3	
	Small omnivorous mammal "mouse"		3.1			0.40		96.2	
Strawberries 2x 125 g/ha BBCH 10-92 7d int.	Small insectivorous mammal "shrew"	0.125	4.2	1.62	0.53	0.45	38.3	85.2	5
	Small herbivorous mammal "vole		28.9			3.09		12.4	
	Large herbivorous mammal "lagomorph"		14.3			1.53		25.0	
	Small omnivorous mammal "mouse"		7.8			0.83		45.9	
Grapes 3x 125 g/ha BBCH 12-89 10d int.	Large herbivorous mammal "lagomorph"	0.125	6.7	1.75	0.53	0.78	38.3	49.3	5
	Small insectivorous mammal "shrew"		4.2			0.49		78.7	
	Small herbivorous mammal "vole		43.4			5.03		7.6	
	Small omnivorous mammal "mouse"		4.7			0.54		70.3	

The refined TER_{LT} values exceed the a-priori acceptability trigger of 5 for long-term exposure. Accordingly, a safe use of the product in all relevant crops can be concluded.

Table 10.1.2- 2: Uncertainty analysis for the refined reproductive risk assessment for wild mammals

Source of uncertainty	Potential to make true risk lower	Explanation	Potential to make true risk higher	Explanation
Use of the BMD$_5$ for 21-d pup weight as reproduction toxicity endpoint	-	BMD$_5$ (= EC5%) for 21-d pup weight is a conservative benchmark selection for ecotoxicological assessments (usually ECx ≥ 10% are considered as acceptable NOAEL surrogates for ecotoxicological assessments).		
Remainder of the factors in the refined risk assessment: unchanged default Tier 1 values/approaches (therefore no difference to overall evaluation on conservatism in mammalian reproductive risk assessment as provided in the EFSA GD (2009), App. C, Tab. 8	- / + *"There are uncertainties in both directions. Because of the potential for wide variation in toxicity between species, some individuals in sensitive species may experience reproductive effects at TER>5, potentially breaching the surrogate protection goal. The assessment procedure is more likely to fulfil the actual protection goal of preventing long-term repercussions on abundance and diversity, due to variation in exposure between individuals and over space and time, and the potential for replacement through recovery and immigration"*			

Long-term risk assessment for mammals drinking contaminated water

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

Table 10.1.2- 3: 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
Trifloxystrobin						
Strawberries	2377	150 × 1.6	38.3	24.5	≤ 3000	No concern

RISK ASSESSMENT OF SECONDARY POISONING

The risk assessment of secondary poisoning for wild mammals is performed following the principles developed in the secondary poisoning risk assessment for birds. The NOAEL obtained for the parent trifloxystrobin is also used as surrogate endpoint for the metabolites under assessment (CGA 357261, CGA 357262, CGA 357276 and NOA 409480). This approach is considered appropriate since the available data suggest in fact lower toxicity of the metabolites than the parent. Furthermore, there are additional margins of safety that can account for any remaining uncertainty.

Table 10.1.2- 4: Mammalian generic focal species for the Tier 1 risk assessment of secondary poisoning

Generic focal species	Body weight [g]	FIR [g]	FIR/bw
Earthworm eater	10	12.8	1.28
Fish eater	3000	425	0.142

Long-term DDD and TER calculation for earthworm-eating mammals

Table 10.1.2- 5: Tier 1 long-term DDD and TER calculation for earthworm eating mammals (trifloxystrobin)

	Orchards	Grapes	Strawberries
Trifloxystrobin			
PEC_{worm} [mg/kg] a)	0.04	0.06	0.10
FIR/bw	1.28	1.28	1.28
DDD [mg a.s./kg bw/d]	0.05	0.07	0.12
NO(A)EL [mg a.s./kg bw/d]	38.3	38.3	38.3
TER_{LT}	739	528	308
Trigger	5	5	5

a) calculation of PEC_{worm} see Table 10.1.1- 11

Table 10.1.2- 6: Tier 1 long-term DDD and TER calculation for earthworm eating mammals (metabolites)

	CGA 357261	CGA 357276	NOA 409480
PEC_{worm} [mg/kg] a)	0.22	0.01	0.06
FIR/bw	1.28	1.28	1.28
DDD [mg/kg bw/d]	0.28	0.02	0.07
NO(A)EL [mg/kg bw/d] b)	38.3	38.3	38.3
TER_{LT}	138	2030	527
Trigger	5	5	5

a) calculation of PEC_{worm} see Table 10.1.1-12
b) endpoint of parent used in estimation

Long-term toxicity exposure ratio for fish-eating mammals

Table 10.1.2- 7: Tier 1 long-term DDD and TER calculation for fish eating mammals

	Orchards	Grapes	Strawberries
Trifloxystrobin			
PEC_{fish} [mg/kg] a)	0.108	0.061	0.025
FIR/bw	0.142	0.142	0.142
DDD [mg a.s./kg bw/d]	0.02	0.01	0.004
NO(A)EL [mg a.s./kg bw/d]	38.3	38.3	38.3
TER_{LT}	2500	4407	10679
Trigger	5	5	5

a) calculation of PEC_{fish} see Table 10.1.1-13

No specific secondary poisoning risk assessment is performed for the metabolites under assessment (CGA 357261, CGA 357262, CGA 357276 and NOA 409480). This approach is considered appropriate since the available data suggest lower toxicity of the metabolites than the parent. The large additional margins of safety in the calculation on the parent can account for any remaining uncertainty.

CP 10.1.2.1 Acute oral toxicity to mammals

No new studies were required.

CP 10.1.2.2 Higher tier data on mammals

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

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

Please refer to Point 8.2.8 of the MCA.

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.

Ecotoxicological endpoints used in risk assessment

Table 10.2- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Trifloxystrobin WG 50	Fish, acute , *Oncorhynchus mykiss*	LC_{50}	0.036 mg product/L	LoEP M-030572-01-1 KCP 10.2.1/06
	Fish, chronic *Oncorhynchus mykiss*	NOEC	3 x 0.0495 mg product/L (corresponding to 3 x 0.0253 mg a.s./L)	LoEP M-056670-01-1 KCP 10.2.3/02
	Invertebrate, acute *Daphnia magna*	EC_{50}	0.0103 mg product/L	LoEP M-051484-01-1 KCP 10.2.1/04
	Invertebrate, acute *Daphnia magna*	EC_{50}	0.017 mg product/L	LoEP M-048117-01-1 KCP 10.2.1/01
	Invertebrate, chronic *Daphnia magna*	NOEC	0.011 mg product/L	LoEP M-031771-01-1 KCP 10.2.3/03
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} E_rC_{50}	0.015 mg product/L 0.15 mg product/L	LoEP M-051263-01-1 KCP 10.2.1/03
Trifloxystrobin	Fish, acute *Oncorhynchus mykiss*	LC_{50}	0.015 mg a.s./L	LoEP M-032048-01-1 KCA 8.2.1/01
	Fish, chronic *Oncorhynchus mykiss*	NOEC	0.0077 mg a.s./L	LoEP M-032080-02-1 KCA 8.2.2.2/01
	Invertebrate, acute *Daphnia magna*	EC_{50}	0.016 mg a.s./L	LoEP M-032085-01-1 KCA 8.2.4.1/02
	Invertebrate, chronic *Daphnia magna*	NOEC	0.00276 mg a.s./L	LoEP M-032097-01-1 KCA 8.2.5.1/01
	Chironomid, chronic *Chironomus riparius*	NOEC	0.200 mg a.s./L	LoEP M-033988-01-1 KCA 8.2.5.3/01
	Algae, growth inhibition *Desmodesmus subspicatus*	E_bC_{50} E_rC_{50}	0.0053 mg a.s./L 0.016 mg a.s./L	LoEP M-032098-01-1 KCA 8.2.6.1/01
	Aquatic plants, growth *Lemna gibba*	$EC_{50\ (frond\ number)}$	> 1.93 mg a.s./L	LoEP M-032662-01-1 KCA 8.2.7/01
	Lentic freshwater community- mesocosm (WG 50)	NOEAEC **NOEC** LOEC	4 x 0.0120 mg a.s./L **4 x 0.0037 mg a.s./L** 4 x 0.0067 mg a.s./L	LoEP M-067201-01-1 KCA 8.2.8/09

Test substance	Test species	Endpoint		Reference
CGA 321113	Fish, acute *Oncorhynchus mykiss*	LC_{50}	> 106 mg p.m./L	LoEP M-032076-01-1 KCA 8.2.1/14
	Fish, chronic *Oncorhynchus mykiss*	NOEC	≥ 100 mg p.m./L	LoEP M-070819-01-1 KCA 8.2.2/01
	Invertebrate, acute *Daphnia magna*	EC_{50}	> 100 mg p.m./L	LoEP M-032091-01-1 KCA 8.2.4.1/05
	Invertebrate, chronic *Daphnia magna*	NOEC	3.2 mg p.m./L	LoEP M-056619-01-1 KCA 8.2.5.1/02
	Chironomid, chronic *Chironomus riparius*	NOEC	25 mg p.m./L	LoEP M-033991-01-1 KCA 8.2.5.3/02
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} E_rC_{50}	> 100 mg p.m./L > 100 mg p.m./L	LoEP M-032651-01-1 KCA 8.2.6.1/04
CGA 357262	Fish, acute *Oncorhynchus mykiss*	LC_{50}	>10.1 mg p.m./L	[redacted] (2012) EBTFL017 M-430569-01-1 KCA 8.2.1/22
	Invertebrate, acute *Daphnia magna*	EC_{50}	3.6 mg p.m./L	[redacted] (2012) EBTFL019 M-431690-01-1 KCA 8.2.4.1/16
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} E_rC_{50}	>2.65 mg p.m./L >2.65 mg p.m./L	[redacted] (2012) EBTFL018 M-429959-01-1 KCA 8.2.6.1/11
CGA 357261	Fish, acute *Oncorhynchus mykiss*	LC_{50}	0.9 mg p.m./L	LoEP M-032074-01-1 KCA 8.2.1/13
	Invertebrate, acute *Daphnia magna*	EC_{50}	1.4 mg p.m./L	LoEP M-032090-01-1 KCA 8.2.4.1/04
	Algae, growth inhibition *Desmodesmus subspicatus*	E_bC_{50} E_rC_{50}	1.4 mg p.m./L 2.0 mg p.m./L	LoEP M-032109-01-1 KCA 8.2.6.1/03
CGA 373466	Fish, acute *Oncorhynchus mykiss*	LC_{50}	≥ 200 mg p.m./L	LoEP M-032078-01-1 KCA 8.2.1/15
	Invertebrate, acute *Daphnia magna*	EC_{50}	>100 mg p.m./L	LoEP M-032092-01-1 KCA 8.2.4.1/06
	Algae, growth inhibition *Desmodesmus subspicatus*	E_bC_{50} E_rC_{50}	> 100 mg p.m./L > 100 mg p.m./L	LoEP M-032653-01-1 KCA 8.2.6.1/05
NOA 413161	Fish, acute *Oncorhynchus mykiss*	LC_{50}	> 100 mg p.m./L	LoEP M-033964-01-1 KCA 8.2.1/17
	Invertebrate, acute *Daphnia magna*	EC_{50}	> 100 mg p.m./L	LoEP M-033972-01-1 KCA 8.2.4.1/08

Test substance	Test species	Endpoint	Reference
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} > 100 mg p.m./L E_rC_{50} > 100 mg p.m./L	LoEP M-033979-01-1 KCA 8.2.6.1 /07
NOA 413163	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100 mg p.m./L	LoEP M-033967-01-1 KCA 8.2.1/18
	Invertebrate, acute *Daphnia magna*	EC_{50} > 100 mg p.m./L	LoEP M-033975-01-1 KCA 8.2.4.1/09
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} > 100 mg p.m./L E_rC_{50} > 100 mg p.m./L	LoEP M-033983-01-1 KCA 8.2.6.1/08
CGA 357276	Invertebrate, acute *Daphnia magna*	EC_{50} 514 mg p.m./L	Riebschläger (2012) EBTFX195 M-433856-01-1 KCA 8.2.4.1/17
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} > 5.88 mg p.m./L E_rC_{50} > 5.88 mg p.m./L	[redacted] (2012) EBTFX196 M-434282-01-1 KCA 8.2.6.1/12
CGA 107170	Fish, acute *Oncorhynchus mykiss*	LC_{50} 13.6 mg p.m./L	LoEP M-032079-01-1 KCA 8.2.1/16
	Invertebrate, acute *Daphnia magna*	EC_{50} 22.7 mg p.m./L	LoEP M-032096-01-1 KCA 8.2.4.1/07
	Algae, growth inhibition *Desmodesmus subspicatus*	E_bC_{50} 30.9 mg p.m./L E_rC_{50} 42.2 mg p.m./L	LoEP M-032659-01-1 KCA 8.2.6.1/06
NOA 409480	Invertebrate, acute *Daphnia magna*	EC_{50} 2.25 mg p.m./L	[redacted] (2012) EBTFX201 M-432300-01-1 KCA 8.2.4.1/18
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_rC_{50} > 5.88 mg p.m./L	[redacted] (2013) EBTFL032 M-467271-01-1 KCA 8.2.6.1/13
2-Hydroxymethyl benzonitrile	Invertebrate, acute *Daphnia magna*	EC_{50} 9.9 mg p.m./L	[redacted] (2012) EBTFX197 M-442300-01-1 KCA 8.2.4.1/19
	Algae, growth inhibition *Pseudokirchneriella subcapitata*	E_bC_{50} 10.99 mg p.m./L E_rC_{50} 33.2 mg p.m./L	[redacted] (2012) EBTFL008 M-441244-01-1 KCA 8.2.6.1/14

Predicted environmental concentrations used in risk assessment

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

Compound	FOCUS Scenario	Orchards, early	Orchards, late	Grapes	Strawberries, early	Strawberries, late
		$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]
Trifloxystrobin	STEP 1	9.927	14.89	13.34	11.14	13.37
	STEP 2 - North	3.931	5.897	3.345	1.150	1.380
	STEP 2 - South	3.931	5.897	3.345	1.150	1.380
CGA 357261	STEP 1	12.21	18.32	15.40	8.003	9.603
	STEP 2 - North	3.376	5.063	3.524	0.886	1.064
	STEP 2 - South	3.376	5.063	3.524	0.886	1.064
CGA 357262	STEP 1	1.191	1.787	1.014	0.232	0.279
	STEP 2 - North	0.828	1.243	0.865	0.205	0.246
	STEP 2 - South	0.828	1.243	0.865	0.205	0.246
CGA 321113	STEP 1	43.33	64.99	62.92	37.71	45.25
	STEP 2 - North	10.03	12.70	12.43	6.504	5.893
	STEP 2 - South	13.17	15.05	17.66	11.27	9.709
CGA 373466	STEP 1	24.06	36.09	36.87	23.11	27.73
	STEP 2 - North	4.103	4.985	5.256	3.247	2.849
	STEP 2 - South	5.664	6.155	7.857	5.865	4.944
NOA 413161	STEP 1	4.420	6.630	7.367	4.911	5.894
	STEP 2 - North	0.417	0.313	0.695	0.645	0.516
	STEP 2 - South	0.834	0.626	1.391	1.291	1.033
NOA 413163	STEP 1	4.636	6.954	7.727	5.151	6.182
	STEP 2 - North	0.435	0.326	0.725	0.675	0.540
	STEP 2 - South	0.870	0.653	1.451	1.350	1.080
CGA 357276	STEP 1	1.069	1.604	1.002	0.312	0.374
	STEP 2 - North	0.319	0.478	0.289	0.093	0.112
	STEP 2 - South	0.319	0.478	0.289	0.093	0.112
CGA 107170	STEP 1	2.924	4.386	2.488	0.570	0.684
	STEP 2 - North	2.033	3.050	2.123	0.503	0.603
	STEP 2 - South	2.033	3.050	2.123	0.503	0.603
NOA 409480	STEP 1	1.313	1.969	2.188	1.459	1.750
	STEP 2 - North	0.122	0.091	0.203	0.190	0.152
	STEP 2 - South	0.243	0.183	0.406	0.379	0.304
CGA 381318	STEP 1	4.075	6.112	6.792	4.528	5.433
	STEP 2 - North	0.308	0.231	0.513	0.522	0.418
	STEP 2 - South	0.616	0.462	1.027	1.044	0.836
2-Hydroxylmethyl benzonitrile	STEP 1	0.773	1.160	0.658	0.151	0.181
	STEP 2 - North	0.538	0.807	0.561	0.133	0.159
	STEP 2 - South	0.538	0.807	0.561	0.133	0.159

BOLD – values considered in risk assessment

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

Compound	FOCUS Scenario	Orchards, early	Orchards, late	Grapes
		$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]	$PEC_{sw, max}$ [µg/L]
Trifloxystrobin	D3 (ditch)	2.740	4.115	-
	D4 (pond)	0.123	0.185	-
	D4 (stream)	2.565	3.981	-
	D5 (pond)	0.123	0.185	-
	D5 (stream)	2.511	4.079	-
	D6 (ditch)	-		2.092
	R1 (pond)	0.123	0.185	0.076
	R1 (stream)	2.095	3.108	1.555
	R2 (stream)	2.776	4.170	2.062
	R3 (stream)	2.964	4.446	2.200
	R4 (stream)	2.108	3.161	1.555

BOLD – values considered in risk assessment

Table 10.2- 4: Initial max PEC_{sw} values – FOCUS Step 4

Compound	FOCUS Scenario	Orchards, early	Orchards, late
		$PEC_{sw,\ max}$ [µg/L]	$PEC_{sw,\ max}$ [µg/L]
50% drift reduction			
Trifloxystrobin	D3 (ditch)	1.370	2.058
	D4 (pond)	0.062	0.092
	D4 (stream)	1.283	1.990
	D5 (pond)	0.062	0.092
	D5 (stream)	1.255	2.039
	R1 (pond)	0.062	0.092
	R1 (stream)	1.048	1.554
	R2 (stream)	1.388	2.085
	R3 (stream)	1.482	2.223
	R4 (stream)	1.054	1.580
5 m buffer zone			
Trifloxystrobin	D3 (ditch)	1.849	2.775
	D4 (pond)	0.141	0.211
	D4 (stream)	2.003	3.108
	D5 (pond)	0.141	0.211
	D5 (stream)	1.960	3.184
	R1 (pond)	0.141	0.211
	R1 (stream)	1.636	2.426
	R2 (stream)	2.167	3.255
	R3 (stream)	2.314	3.471
	R4 (stream)	1.645	2.468
10 m buffer zone			
Trifloxystrobin	D3 (ditch)	-	1.240
	D4 (pond)	-	0.117
	D4 (stream)	-	1.389
	D5 (pond)	-	0.117
	D5 (stream)	-	1.423
	R1 (pond)	-	0.117
	R1 (stream)	-	1.084
	R2 (stream)	-	1.455
	R3 (stream)	-	1.551
	R4 (stream)	-	1.103

Risk assessment for aquatic organisms
ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

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

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_A	Trigger
Orchards, early						
Trifloxystrobin	Fish, acute	LC_{50}	15	3.931	**3.8**	100
	Invertebrate, acute	EC_{50}	16		**4.1**	100
CGA 357261	Fish, acute	LC_{50}	900	3.376	267	100
	Invertebrate, acute	EC_{50}	1400		415	100
CGA 357262	Fish, acute	LC_{50}	>10100	0.828	>12198	100
	Invertebrate, acute	EC_{50}	3600		4348	100
CGA 321113	Fish, acute	LC_{50}	>106000	13.17	>8049	100
	Invertebrate, acute	EC_{50}	>100000		>7593	100
CGA 373466	Fish, acute	LC_{50}	≥200000	5.664	≥35311	100
	Invertebrate, acute	EC_{50}	>100000		>17655	100
NOA 413161	Fish, acute	LC_{50}	>100000	0.834	>119904	100
	Invertebrate, acute	EC_{50}	>100000		>119904	100
NOA 413163	Fish, acute	LC_{50}	>100000	0.870	>114943	100
	Invertebrate, acute	EC_{50}	>100000		>114943	100
CGA 357276	Invertebrate, acute	EC_{50}	524000	0.319	1611285	100
NOA 409480	Invertebrate, acute	EC_{50}	2250	0.243	9259	100
CGA 107170	Fish, acute	LC_{50}	13600	2.033	6690	100
	Invertebrate, acute	EC_{50}	22700		11166	100
CGA 381318	Fish, acute	LC_{50}	≥200000	0.616	≥324675	100
	Invertebrate, acute	EC_{50}	>100000		>162338	100
2-Hydroxylmethyl-benzonitrile	Invertebrate, acute	EC_{50}	9900	0.538	18041	100
Orchards, late						
Trifloxystrobin	Fish, acute	LC_{50}	15	5.897	**2.5**	100
	Invertebrate, acute	EC_{50}	16		**2.7**	100
CGA 357261	Fish, acute	LC_{50}	900	5.063	178	100
	Invertebrate, acute	EC_{50}	1400		277	100
CGA 357262	Fish, acute	LC_{50}	>10100	1.243	>8126	100
	Invertebrate, acute	EC_{50}	3600		2896	100
CGA 321113	Fish, acute	LC_{50}	>106000	15.05	>7043	100
	Invertebrate, acute	EC_{50}	>100000		>6645	100
CGA 373466	Fish, acute	LC_{50}	≥200000	6.155	≥32494	100
	Invertebrate, acute	EC_{50}	>100000		>16247	100
NOA 413161	Fish, acute	LC_{50}	>100000	0.626	>159744	100
	Invertebrate, acute	EC_{50}	>100000		>159744	100
NOA 413163	Fish, acute	LC_{50}	>100000	0.653	>153139	100
	Invertebrate, acute	EC_{50}	>100000		>153139	100
CGA 357276	Invertebrate, acute	EC_{50}	524000	0.478	1075314	100

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_A	Trigger
NOA 409480	Invertebrate, acute	EC_{50}	2250	0.183	12295	100
CGA 107170	Fish, acute	LC_{50}	13600	3.050	4459	100
	Invertebrate, acute	EC_{50}	22700		7443	100
CGA 381318	Fish, acute	LC_{50}	≥200000	0.462	≥432900	100
	Invertebrate, acute	EC_{50}	>100000		>216450	100
2-Hydroxylmethyl-benzonitrile	Invertebrate, acute	EC_{50}	9900	0.807	12268	100
Grapes						
Trifloxystrobin	Fish, acute	LC_{50}	15	3.345	**4.5**	100
	Invertebrate, acute	EC_{50}	16		**4.8**	100
CGA 357261	Fish, acute	LC_{50}	900	3.524	255	100
	Invertebrate, acute	EC_{50}	1400		397	100
CGA 357262	Fish, acute	LC_{50}	>10100	0.865	>11676	100
	Invertebrate, acute	EC_{50}	3600		4162	100
CGA 321113	Fish, acute	LC_{50}	>106000	17.66	>6002	100
	Invertebrate, acute	EC_{50}	>100000		>5663	100
CGA 373466	Fish, acute	LC_{50}	≥200000	7.857	≥25455	100
	Invertebrate, acute	EC_{50}	≥100000		≥12728	100
NOA 413161	Fish, acute	LC_{50}	>100000	1.391	>71891	100
	Invertebrate, acute	EC_{50}	>100000		>71891	100
NOA 413163	Fish, acute	LC_{50}	>100000	1.451	>68918	100
	Invertebrate, acute	EC_{50}	>100000		>68918	100
CGA 357276	Invertebrate, acute	EC_{50}	524000	0.289	1778547	100
NOA 409480	Invertebrate, acute	EC_{50}	2250	0.406	5541	100
CGA 107170	Fish, acute	LC_{50}	13600	2.123	6406	100
	Invertebrate, acute	EC_{50}	22700		10692	100
CGA 381318	Fish, acute	LC_{50}	≥200000	1.027	≥194742	100
	Invertebrate, acute	EC_{50}	>100000		>97371	100
2-Hydroxylmethyl-benzonitrile	Invertebrate, acute	EC_{50}	9900	0.561	17647	100
Strawberries, early						
Trifloxystrobin	Fish, acute	LC_{50}	15	1.150	**13.0**	100
	Invertebrate, acute	EC_{50}	16		**13.9**	100
CGA 357261	Fish, acute	LC_{50}	900	0.886	1016	100
	Invertebrate, acute	EC_{50}	1400		1580	100
CGA 357262	Fish, acute	LC_{50}	>10100	0.205	>49268	100
	Invertebrate, acute	EC_{50}	3600		17561	100
CGA 321113	Fish, acute	LC_{50}	>106000	11.27	>9406	100
	Invertebrate, acute	EC_{50}	>100000		>8873	100
CGA 373466	Fish, acute	LC_{50}	≥200000	5.865	≥34101	100
	Invertebrate, acute	EC_{50}	>100000		>17050	100
NOA 413161	Fish, acute	LC_{50}	>100000	1.291	>77459	100
	Invertebrate, acute	EC_{50}	>100000		>77459	100
NOA 413163	Fish, acute	LC_{50}	>100000	1.350	>74074	100

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER_A	Trigger
	Invertebrate, acute	EC_{50} >100000		>74074	100
CGA 357276	Invertebrate, acute	EC_{50} 524000	0.093	5526882	100
NOA 409480	Invertebrate, acute	EC_{50} 2250	0.379	5937	100
CGA 107170	Fish, acute	LC_{50} 13600	0.503	27038	100
	Invertebrate, acute	EC_{50} 22700		45129	100
CGA 381318	Fish, acute	LC_{50} ≥200000	1.044	≥191571	100
	Invertebrate, acute	EC_{50} >100000		>95785	100
2-Hydroxylmethyl-benzonitrile	Invertebrate, acute	EC_{50} 9900	0.133	74436	100
Strawberries, late					
Trifloxystrobin	Fish, acute	LC_{50} 15	1.380	**10.9**	100
	Invertebrate, acute	EC_{50} 16		**11.6**	100
CGA 357261	Fish, acute	LC_{50} 900	1.064	846	100
	Invertebrate, acute	EC_{50} 1400		1316	100
CGA 357262	Fish, acute	LC_{50} >10100	0.246	>41057	100
	Invertebrate, acute	EC_{50} 3600		14634	100
CGA 321113	Fish, acute	LC_{50} >106000	9.709	>10918	100
	Invertebrate, acute	EC_{50} ≥100000		≥10300	100
CGA 373466	Fish, acute	LC_{50} ≥200000	4.944	≥40453	100
	Invertebrate, acute	EC_{50} >100000		>20227	100
NOA 413161	Fish, acute	LC_{50} >100000	1.033	>96805	100
	Invertebrate, acute	EC_{50} >100000		>96805	100
NOA 413163	Fish, acute	LC_{50} >100000	1.080	>92593	100
	Invertebrate, acute	EC_{50} >100000		>92593	100
CGA 357276	Invertebrate, acute	EC_{50} 524000	0.112	4589286	100
NOA 409480	Invertebrate, acute	EC_{50} 2250	0.304	7401	100
CGA 107170	Fish, acute	LC_{50} 13600	0.603	22554	100
	Invertebrate, acute	EC_{50} 22700		37654	100
CGA 381318	Fish, acute	LC_{50} ≥200000	0.836	≥239234	100
	Invertebrate, acute	EC_{50} >100000		>119617	100
2-Hydroxylmethyl-benzonitrile	Invertebrate, acute	EC_{50} 9900	0.159	62264	100

Bold values do not pass the risk assessment

CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table 10.2- 6: TER_{LT} calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
Orchards, early					
Trifloxystrobin	Fish, chronic	NOEC 7.7	3.931	**2.0**	10
	Invertebrate, chronic	NOEC 2.76		**0.7**	10
	Sediment dweller	NOEC 200		50.9	10
	Green algae, chronic	EC_{50} 5.3		**1.3**	10
	Aquatic plants, chronic	EC_{50} >1930		>491	10
CGA 357261	Green algae, chronic	EC_{50} 1400	3.376	415	10
CGA 357262	Green algae, chronic	EC_{50} >2650	0.828	>3200	10
CGA 321113	Fish, chronic	NOEC ≥100000	13.17	≥7593	10
	Invertebrate, chronic	NOEC 3200		243	10
	Sediment dweller	EC_{50} 25000		1898	10
	Green algae, chronic	EC_{50} >100000		>7593	10
CGA 373466	Green algae, chronic	EC_{50} >100000	5.664	>17655	10
NOA 413161	Green algae, chronic	EC_{50} >100000	0.834	>119904	10
NOA 413163	Green algae, chronic	EC_{50} >100000	0.870	>49188	10
CGA 357276	Green algae, chronic	EC_{50} >5880	0.319	>10929	10
CGA 107170	Green algae, chronic	EC_{50} 30900	2.033	35517	10
NOA 409480	Green algae, chronic	EC_{50} >5880	0.243	>24196	10
CGA 381318	Green algae, chronic	EC_{50} >100000	0.616	>162338	10
2-Hydroxylmethyl-benzonitrile	Green algae, chronic	EC_{50} 10990	0.538	45226	10
Orchards, late					
Trifloxystrobin	Fish, chronic	NOEC 7.7	5.897	**1.3**	10
	Invertebrate, chronic	NOEC 2.76		**0.5**	10
	Sediment dweller	NOEC 200		33.9	10
	Green algae, chronic	EC_{50} 5.3		**0.9**	10
	Aquatic plants, chronic	EC_{50} >1930		>327	10
CGA 357261	Green algae, chronic	EC_{50} 1400	5.063	277	10
CGA 357262	Green algae, chronic	EC_{50} >2650	1.243	>2132	10
CGA 321113	Fish, chronic	NOEC ≥100000	15.05	≥6645	10
	Invertebrate, chronic	NOEC 3200		213	10
	Sediment dweller	EC_{50} 25000		1661	10
	Green algae, chronic	EC_{50} >100000		>6645	10
CGA 373466	Green algae, chronic	EC_{50} >100000	6.155	>16247	10
NOA 413161	Green algae, chronic	EC_{50} >100000	0.626	>159744	10
NOA 413163	Green algae, chronic	EC_{50} >100000	0.653	>153139	10
CGA 357276	Green algae, chronic	EC_{50} >5880	0.478	>12301	10
CGA 107170	Green algae, chronic	EC_{50} 30900	3.050	10131	10
NOA 409480	Green algae, chronic	EC_{50} >5880	0.183	>32131	10
CGA 381318	Green algae, chronic	EC_{50} >100000	0.462	>21645	10

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
2-Hydroxylmethyl-benzonitrile	Green algae, chronic	EC_{50}	10990	0.807	13618	10
Grapes						
Trifloxystrobin	Fish, chronic	NOEC	7.7	3.345	**2.3**	10
	Invertebrate, chronic	NOEC	2.76		**0.8**	10
	Sediment dweller	NOEC	200		59.8	10
	Green algae, chronic	EC_{50}	5.3		**1.6**	10
	Aquatic plants, chronic	EC_{50}	>1930		>577	10
CGA 357261	Green algae, chronic	EC_{50}	1400	3.524	397	10
CGA 357262	Green algae, chronic	EC_{50}	>2650	0.865	>3064	10
CGA 321113	Fish, chronic	NOEC	≥100000	17.66	≥5663	10
	Invertebrate, chronic	NOEC	3200		181	10
	Sediment dweller	EC_{50}	25000		1416	10
	Green algae, chronic	EC_{50}	>100000		>5663	10
CGA 373466	Green algae, chronic	EC_{50}	>100000	7.857	>12728	10
NOA 413161	Green algae, chronic	EC_{50}	>100000	1.391	>71891	10
NOA 413163	Green algae, chronic	EC_{50}	>100000	1.451	>68918	10
CGA 357276	Green algae, chronic	EC_{50}	>5880	0.289	>20346	10
CGA 107170	Green algae, chronic	EC_{50}	30900	2.123	14555	10
NOA 409480	Green algae, chronic	EC_{50}	>5880	0.406	>14483	10
CGA 381318	Green algae, chronic	EC_{50}	>100000	1.027	>97371	10
2-Hydroxylmethyl-benzonitrile	Green algae, chronic	EC_{50}	10990	0.561	19590	10
Strawberries, early						
Trifloxystrobin	Fish, chronic	NOEC	7.7	1.150	**6.7**	10
	Invertebrate, chronic	NOEC	2.76		**2.4**	10
	Sediment dweller	NOEC	200		174	10
	Green algae, chronic	EC_{50}	5.3		**4.6**	10
	Aquatic plants, chronic	EC_{50}	>1930		>1678	10
CGA 357261	Green algae, chronic	EC_{50}	1400	0.886	1580	10
CGA 357262	Green algae, chronic	EC_{50}	>2650	0.205	12927	10
CGA 321113	Fish, chronic	NOEC	≥100000	11.27	≥8873	10
	Invertebrate, chronic	NOEC	3200		284	10
	Sediment dweller	EC_{50}	25000		2218	10
	Green algae, chronic	EC_{50}	>100000		>8873	10
CGA 373466	Green algae, chronic	EC_{50}	>100000	5.865	> 11280	10
NOA 413161	Green algae, chronic	EC_{50}	>100000	1.291	> 77460	10
NOA 413163	Green algae, chronic	EC_{50}	>100000	1.350	> 74074	10
CGA 357276	Green algae, chronic	EC_{50}	>5880	0.093	> 63226	10
CGA 107170	Green algae, chronic	EC_{50}	30900	0.503	61431	10
NOA 409480	Green algae, chronic	EC_{50}	>5880	0.379	>15515	10
CGA 381318	Green algae, chronic	EC_{50}	>100000	1.044	>95785	10

Compound	Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
2-Hydroxylmethyl-benzonitrile	Green algae, chronic	EC_{50}	10990	0.133	82632	10
Strawberries, late						
Trifloxystrobin	Fish, chronic	NOEC	7.7	1.380	**5.6**	10
	Invertebrate, chronic	NOEC	2.76		**2.0**	10
	Sediment dweller	NOEC	200		145	10
	Green algae, chronic	EC_{50}	5.3		**3.8**	10
	Aquatic plants, chronic	EC_{50}	>1930		>1399	10
CGA 357261	Green algae, chronic	EC_{50}	1400	1.064	1316	10
CGA 357262	Green algae, chronic	EC_{50}	>2650	0.246	>10772	10
CGA 321113	Fish, chronic	NOEC	≥100000	9.709	≥10300	10
	Invertebrate, chronic	NOEC	3200		330	10
	Sediment dweller	EC_{50}	25000		2575	10
	Green algae, chronic	EC_{50}	>100000		>10300	10
CGA 373466	Green algae, chronic	EC_{50}	>100000	4.944	>20227	10
NOA 413161	Green algae, chronic	EC_{50}	>100000	1.033	>96805	10
NOA 413163	Green algae, chronic	EC_{50}	>100000	1.080	>92593	10
CGA 357276	Green algae, chronic	EC_{50}	>5880	0.112	>52500	10
CGA 107170	Green algae, chronic	EC_{50}	30900	0.603	51244	10
NOA 409480	Green algae, chronic	EC_{50}	>5880	0.304	>19342	10
CGA 381318	Green algae, chronic	EC_{50}	>100000	0.836	>119617	10
2-Hydroxylmethyl-benzonitrile	Green algae, chronic	EC_{50}	10990	0.159	69119	10

Table 10.2- 7: refined TER calculations using endpoints derived from higher tier studies (NOECs cover acute and chronic exposure) based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Orchards, early					
Trifloxystrobin	Fish species [a]	NOEC 25.3	3.931	**6.4**	10
	Aquatic species except fish [b]	NOEC 3.7		**0.9**	1
Orchards, late					
Trifloxystrobin	Fish species [a]	NOEC 25.3	5.897	**4.3**	10
	Aquatic species except fish [b]	NOEC 3.7		**0.6**	1
Grapes					
Trifloxystrobin	Fish species [a]	NOEC 25.3	3.345	**7.6**	10
	Aquatic species except fish [b]	NOEC 3.7		**1.1**	1
Strawberries, early					
Trifloxystrobin	Fish species [a]	NOEC 25.3	1.150	22.0	10
	Aquatic species except fish [b]	NOEC 3.7		3.2	1
Strawberries, early					
Trifloxystrobin	Fish species [a]	NOEC 25.3	1.380	18.3	10
	Aquatic species except fish [b]	NOEC 3.7		2.7	1

[a] endpoint based on a repeated (3x) peak exposure study with the formulation (WG 50) and the most sensitive fish species (rainbow trout) and life stage (alevin stage larvae) that covers both, acute and chronic effects of trifloxystrobin ([redacted], 2002, M-056670-01-1, KCP 10.2.3/02).

[b] endpoint based on a lentic freshwater community mesocosm with the formulation (KCA 8.2.8/09)

The TER values for the uses in strawberries meet the trigger value based on FOCUS Step 2 PEC values. Therefore, an unacceptable risk to aquatic organisms is not to be expected following the application of the product in these crops.

For the uses in orchards (early and late) and grapes further refinement using FOCUS Step3 values in necessary.

Table 10.2- 8: refined TER calculations using endpoints derived from higher tier studies (NOECs cover acute and chronic exposure) based on FOCUS Step 3

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER	Trigger
Orchards, early						
Trifloxystrobin	Fish, acute and chronic	NOEC 25.3	2.740	D3 (ditch)	**9.2**	10
			0.123	D4 (pond)	206	
			2.565	D4 (stream)	**9.9**	
			0.123	D5 (pond)	206	
			2.511	D5 (stream)	10.1	
			0.123	R1 (pond)	206	
			2.095	R1 (stream)	12.1	
			2.776	R2 (stream)	**9.1**	
			2.964	R3 (stream)	**8.5**	
			2.108	R4 (stream)	12.0	
Trifloxystrobin	Aquatic species except fish	NOEC 3.7	2.740	D3 (ditch)	1.4	1
			0.123	D4 (pond)	30.1	
			2.565	D4 (stream)	1.4	
			0.123	D5 (pond)	30.1	
			2.511	D5 (stream)	1.5	
			0.123	R1 (pond)	30.1	
			2.095	R1 (stream)	1.8	
			2.776	R2 (stream)	1.3	
			2.964	R3 (stream)	1.2	
			2.108	R4 (stream)	1.8	
Orchards, late						
Trifloxystrobin	Fish, acute and chronic	NOEC 25.3	4.115	D3 (ditch)	**6.1**	10
			0.185	D4 (pond)	137	
			3.981	D4 (stream)	**6.4**	
			0.185	D5 (pond)	137	
			4.079	D5 (stream)	**6.2**	
			0.185	R1 (pond)	137	
			3.108	R1 (stream)	**8.1**	
			4.170	R2 (stream)	**6.1**	
			4.446	R3 (stream)	**5.7**	
			3.161	R4 (stream)	**8.0**	
Trifloxystrobin	Aquatic species except fish	NOEC 3.7	4.115	D3 (ditch)	**0.9**	1
			0.185	D4 (pond)	20.0	
			3.981	D4 (stream)	**0.9**	
			0.185	D5 (pond)	20.0	
			4.079	D5 (stream)	**0.9**	
			0.185	R1 (pond)	20.0	
			3.108	R1 (stream)	1.2	
			4.170	R2 (stream)	**0.9**	

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER	Trigger
			4.446	R3 (stream)	**0.8**	
			3.161	R4 (stream)	1.2	
Grapes						
Trifloxystrobin	Fish, acute and chronic	NOEC 25.3	2.092	D6 (ditch)	12.1	10
			0.076	R1 (pond)	333	
			1.555	R1 (stream)	16.3	
			2.062	R2 (stream)	12.3	
			2.200	R3 (stream)	11.5	
			1.555	R4 (stream)	16.3	
Trifloxystrobin	Aquatic species except fish	NOEC 3.7	2.092	D6 (ditch)	1.8	1
			0.076	R1 (pond)	48.7	
			1.555	R1 (stream)	2.4	
			2.062	R2 (stream)	1.8	
			2.200	R3 (stream)	1.7	
			1.555	R4 (stream)	2.4	

The TER values for the use in grapes meet the trigger value based on FOCUS Step 3 PEC 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, early application (fish species only) and orchards, late application, further refinement using FOCUS Step 4 values in necessary.

Table 10.2- 9: refined TER calculations using endpoints derived from higher tier studies (NOECs cover acute and chronic exposure) based on FOCUS Step 4 including mitigation measures

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER	Trigger
Orchards, early						
50% drift reduction						
Trifloxystrobin	Fish species	NOEC 25.3	1.370	D3 (ditch)	18.5	10
			1.283	D4 (stream)	19.7	
			1.388	R2 (stream)	18.2	
			1.482	R3 (stream)	17.1	
5 m buffer zone						
Trifloxystrobin	Fish species	NOEC 25.3	1.849	D3 (ditch)	13.7	10
			2.003	D4 (stream)	12.6	
			2.167	R2 (stream)	11.7	
			2.314	R3 (stream)	10.9	
Orchards, late						
50% drift reduction						
Trifloxystrobin	Fish, acute and chronic	NOEC 25.3	2.058	D3 (ditch)	12.3	10
			1.990	D4 (stream)	12.7	
			2.039	D5 (stream)	12.4	
			1.554	R1 (stream)	16.3	
			2.085	R2 (stream)	12.1	
			2.223	R3 (stream)	11.4	
			1.580	R4 (stream)	16.0	
Trifloxystrobin	Aquatic species except fish	NOEC 3.7	2.058	D3 (ditch)	1.8	1
			1.990	D4 (stream)	1.9	
			2.039	D5 (stream)	1.8	
			1.554	R1 (stream)	2.4	
			2.085	R2 (stream)	1.8	
			2.223	R3 (stream)	1.7	
			1.580	R4 (stream)	2.3	
5 m buffer zone						
Trifloxystrobin	Aquatic species except fish	NOEC 3.7	2.775	D3 (ditch)	1.3	1
			3.108	D4 (stream)	1.2	
			3.184	D5 (stream)	1.2	
			2.426	R1 (stream)	1.5	
			3.255	R2 (stream)	1.1	
			3.471	R3 (stream)	1.1	
			2.468	R4 (stream)	1.5	
10 m buffer zone						
Trifloxystrobin	Fish, acute and chronic	NOEC 25.3	1.240	D3 (ditch)	20.4	10
			1.389	D4 (stream)	18.2	
			1.423	D5 (stream)	17.8	

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER	Trigger
			1.084	R1 (stream)	23.3	
			1.455	R2 (stream)	17.4	
			1.551	R3 (stream)	16.3	
			1.103	R4 (stream)	22.9	

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 50% drift reducing nozzles are used. Alternatively, a buffer zone of 5 m (early application) and 10 m (late application) should be maintained during application of the product.

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

No new studies were necessary.

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

No new studies were necessary.

CP 10.2.3 Further testing on aquatic organisms

No studies were necessary.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

Details of the honeybee testing with the active substance trifloxystrobin are presented in MCA, Section 6, Point 8.3.1, as well as within the existing Review Report for trifloxystrobin (SANCO/4339/2000-Final, 2003).

Table 10.3.1- 1: Acute toxicity of trifloxystrobin (tech.) to bees

Test substance	Test species/study design	Endpoint	Reference
Trifloxystrobin, tech.	Honey bee, 48 h	LD_{50} – oral > 200 µg a.s./bee LD_{50} – contact > 200 µg a.s./bee	LoEP M-032668-01-1 KCA 8.3.1.1.1/01
Trifloxystrobin, tech.	Honey bee, 48h	LD_{50} – oral > 110 µg a.s./bee LD_{50} – contact > 100 µg a.s./bee	[redacted] (2012) 67571035 M-431911-01-1 KCA 8.3.1.1.1/04

Table 10.3.1- 2: Honey bee toxicity data generated with Trifloxystrobin WG 50

Test substance	Test species/study design	Endpoint	Reference
Acute oral and contact toxicity (laboratory)			
Trifloxystrobin WG 50	Honey bee, 48 h	LD_{50} – oral >94.8 µg a.s./bee [1] LD_{50} – contact >101.6 µg a.s./bee [1]	LoEP M-049630-01-1 KCP 10.3.1.1/01
Trifloxystrobin WG 50	Honey bee, 48h	LD_{50} – oral **>107.8 µg a.s./bee** LD_{50} – contact **>100 µg a.s./bee**	[redacted] (2012) 67561035 M-431974-01-1 KCP 10.3.1.1.1/02
Chronic toxicity to adult bees (laboratory)			
Trifloxystrobin WG 50	10 d chronic adult feeding study	LC_{50} > 120 mg a.s./kg NOEC ≥ 120 mg a.s./kg	[redacted] (2013) S13-00149 M- 468755-01-1 KCA 8.3.1.2/01
Bee brood feeding test			
Trifloxystrobin WG 50	Honey bee brood feeding (Oomen *et al.*, 1992)	No adverse effects on mortality, bee brood development (eggs, young larvae, old larvae, pupae) and colony development by feeding honey bee colonies sugar syrup at a trifloxystrobin-concentration typical for a high-volume spray (75 ppm)	[redacted] (2012) 64821031 M-438966-01-1 KCA 8.3.1.3/01
Cage and tunnel studies			
Trifloxystrobin + Propiconazole EC 312.5 (187.5+125)	Semi-field cage study in *Phacelia*, application during full-bloom and bees actively foraging	No adverse effects on mortality, foraging activity, behaviour, queen survival, brood- and colony development after an application corresponding to 186 g trifloxystrobin a.s./ha into full-flowering Phacelia during honey bees actively foraging on the crop under confined conditions	[redacted] (2000) 99106/01-BZEU M-050990-01-1 KCP 10.3.1.5/01
Fluopyram Trifloxystrobin SC 500 (250+250)	Semi-field tunnel study in *Phacelia*; 1st application during imminent pre-flowering (BBCH 59-61) without bees present, 2nd application during full-bloom (BBCH 64-65) and bees actively foraging	No adverse effects on mortality, foraging activity, behaviour, nectar- and pollen storage, queen survival, brood- and colony development (covering two complete brood cycles) after an application corresponding to 146 g trifloxystrobin a.s./ha into full-flowering *Phacelia* during honey bees actively foraging on the crop under confined conditions	[redacted] (2012) 64861037 M-435338-01-1 KCP 10.3.1.5/02

Bold values: Endpoints considered relevant for risk assessment

[1] Based on an analysed active substance content of 50.8% [original 48 h - LD_{50} - values: 186.7 (oral) and 200 (contact) µg product/bee]

Risk assessment for bees

Table 10.3.1- 3: 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
Trifloxystrobin	>107.8	150 [a]	< 1.4	50	yes

[a] maximum application rate (strawberries)

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- 4: 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
Trifloxystrobin	>100	150 [a]	< 1.5	50	yes

[a] maximum application rate (strawberries)

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

Further considerations for the risk assessment

In addition to acute laboratory studies with adult honey bees, trifloxystrobin was further subjected to chronic laboratory testing with adult honey bees.

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 trifloxystrobin a.s./kg in aqueous sugar solution. As trifloxystrobin is only very slightly soluble in water (0.61 mg a.s./L at 25 °C), the test was conducted by using the formulated product Trifloxystrobin WG 50. The nominal test concentration as such equals about 200 × the water solubility of trifloxystrobin. 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 trifloxystrobin (nominal).

In order to reveal whether trifloxystrobin poses a risk to immature honey bee life stages, 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. The study was conducted with Trifloxystrobin WG 50 and the tested concentration corresponded to a typical high-volume use (actual test concentration of trifloxystrobin: 75 mg trifloxystrobin a.s./L). The administration of 1 litre sugar solution per colony, containing 75 ppm trifloxystrobin has neither resulted in adverse acute or chronic effects on adult honey bees nor in adverse effects on immature honey bee life stages (eggs, young larvae, old larvae, pupae) or on the colony itself. Neither mortality of worker bees and pupae (as assessed via dead bee traps) nor the termination rate of eggs, young larvae and old larvae (as assessed via digital imaging of individual marked cells) was statistically significantly different from the untreated control.

Moreover, two cage/tunnel studies were conducted with trifloxystrobin-containing mixture formulations.

In a cage study, trifloxystrobin was applied via Trifloxystrobin + Propiconazole EC 312.5 (187.5+125) at a rate corresponding to 186 g trifloxystrobin a.s./ha during honey bees actively foraging on the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia*. This application rate has not resulted in adverse effects on mortality, foraging activity, behaviour, queen survival, brood- and colony development.

In a tunnel study, trifloxystrobin was applied via Fluopyram + Trifloxystrobin SC 500 (250+250) at a rate corresponding to nominally 140 g trifloxystrobin a.s./ha on the highly bee attractive surrogate crop *Phacelia tanacetifolia* during both, imminent pre-flowering and during full-bloom, respectively. The study comprised in total 6 tunnels in the test item treatment group: three replicate tunnels were exclusively used for apidological assessments whereas the other three replicate tunnels were exclusively used for blossom, nectar and pollen collection for subsequent residue analysis. Two sequential applications were conducted in the test item treatment group: The 1st test item application just at the beginning of the flowering period of the *Phacelia*-crop at BBCH 59 - 61 without honey bees present, followed by the 2nd test item application during full flowering of the *Phacelia*-crop (BBCH 64 - 65), with confined honey bees actively foraging on the crop during application.

Mortality, foraging activity and behaviour was assessed daily throughout the 11 days lasting confinement period (i.e. 3 days before until 7 days after the 2nd test item application; only in those colonies used for apidological assessments), sequential colony assessments (only in those colonies used for apidological assessments) - including assessments of brood, food and colony strength - were performed 6 days before the 2nd test item application and 7 days after the 2nd test item application; after the colonies were released from confinement, colony assessments - including assessments of brood, food and colony strength - were continued on a monitoring site on day 14, 21, 28 and 42 after the 2nd test item application.

In the three tunnels which were exclusively used for residue-sample collection, blossoms were collected by hand whereas honey bees were used as a sampling device for nectar and pollen. Residue samples were collected on the day of the 2nd test item application and on the following day. Collected forager bees were immediately placed in their respective tunnels on dry ice after collection and the bees were kept deep frozen until nectar and pollen extraction from the bees; thereafter, the collected nectar and pollen was continued to be stored deep frozen until residue analysis.

In the three tunnels which were used exclusively for apidological assessments, effectively 145 g trifloxystrobin a.s./ha (1st test item application at BBCH 59 - 61 without honey bees present) and 146 g trifloxystrobin a.s./ha (2nd test item application at BBCH 64 - 65 with confined honey bees actively foraging on the crop during application) were applied; in the three tunnels which were exclusively used for residue-sample collection, the effective application rates were 144 and 143 g trifloxystrobin a.s./ha.

Considering the residue-analytical assessments, the analysis of nectar and pollen samples as collected on the day of the 2nd test item application (day 0) and on the following day (day 1) revealed a decline of trifloxystrobin-residues in nectar and pollen from day 0 to day 1 as well as within temporally consecutive samplings on a given day. The maximum measured trifloxystrobin-residue in nectar was 0.74 mg trifloxystrobin a.s./kg (0.74 ppm), the maximum measured trifloxystrobin-residue in pollen was 25 mg trifloxystrobin a.s./kg (25 ppm).

Considering the apidological assessments, the study revealed no adverse effects on mortality, foraging activity, behaviour, nectar- and pollen storage, queen survival, brood- and colony development (covering two complete honey bee brood cycles) after an application corresponding to 146 g trifloxystrobin a.s./ha into full-flowering *Phacelia* during honey bees actively foraging on the crop under confined conditions.

Synopsis

The calculated Hazard Quotients for trifloxystrobin 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 the bee brood feeding study as well as by the results of the two semi-field studies, covering foliar application rates of up to 186 g trifloxystrobin a.s./ha.

Regarding potential side effects of trifloxystrobin-residues in nectar and pollen on immature honey bee life stages as well as on colony development, the maximum actually measured trifloxystrobin-residue concentration in nectar and pollen in the highly bee attractive surrogate crop *Phacelia* (0.74 ppm and 25 ppm, see above) after two consecutive applications of about 150 g trifloxystrobin a.s./ha (i.e. at imminent pre-flowering and during full-bloom, respectively) was below both, the tested trifloxystrobin-concentration (75 ppm), which had not shown adverse/statistical significant effects on mortality of worker bees and pupae nor adverse/statistically significant effects on the termination rate of eggs, young larvae and old larvae (as assessed via digital imaging of individually marked cells) in the bee brood feeding study on colony level; this maximum actually measured trifloxystrobin-residue concentration in nectar and pollen was as well below the concentration which was tested without adverse effects in the chronic laboratory feeding study with adult honey bees (120 ppm).

In turn, these two consecutive applications of about 150 g trifloxystrobin a.s./ha (i.e. at imminent pre-flowering and during full-bloom, respectively) - with bees actively foraging during the 2nd application at full-bloom of the highly bee attractive surrogate crop *Phacelia* under confined and as such forced exposure conditions - were found not to cause adverse lethal, sub-lethal, behavioural and delayed effects as well as no adverse effects on brood- and colony development (covering two complete honey bee brood cycles).

Overall, it can be concluded that trifloxystrobin, when applied at the maximum envisaged application rate of 150 g a.s./ha even during the flowering period of a bee-attractive crop, 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:	**KCP 10.3.1.1.1/02; [redacted]; (2012)**
Title:	Effects of trifloxystrobin WG 50 W (Acute Contact and Oral) on Honey Bees (*Apis mellifera* L.) in the Laboratory
Report No:	67561035
Document No:	M-431974-01-1
Guidelines:	OECD Guideline 213 and 214 (1998)
Deviations:	None
GLP:	Yes (certified laboratory)

Objective:

The purpose of this study was to determine the acute contact and oral toxicity of trifloxystrobin WG 50 W to the honey bee (*A. 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: Trifloxystrobin WG 50 W: trifloxystrobin (CGA 279202): 50 % w/w (nominal), 49.8 % w/w (analytical), (Origin Batch No.: EDFL011509, Sample description: TOX09344-00; Specification No.: 102000007798 - 02; Material No.: 05584493).
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, *Apis mellifera* (50 worker bees per dose; 10 individuals in 5 replicates per test item dose level, controls and reference item doses) were exposed for 48 hours to a single dose of 100.0 µg a.s. per bee by topical application (contact limit test) and to a single dose of 107.8 µg a.s. per bee by feeding (oral limit test; value based on the actual intake of the test item).

<u>Oral toxicity study</u>

Aqueous stock solutions of the test item and reference item were prepared in order to achieve the target concentrations after being mixed with sugar syrup (ready-to-use syrup, sugar component: 30% sucrose, 31% glucose, 39% fructose) at a ratio of 1 : 1.
After mixing of these test or reference item solutions with ready-to-use sugar syrup, the final concentration of sugar syrup in the test and reference item solutions offered to the bees was 50 % (50 % aqueous test or reference item solution and 50 % syrup (w/w)). For the control, water and sugar syrup was used at the same ratio (50 % water and 50 % syrup (w/w)).
The treated food was offered in syringes, which were weighed before and after introduction into the cages (duration of uptake was 1 hour for the test item treatments). After a maximum of 1 hour, the

uptake was complete and the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.
The mean target dose levels (e.g. 100 µg a.s./bee nominal) would have been obtained if exactly 20 mg/bee of the treated food were ingested. In practice, uptake of the treated sugar solutions differed slightly from the nominal 20 mg/bee and results are given based on the measured consumption.
The test was conducted in darkness, temperature was 25°C and humidity between 57 and 83%.
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 trifloxystrobin WG 50 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[4] was used. 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 25°C and humidity between 57 and 83%. 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.

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 0.16 µg a.s./bee, the LD_{50} (24 h) of the toxic standard in the contact test equals 0.14 µg/bee.
A summary of effects of the test item on mortality and behavioural abnormalities of the bees is given below for both tests:

[4] The Adhäsit was used to improve the adhesion of the droplet on the bee body. Adhäsit is non-toxic to honey bees.

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

dosage [µg a.s./bee]	after 4 hours		after 24 hours		after 48 hours	
	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %
test item 100.0	0.0	0.0	0.0	0.0	0.0	0.0
water	0.0	0.0	0.0	0.0	0.0	0.0
reference item						
0.30	6.0	30.0	90.0	2.0	98.0	0.0
0.20	0.0	8.0	80.0	0.0	82.0	0.0
0.15	2.0	14.0	60.0	8.0	74.0	0.0
0.10	0.0	0.0	10.0	2.0	28.0	0.0

results are averages from five 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

consumed dosage [µg a.s./bee]	after 4 hours		after 24 hours		after 48 hours	
	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %	mortality mean %	behavioural abnormalities mean %
test item 107.8	0.0	0.0	0.0	0.0	0.0	0.0
water	0.0	0.0	0.0	0.0	0.0	0.0
reference item						
0.31	12.0	48.0	98.0	2.0	100.0	0.0
0.16	2.0	12.0	50.0	6.0	64.0	0.0
0.08	0.0	0.0	6.0	2.0	10.0	0.0
0.06	0.0	0.0	0.0	0.0	0.0	0.0

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

Observations:

Contact toxicity test:

At the end of the contact toxicity test (48 hours after application), there was no mortality at 100.0 µg a.s./bee. Also no mortality occurred in the control group (water + 5% Adhäsit). No induced behavioural effects were observed at any time.

Oral toxicity test:

The maximum nominal test level of Trifloxystrobin WG 50 W (i.e. 100 µg a.s./bee) corresponded to an actual intake of 107.8 µg a.s./bee. This dose level led to no mortality after 48 hours. Also no mortality occurred in the control group. No induced behavioural effects were observed at any time.

Conclusion:

Toxicity to Honey Bees; laboratory tests

Test Item	Trifloxystrobin WG 50 W	
Test object	*Apis mellifera*	
Application rate (µg a.s./bee)	100.0	107.8
Exposure	contact (solution in Adhäsit (0.5%)/water)	oral (sugar solution)
LD_{50} µg product/bee	> 100.0	> 107.8

The toxicity of Trifloxystrobin WG 50 W was tested in both, an acute contact and an acute oral toxicity test on honey bees.

The LD_{50} (48 h) value was > 100.0 µg a.s./bee in the contact toxicity test.
The LD_{50} (48 h) value was > 107.8 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 Trifloxystrobin WG 50, the corresponding summary is filed under KCA, point 8.3.1.2/01.

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

A honey bee brood feeding study (Oomen *et al.*) has been conducted with the WG 50-formulation (Schmitzer, 2012, M-438966-01-1) and is included in the MCA document (see MCA 8.3.1.3/01).

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

Report:	**KCP 10.3.1.5/01; [redacted]. (2000)**
Title:	Assessment of side effects of CGA279202 + CGA64250 EC 312.5 (A 9524 B) on the honey bee (*Apis mellifera* L.) under semi-field conditions
Report No:	99106/01-BZEU
Document No:	M-050990-01-1
Guidelines:	EPPO No. 170 (1992)
Deviations:	None
GLP:	Yes (certified laboratory)

Materials and methods:

The side effects of the test substance CGA279202 (=trifloxystrobin) + CGA64250 (=propiconazole) EC 312.5 (187.5 + 125; product code: A 9524 B) were tested on the honey bee (*Apis mellifera* L.) under semi-field conditions according to the guideline of the European and Mediterranean Plant Protection Organization No. 170(EPPO, 1992).

The test substance CGA279202 + CGA64250 EC 312.5 was applied at an application rate of 1000 mL formulation/ha in 300 L water/ha, which corresponds to 186 g trifloxystrobin a.s./ha + 126 g propiconazole a.s./ha, based on the analysed content of both active substances as given in the certificate of analysis.

Plots treated with drinking water served as control. As toxic standard Hostathion 40 EC was applied at a rate of 0.6 L/ha in 300 L water/ha.

The effects of the test substance were examined on small bee colonies in cages placed over plots of flowering *Phacelia tanacelifolia* Benth. The influence of CGA279202 + CGA64250 EC 312.5 (A 9524 B) was evaluated by comparing the effect of the test substance treatment to the effect of the control and toxic standard treatment regarding the following observations:

- Mortality at the edge of the treated area and in the bee traps.
- Foraging activity (number of forager bees/m² flowering Phacelia crop).
- Behaviour of the bees on the crop and around the hive.
- Development of the bee brood.

Dates of experimental work: July 13, 1999 to July 19, 1999

Results:

Effect on honey bee mortality:

The application of CGA279202 + CGA64250 EC 312.5 on flowering *Phacelia* did not result in an acute intoxication of adult bees. Comparing the average pre-application mortality and the average post-application mortality no increase of mortality did occur in the test substance CGA279202 + CGA64250 EC 312.5 treatment when compared to the control.

Effects on honey bee flight intensity:

Shortly before application, an average of approximately 15 bees/m² were observed foraging in all plots. The application of CGA279202 + CGA64250 EC 312.5 did not cause a decrease of flight intensity compared to the average flight intensity in the control treatment on the day of test substance application (average flight intensity in the CGA279202 - CGA64250EC312.5 treatment: 13.4 bees/m^2, and in the control treatment: 12.7 bees/m^2). In the toxic standard treatment, the flight intensity dropped on a low level of 6.1 bees/m^2 on the day of test substance application. On the following evaluation days, no differences were observed concerning the flight intensity in the flowering *Phacelia* between the three treatments.

Effects on honey bee brood development:

In the bee brood development, no abnormal difference which could be attributed to the influence of the test substance was observed between the test substance and control treatments.

Behaviour of the bees:

No abnormal difference in behaviour of the bees was observed between the test substance treatments and the control treatments at any time during the period of assessment.

Conclusions:

It was concluded that this study demonstrates that CGA279202 + CGA64250 EC 312.5 (product code: A 9524 B) did not have a harmful effect on honey bees when applied to a flowering crop of *Phacelia tanacetifolia* at an application rate of 1000 mL formulation/ha in 300 L water/ha.

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Report:	**KCP 10.3.1.5/02; [redacted], (2012)**
Title:	Toxicity testing of fluopyram + trifloxystrobin SC 500 (250+250) G on honey bees (*Apis mellifera* L.) under semi-field conditions - tunnel test -
Report No:	64841037
Document No:	M-435338-01-1
Guidelines:	EPPO No. 170 (2010)
Deviations:	None
GLP:	Yes (certified laboratory)

Materials and methods:

Test Item:

Fluopyram + trifloxystrobin SC 500 (250+250) G; fluopyram (AE C656948): 21.6 % w/w (252.4 g/L), trifloxystrobin (CGA 279202): 21.6 % w/w (252.2 g/L), (all values analytical), Batch ID.: 2011-002701, Sample Description: TOX09384-00, Material No.: 06033007, Specification No.: 102000012886 - 03, density: 1.169 g/mL (20 °C).

Test Species:

Honey bees (*Apis mellifera* carnica L.); small bee colonies were maintained according to normal beekeeping practice, containing 5 combs with honey, pollen and all brood stages present. The mean strength of the colonies per treatment group, six days before the 2nd test item application (prior to exposure to the test item), was similar and ranged between 2280 and 2625 adult bees.

Test Design:

The test was conducted under forced/confined exposure conditions (tunnel), in order to assess the potential effects of fluopyram + trifloxystrobin SC 500 (250+250) G on honey bees and honey bee

colonies. 12 tunnels (14 m length x 5.5 m width x 2.5 m height) were set up on a 40 m² plot of flowering *Phacelia tanacetifolia* (2 x 20 m²).
Six tunnels were treated with the test item:

a) 1 x just at the beginning of the flowering period (at BBCH 59 - 61), without honey bees present (= 1st test item application) and, again,
b) 1 x during full flowering of the crop (at BBCH 64 - 65), with honey bees actively foraging on the crop during application (= 2nd test item application).
Three tunnels were concurrently to the 2nd test item application treated with tap water (controls) and three tunnels were treated with a reference item (Perfekthion EC (BAS 152 11 I), 400 g/L dimethoate), respectively, during honey bees actively foraging on the crop.
The honey bee colonies were introduced into their respective tunnels 11 days before the 2nd test item application (during full flowering) and the corresponding applications in the control group and in the reference item group, respectively. One honey bee colony was used per tunnel.
Three of the six tunnels being treated with the test item were assigned for exclusively monitoring residues, collected by foraging honey bees (pollen and nectar) on the day of 2nd test item application as well as on the day following the 2nd test item application.
The confined exposure phase of the honey bees inside the treated crop was 7 days following the 2nd test item application (during full flowering) and the corresponding applications in the control group and in the reference item group, respectively. The conditions of the colonies were examined until day 42 following the 2nd test item application.
The collected honey bees were dispatched deep-frozen to Bayer CropScience AG in Monheim, Germany, for further processing. The results were reported in a separate study at Bayer CropScience AG. The study number of the report is E 319 4290-8. The analytical report is attached to this biological final report as Appendix III.

Endpoints:
Mortality and foraging activity (flight density) of the honey bees were assessed before and after the 2nd application. Sub-lethal effects, such as changes in behaviour (e.g. intensive cleaning, dis-coordinated movement, exaggerated motility, aggressiveness, lethargy, apathy, obvious symptoms of intoxication, etc.) were also monitored. Colony assessments (nectar stores, pollen stores, eggs, larvae, pupae, colony strength) were made 6 days before the 2nd application and at days 7, 14, 21, 28 and 42 following the 2nd test item application and the corresponding applications in the control group and in the reference item group, respectively.

Test Concentrations:
Test Item:
1st application: 560 mL test item in 400 L water/ha (corresponding to nominally 140 g a.s. fluopyram/ha + 140 g a.s. trifloxystrobin/ha), applied to the *Phacelia*-crop before flowering without honey bees present (at BBCH 59 - 61).
2nd application: 560 mL test item in 400 L water/ha (corresponding to nominally 140 g a.s. fluopyram/ha + 140 g a.s. trifloxystrobin/ha), applied during full flowering of the crop (BBCH 64 - 65) when honey bees were actively foraging on the *Phacelia*-crop.
Reference Item (concurrently to the 2nd test item application):

1.5 L Perfekthion EC in 400 L tap water/ha (corresponding to 3.75 mL/L or 4.03 g/L), applied during honey bees actively foraging on the *Phacelia*-crop.
Control (concurrently to the 2nd test item application):
400 L tap water/ha, applied during honey bees actively foraging on the *Phacelia*-crop.

Test Conditions:
Natural field conditions. Weather conditions were good during both applications. The sky was a little cloudy but warm with no precipitation. First rain occurred following 2 days after the 1st test item application or 6 days after the 2nd test item application. The weather was variable but warm for the remainder of the trial.
Statistics:
Statistical evaluation was done for mortality and the brood termination rates using Shapiro-Wilk`s test (check for normal distribution), Levene`s test (check for homogeneity of variance), Student`s t-test (pairwise). Software: TOX Rat Professional, Version 2.10.05, ® ToxRat Solutions GmbH.

Dates of experimental apidological work: August 08, 2011 to October 10, 2011
Dates of experimental residue-analytical work: March 01, 2012 to March 28, 2012

Results:
Mortality
Starting conditions of the experiment were ideal, indicating similar natural mortality levels among the different treatment groups before the application during full flowering (no statistical significant difference of the colonies, Student t-test, pairwise comparison to the control, two-sided, α = 0.05). On the day of the 2nd test item application and the corresponding applications in the control group and in the reference item group, respectively, mortality rates were slightly higher in the test item group (27.3) compared to the control (19.7), but the number of dead bees found on the day of application in the test item treated group was not statistically significantly increased compared to the control (Student t-test, pairwise comparison, α = 0.05, one-sided greater). Until the end of the confined exposure period, at each assessment day following the 2nd test item application and the corresponding applications in the control group and in the reference item group, respectively, the number of dead bees found in the test item treated tunnels were on a comparable level as the number of dead bees found in the control group. There was no statistical significant difference to the control group (Student t-test, pairwise comparison, one-sided greater, α = 0.05) at any assessment day.

An overall comparison of the mean dead bees found in the traps and on the gauze after the full-flowering application from day 0 to day 7 did also not show a statistical significant difference between the control and the fluopyram + trifloxystrobin SC 500 (250+250) G - treatment (Student t-test, pairwise comparison, one-sided greater, α = 0.05). A mean of 35.4 dead bees per day and tunnel was found for the period from day 0 to day 7 after treatment in the test item group, whereas a mean of 33.5 dead bees were found in the control group.
In contrast to the observations in the test item treatment group and the control group, application of the reference item (dimethoate at a rate of 600 g a.s./ha) resulted in a markedly increased number of dead bees found in the traps and on the gauze strips in the crop between day 0 and day 4, which was statistically significant different from the control (Student t-test, pairwise comparison, α = 0.05, one-

sided greater). Mortality increased up to ca. 24 x the levels of the control values on day 1 following the application.

Foraging Activity

After the 2nd test item application of fluopyram + trifloxystrobin SC 500 (250+250) G, the foraging activity of the bees was comparable or even higher in the test item treatment group compared to the control group. An overall comparison of the mean flight activity did not show a statistical significant difference between the control and the test item treatment (Student t-test, pair-wise comparison to the control, one-sided smaller, $\alpha = 0.05$).
In contrast, the application of the reference item (dimethoate) resulted in a clear decrease of flight intensity until the end of the confined exposure period (day 7), which was statistically significantly lower compared to the control (Student t-test, pairwise comparison, one-sided smaller, $\alpha = 0.05$).

Behavioural Abnormalities

No behavioural abnormalities occurred in the fluopyram + trifloxystrobin SC 500 (250+250) G and in the control group at any assessment day, respectively.
The reference item treatment caused behavioural abnormalities (moving coordination problems, abnormal cleaning) at least until the first day following application.

Brood Assessment

Over the entire assessment period of 42 days (i.e. over a period comprising two complete honey bee brood cycles) following the 2nd test item application and the corresponding applications in the control group and in the reference item group, respectively, the proportions of the different brood stages (eggs, larvae, pupae) fluctuated according to a normal development pattern in the control and in test item treated group, respectively. The observed variability of different brood stages was typical and followed a natural pattern. The total number of brood cells (i.e. sum of eggs + larvae + pupae) in the fluopyram + trifloxystrobin SC 500 (250+250) G treatment group was not statistically significantly different to the control group at any assessment date. Overall, no adverse effects of the test item on honey bee brood have been observed throughout the study. All queens in the respective colonies of the three experimental groups were either directly observed during all colony assessments or at least a sufficient amount of freshly laid eggs was observed during the assessments, as a clear sign of the presence of a healthy queen.

Strength of the Colonies

The mean number of honey bees per colony in all test item groups including the colonies to be used for residue analysis was very similar six days before application and did not differ statistically (mean of 2280 to 2625 per colony). The subsequent development of the colony strength among the colonies in the control and test item treatment groups followed the same pattern. There was no statistical significant difference in the colony strength between the test item treated colonies and the control colonies at any assessment date. Overall, no adverse effects of the test item on colony strength and population development have been observed throughout the study.

Conclusions:

In order to assess the risk of fluopyram + trifloxystrobin SC 500 (250+250) G to honey bees and honey bee colonies, honey bees were exposed under the realistic but severe (forced) exposure conditions of a semi-field test (confinement in gauze tunnels). The test item was applied two times to the highly bee attractive surrogate crop *Phacelia tanacetifolia*, the 1st test item application was conducted at BBCH 59 - 61, just at the beginning of the flowering period, without honey bees present. The 2nd test item application was conducted concurrently to a tap water (control group) and a reference item application (reference item group) during honey bees actively foraging on the full flowering *Phacelia* crop (BBCH 64 - 65). Both test item applications were conducted at a rate of 560 mL of fluopyram + trifloxystrobin SC 500 (250+250) G in 400 L water/ha (corresponding to nominally 140 g a.s. fluopyram/ha + 140 g a.s. trifloxystrobin/ha).

No adverse effects on mortality, foraging activity, behaviour, nectar- and pollen storage, brood-abundance and development, colony strength as well as on queen survival were observed. Based on the results of this study, it can be concluded that fluopyram + trifloxystrobin SC 500 (250+250) G does not adversely affect honey bees and honey bee colonies when applied at a rate of 560 mL during honey bees actively foraging on a bee-attractive, flowering crop.

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, [redacted] et al. 2000[5]).

In the first Annex I listing process non-target arthropod data for two formulations of trifloxystrobin have been submitted and have been evaluated. The formulation TFS EC 125 (Twist) is no longer supported, but the available non-target arthropod data for this formulation are provided as supportive information in the two tables below followed by a table with the NTA data for TFS WG 50 (Flint) which is the representative formulation for the Annex I renewal.

Table 10.3.2- 1: Non-target arthropod studies for Trifloxystrobin EC 125 (Studies were submitted and evaluated during the first Annex I listing process.)

Test species, Dossier-file-No., reference	**Tested Formulation, study type, exposure**	**Ecotoxicological Endpoint**	
Aphidius colemani M-052698-01-1 Rep.No: 963577A [redacted], 1997 KCA 8.3.2/09	TFS EC 125 Laboratory, glass plates 250 g a.s./ha	Corr. Mortality [%] 100	Effect on Reproduction [%] n.a.
Aphidius colemani M-052721-01-1 Rep.No: 963577B [redacted], 1997 KCA 8.3.2/10	TFS EC 125 Laboratory, glass plates 500 g a.s./ha	Corr. Mortality [%] 100	Effect on Reproduction [%] n.a.
Aphidius rhopalosiphi M-031787-01-1 Rep.No: 983761 [redacted], 1998 KCA 8.3.2/11	TFS EC 125 Extended lab., exposure on potted barley plants 10 g a.s./ha 250 g a.s./ha 500 g a.s./ha	Corr. Mortality [%] 3.5 100 100	Effect on Reproduction [%] 20.3 n.a. n.a.
Aphidius rhopalosiphi M-049052-01-1 Rep.No: NOV-99-17 [redacted] 1999 KCA 8.3.2/12	TFS EC 125 Semi-field study, winter wheat, application interval 13 days 2 x 12.5 g a.s./ha 2 x 250 g a.s./ha	Effect on Activity [%] 30 25	Effect on Reproduction [%] -20.4 A -10.2 A
Typhlodromus pyri M-052259-01-1 Rep.No: 972001 [redacted], 1997 KCA 8.3.2/04	TFS EC 125 Laboratory, extended lab. exposure on bean leaves 250 g a.s./ha 500 g a.s./ha	Corr. Mortality [%] 74.1 92.9	Effect on Reproduction [%] 35.3 n.a.

5 [redacted] 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-051235-01-1 Rep.No: 3900063 [redacted], 1998 KCA 8.3.2/05	TFS EC 125 Laboratory, glass plates 10 g a.s./ha 250 g a.s./ha 500 g a.s./ha	Corr. Mortality [%] / Effect on Reproduction [%] -4.9 [B] / -16.5 [A] 3.7 / -6.6 [A] 12.4 / 67.3
Chrysoperla carnea M-048976-01-1 Rep.No: 983760 [redacted], 2000 KCA 8.3.2/21	TFS EC 125 Laboratory, glass plates Control 10 g a.s./ha 250 g a.s./ha 500 g a.s./ha	Corr. Mortality [%] / Eggs/ female/day / Hatching [%] - / 9.3 / 91.4 2.5 / 14.9 / 94.9 15 / 13.6 / 93.6 15 / 16.3 / 92.7
Coccinella septempunctata M-050382-01-1 Rep.No: 97-166-1008 [redacted] 1997 KCA 8.3.2/15	TFS EC 125 Laboratory, glass plates Control 250 g a.s./ha	Corr. Mortality [%] / Fertile Eggs/ Female/Day / Hatching [%] - / 5.4 / 43.6 26.1 / 7.2 / 58.2
Coccinella septempunctata M-050966-01-1 Rep.No: 97-174-1008 [redacted] 1997 KCA 8.3.2/16	TFS EC 125 Laboratory, glass plates Control 500 g a.s./ha	Corr. Mortality [%] / Fertile Eggs/ Female/Day / Hatching [%] - / 5.4 / 43.6 39.1 / 3.5 / 49.1
Poecilus cupreus M-051762-01-1 Rep.No: 963578A [redacted], 1997 KCA 8.3.2/26	TFS EC 125 Laboratory, spray deposits on quartz sand 250 g a.s./ha	Corr. Mortality [%] / Effect on Feeding rate [%] 0 / 0
Poecilus cupreus M-051767-01-1 Rep.No: 963578B [redacted], 1997 KCA 8.3.2/27	TFS EC 125 Laboratory, spray deposits on quartz sand 500 g a.s./ha	Corr. Mortality [%] / Effect on Feeding rate [%] 0 / 0
Aleochara bilineata M-049724-01-1 Rep.No: 97-177-1008 [redacted] 1997 KCA 8.3.2/28	TFS EC 125 Laboratory, spray deposits on quartz sand 250 g a.s./ha	Effect on Reproduction [%] 17.1
Aleochara bilineata M-050424-01-1 Rep.No: 97-178-1008 [redacted] 1997 KCA 8.3.2/29	TFS EC 125 Laboratory, spray deposits on quartz sand 500 g a.s./ha	Effect on Reproduction [%] 9.0

[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.
n.a.: not assessed

Table 10.3.2- 2: New non-target arthropod study for Trifloxystrobin EC 125 (The study was not available during the first Annex I listing process and is provided here as additional information.)

Test species, Dossier-file-No., reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Typhlodromus pyri M-078388-01-1 Rep.No: B105TPE [redacted], 2003 KCA 8.3.2.2/06	TFS EC 125 Extended lab., exposure on detached cowpea leaves 4.7 g a.s./ha 22.4 g a.s./ha 106 g a.s./ha 250 g a.s./ha 500 g a.s./ha	LR_{50} > 500 g a.s./ha; ER_{50} > 500 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 1 / 15 2 / -13 [A] 35 / 19 15 / 10 36 / 27

[A]: A negative value indicates a higher reproduction rate in the treatment than in the control.

Table 10.3.2- 3: Trifloxystrobin WG 50 (current representative formulation), (Studies were submitted and evaluated during the first Annex I listing process.)

Test species, Dossier-file-No., reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Aphidius colemani M-034654-01-1 Rep.No: 963617A [redacted].; 1997 KCP 10.3.2.1/10	TFS WG 50 Laboratory, glass plates 250 g a.s./ha	LR_{50} > 250 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 7.5 / -25.8 [A]
Aphidius colemani M-034667-01-1 Rep.No: 963617B [redacted], C.; 1997 KCP 10.3.2.1/11	TFS WG 50 Laboratory, glass plates 500 g a.s./ha	**LR_{50} > 500 g a.s./ha** Corr. Mortality [%] / Effect on Reproduction [%] 12.5 / 14.7
Typhlodromus pyri M-048971-01-1 Rep.No: 981048048 [redacted]1999 KCP 10.3.2.1/03	TFS WG 50 Laboratory, glass plates 31 g a.s./ha 192 g a.s./ha 383 g a.s./ha	**LR_{50} > 383 g a.s./ha** Corr. Mortality [%] / Effect on Reproduction [%] 1 / -14 [A] 2 / 19 3 / 21
Typhlodromus pyri M-032704-01-1 Rep.No: 963620A [redacted], B.; 1997 KCP 10.3.2.1/06	TFS WG 50 Extended Lab., exposure on detached bean leaves 250 g a.s./ha	LR_{50} > 250 g a.s./ha Corr. Mortality [%] / Effect on Reproduction [%] 7.1 / 6.9
Typhlodromus pyri M-032708-01-1 Rep.No: 963620B [redacted], B.; 1997 KCP 10.3.2.1/07	TFS WG 50 Extended Lab., exposure on detached bean leaves 500 g a.s./ha	**LR_{50} > 500 g a.s./ha** Corr. Mortality [%] / Effect on Reproduction [%] -1.2 [B] / 5.2

Test species, Dossier-file-No., reference	**Tested Formulation, study type, exposure**	**Ecotoxicological Endpoint**
Chrysoperla carnea M-048967-01-1 Rep.No: 98 10 48 049 [redacted] 1999 KCP 10.3.2.1/02	TFS WG 50 Laboratory, glass plates Control 31 g a.s./ha 192 g a.s./ha 383 g a.s./ha	**LR_{50} > 383 g a.s./ha** Corr. Mortality [%] / Eggs/Female / Hatching [%] Control: - / 230.1 / 64 31: 4 / 230.8 / 63 192: 4 / 179.9 / 59 383: 4 / 222.1 / 58
Coccinella septempunctata M-034674-01-1 Rep.No: 97-175-1008 [redacted].; 1997 KCP 10.3.2.1/12	TFS WG 50 Laboratory, glass plates 1[st] test: Control 250 g a.s./ha 2[nd] test: Control 250 g a.s./ha	LR_{50} > 250 g a.s./ha Corr. Mortality [%] / Fertile Eggs/ Female/Day / Hatching [%] 1st test Control: - / 5.4 / 43.6 250: 30.4 / 3.8 / 48.9 2nd test Control: - / 11.5 / not reported 250: 2.13 / 6.6 / not reported
Coccinella septempunctata M-034677-01-1 Rep.No: 97-176-1008 [redacted].; 1997 KCP 10.3.2.1/13	TFS WG 50 Laboratory, glass plates 1[st] test: Control 500 g a.s./ha 2[nd] test: Control 500 g a.s./ha	**LR_{50} > 500 g a.s./ha** Corr. Mortality [%] / Fertile Eggs/ Female/Day / Hatching [%] 1st test Control: - / 5.4 / 43.6 500: 13 / 7.8 / 67.6 2nd test Control: - / 11.5 / not reported 500: 8.7 / 9.0 / not reported
Poecilus cupreus M-032697-01-1 Rep.No: 963618A [redacted], M.; 1997 KCP 10.3.2.1/04	TFS WG 50 Laboratory, spray deposits on quartz sand 250 g a.s./ha	LR_{50} > 250 g a.s./ha Corr. Mortality [%] / Effect on Feeding rate [%] 0 / 2.3
Poecilus cupreus M-032701-01-1 Rep.No: 963618B [redacted], M.; 1997 KCP 10.3.2.1/05	TFS WG 50 Laboratory, spray deposits on quartz sand 500 g a.s./ha	LR_{50} > 500 g a.s./ha Corr. Mortality [%] / Effect on Feeding rate [%] 0.0 / 1.1
Orius laevigatus M-032718-01-1 Rep.No: 963619A [redacted], C., 1997 KCP 10.3.2.1/08	TFS WG 50 Laboratory, glass plates 250 g a.s./ha	LR_{50} < 250 g a.s./ha Corr. Mortality [%] 100
Orius laevigatus M-032725-01-1 Rep.No: 963619B [redacted], C., 1997 KCP 10.3.2.1/09	TFS WG 50 Laboratory, glass plates 500 g a.s./ha	LR_{50} < 500 g a.s./ha Corr. Mortality [%] 100

Test species, Dossier-file-No., reference	Tested Formulation, study type, exposure	Ecotoxicological Endpoint		
Orius laevigatus	TFS WG 50	**LR_{50} 21.6 g a.s./ha**		
M-048955-01-1	Extended lab., spray deposits	Corr.	Effect on	Effect on
Rep.No: 2003647	on detached bean leaves	Mortality [%]	Fecundity [%]	Fertility [%]
[redacted], B.; 2000	6 g a.s./ha	4.3	-19.8 [C]	-0.1 [D]
KCP 10.3.2.1/01	13 g a.s./ha	27.7	-7.4 [C]	0.2
	25 g a.s./ha	74.5	n.a.	n.a.
	51 g a.s./ha	66.0	n.a.	n.a.
	102 g a.s./ha	87.2	n.a.	n.a.
	204 g a.s./ha	95.7	n.a.	n.a.
	407 g a.s./ha	95.7	n.a.	n.a.
	814 g a.s./ha	100	n.a.	n.a.
Aged Residue Studies				
Coccinella septempunctata	TFS WG 50			
M-048983-01-1	Aged residues, spray deposits on potted grapevine plants under semi-field conditions,			
Rep.No: 1047.074.375	3 appl. of 38 or 192 g a.s./ha			
[redacted]. M.; 2000	(2 test rates), interval: 10-14d			
KCP 10.3.2.1/14				
	Control	Corr. Mortality [%]	Fertile Eggs/Female/Day	Hatching [%]
	Residues aged for 0 days:	-	7.7	85.2
	Residues aged for 14 days:	-	9.3	93.3
	Residues aged for 28 days:	-	9.5	91
	3 x 38 g a.s./ha			
	Residues aged for 0 days:	13.0	2.3	78.2
	Residues aged for 14 days:	4.6	6.6	89.2
	Residues aged for 28 days:	-6.5 [B]	11.1	87.9
	3 x 192 g a.s./ha			
	Residues aged for 0 days:	13.0	4.3	80.3
	Residues aged for 14 days:	22.7	7.1	82
	Residues aged for 28 days:	0.0	12.1	83.5

Test species, Dossier-file-No., reference	**Tested Formulation, study type, exposure**	**Ecotoxicological Endpoint**				
Orius laevigatus M-031775-01-1 Rep.No: 983624 [redacted] M. P.; 1998 KCP 10.3.2.1/15	TFS WG 50 Semi-field study with aged residues, spray deposits on potted grapevine plants, 6 appl., interval: 7-10 d, 2 appl. rates (15.1 and 189 g a.s./ha)		Mortality [%]	Eggs/Female/Day		
	Control	0DAT6:	82.0	4.1		
		14DAT6:	22.0	7.9		
		30DAT6:	6.0	6.2		
	6 x 15.1 g a.s./ha	0DAT6:	66.0	3.7		
		14DAT6:	55.0	7.5		
		30DAT6:	2.0	5.9		
	6 x 189 g a.s./ha	0DAT6:	99.0	n.a.		
		14DAT6:	62.0	7.0		
		30DAT6:	11.0	5.1		
			Corr. Mortality [%]	Effect on Fecundity [%]		
	6 x 15.1 g a.s./ha	0DAT6:	-88.9 [B] (invalid)	9.8		
		14DAT6:	42.3	5.1		
		30DAT6:	-4.3 [B]	-4.8		
	6 x 189 g a.s./ha	0DAT6:	94.4 (invalid)	n.a.		
		14DAT6:	51.3	11.4		
		30DAT6:	5.3	17.7		
Field Studies						
Typhlodromus pyri *Kampimodromus aberrans* (predatory mites) M-048963-01-1 Rep.No: 983824 [redacted] M.P.; 1999 KCP 10.3.2.4/01	TFS WG 50 Field study in vineyard, 6 applications at 2 application rates: max. in-field and 3m drift rate (7.5% max. rate), 8-13 d interval Max. in-field application rate (per application): 1st 50, 2nd 76, 3rd 101, 4th 126, 5th 151 and 6th 189 g a.s./ha	No significant effects on in-field and off-field predatory mite populations.				
		Abbott effect	Max. in-field rate [%]	3m drift rate [%]		
		5 DAT1	0.6	1.2		
		7 DAT1	-29.9 [E]	-1 [E]		
		10 DAT2	34.3	34.3		
		7 DAT3	31.1	13.7		
		11 DAT5	-2.1 [E]	-34.5 [E]		
		7 DAT6	-14.3 [E]	-19.9 [E]		
		30 DAT6	26.2	36.5		
		56 DAT6	7	19.1		
Anthocoris sp. (predatory bugs) M-066641-01-1 Rep.No: 20020123193SE046 GEP [redacted].; 2002 KCP 10.3.2.4/02	TFS WG 50 2 field studies in pear orchards, 4 appl. of 75 g a.s./ha, 5-6 d spray interval; sampling by knocking	No significant effects by ANOVA Duncan				
			Study 1: Mean no. nymphs	Study 1: Mean no. adults	Study 2: Mean no. nymphs	Study 2: Mean no. adults
	1 DAT2	Control	14.8	2.3	14.8	0.8
		75 g a.s./ha	9.3	4.0	13.5	1.3
	7 DAT4	Control	3.8	11.5	0.0	2.0
		75 g a.s./ha	0.5	9.0	0.3	1.8

[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 fecundity in the treatment than in the control.

[D]: A negative value indicates a higher fertility in the treatment than in the control.
[E]: A negative value indicates a higher abundance in the treatment than in the control.
DAT: days after treatment
n.a.: not assessed

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

Table 10.3.2- 4: 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 (early)	*T. pyri*	75	2.3	383	0.5	2
	A. rhopalosiphi	75	2.3	500	0.3	2
Orchards (late)	*T. pyri*	112.5	2.3	383	0.7	2
	A. rhopalosiphi	112.5	2.3	500	0.5	2
Strawberries	*T. pyri*	150	1.7	383	0.7	2
	A. rhopalosiphi	150	1.7	500	0.5	2
Grapes (late)	*T. pyri*	125	2.3	383	0.6	2
	A. rhopalosiphi	125	2.3	500	0.8	2

Table 10.3.2- 5: Tier 1 off-field risk assessment for non-target arthropods

Crop	Species	Appl. rate [g/ha]	MAF	Drift [%]	VDF	Correction factor	LR_{50} [g/ha]	HQ	Trigger
Orchards (early)	*T. pyri*	75	2.3	23.96	10	10	383	0.11	2
	A. rhopalosiphi	75	2.3	23.96	10	10	500	0.08	2
Orchards (late)	*T. pyri*	112.5	2.3	11.01	10	10	383	0.07	2
	A. rhopalosiphi	112.5	2.3	11.01	10	10	500	0.06	2
Strawberries	*T. pyri*	150	1.7	2.38	10	10	383	0.02	2
	A. rhopalosiphi	150	1.7	2.38	10	10	500	0.01	2
Grapes (late)	*T. pyri*	125	2.3	6.9	10	10	383	0.05	2
	A. rhopalosiphi	125	2.3	6.9	10	10	500	0.04	2

The tier 1 in-field and off-field risk assessment does not trigger a concern. Nevertheless, a tier 2 risk assessment is provided below to address potential concerns due to the observed sensitivity of *Orius laevigatus*.

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

Table 10.3.2- 6: 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 (early) / 3	75	2.3	173
Orchards (late) / 3	112.5	2.3	259
Strawberries / 2	150	1.7	255
Grapes / 3	125	2.3	288

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

Crop	Species	In-field PEC_{max} [g/ha]	LR_{50} [g/ha]	Risk acceptable if	Refined risk assessment required
Orchards (early)	*T. pyri*	173	>500	Effects are < 50%	No
	A. colemani		>500	Effects are < 50%	No
	C. carnea		>383	Effects are < 50%	No
	C. septempunctata		>500	Effects are < 50%	No
	O. laevigatus		21.6	Effects are < 50%	**Yes**
Orchards (late)	*T. pyri*	259	>500	Effects are < 50%	No
	A. colemani		>500	Effects are < 50%	No
	C. carnea		>383	Effects are < 50%	No
	C. septempunctata		>500	Effects are < 50%	No
	O. laevigatus		21.6	Effects are < 50%	**Yes**
Strawberries	*T. pyri*	255	>500	Effects are < 50%	No
	A. colemani		>500	Effects are < 50%	No
	C. carnea		>383	Effects are < 50%	Yes
	C. septempunctata		>500	Effects are < 50%	No
	O. laevigatus		21.6	Effects are < 50%	**Yes**
Grapes	*T. pyri*	288	>500	Effects are < 50%	No
	A. colemani		>500	Effects are < 50%	No
	C. carnea		>383	Effects are < 50%	No
	C. septempunctata		>500	Effects are < 50%	No
	O. laevigatus		21.6	Effects are < 50%	**Yes**

The results of the tier 2 in-field risk assessments indicate no concern for non-target arthropod species with sensitivity like *Typhlodromus, Aphidius, Chrysoperla*, or *Coccinella* but initial effects in the in-field area on non-target arthropod species with sensitivity like *Orius* are to be expected. Therefore, a further evaluation is required.

Refined* in-field risk assessment for *Orius laevigatus

The tier 2 risk assessment indicates that initial effects on *Orius laevigatus* are to be expected. To demonstrate the potential for recovery an aged residue study has been conducted under semi-field conditions ([redacted] 1998; reference KCP 10.3.2.4/01). In this study the product was applied 6 times to potted grapevines at rates of 15 and 187.5 g a.s./ha at intervals of 7-10 days. *O. laevigatus* was exposed to dried residues on leaves at three timings: just after the last treatment (a total of 6 having been applied), 14 and 30 days after the last application. Results from the first bioassay (exposure just after the last application) are considered inconclusive due to excessive mortality (i.e. 82%) in the control. However data from the second bioassay, where residues aged 14 days were assessed, indicated that there was a significant increase in mortality compared to the control from both, the 6 × 15 and 6 × 187.5 g a.s./ha treatments. This, however, did not cause a significant effect on the reproductive capacity of *O. laevigatus*. In the third bioassay (exposure 30 days after last application), there was no effect of both, the 15 and 187.5 g a.s./ha treatments on either survival or reproductive capacity. These data indicate that whilst Trifloxystrobin WG 50 may initially cause an impact on *O. laevigatus*, the residual toxicity is transient and potential for recovery can be expected within 1 month after the last application. The maximum applied rate of 6 × 187.5 g a.s./ha as tested in the semi-field study clearly exceeds the maximum intended use pattern of 2 × 150 g a.s./ha in Strawberries, 3 ×125 g a.s./ha in grapes, or 112.5 g a.s./ha in orchards.

In addition to the aged residue study conducted with TFS WG 50 on the most sensitive species *Orius laevigatus*, several aged residue studies have been performed on the same species with different formulations containing trifloxystrobin (Table 10.3.2- 8). Table 10.3.2- 8 and Table 10.3.2- 9 show how much trifloxystrobin was applied in these studies. The rates of trifloxystrobin used exceed or are close to the worst-case in-field PECmax of 288 g a.s./ha (2.3 x 125 g a.s./ha) for the intended application of TFS WG 50.

Table 10.3.2- 8: Additional aged residue studies for *Orius laevigatus*

Test species, Dossier-file-No. Reference	**Tested Formulation, study type, exposure based on the amount of TFS in the products**	**Ecotoxicological Endpoint**		
Orius laevigatus M-103354-01-1 Rep.No: 031048084 [redacted], 2003 KCP 10.3.2.2/02	CCZ + TFS SC 535 Aged residues, spray deposits on grape-vine plants, 1 appl. of 1 L prod./ha (368 g TFS/ha)	Corrected Mortality [%]	Reduction in Fecundity [%]	Reduction in Fertility [%]
	Residues aged for 0 d:	96.2	n.a.	n.a.
	Residues aged for 14 d:	70.8	n.a.	n.a.
	Residues aged for 35 d:	10.0	6.8	14.9
Orius laevigatus M-398645-01-1 Rep. no: 10 10 48 037 A [redacted], 2011 KCP 10.3.2.2/03	IPD + TFS SC 272.4 Aged residue spray deposits on maize plants, 2 appl. of 17.0 L prod./ha (2 x 270 g TFS/ha), spray interval of 14 d	Corrected Mortality [%]	Reduction in Fecundity [%]	Reduction in Fertility [%]
	Residues aged for 0 d:	89.8	n.a.	n.a.
	Residues aged for 14 d:	89.1	n.a.	n.a.
	Residues aged for 28 d:	2.2	9.5	16.7
	Residues aged for 42 d:	-3.9[A]	2.3	19.7
Orius laevigatus M-297471-01-1 Rep.No: 07 10 48 005 A [redacted], M., 2008 KCP 10.3.2.2/04	FLU+TFS SC 500 Aged residues, spray deposits on grape vine plants, 2 appl. of 0.8 L prod/ha (2 x 197 g TFS/ha), spray interval 7d	Corrected Mortality [%]	Reduction in Fecundity [%]	Reduction in Fertility [%]
	residues aged for 0 d	96.1	n.a.	n.a.
	residues aged for 7 d	88.7	n.a.	n.a.
	residues aged for 14 d	51.9	n.a.	n.a.
	residues aged for 21 d	7.0	2.9	-1.8[C]
	residues aged for 28 d	7.3	-5.6[B]	-2.1[C]
Orius laevigatus M-001111-01-1 Rep.No: 20031276/01-NEOr [redacted]., 2004 KCP 10.3.2.2/05	PTZ + TFS SC 325 Aged residues spray deposits on maize plants, 2 appl. of 1 L prod./ha (157 g TFS/ha), spray interval 14 d	Corrected Mortality [%]	Reduction in Fecundity [%]	Reduction in Fertility [%]
	residues aged for 0 d:	82.9	n.a.	n.a.
	residues aged for 14 d:	62.6	n.a.	n.a.
	residues aged for 28 d:	23.7	7	1.1
	residues aged for 42 d:	-4.4[A]	n.a.	n.a.

[A] A negative value indicates a lower mortality rate in the treatment than in the control.
[B] A negative value indicates a higher fecundity in the treatment than in the control.
[C] A negative value indicates a higher fertility in the treatment than in the control.

Table 10.3.2- 9: Additional studies for terrestrial non-target arthropods

Formulation	Trifloxystrobin [g a.s./ha]	DAT of last bioassay with corr. mortality > 50%	DAT until effects < 50%
Study with representative formulation			
TFS WG 50	6 x 189	14 (51.3%)	30
Studies whose application rates cover all AIR3 uses			
TFS + CCZ SC 535	1 x 367.9	14 (70.8%)	35
TFS + IPD SC 272.4	2 x 270.3	14 (89.1%)	28
TFS + FLU SC 500	2 x 196.6	14 (51.9%)	21
TFS + PTZ SC 325	2 x 156.7	14 (62.6%)	28

DAT: days after last treatment
TFS: trifloxystrobin, CCZ: cyproconazole, IPD: iprodione, FLU: fluopyram, PTZ: prothioconazole

Initial adverse effects with mortality exceeding 50% in bioassays up to 14 days after application indicate that *O. laevigatus* is indeed sensitive to formulations containing trifloxystrobin. After 21 – 35 days, corrected mortality was below 50% in all studies (2.2 to 23.7%). No study showed adverse effects on reproduction. These results closely match the findings of the aged residue study with the straight trifloxystrobin formulation TFS WG 50 (no effects > 50% 30 days after application). Under the conservative assumption that all adverse effects observed in these studies with mixture products are attributed to trifloxystrobin, the potential for recovery for the most sensitive species *O. laevigatus* is given within three to five weeks. This confirms the conclusion that the potential for recovery is given and no unacceptable in-field risk has to be expected for non-target arthropods from the use of TFS WG 50 according to the proposed use pattern.

Tier 2 off-field exposure assessment for other non-target arthropods

Table 10.3.2- 10: Exposure assessment for off-field risk assessment (Tier 2)

Appl. rate [g a.s./ha]	MAF	Drift [%]	Veg. distr. factor	Correction factor	off-field $PEC_{max.}$ [g a.s./ha]	Remark
Orchards (early)						
75	2.3	23.96	10	5	20.7	in case of 2-D study design
Orchards (late)						
112.5	2.3	11.01	10	5	14.2	in case of 2-D study design
Strawberries						
150	1.7	2.38	10	5	3.0	in case of 2-D study design
Grapes (late)						
125	2.3	6.9	10	5	9.9	in case of 2-D study design

Table 10.3.2- 11: Risk assessment for terrestrial non-target arthropods for the off-field scenario

Crop	Species	Study design	Off-field PEC_{max} [g/ha]	LR_{50} [g/ha]	Risk acceptable if	Refined risk assessment required?
Orchards (early)	*T. pyri*	2D	20.7	>500	Effects are < 50%	No
	A. colemani	2D		>500	Effects are < 50%	No
	C. carnea	2D		>383	Effects are < 50%	No
	C. septempunctata	2D		>500	Effects are < 50%	No
	O. laevigatus	2D		21.6	Effects are < 50%	No
Orchards (late)	*T. pyri*	2D	14.2	>500	Effects are < 50%	No
	A. colemani	2D		>500	Effects are < 50%	No
	C. carnea	2D		>383	Effects are < 50%	No
	C. septempunctata	2D		>500	Effects are < 50%	No
	O. laevigatus	2D		21.6	Effects are < 50%	No
Strawberries	*T. pyri*	2D	3.0	>500	Effects are < 50%	No
	A. colemani	2D		>500	Effects are < 50%	No
	C. carnea	2D		>383	Effects are < 50%	No
	C. septempunctata	2D		>500	Effects are < 50%	No
	O. laevigatus	2D		21.6	Effects are < 50%	No
Grapes	*T. pyri*	2D	9.9	>500	Effects are < 50%	No
	A. colemani	2D		>500	Effects are < 50%	No
	C. carnea	2D		>383	Effects are < 50%	No
	C. septempunctata	2D		>500	Effects are < 50%	No
	O. laevigatus	2D		21.6	Effects are < 50%	No

The tier 2 off-field risk assessment indicates that no unacceptable adverse effects on non-target arthropods in the off-field area are to be expected from the use of TFS WG 50.

Based on the presented data and risk assessment it can be concluded that the use of Trifloxystrobin WG 50 according to the intended use pattern does not result in unacceptable adverse effects on non-target arthropods in the in-field or off-field area.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

No new studies are required.

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

Report:	**KCP 10.3.2.2/02, [redacted] M. 2003**
Title:	Toxicity of Trifloxystrobin & Cyproconazole SC 535 to the predatory bug *Orius laevigatus* (Fieber) (Heteroptera: Anthocoridae) under extended laboratory conditions using semi-field-aged residues on grape-vine.
Report No:	031048084
Document No:	M-103354-01-1
Guidelines:	IOBC Guideline (Bakker et al. 2000), modified
Deviations:	None
GLP:	Yes (certified laboratory)

Objective:

The purpose of this study was to determine the effects of fresh and aged residues of the test item on the survival and reproduction of the predatory bug *Orius laevigatus* (FIEBER) under extended laboratory conditions using semi-field aged residues.

Materials and methods:

Fresh and aged residues of the test item Sphere 535 SC (156.04 g/L Cyproconazole & 367.90 g/L Trifloxystrobin; specification: Article No.: 0005907403, Batch: 08140/0034(0032), TOX No.: 6387-00) were tested under extended laboratory conditions on the predatory bug *Orius laevigatus* after contact exposure on leaf discs prepared from semi-field sprayed grape-vines with aged residues. Endpoints were the mortality of exposed nymphs and the reproductive performance of adult bugs compared to control after exposure on day 0, 14 and 35 after application. Statistical significance of differences to the control was evaluated with Chi^2-Test (mortality) and STUDENT t-test (reproduction), with a = 0.05.

Results:

Effects on the predatory bug (*Orius laevigatus*) exposed to Trifloxystrobin & Cyproconazole SC 535 in an extended laboratory test under semi-field conditions.

Treatment group/ Application rate	**Surviving nymphs/ adults**	Mortality		**Eggs/ female/ day**[x]	Viable eggs/ female/ day[x]	Hatched nymphs/ egg	**Reduction in**	
		absolute	Corrected (according to Abbott)				**fecund-dity**	**fertility**
(L/ha)	**(no.)**	**(%)**	**(%)**	(mean no)	**(mean**	**(%)**	**(%)**	**(%)**
				1st bioassay (DAT 0)				
Control	53	11.7	-	-	-	-	-	-
Toxic reference Dimethoate EC 400 (0.08 L/ha)	0	100*	100	-	-	-	-	-
Test item Sphere 535 SC (1.0 L/ha)	2	96.7*	96.2	-	-	-	-	-
				2nd bioassay (DAT 14)				
Control	48	20.0	-	-	-	-	-	-
Toxic reference Dimethoate EC 400 (0.08 L/ha)	0	100*	100	-	-	-	-	-
Test item (1.0 L/ha)	14	76.7*	70.8	-	-	-	-	-
				3rd bioassay (DAT 35)				
Control	50	16.7	-	5.4	5.6	83.9	-	-
Toxic reference Dimethoate EC 400 (0.08 L/ha)	0	100*	100	-	-	-	-	-
Test item (1.0 L/ha)	45	25.0	10.0	5.0	4.8	85.5	6.8	14.9

* Statistically significant ($p<0.05$)

Observations:

During three successive bioassays started on DAT 0, 14 and 35 and with an exposure period of 11, 11 and 9 days, mortalities of 11.7, 20.0 and 16.7 % and 96.7, 76.7 and 25.0 % were recorded for the control and at a test item application rate of 1.0 L/ha, respectively. The exposure on DAT 0, 14 and 35 resulted in a corrected mortality according to Abbott of 96.2, 70.8 and 10.0 % at the test item application rate of 1.0 L/ha, respectively. No statistically significant effect on survival was found for the test item application rate of 1.0 L/ha after exposure of *Orius laevigatus* nymphs on residues aged on grape-vine leaves for 35 days.

After exposure of *Orius laevigatus* nymphs on the day of application and to 14 days aged residues of Sphere 535 SC, applied at an application rate of 1 L/ha, the assessed mortality of 96.7 and 76.7 % was statistically significantly higher than observed in the control.

After exposure on DAT 35 the mean daily oviposition was 5.4 and 5.0 eggs/female/day in the control and in the 1.0 L/ha treatment level, respectively.

The mean percent hatching rate of eggs laid during the oviposition period after exposure on DAT 35 was 83.9 and 85.5 % in the control and in the 1.0 L/ha treatment level, respectively. No statistically significant effects in the average number eggs/female/day or the hatching rate were found between the control and the 1.0 L/ha treatment level. Due to high mortality observed at 1.0 L/ha during the exposure phase started on DAT 0 and 14, no reproduction phase test was conducted. The reference

item Dimethoate EC 400 was applied at 0.08 L product/ha (equivalent to 32.1 g a.s./ha) on DAT 0,14 and 35 and caused 100, 100 and 100 % nymphal mortality, relative to control.
The validity criteria were accomplished.

Conclusion:

The exposure to 35 days aged residues of Sphere 535 SC applied on grape-vine resulted in 10 % mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were reduced by 6.8 % and 14.9 %, respectively, relative to control.

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Report:	**KCP 10.3.2.2/03, [redacted] M. 2011**
Title:	Toxicity of Iprodione + Trifloxystrobin SC 272.4 (256.4 + 16 g/L) to the predatory bug *Orius laevigatus* (Fieber) (Heteroptera: Anthocoridae) under extended laboratory conditions using semi-field-aged residues on maize
Report No:	10 10 48 037 A
Document No:	M-398645-01-1
Guidelines:	IOBC (BAKKER et al. 2000) modified for the exposure on natural substrate
Deviations:	None
GLP:	Yes (certified laboratory)

Objective:

The purpose of this study was to determine the effects of fresh and aged residues of the test item on the survival and reproduction of the predatory bug *Orius laevigatus* (FIEBER) under extended laboratory conditions using semi-field aged residues.

Materials and methods:

Aged residues of the test item Iprodione + Trifloxystrobin SC 272.4 [analysed active ingredients: 263.1 g/L (23.7 % w/w) Iprodione; 15.9 g/L (1.43 % w/w) Trifloxystrobin, Specification No.: 102000021104, Batch No.: NK43AX0041, Material No.: 79653646, density: 1.11 g/cm^3] were tested under extended laboratory conditions on the predatory bug *Orius laevigatus* after contact exposure on leaf discs prepared from semi-field sprayed maize. Endpoints were the mortality of exposed nymphs and the reproductive performance of adult bugs compared to control after exposure starting on day 0, 14, 28 and 42 after last application. Statistical significance of differences to the control was evaluated with Chi^2-Test (mortality) and Student t-test (reproduction), with $\alpha = 0.05$.
Application rate in the test was 2 applications each with an application rate of 17.0 L product/ha with an application interval of 14 days.
Four bioassays were conducted with an exposure period of 11 days each, initiated on the day of the 2nd (last) application (DAT 0, bioassay 1), 14 days after the last application (DAT 14, bioassay 2), 28 days after the last application (DAT 28, bioassay 3), and 42 days after the last application (DAT 42, bioassay 4).

Results:

Effects on the predatory bug (*Orius laevigatus*) exposed to Iprodione & Trifloxystrobin SC 272.4 in an extended laboratory test under semi-field conditions.

Treatment group/ Application rate	Surviving nymphs/ adults	Mortality		Eggs/ female/ day	Viable eggs/ female/ day	Hatched nymphs/ egg	Reduction in	
		absolute	Corrected (according to Abbott)				fecund-dity	fertility
(L/ha)	(no.)	(%)	(%)	(mean no)	(mean no)	(%)	(%)	(%)
1st bioassay (DAT 0)								
Control	49	18.3	-	-	-	-	-	-
Toxic reference)	0	100*	100	-	-	-	-	-
Test item (2x17 L/ha)	5	91.7*	89.8	- (a)	-	-	-	-
2nd bioassay (DAT 7)								
Control	46	23.3	-	-	-	-	-	-
Toxic reference)	0	100*	100	-	-	-	-	-
Test item (2x17 L/ha)	5	91.7*	89.1	- (a)	-	-	-	-
3rd bioassay (DAT 14)								
Control	46	23.3	-	3.9	3.2	92.5	-	-
Toxic reference)	3	95.0*	93.5	-	-	-	-	-
Test item (2x17 L/ha)	45	25.0	2.2	3.5	2.7	89.9	9.5	16.7
4th bioassay (DAT 21)								
Control	51	15.0	-	4.4	3.9	87.8	-	-
Toxic reference)	3	95.0*	94.1	-	-	-	-	-
Test item (2x17 L/ha)	53	11.7	-3.9	4.3	3.1	91.6	2.3	19.7

* Statistically significant ($p \leq 0.05$)
(a) no reproduction phase conducted due to high mortality during the exposure period
(negative values indicating an increase compared to control)

The validity criteria (control mortality ≤ 25%, mortality for the toxic standard > 40%, reproduction performance for the control: ≤ 5 females producing no eggs, ≥ 2 eggs/female/day, hatching rate ≥ 70%) were accomplished in all 4 bioassays.

Observations:

During these successive bioassays, mortalities of 18.3, 23.3, 23.3 and 15.0% for the control and 91.7, 91.7, 25.0 and 11.7% for the test item were recorded in bioassay 1, 2, 3 and 4, respectively.
For the test item a corrected mortality (Abbott) of 89.8, 89.1, 2.2 and -3.9% was determined in the four bioassays.
Effects on reproduction were not assessed in bioassays 1 and 2. In bioassays 3 and 4 (started on DAT 28 and 42) the reproductive performance of the test item group was 16.7% and 19.7% reduced, respectively, in comparison to the control group.

The exposure to residues of Iprodione + Trifloxystrobin SC 272.4 applied on maize leaves that started on the day of the last application (DAT 0) and 14 days after the last application (14 DAT) resulted in

89.8% and 89.1% corrected mortality (Abbott) of *Orius laevigatus* nymphs until adulthood, respectively.
The exposure to 28 days aged residues (DAT 28) of Iprodione + Trifloxystrobin SC 272.4 resulted in 2.2% corrected mortality of *Orius laevigatus* nymphs until adulthood. The fecundity and fertility of the surviving adults were not statistically significant reduced compared to the control (9.5% and 16.7%, respectively).
The exposure to 42 days aged residues (DAT 42) of Iprodione + Trifloxystrobin SC 272.4 applied on maize leaves resulted in -3.9 % corrected mortality of *Orius laevigatus* nymphs until adulthood. The fecundity and fertility of the surviving adults were not statistically significant reduced compared to the control (2.3% and 19.7%, respectively).

The toxic reference item perfekthion EC 400 was applied at 0.08 L product/ha (equivalent to 33.2 g a.s./ha) on DAT 0 and at 0.02 L product/ha (equivalent to 8.3 g a.s./ha) on DAT, 14, 28 and 42 and caused 100, 100, 93.5 and 94.1% nymphal mortality, relative to control.

Conclusion:

In conclusion, potential for recovery was demonstrated 28 days after the last application.

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Report:	**KCP 10.3.2.2/04, [redacted] M. 2008**
Title:	Toxicity of AE C656948 & Trifloxystrobin SC 250 + 250 to the predatory bug *Orius laevigatus* (FIEBER) (Heteroptera: Anthocoridae) under extended laboratory conditions using semi-field-aged residues on grape-vine
Report No:	07 10 48 005 A
Document No:	M-297471-01-1
Guidelines:	IOBC (BAKKER et al. 2000) modified for the exposure on natural substrate
Deviations:	None
GLP:	Yes (certified laboratory)

Objective:

The purpose of this study was to determine the effects of fresh and aged residues of the test item on the survival and reproduction of the predatory bug *Orius laevigatus* (FIEBER) under extended laboratory conditions using semi-field aged residues.

Materials and methods:

Fresh and aged residues of the test item AE C656948 (Fluopyram) & Trifloxystrobin SC 250 + 250 (246.1 g/L Fluopyram & 245.8 g/L Trifloxystrobin; specification: No.: 102000012886, Batch: 2006-004983, TOX No.: 07762-00) were tested under extended laboratory conditions on the predatory bug *Orius laevigatus* after contact exposure on leaf discs prepared from semi-field sprayed grape-vines. Endpoints were the mortality of exposed nymphs and the reproductive performance of adult bugs compared to control after exposure on day 0, 7, 14, 21 and 28 after last application. Statistical significance of differences to the control was evaluated with Chi^2-Test (mortality) and Student t-test (reproduction), with $\alpha = 0.05$.

Application rate in the test was 2 single applications each with an application rate of 0.8 L product/ha in 300 L/ha with an application interval of 7 days resulting in a total application rate of 1.6 L/ha per season.
Five bioassays were conducted with an exposure period of 10 days each, initiated on the day of the 2nd (last) application (DAT 0, bioassay 1), 7 days after the last application (DAT 7, bioassay 2), 14 days after the last application (DAT 14, bioassay 3), 21 days after last application (DAT 21, bioassay 4) and 28 days after the last application (DAT 28, bioassay 5).

Results:

Effects on the predatory bug (*Orius laevigatus*) exposed to Fluopyram & Trifloxystrobin SC 535 in an extended laboratory test under semi-field conditions.

Treatment group/ Application rate	Surviving nymphs/ adults	Mortality		Eggs/ female/ day	Viable eggs/ female/ day	Hatched nymphs/egg	Reduction in	
		absolute	Corrected (according to Abbott)				fecund-dity	fertility
(L/ha)	(no.)	(%)	(%)	(mean no.)	(mean no.)	(%)	(%)	(%)
1st bioassay (DAT 0)								
Control	51	15.0	-	-	-	-	-	-
Toxic reference)	0	100*	100	-		-	-	-
Test item (2x0.8 L/ha)	2	96.7*	96.1	- (a)	-	-	-	-
2nd bioassay (DAT 7)								
Control	53	11.7	-	-	-	-	-	-
Toxic reference)	0	100*	100	-	-	-	-	-
Test item (2x0.8 L/ha)	6	90.0*	88.7	- (a)	-	-	-	-
3rd bioassay (DAT 14)								
Control	52	13.3	-	-	-	-	-	-
Toxic reference)	0	100*	100	-	-	-	-	-
Test item (2x0.8 L/ha)	25	58.3*	51.9	- (a)	-	-	-	-
4th bioassay (DAT 21)								
Control	57	5.0	-	6.8	5.7	89.7	-	-
Toxic reference)	0	100*	100	-	-	-	-	-
Test item (2x0.8 L/ha)	53	11.7	7.0	6.6	5.8	93.7	2.9	-1.8
5th bioassay (DAT 28)								
Control	55	8.3	-	5.4	4.8	91.4	-	-
Toxic reference)	1	98.3*	98.2	-	-	-	-	-
Test item (2x0.8 L/ha)	51	15.0	7.3	5.7	4.9	91.3	-5.6	-2.1

* Statistically significant ($p \leq 0.05$)
(a) no reproduction phase conducted due to high mortality during the exposure period
(negative values indicating an increase compared to control)

The validity criteria for the control group and the toxic standard were accomplished:

- mortality in the control group:	≤ 25 % (being 15.0, 11.7, 13.3, 5.0 and 8.3 % during 1st, 2nd, 3rd, 4th and 5th bioassay)
- mortality in the reference item:	> 40 % (being 100, 100, 100, 100 and 98.3 % during 1st, 2nd, 3rd, 4th and 5th bioassay)
- number of eggs/female/day in the control:	≥ 2.0 (being 6.8 and 5.4 during 4th and 5th bioassay)
- number of females in the control producing no eggs:	< 5 (being 1 during 4th and 5th bioassay)
- hatching rate in the control:	≥ 70 % (being 89.7 and 91.4 % during 4th and 5th bioassay)

Observations:

During the successive bioassays, mortalities of 15.0, 11.7, 13.3, 5.0 and 8.3 % and 96.7, 90.0, 58.3, 11.7 and 15.0 % were recorded for the control and the test item in bioassay 1, 2, 3, 4 and 5, respectively.
The corresponding corrected mortality (according to Abbott) in these five bioassays was calculated at 96.1, 88.7, 51.9, 7.0 and 7.3 %, respectively.
No reproduction phase was conducted in bioassays 1, 2 and 3. In bioassays 4 and 5 (started on DAT 21 and 28) the relative effect on reproductive performance was -1.8 % (increased) and -2.1 % (increased), respectively, in the test item treatment group.
The exposure to 14 days aged residues of AE C656948 & Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 51.9 % mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). No fecundity and fertility test was performed due to less numbers of surviving adults.
The exposure to 21 days aged residues of AE C656948 & Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 7.0 % mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were reduced by 2.9 % and increased by 1.8 %, respectively, relative to control.
The exposure to 28 days aged residues of AE C656948 & Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 7.3 % mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were increased by 5.6 % and 2.1 %, respectively, relative to control.
The toxic reference item perfekthion EC 400 was applied at 0.08 L product/ha (equivalent to 31.0 g a.s./ha) on DAT 0, 7, 14, 21 and 28 and caused 100, 100, 100, 100 and 98.3 % nymphal mortality, relative to control.

Conclusion:

In conclusion, potential for recovery can be considered after 14 days following the last application but was evident 21 days following the last application, with exposure to aged residues resulting effects on survival and reproduction below 50 %.

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Report:	**KCP 10.3.2.2/05; [redacted]., 2004**
Title:	Prothioconazole & Trifloxystrobin SC 325 Toxicity to the Predatory Bug *Orius laevigatus* Fieber (Heteroptera, Anthocoridae) Using an Extended Laboratory Test with Freshly Applied and Aged Residues
Report No:	20031276/01-NEOr
Document No:	M-001111-01-1
Guidelines:	IOBC Guideline (Bakker et al. 2000), modified
Deviations:	none
GLP:	Yes (certified laboratory)

Objective:

The aim of the study was to determine the effects of freshly applied and aged residues of Prothioconazole & Trifloxystrobin SC 325 on the predatory bug *Typhlodromus pyri*.

Materials and Methods:

Test item: A SC formulation of Prothioconazole & Trifloxystrobin SC 325 was tested, specified by batch number [analysed content of active ingredients: Prothioconazole: 184.64 g/L and Trifloxystrobin: 156.66 g/L; Batch number: 07996/0056(0056); sample no.: TOX06396-00; density: 1.119 g/ml].

The test item was applied with a boom sprayer to potted maize plants (*Zea mays*) two times with an interval of 14 days at a rate equivalent to 1000 mL product/ha. Perfektion (400 g/L dimethoate, nominal) was used as a toxic standard and was applied only at the 2nd application with a rate of 49.85 mL product/ha in 300 L water/ha and for the following bioassays with 31.16 mL/ha in 200 L deionised water/ha on detached maize leaves using a laboratory sprayer (Schachtner).

For both applications at the outside area of the testing facility, 40 maize plants with a grow stage of 5 to 9 leaves (BBCH 15-17 and 17-19) were used for the control and the treatment group. At the 2nd application for the toxic standard 7 maize plants at the same grow stage were used. The plot size was 33.0 m^2 for all treatment groups.

All treatment groups included 40 replicates each consisting of two nymphs of *Orius leavigatus*. When the spray layer was dry, two 2nd instar nymphs were exposed to the dried spray deposits. The preimaginal mortality was calculated 9 days after start of exposure, when 80 % were adult. The ageing of the sprayed maize plants was carried out between the first and second application and 7 days after the 2nd application under an UV-permeable rain cover. A reproduction assessment was accomplished at the 3rd bioassay, as the mortality in the treatment group was < 50 %.

For the test substance treatment group and the control treatment group in the 3rd bioassay, the pre-reproduction was carried out for 5 days. After this time, the reproduction performance of the females was determined by counting the eggs/female/day over a period of 4 days and the hatching rate was determined by counting the hatched eggs, which were stored 5 days more. The mortality in the reference treatment was above 70 % in all bioassays.

Dates of experimental work: August 18 to October 22, 2003

Results:

Validity Criteria	Recommended by the guideline	Obtained in this study
Mortality in water control	≤ 25%	5 - 15%
Corrected mortality reference item	> 40%	72.5 - 100%
Level of fecundity (eggs/female/day)	≥ 2	5.7
Level of fertility	>70%	90%

All validity criteria for the study were met

Mortality and reproduction of *Orius laevigatus* after exposure to PTZ + TFS EC 325

Test substance	**Prothioconazole & Trifloxystrobin EC 325**			
Test species	***Orius laevigatus***			
Exposure	**Maize leaves**			
Bioassay No. 1 (Day 0)	**Mortality [%] [1]**	**Corr. Mortality [%] [2]**	**Eggs/female/day**	**Hatching rate [%]**
control	5.0	-	-	-
Treatment group	83.8*	82.9	-	-
Toxic standard	96.3*	96.1	-	-
Bioassay No. 2 (Day 14)	**Mortality [%] [1]**	**Corr. Mortality [%] [2]**	**Eggs/female/day**	**Hatching rate [%]**
control	6.3	-	-	-
Treatment group	65.0*	62.6	-	-
Toxic standard	100*	100*	-	-
Bioassay No. 3 (Day 28)	**Mortality [%] [1]**	**Corr. Mortality [%] [2]**	**Eggs/female/day**	**Hatching rate [%]**
Control	10.0	-	5.7	90.0
Treatment group	31.3*	23.7	5.3	89.0
Toxic standard	100*	100	-	-
Bioassay No. 4 (Day 42)	**Mortality [%] [1]**	**Corr. Mortality [%] [2]**	**Eggs/female/day**	**Hatching rate [%]**
Control	15.0	-	-	-
Treatment group	11.3	-4.4	-	-
Toxic standard	72.5*	67.7	-	-

[1]= pre-imaginal mortality, including not recovered, moribund and dead nymphs
[2]= corrected mortality, according to Schneider-Orelli (1947)
*= statistically significant different compared to the control (Fisher´s Exact Test, p ≤ 0.05)

Conclusion:

The mortality of *O. leavigatus* exposed on maize leaves treated with Prothioconazole & Trifloxystrobin SC 325 on day of 2nd application resulted in 83.3 %. For exposures started 14, 28 and

42 days after application, the mortality declined with time and resulted in 65.0 %, 31.3 % and 11.3 %, respectively.
The reproduction was carried out after 28 days, for the 3rd bioassay. No effects were observed. The level of the treatment group was similar to that of the control in point of fecundity and hatching rate. The reduction in reproduction was 7.0 % for fecundity and 1.1 % for the hatching rate compared to the control.

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Report:	**KCP 10.3.2.2/06; [redacted], M.; [redacted], P.; [redacted], A.; [redacted], P.; [redacted], J.; [redacted], S.; [redacted], A. (2010)**
Title:	Reducing the impact of pesticides on biological control in Australian vineyards: pesticide mortality and fecundity effects on an indicator species, the predatory mite Euseius victoriensis (Acari: Phytoseiidae).
Source:	J. Econ. Entomol., Volume 103, Issue 6, p 2061-2071 (2010)
DOI No:	10.1603/EC09357
Guidelines:	None
GLP:	No
Classification:	b) supplementary information (EFSA Journal 2011;9(2):2092)

EXECUTIVE SUMMARY

Laboratory bioassays on detached soybean, *Glycine max* (L.) Merr., leaves were used to test trifloxystrobin on a key Australian predatory mite species *Euseius victoriensis* (Womersley) in "worst-case scenario" direct overspray assays. Zero- to 48-h-old juveniles, their initial food, and water supply were sprayed to runoff with a Potter tower. Tests were standardized to deliver a pesticide dose comparable with commercial application of highest label rates at 1,000 liter/ha. Cumulative mortality was assessed 48 h, 4 d, and 7 d after spraying. Fecundity was assessed for 7 d from start of oviposition. No significant mortality or fecundity effects were detected for trifloxystrobin.

MATERIAL AND METHODS

A. Material

1. Test material

Test item:	Flint 500 WG
Active substance(s):	Trifloxystrobin
Chemical state and description:	n/a
Source of test item:	n/a
Batch number:	n/a
Purity:	n/a
Storage conditions:	n/a
Water solubility:	n/a

2. Test organism(s)

Species:	*Euseius victoriensis*
Common name:	mite
Source of test species:	originated from field collected material near Loxton, South Australia (140.57° E, 34.46° S)

B. Study design and methods

1. Test procedure

Test design:	Each test unit replicate was constructed from two open petri dishes lined with cotton wool. The inner dish had an upturned bean leaf embedded in cotton wool, and a sticky barrier applied to its rim as per in Bernard et al. 2004. Mites straying into the cotton wool thus received the same pesticide exposure as those on the leaf, and were returned to the leaf surface instead of being designated as escapees.
Test concentration(s):	0.081 mL/L
Control(s):	toxic reference mancozeb, nonyl phenol ethylene oxide, and spinosad residue
Number of replicates:	Four, for the toxic control three replicates
Test conditions:	24.0 +/- 1°C, 80 +/- 10% RH, a photoperiod of 16:8 (L:D) h, and 750-1050 lux, in an externally vented constant temperature cabinet as per Bernard et al. (2004). Cabinet temperature was lowered to 23.0 +/- 1°C during mortality assessments, to reduce mite movement and aid the accuracy of assessments.
Feeding:	*Typha orientalis* Presl (cumbungi) pollen and 22-25 predator eggs were added to each test unit and additional diet of laboratory reared *Aculops lycopersici* (Massee).
Medium renewal:	n/a
Frequency of test item application:	Treatments were replicated four times
Test duration:	n/a
Endpoints:	mortality and fecundity
Statistics:	ANOVA

2. Measurements during the test

Assessment of juveniles:	Juveniles were counted, and dead larvae removed, just before spraying. Mortality was then scored 48 h, 4 d, and 7 d after spraying; all dead and live mites were counted, and dead mites removed. Mites were considered dead when they failed to move after gentle prodding with a brush. Predator eggs and larvae were counted and removed daily for 7-8 d, from 5 to 12 d after spraying, excluding a 24-h preoviposition period from the analysis. Assessments were made with a dissecting microscope at 12-18x magnification, under a cold light.

RESULTS

1. Validity criteria:

No validity criteria defined.

2. Biological findings:

Post hoc tests on mortality indicate that mancozeb was significantly more toxic, whereas trifloxystrobin had no significant effects. Post hoc tests on fecundity indicate trifloxystrobin had no significant fecundity effects ($F = 1.229$; $df = 5, 18$; $P = 0.34$) compared with the control. Mancozeb exposure resulted in complete fecundity suppression (Table 1).

Table 1. Mean cumulative mortality (95% CI) and fecundity (mean+-SE) of *E. victoriensis*, after topical pesticide overspray to runoff, of juveniles (0–48 h old) on soybean leaf substrate

Treatment	% mortality 48 h (95% CI)	% mortality 4 d (95% CI)	% mortality 7 d (95% CI)	Reproduction (*R*)[a] per Surviving female +/- SE 6-12 d after spraying	% fecundity reduction
Control	8.18ab (2.11, 15.0)	14.9a (6.46, 22.0)	23.0a (13.0, 33.3)	10.8 +/- 1.56a	
Trifloxystrobin	9.86ab (5.01, 15.0)	18.7a (11.4, 21.4)	26.6a (21.6, 31.7)	11.6 +/- 0.31a	0
Mancozeb	81.0c (73.2, 88.2)	96.4b (90.7, 100)	98.5b (95.6, 100)	0.00 +/- 0.00	100

Means are based on four replicates, except for mancozeb, nonyl phenol ethylene oxide, and spinosad residue, based on three replicates. Means within the same bioassay and column followed by a different letter are significantly different (P < 0.001; *P > 0.01; Tukey b test).

[a] Reproduction (*R*) per female measured for 7 d from maturity, excluding the preoviposition period

RESULTS SUMMARY

Trifloxystrobin has no significant effects based on mortality or fecundity to *E. victoriensis*.

REFERENCES

Bernard, M. B., P. A. Horne, and A. A. Hoffmann. 2004. Developing eco-toxicological testing standard for predatory mites in Australia: acute and sub-lethal effects of fungicides on *Euseius victoriensis* and *Galendromus occidentalis* (Acarina: Phytoseiidae). J. Econ. Entomol. 97: 891-899.

Comment by the Notifier

The publication confirms the low toxicity of the TFS WG50 formulation to predatory mites. Therefore, the information is classified as b) supplementary information (EFSA Journal 2011;9(2):2092).

CP 10.3.2.3 Semi-field studies with non-target arthropods

No new semi-field studies were deemed necessary.

CP 10.3.2.4 Field studies with non-target arthropods

No new 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.

Predicted environmental concentrations used in risk assessment

The PEC_{soil} values below are taken from MCP Sec.9, Point 9.1.3. Since the PEC_{soil} values for orchards (early) scenario are below the values for the orchard (late) scenario, only the values for the orchard (late) are presented here. The same applies for the strawberries (early) scenario for which the PEC_{soil} values exceed the strawberries (late) scenario values.

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

Compound	Orchards, late	Grapes	Strawberries, early
	$PEC_{soil, max}$ [mg/kg]	$PEC_{soil, max}$ [mg/kg]	$PEC_{soil, max}$ [mg/kg]
Trifloxystrobin	0.053	0.067	**0.121**
CGA 357261	0.018	0.023	**0.030**
CGA 321113	0.076	0.097	0.115
CGA 373466	0.043	0.055	**0.068**
CGA 381318	0.007	0.009	**0.013**
NOA 413161	0.009	0.011	**0.013**
NOA 413163	0.009	0.011	**0.014**
CGA 357276	0.003	0.003	**0.004**
NOA 409480	0.010	0.013	**0.016**

Table 10.4- 2: $PEC_{soil\ accu}$ values (mixing depth of 10 and 20 cm for plateau calculation; bold values were used in the tier 1 risk assessment)

Compound	Orchards, late		Grapes		Strawberries, early	
	$PEC_{soil, plateau}$ [mg/kg]	$PEC_{soil, accu}$ [a] [mg/kg]	$PEC_{soil, plateau}$ [mg/kg]	$PEC_{soil, accu}$ [a] [mg/kg]	$PEC_{soil, plateau}$ [mg/kg]	$PEC_{soil, accu}$ [a] [mg/kg]
Mixing depth	**10 cm**					
CGA 321113	0.037	0.113	0.047	0.144	0.056	**0.171**
NOA 413161	<0.001	0.009	<0.001	0.011	<0.001	**0.013**
Mixing depth	**20 cm**					
CGA 321113	0.019	0.095	0.024	0.121	0.028	0.142
NOA 413161	<0.001	0.009	<0.001	0.011	<0.001	0.014

[a] $PEC_{soil, accu}$ means the sum of $PEC_{soil, max}$ and $PEC_{soil, plateau}$

The tier 1 risk assessments are based on the worst case PEC_{soil} values from all intended uses.

CP 10.4.1 Earthworms

Table 10.4.1- 1: Endpoints used in risk assessment

Test item	Test species, test design	Ecotoxicological endpoint		Reference
Trifloxstrobin WG 50	*Eisenia fetida* reproduction 56 d, mixed	NOEC NOEC$_{,corr.}$	≥28 mg a.s./kg ≥14 mg a.s./kg [a]	[redacted] (2013) M-464327-01-1 Kra/Rg-R-148/13 KCP 10.4.1.1/01
Trifloxstrobin (tech.)	*Eisenia fetida* reproduction 56 d, mixed	**NOEC$_{corr.}$**	**3.5 mg a.s./kg dws** [a]	[redacted] (2009) LRT-Rg-R-56/09 M-350077-01-1 KCA 8.4.1/03
CGA 357261	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) kra-Rg-R-111/11 M-428262-02-1 KCA 8.4.1/04
CGA 321113	*Eisenia fetida* reproduction 56 d, mixed	**NOEC$_{corr.}$**	**≥50 mg/kg dws** [a]	[redacted] (2013) Kra/Rg-R-149/13 M-464328-01-1 KCA 8.4.1/05
CGA 373466	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2011) LRT-Rg-R-114/11 M-414741-01-1 KCA 8.4.1/06
CGA 381318	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2013) Kra/Rg-R-150/13 M-466037-01-1 KCA 8.4.1/07
NOA 413161	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥91.8 mg/kg dws**	[redacted] (2011) LRT-Rg-R-116/11 M-416856-01-1 KCA 8.4.1/08
NOA 413163	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) EBTFN011 M-445494-01-1 KCA 8.4.1/09
CGA 357276	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**50 mg/kg dws**	[redacted] (2012) kra-Rg-R-115/12 M-437130-01-1 KCA 8.4.1/10
NOA 409480	*Eisenia fetida* reproduction 56 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) kra-Rg-R-106/11 M-424075-01-1 KCA 8.4.1/11

[a] corrected by factor of 2 due to lipophilic substance (log P_{ow} > 2)
dws = dry weight soil; a.s. = active substance; prod. = product; corr. = corrected
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
TFS WG 50	Earthworm, reproduction	NOEC ≥14 [a,b]	0.121	116	5
Trifloxystrobin	Earthworm, reproduction	NOEC 3.5 [a]	0.121	29	5
CGA 357261	Earthworm, reproduction	NOEC ≥100	0.030	3333	5
CGA 321113	Earthworm, reproduction	NOEC ≥50 [a]	0.171[c]	292	5
CGA 373466	Earthworm, reproduction	NOEC ≥100	0.068	1471	5
CGA 381318	Earthworm, reproduction	NOEC ≥100	0.013	7692	5
NOA 413161	Earthworm, reproduction	NOEC ≥91.8	0.013[c]	7062	5
NOA 413163	Earthworm, reproduction	NOEC ≥100	0.014	7143	5
CGA 357276	Earthworm, reproduction	NOEC 50	0.004	12500	5
NOA 409480	Earthworm, reproduction	NOEC ≥100	0.016	6250	5

[a] Adjusted by a factor of 2 to address the log $P_{ow} > 2$
[b] The NOEC of TFS WG 50 study is given in mg a.s./kg soil
[c] worst-case PEC_{soil} resulting from calculations taking into account the potential for accumulation in soil

All TER values calculated with the worst case $PEC_{soil,\ max}$ or $PEC_{soil,\ accu}$ 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 Trifloxystrobin WG 50.

CP 10.4.1.1 Earthworms sub-lethal effects

Report: **KCP 10.4.1.1/01; [redacted], M.-A., 2013**
Title: Trifloxystrobin WG 50 W: Effects on survival, growth and reproduction on the earthworm *Eisenia fetida* tested in artificial soil
Report No: Kra/Rg-R-148/13
Document No: M-464327-01-1
Guidelines: OECD-Guideline No. 222 (2004)
ISO 11268-2 (1998)
Deviations: None
GLP: Yes (certified laboratory)

Objectives:

The purpose of this study was to assess the sublethal effects of Trifloxystrobin WG 50 W on reproduction, mortality and growth of the earthworm *Eisenia fetida* during an exposure in an artificial soil with 5 different test concentrations.

Materials and Methods:

Test material: Trifloxystrobin WG 50 W; (Sample description: FAR01568-00; Batch ID: EDFL011509; Material No. 05584493; Specification No. 102000007798 - 02; content: 49.8 %w/w).

Adult earthworms (*Eisenia fetida*, about 6 months old, 8 × 10 animals for the control group and 4 × 10 animals per test concentration of the treatment group) were exposed in an artificial soil (with 10% peat content) to the nominal test concentrations of 5.6, 10.0, 17.8, 31.6 and 56.2 mg test item/kg soil dry weight.

Toxic standard: 1.25, 2.5, 5.0 mg Carbendazim (360 g a.s./L)/ kg dry weight soil.; control: quartz sand.

Artificial soil composition was 68.5% quartz sand, 20% kaolin clay, 10% sphagnum peat and 0.5% $CaCO_3$. The vessels were kept in a temperature-controlled room at 20 ± 2 °C under a 16-hour light to 8-hour darkness photoperiod and a light intensity at light period between approximately 400 – 800 Lux. Earthworms were fed with dried animal manure.

The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

Dates of experimental work: February 14 to April 15, 2013

Results:

Validity Criteria	Recommended	Obtained
Adult mortality	≤ 10%	0%
Number of juveniles per replicate	≥ 30	374, 302, 329, 287, 356, 387, 336, 386
Coefficient of variation of reproduction	≤ 30%	10.9%

All validity criteria for the study were met

To verify the sensitivity of the test system, the reference item Derosal flüssig (Carbendazim, 360 g/L) is routinely tested at concentrations of 1.25, 2.5 and 5.0 mg product/kg soil dry weight.

In the most recent toxic standard study with the reference test item mixed into the artificial soil, was performed from September 21 to November 28, 2012. No mortality of the adult earthworms was observed 28 days after application. The change of body weight of the adult earthworms of the test concentration of 5.0 mg a.s./kg dry weight soil was statistically significant reduced in comparison to the control.

The number of juveniles per test vessel of the two highest test concentrations were statistically significant reduced in comparison to the control. The EC_{50} for reproduction was calculated to be 3.54 mg a.s./kg dry weight soil. Confidence limits (95%) could not be calculated.

The results of the reference test item indicated that the test system was sensitive to the reference test item.

Effects on mortality, growth and reproduction of the earthworms

Test item Test object Exposure	Trifloxystrobin WG 50 W *Eisenia fetida* Artificial soil		
	Adult mortality	Biomass change [mg test item /kg dws]	Reproduction
LOEC	>56.2	>56.2	>56.2
NOEC	≥56.2	≥56.2	≥56.2

	Trifloxystrobin WG 50 W [mg test item /kg dws]					
	Control	**5.6**	**10.0**	**17.8**	**31.6**	**56.2**
	Mortality of adult worms after 4 weeks					
Mortality [%]	0	0	0	0	0	0
	Biomass change (change in fresh weight after 4 weeks relative to initial fresh weight)					
Mean ± SD [%] [a]	+22.51 ± 6.94	+2.08 ± 3.79	+22.38 ± 4.98	+21.62 ± 2.38	+24.82 ± 10.40	+24.58 ± 5.71
	Number of juveniles per replicate after 8 weeks					
Mean± SD [b]	344.6±37.7	358.3± 53.4	406.3±23.1	338.8±60.3	338.5±51.5	344.5 ± 77.7
	Reproduction compared to control [%]					
% to control	-	104.0	117.9	98.3	98.2	100.0

[a] no statistical significance compared to control (Williams Multiple Sequential t-test, two-sided, $\alpha = 0.05$)
[b] no statistical significance compared to control (Williams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$)

After 28 days of exposure no worms died in the control group and no mortality was observed at any test item concentration.
Statistically significant different values for the growth relative to the control were not observed.
No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at any test concentration.

Conclusions:

Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is ≥ 56.2 mg test item/kg dry weight artificial soil. Thus, the overall LOEC is determined to be > 56.2 mg test item/kg dry weight artificial soil.
Therefore, based on the statistical significance:
NOEC related to reproduction: ≥56.2 mg test item/kg dry weight artificial soil
LOEC related to reproduction: >56.2 mg test item/kg dry weight artificial soil

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)

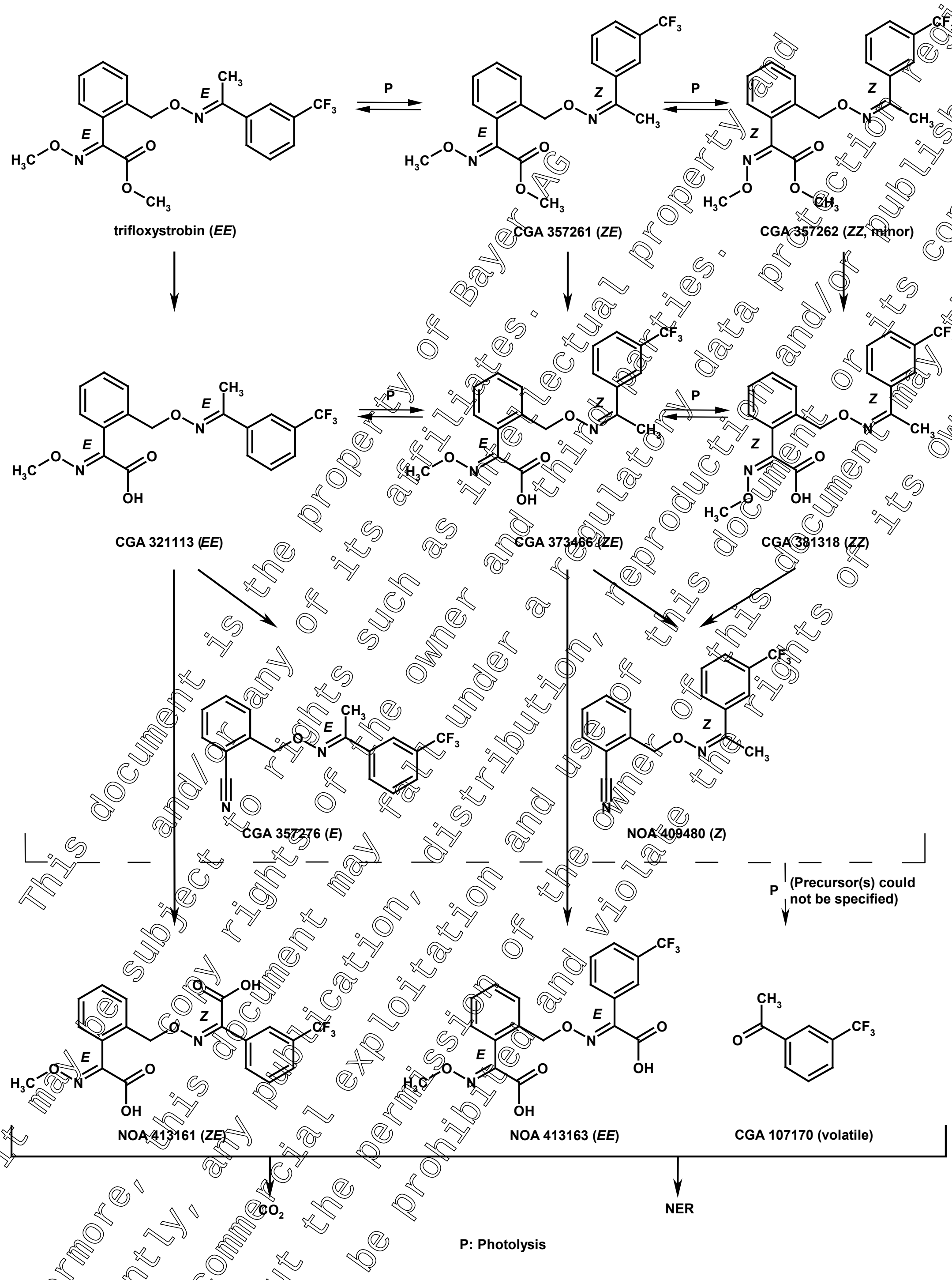
Table 10.4.2- 1: Endpoints used in risk assessment

Test item	Test species, test design	Ecotoxicological endpoint		Reference
Collembola, reproduction				
TFS WG 50	*Folsomia candida* reproduction 28 d, mixed	NOEC **NOEC$_{corr.}$**	≥1000 mg prod./kg dws ≥498 mg a.s./kg dws **≥249 mg a.s./kg dws[a]**	[redacted] (2011) FRM-COLL-121/11 M-415346-01-1 KCA 8.4.2.1/03
CGA 357261	*Folsomia candida* reproduction 28 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) FRM-Coll-150/12 M-443697-01-1 KCA 8.4.2.1/05
CGA 321113	*Folsomia candida* reproduction 28 d, mixed	NOEC **NOEC$_{corr}$**	316 mg/kg dws **158 mg/kg dws[a]**	LoEP M-033523-01-1 KCA 8.4.2.1 /01
CGA 373466	*Folsomia candida* reproduction 28 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) FRM-Coll-146/12 M-440109-01-1 KCA 8.4.2.1/08
NOA 413161	*Folsomia candida* reproduction 28 d, mixed	**NOEC**	**9.18 mg/kg dws**	LoEP M-090863-02-1 KCA 8.4.2.1 /02
NOA 413163	*Folsomia candida* reproduction 28 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2013) EBTFN012 M-444419-01-1 KCA 8.4.2.1/11
CGA 357276	*Folsomia candida* reproduction 28 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) FRM-Coll-145/12 M-441251-01-1 KCA 8.4.2.1/12
Soil mites, reproduction				
TFS WG 50	*Hypoaspis aculeifer* reproduction 14 d, mixed	NOEC **NOEC$_{corr.}$**	≥1000 mg prod./kg dws ≥498 mg a.s./kg dws **≥249 mg a.s./kg dws[a]**	[redacted] (2012) KRA-HR-76/12 M-443226-01-1 KCA 8.4.2.1/04
CGA 357261	*Hypoaspis aculeifer* reproduction 14 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) kra-HR-80/12 M-443311-01-1 KCA 8.4.2.1/06
CGA 321113	*Hypoaspis aculeifer* reproduction 14 d, mixed	**NOEC**	**≥50 mg/kg dws[a]**	[redacted] (2012) kra-HR-75/12 M-443145-01-1 KCA 8.4.2.1/07
CGA 373466	*Hypoaspis aculeifer* reproduction	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) kra-HR-73/12

	14 d, mixed			M-440955-01-1 KCA 8.4.2.1/09
NOA 413161	*Hypoaspis aculeifer* reproduction 14 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2013) kra-HR-91/13 M-455220-01-1 KCA 8.4.2.1/10
CGA 357276	*Hypoaspis aculeifer* reproduction 14 d, mixed	**NOEC**	**≥100 mg/kg dws**	[redacted] (2012) kra-HR-74/12 M-440367-01-1 KCA 8.4.2.1/13

[a] corrected by factor of 2 due to lipophilic substance (log P_{ow} >2);
dws = dry weight soil; a.s. = active substance; prod. = product; corr. = corrected
Bold values: endpoints used for risk assessment

Figure 10.4.2- 1: Proposed degradation pathway of trifloxystrobin in soil (major degradation products) (For further details see CA 7.1.1)



Studies with Folsomia and Hypoaspis were performed with the trifloxystrobin WG 50 formulation and most of the major soil degradation products. For some of these metabolites studies with Folsomia and Hypoaspis are not considered necessary as justified in the text below.

For the **metabolite CGA 381318** no studies with Folsomia and Hypoaspis are considered necessary, since Folsomia and Hypoaspis studies which have been performed with the structurally very similar parent compound trifloxystrobin, with the EE-isomer (CGA 321113) and the ZE-isomer (CGA 373466) did not show toxicity to either Hypoaspis or Folsomia (all NOEC values > 100 mg metabolite/kg soil). Also the chronic earthworm study did not indicate any toxicity of this metabolite (NOEC value > 100 mg metabolite/kg soil). Furthermore, CGA 381318 has a maximum occurrence rate in soil of only 6.2%. Therefore, the risk from the metabolite CGA 381318 to soil macro organisms is considered to be low.

Studies with Folsomia and Hypoaspis have been not conducted with the **metabolite NOA 409480**, since the structural similar precursor metabolite CGA 373466 and the E-isomer (CGA 357276) of the metabolite NOA 409480 did not indicate to be toxic to these soil macro organisms, and also the chronic earthworm study did not indicate any toxicity of this metabolite (NOEC value > 100 mg metabolite/kg soil). Therefore, the risk from the metabolite NOA 409480 to soil macro organisms is considered to be low.

For **metabolite NOA 413163** a study has been conducted with Folsomia. Testing Hypoaspis was not considered to be required since the precursor metabolite CGA 373466 did not show any toxicity to either Folsomia or Hypoaspis, and also the ZE-isomer (NOA 413161) of NOA 413163 showed no toxicity to Hypoaspis. Furthermore, the maximum occurrence of the metabolite NOA 413163 was only 6.0%. and the metabolite showed a low toxicity to either Folsomia and earthworms (NOEC > 100 mg metabolite/kg soil). Therefore, it can be concluded that the risk from the metabolite NOA 413163 to soil macro organisms is low.

For these metabolites consequently no quantitative risk assessment is considered to be required.

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
TFS WG 50	*Folsomia candida*	NOEC ≥ 249 [a, b]	0.121	2058	5
	Hypoaspis aculeifer	NOEC ≥ 249 [a, b]		2058	5
CGA 357261	*Folsomia candida*	NOEC ≥ 100	0.030	3333	5
	Hypoaspis aculeifer	NOEC ≥ 100		3333	5
CGA 321113	*Folsomia candida*	NOEC 158 [a]	0.171 [c]	924	5
	Hypoaspis aculeifer	NOEC ≥ 50 [a]		292	5
CGA 373466	*Folsomia candida*	NOEC ≥ 100	0.068	1471	5
	Hypoaspis aculeifer	NOEC ≥ 100		1471	5
NOA 413161	*Folsomia candida*	NOEC 9.18	0.013 [c]	706	5
	Hypoaspis aculeifer	NOEC ≥ 100		7692	5
NOA 413163	*Folsomia candida*	NOEC ≥ 100	0.014	7143	5
CGA 357276	*Folsomia candida*	NOEC ≥ 100	0.004	25000	5
	Hypoaspis aculeifer	NOEC ≥ 100		25000	5

[a] corrected by factor of 2 due to lipophilic substance (log P_{ow} >2)
[b] The NOEC of these TFS WG 50 studies are given in mg a.s./kg soil
[c] worst-case PEC$_{soil}$ resulting from calculations taking into account the potential for accumulation in soil

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 Trifloxystrobin WG 50.

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				
TFS WG 50	Study duration 28 d	no unacceptable effects	≥0.5 kg prod./ha **≥0.272 mg a.s./kg dws[b]**	LoEP M-051718-01-1 KCP 10.5/01 [a]
Trifloxystrobin (tech.)	Study duration 28 d	no unacceptable effects	**≥13.33 mg a.s./kg dws**	LoEP M-034686-01-1 KCA 8.5/01 [a]
CGA 357261	Study duration 42 d	no unacceptable effects	**≥3.353 mg/kg dws**	Schulz (2013) 13 10 48 093 N M-464875-01-1 KCA 8.5/15
CGA 321113	Study duration 28 d	no unacceptable effects	**≥3.261 mg/kg dws**	[redacted] (2013) 13 10 48 092 N M-464870-01-1 KCA 8.5/16
CGA 373466	Study duration 28 d	no unacceptable effects	**≥3.47 mg/kg dws**	LoEP M-070537-01-1 KCA 8.5/02 [a]
NOA 413161	Study duration 28 d	no unacceptable effects	**≥3.41 mg/kg dws**	LoEP M-071668-01-1 KCA 8.5/13[a]

[a] studies already evaluated during the first EU review of trifloxystrobin
[b] 0.08 mg formulation containing 0.041 mg a.s. were sprayed onto 150 g soil resulting in 0.272 mg a.s./kg soil.

For all metabolites with maximum occurrence in soil of ≥ 10 % studies on the influence on the nitrogen-transformation were performed. In no case a relevant influence on the nitrogen-transformation was found at the tested soil concentrations. Therefore the risk from soil metabolites with a maximum occurrence rate of lower than 10 % to soil microorganisms is considered to be low since they would not indicate an unacceptable risk even if they would be 10 times more toxic as the parent compound trifloxystrobin. Therefore, no study on the nitrogen-transformation is considered necessary for the metabolites CGA 381318, CGA 357276, NOA 413163 and NOA 409480 and no quantitative risk assessment will be conducted.

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
TFS WG 50	Soil micro-organisms	≥ 0.272 [b]	0.121	No
Trifloxystrobin	Soil micro-organisms	≥ 13.33	0.121	No
CGA 373466	Soil micro-organisms	≥ 100	0.068	No
NOA 413161	Soil micro-organisms	≥ 91.8	0.013 [a]	No
CGA 357261	Soil micro-organisms	≥ 100	0.030	No
CGA 321113	Soil micro-organisms	≥ 100	0.171 [a]	No

[a] worst-case PEC_{soil} resulting from calculations taking into account the potential for accumulation in soil
[b] The NOEC of this TFS WG 50 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 or 42 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 Trifloxystrobin WG 50. Since study results were originally reported on an active substance basis, the summary of endpoints and subsequent TER calculations are provided on an active substance basis as well.

Table 10.6- 1: Endpoints used in risk assessment

Test organism	Study type	Max. effects at 279 g a.s./ha	Most sensitive species	References
Terrestrial non-target plants; 10 species	Vegetative vigour; Tier 1 single dose 21 days	10% reduction of shoot dry weight	tomato	[redacted], 1997; M-034000-1-1 KCP 10.5/02 KCA 8.6.2/02
Terrestrial non-target plants; 10 species	Seedling emergence; Tier 1 single dose 21 days	13% reduction of shoot dry weight	cabbage	[redacted], 1997; M-034000-1-1 KCP 10.5/02 KCA 8.6.2/02

In the case of Trifloxystrobin WG 50, neither the tier 1 seedling emergence nor the vegetative vigour studies showed phytotoxic effects ≥50% at the tested rate of 279 g a.s./ha (equivalent to 558 g product/ha).
To demonstrate the low risk of the formulation to non-target plants, TER calculations have been performed for those crops for which high drift rates have to be considered. The test rate of 279 g a.s./ha was used as a most conservative endpoint estimate (ER_{50} > 279 g a.s./ha).

Table 10.6- 2: Deterministic risk assessment based on the ER_{50} > 279 g a.s./ha

Crop	Use pattern	Distance from field edge [m]	Drift [%]	PER [g a.s./ha]	TER (Trigger = 5)
Apple/Pear/Quince (early)	3 x 75 g a.s./ha (10 days interval)	3	23.96[1)]	32.35[2)]	> 8.6
Apple/Pear/Quince (late)	3 x 112.5 g a.s./ha (10 days interval)	3	11.01[3)]	22.30[2)]	> 12.5
Grapes	3 x 125 g a.s./ha (10 days interval)	3	6.90[3)]	15.53[4)]	> 18.0

[1)] Basic drift value for three applications in fruit early
[2)] Considering MAF = 1.8 from EFSA GD Birds & Mammals (2009)
[3)] Basic drift value for three applications in fruit late
[4)] Basic drift value for three applications in grapes late

The calculations clearly show that even with most conservative assumptions regarding endpoints and drift rates, an acceptable risk (i.e. TER > 5) can be demonstrated for the critical uses in high crops. It can therefore be concluded that effects of the product on non-target terrestrial plants in off-crop areas are not to be expected.

CP 10.6.1 Summary of screening data

No new studies are required.

CP 10.6.2 Testing on non-target plants

No new studies are required.

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

In view of the results presented above, no further studies are deemed necessary.

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

No studies are required.

CP 10.8 Monitoring data

No monitoring data available.