A8637C

Cyprodinil 500 g/kg WG

NOTIFICATION OF AN ACTIVE SUBSTANCE UNDER COMMISSION REGULATION (EU) 844/2012

DOCUMENT M-CP, Section 10

ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
20 May 2016	New data included in response to questions from RMS: Earthworm-eating vertebrate secondary poisoning risk assessment updated using soil accumulation 21-day time-weighted average concentrations Aquatic risk assessment updated using re-modelled surface water concentrations. New RAC values used from the mesocosm study for higher tier refinement of the long-term risk to aquatic invertebrates Some algae statistics updated in order to attempt to derive E_rC_{50} values. Also updated some endpoints based on mean measured concentrations. (All changes highlighted in yellow)	A8637C_10303 9 October 2015 updated 20/5/16
3 February 2017	Summary of new non-target arthropod report added following RMS recommendation. The non-target arthropod risk assessment has been updated accordingly. (All changes highlighted in green)	A8637C_10303 9 October 2015 updated 20/5/16, 3/2/17

[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 PLANT PROTECTION PRODUCTS

This document supports the application for renewal of the regulatory approval of cyprodinil under Commission Implementing Regulation (EU) 844/2012 of 18 September 2012. This document reviews the ecotoxicological studies for the product A8637C containing:

- 500 g/kg cyprodinil which was included into Annex I of Council Directive 91/414/EEC (Commission Directive 2006/64/CE of 18 July 2006). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

A8637C is a water dispersible granule (WG) containing 500 g/kg cyprodinil for use as a fungicide on apples. A8637C was one of the representative formulations in the EU review of cyprodinil. UNIX 75 WG (A8779A) was also a representative formulation.

In accordance with Commission Implementing Regulation (EU) 844/2012, this document summarises new information which are relevant for the renewal of the approval of cyprodinil under Regulation (EC) 1107/2009. Where appropriate this document refers to the Commission Implementing Regulation (EU) No. 540/2011 for cyprodinil and to the Review Report for cyprodinil (SANCO/4343/2000 final (revised) 28 September 2006), and in particular the endpoints provided in Appendices I and II thereof.

This document covers data and risk assessments which were not part of the original dossier and which are necessary to reflect changes:

- In requirements under Commission Regulation (EU) No 284/2013, and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC
- In scientific and technical knowledge since the approval or last renewal of the approval
- To representative uses

The proposed representative use pattern is included in Document D1.

Each section of this document provides the agreed EU endpoints and if relevant proposals for amended endpoints.

Where new guidance documents have been introduced since the EU review of cyprodinil, an updated evaluation of cyprodinil and A8637C has been included. To adequately assess cyprodinil to the new guidance documents, it may have been necessary to provide new data, if so these are also included.

Information on the detailed composition of A8637C can be found in the confidential dossier of this submission (Document J).

Details of all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and plant protection products containing the active substance have been provided in the **Document M-CA Section 9** and are discussed within the relevant data point of the associated dossier for the active substance, cyprodinil. If the published literature is also relevant to A8637C, it has been discussed within the relevant data point in this document.

Introduction

This section of the submission summarises the ecotoxicological effects of the formulation and evaluates the potential risk to various representatives of terrestrial and aquatic organisms.

Formulation composition details are given in Document J of this submission (Confidential Information).

Table 10-1: Use pattern of A8637C

Crop	Application method	Spray volume (L/ha)	Maximum individual application rate (g a.s./ha)	Number of applications	Minimum application interval (days)	Application timing
Apple	Spray	450 - 1500	375	2-3	21	BBCH 10-71

All Toxicity Exposure Ratios (TERs) and Hazard Quotients (HQs) in the following document are given to 2 significant figures.

Consideration of metabolites

The metabolites that require ecotoxicological assessment according to the EFSA Guidance Documents are given below.

The occurrence and risk from metabolites of cyprodinil have been considered and are discussed in **M-CP Section 9**.

Table 10-2: Metabolites of cyprodinil considered for ecotoxicological risk assessment

Compartment	Metabolites considered for risk assessment
Soil	CGA249287, CGA275535, CGA321915
Surface water	CGA249287, CGA275535, CGA321915, CGA048109 (guanidine), CGA263208 (phenyl guanidine), CA1139A (phenyl guanidine), R008591 (succinic acid), U2, U4,
Sediment	CGA249287

Further information on these metabolites can be found in **M-CA Section 7** for cyprodinil.

The crop metabolism of cyprodinil has been investigated in three crop groups; fruit crops (apple, peach and tomato), root crops (potato) and cereals (wheat), following foliar applications (see MCA Section 6.2.1). It has been concluded that the metabolism pathway is similar in all crops with the parent compound remaining the dominant residue except in potato tubers where the metabolic profile results from the translocation of degradation products through the plant from the soil metabolism of cyprodinil. Where there is a direct contact of cyprodinil with the edible part of the crop, metabolism proceeds mainly via hydroxylation of the phenyl and pyrimidine rings forming metabolites, which then undergo sugar conjugation. Lower levels of other hydroxylated metabolites are also detected. These metabolites are encountered in the rat metabolism and considered covered by the toxicological profile of parent cyprodinil.

Where the edible part of the crop is not exposed to the fungicide spray, metabolism results mainly from the cleavage of the pyrimdine ring with other hydroxylated metabolites identified in both their free and conjugated forms. These potato specific metabolites were not found in the rat metabolism study, but due to the low absolute levels at which they were found in the potato metabolism study, they are not of toxicological relevance.

The metabolism of cyprodinil was investigated in four confined rotational crops studies elucidating the nature of residues following different plant-back intervals. In these studies, cyprodinil radiolabelled in the phenyl or pyrimidinyl rings was applied to bare soil or crops. When radiolabelled cyprodinil was applied on a primary crop at an application rate of 1.25 kg a.s./ha, significant cyprodinil residues were not found in any of the edible parts of the succeeding crops. When cyprodinil was applied to bare soil, the studies identified four major cyprodinil metabolites in the succeeding crops sown at any of the replant intervals. It is concluded that the metabolism of cyprodinil in rotational crops is sufficiently elucidated. Studies on the magnitude of residues in rotational crops confirmed the presence of two plant metabolites which were found at measurable levels at the earliest replanting interval of 30 DAT, whilst parent cyprodinil occurred rarely.- However, these metabolites were found to be of no toxicological concern.

The nature of cyprodinil residues in commodities of animal origin was investigated in three metabolism studies, one study in lactating goats and two studies in laying hens, using radiolabelled cyprodinil. The metabolism studies in both ruminants and poultry show that cyprodinil is extensively metabolised and proceeds predominantly via hydroxylation of the phenyl and pyrimidine rings and conjugation with sulphate or glucuronic acid. The majority of the radioactivity was eliminated in the urine and faeces. The four metabolites identified in the studies were all found in the rat metabolism study.

CP 10.1 Effects on Birds and Other Terrestrial Vertebrates

CP 10.1.1 Effects on birds

Toxicity

Summary of endpoints relevant for the risk assessment are presented below:

Table 10.1.1-1: Table of endpoints to assess risk from use of A8637C

Organism	Test type	Endpoint		Endpoints used for the risk assessment	Reference (author, date, Syngenta File No.)
Mallard duck	Acute oral	EU	14 d LD_{50} > 500 mg/kg bw	-	***Hakin & Rogers (1992) CGA219417/0062***
Bobwhite quail			14 d LD_{50} > 2000 mg/kg bw	14 d LD_{50} 3776 mg/kg bw [a]	***Hakin & Rogers (1992) CGA219417/0067***
Canary		New	5 d LD_{50} > 5620 mg/kg bw	-	***Hubbard (2015) CGA219417_50779***
Mallard duck	Sub-chronic and reproductive	EU	22 week NOEC = 600 mg/kg diet; NOEL = 102 mg/kg bw	-	***Rogers (1995) CGA219417/0477***
Bobwhite quail		EU	22 week NOEC = 600 mg/kg diet; NOEL = 64 mg/kg bw	64 mg/kg bw	***Rogers (1995) CGA219417/0478***

[a] Value extrapolated according to EFSA 2009
[b] Estimated attempted in accordance with **Commission Regulation (EU) No 283/2013**

Note on acute oral studies.

Acute toxicity studies were performed with bobwhite quail and mallard duck. In all cases, no mortalities occurred and no toxic symptoms were seen. Regurgitation occurred in the mallard duck study at the two highest dose levels of 1000 and 2000 mg a.s./kg, and the endpoint in the LoEP was set at >500 mg a.s./kg.

The EFSA guidance document states the following:

According to Annex II of Directive 91/414/EEC, the acute oral toxicity of an active substance to a quail species (Japanese quail, Coturnix coturnix japonica or bobwhite quail, Colinus virginianus) or to mallard duck (Anas platyrhynchos) must be determined. The highest dose used in tests need not normally exceed 2000 mg/kg body weight. Due to issues of regurgitation it is recommended not to use the mallard duck (EFSA, 2007). Where regurgitation or emesis occurs at doses used for risk assessment, additional information is essential to complete the risk assessment. The amount of regurgitated material should be assessed for determination of the ingested dose. In the absence of this information, the lowest overall no observed effect level (NOEL) must be used for risk assessment purposes. Where more than one study has been submitted, the study/studies where no regurgitation has occurred should be used. If, however, mortalities appear in the study in which regurgitation has occurred (at dose levels at or around the LD50 value for the non-regurgitation study), then it is proposed to use the NOEL (for regurgitation or mortality, whichever is lower) from the study where regurgitation has occurred.

Since no other signs of toxicity other than vomiting were seen in the studies with the mallard, and no effects were seen in the study with the bobwhite quail, it is proposed to use the LD_{50} of >2000 mg a.s./kg.

Cyprodinil metabolites

Since metabolites are formed at <10% of parent level in edible crop parts and mammalian testing indicates that they are less toxic than the parent, it can be concluded that the risk to birds will be low and no further risk assessment is conducted (**Cyprodinil; EFSA Scientific Report 51, 2005**).

Exposure

Exposure of birds will be predominantly dietary, through the consumption of residues on food items. Direct exposure of birds to A8637C applications is considered unlikely, since at the time of application and for a short period thereafter, most birds will leave the immediate vicinity of spray operations in response to the human disturbance.

Exposure is calculated according to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)**.

Screening step

The Screening step crop group and critical use pattern relevant to the uses of A8637C is given in the table below.

Table 10.1.1-2: Screening step crop group and critical use pattern relevant to the use of A8637C

Crop group	GAP crop species	Indicator species	Critical use pattern		
			Rate (kg a.s./ha)	No. of apps	App. Interval (days
Orchards	Apple	Small insectivorous bird	0.375	3	21

The acute 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the 90th percentile residues by the application rate in kg a.s./ha.

$$DDD_{\text{multiple applications}} = \text{application rate (kg a.s./ha)} \times SV \times MAF_{90}$$

The daily dietary dose for acute exposure to cyprodinil following use of A8637C according to the proposed uses is given in the table below.

Table 10.1.1-3: Screening step – estimates of acute exposure to cyprodinil

Compound	Crop group	Indicator species	Shortcut value (mg/kg bw)	App. rate (kg/ha)	No. of apps	App. Interval (days)	MAF	DDD (mg/kg bw)
Cyprodinil	Orchards	Small insectivorous bird	46.8	0.375	3	21	1.2	21.1

The long-term 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the mean residues by the application rate in kg a.s./ha.

$DDD_{multiple\ applications}$ = application rate (kg a.s./ha) × SV × f_{twa} × MAF_m

The f_{twa} based upon a default DT_{50} of 10 days is 0.53, as given in the EFSA Guidance Document.

The daily dietary dose for long-term exposure to cyprodinil following use of A8637C according to the proposed uses is given in the table below.

Table 10.1.1-4: Screening step - estimates of long-term exposure to cyprodinil

Compound	Crop group	Indicator species	Shortcut value (mg/kg bw/day)	App. rate (kg/ha)	No. of apps	App. Interval (days)	MAF	f_{twa}	DDD (mg/kg bw/day)
Cyprodinil	Orchards	Small insectivorous bird	18.2	0.375	3	21	1.3	0.53	4.70

Risks for birds through drinking water

There are two scenarios provided in the EFSA Guidance Document for assessing the risk from drinking water.

Leaf scenario

The 'Leaf scenario' is relevant for birds taking water that is collected in leaf whorls after application and applies to leafy vegetables forming heads or with a morphology that facilitates collection of rain/irrigation water sufficiently to attract birds. Since the proposed use of A8637C is for application to pome fruit, the leaf scenario does not apply.

Puddle scenario

This scenario is relevant for birds 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. This scenario is relevant for all uses of A8637C and should therefore be assessed. The EFSA Guidance Document (ref. 5.5, Step 2b) states the following:

"Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary since the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 3000 in the case of *more sorptive substances* (Koc > 500 L/kg) as specified in".

When multiple spray applications are considered, a MAF_m based on the DT_{50} in soil (single first order kinetics, geometric mean as used for PEC_{gw} and PEC_{sw}) may be applied to calculate the effective application rate $AR_{eff.}$

$$AR_{eff} = AR \times MAF_m = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

Where:

AR = application rate [g/ha]
k = ln(2)/DT_{50} (rate constant)
n = number of applications
i = application interval (d)

Table 10.1.1-5: Acute risk to birds from drinking water – puddle scenario

Crop group	Compound	Soil DT_{50} (days)	K_{oc} [L/kg]	AR [g a.s./ha]	MAF_m	AR_{eff} [a] [mg a.s./m²]	LD_{50} [mg a.s./kg bw]	Ratio (AR_{eff} / LD_{50})	No concern ratio
Orchards	Cyprodinil	35.5 ~~33.6~~	1706	375	2.10 ~~2.07~~	78.8 ~~77.6~~	3776	0.0210 ~~0.0206~~	≤3000
		114.2 ~~118.9~~ [b]			2.66 ~~2.67~~	99.8 ~~100~~		0.0264 ~~0.0265~~	

[a] The application rate is divided by 10 to convert from g/ha to mg/m²
[b] this represents the DT_{50} in acidic soils

Table 10.1.1–6: Long-term risk to birds from drinking water – puddle scenario

Compound	Compound	Soil DT_{50} (days)	K_{oc} [L/kg]	AR [g a.s./ha]	MAF_m	AR_{eff} [a] [mg a.s./m²]	NOEL [mg a.s./kg bw/d]	Ratio (AR_{eff} / NOEL)	No concern ratio
Orchards	Cyprodinil	35.5 ~~33.6~~	1706	375	2.10 ~~2.07~~	78.8 ~~77.6~~	64	1.23 ~~1.21~~	≤3000
		114.2 ~~118.9~~ [b]			2.66 ~~2.67~~	99.8 ~~100~~		1.56	

[a] The application rate is divided by 10 to convert from g/ha to mg/m²
[b] this represents the DT_{50} in acidic soils

The ratios of the application rates to the toxicity endpoints are clearly less than 3000 indicating low concern for acute and long-term exposure to birds in drinking water from puddles and no need to carry out further calculations of exposure in puddle water.

Risk assessment for birds

Acute toxicity exposure ratio (TER_A)

Acute risk is assessed by comparing the relevant DDD from Table 10.1.1-3 with the appropriate LD_{50} endpoint (summarised in Table 10.1-1) to give an acute Toxicity: Exposure Ratio (TER_A):

$$TER_A = \frac{LD_{50}\ \text{(mg/kg bw)}}{\text{DDD}}$$

The resulting TER_A value is given in the table below.

Table 10.1.1-7: Screening step - Acute risk (TER_A) to birds from cyprodinil

Compound	Crop group	Indicator species	LD_{50} (mg/kg bw)	DDD (mg/kg bw)	TER_A
Cyprodinil	Orchards	Small insectivorous bird	3776	21.1	180

The TER_A value is greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to birds is acceptable following use of A8637C according to the proposed use pattern.

Acute risk assessment to birds through drinking water

Cyprodinil has negligible potential for acute exposure of birds to drinking water (see Table 10.1.1-5).

Long-term toxicity exposure ratio (TER_{LT})

Long-term risk is assessed by comparing the long-term DDD with the worst case NOEC from the reproduction study, expressed as daily dietary dose, to give a Long-term Toxicity:Exposure Ratio (TER_{LT}):

$$TER_{LT} = \frac{LD_{50}\ (\text{mg/kgbw/day})}{DDD(\text{mg/kgbw/day})}$$

The EFSA Guidance Document indicates that the acute $LD_{50}/10$ should be used as an endpoint in long-term risk assessment where it is lower than the long-term endpoint.

The endpoint of 64 mg/kg bw/day from a reproduction study has been used in calculations of the TER values since this is lower than the $LD_{50}/10$ value for the LD_{50} endpoint used in the acute risk assessment.

Screening step risk assessment

The TER value calculated for the crop grouping relevant for the use of A8637C is given below:

Table 10.1.1-8: Screening step – long-term (TER_{LT}) to birds from cyprodinil

Compound	Crop group	Indicator species	NOEL (mg a.s./kg bw/day)	DDD (mg a.s./kg bw/day)	TER_{LT}
Cyprodinil	Orchards	Small insectivorous bird	64	4.70	14

The TER_{LT} value is greater than the Commission Regulation (EU) No. 546/2011 trigger of 5, indicating that long-term risk to birds is acceptable following use of A8637C according to this use pattern.

Long-term risk assessment to birds through drinking water

Cyprodinil has negligible potential for long-term exposure of birds to drinking water (see Table 10.1.1-6).

Effects of secondary poisoning

According to **EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009**, substances with a log P_{OW} greater than 3 have potential for bioaccumulation. Cyprodinil has a log P_{OW} of 4.0 indicating a potential risk of secondary poisoning therefore a risk assessment is provided.

Risk to earthworm-eating birds

A risk assessment of the risk of secondary poisoning to earthworm-eating birds is conducted using the following equation:

$$TER = \frac{NOEL\,(mg/kg\,bw/day)}{PEC_{worm}\,(mg/kg) \times 1.05}$$

Where:

PEC_{worm} = 21 d time-weighted average $PEC_{soil} \times BCF$
$BCF = C_{worm}/C_{soil} = (0.84 + 0.012\ K_{ow}) / f_{oc} \times K_{oc}$
K_{ow} = Octanol water partition coefficient
K_{oc} = Organic carbon adsorption coefficient
f_{oc} = Organic carbon content of soil (0.02 taken as a default value)

1.05 is a constant used to convert the PEC_{worm} to a daily dose and is based on a 100 g bird eating 104.6 g of worms per day (**Smit 2005** in EFSA Guidance).

The 21-day time-weighted average accumulation soil PEC was used. For details of soil PEC calculations, see the supporting **Document M-CP Section 9**.

The resulting TER value is given in the table below:

Table 10.1.1-9: Long-term risk from secondary poisoning to earthworm-eating birds

Compound	21-day twa PEC_{soil} (mg/kg)	K_{ow}	f_{oc}	Koc	BCF	PEC_{worm} (mg/kg)	DDD (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER_{worm}
Cyprodinil	0.986 ~~0.556~~	10000	0.02	1706	3.54	3.49 ~~1.97~~	3.67 ~~2.07~~	64	17 ~~31~~

The TER value exceeds the long-term trigger value of 5, indicating that A8637C poses an acceptable risk to earthworm eating birds.

The main soil metabolites of cyprodinil (CGA249287, CGA275535 and CGA321915) are of low acute oral toxicity to mammals (rat acute oral LD_{50} >2000 mg/kg; refer to **Cyprodinil; EFSA Scientific Report 51, 2005**). Highest log P_{OW} values for CGA249287 and CGA321915 are 1.5 and -0.10, respectively indicating low potential for bioaccumulation. CGA275535 has a log P_{OW} value above 3 (log P_{OW} 3.3 at pH 7.0). Given that the metabolites will be found at lower concentrations than the parent active substance, the risk assessment for the parent is considered to cover the metabolites.

Risk to fish eating birds

A risk assessment of the risk from secondary poisoning to fish-eating birds is conducted using the following equation:

TER = long-term NOEC as daily dietary dose / (PEC_{fish} × 0.159)

Where: $PEC_{fish} = PEC_{water\ (highest\ 3\ wk\ twa)} * BCF_{(whole\ body)}$

The factor of 0.159 is based on a 1000 g bird eating 159 g per day (**Smit, 2005** in EFSA Guidance), and converts the PEC_{fish} to a daily dose.

The worst case Step 2, 21-day time-weighted average surface water PECsw following use of A8637C in pome fruit was used. For details of surface water PEC calculations, see the supporting **M-CP Section 9.**

The resulting TER value is given in the table below:

Table 10.1.1-10: Long-term risk from secondary poisoning to fish-eating birds

Substance	PEC_{water} 21 day TWA (mg/L)	BCF	PEC_{fish} (mg/kg)	DDD (mg/kg/bw/ day)	NOEL (mg/kg bw/day)	TER_{fish}
Cyprodinil	0.0543	400	21.7	3.45	64	19

The TER value exceeds the long-term trigger value of 5, indicating that A8637C poses an acceptable risk to fish eating birds.

Conclusion

The risk assessment indicates that A8637C poses an acceptable risk to birds from secondary poisoning following the proposed use.

Biomagnification in terrestrial food chains

The results from adsorption, distribution, metabolism and excretion (ADME) studies did not indicate a potential for cyprodinil accumulation, as the tissue residues 7 days after application were always <1% of applied dose (refer to the respective **EFSA Scientific Report for cyprodinil**).

Also, fish bioaccumulation studies showed rapid depuration of residues of both the parent active substances and major metabolites formed (see Annex Point IIIA 10.2.4).

CP 10.1.1.1 Acute oral toxicity

Avian toxicity tests with the formulation were not performed, since the risk from A8637C can be adequately assessed from risk assessment for cyprodinil. In addition, it is highly unlikely that birds will be exposed to the intact product as their main route of exposure is to dried residues on food items and the risk from A8637C can be adequately assessed from risk assessment for cyprodinil.

CP 10.1.1.2 Higher tier data on birds

No other higher tier data on birds are required as the risk assessment presented above indicates an acceptable risk from the supported uses of A8637C.

Relevant Literature on Birds

No scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Toxicity

Summary of endpoints relevant for risk assessment:

Table 10.1.2-1: Table of endpoints to assess risk from use of A8637C

Test type	Test item	Organism	EU endpoint	Proposed endpoint for risk assessment	Reference (author, date, Syngenta File No.)
Acute	A8779A [a]	Rat	LD_{50} >2000 mg/kg bw	LD_{50} >2000 mg/kg bw	***Hartmann (1992) CGA219417/0083***
Acute	Cyprodinil	Rat	LD_{50} >2000 mg/kg bw	LD_{50} >2000 mg/kg bw	***Hartmann (1992) CGA219417/0020***
Sub-chronic and reproductive	Cyprodinil	Rat	NOAEL = 72.7 mg/kg bw/day [b]	NOAEL = 72.7 mg/kg bw/day	***Khalil (1993) CGA219417/0162***

[a] The acute toxicity study was conducted with the closely related product (A8779A). Both formulations contain qualitatively similar ingredients. Quantitatively, A8779A contains more cyprodinil (75% w/w) and accordingly less inert ingredients than A8637C (50% w/w). Due to the low acute toxic potential of the auxiliaries, the toxic potential of A8637C is considered to be similar to that of A8779A.
[b] The lowest overall mean value was calculated from all of the mean weekly consumption values for the individual sexes (72.7 mg/kg bw/day for males and 96.6 mg/kg bw/day for females)

Cyprodinil metabolites

Exposure of mammals will be predominantly dietary, through the consumption of residues on food items. Direct exposure of mammals to A8637C applications is considered unlikely, since at the time of application and for a short period thereafter, most mammals will leave the immediate vicinity of spray operations in response to the human disturbance.

Exposure is calculated according to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009**.

Screening step

The Screening step crop groupings and critical use patterns relevant to the uses of A8637C are given in the table below.

Table 10.1.2-2: Screening step crop groupings and critical use patterns relevant to the use of A8637C

Crop group	GAP crop species	Indicator species	Critical use pattern		
			Rate (kg a.s./ha)	No. of apps	App. Interval (days
Orchards	Pome fruit	Small herbivorous mammal	0.375	3	21

The acute 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the 90^{th} percentile residues by the application rate in kg a.s./ha.

$$DDD_{multiple\ applications} = \text{application rate (kg as/ha)} \times SV \times MAF_{90}$$

Daily dietary doses for acute exposure to A8637C and cyprodinil following proposed use in pome fruit are given in the table below.

Table 10.1.2-3: Screening step – estimates of acute exposure to cyprodinil

Compound	Crop group	Indicator species	Shortcut value (mg/kg bw)	App. rate (kg/ha)	No. of apps	App. Interval (days)	MAF	DDD (mg/kg bw)
A8779A	Orchards	Small herbivorous mammal	136.4	0.75	3	21	1.2	123
Cyprodinil				0.375				61.4

The long-term 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the mean residues by the application rate in kg a.s./ha.

$DDD_{multiple\ applications}$ = application rate (kg a.s./ha) × SV × f_{twa} × MAF_m

The f_{twa} based upon a default DT_{50} of 10 days is 0.53, as given in the EFSA Guidance Document.

The daily dietary dose for long-term exposure to cyprodinil following proposed use in pome fruit is given in the table below.

Table 10.1.2-4: Screening step – estimate of long-term exposure to cyprodinil

Compound	Crop group	Indicator species	Shortcut value (mg/kg bw/day)	App. rate (kg/ha)	No. of apps	App. Interval (days)	MAF	f_{twa}	DDD (mg/kg bw/day)
Cyprodinil	Orchards	Small herbivorous mammal	72.3	0.375	3	21	1.3	0.53	18.7

Tier 1 risk assessment

For the long-term risk assessment, the TER_{LT} value for cyprodinil at the screening step is less than the relevant trigger value and so a Tier 1 assessment is required.

The Tier 1 assessment initially requires identification of the appropriate crop groupings and generic focal mammal species in Annex I of the EFSA Guidance Document on Bird and Mammal risk assessment.

The Tier 1 crop grouping and critical use pattern relevant to the use of A8637C is given in the table below.

Table 10.1.2-5: Tier 1 crop groupings relevant to the use of A8637C

Crop group	GAP crop species	GAP growth stage window (BBCH)	Critical use pattern		
			Rate (kg a.s./ha)	No. of apps	App. Interval (days)
Orchards	Apple	BBCH 10-71	0.375	3	21

The generic focal species that are relevant for the proposed uses are considered with worst case application rates to calculate long-term DDD values as shown in table below.

Table 10.1.2-6: Tier 1 – Long-term DDD values for focal species relevant to the use of A8637C

Compound	Crop grouping / growth stage	Generic focal species	Shortcut value (mg/kg bw/day)	App. rate (kg/ha)	No. of apps	App. Interval (days)	MAF	f_{twa}	DDD (mg/kg bw/day)
Cyprodinil	Orchards BBCH 10-19	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	57.8	0.375	3	21	1.3	0.53	14.9
	Orchards BBCH 20-40		43.4						11.2
	Orchards BBCH ≥40		21.7						5.61
	Orchards BBCH 71-79	Frugivorous mammal “dormouse” Garden dormouse (*Eliomys quercinus*)	22.7						5.87
	Orchards BBCH 10-19	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)	11.5						2.97
	Orchards BBCH 20-40		8.6						2.22
	Orchards BBCH ≥40		4.3						1.11
	Orchards BBCH 10-19	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)	6.2						1.60
	Orchards BBCH 20-40		4.7						1.21
	Orchards BBCH ≥40		2.3						0.594

Exposure to mammals through drinking water

Only the puddle scenario is relevant for risk assessment for mammals through drinking water.

Puddle scenario

The EFSA Guidance Document states:

“Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary since the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 3000 in the case of *more sorptive substances* (Koc > 500 L/kg).”.

When multiple spray applications are considered, a MAF_m based on the DT_{50} in soil (single first order kinetics, geometric mean as used for PEC_{gw} and PEC_{sw}) may be applied to calculate the effective application rate $AR_{eff.}$

$$AR_{eff} = AR \times MAF_m = AR \times \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

Where:

AR = application rate [g/ha]
k = ln(2)/DT_{50} (rate constant)
n = number of applications
i = application interval (d)

Table 10.1.2-7: Acute risk to mammals from drinking water – puddle scenario

Crop group	Compound	Soil DT_{50} (days)	K_{oc} [L/kg]	AR [g a.s./ha]	MAF_m	AR_{eff} [a] [mg a.s./m²]	LD_{50} [mg a.s./kg bw]	Ratio (AR_{eff} / LD_{50})	No concern ratio
Orchards	Cyprodinil	35.5 ~~33.6~~	1706	375	2.10 ~~2.07~~	78.8 ~~77.6~~	>2000	<0.039	≤3000
		114.2 ~~118.9~~ [b]			2.66 ~~2.67~~	99.8 ~~100~~		<0.050	

[a] The application rate is divided by 10 to convert from g/ha to mg/m²
[b] this represents the DT_{50} in acidic soils

Table 10.1.2-8: Long-term risk to mammals from drinking water – puddle scenario

Compound	Compound	Soil DT_{50} (days)	K_{oc} [L/kg]	AR [g a.s./ha]	MAF_m	AR_{eff} [a] [mg a.s./m²]	NOEL [mg a.s./kg bw]	Ratio (AR_{eff} / NOEL)	No concern ratio
Orchards	Cyprodinil	35.5 ~~33.6~~	1706	375	2.10 ~~2.07~~	78.8 ~~77.6~~	72.7	1.08 ~~1.07~~	≤3000
		114.2 ~~118.9~~ [b]			2.66 ~~2.67~~	99.8 ~~100~~		1.37 ~~1.38~~	

[a] The application rate is divided by 10 to convert from g/ha to mg/m²
[b] this represents the DT_{50} in acidic soils

The ratios of the application rates to the toxicity endpoints are below 3000 indicating low concern for acute and long-term exposure to birds in drinking water from puddles and no need to carry out further calculations of exposure in puddle water.

Risk assessment for other terrestrial vertebrates

Acute toxicity exposure ratio (TER_A)

The acute risk to mammals was assessed by calculation of toxicity exposure ratios (TER_A) according to the following equation:

$$TER_A = \frac{LD_{50}\ (\text{mg/kg bw})}{DDD\ (\text{mg/kg bw/d})}$$

Acute risk was calculated using the lowest acute LD_{50} value for cyprodinil. According to the Commission Regulation (EU) No. 546/2011, a TER_A value below 10 indicates a potential acute risk to mammals. The results are presented below.

Table 10.1.2-9: Screening step - Acute risk (TER_A) to mammals from cyprodinil

Compound	Crop group	Indicator species	LD_{50} (mg/kg bw)	DDD (mg a.s./kg bw)	TER_A
A8779A	Orchards	Small herbivorous mammal	>2000	123	>16
Cyprodinil			>2000	61.4	>33

The TER_A values are greater than the Commission Regulation (EU) No. 546/2011 trigger of 10, indicating that acute risk to mammals is acceptable following use of A8637C according to the proposed use pattern.

Acute risk assessment to birds through drinking water

Cyprodinil has negligible potential for acute exposure of mammals to drinking water (see Table 10.1.2-7).

Long-term toxicity exposure ratio (TER_{LT})

According to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals 2009**, short-term risk to mammals is not presented as it is covered by the long-term risk assessment.

The long-term risk to mammals was assessed by calculation of toxicity exposure ratio (TER_{LT}) according to the following equation:

$$TER_{LT} = \frac{\text{NOEC(mg/kg bw/day)}}{\text{Long-term DDD(mg/kg bw/day)}}$$

The lowest NOEL value for cyprodinil was used to calculate the TER value in order to provide a worst-case scenario. The resulting TER_{LT} value is given below.

Table 10.1.2-10: Screening step - long-term risk (TER_{LT}) to mammals

Compound	Crop group	Indicator species	NOEL (mg a.s./kg bw/day)	DDD (mg a.s./kg bw/day)	TER_{LT}
Cyprodinil	Orchards	Small herbivorous mammal	72.7	18.7	**3.9**

The TER_{LT} is lower than the Commission Regulation (EU) No. 546/2011 trigger value of 5, indicating that a Tier 1 risk assessment is required.

Tier 1 risk assessment

The Tier 1 TER values calculated for cyprodinil are given in the table below.

Table 10.1.2-11: Tier 1 - long-term TER values for focal species relevant to the use of A8637C

Compound	Crop grouping / growth stage	Generic focal species	NOEL (mg a.s./kg bw/day	DDD (mg/kg bw/day)	TER_{LT}
Cyprodinil	Orchards BBCH 10-19	Small herbivorous mammal “vole” Common vole (*Microtus arvalis*)	72.7	14.9	**4.9**
	Orchards BBCH 20-40			11.2	6.5
	Orchards BBCH ≥40			5.61	13
	Orchards BBCH 71-79	Frugivorous mammal “dormouse” Garden dormouse (*Eliomys quercinus*)		5.87	12
	Orchards BBCH 10-19	Large herbivorous mammal “lagomorph” Rabbit (*Oryctolagus cuniculus*)		2.97	24
	Orchards BBCH 20-40			2.22	33
	Orchards BBCH ≥40			1.11	65
	Orchards BBCH 10-19	Small omnivorous mammal “mouse” Wood mouse (*Apodemus sylvaticus*)		1.60	45
	Orchards BBCH 20-40			1.21	60
	Orchards BBCH ≥40			0.594	120

TERs shown in **bold** fall below the relevant trigger

For one scenario (vole feeding on grass between BBCH 10-19) the TER_{LT} is below the Annex VI trigger value of 5. Therefore further consideration is needed.

Refinement of long-term risk for voles foraging in orchards at BBCH 10-19

Appendix E of the EFSA Guidance on Bird and Mammal Risk Assessment on ‘Impact of crop interception on residues on plant food items’, in referring to deposition estimates for Tier 1, states that “*The deposition factors provided for the different crops and growth stages are likely to reflect conservative estimates. In the context of a higher-tier assessment, the more detailed values of FOCUS groundwater report (FOCUS, 2000) may therefore also be used.*” Therefore, this risk assessment will be refined using FOCUS groundwater interception values.

For orchards at growth stage 10-19, the interception estimated at Tier 1 is 20%. According to **EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values of active substances of plant protection products and transformation products of these active substances in soil**[1], a realistic interception would be 60%. The risk assessment has been refined using the interception value of 60% and is presented below:

[1] European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

Table 10.1.2-12: Refined long-term DDD values for cyprodinil for voles feeding on grass in pome fruit (BBCH 10-19)

Crop	Focal species	Diet and crop BBCH	Mean RUD	FIR/bw	App. rate (kg a.s./ha)	Deposition factor	MAF	f_{twa}	DDD (mg a.s/kg bw/day)
Orchard	Vole	Grass BBCH 10-19	54.2	1.33	0.375	0.4	1.3	0.53	7.45

The TER values can then be re-calculated as presented in the table below

Table 10.1.2-13: Long-term risk (TER_{LT}) to mammals from cyprodinil – refinement for voles feeding on grass in pome fruit (BBCH 10-19)

Crop	Focal species	Diet and crop BBCH	NOEL (mg/kg bw/d	DDD (mg a.s/kg bw/day)	TER
Orchard	Vole	Grass BBCH 10-19	72.7	7.45	9.8

The refined TER_{LT} value is greater than the Regulation (EU) 546/2011 trigger of 5, indicating that long- term risk to mammals is acceptable following use of A8637C according to the proposed use pattern.

Long-term risk assessment to mammals through drinking water

Cyprodinil has negligible potential for long-term exposure of mammals to drinking water (see Table 10.1.2-8).

Effects on secondary poisoning

According to **EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009**, substances with a log P_{OW} greater than 3 have potential for bioaccumulation. Cyprodinil has a log Pow of 4.0, indicating a potential risk of secondary poisoning therefore a risk assessment is provided.

Risk to earthworm eating mammals

A risk assessment of the risk of secondary poisoning to earthworm-eating mammals is conducted using the following equation:

$$TER = \frac{\text{NOEL (mg/kg)}}{PEC_{worm}\text{ (mg/kg)} \;\; x\, 1.28}$$

Where:

PEC_{worm} = 21 d time-weighted average $PEC_{soil} \times$ BCF
BCF = $C_{worm}/C_{soil} = (0.84 + 0.012\ K_{ow}) / f_{oc} \times K_{oc}$
K_{ow} = Octanol water partition coefficient
K_{oc} = Organic carbon adsorption coefficient
f_{oc} = Organic carbon content of soil (0.02 taken as a default value)

1.28 is a constant used to convert the PEC_{worm} to a daily dose and is based on a 10 g mammal eating 12.8 g of worms per day (**Smit 2005** in EFSA Guidance).

The 21-day time-weighted average accumulation soil PEC was used. For details of soil PEC calculations, see the supporting **Document M-CP Section 9**.

The resulting TER value is given in the table below:

Table 10.1.2-14: Long-term risk from secondary poisoning to earthworm-eating mammals

Compound	PEC $_{soil}$ (mg/kg)	K_{ow}	f_{oc}	Koc	BCF	PEC_{worm} (mg/kg)	DDD (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER_{worm}
Cyprodinil	0.986 ~~0.556~~	10000	0.02	1706	3.54	3.49 ~~1.97~~	4.47 ~~2.52~~	72.7	16 ~~29~~

The TER value for cyprodinil exceeds the long-term trigger value of 5, indicating that it poses an acceptable risk to earthworm eating mammals.

The main soil metabolites of cyprodinil (CGA249287, CGA275535 and CGA321915) are of low acute oral toxicity to mammals (rat acute oral LD_{50} >2000 mg/kg; refer to **Cyprodinil; EFSA Scientific Report 51, 2005**). Highest log P_{OW} values for CGA249287 and CGA321915 are 1.5 and -0.10, respectively indicating low potential for bioaccumulation. CGA275535 has a log P_{OW} value above 3 (log P_{OW} 3.3 at pH 7.0). Given that the metabolites will be found at lower concentrations than the parent active substance, the risk assessment for the parent is considered to cover the metabolites.

Risk to fish eating mammals

A risk assessment of the risk from secondary poisoning to fish-eating mammals is conducted using the following equation:

TER = long-term NOEC as daily dietary dose / (PEC_{fish} × 0.142)

Where: $PEC_{fish} = PEC_{water\ (highest\ 3\ wk\ twa)} * BCF_{(whole\ body)}$

The factor of 0.142 is based on a 3000 g mammal eating 425 g fish per day (**Smit, 2005** in EFSA Guidance), and converts the PEC_{fish} to a daily dose.

The worst case Step 2 21-day time-weighted average surface water PECsw following use of A8637C in pome fruit was used. For details of surface water PEC calculations, see the supporting **M-CP Section 9.**

The resulting TER values are given in the table below:

Table 10.1.2-15: Long-term risk from secondary poisoning to fish-eating mammals

Substance	PEC_{water} 21 day TWA (mg/L)	BCF	PEC_{fish} (mg/kg)	ETE (mg/kg/bw/ day)	Long-term NOEL (mg/kg bw/day)	TER_{fish}
Cyprodinil	0.0543	400	21.7	3.08	72.7	24

The TER values for cyprodinil and fludioxonil exceed the long-term trigger value of 5, indicating that they pose an acceptable risk to fish eating mammals.

Conclusion

The risk assessment indicates that A8637C poses an acceptable risk to mammals from secondary poisoning following the proposed use.

Biomagnification in terrestrial food chains

The results from adsorption, distribution, metabolism and excretion (ADME) studies did not indicate a potential for cyprodinil accumulation, as the tissue residues 7 days after application were always <1% of applied dose (refer to the respective **EFSA Scientific Reports for cyprodinil**).

Also, fish bioaccumulation studies showed rapid depuration of residues of cyprodinil and major metabolites formed (see Annex Point IIIA 10.2.4).

CP 10.1.2.1 Acute oral toxicity to mammals

A mammalian toxicity study, performed on A8779A has been conducted and was provided in the original EU review. The endpoints are summarised in Table 10.1.2-1 above and discussed in **M-CP, Section 7**.

The acute oral LD_{50} of A8779A in this study to both male and female rats is in excess of 2000 mg/kg bw.

CP 10.1.2.2 Higher tier data on mammals

No other higher tier data on mammals are required as the risk assessment presented above indicates an acceptable risk from the supported uses of A8637C.

Relevant Literature on Wild Mammals

No scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

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

Toxicity

Table 10.1.3-1: Table of endpoints to assess risk from use of A8637C

Organism	Test item	Test type	Endpoint	Reference (author, date, Syngenta File No.)
Xenopus laevis	Cyprodinil	Acute	LC_{50} = 12.3 mg/L	***Zhao (2009) CGA219417_11635***

Risk assessment

Guidance on the risk assessment for other terrestrial vertebrate wildlife has yet to be developed. An endpoint is available for effects of cyprodinil on the aquatic phase of *Xenopus laevis* (i.e. tadpoles) so it is appropriate to use surface water concentrations and to derive a Toxicity Exposure Ratio (TER). The TER_A value has been derived using the worst case FOCUS Step 2 PEC_{SW} value and the result is presented below.

Table 10.1.3-2: Amphibian acute TER value for cyprodinil

Test organism	Test substance	LC_{50} (µg/L)	PEC_{SW} (µg/L)	TER_A	Trigger value
Xenopus laevis	Cyprodinil	12300	64.2	190	100

The TER_A value is greater than the trigger indicating that A8637C would pose an acceptable acute risk to amphibian larvae when applied according to proposed use patterns. In addition, there is currently no guidance addressing terrestrial life stages of amphibians and reptiles in PPP risk assessments. Therefore, the risk assessment provided above for birds and mammals is considered to be protective of terrestrial amphibian and reptile species.

Relevant Literature on Other Terrestrial Vertebrate Wildlife (reptiles and amphibians)

No scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

CP 10.2 Effects on Aquatic Organisms

Toxicity

Summary of endpoints relevant for risk assessment:

Table 10.2-1: Aquatic vertebrate toxicity data for A8637C and cyprodinil

Organism	Test item	Endpoint (mg/L)		Proposed endpoint for risk assessment (mg/L)	Reference (author, date, Syngenta File No.)
Acute					
Rainbow trout (*Oncorhynchus mykiss*)	A8637C	EU	96 h LC_{50} = 6.2$_{(nom)}$	96 h LC_{50} = 6.2	***Rufli (1996) CGA219417/0712***
Sheepshead minnow *(Cyprinodon variegatus)*	Cyprodinil		96 h LC_{50} = 1.25$_{(mm)}$	96 h LC_{50} = 1.25	***Ward et al. (1995) CGA219417/0652***
Xenopus laevis tadpoles			96 h LC_{50} = 12.3	96 h LC_{50} = 12.3	***Zhao (2009) CGA219417_11635***
Chronic					
Fathead minnow *(Pimephales promelas)*	Cyprodinil	EU	NOEC = 0.231$_{(mm)}$	NOEC 0.231	***Ward et al. (1995) CGA219417/0653***
Sheepshead minnow		New	NOEC (growth) = 0.0406$_{(mm)}$	NOEC (growth) = 0.0406	***Minderhout et al. (2014) CGA219417_50676***

nom = Endpoint derived using nominal concentration
mm = Endpoint derived using mean measured concentration
'New' refers to an endpoint from a study conducted since the previous submission of cyprodinil or a study which was not previously submitted

Table 10.2-2: Aquatic invertebrate data for A8637C and cyprodinil

Organism	Test item	Endpoints (mg/L)		Proposed endpoint for risk assessment (mg/L)	Reference (author, date, Syngenta File No.)
Acute					
Daphnia magna	A8637C	EU	48 h EC_{50} = 0.14$_{(nom)}$	48 h EC_{50} = 0.14	***Wallace (2001) CGA219417/1032***
	Cyprodinil		48 h EC_{50} = 0.033$_{(mm)}$	48 h EC_{50} = 0.033$_{(mm)}$	***Boeri et al. (1995) CGA219417/0461***
Daphnia longispina			48 h EC_{50} = 0.22$_{(mm)}$	48 h EC_{50} = 0.22$_{(mm)}$	***Peither (2000) CGA219417/0993***
Daphniopsis sp.			24 h EC_{50} = 0.21$_{(mm)}$	24 h EC_{50} = 0.21$_{(mm)}$	***Peither (2000) CGA219417/0990***
Simocephalus vetulus			48 h EC_{50} = 0.15$_{(mm)}$	48 h EC_{50} = 0.15$_{(mm)}$	***Peither (2000) CGA219417/0994***
Gammarus sp.			48 h EC_{50} = 1.8$_{(mm)}$	48 h EC_{50} = 1.8$_{(mm)}$	***Peither (2000)***

Organism	Test item	Endpoints (mg/L)		Proposed endpoint for risk assessment (mg/L)	Reference (author, date, Syngenta File No.)
					CGA219417/0998
Thamnocephalus platyurus			24 h EC_{50} = 0.12$_{(mm)}$	24 h EC_{50} = 0.12$_{(mm)}$	***Peither (2000) CGA219417/0991***
Ostracoda sp.			48 h EC_{50} = 1.1$_{(mm)}$	48 h EC_{50} = 1.1$_{(mm)}$	***Peither (2000) CGA 249417/0995***
Brachionus calyciflorus			24 h EC_{50} >9.5$_{(mm)}$	24 h EC_{50} >9.5$_{(mm)}$	***Peither (2000) CGA219417/0992***
Cloeon sp.			48 h EC_{50} = 3.5$_{(mm)}$	48 h EC_{50} = 3.5$_{(mm)}$	***Peither (2000) CGA219417/0996***
Chaoborus sp.			48 h EC_{50} = 4.0$_{(mm)}$	48 h EC_{50} = 4.0$_{(mm)}$	***Peither (2000) CGA219417/0999***
Bay shrimp (*Mysidopsis bahia*)		New	96 h LC_{50} = 0.00805$_{(mm)}$	96 h LC_{50} = 0.00805$_{(mm)}$ [a]	***Ward et al. (1995) CGA219417/0649***
Lymnea stagnalis		EU	48 h EC_{50} = 2.9$_{(mm)}$	48 h EC_{50} = 2.9$_{(mm)}$	***Peither (2000) CGA219417/0997***
Crassostrea virginica		New	48 h EC_{50} = 0.36$_{(mm)}$	-	***Ward et al. (1995) CGA219417/0650***
~~*Asellus aquaticus* (adults)~~			~~96 h EC_{50} = 1.96$_{(nom)}$~~	~~96 h EC_{50} = 1.96$_{(nom)}$~~	~~***Maynard (2011) CGA219417_11454***~~
Asellus aquaticus (nymphs)			96 h EC_{50} = 2.64$_{(nom)}$	96 h EC_{50} = 2.64$_{(nom)}$	***Maynard (2011) CGA219417_11453***
Grandidierella japonica			10 day LC_{50} = 0.42 mg a.s./kg dry weight sediment $_{(mm)}$	10 day LC_{50} = 0.42 mg a.s./kg dry weight sediment $_{(mm)}$	***Kreuger & Sutherland (1998) CGA219417/0893***
Hyalella azteca			10 day LC_{50} = 0.73 mg a.s./kg dry weight sediment $_{(mm)}$	-	***Sutherland & Krueger (1998) CGA219417/0892***
~~*Gammarus pulex*~~		~~LIT~~	~~96 h LC_{50} = 0.69~~	~~96 h LC_{50} = 0.69~~	~~***Beketov & Liess (2008)***~~
Chronic					
Mysidopsis bahia	Cyprodinil	New	30 day NOEC = 0.0019$_{(mm)}$	EC_{10} = 0.00197	***Drottar & Kreuger (1999) CGA219417/0926***
Chironomus riparius		EU	28 d NOEC = 25.6 mg/kg sediment$_{(nom)}$ (static test)	28 d NOEC = 25.6 mg/kg sediment$_{(nom)}$	***Grade (2001) CGA249217/0024***
Higher tier studies (micro-mesocosm)					
Aquatic invertebrates	Cyprodinil [a]	New	NOAEAC = 14.6max; 10nom NOEC = 1.8max; 1.5nom ~~NOEC (ETO-RAC, class 2) = 0.0146;~~	NOAEAC = 14.6max; 10nom NOEC = 1.8max; 1.5nom ~~NOEC (ETO-RAC) = 0.0146~~	***Ashwell et al. (2007) CGA219417/1683***

[a] Applied as A14325E
mm = Endpoint derived using mean measured concentration
nom = Endpoint derived using nominal concentration
'New' refers to an endpoint from a study conducted since the previous submission of cyprodinil or a study which was not previously submitted

Comment from RMS: *Concerning the 96h-LC50 of 1.96 mg/L determined for adult Asellus aquaticus (K-CA 8.2.4 .2/02; Maynard 2011a), this endpoint should not be used in the risk assessment given that*

10% mortality in control are already reached at 24 hours. This validity criterion is also exceeded at 72 and 96 hours in the similar study conducted with juvenile Asellus aquaticus (K-CA 8.2.4.2/01; Maynard 2011). The study design without sediment is questionable given the type of organism. However, it is the opinion of RMS that the 48h-LC 50 of 2.35 mg/L determined with juvenile Aselfus aquaticus (K-CA 8.2.4.2/01; Maynard 2011) can be used given that only 5% mortality in the control was observed at this time.

Response from Syngenta: The validity criterion selected by the study director for mortality of the adult *Asellus aquaticus* was on the basis of the adult mortality criterion used for the *Daphnia magna* reproduction test given that the test organisms were confined individually and in the absence of a test guideline. However, the endpoint has been removed from Table 10.2-2 and has not been used in the SSD analysis.

Comment from RMS: *Concerning the LC50 of 0.69 mg/L determined for Gammarus pulex in the publication of Beketov and Liess (2008), can you please provide further details concerning the mortalities in control and test item concentrations? Otherwise, this endpoint could not be used in the risk assessment.*

Response from Syngenta: Control mortality data were not reported in this research article. As requested the endpoint has been removed form Table 10.2-2 and the SSD has been re-run having omitted it. Syngenta originally included this endpoint for transprarency.

Comment from RMS: *Concerning the microcosm study of Ashwell et al. (2007), RMS does not agree with the NOEC of 10 µg/L proposed by applicant. The results clearly demonstrate that Asellus is the critical taxa for defining the study endpoint, due to transient effects observed at low concentration (5 µg/L; class 3a effects) and due to pronounced effects without recovery observed at high concentrations (20 and 50 µg/L). The effects of the class 3a at the test concentration of 5 µg/L in the sample obtained by sweep nets is based on significant reduction of Asellus population compared to the control in at least 4 sampling dates (day 44, day 86, day 100 and day 114) as shown in Table 85 and Figure 91 of the volume 1 (p.187). No clear recovery occurred at the test concentration of 5 µg/L until the end of the test. The significance of the effects observed at 5 µg/L for the sweep net sampling method is supported by the abundance of Asellus population measured in the samples, obtained using the ESAS method (See Table 68 and Figure 72). In Table 68, abundance of Asellus in the 5 µg/L and 10 µg/L at sampling day 57 is statistically reduced when compared to the abundance of control and 1.5 µg/L concentration. Even if it is not statistically significant, abundance is also reduced at sampling days 71, 99 and 113 in the 5 µg/L and 10 µg/L when compared to the control. Moreover, when considering the MDD calculations presented in Tables 4 and 6 for Asellus aquaticus in the statistical reanalysis report (Taylor and Dark, 2015), the overall NOEC for ESAS and Sweep nets sampling is stated to be at 1.5 µg/L. Therefore, the NOEC to be used for the ETO-RAC determination has to be 1.5 µg/L. The similarity of the transient effects observed at 5 and 10 µg/L suggests setting the NOEAEC at 10 µg/L for the ERO-RAC determination . The NOEC and NOEAEC from this study should be expressed in nominal concentrations.*

Response from Syngenta: Syngenta consider any effects seen on *Asellus aquaticus* to be transient and not concentration related. The lowest NOEC value reported for *Asellus aquaticus* was 1.5 µg/L in the MDD re-analysis report (Table 6, Taylor & Dark, 2016). However, it should be noted that this reported NOEC value occurred on Day 44 and is bracketed by NOECs of 20 and 50 µg/L on Days 30 and 58 respectively.

No significant effects on *Asellus* abundance was observed at 5 or 10 µg/L in the leaf litterbag samplers at any timepoint within the study, supporting the use of 10 µg/L as the ETO concentration.

In the request for additional information letter ANSES have commented that the NOEC and NOEAEC should be expressed in nominal concentrations. However, according to the aquatic guidance document the maximum measured concentration can be used to derive the mesocosm endpoint. In Section 9.3.5.2 it is stated:

"To evaluate chronic risks (triggered by the tier 1 chronic core data) either the peak concentration or a TWA concentration of the PPP in the relevant matrix (water, sediment) may be used as estimate of $RAC_{sw:ch}$ and PEC estimate"

The higher tier risk assessment for the long-term risk to aquatic invertebrates has been updated using RAC values based on nominal and maximum measured concentrations derived for the NOEC and NOEAEC.

Table 10.2-3: Algae and aquatic macrophyte data for A8637C and cyprodinil

Organism	Test item	Endpoint (mg/L)		Proposed endpoint for risk assessment (mg/L)	Reference (author, date, Syngenta File No.)
Algae					
Pseudokirchneriella subcapitata	A8637C	EU	72h E_bC_{50} = 4.1$_{(nom)}$	72h E_bC_{50} = 4.1	***Wallace (2001) CGA219417/1031***
Pseudiokirchneriella subcapitata ~~*Skeletonema costatum*~~	Cyprodinil		72 h E_rC_{50} = 3.28$_{(mm)}$ [a] ~~96 h E_bC_{50} = 1.75$_{(im)}$~~	72 h E_rC_{50} = 3.28 96 h E_bC_{50} = 1.75	***Ward et al. (1995) CGA219417/0644***
Macrophytes					
Lemna gibba	Cyprodinil	EU	72 h E_yC_{50} = 7.42$_{(im)}$ [a] 7 d EC_{50} = 7.71$_{(im)}$	72 h E_yC_{50} = 7.42$_{(im)}$ 7 d EC_{50} = 7.71	***Ward et al. (1995) CGA219417/0645***

nom = Endpoint derived using nominal concentration
im = Endpoint derived using initial measured concentration
'New' refers to an endpoint from a study conducted since the previous submission of cyprodinil or a study which was not previously submitted
[a] Endpoints modified following re-analysis of the data

Metabolites of cyprodinil

Aquatic organisms may be exposed to metabolites of cyprodinil. Tests have been conducted with CGA249287, CGA275535, CGA321915, CGA263208 and CA1139A.

The results from toxicity tests with representative freshwater species conducted with metabolites are summarised in the tables below.

Table 10.2-4: Toxicity to aquatic organisms to cyprodinil metabolites

Test species	Metabolite	Endpoint	Value (mg/L)	Reference (author, date, Syngenta No.)
Fish				
Oncorhynchus mykiss	CGA249287	96-h acute LC_{50}	55	***Maetzler (1999) CGA249287/0007***
	CGA275535		2.1	***Pfeifle (2001) CGA275535/0017***
	CGA263208 (phenyl guanidine)		2.1	***Vial (1991) CA1059/0009***
	CA1139A (carbonate salt of phenyl guanidine)		>100	***Grade (1992) CA1139/0008***
Aquatic invertebrates				
Daphnia magna	CGA249287	48-h acute EC_{50}	>100	***Maetzler (1999) CGA249287/0008***
	CGA275535		6.8	***Maetzler (2001) CGA275535/0016***

Test species	Metabolite	Endpoint	Value (mg/L)	Reference (author, date, Syngenta No.)
	CGA321915		>98	***Eckenstein (2015) CGA321915_10005***
	CGA263208 (phenyl guanidine)		20.6	***Vial (1991) CA1059/0010***
	CA1139A (carbonate salt of phenyl guanidine)		15.7	***Grade (1992) CA1139/0009***
Chironomus riparius [a]	CGA321915		>97	***Tobler (2015) CGA321915_10009***
Algae				
Pseudokirchneriella subcapitataa	CGA249287	72-h E_rC_{50}	>100	***Maetzler (1999) CGA249287/0006***
	CGA275535	72-h E_rC_{50}	18	***Maetzler (2001) CGA275535/0015***
	CGA321915	72-h E_bC_{50}	>99	***Eckenstein (2015) CGA321915_10004***
Desmodesmus subspicatus	CGA263208 (phenyl guanidine)	72-h E_bC_{50}	1.86	***Vial (1991) CA1059/0012***
	CA1139A (carbonate salt of phenyl guanidine)	72-h E_bC_{50}	3.80	***Rufli (1992) CA1139/0010***
Sediment dwellers				
Chironomus riparius	CGA249287	28 d NOEC	25.6 mg/kg	***Grade (2001) CGA249217/0024***

[a] although *Chironomus riparius* is a sediment dweller, this data is presented in this section because the exposure regime was acute and young larvae were exposed in water only, no sediment being present

An aqueous photolysis study carried out in 2015 has yielded several new metabolites including guanidine (CGA048109), phenyl guanidine (CGA263208), succinic acid (R008591), U2 and U4. Studies have previously been conducted with phenyl guanidine as carbonic acid (CGA263208) and carbonate (CA1139A) salts. These endpoints are presented in Table 10.2-4. As U2 and U4 have yet to be identified at the time of writing this document no further discussion on these metabolites is presented here.

Guanidine and succinic acid are ubiquitous compounds in the terrestrial and aquatic environments. Also, according to **Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater**[2] ……. *if a substance is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern."* Also succinic acid is designated "Generally Recognised as Safe" or GRAS by USFDA therefore can be added to food without testing.

Exposure

Aquatic organisms may be exposed to A8637C, cyprodinil and its major metabolites through spray drift, run-off and drainage from the application site into adjacent water bodies. Exposure of aquatic organisms from these routes was estimated by calculating Predicted Environmental Concentrations in surface water (PEC_{SW}) (see **M-CP Section 9** for details of calculations).

[2] Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC. (SANCO/221/2000-rev.10; 25 February 2003).

A8637C

Due to the differences in environmental fate and behaviour of the constituents of A8637C in aquatic systems, the only PEC_{SW} relevant for risk assessment is the maximum instantaneous PEC_{SW} from entry through spray-drift immediately after a single application. This PEC_{SW} was calculated using the following equation:

$$PEC_{SW}\ [\mu g/L] = \frac{\%\ \text{drift (90th percentile)} \times \text{application rate [g/ha]}}{\text{water depth (30 cm)} \times 10}$$

The PEC_{SW} values following a single application of A8637C to pome fruits are presented below.

Table 10.2-5: A8637C: Predicted Environmental Concentrations (PEC) in surface water

Application rate [g A8637C /ha]	Crop	Drift buffer [m]	Drift rate [%]	Initial PEC_{SW} [µg A8637C/L]
1 application (90th percentile drift)				
750	Pome fruit (early applications	3	29.2	73.0
		10	11.81	29.5
		15	5.55	13.9
		20	2.77	6.93
		30	1.04	2.60
		40	0.52	1.30
	Pome fruit (late applications	3	15.73	39.3
		10	3.60	9.00
		15	1.81	4.53
		20	1.09	2.73
		30	0.54	1.35

Cyprodinil and its metabolites

PEC_{SW} values for cyprodinil and its relevant metabolites were calculated using the FOCUS surface water models following one and three applications of A8637C. FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} values were calculated using an extreme worst-case exposure scenario. For full details of the assumptions used in the exposure calculations, see **M-CP Section 9**.

The resulting worst-case FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} values for cyprodinil and its metabolites are presented below. For FOCUS Step 2, concentrations were estimated for Northern and Southern Europe.

Table 10.2-6: FOCUS Step 1 and 2 PEC_{SW} values for cyprodinil following application of A8637C to pome fruit

Use pattern	Timing of application	Step	Region	Max PEC_{SW} [µg/L]	Max PEC_{SED} [µg/kg]
Pome fruit 1 × 375g a.s./ha	-	Step 1	-	74.8	836
	'Early' (Mar – May)	Step 2	North Europe	36.5	287
	'Late' (Jun - Sept)			36.5	287
	'Early' (Mar – May)		South Europe	36.5	388
	'Late' (Jun - Sept)			36.5	337

Use pattern	Timing of application	Step	Region	Max PEC_{SW} [µg/L]	Max PEC_{SED} [µg/kg]
Pome fruit 3 × 375g a.s./ha	-	Step 1	-	224	2510
	'Early' (Mar – May)	Step 2	North Europe	50.8	~~688~~ 687
	'Late' (Jun - Sept)			50.8	~~688~~ 687
	'Early' (Mar – May)		South Europe	~~64.2~~ 64.0	~~958~~ 955
	'Late' (Jun - Sept)			~~56.2~~ 56.1	~~823~~ 821

The worst-case Step 2, 21-day time weighted average (TWA) surface water concentration used for vertebrate secondary poisoning assessments = ~~54.3~~ 54.2 µg/L. This value was derived for 3 'early' applications from March to May in southern Europe.

Table 10.2-7: FOCUS Step 1 and 2 PEC_{SW} values for CGA249287, CGA275535, CGA321915 and CGA263208 following application of A8637C to pome fruit

Step	No of apps	Region	CGA275535	CGA321915	CGA263208	CGA249287	
			Max PEC_{SW} [µg/L]				Max PEC_{SED} [µg/kg]
1	1	-	8.35	~~4.28~~ 4.31	13.7	~~14.7~~ 24.2	~~23.8~~ 89.5
	3		~~454~~ 25.1	~~12.8~~ 12.9		~~71.4~~ 72.7	~~12.8~~ 269
2	1	North Europe	0.108	~~0.658~~ 0.673	3.11	~~5.93~~ 6.77	~~9.78~~ 25.3
	3		0.108	~~1.62~~ 1.80		~~15.1~~ 17.5	~~24.9~~ 65.5
	1	South Europe	0.215	~~1.32~~ 1.35	~~3.93~~ 3.92	~~7.46~~ 9.78	~~12.4~~ 37.3
	3		0.215	~~3.24~~ 3.59		~~19.4~~ 25.9	~~32.4~~ 98.9

Table 10.2-8: Maximum PEC_{SW} values for cyprodinil following a single and three applications to pome fruit at FOCUS Step 3 (all scenarios) for early and late sprays

~~Crop / surrogate crop* / timing~~	~~Scenario~~	~~Water body~~	~~Single application~~			~~Multiple application~~		
			~~PEC_{SW} [µg/L]~~	~~PEC_{SED} [µg/kg]~~	~~Main route of entry to water body for max. PEC_{SW}~~	~~PEC_{SW} [µg/L]~~	~~PEC_{SED} [µg/kg]~~	~~Main route of entry to water body for max. PEC_{SW}~~
~~Apple / pome fruit (early appl.) / 'early' window~~	~~D3~~	~~Ditch~~	~~29.1~~	~~19.3~~	~~Drift~~	~~23.5~~	~~29.0~~	~~Drift~~
	~~D4~~	~~Pond~~	~~1.77~~	~~13.5~~	~~Drift~~	~~3.14~~	~~31.1~~	~~Drift~~
	~~D4~~	~~Stream~~	~~29.6~~	~~2.42~~	~~Drift~~	~~24.4~~	~~4.34~~	~~Drift~~
	~~D5~~	~~Pond~~	~~1.77~~	~~14.1~~	~~Drift~~	~~3.15~~	~~32.8~~	~~Drift~~
	~~D5~~	~~Stream~~	~~28.8~~	~~0.886~~	~~Drift~~	~~26.7~~	~~7.88~~	~~Drift~~
	~~R1~~	~~Pond~~	~~1.76~~	~~12.3~~	~~Drift~~	~~3.02~~	~~27.5~~	~~Drift~~
	~~R1~~	~~Stream~~	~~23.5~~	~~2.99~~	~~Drift~~	~~18.9~~	~~4.77~~	~~Drift~~
	~~R2~~	~~Stream~~	~~31.1~~	~~1.93~~	~~Drift~~	~~25.3~~	~~4.18~~	~~Drift~~
	~~R3~~	~~Stream~~	~~33.2~~	~~7.62~~	~~Drift~~	~~26.6~~	~~8.92~~	~~Drift~~
	~~R4~~	~~Stream~~	~~23.6~~	~~3.51~~	~~Drift~~	~~18.9~~	~~7.94~~	~~Drift~~
~~Apple / pome fruit~~	~~D3~~	~~Ditch~~	~~13.7~~	~~12.9~~	~~Drift~~	~~9.84~~	~~22.4~~	~~Drift~~
	~~D4~~	~~Pond~~	~~0.615~~	~~5.04~~	~~Drift~~	~~0.948~~	~~11.2~~	~~Drift~~
	~~D4~~	~~Stream~~	~~13.8~~	~~2.75~~	~~Drift~~	~~9.85~~	~~2.73~~	~~Drift~~
	~~D5~~	~~Pond~~	~~0.616~~	~~5.27~~	~~Drift~~	~~0.988~~	~~11.3~~	~~Drift~~

~~Crop / surrogate crop[a] / timing~~	~~Scenario~~	~~Water body~~	~~Single application~~			~~Multiple application~~		
			~~PEC_{SW} [µg/L]~~	~~PEC_{SED} [µg/kg]~~	~~Main route of entry to water body for max. PEC_{SW}~~	~~PEC_{SW} [µg/L]~~	~~PEC_{SED} [µg/kg]~~	~~Main route of entry to water body for max. PEC_{SW}~~
~~(late appl.) / 'late' window~~	~~D5~~	~~Stream~~	~~14.9~~	~~4.07~~	~~Drift~~	~~10.6~~	~~4.35~~	~~Drift~~
	~~R1~~	~~Pond~~	~~0.615~~	~~4.94~~	~~Drift~~	~~0.977~~	~~9.97~~	~~Drift~~
	~~R1~~	~~Stream~~	~~10.6~~	~~3.18~~	~~Drift~~	~~7.53~~	~~3.34~~	~~Drift~~
	~~R2~~	~~Stream~~	~~14.1~~	~~1.57~~	~~Drift~~	~~10.1~~	~~1.96~~	~~Drift~~
	~~R3~~	~~Stream~~	~~14.9~~	~~3.96~~	~~Drift~~	~~10.6~~	~~4.63~~	~~Drift~~
	~~R4~~	~~Stream~~	~~10.6~~	~~2.13~~	~~Drift~~	~~7.53~~	~~5.45~~	~~Drift~~

Crop / surrogate crop[a] / timing	**Scenario**	**Water body**	**Single application**			**Multiple application**		
			PEC_{SW} [µg/L]	**PEC_{SED} [µg/kg]**	**Main route of entry to water body for max. PEC_{SW}**	**PEC_{SW} [µg/L]**	**PEC_{SED} [µg/kg]**	**Main route of entry to water body for max. PEC_{SW}**
Apple / pome fruit (early appl.) / 'early' window	D3	Ditch	29.1	19.3	Drift	23.5	29	Drift
	D4	Pond	1.77	13.5	Drift	3.14	31.1	Drift
	D4	Stream	29.6	2.42	Drift	24.4	4.34	Drift
	D5	Pond	1.77	14.1	Drift	3.15	32.8	Drift
	D5	Stream	28.8	0.886	Drift	26.7	7.88	Drift
	R1	Pond	1.76	12.3	Drift	3.02	27.5	Drift
	R1	Stream	23.5	2.99	Drift	18.9	4.77	Drift
	R2	Stream	31.1	1.93	Drift	25.3	4.18	Drift
	R3	Stream	33.2	7.62	Drift	26.6	8.92	Drift
	R4	Stream	23.6	3.51	Drift	18.9	7.94	Drift
Apple / pome fruit (late appl.) / 'late' window	D3	Ditch	13.7	12.9	Drift	9.84	22.4	Drift
	D4	Pond	0.615	5.04	Drift	0.948	11.2	Drift
	D4	Stream	13.8	2.75	Drift	9.85	2.73	Drift
	D5	Pond	0.616	5.27	Drift	0.988	11.3	Drift
	D5	Stream	14.9	4.07	Drift	10.6	4.35	Drift
	R1	Pond	0.615	4.94	Drift	0.977	9.97	Drift
	R1	Stream	10.6	3.18	Drift	7.53	3.34	Drift
	R2	Stream	14.1	1.57	Drift	10.1	1.96	Drift
	R3	Stream	14.9	3.96	Drift	10.6	4.63	Drift
	R4	Stream	10.6	2.13	Drift	7.53	5.45	Drift

Table 10.2-9: Maximum PEC_{SW} values for cyprodinil following a single and three applications to pome fruit at FOCUS Step 4 (all scenarios) for early and late sprays

Crop / surrogate crop[a] / timing	Scenario	Water body	Single application PEC$_{SW}$ [µg/L]			Multiple application PEC$_{SW}$ [µg/L]		
Run-off mitigation			-	-	-	-	-	-
Spray-drift buffer			10 m	15 m	20 m	10 m	15 m	20 m
Drift-reducing nozzle			-	-	-	-	-	-
Apple / pome fruit (early appl.) / 'early' window	D3	Ditch	14.0	6.30	3.20	10.6	5.98	2.75
	D4	Pond	nr	nr	nr	nr	nr	nr
	D4	Stream	15.7	7.05	3.59	12.2	6.85	3.16
	D5	Pond	nr	nr	nr	nr	nr	nr
	D5	Stream	15.2	6.85	3.48	13.3	7.49	3.45
	R1	Pond	nr	nr	nr	nr	nr	nr
	R1	Stream	12.4	5.57	2.83	9.43	5.30	2.44
	R2	Stream	16.4	7.38	3.75	12.6	7.10	3.27
	R3	Stream	17.5	7.89	4.01	13.3	7.46	3.43
	R4	Stream	12.5	5.61	2.85	9.43	5.30	4.54
Apple / pome fruit (late appl.) / 'late' window	D3	Ditch	4.14	2.09	1.28	3.14	1.57	0.930
	D4	Pond	nr	nr	nr	nr	nr	nr
	D4	Stream	4.81	2.44	1.50	3.63	1.81	1.06
	D5	Pond	nr	nr	nr	nr	nr	nr
	D5	Stream	5.20	2.62	1.60	3.91	1.94	1.14
	R1	Pond	nr	nr	nr	nr	nr	nr
	R1	Stream	3.68	1.86	1.19	2.77	1.37	1.35
	R2	Stream	4.92	2.48	1.52	3.71	1.84	1.07
	R3	Stream	5.19	2.62	1.60	5.06	3.66	3.09
	R4	Stream	3.68	1.86	1.64	2.94	2.94	2.94

nr = not relevant

Table 10.2-9: Maximum PEC_{SW} values for cyprodinil following a single applications to pome fruit at FOCUS Step 4 (all scenarios) for early sprays

Scenario	Mitigation options		Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)								
	Vegetative strip	Nozzle reduction	-	5 m	10 m	15 m	20 m	25 m	30 m	40 m	45 m
			PEC_{SW} (µg/L)								
D3 / ditch	0 m	0 %	-	22.8	14	6.3	3.2	1.89	1.22	0.621	-
		50 %	14.5	11.4	7.01	3.15	1.6	0.944	0.617	-	-
		75 %	7.26	5.7	3.5	1.58	0.8	0.486	-	-	-
		90 %	2.9	2.28	1.4	0.647	0.346	-	-	-	-
D4 / pond	0 m	0 %	-	1.99	1.1	0.582	0.359	0.247	0.183	0.114	-
		50 %	0.905	1.01	0.558	0.301	0.188	0.133	0.10	-	-
		75 %	0.477	0.52	0.294	0.162	0.103	0.075	-	-	-
		90 %	0.221	0.233	0.136	0.079	0.052	-	-	-	-
D4 / stream	0 m	0 %	-	25.5	15.7	7.06	3.6	2.13	1.39	0.714	-
		50 %	14.9	12.8	7.86	3.55	1.81	1.08	0.709	-	-
		75 %	7.48	6.42	3.95	1.79	0.919	0.553	-	-	-
		90 %	3.04	2.61	1.61	0.738	0.385	-	-	-	-
D5 / pond	0 m	0 %	-	1.99	1.1	0.582	0.359	0.247	0.183	0.114	-
		50 %	0.904	1.01	0.558	0.301	0.188	0.133	0.101	-	-
		75 %	0.476	0.52	0.294	0.162	0.103	0.076	-	-	-
		90 %	0.221	0.233	0.137	0.079	0.052	-	-	-	-
D5 / stream	0 m	0 %	-	24.8	15.2	6.85	3.49	2.06	1.34	0.68	-
		50 %	14.4	12.4	7.62	3.43	1.75	1.04	0.675	-	-
		75 %	7.24	6.21	3.82	1.72	0.88	0.524	-	-	-
		90 %	2.91	2.5	1.54	0.698	0.359	-	-	-	-
R1 / pond	0 m	0 %	-	1.99	1.1	0.582	0.359	0.247	0.182	0.114	-
		50 %	0.905	1.01	0.558	0.301	0.188	0.133	0.10	-	-
		75 %	0.476	0.52	0.294	0.162	0.103	0.075	-	-	-
		90 %	0.221	0.232	0.136	0.079	0.052	-	-	-	-
	10 – 12 m	0 %	-	1.99	1.1	0.582	-	-	-	-	-
		50 %	-	1.01	0.558	0.301	-	-	-	-	-
		75 %	-	0.52	0.294	0.162	-	-	-	-	-
		90 %	-	0.232	0.136	0.079	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	0.359	0.247	0.182	0.114	0.094
		50 %	-	-	-	-	0.133	0.133	0.10	0.066	-
		75 %	-	-	-	-	0.075	0.075	0.059	-	-
		90 %	-	-	-	-	-	-	-	-	-
R1 / stream	0 m	0 %	-	20.2	12.4	5.61	2.86	1.7	1.11	0.73	-
		50 %	11.8	10.2	6.24	2.82	1.45	0.866	0.73	-	-
		75 %	5.95	5.1	3.14	1.43	0.739	0.73	-	-	-
		90 %	2.44	2.09	1.29	0.73	0.73	-	-	-	-
	10 – 12 m	0 %		20.2	12.4	5.61	-	-	-	-	-
		50 %		10.2	6.24	2.82	-	-	-	-	-
		75 %		5.1	3.14	1.43	-	-	-	-	-
		90 %	-	2.09	1.29	0.6	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	2.86	1.7	1.11	0.577	0.444
		50 %	-	-	-	-	1.45	0.866	0.573	0.306	-
		75 %	-	-	-	-	0.739	0.45	0.304	-	-
		90 %	-	-	-	-	0.316	-	-	-	-
R2 / stream	0 m	0 %	-	26.8	16.5	7.42	3.78	2.24	1.46	0.748	-
		50 %	15.6	13.4	8.25	3.73	1.9	1.13	0.743	-	-
		75 %	7.85	6.74	4.15	1.88	0.963	0.579	-	-	-
		90 %	3.18	2.73	1.69	0.772	0.403	-	-	-	-
	10 – 12 m	0 %		26.8	16.5	7.42	-	-	-	-	-
		50 %		13.4	8.25	3.73	-	-	-	-	-
		75 %		6.74	4.15	1.88	-	-	-	-	-
		90 %	-	2.73	1.69	0.772	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	3.78	2.24	1.46	0.748	0.571
		50 %	-	-	-	-	1.9	1.13	0.743	0.387	-
		75 %	-	-	-	-	0.963	0.579	0.384	-	-

Scenario	Mitigation options		Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)								
	Vegetative strip	Nozzle reduction	-	5 m	10 m	15 m	20 m	25 m	30 m	40 m	45 m
			PEC$_{SW}$ (µg/L)								
		90 %	-	-	-	-	0.401	-	-	-	-
R3 / stream	0 m	0 %	-	28.6	17.6	7.9	4.02	2.38	1.56	1.49	-
		50 %	16.6	14.3	8.78	3.96	2.02	1.49	1.49	-	-
		75 %	8.34	7.16	4.41	2	1.49	1.49	-	-	-
		90 %	3.4	2.91	1.8	1.49	1.49	-	-	-	-
	10 – 12 m	0 %		28.6	17.6	7.9	-	-	-	-	-
		50 %		14.3	8.78	3.96	-	-	-	-	-
		75 %		7.16	4.41	2	-	-	-	-	-
		90 %	-	2.91	1.8	0.839	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	4.02	2.38	1.56	0.806	0.621
		50 %	-	-	-	-	2.02	1.21	0.8	0.429	-
		75 %	-	-	-	-	1.03	0.629	0.427	-	-
		90 %	-	-	-	-	0.444	-	-	-	-
R4 / stream	0 m	0 %	-	20.4	12.5	5.63	2.87	1.71	1.16	1.16	-
		50 %	11.9	10.2	6.27	2.84	1.45	1.16	1.16	-	-
		75 %	5.98	5.13	3.16	1.44	1.16	1.16	-	-	-
		90 %	2.44	2.1	1.3	1.16	1.16	-	-	-	-
	10 – 12 m	0 %		20.4	12.5	5.63	-	-	-	-	-
		50 %		10.2	6.27	2.84	-	-	-	-	-
		75 %		5.13	3.16	1.44	-	-	-	-	-
		90 %	-	2.1	1.3	0.605	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	2.87	1.71	1.12	0.581	0.448
		50 %	-	-	-	-	1.45	0.869	0.577	0.31	-
		75 %	-	-	-	-	0.742	0.454	0.308	-	-
		90 %	-	-	-	-	0.32	-	-	-	-

Table 10.2-10: Maximum PEC_{SW} values for cyprodinil following a multiple applications to pome fruit at FOCUS Step 4 (all scenarios) for early sprays

Scenario	Mitigation options		Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)							
	Vegetative strip	Nozzle reduction	-	5 m	10 m	15 m	20 m	25 m	30 m	40 m
			PEC_{SW} (µg/L)							
D3 / ditch	0 m	0 %		18.1	10.6	5.98	2.75	1.5	0.915	0.419
		50 %	-	18.1	10.6	5.98	2.75	1.5	0.918	0.444
		75 %	11.8	9.04	5.32	2.99	1.38	0.76	0.482	-
		90 %	5.87	4.52	2.66	1.5	0.7	0.407	-	-
D4 / pond	0 m	0 %	2.36	1.82	1.09	0.631	0.32	-	-	-
		50 %	-	3.59	2.03	1.06	0.603	0.392	0.278	0.165
		75 %	1.64	1.81	1.04	0.55	0.318	0.214	0.16	-
		90 %	0.868	0.94	0.547	0.298	0.177	0.125	-	-
D4 / stream	0 m	0 %	0.409	0.425	0.256	0.148	0.093	-	-	-
		50 %	-	20.7	12.2	6.86	3.16	1.74	1.07	0.507
		75 %	12.2	10.4	6.11	3.44	1.6	0.883	0.552	-
		90 %	6.15	5.21	3.08	1.74	0.811	0.461	-	-
D5 / pond	0 m	0 %	2.5	2.12	1.26	0.722	0.365	-	-	-
		50 %	-	3.59	2.04	1.07	0.606	0.395	0.281	0.169
		75 %	1.65	1.82	1.04	0.553	0.321	0.217	0.161	-
		90 %	0.871	0.943	0.55	0.301	0.18	0.129	-	-
D5 / stream	0 m	0 %	0.412	0.428	0.26	0.151	0.097	-	-	-
		50 %	-	22.6	13.3	7.49	3.45	1.88	1.15	0.542
		75 %	13.4	11.3	6.66	3.75	1.73	0.952	0.591	-
		90 %	6.68	5.66	3.33	1.88	0.874	0.493	-	-
R1 / pond	0 m	0 %	2.7	2.29	1.36	0.772	0.372	-	-	-
		50 %	-	3.44	1.96	1.03	0.592	0.39	0.281	0.174
		75 %	1.58	1.75	1.01	0.541	0.319	0.22	0.17	-
		90 %	0.843	0.912	0.537	0.3	0.185	0.136	-	-
	10 – 12 m	0 %	0.406	0.421	0.261	0.158	0.105	-	-	-
		50 %	-	3.43	1.95	1.02	-	-	-	-
		75 %	-	1.74	0.995	0.531	-	-	-	-
		90 %	-	0.902	0.528	0.291	-	-	-	-
	18 – 20 m	0 %	-	0.412	0.251	0.148	-	-	-	-
		50 %	-	-	-	-	0.579	0.377	0.268	0.161
		75 %	-	-	-	-	0.207	0.207	0.15	-
		90 %	-	-	-	-	0.123	0.123	-	-
R1 / stream	0 m	0 %	-	-	-	-	-	-	-	-
		50 %	-	16.1	9.46	5.33	2.47	1.55	1.55	1.55
		75 %	9.51	8.06	4.76	2.68	1.55	1.55	1.55	-
		90 %	4.8	4.06	2.41	1.55	1.55	1.55	-	-
	10 – 12 m	0 %	1.98	1.67	1.55	1.55	1.55	-	-	-
		50 %		16.1	9.46	5.33	-	-	-	-
		75 %		8.06	4.75	2.68	-	-	-	-
		90 %		4.06	2.4	1.36	-	-	-	-
	18 – 20 m	0 %	-	1.67	0.999	0.667	-	-	-	-
		50 %	-	-	-	-	2.46	1.36	0.84	0.404
		75 %	-	-	-	-	1.25	0.697	0.44	-
		90 %	-	-	-	-	0.642	0.368	-	-
R2 / stream	0 m	0 %	-	-	-	-	0.346	-	-	-
		50 %	-	21.6	12.7	7.15	3.3	1.82	1.12	1.03
		75 %	12.8	10.8	6.37	3.59	1.67	1.03	1.03	-
		90 %	6.42	5.44	3.22	1.82	1.03	1.03	-	-
	10 – 12 m	0 %	2.63	2.22	1.32	1.03	1.03	-	-	-
		50 %		21.6	12.7	7.15	-	-	-	-
		75 %		10.8	6.37	3.59	-	-	-	-
		90 %		5.44	3.22	1.82	-	-	-	-
	18 – 20 m	0 %	-	2.22	1.32	0.754	-	-	-	-
		50 %	-	-	-	-	3.3	1.82	1.12	0.528
		75 %	-	-	-	-	1.67	0.926	0.577	-
		90 %	-	-	-	-	0.851	0.48	-	-

Scenario	Mitigation options		Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)							
	Vegetative strip	Nozzle reduction	-	5 m	10 m	15 m	20 m	25 m	30 m	40 m
			PEC$_{SW}$ (µg/L)							
R3 / stream	0 m	0 %	-	-	-	-	0.36	-	-	-
		50 %	-	22.6	13.3	7.47	3.44	1.9	1.58	1.58
		75 %	13.3	11.3	6.65	3.74	1.74	1.58	1.58	-
		90 %	6.69	5.67	3.35	1.9	1.58	1.58	-	-
	10 – 12 m	0 %	2.75	2.32	1.58	1.58	1.58	-	-	-
		50 %		22.6	13.3	7.47	-	-	-	-
		75 %		11.3	6.65	3.74	-	-	-	-
		90 %		5.67	3.35	1.9	-	-	-	-
	18 – 20 m	0 %	-	2.32	1.39	0.798	-	-	-	-
		50 %	-	-	-	-	3.44	1.89	1.17	0.561
		75 %	-	-	-	-	1.74	0.969	0.61	-
		90 %	-	-	-	-	0.891	0.51	-	-
R4 / stream	0 m	0 %	-	-	-	-	0.388	-	-	-
		50 %	-	16.1	9.46	5.32	4.47	4.47	4.47	4.47
		75 %	9.51	8.05	4.75	4.47	4.47	4.47	4.47	-
		90 %	4.8	4.47	4.47	4.47	4.47	4.47	-	-
	10 – 12 m	0 %	4.47	4.47	4.47	4.47	4.47	-	-	-
		50 %		16.1	9.46	5.32	-	-	-	-
		75 %		8.05	4.75	2.68	-	-	-	-
		90 %		4.06	2.4	2.03	-	-	-	-
	18 – 20 m	0 %	-	2.03	2.03	2.03	-	-	-	-
		50 %	-	-	-	-	2.46	1.36	1.06	1.06
		75 %	-	-	-	-	1.25	1.06	1.06	-
		90 %	-	-	-	-	1.06	1.06	-	-

Table 10.2-11: Maximum PEC_{SW} values for cyprodinil following a single applications to pome fruit at FOCUS Step 4 (all scenarios) for late sprays

Scenario	Mitigation options		Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)								
	Vegetative strip	Nozzle reduction	-	5 m	10 m	15 m	20 m	25 m	30 m	40 m	45 m
			PEC_{SW} (µg/L)								
D3 / ditch	0 m	0 %	-	9.28	4.14	2.09	1.28	0.877	0.653	0.421	-
		50 %	6.87	4.64	2.07	1.06	0.657	0.465	0.362	-	-
		75 %	3.43	2.32	1.07	0.569	0.364	0.277	-	-	-
		90 %	1.45	1	0.512	0.3	0.202	-	-	-	-
D4 / pond	0 m	0 %	-	0.725	0.411	0.266	0.191	0.15	0.122	0.09	-
		50 %	0.352	0.384	0.222	0.146	0.105	0.085	0.07	-	-
		75 %	0.204	0.214	0.128	0.086	0.063	0.052	-	-	-
		90 %	0.115	0.112	0.072	0.05	0.037	-	-	-	-
D4 / stream	0 m	0 %	-	10.8	4.81	2.44	1.5	1.03	0.759	0.476	-
		50 %	6.91	5.39	2.43	1.24	0.764	0.531	0.401	-	-
		75 %	3.5	2.73	1.24	0.644	0.403	0.289	-	-	-
		90 %	1.46	1.14	0.542	0.295	0.189	-	-	-	-
D5 / pond	0 m	0 %	-	0.727	0.413	0.268	0.193	0.151	0.124	0.091	-
		50 %	0.354	0.386	0.224	0.148	0.107	0.086	0.073	-	-
		75 %	0.205	0.216	0.13	0.087	0.064	0.054	-	-	-
		90 %	0.116	0.114	0.073	0.051	0.038	-	-	-	-
D5 / stream	0 m	0 %	-	11.6	5.2	2.62	1.6	1.1	0.811	0.508	-
		50 %	7.45	5.81	2.6	1.33	0.816	0.567	0.426	-	-
		75 %	3.74	2.92	1.33	0.687	0.428	0.306	-	-	-
		90 %	1.55	1.22	0.575	0.314	0.204	-	-	-	-
R1 / pond	0 m	0 %	-	0.725	0.411	0.285	0.227	0.195	0.174	0.149	
		50 %	0.352	0.384	0.251	0.192	0.161	0.145	0.14	-	-
		75 %	0.237	0.245	0.178	0.146	0.128	0.12	-	-	-
		90 %	0.168	0.166	0.135	0.118	0.108	-	-	-	-
	10 – 12 m	0 %	-	0.725	0.41	0.266	-	-	-	-	-
		50 %	-	0.383	0.222	0.146	-	-	-	-	-
		75 %	-	0.214	0.131	0.098	-	-	-	-	-
		90 %	-	0.118	0.087	0.07	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	0.191	0.149	0.122	0.09	
		50 %	-	-	-	-	0.085	0.085	0.07		-
		75 %	-	-	-	-	0.056	0.056		-	-
		90 %	-	-	-	-	-	-	-	-	-
R1 / stream	0 m	0 %	-	8.29	3.73	1.9	1.17	1.17	1.17	1.17	-
		50 %	5.35	4.18	1.89	1.17	1.17	1.17	1.17	-	-
		75 %	2.73	2.13	1.17	1.17	1.17	1.17	-	-	-
		90 %	1.17	1.17	1.17	1.17	1.17	-	-	-	-
	10 – 12 m	0 %		8.29	3.73	1.9	-	-	-	-	-
		50 %		4.18	1.89	0.975	-	-	-	-	-
		75 %		2.13	0.984	0.528	-	-	-	-	-
		90 %	-	0.912	0.528	0.528	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	1.17	0.807	0.601	0.381	
		50 %	-	-	-	-	0.604	0.425	0.322		-
		75 %	-	-	-	-	0.323	0.276		-	-
		90 %	-	-	-	-	0.276	-	-	-	-
R2 / stream	0 m	0 %	-	11.1	4.99	2.53	1.56	1.07	0.79	0.494	-
		50 %	7.16	5.59	2.52	1.29	0.795	0.553	0.413	-	-
		75 %	3.63	2.84	1.29	0.669	0.415	0.338		-	-
		90 %	1.51	1.18	0.554	0.338	0.338			-	-
	10 – 12 m	0 %		11.1	4.99	2.53	-	-	-	-	-
		50 %		5.59	2.52	1.29	-	-	-	-	-
		75 %		2.84	1.29	0.669	-	-	-	-	-
		90 %	-	1.18	0.554	0.296	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	1.56	1.07	0.79	0.494	
		50 %	-	-	-	-	0.795	0.553	0.413		-
		75 %	-	-	-	-	0.415	0.295			-

Scenario	**Mitigation options**		**Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**								
	Vegetative strip	**Nozzle reduction**	**-**	**5 m**	**10 m**	**15 m**	**20 m**	**25 m**	**30 m**	**40 m**	**45 m**
			PEC_{SW} (µg/L)								
		90 %	-	-	-	-	0.188	-	-	-	-
R3 / stream	0 m	0 %		11.6	5.2	2.64	1.62	1.12	0.829	0.523	-
		50 %	7.46	5.82	2.63	1.35	0.834	0.583	0.441		-
		75 %	3.79	2.96	1.36	0.706	0.444	0.322			-
		90 %	1.6	1.25	0.602	0.332	0.257				-
	10 – 12 m	0 %		11.6	5.2	2.64					-
		50 %		5.82	2.63	1.35					-
		75 %		2.96	1.36	0.706					-
		90 %		1.25	0.602	0.332					-
	18 – 20 m	0 %					1.62	1.12	0.829	0.523	
		50 %					0.834	0.583	0.441		-
		75 %					0.444	0.322			-
		90 %					0.215				-
R4 / stream	0 m	0 %		8.29	3.73	1.9	1.6	1.6	1.6	1.6	-
		50 %	5.35	4.18	1.89	1.6	1.6	1.6	1.6		-
		75 %	2.73	2.13	1.6	1.6	1.6	1.6			-
		90 %	1.6	1.6	1.6	1.6	1.6				-
	10 – 12 m	0 %		8.29	3.73	1.9					-
		50 %		4.18	1.89	0.975					-
		75 %		2.13	0.983	0.717					-
		90 %		0.911	0.717	0.717					-
	18 – 20 m	0 %					1.17	0.807	0.6	0.381	
		50 %					0.604	0.425	0.373		-
		75 %					0.373	0.373			-
		90 %					0.373				-

Table 10.2-12: Maximum PEC_{SW} values for cyprodinil following a multiple applications to pome fruit at FOCUS Step 4 (all scenarios) for late sprays

Scenario	Mitigation options		Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)								
	Vegetative strip	Nozzle reduction	-	5 m	10 m	15 m	20 m	25 m	30 m	40 m	45 m
			PEC_{SW} (µg/L)								
D3 / ditch	0 m	0 %	-	6.74	3.14	1.57	0.931	0.636	0.478	0.323	-
		50 %	4.92	3.38	1.61	0.834	0.507	0.369	0.296	-	-
		75 %	2.53	1.75	0.879	0.482	0.309	0.243	-	-	-
		90 %	1.16	0.832	0.468	0.285	0.195	-	-	-	-
D4 / pond	0 m	0 %	-	1.16	0.652	0.405	0.281	0.251	0.235	0.217	-
		50 %	0.578	0.622	0.359	0.255	0.229	0.217	0.21	-	-
		75 %	0.345	0.355	0.25	0.222	0.206	0.2	-	-	-
		90 %	0.247	0.243	0.217	0.202	0.193	-	-	-	-
D4 / stream	0 m	0 %	-	7.77	3.63	1.81	1.06	0.874	0.874	0.874	-
		50 %	4.96	3.91	1.84	0.927	0.874	0.874	0.874	-	-
		75 %	2.52	1.99	0.952	0.874	0.874	0.874	-	-	-
		90 %	1.08	0.874	0.874	0.874	0.874	-	-	-	-
D5 / pond	0 m	0 %	-	1.21	0.682	0.425	0.295	0.229	0.187	0.137	-
		50 %	0.605	0.65	0.377	0.24	0.169	0.136	0.115	-	-
		75 %	0.362	0.373	0.226	0.149	0.107	0.09	-	-	-
		90 %	0.218	0.208	0.136	0.094	0.07	-	-	-	-
D5 / stream	0 m	0 %	-	8.38	3.91	1.94	1.14	0.756	0.546	0.335	-
		50 %	5.32	4.19	1.97	0.989	0.585	0.399	0.296	-	-
		75 %	2.69	2.12	1.01	0.522	0.315	0.226	-	-	-
		90 %	1.15	0.905	0.454	0.253	0.2	-	-	-	-
R1 / pond	0 m	0 %	-	1.18	0.686	0.445	0.323	0.26	0.22	0.174	-
		50 %	0.614	0.657	0.4	0.271	0.204	0.173	0.15	-	-
		75 %	0.386	0.396	0.257	0.185	0.145	0.13	-	-	-
		90 %	0.25	0.24	0.172	0.133	0.116	-	-	-	-
	10 – 12 m	0 %	-	1.16	0.658	0.416	-	-	-	-	-
		50 %	-	0.628	0.371	0.242	-	-	-	-	-
		75 %	-	0.367	0.229	0.156	-	-	-	-	-
		90 %	-	0.212	0.144	0.105	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	0.285	0.222	0.182	0.136	-
		50 %	-	-	-	-	0.135	0.135	0.12	-	-
		75 %	-	-	-	-	0.092	0.092	-	-	-
		90 %	-	-	-	-	-	-	-	-	-
R1 / stream	0 m	0 %	-	5.99	2.81	1.41	1.32	1.32	1.32	1.32	-
		50 %	3.85	3.04	1.44	1.32	1.32	1.32	1.32	-	-
		75 %	1.98	1.57	1.32	1.32	1.32	1.32	-	-	-
		90 %	1.32	1.32	1.32	1.32	1.32	-	-	-	-
	10 – 12 m	0 %		5.99	2.81	1.41	-	-	-	-	-
		50 %		3.04	1.44	0.734	-	-	-	-	-
		75 %		1.57	0.758	0.598	-	-	-	-	-
		90 %	-	0.684	0.598	0.598	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	0.833	0.561	0.41	0.313	-
		50 %	-	-	-	-	0.438	0.313	0.313	-	-
		75 %	-	-	-	-	0.313	0.313	-	-	-
		90 %	-	-	-	-	0.313	-	-	-	-
R2 / stream	0 m	0 %	-	8.04	3.77	1.89	1.11	0.74	0.534	0.46	-
		50 %	5.15	4.06	1.92	0.968	0.572	0.46	0.46	-	-
		75 %	2.63	2.07	0.991	0.508	0.46	0.46	-	-	-
		90 %	1.11	0.88	0.46	0.46	0.46	-	-	-	-
	10 – 12 m	0 %		8.04	3.77	1.89	-	-	-	-	-
		50 %		4.06	1.92	0.968	-	-	-	-	-
		75 %		2.07	0.991	0.508	-	-	-	-	-
		90 %	-	0.88	0.435	0.233	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	1.11	0.74	0.534	0.325	-
		50 %	-	-	-	-	0.572	0.388	0.286	-	-
		75 %	-	-	-	-	0.305	0.213	-	-	-

Scenario	Mitigation options: Vegetative strip	Mitigation options: Nozzle reduction	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -	5 m	10 m	15 m	20 m	25 m	30 m	40 m	45 m
			PEC$_{SW}$ (µg/L)								
		90 %	-	-	-	-	0.144	-	-	-	-
R3 / stream	0 m	0 %	-	8.38	5.06	3.67	3.09	2.82	2.67	2.51	-
		50 %	6.07	5.27	3.68	2.98	2.69	2.56	2.48	-	-
		75 %	4.18	3.78	2.99	2.64	2.49	2.43	-	-	-
		90 %	3.05	2.89	2.57	2.43	2.37	-	-	-	-
	10 – 12 m	0 %		8.38	3.92	2.46	-	-	-	-	-
		50 %		4.22	2.48	1.76	-	-	-	-	-
		75 %		2.58	1.76	1.4	-	-	-	-	-
		90 %	-	1.66	1.33	1.19	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	1.38	1.1	0.937	0.774	-
		50 %	-	-	-	-	0.967	0.823	0.744	-	-
		75 %	-	-	-	-	0.758	0.687	-	-	-
		90 %	-	-	-	-	0.633	-	-	-	-
R4 / stream	0 m	0 %	-	5.99	2.87	2.87	2.87	2.87	2.87	2.87	-
		50 %	3.85	3.04	2.87	2.87	2.87	2.87	2.87	-	-
		75 %	2.87	2.87	2.87	2.87	2.87	2.87	-	-	-
		90 %	2.87	2.87	2.87	2.87	2.87	-	-	-	-
	10 – 12 m	0 %		5.99	2.81	1.41	-	-	-	-	-
		50 %		3.03	1.44	1.3	-	-	-	-	-
		75 %		1.57	1.3	1.3	-	-	-	-	-
		90 %	-	1.3	1.3	1.3	-	-	-	-	-
	18 – 20 m	0 %	-	-	-	-	0.833	0.682	0.682	0.682	-
		50 %	-	-	-	-	0.682	0.682	0.682	-	-
		75 %	-	-	-	-	0.682	0.682	-	-	-
		90 %	-	-	-	-	0.682	-	-	-	-

Table 10.2-10: Time-weighted average PEC_{SW} values for cyprodinil following a single and three applications to pome fruit at FOCUS Step 3 (all scenarios) for early and late sprays

Crop / surrogate crop[a] / timing	Scenario	Water body	Single application TWA PEC_{SW} [µg/L]			Multiple application TWA PEC_{SW} [µg/L]		
			7 day	21 day	28 day	7 day	21 day	28 day
Apple / pome fruit (early appl.) / 'early' window	D3	Ditch	4.66	1.58	1.19	5.72	1.97	1.65
	D4	Pond	1.60	1.42	1.36	2.97	2.75	2.66
	D4	Stream	0.473	0.158	0.118	0.701	0.235	0.270
	D5	Pond	1.59	1.42	1.36	2.98	2.79	2.71
	D5	Stream	0.179	0.060	0.045	1.48	0.496	0.372
	R1	Pond	1.59	1.39	1.32	2.82	2.57	2.46
	R1	Stream	0.581	0.194	0.152	0.725	0.243	0.288
	R2	Stream	0.378	0.143	0.107	0.391	0.184	0.138
	R3	Stream	1.54	0.587	0.441	1.45	0.490	0.675
	R4	Stream	0.686	0.249	0.207	0.993	0.498	0.407
Apple / pome fruit (late appl.) / 'late' window	D3	Ditch	3.34	1.15	0.868	5.38	2.21	1.68
	D4	Pond	0.556	0.492	0.471	0.891	0.820	0.792
	D4	Stream	0.546	0.183	0.137	0.413	0.138	0.201
	D5	Pond	0.560	0.500	0.479	0.934	0.867	0.840
	D5	Stream	0.824	0.276	0.207	0.588	0.198	0.295
	R1	Pond	0.551	0.512	0.491	0.913	0.828	0.795
	R1	Stream	0.323	0.159	0.120	0.231	0.135	0.102
	R2	Stream	0.218	0.090	0.068	0.161	0.071	0.053
	R3	Stream	0.802	0.269	0.202	0.573	0.205	0.240
	R4	Stream	0.322	0.213	0.190	0.711	0.341	0.344

Crop / surrogate crop[a] / timing	Scenario	Water body	Single application TWA PEC_{SW} [µg/L]			Multiple application TWA PEC_{SW} [µg/L]		
			7 day	21 day	28 day	7 day	21 day	28 day
Apple / pome fruit (early appl.) / 'early' window	D3	Ditch	4.63	1.57	1.18	5.70	1.96	1.65
	D4	Pond	1.6	1.42	1.36	2.97	2.75	2.66
	D4	Stream	0.454	0.152	0.114	0.685	0.229	0.262
	D5	Pond	1.59	1.42	1.36	2.98	2.79	2.71
	D5	Stream	0.163	0.054	0.041	1.46	0.489	0.367
	R1	Pond	1.59	1.39	1.32	2.82	2.57	2.46
	R1	Stream	0.565	0.189	0.148	0.711	0.238	0.281
	R2	Stream	0.36	0.136	0.102	0.375	0.178	0.134
	R3	Stream	1.52	0.579	0.435	1.43	0.483	0.665
	R4	Stream	0.67	0.244	0.203	0.993	0.494	0.404
Apple / pome fruit (late appl.) / 'late' window	D3	Ditch	3.33	1.15	0.864	5.38	2.21	1.68
	D4	Pond	0.556	0.493	0.471	0.892	0.82	0.792
	D4	Stream	0.535	0.179	0.134	0.406	0.136	0.197
	D5	Pond	0.56	0.5	0.479	0.934	0.867	0.84
	D5	Stream	0.813	0.272	0.205	0.581	0.195	0.291
	R1	Pond	0.551	0.512	0.492	0.913	0.828	0.795
	R1	Stream	0.316	0.157	0.118	0.226	0.134	0.101
	R2	Stream	0.209	0.087	0.065	0.155	0.069	0.052
	R3	Stream	0.791	0.265	0.199	0.565	0.204	0.237
	R4	Stream	0.315	0.21	0.188	0.703	0.339	0.341

Table 10.2-11: Time-weighted average PEC_{SW} values for cyprodinil following a single and three applications to pome fruit at FOCUS Step 4 (all scenarios) for early sprays

Crop / surrogate crop[a] / timing	Scenario	Water body	Single application TWA PEC_{SW} [µg/L]			Multiple application TWA PEC_{SW} [µg/L]		
			7 day	21 day	28 day	7 day	21 day	28 day
Apple / pome fruit (early appl.) / 'early' window	D3	Ditch	0.519	0.177	0.133	0.678	0.235	0.197
	D4	Pond	nr	nr	nr	nr	nr	nr
	D4	Stream	0.058	0.019	0.015	0.092	0.031	0.036
	D5	Pond	nr	nr	nr	nr	nr	nr
	D5	Stream	0.022	0.007	0.005	0.195	0.065	0.049
	R1	Pond	nr	nr	nr	nr	nr	nr
	R1	Stream	0.071	0.027	0.030	0.246	0.082	0.090
	R2	Stream	0.049	0.032	0.024	0.160	0.070	0.053
	R3	Stream	0.216	0.135	0.102	0.391	0.132	0.139
	R4	Stream	0.256	0.112	0.099	0.993	0.403	0.335

nr = not relevant

Risk assessment for aquatic organisms

The A8637C and cyprodinil risk assessments were carried out following application according to the proposed use.

The risk assessments followed the recently noted EFSA (2013) Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. The assessment is a tiered procedure which derives Regulatory Acceptable Concentrations (RACs) from the effects data by applying assessment factors appropriate to the taxon and tier assessed. The RAC is compared to the appropriate PEC_{SW} value. If the RAC is > PEC, then the risk is acceptable, otherwise the assessment should be refined with higher tiers.

Table 10.2-12: Derivation of RAC values for use in the Tier I risk assessment – A8637C

Species	Substance	Exposure System	Results (µg/L)	Assessment Safety factor	RAC (µg/L)
Oncorhynchus mykiss	A8637C	96 h, s	LC_{50} = 6200	100	62
Daphnia magna		48 h, s	EC_{50} = 140	100	1.4
Pseudiokirchneriella subcapitata		72 h, s	E_rC_{50} = 4100	10	410

s = static system

Table 10.2-13: Derivation of RAC values for use in the Tier I risk assessment – cyprodinil and metabolites

Test organism	Substance	Exposure system	Endpoints (µg/L)	AF	Tier 1-RAC (µg/L)
Fish					
Cyprinodon variegatus	Cyprodinil	96 h, f	LC_{50} = 1 250	100	12.5
Oncorhynchus mykiss	CGA249287	96 h, s	LC_{50} = 55 000		550
	CGA275535	96 h, s	LC_{50} = 2 100		21
	CGA263208 [a]	96 h, s	LC_{50} = 2 100		21
Cyprinodon variegatus	Cyprodinil	34 d, f	NOEC = 40.6	10	4.06
Aquatic invertebrates					
Mysidopsis bahia	Cyprodinil	96 h, f	LC_{50} = 8.05	100	**0.0805**
Daphnia magna	CGA249287	48 h, s	EC_{50} >100 000		>1 000
	CGA275535	48 h, s	EC_{50} = 6 800		68
	CGA321915	48 h, s	EC_{50} >98 000		>980
	CGA263208 [a]	48 h, s	EC_{50} = 20 600		206
Mysidopsis bahia	Cyprodinil	30 d, f	EC_{10} = 1.97	10	**0.197**
Aquatic insect					
Chironomus riparius	CGA321915	48 h, s	EC_{50} >97 000	100	970
Sediment dwellers					
Chironomus riparius	Cyprodinil	27 d, spiked sediment	NOEC = 80 000 (µg/kg)	10	8 000 µg/kg
Grandidierella japonica		10 d, spiked sediment	LC_{50} = 420 (µg/kg)	100	4.2
Chironomus riparius	CGA249287	28 d, spiked sediment	NOEC = 25 600 (µg/kg)	10	2 560 µg/kg
Algae					
Psudokirchneriella subcapitata ~~*Skeletonema costatum*~~	Cyprodinil	72 h, s	E_rC_{50} = 3 280 ~~EC_{50} = 1 750~~	10	~~175~~ 328
Psudokirchneriella subcapitata	CGA249287		$E_{rb}C_{50}$ >100 000		>10 000
	CGA275535		E_rC_{50} = 18 000		1 800
	CGA321915		$E_{rb}C_{50}$ >99 000		>9 900
	CGA263208		E_bC_{50} = 1 860		186
Macrophytes					
Lemna gibba	Cyprodinil	14~~7~~ d, s	EC_{50} = 7 420 ~~7 710~~	10	742 ~~771~~
Mesocosm					
Invertebrates	Cyprodinil [b]		NOEC = 14.6	2	7.3

s = static system
f = flow-through system
[a] result was derived from a study conducted with CA1139A, a carbonate salt of phenyl guanidine
[b] tested as A14325E

Risk assessment for A8637C

Following the EFSA Guidance Document on Aquatic Risk Assessment (July 2013)[3], the RACs are compared to the exposure values using the PEC/RAC ratio. The risk assessment is presented in the table below.

Table 10.2-14: Tier 1 risk assessment for A8637C based on spray drift following 'early' and 'late' applications to pome fruit

Application timing	Spray drift distance (m)	PEC (µg/L)	Fish – acute RAC (µg/L)	Invertebrate – acute RAC (µg/L)	Algae RAC (µg/L)
			62	1.4	410
			PEC/RAC Ratio		
Early	3	73.0	**1.2**	**52**	0.18
	10	29.5	0.48	**21**	-
	15	13.9	-	**9.9**	-
	20	6.93	-	**5.0**	-
	30	2.60	-	**1.9**	-
	40	1.30	-	0.93	-
Late	3	39.3	0.63	**28**	0.096
	10	9.00	-	**6.4**	-
	15	4.53	-	**3.2**	-
	20	2.73	-	**2.0**	-
	30	1.35	-	0.96	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

For the 'early' application scenario the PEC/RAC ratio for fish is below 1 for a 10 m spray buffer indicating acceptable risk to this group when this mitigation is considered. For the 'late' application scenario the PEC/RAC ratios for fish and algae are below 1 for a 3 m spray drift buffer indicating acceptable risk for these groups. For the acute risk to aquatic invertebrates, however, a 40 and 30 m drift buffer was required to achieve acceptable risk for the early and late scenarios, respectively.

It is clear from the list of endpoints table (Table 10.2.1 to 10.2-3) that the toxicity of cyprodinil to fish, *Daphnia* and algae is not significantly enhanced by formulating it as A8637C. The toxicity of A8637C is therefore considered to be driven by the active substance and the acute risk to fish and aquatic invertebrates will be refined by consideration of the toxicity of cyprodinil.

Risk assessment for cyprodinil

From Table 10.2-14 it is clear that the lowest tier 1 $RAC_{sw;ac}$ is 0.0805 µg/L, based on the toxicity to the aquatic invertebrate species *Mysidopsis bahia* (mysid).

The lowest tier 1 $RAC_{sw;ch}$ is 0.197 µg/L, based on aquatic invertebrates, the mysid.

Following the EFSA Guidance Document on Aquatic Risk Assessment (July 2013), the tier 1 RACs are compared to the exposure values derived for FOCUS Steps 1 to 3. These are presented in Tables 10.2-15 to 10.2-18.

[3] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. doi:10.2903/j.efsa.2013.3290.

Table 10.2-15: Tier 1 risk assessment for cyprodinil based on FOCUS Step 1, 2 and 3 PECs for pome fruit (1 × 375 g a.s./ha for 'early' application)

Group			**Fish - acute**	**Fish - chronic**	**Invertebrate - acute**	**Invertebrate - chronic**	**Algae**	**Macrophyte**	**Group**	**Sediment dweller - acute**	**Sediment dweller - chronic**
Tier 1 RAC (µg/L)			**12.5**	**4.06**	**0.0805**	**0.197**	**320**	**742**	**Tier 1 RAC (µg/kg)**	**4.2**	**8000**
FOCUS Scenario		**PEC$_{sw}$ (µg/L)**	**PEC/RAC (pelagic species)**						**PEC$_{sed}$ (µg/kg)**	**PEC/RAC (benthic species)**	
Step 1		74.8	**6.0**	**18**	**930**	**380**	0.23	0.10	836	200	0.10
Step 2	N EU	36.5	**2.9**	**9**	**450**	**190**	0.11	0.049	287	**68**	-
	S EU	36.5	**2.9**	**9**	**450**	**190**	0.11	0.049	388	**92**	-
Step 3	D3 ditch	29.1	**2.3**	**7.2**	**360**	**150**	-	-	19.3	**4.6**	-
	D4 pond	1.77	0.14	0.44	**22**	**9.0**	-	-	13.5	**3.2**	-
	D4 stream	29.6	**2.4**	**7.3**	**370**	**150**	-	-	2.42	0.6	-
	D5 pond	1.77	0.14	0.44	**22**	**9.0**	-	-	14.1	**3.4**	-
	D5 stream	28.8	**2.3**	**7.1**	**360**	**150**	-	-	0.886	0.21	-
	R1 pond	1.76	0.14	0.43	**22**	**8.9**	-	-	12.3	**2.9**	-
	R1 stream	23.5	**1.9**	**5.8**	**290**	**120**	-	-	2.99	0.71	-
	R2 stream	31.1	**2.5**	**7.7**	**390**	**160**	-	-	1.93	0.46	-
	R3 stream	33.2	**2.7**	**8.2**	**410**	**170**	-	-	7.62	**1.8**	-
	R4 stream	23.6	**1.9**	**5.8**	**290**	**120**	-	-	3.51	0.84	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Group			**Fish - acute**	**Fish – chronic**	**Invertebrate – acute**	**Invertebrate – chronic**	**Algae**	**Macrophyte**	**Group**	**Sediment dweller - acute**	**Sediment dweller - chronic**
Tier 1 RAC (µg/L)			**12.5**	**4.06**	**0.0805**	**0.197**	**175**	**771**	**Tier 1 RAC (µg/kg)**	**4.2**	**8000**
FOCUS Scenario		**PEC_{sw} (µg/L)**	**PEC/RAC (pelagic species)**						**PEC_{sed} (µg/kg)**	**PEC/RAC (benthic species)**	
Step 1		74.8	**6.0**	**18**	**930**	**380**	0.43	0.10	836	**200**	0.10
Step 2	N EU	36.5	**2.9**	**9.0**	**450**	**190**	-	-	287	**68**	-
	S EU	36.5	**2.9**	**9.0**	**450**	**190**	-	-	388	**92**	-
Step 3	D3 ditch	29.1	**2.3**	**7.2**	**360**	**150**	-	-	19.3	**4.6**	-
	D4 pond	1.77	0.14	0.44	**22**	**9.0**	-	-	13.5	**3.2**	-
	D4 stream	29.6	**2.4**	**7.3**	**370**	**150**	-	-	2.42	0.58	-
	D5 pond	1.77	0.14	0.44	**22**	**9.0**	-	-	14.1	**3.4**	-
	D5 stream	28.8	**2.3**	**7.1**	**360**	**150**	-	-	0.886	0.21	-
	R1 pond	1.76	0.14	0.43	**22**	**8.9**	-	-	12.3	**2.9**	-
	R1 stream	23.5	**1.9**	**5.8**	**290**	**120**	-	-	2.99	0.71	-
	R2 stream	31.1	**2.5**	**7.7**	**390**	**160**	-	-	1.93	0.46	-
	R3 stream	33.2	**2.7**	**8.2**	**410**	**170**	-	-	7.62	**1.8**	-
	R4 stream	23.6	**1.9**	**5.8**	**290**	**120**	-	-	3.51	0.84	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-16: Tier 1 risk assessment for cyprodinil based on FOCUS Step 1, 2 and 3 PECs for pome fruit (1 × 375 g a.s./ha for 'late' application)

Group			Fish - acute	Fish - chronic	Invertebrate - acute	Invertebrate - chronic	Algae	Macrophyte	Group	Sediment dweller - acute	Sediment dweller - chronic
Tier 1 RAC (µg/L)			12.5	4.06	0.0805	0.197	328	742	Tier 1 RAC (µg/kg)	4.2	8000
FOCUS Scenario		PEC_{sw} (µg/L)	PEC/RAC (pelagic species)						PEC_{sed} (µg/kg)	PEC/RAC (benthic species)	
Step 1		74.8	**6.0**	**18**	**930**	**380**	0.23	0.10	836	**200**	0.10
Step 2	N EU	**36.5**	**2.9**	**9**	**450**	**190**	0.11	0.049	287	**68**	-
	S EU	**36.5**	**2.9**	**9**	**450**	**190**	0.11	0.049	337	**80**	-
Step 3	D3 ditch	13.8	**1.1**	**3.4**	**170**	**70**	-		12.8	**3.0**	-
	D4 pond	0.615	0.049	0.15	**7.6**	**3.1**	-		5.03	**1.2**	-
	D4 stream	13.8	**1.1**	**3.4**	**170**	**70**	-		2.75	0.65	-
	D5 pond	0.617	0.049	0.15	**7.7**	**3.1**	-		5.27	**1.3**	-
	D5 stream	14.9	**1.2**	**3.7**	**190**	**76**	-		4.07	0.97	-
	R1 pond	0.616	0.049	0.15	**7.6**	**3.1**	-		4.94	**1.2**	-
	R1 stream	10.6	0.85	**2.6**	**130**	**54**	-		3.19	0.76	-
	R2 stream	14.1	**1.1**	**3.5**	**180**	**72**	-		1.57	0.37	-
	R3 stream	14.9	**1.2**	**3.7**	**190**	**76**	-		3.96	0.94	-
	R4 stream	10.6	0.85	**2.6**	**130**	**54**	-		2.12	0.50	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Group			Fish – acute	Fish – chronic	Invertebrate – acute	Invertebrate – chronic	Algae	Macrophyte	Group	Sediment dweller – acute	Sediment dweller – chronic
Tier 1 RAC (µg/L)			12.5	4.06	0.0805	0.197	175	771	Tier 1 RAC (µg/kg)	4.2	8000
FOCUS Scenario		PEC_{sw} (µg/L)	PEC/RAC (pelagic species)						PEC_{sed} (µg/kg)	PEC/RAC (benthic species)	
Step 1		74.8	**6.0**	**18**	**930**	**380**	0.43	0.10	836	**200**	0.10
Step 2	N EU	36.5	**2.9**	**9.0**	**450**	**190**	-	-	287	**68**	-
	S EU	36.5	**2.9**	**9.0**	**450**	**190**	-	-	388	**92**	-
Step 3	D3 ditch	13.7	**1.1**	**3.4**	**170**	**70**	-	-	12.9	**3.1**	-
	D4 pond	0.615	0.05	0.15	**7.6**	**3.1**	-	-	5.04	**1.2**	-
	D4 stream	13.8	1.1	**3.4**	**171**	**70**	-	-	2.75	0.65	-
	D5 pond	0.616	0.049	0.15	**7.7**	**3.1**	-	-	5.27	**1.3**	-
	D5 stream	14.9	**1.2**	**3.7**	**190**	**76**	-	-	4.07	0.97	-
	R1 pond	0.615	0.049	0.15	**7.6**	**3.1**	-	-	4.94	**1.2**	-
	R1 stream	10.6	0.85	**2.6**	**130**	**54**	-	-	3.18	0.76	-
	R2 stream	14.1	**1.1**	**3.5**	**180**	**72**	-	-	1.57	0.37	-
	R3 stream	14.9	**1.2**	**3.7**	**190**	**76**	-	-	3.96	0.94	-
	R4 stream	10.6	0.85	**2.6**	**130**	**54**	-	-	2.13	0.51	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-17: Tier 1 risk assessment for cyprodinil based on FOCUS Step 1, 2 and 3 PECs for pome fruit (3 × 375 g a.s./ha for 'early' application)

Group			Fish - acute	Fish - chronic	Invertebrate - acute	Invertebrate - chronic	Algae	Macrophyte	Group	Sediment dweller - acute	Sediment dweller - chronic
Tier 1 RAC (µg/L)			**12.5**	**4.06**	**0.0805**	**0.197**	**328**	**742**	**Tier 1 RAC (µg/kg)**	**4.2**	**8000**
FOCUS Scenario		**PEC (µg/L)**	**PEC/RAC (pelagic species)**						**PEC_{sed} (µg/kg)**	**PEC/RAC (benthic species)**	
Step 1		224	**18**	**55**	**2800**	**1100**	0.70	0.10	2510	**600**	0.31
Step 2	N EU	50.8	**4.1**	**13**	**630**	**260**	0.16	0.068	687	**160**	-
	S EU	64.0	**5.1**	**16**	**800**	**320**	0.20	0.076	821	**230**	-
Step 3	D3 ditch	23.5	**1.9**	**5.8**	**290**	**120**	-	-	29	**6.9**	-
	D4 pond	3.14	0.25	0.77	**39**	**16**	-	-	31.1	**7.4**	-
	D4 stream	24.4	**2.0**	**6.0**	**300**	**140**	-	-	4.34	**1.0**	-
	D5 pond	3.15	0.25	0.78	**39**	**15**	-	-	32.8	**7.8**	-
	D5 stream	26.7	**2.1**	**6.6**	**330**	**140**	-	-	7.88	**1.9**	-
	R1 pond	3.02	0.24	0.74	**38**	**15**	-	-	27.5	**6.5**	-
	R1 stream	18.9	**1.5**	**4.7**	**230**	**96**	-	-	4.76	**1.1**	-
	R2 stream	25.3	**2.0**	**6.2**	**310**	**130**	-	-	4.16	**1.0**	-
	R3 stream	26.6	**2.1**	**6.6**	**330**	**140**	-	-	8.92	**2.1**	-
	R4 stream	18.9	**1.5**	**4.7**	**230**	**96**	-	-	7.95	**1.9**	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Group			Fish - acute	Fish - chronic	Invertebrate - acute	Invertebrate - chronic	Algae	Macrophyte	PEC (µg/kg)	Sediment dweller - acute	Sediment dweller - chronic
Tier 1 RAC (µg/L)			**12.5**	**4.06**	**0.0805**	**0.197**	**175**	**771**	**Tier 1 RAC (µg/kg)**	**4.2**	**8 000**
FOCUS Scenario		**PEC (µg/L)**	**PEC/RAC (pelagic species)**							**PEC/RAC (benthic species)**	
Step 1		224	**18**	**55**	**2800**	**1100**	**1.28**	0.29	2510	**600**	0.31
Step 2	N EU	50.8	**4.1**	**13**	**630**	**260**	0.29	-	688	**164**	-
	S EU	64.2	**5.1**	**16**	**800**	**330**	0.37	-	958	**228**	-
Step 3	D3 ditch	23.5	**1.9**	**5.8**	**290**	**120**	-	-	29.0	**6.9**	-
	D4 pond	3.14	0.25	0.77	**39**	**16**	-	-	31.1	**7.4**	-
	D4 stream	24.4	**2.0**	**6.0**	**300**	**120**	-	-	4.34	**1.0**	-
	D5 pond	3.15	0.25	0.78	**39**	**16**	-	-	32.8	**7.8**	-
	D5 stream	26.7	**2.1**	**6.6**	**330**	**140**	-	-	7.88	**1.9**	-
	R1 pond	3.02	0.24	0.74	**38**	**15**	-	-	27.5	**6.5**	-
	R1 stream	18.9	**1.5**	**4.7**	**240**	**96**	-	-	4.77	**1.1**	-
	R2 stream	25.3	**2.0**	**6.2**	**310**	**130**	-	-	4.18	**1.0**	-
	R3 stream	26.6	**2.1**	**6.6**	**330**	**140**	-	-	8.92	**2.1**	-
	R4 stream	18.9	**1.5**	**4.7**	**240**	**96**	-	-	7.94	**1.9**	-

Table 10.2-18: Tier 1 risk assessment for cyprodinil based on FOCUS Step 1, 2 and 3 PECs for pome fruit (3 × 375 g a.s./ha for 'late' application)

Group			Fish - acute	Fish - chronic	Invertebrate - acute	Invertebrate - chronic	Algae	Macrophyte	Group	Sediment dweller - acute	Sediment dweller - chronic
Tier 1 RAC (µg/L)			**12.5**	**4.06**	**0.0805**	**0.197**	**320**	**742**	Tier 1 RAC (µg/kg)	**4.2**	**8000**
FOCUS Scenario		PEC (µg/L)	PEC/RAC (pelagic species)						PEC_{sed} (µg/kg)	PEC/RAC (benthic species)	
Step 1		224	**18**	**55**	**2800**	**1100**	0.70	0.30	2510	**600**	0.31
Step 2	N EU	50.8	**4.1**	**13**	**630**	**260**	0.16	0.068	687	**160**	-
	S EU	56.1	**4.5**	**14**	**700**	**280**	0.18	0.076	821	**200**	-
Step 3	D3 ditch	9.84	0.79	**2.4**	**120**	**50**	-	-	22.4	**5.3**	-
	D4 pond	0.948	0.076	0.23	**12**	**4.8**	-	-	11.2	**2.7**	-
	D4 stream	9.85	0.79	**2.4**	**120**	**50**	-	-	2.73	0.65	-
	D5 pond	0.988	0.079	0.24	**12**	**5.0**	-	-	11.3	**2.7**	-
	D5 stream	10.6	0.85	**2.6**	**130**	**54**	-	-	4.35	**1.0**	-
	R1 pond	0.977	0.078	0.24	**12**	**5.0**	-	-	9.97	**2.4**	-
	R1 stream	7.53	0.60	**1.9**	**94**	**38**	-	-	3.34	0.80	-
	R2 stream	10.1	0.81	**2.5**	**130**	**51**	-	-	1.96	0.47	-
	R3 stream	10.6	0.85	**2.6**	**130**	**54**	-	-	4.63	**1.1**	-
	R4 stream	7.53	0.60	**1.9**	**94**	**38**	-	-	5.45	**1.3**	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Group			Fish – acute	Fish – chronic	Invertebrate – acute	Invertebrate – chronic	Algae	Macrophyte		Sediment dweller – acute	Sediment dweller – chronic
Tier 1 RAC (µg/L)			**12.5**	**4.06**	**0.0805**	**0.197**	**175**	**771**	**Tier 1 RAC (µg/kg)**	**4.2**	**8000**
FOCUS Scenario		**PEC (µg/L)**	**PEC/RAC (pelargic species)**						**PEC (µg/kg)**	**PEC/RAC (benthic species)**	
Step 1		224	**18**	**55**	**2800**	**1100**	**1.28**	0.29	2510	**600**	0.10
Step 2	N EU	50.8	**4.1**	**13**	**630**	**260**	0.29	-	688	**160**	-
	S EU	56.2	**4.5**	**14**	**700**	**290**	0.32	-	823	**200**	-
Step 3	D3 ditch	9.84	0.79	**2.4**	**120**	**50**	-	-	22.4	**5.3**	-
	D4 pond	0.948	0.08	0.2	**12**	**4.8**	-	-	11.2	**2.7**	-
	D4 stream	9.85	0.79	**2.4**	**120**	**50**	-	-	2.73	0.65	-
	D5 pond	0.988	0.08	0.2	**12**	**5.0**	-	-	11.3	**2.7**	-
	D5 stream	10.6	0.85	**2.6**	**130**	**54**	-	-	4.35	1.0	-
	R1 pond	0.977	0.08	0.2	**12**	**5.0**	-	-	9.97	**2.4**	-
	R1 stream	7.53	0.60	**1.9**	**94**	**38**	-	-	3.34	0.80	-
	R2 stream	10.1	0.81	**2.5**	**130**	**51**	-	-	1.96	0.47	-
	R3 stream	10.6	0.85	**2.6**	**130**	**54**	-	-	4.63	**1.1**	-
	R4 stream	7.53	0.60	**1.9**	**94**	**38**	-	-	5.45	**1.3**	-

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

For taxa/scenario combinations where the PEC/RAC ratio is above the trigger value of 1, with the exception of the acute risk to sediment dwellers, the risk assessment has been refined using FOCUS Step 4 PEC_{SW} values. These refinements are presented below:

Refinement of the acute risk to aquatic invertebrates

Given that the RAC for aquatic invertebrates represents the lowest endpoint for the acute risk assessment, refinement of the risk to this group will be protective of acute toxicity to other groups.

The acute invertebrate risk assessment for cyprodinil is based on a 96-hour LC_{50} of 8.05 µg a.s./L for *Mysidopsis bahia*. This value is the lowest endpoint generated from tests with 13-other species, where EC_{50} values range between 0.033 and >9.5 mg a.s./L.

Given the number of endpoints that are available, one refinement option is to construct a species sensitivity distribution using the program ETX 2.0[4]. For convenience the list of endpoints for acute invertebrates is presented in the table below.

Table 10.2-19: Acute cyprodinil toxicity endpoints for aquatic invertebrates, for probabilistic risk assessment

Test organism	Taxonomy		EC/LC_{50} (mg-a.s./L)	Reference
	Subphylum	Order		
Mysidopsis bahia	Crustacean	Mysida	0.00805	***Ward (1995)***
Daphnia magna	Crustacean	Cladocera	0.033	***Boeri et al (1995)***
Thamnocephalus platyurus	Crustacean	Anostraca	0.12	***Peither (2000)***
Simocephalus vetulus	Crustacean	Anomopoda	0.15	***Peither (2000)***
Daphniopsis sp.	Crustacean	Cladocera	0.21	***Peither (2000)***
Daphnia longispina	Crustacean	Cladocera	0.22	***Peither (2000)***
Ostracoda	Crustacean	Podocopa	1.1	***Peither (2000)***
Gammarus sp.	Crustacean	Amphipoda	1.8	***Peither (2000)***
Lymnea stagnalis	Mollusca (phylum)	-	2.9	***Peither (2000)***
Cloeon sp.	Arthropoda (phylum)	-	3.5	***Peither (2000)***
Chaoborus sp.	Hexapoda	-	4.0	***Peither (2000)***
Brachionus calyciflorus	Rotifera	Ploima	> 9.5	***Peither (2000)***
Asellus aquaticus (nymphs)	Crustacean	Isopoda	2.35	***Maynard (2011)***
Asellus aquaticus (adults)	Crustacean	Isopoda	1.96	***Maynard (2011)***
Gammarus pulex	Crustacean	Amphipoda	0.69	***Beketov & Liess (2008)***

Clearly the most sensitive taxa are the crustaceans. As discussed in the aquatic guidance document when considering the quality of acute toxicity data used to construct the SSD:

'If the toxicity data comprise several different genera/families/orders of the potentially sensitive taxonomic group (see section 8.4.3 for further guidance), including Ephemeroptera/Plecoptera/Trichoptera taxa (EPT) for insecticides, a lower AF in the proposed range may be selected. However, if another valid SSD can be constructed with a more limited dataset containing the most sensitive species, and the HC_5 derived from this SSD curve is lower than that of the

[4] Vlaardingen PLA van, Traas TP, Wintersen AM, Aldenberg T. ETX 2.0. A Program to Calculate Hazardous Concentrations and Fraction Affected, Based on Normally Distributed Toxicity Data. RIVM The Netherlands.

SSD curve using toxicity data for a wider array of taxa, a higher AF in the proposed range may be selected to be applied to the SSD from the wider set.'

Given that the crustaceans are the most sensitive group an SSD has been constructed based on endpoints derived for them. The SSD distribution is presented in Figure 10.2-1.
The resulting median HC_5 value is ~~13.6~~ 14.14 µg a.s./L (95% CI 1.71 – 50.4 µg a.s./L).

According to the aquatic guidance document an assessment factor (AF) of 3 – 6 is recommended for this type of data. Several aspects need to be considered when selecting an appropriate AF from an SSD distribution. For ease of reference these are directly quoted below.

1. *The quality of the acute toxicity data used to construct the SSD*. If the toxicity data comprise several different genera/families/orders of the potentially sensitive taxonomic group (see section 8.4.3 for further guidance), including Ephemeroptera/Plecoptera/Trichoptera taxa (EPT) for insecticides, a lower AF in the proposed range may be selected. However, if another valid SSD can be constructed with a more limited dataset containing the most sensitive species, and the HC_5 derived from this SSD curve is lower than that of the SSD curve using toxicity data for a wider array of taxa, a higher AF in the proposed range may be selected to be applied to the SSD from the wider set.

2. *The lower limit value of the HC_5*. If the lower limit HC_5 derived from the curve is less than 1/3 of the median HC_5, a higher AF in the proposed range may be warranted.

3. *The lower tier RACs on the basis of standard toxicity data (tier 1), standard and additional toxicity data (Geomean approach) and tier 3 data*. The size of the AF should ideally not result in an SSD-$RAC_{sw;ac}$ higher than the tier 3 RAC derived from effect class 1 and 2 of micro- mesocosm studies, nor should it result in an SSD-$RAC_{sw;ac}$ lower than the tier 1 $RAC_{sw;ac}$ on the basis of standard test species and/or the Geomean- $RAC_{sw;ac}$ and/or method 3 to 5 (EFSA, 2006a) on the basis of the same toxicity data that were used to construct the SSD. Note that according to EFSA (2006a), the Geomean approach aims to achieve the same average level of protection as in the tier 1 effect assessment but can be predicted more accurately because of the availability of additional toxicity data for the relevant taxonomic groups.

4. *The position of the toxicity data in the lower tail of the SSD (around the HC_5)*. If in the lower tail the toxicity data, overall, are positioned on the right side of the SSD curve, the derived HC_5 estimate may be considered relatively "conservative" for the most sensitive species. This may be a reason to adopt a lower AF from the proposed range. In contrast, if in the lower tail the toxicity data are, overall, positioned on the left side of the SSD curve, this may be a reason to adopt a higher AF from the proposed range.

5. *The steepness of the SSD curve*. In the case of a relatively steep SSD curve (e.g. less than a factor of 100 between lowest and highest $L(E)C_{50}$ value used to construct the SSD curve), a higher AF from the proposed range is recommended since exposure concentrations that exceed the $RAC_{sw;ac}$ may have ecotoxicological consequences for a larger number of taxa.

6. *Considering information on chronic effects*. If acute to chronic ration (acute EC_{50}/chronic EC_{10}) is larger than 10, then an AF in the higher range may be warranted.

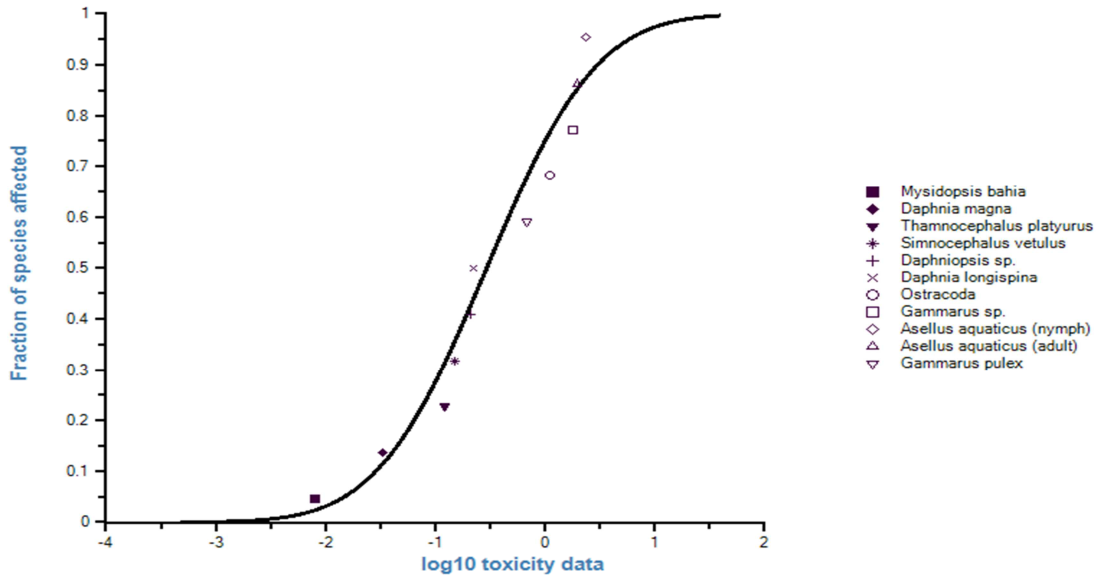

Figure 10.2-1: Species sensitivity distribution (SSD) for acute exposure of crustaceans to cyprodinil

It is proposed that an AF of 3 is applied to the HC_5 of 14.14 ~~13.6~~ µg a.s./L giving an $SSD\text{-}RAC_{sw;ac}$ of 4.71 ~~4.53~~ µg a.s./L. Justification is provided below by considering the data set presented in Table 10.2-20 against the above aspects:

1. The most sensitive taxa have been used to construct the SSD and several different orders are represented – **therefore a lower assessment factor can be justified here.**

2. The lower limit of the HC_5 is less than 1/3 of the median HC_5.

3. The size of the AF should ideally not result in an $SSD\text{-}RAC_{sw;ac}$ higher than the tier 3 RAC derived from effect class 1 and 2 of micro- mesocosm studies, nor should it result in an $SSD\text{-}RAC_{sw;ac}$ lower than the tier 1 $RAC_{sw;ac}$ on the basis of standard test species – **therefore a lower assessment factor can be justified here.**

4. In the lower tail, the toxicity data, overall, are positioned on the right side of the SSD curve - **therefore a lower assessment factor can be justified here.**

5. The SSD curve is relatively shallow in that there is greater than a factor of 100 between lowest and highest $L(E)C_{50}$ - **therefore a lower assessment factor can be justified here.**

6. **The acute to chronic ratio for** *Mysidopsis bahia* is 4 - **therefore a lower assessment factor can be justified here.**

In addition to these points, the test for normality was acceptable for all three tests (Anderson-Darling, Kolmogorov-Smirnov and Cramer von Mises) for all significance levels.

The FOCUS Step 3 PEC_{SW} values for all application scenarios have been compared with the $SSD\text{-}RAC_{sw;ac}$ RAC of 4.71 ~~4.53~~ µg a.s./L. These are shown in the table below.

Table 10.2-20: Higher-tier acute risk assessment using a refined SSD-RAC of 4.71 ~~4.53~~ µg a.s./L for aquatic invertebrates for cyprodinil – FOCUS Step 3

~~Application timing~~	~~Scenario~~	~~Number of applications~~			
		~~1 × 375 g a.s./ha~~		~~3 × 375 g a.s./ha~~	
		~~PEC (µg/L)~~	~~PEC/RAC ratio~~	~~PEC (µg/L)~~	~~PEC/RAC ratio~~
~~'Early'~~	~~D3 ditch~~	~~29.1~~	**~~6.4~~**	~~23.5~~	**~~5.2~~**
	~~D4 pond~~	~~1.77~~	~~0.39~~	~~3.14~~	~~0.69~~
	~~D4 stream~~	~~29.6~~	**~~6.5~~**	~~24.4~~	**~~5.4~~**
	~~D5 pond~~	~~1.77~~	~~0.39~~	~~3.15~~	~~0.70~~
	~~D5 stream~~	~~28.8~~	**~~6.4~~**	~~26.7~~	**~~5.9~~**
	~~R1 pond~~	~~1.76~~	~~0.39~~	~~3.02~~	~~0.67~~
	~~R1 stream~~	~~23.5~~	**~~5.2~~**	~~18.9~~	**~~4.2~~**
	~~R2 stream~~	~~31.1~~	**~~6.9~~**	~~25.3~~	**~~5.6~~**
	~~R3 stream~~	~~33.2~~	**~~7.3~~**	~~26.6~~	**~~5.9~~**
	~~R4 stream~~	~~23.6~~	**~~5.2~~**	~~18.9~~	**~~4.2~~**
~~'Late'~~	~~D3 ditch~~	~~13.7~~	**~~3.0~~**	~~9.84~~	**~~2.2~~**
	~~D4 pond~~	~~0.615~~	~~0.14~~	~~0.948~~	~~0.21~~
	~~D4 stream~~	~~13.8~~	**~~3.0~~**	~~9.85~~	**~~2.2~~**
	~~D5 pond~~	~~0.616~~	~~0.14~~	~~0.988~~	~~0.22~~
	~~D5 stream~~	~~14.9~~	**~~3.3~~**	~~10.6~~	**~~2.3~~**
	~~R1 pond~~	~~0.615~~	~~0.14~~	~~0.977~~	~~0.22~~
	~~R1 stream~~	~~10.6~~	**~~2.3~~**	~~7.53~~	**~~1.7~~**
	~~R2 stream~~	~~14.1~~	**~~3.1~~**	~~10.1~~	**~~2.2~~**
	~~R3 stream~~	~~14.9~~	**~~3.3~~**	~~10.6~~	**~~2.3~~**
	~~R4 stream~~	~~10.6~~	**~~2.3~~**	~~7.53~~	**~~1.7~~**

Application timing	**Scenario**	**Number of applications**			
		1 × 375 g a.s./ha		**3 × 375 g a.s./ha**	
		PEC (µg/L)	**PEC/RAC ratio**	**PEC (µg/L)**	**PEC/RAC ratio**
'Early'	D3 ditch	29.1	**6.2**	23.5	**5.0**
	D4 pond	1.77	0.38	3.14	0.67
	D4 stream	29.6	**6.3**	24.4	**5.2**
	D5 pond	1.77	0.38	3.15	0.67
	D5 stream	28.8	**6.1**	26.7	**5.7**
	R1 pond	1.76	0.37	3.02	0.64
	R1 stream	23.5	**5.0**	18.9	**4.0**
	R2 stream	31.1	**6.6**	25.3	**5.4**
	R3 stream	33.2	**7.0**	26.6	**5.6**
	R4 stream	23.6	**5.0**	18.9	**4.0**
'Late'	D3 ditch	13.8	**2.9**	9.84	**2.1**
	D4 pond	0.615	0.13	0.948	0.20
	D4 stream	13.8	**2.9**	9.85	**2.1**
	D5 pond	0.617	0.13	0.988	0.21
	D5 stream	14.9	**3.2**	10.6	**2.3**
	R1 pond	0.616	0.13	0.977	0.21

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
	R1 stream	10.6	**2.3**	7.53	**1.6**
	R2 stream	14.1	**3.0**	10.1	**2.1**
	R3 stream	14.9	**3.2**	10.6	**2.3**
	R4 stream	10.6	**2.3**	7.53	**1.6**

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

The PEC/SSD-$RAC_{sw;ac}$ values are all greater than 1 for the ditch and stream scenarios, indicating the need for further consideration of the risk to aquatic invertebrates. Refinement is presented below in which the PEC/RAC values have been calculated using FOCUS Step 4 values.

Table 10.2-21: Refinement of acute risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application) (RAC-SSD = 4.71 µg a.s./L)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	22.8	**4.8**	14	**3.0**	6.3	**1.3**	3.2	0.68	1
		50	14.5	**3.1**	11.4	**2.4**	7.01	**1.5**	3.15	0.67	1.6	0.34	
		75	7.26	**1.5**	5.7	**1.2**	3.5	0.74	-	-	-	-	
		90	2.9	0.62	2.28	0.48	-	-	-	-	-	-	
D4 / stream	-	0	-	-	25.5	**5.4**	15.7	**3.3**	7.06	**1.5**	3.6	0.76	1
		50	14.9	**3.2**	12.8	**2.7**	7.86	**1.7**	3.55	0.75	-	--	
		75	7.48	**1.6**	6.42	**1.4**	3.95	0.84	-	-	-	--	
		90	3.04	0.65	2.61	0.55	-	-	-	-	-	--	
D5 / stream	-	0	-	-	24.8	**5.3**	15.2	**3.2**	6.85	**1.5**	3.49	0.74	1
		50	14.4	**3.1**	12.4	**2.6**	7.62	**1.6**	3.43	0.73	-	--	
		75	7.24	**1.5**	6.21	**1.3**	3.82	0.81	-	-	-	--	
		90	2.91	0.62	2.5	0.53	-	-	-	-	-	--	
R1 / stream	0	0	-	-	20.2	**4.3**	12.4	**2.6**	5.61	**1.2**	2.86	0.61	1
		50	11.8	**2.5**	10.2	**2.2**	6.24	**1.3**	2.82	0.60	1.45	0.31	
		75	5.95	**1.3**	5.1	**1.1**	3.14	0.67	-	-	-	--	
		90	2.44	0.52	2.09	0.44	-	-	-	-	-	--	
R2 / stream	0	0	--	--	26.8	**5.7**	16.5	**3.5**	7.42	**1.6**	3.78	0.80	
		50	15.6	**3.3**	13.4	**2.8**	8.25	**1.8**	3.73	0.79	-	-	
		75	7.85	**1.7**	6.74	**1.4**	4.15	0.88	-	-	-	-	
		90	3.18	0.68	2.73	0.58	-	-	-	-	-	-	
R3 / stream	0	0	--	--	28.6	**6.1**	17.6	**3.7**	7.9	**1.70**	4.02	0.85	
		50	16.6	**3.5**	14.3	**3.0**	8.78	**1.9**	3.96	0.84			
		75	8.34	**1.8**	7.16	**1.5**	4.41	0.94	-	-	-	--	
		90	3.4	0.72	2.91	0.62	1.8	0.38	-	-	-	--	
R4 / stream	0	0	--	--	20.4	**4.3**	12.5	**2.7**	5.63	**1.20**	2.87	0.61	
		50	11.9	**2.5**	10.2	**2.2**	6.27	**1.3**	2.84	0.60	-	-	
		75	5.98	**1.3**	5.13	**1.1**	3.16	0.67	-	-	-	--	

Scenario	**Mitigation options**	**Nozzle reduction (%)**	**Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**										**Trigger**
	Vegetative strip (m)		**-**		**5 m**		**10 m**		**15 m**		**20 m**		
			PEC_{SW} (µg/L)	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	
		90	2.44	0.52	2.1	0.45			-	-	-	--	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-22: Refinement of acute risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application) (RAC-SSD = 4.71 µg a.s./L)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	18.1	**3.8**	10.6	**2.3**	5.98	**1.3**	2.75	0.58	1
		50	11.8	**2.5**	9.04	**1.9**	5.32	**1.1**	2.99	0.63	-	-	
		75	5.87	**1.2**	4.52	0.96	2.66	0.56	-	-	-	-	
		90	2.36	0.50	-	-	-	-	-	-	-	-	
D4 / stream	-	0	--	--	20.7	**4.4**	12.2	**2.6**	6.86	**1.5**	3.16	0.67	1
		50	12.2	**2.6**	10.4	**2.2**	6.11	**1.3**	3.44	0.73	-	-	
		75	6.15	**1.3**	5.21	**1.1**	3.08	0.65	-	-	-	-	
		90	2.5	0.53	2.12	0.45	-	-	-	-	-	-	
D5 / stream	-	0	--	--	22.6	**4.8**	13.3	**2.8**	7.49	**1.6**	3.45	0.73	1
		50	13.4	**2.8**	11.3	**2.4**	6.66	**1.4**	3.75	0.8	-	-	
		75	6.68	**1.4**	5.66	**1.2**	3.33	0.71	-	-	-	-	
		90	2.7	0.57	2.29	0.49	-	-	-	-	-	-	
R1 / stream	0	0	--	--	16.1	**3.4**	9.46	**2.0**	5.33	**1.1**	2.47	0.52	1
		50	9.51	**2.0**	8.06	**1.7**	4.76	1.0	2.68	0.57	-	-	
		75	4.8	1.0	4.06	0.86	2.41	0.51	1.55		-	-	
R2 / stream	0	0	-	-	21.6	**4.6**	12.7	**2.7**	7.15	**1.5**	3.3	0.70	
		50	12.8	**2.7**	10.8	**2.3**	6.37	**1.4**	3.59	0.76	-	-	
		75	6.42	**1.4**	5.44	**1.2**	3.22	0.68	-	-	-	-	
		90	2.63	0.56	2.22	0.47	-	-	-	-	-	-	
R3 / stream	0	0	-	-	22.6	**4.8**	13.3	**2.8**	7.47	**1.6**	3.44	0.73	
		50	13.3	**2.8**	11.3	**2.4**	6.65	**1.4**	3.74	0.79	-	-	
		75	6.69	**1.4**	5.67	**1.2**	3.35	0.71	-	-	-	-	
		90	2.75	0.58	2.32	0.49	-	-	-	-	--	--	
R4 / stream	0	0	-	-	16.1	**3.4**	9.46	**2.0**	5.32	**1.1**	4.47	0.95	
		50	9.51	**2.0**	8.05	**1.7**	4.75	1.0	4.47	0.95	-	-	
		75	4.8	**1.0**	4.47	0.95	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-23: Refinement of acute risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application) (RAC-SSD = 4.71 µg a.s./L)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	9.28	**2.0**	4.14	0.88	-	-	1
		50	6.87	**1.5**	4.64	0.99	-	-	-	-	
		75	3.43	0.73	-	-	-	-	-	-	
D4 / stream	-	0	-	-	10.8	**2.3**	4.81	1.0	-	-	1
		50	6.91	**1.5**	5.39	**1.1**	2.43	0.52	-	-	
		75	3.5	0.74	2.73	0.58	-	-	-	-	
D5 / stream	-	0	-	-	11.6	**2.5**	5.2	**1.1**	2.62	0.56	1
		50	7.45	**1.6**	5.81	**1.2**	2.6	0.55	-	-	
		75	3.74	0.79	2.92	0.62	-	-	-	-	
R1 / stream	0	0	-	-	8.29	**1.8**	3.73	0.79	-	-	1
		50	5.35	**1.1**	4.18	0.89	-	-	-	-	
		75	2.73	0.58	-	-	-	-	-	-	
	10 - 12	0	-	-	8.29	**1.8**	3.73	0.79	-	-	
		50	-	-	4.18	0.89	-	-	-	-	
R2 / stream	0	0	-	-	11.1	**2.4**	4.99	**1.1**	2.53	0.54	1
		50	7.16	**1.5**	5.59	**1.2**	2.52	0.54	-	-	
		75	3.63	0.77	2.84	0.6	-	-	-	-	
	10 - 12	0	-	-	11.1	**2.4**	4.99	**1.1**	2.53	0.54	
		50	-	-	5.59	**1.2**	2.52	0.54	-	-	
		75	-	-	2.84	0.60	-	-	-	-	
R3 / stream	0	0	-	-	11.6	**2.5**	5.2	**1.1**	2.64	0.56	1
		50	7.46	**1.6**	5.82	**1.2**	2.63	0.56	1.35	0.29	
		75	3.79	0.8	2.96	0.63	1.36	0.29	0.706	0.15	
R4 / stream	0	0	-	-	8.29	**1.8**	3.73	0.79	-	-	1
		50	5.35	**1.1**	4.18	0.89	-	-	-	-	
		75	2.73	0.58	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-24: Refinement of acute risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application) (RAC-SSD = 4.71 µg a.s./L)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	6.74	**1.4**	3.14	0.67	-	-	1
		50	4.92	1.0	3.38	0.72	-	-	-	-	
D4 / stream	-	0	-	-	7.77	**1.6**	3.63	0.77	-	-	1
		50	4.96	**1.1**	3.91	0.83	-	-	-	-	
		75	2.52	0.54	-	-	-	-	-	-	
D5 / stream	-	0	-	-	8.38	**1.8**	3.91	0.83	-	-	1
		50	5.32	**1.1**	4.19	0.89	-	-	-	-	
		75	2.69	0.57	-	-	-	-	-	-	
R1 / stream	0	0	-	-	5.99	**1.3**	2.81	0.6	-	-	1
		50	3.85	0.82	3.04	0.65	-	-	-	-	
R2 / stream	0	0	-	-	8.04	**1.7**	3.77	0.80	-	-	1
		50	5.15	**1.1**	4.06	0.86	-	-	-	-	
		75	2.63	0.56	-	-	-	-	-	-	
R3 / stream	0	0	-	-	8.38	**1.8**	5.06	**1.1**	3.67	0.78	1
		50	6.07	**1.3**	5.27	**1.1**	3.68	0.78	-	-	
		75	4.18	0.89	3.78	0.80	-	-	-	-	
R4 / stream	0	0	-	-	5.99	**1.3**	2.87	0.61	-	-	1
		50	3.85	0.82	3.04	0.65	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Refinement of acute risk to aquatic invertebrates using the Ashwell *et al.* (2007) mesocosm ETO-RAC

A mesocosm study was conducted using a 300 EC formulation A14325E (***Ashwell et al, 2007***) (details are provided in M-CA Section 8, CA 8.2-8) to a community typical for a lentic freshwater community, containing phyto- and zooplankton and macroinvertebrates. Intended initial concentrations were 0 – 1.5 – 5 – 10 – 20 – 50 µg a.s./L. Immediately after each of the three applications, the test compound was mixed in the water layer of the microcosms. Measurements in dosing solutions and water indicated that the test systems received the intended doses. Shortly after the applications, 75-80%, 119-154% and 118-156% of the target amount was measured in the water of the test systems.

MDD analysis of the available data for zooplankton demonstrated that typically small to large effects could be determined throughout the study for five parameters. As these evaluations included sensitive taxa (*Daphnia* sp.) and organisms from the three main zooplankton groups (cladocera, copepoda and rotifera), the data generated are considered robust and reliable for ETO-RAC derivation and a NOEC (class 1) of 10 µg a.s./L (based on nominal concentrations) and 14.6 µg a.s./L (based on measured concentrations) is recommended for zooplankton. If an NOEAEC (class 3A) is required for ERO-RAC, it can be considered to be 67.5 µg a.s./L (based on measured concentrations).

The NOEC (Effect class 1) from this study has been determined as 14.6 µg a.s./L. The appropriate assessment factor recommended by the EFSA aquatic guidance is 2, resulting in an ETO-RAC of 7.3 µg a.s./L.

In the table below, the PEC/RAC values based on the ETO- RAC of 7.3 µg a.s./L have been presented for mitigation options ranging from 10 to 20 m drift reduction buffers.

Table 10.2-21: Higher-tier acute risk assessment for aquatic invertebrates incorporating exposure mitigation options for pome fruit using a refined ETO-RAC of 7.3 µg a.s./L derived from a mesocosm study conducted with A14325E

Application timing	Scenario	Spray drift buffer	Number of applications			
			1 × 375 g a.s./ha		3 × 375 g a.s./ha	
			PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	10 m	14.0	**1.9**	10.6	**1.5**
	D4 stream		15.7	**2.2**	12.2	**1.7**
	D5 stream		15.2	**2.1**	13.3	**1.8**
	R1 stream		12.4	**1.7**	9.43	**1.3**
	R2 stream		16.4	**2.2**	12.6	**1.7**
	R3 stream		17.5	**2.4**	13.3	**1.8**
	R4 stream		12.5	**1.7**	9.43	**1.3**
	D3 ditch	15 m	6.30	0.86	5.98	0.82
	D4 stream		7.05	0.97	6.85	0.94
	D5 stream		6.85	0.94	7.49	**1.03**
	R1 stream		5.57	0.76	5.30	0.73
	R2 stream		7.38	**1.01**	7.10	0.97
	R3 stream		7.89	**1.1**	7.46	**1.02**
	R4 stream		5.61	0.77	5.3	0.73
	D3 ditch	20 m	3.20	0.44	2.75	0.38
	D4 stream		3.59	0.49	3.16	0.43
	D5 stream		3.48	0.48	3.45	0.47

	R1 stream		2.83	0.39	2.44	0.33
	R2 stream		3.75	0.51	3.27	0.45
	R3 stream		4.01	0.55	3.43	0.47
	R4 stream		2.85	0.39	4.54	0.62
'Late'	D3 ditch	10 m	4.14	0.57	3.14	0.43
	D4 stream		4.81	0.66	3.63	0.50
	D5 stream		5.20	0.71	3.91	0.54
	R1 stream		3.68	0.50	2.77	0.38
	R2 stream		4.92	0.67	3.71	0.51
	R3 stream		5.19	0.71	5.06	0.69
	R4 stream		3.68	0.50	2.94	0.40

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations
PEC_{SW} values have not been generated for the 'pond' scenarios as these represent least worst case.
PEC/RAC values have been generated only for those scenarios which failed at Step 3

The acute risk to aquatic invertebrates is acceptable, having refined the risk assessment using the ETO-RAC of 7.3 µg a.s./L derived from the Ashwell *et al*. (2007) mesocosm study. Mitigation required for the scenario application number and timing is presented in the table below:

Table 10.2-22: Mitigation measures required to resolve the acute risk assessment

Crop/timing	Scenario						
	D3 ditch	D4 stream	D5 stream	R1 stream	R2 stream	R3 stream	R4 stream
Pome fruit 1 × 375 g a.s./ha ('early' appl.)	15 m DB	15 m DB	15 m DB	15 m DB	20 m DB	20 m DB	15 m DB
Pome fruit 1 × 375 g a.s./ha ('late' appl.)	10 m DB	10 m DB	10 m DB	10 m DB	10 m DB	10 m DB	10 m DB
Pome fruit 3 × 375 g a.s./ha ('early' appl.)	15 m DB	15 m DB	20 m DB	15 m DB	15 m DB	20 m DB	15 m DB
Pome fruit 3 × 375 g a.s./ha ('late' appl.)	10 m DB	10 m DB	10 m DB	10 m DB	10 m DB	10 m DB	10 m DB

DB = Drift buffer

Acute risk to fish

For the acute risk assessment for fish, the PEC/RAC ratios were greater than 1 for several FOCUS step 3 scenarios (please refer to Tables 10.2.15 to 10.2-18). Given that the acute RAC for fish is 12.5 µg a.s./L and is therefore higher than the ~~mesocosm~~ SSD-$RAC_{sw;ac}$ RAC of 4.71 µg a.s./L for invertebrates ~~of 5.0 µg a.s./L~~, the mitigation measures required to be protective of acute risk assessment to invertebrates would be protective of the acute risk to fish.

Refinement of the acute risk to sediment dwellers

For the acute risk assessment to sediment dwellers, some of the PEC/RAC ratios presented in Tables 10.2-15 to 10.2-18 are above 1 indicating the need for further refinement.

In the mesocosm study conducted by Ashwell *et al.* (2007) the effects of cyprodinil, applied as A14325E, on Chironomidae were evaluated. %MDD values for Chironomidae ranged from 17 to 29 between day -27 and day 29, meaning small effects could be reliably determined for this sampling period, which included all three applications of the test item. From day 43 to day 71, %MDD values were >100, meaning no effects could be reliably determined. From day 85 and for the remainder of the study, %MDD values ranged between 62 and 88, meaning medium to large effects could be reliably determined.

As a result, the data for this taxon are considered reliable (category one) and suitable for use in ETO-RAC derivation. In addition, as no clear treatment related effects were seen at the maximum tested concentration (50 µg a.s./L), the endpoint for Chironomidae are also suitable for ERO-RAC derivation. Therefore, the mitigation proposed to address the acute risk to invertebrates will also address the acute risk to sediment-dwellers.

Overall conclusion

When applied in accordance with the uses supported in this submission A8637C poses an acceptable acute risk when considering the mitigation measures as summarised in Table 10.2-22.

Long-term risk to aquatic invertebrates

The lowest tier 1 $RAC_{sw;ch}$ is 0.197 µg a.s./L, based on data for aquatic invertebrates, the mysid shrimp. As shown in Tables 10.2-15 to 10.2-18, acceptable risk was not achieved when this $RAC_{sw;ch}$ was compared to FOCUS Step 3 surface water concentrations.

Based on EFSA Aquatic Guidance, the chronic risk can be refined using a default 7-d twa. However, it should not be used if the following apply:

- If the RAC is from studies where exposure is not maintained – *exposure was maintained throughout the mysid study.*
- When the effect is based on a developmental endpoint during a specific lifestage that may last a short time only – *the endpoint is based on survival of the F1 generation.*
- When the effect is based on mortality early in the test or the acute:chronic ratio both based on mortality is <10 – *mortality did not occur early in the test.*
- If latency has been demonstrated or might be expected – *there is no evidence for latency of effects*.

There is no reason not to use the 7-d twa in the chronic risk assessment. PEC/RAC values for FOCUS Step 3 7 d TWA concentrations are presented in the table below.

Table 10.2-25: Higher-tier long-term risk assessment for aquatic invertebrates using FOCUS Step 3 7 d TWA PEC_{SW} concentrations ($RAC_{sw;ch}$ = 0.197 µg a.s./L)

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		7 d TWA PEC (µg/L)	PEC/RAC ratio	7 d TWA PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	4.63	**24**	5.7	**29**
	D4 pond	1.6	**8.1**	2.97	**15**
	D4 stream	0.454	**2.3**	0.685	**3.5**
	D5 pond	1.59	**8.1**	2.98	**15**
	D5 stream	0.163	0.83	1.46	**7.4**
	R1 pond	1.59	**8.1**	2.82	**14.0**
	R1 stream	0.565	**2.9**	0.711	**3.6**
	R2 stream	0.36	**1.8**	0.375	**1.9**
	R3 stream	1.52	**7.7**	1.43	**7.3**
	R4 stream	0.67	**3.4**	0.993	**5.0**
'Late'	D3 ditch	3.33	**17**	5.38	**27**
	D4 pond	0.556	**2.8**	0.892	**4.5**
	D4 stream	0.535	**2.7**	0.406	**2.1**
	D5 pond	0.56	**2.8**	0.934	**4.7**
	D5 stream	0.813	**4.1**	0.581	**2.9**
	R1 pond	0.551	**2.8**	0.913	**4.6**
	R1 stream	0.316	**1.6**	0.226	**1.1**
	R2 stream	0.209	**1.1**	0.155	0.79
	R3 stream	0.791	**4.0**	0.565	**2.9**
	R4 stream	0.315	**1.6**	0.703	**3.6**

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

All but ~~1~~ 2 of the PEC/RAC ratios are greater than 1 and therefore further refinement is required.

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		7 d TWA PEC (µg/L)	PEC/RAC ratio	7 d TWA PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	4.66	**24**	5.72	**29**
	D4 pond	1.60	**8.1**	2.97	**15**
	D4 stream	0.473	**2.4**	0.701	**3.6**
	D5 pond	1.59	**8.1**	2.98	**15**
	D5 stream	0.179	**0.91**	1.48	**7.5**
	R1 pond	1.59	**8.1**	2.82	**14**
	R1 stream	0.581	**2.9**	0.725	**3.7**
	R2 stream	0.378	**1.9**	0.391	**2.0**
	R3 stream	1.54	**7.8**	1.45	**7.4**
	R4 stream	0.686	**3.5**	0.993	**5.0**
'Late'	D3 ditch	3.34	**17**	5.38	**27**
	D4 pond	0.556	**2.8**	0.891	**4.5**
	D4 stream	0.546	**2.8**	0.413	**2.1**
	D5 pond	0.56	**2.8**	0.934	**4.7**
	D5 stream	0.824	**4.2**	0.588	**3.0**
	R1 pond	0.551	**2.8**	0.913	**4.6**
	R1 stream	0.323	**1.6**	0.231	**1.2**
	R2 stream	0.218	**1.1**	0.161	0.82
	R3 stream	0.802	**4.1**	0.573	**2.9**
	R4 stream	0.322	**1.6**	0.711	**3.6**

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Further refinement of the long-term risk to aquatic invertebrates (RACsw;ch)

A robust mesocosm study has been conducted (Ashwell *et al*. (2007). **The long-term risk to aquatic invertebrates is acceptable when consideration is given to mitigation presented in Table 10.2-22 based on an ETO–RAC of 7.3 µg a.s./L.**

A robust mesocosm study has been conducted (Ashwell *et al*. 2007). The long-term risk to aquatic invertebrates will be refined using the ETO–RACs of 0.75 and 0.90 µg a.s./L and ERO-RACs of 3.33 and 4.86 µg a.s./L, derived following re-evaluation of the data from the study.

Table 10.2-26: Higher-tier long-term risk assessment using an ETO-RAC of 0.75 µg a.s./L derived from the Ashwell *et al.* mesocosm study – FOCUS Step 3 for pome fruit

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	29.1	**39**	23.5	**31**
	D4 pond	1.77	**2.4**	3.14	**4.2**
	D4 stream	29.6	**39**	24.4	**33**
	D5 pond	1.77	**2.4**	3.15	**4.2**
	D5 stream	28.8	**38**	26.7	**36**
	R1 pond	1.76	**2.3**	3.02	**4.0**
	R1 stream	23.5	**31**	18.9	**25**
	R2 stream	31.1	**41**	25.3	**34**
	R3 stream	33.2	**44**	26.6	**35**
	R4 stream	23.6	**31**	18.9	**25**
'Late'	D3 ditch	13.8	**18**	9.84	**13**
	D4 pond	0.615	0.82	0.948	**1.3**
	D4 stream	13.8	**18**	9.85	**13**
	D5 pond	0.617	0.82	0.988	**1.3**
	D5 stream	14.9	**20**	10.6	**14**
	R1 pond	0.616	0.82	0.977	**1.3**
	R1 stream	10.6	**14**	7.53	**10**
	R2 stream	14.1	**19**	10.1	**13**
	R3 stream	14.9	**20**	10.6	**14**
	R4 stream	10.6	**14**	7.53	**10**

Table 10.2-27: Higher-tier long-term risk assessment using an ETO-RAC of 0.90 µg a.s./L derived from the Ashwell *et al.* mesocosm study – FOCUS Step 3 for pome fruit

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	29.1	**32**	23.5	**26**
	D4 pond	1.77	**2.0**	3.14	**3.5**
	D4 stream	29.6	**33**	24.4	**27**
	D5 pond	1.77	**2.0**	3.15	**3.5**
	D5 stream	28.8	**32**	26.7	**30**
	R1 pond	1.76	**2.0**	3.02	**3.4**
	R1 stream	23.5	**26**	18.9	**21**
	R2 stream	31.1	**35**	25.3	**28**
	R3 stream	33.2	**37**	26.6	**30**
	R4 stream	23.6	**26**	18.9	**21**
'Late'	D3 ditch	13.8	**15**	9.84	**11**
	D4 pond	0.615	0.68	0.948	**1.1**
	D4 stream	13.8	**15**	9.85	**11**
	D5 pond	0.617	0.69	0.988	**1.1**
	D5 stream	14.9	**17**	10.6	**12**
	R1 pond	0.616	0.68	0.977	**1.1**
	R1 stream	10.6	**12**	7.53	**8.4**
	R2 stream	14.1	**16**	10.1	**11**
	R3 stream	14.9	**17**	10.6	**12**
	R4 stream	10.6	**12**	7.53	**8.4**

Table 10.2-28: Higher-tier long-term risk assessment using an ERO-RAC of 3.33 µg a.s./L derived from the Ashwell *et al.* mesocosm study – FOCUS Step 3 for pome fruit

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	29.1	**8.7**	23.5	**7.1**
	D4 pond	1.77	0.53	3.14	0.94
	D4 stream	29.6	**8.9**	24.4	**7.3**
	D5 pond	1.77	0.53	3.15	**1.0**
	D5 stream	28.8	**8.6**	26.7	**8.0**
	R1 pond	1.76	0.50	3.02	0.91
	R1 stream	23.5	**7.1**	18.9	**5.7**
	R2 stream	31.1	**9.3**	25.3	**7.6**
	R3 stream	33.2	**10**	26.6	**8.0**
	R4 stream	23.6	**7.1**	18.9	**5.7**
'Late'	D3 ditch	13.8	**4.1**	9.84	**3.0**
	D4 pond	0.615	0.18	0.948	0.28
	D4 stream	13.8	**4.1**	9.85	**3.0**
	D5 pond	0.617	0.19	0.988	0.30
	D5 stream	14.9	**4.5**	10.6	**3.2**
	R1 pond	0.616	0.18	0.977	0.29
	R1 stream	10.6	**3.2**	7.53	**2.3**
	R2 stream	14.1	**4.2**	10.1	**3.0**
	R3 stream	14.9	**4.5**	10.6	**3.2**
	R4 stream	10.6	**3.2**	7.53	**2.3**

Table 10.2-29: Higher-tier long-term risk assessment using an ERO-RAC of 4.86 µg a.s./L derived from the Ashwell *et al*. mesocosm study – FOCUS Step 3 for pome fruit

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	29.1	**6.0**	23.5	**4.8**
	D4 pond	1.77	0.36	3.14	0.65
	D4 stream	29.6	**6.1**	24.4	**5.0**
	D5 pond	1.77	0.36	3.15	0.65
	D5 stream	28.8	**5.9**	26.7	**5.5**
	R1 pond	1.76	0.36	3.02	0.62
	R1 stream	23.5	**4.8**	18.9	**3.9**
	R2 stream	31.1	**6.4**	25.3	**5.2**
	R3 stream	33.2	**6.8**	26.6	**5.5**
	R4 stream	23.6	**4.9**	18.9	**3.9**
'Late'	D3 ditch	13.8	**2.8**	9.84	**2.0**
	D4 pond	0.615	0.13	0.948	0.20
	D4 stream	13.8	**2.8**	9.85	**2.0**
	D5 pond	0.617	0.13	0.988	0.20
	D5 stream	14.9	**3.1**	10.6	**2.2**
	R1 pond	0.616	0.13	0.977	0.20
	R1 stream	10.6	**2.2**	7.53	**1.5**
	R2 stream	14.1	**2.9**	10.1	**2.1**
	R3 stream	14.9	**3.1**	10.6	**2.2**
	R4 stream	10.6	**2.2**	7.53	**1.5**

Table 10.2-30: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.75 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	22.8	**30**	14	**19**	6.3	**8.4**	3.2	**4.30**	1
		50	14.5	**19.0**	11.4	**15**	7.01	**9.3**	3.15	**4.20**	1.6	**2.10**	
		75	7.26	**9.7**	5.7	**7.6**	3.5	**4.7**	1.58	**2.1**	0.8	**1.10**	
		90	2.9	**3.9**	2.28	**3.0**	1.4	**1.9**	0.647	0.86	0.346	0.46	
D4 / pond	-	0	--	--	1.99	**2.7**	1.1	**1.5**	0.582	0.78	0.359	0.5	1
		50	0.905	**1.2**	1.01	**1.3**	0.558	0.74	-	-	-	-	
		75	0.477	0.64	0.52	0.69	-	-	-	-	-	-	
D4 / stream	-	0	--	--	25.5	**34**	15.7	**21**	7.06	**9.4**	3.6	**4.80**	1
		50	14.9	**20.0**	12.8	**17**	7.86	**10**	3.55	**4.70**	1.81	**2.40**	
		75	7.48	**10**	6.42	**8.6**	3.95	**5.3**	1.79	**2.4**	0.919	**1.20**	
		90	3.04	**4.1**	2.61	**3.5**	1.61	**2.1**	0.738	0.98	0.385	0.51	
D5 / pond	-	0	--	--	1.99	**2.7**	1.1	**1.5**	0.582	0.78	0.359	0.5	1
		50	0.904	**1.2**	1.01	**1.3**	0.558	0.74	-	-	-	-	
		75	0.476	0.6	0.52	0.69	-	-	-	-	-	-	
D5 / stream	-	0	--	--	24.8	**33**	15.2	**20**	6.85	**9.1**	3.49	**4.70**	1
		50	14.4	**19.0**	12.4	**17**	7.62	**10**	3.43	**4.60**	1.75	**2.30**	
		75	7.24	**9.7**	6.21	**8.3**	3.82	**5.1**	1.72	**2.3**	0.88	**1.20**	
		90	2.91	**3.9**	2.5	**3.3**	1.54	**2.1**	0.698	0.93	0.359	0.480	
R1 / pond	0	0	--	--	1.99	**2.7**	1.1	**1.5**	0.582	0.78	-	-	1
		50	0.905	**1.2**	1.01	**1.3**	0.558	0.74	-	-	-	-	
		75	0.476	0.63	0.52	0.69	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-30: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R1 / stream	0	0	0	-	20.2	**27**	12.4	**17**	5.61	**7.5**	2.86	**3.8**	1
		50	11.8	**16**	10.2	**14**	6.24	**8.3**	2.82	**3.8**	1.45	**1.9**	
		75	5.95	**7.9**	5.1	**6.8**	3.14	**4.2**	1.43	**1.9**	0.739	1.0	
		90	2.44	**3.3**	2.09	**2.8**	1.29	**1.7**	0.73	0.97	-	-	
R2 / stream	0	0	--	--	26.8	**36**	16.5	**22**	7.42	**9.9**	3.78	**5.0**	1
		50	15.6	**21**	13.4	**18**	8.25	**11**	3.73	**5.0**	1.9	**2.5**	
		75	7.85	**10**	6.74	**9.0**	4.15	**5.5**	1.88	**2.5**	0.963	**1.3**	
		90	3.18	**4.2**	2.73	**3.6**	1.69	**2.3**	0.772	**1.0**	0.403	0.5	
R3 / stream	0	0	--	--	28.6	**38**	17.6	**23**	7.9	**11**	4.02	**5.4**	
		50	16.6	**22.0**	14.3	**19**	8.78	**12.0**	3.96	**5.3**	2.02	**2.7**	
		75	8.34	**11.0**	7.16	**9.5**	4.41	**5.9**	2	**2.7**	1.49	**2.0**	
		90	3.4	**4.5**	2.91	**3.9**	1.8	**2.4**	1.49	**2**	1.49	**2.0**	
R4 / stream	0	0	--	--	20.4	**27**	12.5	**17**	5.63	**7.5**	2.87	**3.8**	
		50	11.9	**16**	10.2	**14**	6.27	**8.4**	2.84	**3.8**	1.45	**1.90**	
		75	5.98	**8.0**	5.13	**6.8**	3.16	**4.2**	1.44	**1.9**	1.16	**1.50**	
		90	2.44	**3.3**	2.1	**2.8**	1.3	**1.7**	1.16	**1.5**	1.16	**1.5**	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-30: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application: ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)						Trigger
	Vegetative strip (m)		25 m		30 m		40 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	1.89	**2.5**	1.22	**1.60**	0.621	0.83	1
		50	0.944	**1.3**	0.617	0.82	--	--	
		75	0.486	0.65	--	--	--	--	
D4 / stream	-	0	2.13	**2.8**	1.39	**1.90**	0.714	0.95	1
		50	1.08	**1.4**	0.709	0.95	--	--	
		75	0.553	0.74	--	--	--	--	
D5 / stream	-	0	2.06	**2.7**	1.34	**1.80**	0.68	0.91	1
		50	1.04	**1.4**	0.675	0.90	--	--	
		75	0.524	0.70	--	--	--	--	
R1 / stream	0	0	1.7	**2.3**	1.11	**1.5**	0.73	0.97	1
		50	0.866	**1.2**	0.73	0.97	--	--	
		75	0.73	0.97	--	--	--	--	
R2 /stream	0	0	2.24	**3.0**	1.46	**1.9**	0.748	**1.0**	1
		50	1.13	**1.5**	0.743	0.99	-	-	
		75	0.579	0.77	-	-	-	-	
R3 / stream	0	0	2.38	**3.2**	1.56	**2.1**	1.49	**2.0**	1
		50	1.49	**2.0**	1.49	**2.0**	-	-	
		75	1.49	**2.0**	-	-	-	-	
	18 - 20	0	2.38	**3.2**	1.56	**2.1**	0.806	**1.10**	
		50	1.21	**1.6**	0.8	**1.1**	-	-	
		75	0.629	0.84	-	-	-	-	
R4 /stream	0	0	1.71	**2.3**	1.16	**1.5**	-	-	1
		50	1.16	**1.5**	-	-	-	-	
	18 - 20	0	1.71	**2.3**	1.12	**1.5**	0.581	0.77	
		50	0.869	**1.2**	0.577	0.77	-	-	
		75	0.454	0.61	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-31: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.75 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	18.1	**24**	10.6	**14**	5.98	**8.0**	2.75	**3.7**	1
		50	11.8	**16**	9.04	**12**	5.32	**7.1**	2.99	**4.0**	1.38	**1.80**	
		75	5.87	**7.8**	4.52	**6.0**	2.66	**3.5**	1.5	**2.0**	0.7	0.93	
		90	2.36	**3.1**	1.82	**2.4**	1.09	**1.5**	0.631	0.84	-	-	
D4 / pond	-	0	--	--	3.59	**4.8**	2.03	**2.7**	1.06	**1.4**	0.603	0.80	1
		50	1.64	**2.2**	1.81	**2.4**	1.04	**1.4**	0.55	0.73	-	-	
		75	0.868	**1.2**	0.94	**1.3**	0.547	0.73	-	-	-	-	
		90	0.409	0.55	0.425	0.57	-	-	-	-	-	-	
D4 / stream	-	0	--	--	20.7	**28**	12.2	**16**	6.86	**9.1**	3.16	**4.2**	1
		50	12.2	**16**	10.4	**14**	6.11	**8.1**	3.44	**4.6**	1.6	**2.1**	
		75	6.15	**8.2**	5.21	**6.9**	3.08	**4.1**	1.74	**2.3**	0.811	**1.1**	
		90	2.5	**3.3**	2.12	**2.8**	1.26	**1.7**	0.722	0.96	0.365	0.49	
D5 / pond	-	0	--	--	3.59	**4.8**	2.04	**2.7**	1.07	**1.4**	0.606	0.81	1
		50	1.65	**2.2**	1.82	**2.4**	1.04	**1.4**	0.553	0.74	-	-	
		75	0.871	**1.2**	0.943	**1.3**	0.55	0.73	-	-	-	-	
		90	0.412	0.55	0.428	0.57	-	-	-	-	-	-	
D5 / stream	-	0	-	-	22.6	**30**	13.3	**18**	7.49	**10**	3.45	**4.6**	1
		50	13.4	**18**	11.3	**15**	6.66	**8.9**	3.75	**5.0**	1.73	**2.3**	
		75	6.68	**8.9**	5.66	**7.5**	3.33	**4.4**	1.88	**2.5**	0.874	**1.2**	
		90	2.7	**3.6**	2.29	**3.1**	1.36	**1.8**	0.772	**1.0**	0.372	0.50	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-31: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R1 / pond	0	0	--	--	3.44	**4.6**	1.96	**2.6**	1.03	**1.4**	0.592	0.79	1
		50	1.58	**2.1**	1.75	**2.3**	1.01	**1.3**	0.541	0.72	--	--	
		75	0.843	**1.1**	0.912	**1.2**	0.537	0.72	0.3	0.40	--	--	
		90	0.406	0.54	0.421	0.56	-	-	-	-	--	--	
R1 / stream	0	0	--	--	16.1	**21**	9.46	**13**	5.33	**7.1**	2.47	**3.3**	1
		50	9.51	**13**	8.06	**11**	4.76	**6.3**	2.68	**3.6**	1.55	**2.1**	
		75	4.8	**6.4**	4.06	**5.4**	2.41	**3.2**	1.55	**2.1**	1.55	**2.1**	
		90	1.98	**2.6**	1.67	**2.2**	1.55	**2.1**	1.55	**2.1**	1.55	**2.1**	
	10 - 12	0	--	--	16.1	**21**	9.46	**13**	5.33	**7.1**	--	--	
		50	--	--	8.06	**11**	4.75	**6.3**	2.68	**3.6**	--	--	
		75	--	--	4.06	**5.4**	2.4	**3.2**	1.36	**1.80**	--	--	
		90	--	--	1.67	**2.2**	0.999	**1.30**	0.667	0.89	--	--	
	18 - 20	0	--	--	--	--	--	--	--	--	2.46	**3.3**	
		50	--	--	--	--	--	--	--	--	1.25	**1.7**	
		75	--	--	--	--	--	--	--	--	0.642	0.86	
R2 / stream	0	0	-	-	21.6	**29**	12.7	**17.0**	7.15	**9.5**	3.3	**4.4**	1
		50	12.8	**17**	10.8	**14**	6.37	**8.5**	3.59	**4.8**	1.67	**2.2**	
		75	6.42	**8.6**	5.44	**7.3**	3.22	**4.3**	1.82	**2.4**	1.03	**1.4**	
		90	2.63	**3.5**	2.22	**3.0**	1.32	**1.8**	1.03	**1.4**	1.03	**1.4**	
	10 - 12	0	--	--	21.6	**29**	12.7	**17.0**	7.15	**9.5**	--	--	
		50	--	--	10.8	**14**	6.37	**8.5**	3.59	**4.8**	--	--	
		75	--	--	5.44	**7.3**	3.22	**4.3**	1.82	**2.4**	--	--	
		90	--	--	2.22	**3.0**	1.32	**1.8**	0.754	**1.0**	--	--	
	18 - 20	0	--	--	--	--	--	--	--	--	3.3	**4.4**	
		50	--	--	--	--	--	--	--	--	1.67	**2.20**	
		75	--	--	--	--	--	--	--	--	0.851	**1.10**	

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): - PECsw (µg/L)	- PEC/RAC ratio	5 m PECsw (µg/L)	5 m PEC/RAC ratio	10 m PECsw (µg/L)	10 m PEC/RAC ratio	15 m PECsw (µg/L)	15 m PEC/RAC ratio	20 m PECsw (µg/L)	20 m PEC/RAC ratio	Trigger
		90	--	--	--	--	--	--	--	--	0.36	0.48	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-31: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): - PECsw (µg/L)	- PEC/RAC ratio	5 m PECsw (µg/L)	5 m PEC/RAC ratio	10 m PECsw (µg/L)	10 m PEC/RAC ratio	15 m PECsw (µg/L)	15 m PEC/RAC ratio	20 m PECsw (µg/L)	20 m PEC/RAC ratio	Trigger
R3 / stream	0	0	-	-	22.6	**30**	13.3	**18**	7.47	**10**	3.44	**4.6**	1
		50	13.3	**18**	11.3	**15**	6.65	**8.9**	3.74	**5**	1.74	**2.3**	
		75	6.69	**8.9**	5.67	**7.6**	3.35	**4.5**	1.9	**2.5**	1.58	**2.1**	
		90	2.75	**3.7**	2.32	**3.1**	1.58	**2.1**	1.58	**2.1**	1.58	**2.1**	
	10 - 12	0	--	--	22.6	**30**	13.3	**18**	7.47	**10**	--	--	
		50	--	--	11.3	**15**	6.65	**8.9**	3.74	**5.0**	--	--	
		75	--	--	5.67	**7.6**	3.35	**4.5**	1.9	**2.5**	--	--	
		90	--	--	2.32	**3.1**	1.39	**1.9**	0.798	**1.1**	--	--	
	18 - 20	0	--	--	--	--	--	--	--	--	3.44	**4.6**	
		50	--	--	--	--	--	--	--	--	1.74	**2.3**	
		75	--	--	--	--	--	--	--	--	0.891	**1.2**	
		90	--	--	--	--	--	--	--	--	0.388	0.52	
R4 / stream	0	0	--	--	16.1	**21**	9.46	**13**	5.32	**7.1**	4.47	**6.0**	1
		50	9.51	**13**	8.05	**11**	4.75	**6.3**	4.47	**6.0**	4.47	**6.0**	
		75	4.8	**6.4**	4.47	**6.0**	4.47	**6.0**	4.47	**6.0**	4.47	**6.0**	
		90	4.47	**6.0**	4.47	**6.0**	4.47	**6.0**	4.47	**6.0**	4.47	**6.0**	
	10 - 12	0	--	--	16.1	**21**	9.46	**13**	5.32	**7.1**	--	--	
		50	--	--	8.05	**11**	4.75	**6.3**	2.68	**3.6**	--	--	
		75	--	--	4.06	**5.4**	2.4	**3.2**	2.03	**2.7**	--	--	

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
		90	--	--	2.03	**2.7**	2.03	**2.7**	2.03	**2.7**	--	--	
	18 - 20	0	--	--	--	--	--	--	--	--	2.46	**3.3**	
		50	--	--	--	--	--	--	--	--	1.25	**1.7**	
		75	--	--	--	--	--	--	--	--	1.06	**1.4**	
		90	--	--	--	--	--	--	--	--	1.06	**1.4**	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-31: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)						Trigger
	Vegetative strip (m)		25 m		30 m		40 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	1.5	**2.0**	0.918	**1.2**	0.444	0.59	1
		50	0.76	**1.0**	0.482	0.64	--	--	
		75	0.407	0.54	--	--	--	--	
D4 / stream	-	0	1.74	**2.3**	1.07	**1.4**	0.507	0.68	1
		50	0.883	**1.2**	0.552	0.74	--	--	
		75	0.461	0.61	--	--	--	--	
D5 / stream	-	0	1.88	**2.5**	1.15	**1.5**	0.542	0.72	1
		50	0.952	**1.3**	0.591	0.79	--	--	
		75	0.493	0.66	--	--	--	--	
R1 / stream	0	0	1.55	**2.1**	1.55	**2.1**	1.55	**2.1**	
		50	1.55	**2.1**	1.55	**2.1**	--	--	
		75	1.55	**2.1**	--	--	--	--	
	18 - 20	0	1.36	**1.8**	0.84	**1.1**	0.404	0.54	
		50	0.697	0.93	0.44	0.59	--	--	
R2 /stream	0	0	1.82	**2.4**	1.12	**1.5**	1.03	**1.4**	
		50	1.03	**1.4**	1.03	**1.4**	--	--	
		75	1.03	**1.4**	--	--	--	--	
	18 - 20	0	1.82	**2.4**	1.12	**1.5**	0.528	0.70	
		50	0.926	**1.2**	0.577	0.77	--	--	
		75	0.48	0.64	--	--	--	--	
R3 / stream	0	0	1.8 9	**2.5**	1.58	**2.1**	1.58	**2.1**	
		50	1.58	**2.1**	1.58	**2.1**	--	--	
		75	1.58	**2.1**	--	--	--	--	
	18 - 20	0	1.89	**2.5**	1.17	**1.6**	0.561	0.75	
		50	0.969	**1.3**	0.61	0.81	--	--	
		75	0.51	0.68	--	--	--	--	
R4 /stream	0	0	4.47	**6.0**	4.47	**6.0**	4.47	**6.0**	
		50	4.47	**6.0**	4.47	**6.0**	--	--	

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)						Trigger
	Vegetative strip (m)		25 m		30 m		40 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
		75	4.47	**6.0**	--	--	--	--	
	18 - 20	0	1.36	**1.8**	1.06	**1.4**	1.06	**1.4**	
		50	1.06	**1.4**	1.06	**1.4**	--	--	
		75	1.06	**1.4**	--	--	--	--	

Table 10.2-32: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.75 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	9.28	**12**	4.14	**5.5**	2.09	**2.8**	1.28	**1.7**	1
		50	6.87	**9.2**	4.64	**6.2**	2.07	**2.8**	1.06	**1.4**	0.657	0.88	
		75	3.43	**4.6**	2.32	**3.1**	1.07	**1.4**	0.569	0.76	-	-	
		90	1.45	**1.9**	1.0	**1.3**	0.512	0.68	-	-	-	-	
D4 / stream	-	0	--	--	10.8	**14**	4.81	**6.4**	2.44	**3.3**	1.5	**2.0**	1
		50	6.91	**9.2**	5.39	**7.2**	2.43	**3.2**	1.24	**1.7**	0.764	**1.0**	
		75	3.5	**4.7**	2.73	**3.6**	1.24	**1.7**	0.644	0.86	-	-	
		90	1.46	**1.9**	1.14	**1.5**	0.542	0.72	-	-	-	-	
D5 / stream	-	0	--	--	11.6	**15**	5.2	**6.9**	2.62	**3.5**	1.6	**2.1**	1
		50	7.45	**9.9**	5.81	**7.7**	2.6	**3.5**	1.33	**1.8**	0.816	**1.1**	
		75	3.74	**5.0**	2.92	**3.9**	1.33	**1.8**	0.687	0.92	0.428	0.57	
		90	1.55	**2.1**	1.22	**1.6**	0.575	0.77	-	-	-	-	
R1 / stream	0	0	-	--	8.29	**11**	3.73	**5.0**	1.9	**2.5**	1.17	**1.6**	1
		50	5.35	**7.1**	4.18	**5.6**	1.89	**2.5**	1.17	**1.6**	1.17	**1.6**	
		75	2.73	**3.6**	2.13	**2.8**	1.17	**1.6**	1.17	**1.6**	1.17	**1.6**	
		90	1.17	**1.6**	1.17	**1.6**	1.17	**1.6**	1.17	**1.6**	1.17	**1.6**	
	10 - 12	0	-	-	8.29	**11**	3.73	**5.0**	1.9	**2.5**	-	-	
		50	-	-	4.18	**5.6**	1.89	**2.5**	0.975	**1.3**	-	-	
		75	-	-	2.13	**2.8**	0.984	**1.3**	0.528	0.7	-	-	
		90	-	-	0.912	**1.2**	0.528	0.7	-	-	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	1.17	**1.6**	
		50	-	-	-	-	-	-	-	-	0.604	0.8	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-32: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R2 / stream	0	0	-	-	11.1	**15**	4.99	**6.7**	2.53	**3.4**	1.56	**2.1**	1
		50	7.16	**9.5**	5.59	**7.5**	2.52	**3.4**	1.29	**1.7**	0.795	**1.1**	
		75	3.63	**4.8**	2.84	**3.8**	1.29	**1.7**	0.669	0.89	0.415	0.55	
		90	1.51	**2.0**	1.18	**1.6**	0.554	0.74	-	-	-	-	
R3 / stream	0	0	-	-	11.6	**15**	5.2	**6.9**	2.64	**3.5**	1.62	**2.2**	1
		50	7.46	**9.9**	5.82	**7.8**	2.63	**3.5**	1.35	**1.8**	0.834	**1.1**	
		75	3.79	**5.1**	2.96	**3.9**	1.36	**1.8**	0.706	0.94	0.444	0.59	
		90	1.6	**2.1**	1.25	**1.7**	0.602	0.80	-	-	-	-	
R4 / stream	0	0	--	--	8.29	**11**	3.73	**5.0**	1.9	**2.5**	1.6	**2.1**	1
		50	5.35	**7.1**	4.18	**5.6**	1.89	**2.5**	1.6	**2.1**	1.6	**2.1**	
		75	2.73	**3.6**	2.13	**2.8**	1.6	**2.1**	1.6	**2.1**	1.6	**2.1**	
		90	1.6	**2.1**	1.6	**2.1**	1.6	**2.1**	1.6	**2.1**	1.6	**2.1**	
	10 - 12	0	-	-	8.29	**11**	3.73	**5.0**	1.9	**2.5**	--	--	
		50	-	-	4.18	**5.6**	1.89	**2.5**	0.975	**1.3**	--	--	
		75	-	-	2.13	**2.8**	0.983	**1.3**	0.717	0.96	--	--	
		90	-	-	0.911	**1.2**	0.717	0.96	0.717	0.96	--	--	
	18 - 20	0	-	-	-	-	-	-	-	-	1.17	**1.6**	
		50	-	-	-	-	-	-	-	-	0.604	0.81	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-32: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): 25 m PEC$_{SW}$ (µg/L)	25 m PEC/RAC ratio	30 m PEC$_{SW}$ (µg/L)	30 m PEC/RAC ratio	40 m PEC$_{SW}$ (µg/L)	40 m PEC/RAC ratio	Trigger
D3 / ditch	-	0	0.877	**1.2**	0.653	0.87	-	--	1
		50	0.465	0.62	-	-	--	--	
D4 / stream	-	0	1.03	**1.4**	0.759	1.0	-	--	1
		50	0.531	0.71	-	--	--	--	
D5 / stream	-	0	1.1	**1.5**	0.811	**1.1**	0.508	0.68	1
		50	0.567	0.76	0.426	0.57	--	--	
R1 / stream	0	0	1.17	**1.6**	1.17	**1.6**	1.17	**1.6**	1
		50	1.17	**1.6**	1.17	**1.6**	--	--	
		75	1.17	**1.6**	--	--	--	--	
	18 - 20	0	0.807	**1.1**	0.601	0.80	--	--	
		50	0.425	0.57	--	--	--	--	
R2 /stream	0	0	1.07	**1.4**	0.79	**1.1**	0.494	0.66	1
		50	0.553	0.74	0.413	0.55	--	--	
	18 - 20	0	1.07	**1.4**	0.79	**1.1**	0.494	0.66	
		50	0.553	0.74	0.413	0.55	--	--	
R3 / stream	0	0	1.12	**1.5**	0.829	**1.1**	0.523	0.70	1
		50	0.583	0.78	0.441	0.59	--	--	
R4 /stream	0	0	1.6	**2.1**	1.6	**2.1**	1.6	**2.1**	1
		50	1.6	**2.1**	1.6	**2.1**	--	--	
		75	1.6	**2.1**	--	--	--	-	
	18 - 20	0	0.807	**1.1**	0.6	0.80	-	-	
		50	0.425	0.57	-	-	--	--	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-33: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.75 µg a.s./L

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	6.74	**9.0**	3.14	**4.2**	1.57	**2.1**	0.931	**1.2**	1
		50	4.92	**6.6**	3.38	**4.5**	1.61	**2.1**	0.834	**1.1**	0.507	0.68	
		75	2.53	**3.4**	1.75	**2.3**	0.879	**1.2**	0.482	0.64	-	-	
		90	1.16	**1.5**	0.832	**1.1**	0.468	0.62	-	-	-	-	
D4 / pond	-	0	-	--	1.16	**1.5**	0.652	0.87	-	-	-	-	1
		50	0.578	0.77	0.622	0.83	0.359	0.48	-	-	-	-	
D4 / stream	-	0	--	--	7.77	**10**	3.63	**4.8**	1.81	**2.4**	1.06	**1.4**	1
		50	4.96	**6.6**	3.91	**5.2**	1.84	**2.5**	0.927	**1.2**	0.874	**1.2**	
		75	2.52	**3.4**	1.99	**2.7**	0.952	**1.3**	0.874	**1.2**	0.874	**1.2**	
		90	1.08	**1.4**	0.874	**1.2**	0.874	**1.2**	0.874	**1.2**	0.874	**1.2**	
D5 / pond	-	0	-	--	1.21	**1.6**	0.682	0.91	-	-	-	-	1
		50	0.605	0.81	0.65	0.87	0.377	0.50	-	-	-	-	
D5 / stream	-	0	--	--	8.38	**11**	3.91	**5.2**	1.94	**2.6**	1.14	**1.5**	1
		50	5.32	**7.1**	4.19	**5.6**	1.97	**2.6**	0.989	**1.3**	0.585	0.78	
		75	2.69	**3.6**	2.12	**2.8**	1.01	**1.3**	0.522	0.7	-	-	
		90	1.15	**1.5**	0.905	**1.2**	0.454	0.61	-	-	-	-	
R1 / pond	0	0	--	--	1.18	**1.6**	0.686	0.91	-	-	-	-	1
		50	0.614	0.82	0.657	0.88	0.4	0.53	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-33: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): - PEC$_{SW}$ (µg/L)	- PEC/RAC ratio	5 m PEC$_{SW}$ (µg/L)	5 m PEC/RAC ratio	10 m PEC$_{SW}$ (µg/L)	10 m PEC/RAC ratio	15 m PEC$_{SW}$ (µg/L)	15 m PEC/RAC ratio	20 m PEC$_{SW}$ (µg/L)	20 m PEC/RAC ratio	Trigger
R1 / stream	0	0	--	--	5.99	**8**	2.81	**3.7**	1.41	**1.9**	1.32	**1.8**	1
		50	3.85	**5.1**	3.04	**4.1**	1.44	**1.9**	1.32	**1.8**	1.32	**1.8**	
		75	1.98	**2.6**	1.57	**2.1**	1.32	**1.8**	1.32	**1.8**	1.32	**1.8**	
		90	1.32	**1.8**	1.32	**1.8**	1.32	**1.8**	1.32	**1.8**	1.32	**1.8**	
	10 - 12	0	-	-	5.99	**8**	2.81	**3.7**	1.41	**1.9**	-	-	
		50	-	-	3.04	**4.1**	1.44	**1.9**	0.734	0.98	-	-	
		75	-	-	1.57	**2.1**	0.758	1.0	-	-	-	-	
		90	-	-	0.684	0.91	-	-	-	-	-	-	
R2 / stream	0	0	--	--	8.04	**11**	3.77	**5.0**	1.89	**2.5**	1.11	**1.5**	1
		50	5.15	**6.9**	4.06	**5.4**	1.92	**2.6**	0.968	**1.3**	0.572	0.76	
		75	2.63	**3.5**	2.07	**2.8**	0.991	**1.3**	0.508	0.68	-	-	
		90	1.11	**1.5**	0.88	**1.2**	0.46	0.61	-	-	-	-	
R3 / stream	0	0	-	-	8.38	**11**	5.06	**6.7**	3.67	**4.9**	3.09	**4.1**	1
		50	6.07	**8.1**	5.27	**7.0**	3.68	**4.9**	2.98	**4.0**	2.69	**3.6**	
		75	4.18	**5.6**	3.78	**5.0**	2.99	**4.0**	2.64	**3.5**	2.49	**3.3**	
		90	3.05	**4.1**	2.89	**3.9**	2.57	**3.4**	2.43	**3.2**	2.37	**3.2**	
	10 - 12	0	-	-	8.38	**11**	3.92	**5.2**	2.46	**3.3**	-	-	
		50	-	-	4.22	**5.6**	2.48	**3.3**	1.76	**2.3**	-	-	
		75	-	-	2.58	**3.4**	1.76	**2.3**	1.4	**1.9**	-	-	
		90	-	-	1.66	**2.2**	1.33	**1.8**	1.19	**1.6**	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	1.38	**1.8**	
		50	-	-	-	-	-	-	-	-	0.967	**1.3**	
		75	-	-	-	-	-	-	-	-	0.758	**1.0**	
R4 /stream	0	0	-	-	5.99	**8.0**	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	
		50	3.85	**5.1**	3.04	**4.1**	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	
		75	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	
		90	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
	10 - 12	0	-	-	5.99	**8.0**	2.81	**3.7**	1.41	**1.9**	-	-	
		50	-	-	3.03	**4.0**	1.44	**1.9**	1.3	**1.7**	-	-	
		75	-	-	1.57	**2.1**	1.3	**1.7**	1.3	**1.7**	-	-	
		90	-	-	1.3	**1.7**	1.3	**1.7**	1.3	**1.7**	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	0.833	**1.1**	
		50	-	-	-	-	-	-	-	-	0.682	0.91	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-33: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.75 µg a.s./L (continued)

Scenario	**Mitigation options**		**Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**								**Trigger**
	Vegetative strip (m)		**25 m**		**30 m**		**40 m**		**45 m**		
			PEC_{SW} (µg/L)	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	
D3 / ditch	-	0	0.636	0.85	-	-	-	-	-	-	1
D4 / stream	-	0	0.874	**1.2**	0.874	**1.2**	0.874	**1.2**	-	-	1
		50	0.874	**1.2**	0.874	**1.2**	-	-	-	-	
		75	0.874	**1.2**	-	-	-	-	-	-	
		90	0.74	0.99	-	-	-	-	-	-	
D5 / stream	-	0	0.756	**1.0**	0.546	0.73	-	-	-	-	1
		50	0.399	0.53	-	-	-	-	-	-	
R1 / stream	0	0	1.32	**1.8**	1.32	**1.8**	1.32	**1.8**	-	-	1
		50	1.32	**1.8**	1.32	**1.8**	-	-	-	-	
		75	1.32	**1.8**	-	-	-	-	-	-	
	18 - 20	0	0.561	0.75	0.41	0.55	-	-	-	-	
R2 / stream	0	0	0.74	0.99	-	-	-	-	-	-	1
R3 / stream	0	0	2.82	**3.8**	2.67	**3.6**	2.51	**3.3**	--	--	1
		50	2.56	**3.4**	2.48	**3.3**	-	-	-	-	
		75	2.43	**3.2**	-	-	-	-	-	-	
	18 - 20	0	1.1	**1.5**	0.937	**1.2**	0.774	**1.0**	0.729	0.97	
		50	0.823	**1.1**	0.744	0.99	0.662	0.88	--	--	
		75	0.687	0.92	-	-	-	-	-	-	
R4 / stream	0	0	2.87	**3.8**	2.87	**3.8**	2.87	**3.8**	--	--	1
		50	2.87	**3.8**	2.87	**3.8**	-	-	-	-	
		75	2.87	**3.8**	-	-	-	-	-	-	
	18 - 20	0	0.682	0.91	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

The table below indicates mitigation required to be protective of the long-term risk to aquatic invertebrates

Table 10.2-34: Mitigation required to be protective of the long-term risk to aquatic invertebrates for ETO-RAC of 0.90 µg a.s./L

Scenario	1 x 375 g a.s./ha, early	3 x 375 g a.s./ha, early	1 x 375 g a.s./ha, late	3 x 375 g a.s./ha, late
D3 ditch	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 30 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB
D4 pond	75% NR or 50% NR + 10 m DB or 15 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	NA	50% NR or 10 m DB
D4 stream	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 25 m DB or 30 m DB	90% NR + 25 m DB
D5 pond	75% NR or 50% NR + 10 m DB or 15 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB	NA	50% NR or 10 m DB
D5 stream	90% NR + 15 m DB 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 20 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 25 m DB or 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 30 m DB
R1 pond	75% NR or 50% NR + 10 m DB or 15 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	NA	50% NR or 10 m DB
R1 stream	90% NR + 15 m DB 75% NR + 20 m DB 50% NR + 30 m DB or 40 m DB	10 – 12 m VS + 90% NR + 15 m DB or 18 – 20 m VS + 75% NR + 20 m DB or 18 – 20 m VS + 50% NR + 25 m DB or 18 – 20 m VS + 40 m DB	10 – 12 m VS + 90% NR + 10 m DB or 10 – 12 m VS + 75% NR + 15 m DB or 18 – 20 m VS + 50% NR + 20 m DB or 18 – 20 m VS + 30 m DB	10 – 12 m VS + 90% NR + 5 m DB or 10 – 12 m VS + 75% NR + 10 m DB or 10 – 12 m VS + 50% NR + 15 m DB or 18 – 20 m VS + 25 m DB
R2 stream	90% NR + 20 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB	18 – 20 m VS + 90% NR + 20 m DB 18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB	90% NR + 10 m DB or 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 25 m DB or 18 – 20 m VS + 30 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB

Scenario	1 x 375 g a.s./ha, early	3 x 375 g a.s./ha, early	1 x 375 g a.s./ha, late	3 x 375 g a.s./ha, late
R3 stream	18 – 20 m VS + 75% NR + 25 m DB	18 – 20 m VS + 90% NR + 20 m DB or 18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB	90% NR + 10 m DB or 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 25 m DB or 18 – 20 m VS + 40 m DB	18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB
R4 stream	18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB	NS	10 - 12 m VS + 90% NR + 10 m DB or 10 - 12 m VS + 75% NR + 15 m DB or 18 - 20 m VS + 50% NR + 25 m DB or 18 – 20 m VS + 30 m DB	18 - 20 m VS + 50% NR + 20 m DB or 18 – 20 m VS + 25 m DB

NR = drift reducing nozzles
DB = drift buffer
VS = vegetated filter strip
NS = no safe use
NA = No mitigation necessary for this scenario

Table 10.2-35: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.90 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	22.8	**25**	14	**16**	6.3	**7.0**	3.2	**3.6**	1
		50	14.5	**16.0**	11.4	**13**	7.01	**7.8**	3.15	**3.50**	1.6	**1.8**	
		75	7.26	**8.1**	5.7	**6.3**	3.5	**3.9**	1.58	**1.8**	0.8	0.89	
		90	2.9	**3.2**	2.28	**2.5**	1.4	**1.6**	0.647	0.72	-	-	
D4 / pond	-	0	-	-	1.99	**2.2**	1.1	**1.2**	0.582	0.65	-	-	1
		50	0.905	**1.0**	1.01	**1.1**	0.558	0.62	-	-	-	-	
		75	0.477	0.53	0.52	0.58	-	-	-	-	-	-	
D4 / stream	-	0	-	-	25.5	**28**	15.7	**17**	7.06	**7.8**	3.6	**4.0**	1
		50	14.9	**17.0**	12.8	**14**	7.86	**8.7**	3.55	**3.90**	1.81	**2.0**	
		75	7.48	**8.3**	6.42	**7.1**	3.95	**4.4**	1.79	**2.0**	0.919	**1.0**	
		90	3.04	**3.4**	2.61	**2.9**	1.61	**1.8**	0.738	0.82	0.385	0.43	
D5 / pond	-	0			1.99	**2.2**	1.1	**1.2**	0.582	0.65	-	-	1
		50	0.904	**1.0**	1.01	**1.1**	0.558	0.62	-	-	-	-	
		75	0.476	0.53	0.52	0.58	-	-	-	-	-	-	
D5 / stream	-	0	-	-	24.8	**28**	15.2	**17**	6.85	**7.6**	3.49	**3.90**	1
		50	14.4	**16**	12.4	**14**	7.62	**8.5**	3.43	**3.8**	1.75	**1.90**	
		75	7.24	**8.0**	6.21	**6.9**	3.82	**4.2**	1.72	**1.9**	0.88	0.98	
		90	2.91	**3.2**	2.5	**2.8**	1.54	**1.7**	0.698	0.78	-	-	
R1 / pond	0	0	-	-	1.99	**2.2**	1.1	**1.2**	0.582	0.65	-	-	1
		50	0.905	**1.0**	1.01	**1.1**	0.558	0.62	-	-	-	-	
		75	0.476	0.53	0.52	0.58	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-35: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
			-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R1 / stream	0	0	-	-	20.2	22	12.4	14	5.61	6.2	2.86	3.2	1
		50	11.8	13	10.2	11	6.24	6.9	2.82	3.1	1.45	1.6	
		75	5.95	6.6	5.1	5.7	3.14	3.5	1.43	1.6	0.739	0.82	
		90	2.44	2.7	2.09	2.3	1.29	1.4	0.73	0.81	-	-	
R2 / stream	0	0	-	-	26.8	30	16.5	18	7.42	8.2	3.78	4.2	1
		50	15.6	17	13.4	15	8.25	9.2	3.73	4.1	1.9	2.1	
		75	7.85	8.7	6.74	7.5	4.15	4.6	1.88	2.1	0.963	1.1	
		90	3.18	3.5	2.73	3.0	1.69	1.9	0.772	0.86	0.403	0.45	
R3 / stream	0	0	-	-	28.6	32	17.6	20	7.9	8.8	4.02	4.5	1
		50	16.6	18.0	14.3	16	8.78	9.8	3.96	4.4	2.02	2.2	
		75	8.34	9.3	7.16	8.0	4.41	4.9	2	2.2	1.49	1.7	
		90	3.4	3.8	2.91	3.2	1.8	2.0	1.49	1.7	1.49	1.7	
	10 - 12	0	-	-	28.6	32	17.6	20	7.9	8.8	-	-	
		50	-	-	14.3	16	8.78	9.8	3.96	4.4	-	-	
		75	-	-	7.16	8.0	4.41	4.9	2.0	2.2	-	-	
		90	-	-	2.91	3.2	1.8	2.0	0.839	0.93	-	-	
R4 / stream	0	0	-	-	20.4	23	12.5	14	5.63	6.3	2.87	3.2	1
		50	11.9	13	10.2	11	6.27	7	2.84	3.2	1.45	1.6	
		75	5.98	6.6	5.13	5.7	3.16	3.5	1.44	1.6	1.16	1.3	
		90	2.44	2.7	2.1	2.3	1.3	1.4	1.16	1.3	1.16	1.3	
	10 - 12	0	-	23	20.4	23	12.5	14	5.63	6.3	-	-	
		50	-	11	10.2	11	6.27	7.0	2.84	3.2	-	-	
		75	-	5.7	5.13	5.7	3.16	3.5	1.44	1.6	-	-	
		90	-	2.3	2.1	2.3	1.3	1.4	0.605	0.67	-	-	

Table 10.2-35: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application: ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)						Trigger
	Vegetative strip (m)		25 m		30 m		40 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	1.89	**2.1**	1.22	**1.40**	0.621	0.69	1
		50	0.944	**1.0**	0.617	0.69	-	-	
		75	0.486	0.54	-	-	-	-	
D4 / stream	-	0	2.13	**2.4**	1.39	**1.50**	0.714	0.79	1
		50	1.08	**1.2**	0.709	0.79	-	-	
		75	0.553	0.61	-	-	-	-	
D5 / stream	-	0	2.06	**2.3**	1.34	**1.50**	0.680	0.76	1
		50	1.04	**1.2**	0.675	0.75	-	-	
		75	0.524	0.58	-	-	-	-	
R1 / stream	0	0	1.7	**1.9**	1.11	**1.2**	0.73	0.81	1
		50	0.866	0.96	0.73	0.81	-	-	
R2 /stream	0	0	2.24	**2.5**	1.46	**1.6**	0.748	0.83	1
		50	1.13	**1.3**	0.743	0.83	-	-	
		75	0.579	0.64	-	-	-	-	
R3 / stream	0	0	2.38	**2.6**	1.56	**1.7**	1.49	**1.7**	1
		50	1.49	**1.7**	1.49	**1.7**	-	-	
		75	1.49	**1.7**	-	-	-	-	
	18 - 20	0	2.38	**2.6**	1.56	**1.7**	0.806	0.90	
		50	1.21	**1.3**	0.8	0.89	-	-	
		75	0.629	0.70	-	-	-	-	
R4 /stream	0	0	1.71	**1.9**	1.16	**1.3**	-	-	1
		50	1.16	**1.3**	-	-	-	-	
	18 - 20	0	1.71	**1.9**	1.12	**1.2**	0.581	0.65	
		50	0.869	0.97	0.577	0.64	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-36: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.90 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	18.1	**20**	10.6	**12**	5.98	**6.6**	2.75	**3.1**	1
		50	11.8	**13**	9.04	**10**	5.32	**5.9**	2.99	**3.3**	1.38	**1.50**	
		75	5.87	**6.5**	4.52	**5.0**	2.66	**3.0**	1.5	**1.7**	0.7	0.78	
		90	2.36	**2.6**	1.82	**2.0**	1.09	**1.2**	0.631	0.70	-	-	
D4 / pond	-	0	-	-	3.59	**4.0**	2.03	**2.3**	1.06	**1.2**	0.603	0.67	1
		50	1.64	**1.8**	1.81	**2.0**	1.04	**1.2**	0.55	0.61	-	-	
		75	0.868	0.96	0.94	**1.0**	0.547	0.61	-	-	-	-	
		90	0.409	0.45	0.425	0.47	-	-	-	-	-	-	
D4 / stream	-	0	-	-	20.7	**23**	12.2	**14**	6.86	**7.6**	3.16	**3.5**	1
		50	12.2	**14**	10.4	**12**	6.11	**6.8**	3.44	**3.8**	1.6	**1.8**	
		75	6.15	**6.8**	5.21	**5.8**	3.08	**3.4**	1.74	**1.9**	0.811	0.90	
		90	2.5	**2.8**	2.12	**2.4**	1.26	**1.4**	0.722	0.80	-	-	
D5 / pond	-	0	-	-	3.59	**4.0**	2.04	**2.3**	1.07	**1.2**	0.606	0.67	1
		50	1.65	**1.8**	1.82	**2.0**	1.04	**1.2**	0.553	0.61	-	-	
		75	0.871	0.97	0.943	**1.0**	0.55	0.61	-	-	-	-	
		90	-	-	0.428	0.48	-	-	-	-	-	-	
D5 / stream	-	0	-	-	22.6	**25**	13.3	**15**	7.49	**8.3**	3.45	**3.8**	1
		50	13.4	**15**	11.3	**13**	6.66	**7.4**	3.75	**4.2**	1.73	**1.90**	
		75	6.68	**7.4**	5.66	**6.3**	3.33	**3.7**	1.88	**2.1**	0.874	0.97	
		90	2.7	**3.0**	2.29	**2.5**	1.36	**1.5**	0.772	0.86	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-36: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R1 / pond	0	0	-	-	3.44	**3.8**	1.96	**2.2**	1.03	**1.1**	0.592	0.66	1
		50	1.58	**1.8**	1.75	**1.9**	1.01	**1.1**	0.541	0.60	-	-	
		75	0.843	0.94	0.912	**1.0**	0.537	0.60	-	-	-	-	
		90	-	-	0.421	0.47	-	-	-	-	-	-	
R1 / stream	0	0	-	-	16.1	**18**	9.46	**11**	5.33	**5.9**	2.47	**2.7**	1
		50	9.51	**11**	8.06	**9.0**	4.76	**5.3**	2.68	**3.0**	1.55	**1.7**	
		75	4.8	**5.3**	4.06	**4.5**	2.41	**2.7**	1.55	**1.7**	1.55	**1.7**	
		90	1.98	**2.2**	1.67	**1.9**	1.55	**1.7**	1.55	**1.7**	1.55	**1.7**	
	10 - 12	0	-	-	16.1	**18**	9.46	**11**	5.33	**5.9**	-	-	
		50	-	-	8.06	**9.0**	4.75	**5.3**	2.68	**3.0**	-	-	
		75	-	-	4.06	**4.5**	2.4	**2.7**	1.36	**1.50**	-	-	
		90	-	-	1.67	**1.9**	0.999	**1.10**	0.667	0.74	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	2.46	**2.7**	
		50	-	-	-	-	-	-	-	-	1.25	**1.4**	
		75	-	-	-	-	-	-	-	-	0.642	0.71	
R2 / stream	0	0	-	-	21.6	**24**	12.7	**14.0**	7.15	**7.9**	3.3	**3.7**	1
		50	12.8	**14**	10.8	**12**	6.37	**7.1**	3.59	**4.0**	1.67	**1.9**	
		75	6.42	**7.1**	5.44	**6.0**	3.22	**3.6**	1.82	**2.0**	1.03	**1.1**	
		90	2.63	**2.9**	2.22	**2.5**	1.32	**1.5**	1.03	**1.1**	1.03	**1.1**	
	10 - 12	0	-	-	21.6	**24**	12.7	**14.0**	7.15	**7.9**	-	-	
		50	-	-	10.8	**12**	6.37	**7.1**	3.59	**4.0**	-	-	
		75	-	-	5.44	**6.0**	3.22	**3.6**	1.82	**2.0**	-	-	
		90	-	-	2.22	**2.5**	1.32	**1.5**	0.754	0.84	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	3.3	**3.7**	
		50	-	-	-	-	-	-	-	-	1.67	**1.9**	
		75	-	-	-	-	-	-	-	-	0.851	0.95	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-36: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R3 / stream	0	0	-	-	22.6	**25**	13.3	**15**	7.47	**8.3**	3.44	**3.8**	1
		50	13.3	**15**	11.3	**13**	6.65	**7.4**	3.74	**4.2**	1.74	**1.9**	
		75	6.69	**7.4**	5.67	**6.3**	3.35	**3.7**	1.9	**2.1**	1.58	**1.8**	
		90	2.75	**3.1**	2.32	**2.6**	1.58	**1.8**	1.58	**1.8**	1.58	**1.8**	
	10 - 12	0	-	-	22.6	**25**	13.3	**15**	7.47	**8.3**	-	-	
		50	-	-	11.3	**13**	6.65	**7.4**	3.74	**4.2**	-	-	
		75	-	-	5.67	**6.3**	3.35	**3.7**	1.9	**2.1**	-	-	
		90	-	-	2.32	**2.6**	1.39	**1.5**	0.798	0.89	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	3.44	**3.8**	
		50	-	-	-	-	-	-	-	-	1.74	**1.9**	
		75	-	-	-	-	-	-	-	-	0.891	1.0	
R4 / stream	0	0	-	-	16.1	**18**	9.46	**11**	5.32	**5.9**	4.47	**5.0**	1
		50	9.51	**11**	8.05	**8.9**	4.75	**5.3**	4.47	**5.0**	4.47	**5.0**	
		75	4.8	**5.3**	4.47	**5.0**	4.47	**5.0**	4.47	**5.0**	4.47	**5.0**	
		90	4.47	**5.0**	4.47	**5.0**	4.47	**5.0**	4.47	**5.0**	4.47	**5.0**	
	10 - 12	0	-	-	16.1	**18**	9.46	**11**	5.32	**5.9**	-	-	
		50	-	-	8.05	**8.9**	4.75	**5.3**	2.68	**3.0**	-	-	
		75	-	-	4.06	**4.5**	2.4	**2.7**	2.03	**2.3**	-	-	
		90	-	-	2.03	**2.3**	2.03	**2.3**	2.03	**2.3**	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	2.46	**2.7**	
		50	-	-	-	-	-	-	-	-	1.25	**1.4**	
		75	-	-	-	-	-	-	-	-	1.06	**1.2**	
		90	-	-	-	-	-	-	-	-	1.06	**1.2**	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-36: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): 25 m		30 m		40 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	1.5	**1.7**	0.918	**1.0**	0.444	**0.49**	1
		50	0.76	0.84	0.482	0.54	-	-	
D4 / stream	-	0	1.74	**1.9**	1.07	**1.2**	0.507	0.56	1
		50	0.883	0.98	0.552	0.61	-	-	
D5 / stream	-	0	1.88	**2.1**	1.15	**1.3**	0.542	0.60	1
		50	0.952	**1.1**	0.591	0.66	-	-	
		75	0.493	0.55	-	-	-	-	
R1 / stream	0	0	1.55	**1.7**	1.55	**1.7**	1.55	**1.7**	1
		50	1.55	**1.7**	1.55	**1.7**	-	-	
		75	1.55	**1.7**	-	-	-	-	
	18 - 20	0	1.36	**1.5**	0.84	0.93	-	-	
		50	0.697	0.77	-	-	-	-	
R2 /stream	0	0	1.82	**2.0**	1.12	**1.2**	1.03	**1.1**	1
		50	1.03	**1.1**	1.03	**1.1**	-	-	
		75	1.03	**1.1**	-	-	-	-	
	18 - 20	0	1.82	**2.0**	1.12	**1.2**	0.528	0.59	
		50	0.926	**1.0**	0.577	0.64	-	-	
		75	0.48	0.53	-	-	-	-	
R3 / stream	0	0	1.9	**2.1**	1.58	**1.8**	1.58	**1.8**	1
		50	1.58	**1.8**	1.58	**1.8**	-	-	
		75	1.58	**1.8**	-	-	-	-	
	18 - 20	0	1.89	**2.1**	1.17	**1.3**	0.561	0.62	
		50	0.969	**1.1**	0.61	0.68	-	-	
		75	0.51	0.57	-	-	-	-	
R4 /stream	0	0	4.47	**5.0**	4.47	**5.0**	4.47	**5.0**	1
		50	4.47	**5.0**	4.47	**5.0**	-	-	
		75	4.47	**5.0**	-	-	-	-	
	18 - 20	0	1.36	**1.5**	1.06	**1.2**	1.06	**1.2**	
		50	1.06	**1.2**	1.06	**1.2**	-	-	
		75	1.06	**1.2**	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-37: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.90 µg a.s./L

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	9.28	**10**	4.14	**4.6**	2.09	**2.3**	1.28	**1.4**	1
		50	6.87	**7.6**	4.64	**5.2**	2.07	**2.3**	1.06	**1.2**	0.657	0.73	
		75	3.43	**3.8**	2.32	**2.6**	1.07	**1.2**	0.569	0.63	-	-	
		90	1.45	**1.6**	1	**1.1**	0.512	0.57	-	-	-	-	
D4 / stream	-	0	-	-	10.8	**12**	4.81	**5.3**	2.44	**2.7**	1.5	**1.7**	1
		50	6.91	**7.7**	5.39	**6.0**	2.43	**2.7**	1.24	**1.4**	0.764	0.85	
		75	3.5	**3.9**	2.73	**3.0**	1.24	**1.4**	0.644	0.72	-	-	
		90	1.46	**1.6**	1.14	**1.3**	0.542	0.60	-	-	-	-	
D5 / stream	-	0	-	-	11.6	**13**	5.2	**5.8**	2.62	**2.9**	1.6	**1.8**	1
		50	7.45	**8.3**	5.81	**6.5**	2.6	**2.9**	1.33	**1.5**	0.816	0.91	
		75	3.74	**4.2**	2.92	**3.2**	1.33	**1.5**	0.687	0.76	-	-	
		90	1.55	**1.7**	1.22	**1.4**	0.575	0.64	-	-	-	-	
R1 / stream	0	0	-	-	8.29	**9.2**	3.73	**4.1**	1.9	**2.1**	1.17	**1.3**	
		50	5.35	**5.9**	4.18	**4.6**	1.89	**2.1**	1.17	**1.3**	1.17	**1.3**	
		75	2.73	**3.0**	2.13	**2.4**	1.17	**1.3**	1.17	**1.3**	1.17	**1.3**	
		90	1.17	**1.3**	1.17	**1.3**	1.17	**1.3**	1.17	**1.3**	1.17	**1.3**	
	10 - 12	0	-	-	8.29	**9.2**	3.73	**4.1**	1.9	**2.1**	-	-	
		50	-	-	4.18	**4.6**	1.89	**2.1**	0.975	**1.1**	-	-	
		75	-	-	2.13	**2.4**	0.984	**1.1**	0.528	0.59	-	-	
		90	-	-	0.912	**1.0**	0.528	0.59	-	-	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	1.17	**1.3**	
		50	-	-	-	-	-	-	-	-	0.604	0.67	
		75	-	-	-	-	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-37: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R2 / stream	0	0	-	-	11.1	**12**	4.99	**5.5**	2.53	**2.8**	1.56	**1.7**	1
		50	7.16	**8.0**	5.59	**6.2**	2.52	**2.8**	1.29	**1.4**	0.795	0.88	
		75	3.63	**4.0**	2.84	**3.2**	1.29	**1.4**	0.669	0.74	-	-	
		90	1.51	**1.7**	1.18	**1.3**	0.554	0.62	-	-	-	-	
R3 / stream	0	0	-	-	11.6	**13**	5.2	**5.8**	2.64	**2.9**	1.62	**1.8**	
		50	7.46	**8.3**	5.82	**6.5**	2.63	**2.9**	1.35	**1.5**	0.834	0.93	
		75	3.79	**4.2**	2.96	**3.3**	1.36	**1.5**	0.706	0.78	-	-	
		90	1.6	**1.8**	1.25	**1.4**	0.602	0.67	-	-	-	-	
R4 / stream	0	0	-	-	8.29	**9.2**	3.73	**4.1**	1.9	**2.1**	1.6	**1.8**	
		50	5.35	**5.9**	4.18	**4.6**	1.89	**2.1**	1.6	**1.8**	1.6	**1.8**	
		75	2.73	**3.0**	2.13	**2.4**	1.6	**1.8**	1.6	**1.8**	1.6	**1.8**	
		90	1.6	**1.8**	1.6	**1.8**	1.6	**1.8**	1.6	**1.8**	1.6	**1.8**	
	10 - 12	0			8.29	**9.2**	3.73	**4.1**	1.9	**2.1**	-	-	
		50			4.18	**4.6**	1.89	**2.1**	0.975	**1.1**	-	-	
		75			2.13	**2.4**	0.983	**1.1**	0.717	0.80	-	-	
		90	-		0.911	**1.0**	0.717	0.80	-	-	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	1.17	**1.3**	
		50	-	-	-	-	-	-	-	-	0.604	0.67	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-37: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction) 25 m		30 m		40 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	0.877	0.97					
D4 / stream	-	0	1.03	**1.1**	0.759	0.84	-	-	1
		50	0.531	0.59	-	-	-	-	
D5 / stream	-	0	1.1	**1.2**	0.811	0.90	-	-	1
		50	0.567	0.63	-	-	-	-	
R1 / stream	0	0	1.17	**1.3**	1.17	**1.3**	1.17	**1.3**	1
		50	1.17	**1.3**	1.17	**1.3**	-	-	
		75	1.17	**1.3**	-	-	-	-	
	18 - 20	0	0.807	0.90	-	-	-	-	
R2 /stream	0	0	1.07	**1.2**	0.79	0.88	-	-	1
		50	0.553	0.61	-	-	-	-	
R3 / stream	0	0	1.12	**1.2**	0.829	0.92	-	-	1
		50	0.583	0.65	-	-	-	-	
R4 /stream	0	0	1.6	**1.8**	1.6	**1.8**	1.6	**1.8**	1
		50	1.6	**1.8**	1.6	**1.8**	-	-	
		75	1.6	**1.8**	-	-	-	-	
	18 - 20	0	0.807	0.90	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-38: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.90 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
			-		5 m		10 m		15 m		20 m		
	Vegetative strip (m)		PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	6.74	**7.5**	3.14	**3.5**	1.57	**1.7**	0.931	**1.0**	1
		50	4.92	**5.5**	3.38	**3.8**	1.61	**1.8**	0.834	0.93	0.507	0.56	
		75	2.53	**2.8**	1.75	**1.9**	0.879	0.98	-	-	-	-	
		90	1.16	**1.3**	0.832	0.92	-	-	-	-	-	-	
D4 / pond	-	0	-	-	1.16	**1.3**	0.652	0.72	-	-	-	-	1
		50	0.578	0.64	0.622	0.69	-	-	-	-	-	-	
D4 / stream	-	0	-	-	7.77	**8.6**	3.63	**4.0**	1.81	**2.0**	1.06	**1.2**	1
		50	4.96	**5.5**	3.91	**4.3**	1.84	**2.0**	0.927	**1.0**	0.874	0.97	
		75	2.52	**2.8**	1.99	**2.2**	0.952	**1.1**	0.874	0.97	-	-	
		90	1.08	**1.2**	0.874	0.97	0.874	0.97	-	-	0.874	1.0	
D5 / pond	-	0	-	-	1.21	**1.3**	0.682	0.76	-	-	-	-	1
		50	0.605	0.67	0.65	0.72	-	-	-	-	-	-	
D5 / stream	-	0	-	-	8.38	**9.3**	3.91	**4.3**	1.94	**2.2**	1.14	**1.3**	1
		50	5.32	**5.9**	4.19	**4.7**	1.97	**2.2**	0.989	**1.1**	0.585	0.65	
		75	2.69	**3.0**	2.12	**2.4**	1.01	**1.1**	0.522	0.58	-	-	
		90	1.15	**1.3**	0.905	**1.0**	0.454	0.50	-	-	-	-	
R1 / pond	0	0	-	-	1.18	**1.3**	0.686	0.76	-	-	-	-	
		50	0.614	0.68	0.657	0.73	-	-	-	-	-	-	
	10 - 12	0	-	-	1.16	**1.3**	-	-	-	-	-	-	
		50	-	-	0.628	0.70	-	-	-	-	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	0.285	0.32	
R1 / stream	0	0	-	-	5.99	**6.7**	2.81	**3.1**	1.41	**1.6**	1.32	**1.5**	
		50	3.85	**4.3**	3.04	**3.4**	1.44	**1.6**	1.32	**1.5**	1.32	**1.5**	
		75	1.98	**2.2**	1.57	**1.7**	1.32	**1.5**	1.32	**1.5**	1.32	**1.5**	
		90	1.32	**1.5**	1.32	**1.5**	1.32	**1.5**	1.32	**1.5**	1.32	**1.5**	
	10 - 12	0		-	5.99	**6.7**	2.81	**3.1**	1.41	**1.6**	-	-	
		50		-	3.04	**3.4**	1.44	**1.6**	0.734	0.82	-	-	
		75		-	1.57	**1.7**	0.758	0.84	-	-	-	-	
		90	-	-	0.684	0.76	-	-	-	-	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	0.833	0.93	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-38: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
			-		5 m		10 m		15 m		20 m		
	Vegetative strip (m)		PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
R2 / stream	0	0	-	-	8.04	**8.9**	3.77	**4.2**	1.89	**2.1**	1.11	**1.2**	1
		50	5.15	**5.7**	4.06	**4.5**	1.92	**2.1**	0.968	**1.1**	0.572	0.64	
		75	2.63	**2.9**	2.07	**2.3**	0.991	**1.1**	0.508	0.56	-	-	
		90	1.11	**1.2**	0.88	0.98	0.46	0.51	-	-	-	-	
R3 / stream	0	0	-	-	8.38	**9.3**	5.06	**5.6**	3.67	**4.1**	3.09	**3.4**	1
		50	6.07	**6.7**	5.27	**5.9**	3.68	**4.1**	2.98	**3.3**	2.69	**3.0**	
		75	4.18	**4.6**	3.78	**4.2**	2.99	**3.3**	2.64	**2.9**	2.49	**2.8**	
		90	3.05	**3.4**	2.89	**3.2**	2.57	**2.9**	2.43	**2.7**	2.37	**2.6**	
	10 - 12	0		-	8.38	**9.3**	3.92	**4.4**	2.46	**2.7**	-	-	
		50		-	4.22	**4.7**	2.48	**2.8**	1.76	**2.0**	-	-	
		75		-	2.58	**2.9**	1.76	**2.0**	1.4	**1.6**	-	-	
		90	-	-	1.66	**1.8**	1.33	**1.5**	1.19	**1.3**	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	1.38	**1.5**	
		50	-	-	-	-	-	-	-	-	0.967	**1.1**	
		75	-	-	-	-	-	-	-	-	0.758	0.84	
R4 / stream	0	0	-	-	5.99	**6.7**	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	1
		50	3.85	**4.3**	3.04	**3.4**	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	
		75	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	
		90	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	2.87	**3.2**	
	10 - 12	0		-	5.99	**6.7**	2.81	**3.1**	1.41	**1.6**	-	-	
		50		-	3.03	**3.4**	1.44	**1.6**	1.3	**1.4**	-	-	
		75		-	1.57	**1.7**	1.3	**1.4**	1.3	**1.4**	-	-	
		90	-	-	1.3	**1.4**	1.3	**1.4**	1.3	**1.4**	-	-	
	18 - 20	0	-	-	-	-	-	-	-	-	0.833	0.93	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-38: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ETO-RAC of 0.90 µg a.s./L (continued)

Scenario	Mitigation options Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)								Trigger
			25 m		30 m		40 m		45 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	0.636	0.71	-	-	-	-	-	-	1
D4 / stream	-	0	0.874	0.97	-	-	-	-	-	-	1
D5 / stream	-	0	0.756	0.84							
R1 / stream	0	0	1.32	**1.5**	1.32	**1.5**	1.32	**1.5**	-	-	1
		50	1.32	**1.5**	1.32	**1.5**	-	-	-	-	
		75	1.32	**1.5**	-	-	-	-	-	-	
R2 / stream	0	0	0.74	0.82							
R3 / stream	0	0	2.82	**3.1**	2.67	**3.0**	2.51	**2.8**	-	-	1
		50	2.56	**2.8**	2.48	**2.8**	-	-	-	-	
		75	2.43	**2.7**	-	-	-	-	-	-	
	18 - 20	0	1.1	**1.2**	0.937	**1.0**	-	-	-	-	
		50	0.823	0.91	0.744	0.83	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

The table below indicates mitigation required to be protective of the long-term risk to aquatic invertebrates

Table 10.2-39: Mitigation required to be protective of the long-term risk to aquatic invertebrates for ETO-RAC of 0.90 µg a.s./L

Scenario	1 x 375 g a.s./ha, early	3 x 375 g a.s./ha, early	1 x 375 g a.s./ha, late	3 x 375 g a.s./ha, late
D3 ditch	90% NR + 15 m DB or 75% NR + 20 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 15 m DB or 75% NR + 20 m DB or 50% NR + 25 m DB or 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB	90% NR + 5 m DB or 75% NR + 10 m DB or 50% NR + 15 m DB or 25 m DB
D4 pond	75% NR or 50% NR + 10 m DB or 15 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	NA	50% NR or 10 m DB
D4 stream	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 15 m DB or 75% NR + 20 m DB or 50% NR + 25 m DB or 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 30 m DB	90% NR + 5 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB
D5 pond	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 15 m DB or 20 m DB	NA	50% NR or 10 m DB
D5 stream	90% NR + 15 m DB or 75% NR + 20 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 30 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB
R1 pond	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 15 m DB or 20 m DB	NA	50% NR or 10 m DB
R1 stream	90% NR + 15 m DB 75% NR + 20 m DB 50% NR + 25 m DB or 40 m DB	10 – 12 m VS + 90% NR + 15 m DB or 18 – 20 m VS + 75% NR + 20 m DB or 18 – 20 m VS + 50% NR + 25 m DB or 18 – 20 m VS + 30 m DB	10 – 12 m VS + 90% NR + 10 m DB or 10 – 12 m VS + 75% NR + 15 m DB or 18 – 20 m VS + 50% NR + 20 m DB or 18 – 20 m VS + 25 m DB	10 – 12 m VS + 90% NR + 5 m DB or 10 – 12 m VS + 75% NR + 10 m DB or 10 – 12 m VS + 50% NR + 15 m DB or 18 – 20 m VS + 20 m DB
R2 stream	90% NR + 15 m DB or 75% NR + 25 m DB or 50% NR + 30 m DB or 40 m DB	10 – 12 m VS + 90% NR + 15 m DB or 18 – 20 m VS + 75% NR + 20 m DB 18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 30 m DB	90% NR + 5 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB

Scenario	1 x 375 g a.s./ha, early	3 x 375 g a.s./ha, early	1 x 375 g a.s./ha, late	3 x 375 g a.s./ha, late
R3 stream	18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB	10 – 12 m VS + 90% NR + 15 m DB or 18 – 20 m VS + 75% NR + 20 m DB 18 – 20 m VS + 75% NR + 25 m DB or 18 – 20 m VS + 50% NR + 30 m DB or 18 – 20 m VS + 40 m DB	90% NR + 10 m DB or 75% NR + 15 m DB or 50% NR + 20 m DB or 30 m DB	18 - 20 m VS + 75% NR + 20 m DB or
R4 stream	10 – 12 m VS + 90% NR + 15 m DB or 18 – 20 m VS + 50% NR + 25 m DB or 18 – 20 m VS + 40 m DB	NS	10 - 12 m VS + 90% NR + 10 m DB or 10 - 12 m VS + 75% NR + 15 m DB or 18 - 20 m VS + 50% NR + 20 m DB or 18 - 20 m VS + 50% NR + 20 m DB or 18 – 20 m VS + 25 m DB	18 – 20 m VS + 20 m DB

NR = drift reducing nozzles
DB = drift buffer
VS = vegetated filter strip
NS = no safe use
NA = No mitigation necessary for this scenario

Table 10.2-40: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application): ERO-RAC of 3.33 µg a.s./L

Scenario	Mitigation options Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		25 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	22.8	**6.80**	14	**4.2**	6.3	**1.9**	3.2	0.96	-	-	1
		50	14.5	**4.4**	11.4	**3.40**	7.01	**2.1**	3.15	0.950	-	-	-	-	
		75	7.26	**2.2**	5.7	**1.7**	3.5	**1.1**	1.58	0.47	-	-	-	-	
		90	2.9	0.87	2.28	0.68	1.4	0.42	0.647	0.19	0.346	0.10	-	-	
D4 / stream	-	0	--	--	25.5	**7.7**	15.7	**4.7**	7.06	**2.1**	3.6	**1.1**	2.13	0.64	1
		50	14.9	**4.5**	12.8	**3.8**	7.86	**2.4**	3.55	**1.1**	1.81	0.54	-	-	
		75	7.48	**2.2**	6.42	**1.9**	3.95	**1.2**	1.79	0.54	-	-	-	-	
		90	3.04	0.91	2.61	0.780	1.61	0.48	-	-	-	-	-	-	
D5 / stream	-	0	--	--	24.8	**7.4**	15.2	**4.6**	6.85	**2.1**	3.49	**1.0**	2.06	0.62	1
		50	14.4	**4.30**	12.4	**3.7**	7.62	**2.3**	3.43	**1.0**	1.75	0.53	-	-	
		75	7.24	**2.2**	6.21	**1.9**	3.82	**1.1**	1.72	0.52	-	-	-	-	
		90	2.91	0.87	2.5	0.75	-	-	-	-	-	-	-	-	
R1 / stream	0	0	-	--	20.2	**6.1**	12.4	**3.7**	5.61	**1.7**	2.86	0.86	-	-	1
		50	11.8	**3.5**	10.2	**3.1**	6.24	**1.9**	2.82	0.85	-	-	-	-	
		75	5.95	**1.8**	5.1	**1.5**	3.14	0.94	-	-	-	-	-	-	
		90	2.44	0.73	2.09	0.63	-	-	-	-	-	-	-	-	
R2 / stream	0	0	--	--	26.8	**8.0**	16.5	**5.0**	7.42	**2.2**	3.78	**1.1**	2.24	0.67	1
		50	15.6	**4.7**	13.4	**4.0**	8.25	**2.5**	3.73	**1.1**	1.9	0.57	-	-	
		75	7.85	**2.4**	6.74	**2.0**	4.15	**1.2**	1.9	0.56	0.963	0.29	-	-	
		90	3.18	1.0	2.73	0.82	1.69	0.51	0.772	0.23	0.403	0.12	-	-	
R3 / stream	0	0	--	--	28.6	**8.6**	17.6	**5.3**	7.9	**2.4**	4.02	**1.2**	2.38	0.71	1
		50	16.6	**5.0**	14.3	**4.3**	8.78	**2.6**	3.96	**1.2**	2.02	0.61	-	-	
		75	8.34	**2.5**	7.16	**2.2**	4.41	**1.3**	2	0.60	-	-	-	-	
		90	3.4	**1.0**	2.91	0.87	-	-	-	-	-	-	-	-	
R4 / stream	0	0	--	--	20.4	**6.1**	12.5	**3.8**	5.63	**1.7**	2.87	0.86	-	-	1
		50	11.9	**3.6**	10.2	**3.1**	6.27	**1.9**	2.84	0.85	-	-	-	-	
		75	5.98	**1.8**	5.13	**1.5**	3.16	0.95			-	-	-	-	
		90	2.44	0.73	2.1	0.63	-	-	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-41: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ERO-RAC of 3.33 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)												Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		25 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	18.1	**5.4**	10.6	**3.2**	5.98	**1.8**	2.75	0.83	-	-	1
		50	11.8	**3.5**	9.04	**2.7**	5.32	**1.6**	2.99	0.90	-	-	-	-	
		75	5.87	**1.8**	4.52	**1.4**	2.66	0.80	-	-	-	-	-	-	
		90	2.36	0.71	1.82	0.55	-	-	-	-	-	-	-	-	
D4 / stream	-	0	--	--	20.7	**6.2**	12.2	**3.7**	6.86	**2.1**	3.16	1.0	-	-	1
		50	12.2	**3.7**	10.4	**3.1**	6.11	**1.8**	3.44	**1.0**	1.6	0.48	-	-	
		75	6.15	**1.8**	5.21	**1.6**	3.08	0.92	1.74	0.52	-	-	-	-	
		90	2.5	0.75	2.12	0.64	-	-	-	-	-	-	-	-	
D5 / stream	-	0	--	--	22.6	**6.8**	13.3	**4.0**	7.49	**2.2**	3.45	**1.0**	1.88	0.56	1
		50	13.4	**4.0**	11.3	**3.4**	6.66	**2.0**	3.75	**1.1**	1.73	0.52	-	-	
		75	6.68	**2.0**	5.66	**1.7**	3.33	**1.0**	1.88	0.56	-	-	-	-	
		90	2.7	0.81	2.29	0.69	1.36	0.41	-	-	-	-	-	-	
R1 / stream	0	0	-	-	16.1	**4.8**	9.46	**2.8**	5.33	**1.6**	2.47	0.74	-	-	1
		50	9.51	**2.9**	8.06	**2.4**	4.76	**1.4**	2.68	0.80	-	-	-	-	
		75	4.8	**1.4**	4.06	**1.2**	2.41	0.72	-	-	-	-	-	-	
		90	1.98	0.59	1.67	0.50	-	-	-	-	-	-	-	-	
R2 / stream	0	0	--	--	21.6	**6.5**	12.7	**3.8**	7.15	**2.1**	3.3	1.0	-	-	1
		50	12.8	**3.8**	10.8	**3.2**	6.37	**1.9**	3.59	**1.1**	1.67	0.50	-	-	
		75	6.42	**1.9**	5.44	**1.6**	3.22	0.97	1.82	0.55	-	-	-	-	
		90	2.63	0.79	2.22	0.67	-	-	-	-	-	-	-	-	
R3 / stream	0	0	-	-	22.6	**6.8**	13.3	**4.0**	7.47	**2.2**	3.44	**1.0**	1.9	0.57	1
		50	13.3	**4.0**	11.3	**3.4**	6.65	**2.0**	3.74	**1.1**	1.74	0.52	-	-	
		75	6.69	**2.0**	5.67	**1.7**	3.35	**1.0**	1.9	0.57	-	-	-	-	
		90	2.75	0.83	2.32	0.70	1.58	0.47	-	-	-	-	-	-	
R4 / stream	0	0	--	--	16.1	**4.8**	9.46	**2.8**	5.32	**1.6**	4.47	**1.3**	4.47	**1.3**	1
		50	9.51	**2.9**	8.05	**2.4**	4.75	**1.4**	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	
		75	4.8	**1.4**	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	
		90	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	4.47	**1.3**	-	-	
	10 - 12	0	-	--	16.1	**4.8**	9.46	**2.8**	5.32	**1.6**	-	-	-	-	1
		50	-	--	8.05	**2.4**	4.75	**1.4**	2.68	0.80	-	-	-	-	
		75	-	--	4.06	**1.2**	2.4	0.72	2.03	0.61	-	-	-	-	
		90	--	--	2.03	0.61	2.03	0.61	2.03	0.61	-	-	-	-	

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)												Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		25 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
	18 - 20	0	--	--	--	--	--	--	--	--	2.46	0.74	1.36	0.41	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-42: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ERO-RAC of 3.33 µg a.s./L

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	9.28	**2.8**	4.14	**1.2**	2.09	0.63	-	-	1
		50	6.87	**2.1**	4.64	**1.4**	2.07	0.62	-	-	-	-	
		75	3.43	**1.0**	2.32	0.70	-	-	-	-	-	-	
		90	1.45	0.44	-	-	-	-	-	-	-	-	
D4 / stream	-	0	--	--	10.8	**3.2**	4.81	**1.4**	2.44	0.73	-	-	1
		50	6.91	**2.1**	5.39	**1.6**	2.43	0.73	-	-	-	-	
		75	3.5	**1.1**	2.73	0.82	1.24	0.37	-	-	-	-	
		90	1.46	0.44	-	-	-	-	-		-	-	
D5 / stream	-	0	--	--	11.6	**3.5**	5.2	**1.6**	2.62	0.79	-	-	1
		50	7.45	**2.2**	5.81	**1.7**	2.6	0.78	-	-	-	-	
		75	3.74	**1.1**	2.92	0.88	-	-	-	-	-	-	
		90	1.55	0.47	-	-	-	-	-	-	-	-	
R1 / stream	0	0	--	--	8.29	**2.5**	3.73	**1.1**	1.9	0.57	-	-	1
		50	5.35	**1.6**	4.18	**1.3**	1.89	0.57	-	-	-	-	
		75	2.73	0.82	2.13	0.64	-	-	-	-	-	-	
R2 / stream	0	0	--	--	11.1	**3.3**	4.99	**1.5**	2.53	0.76	-	-	1
		50	7.16	**2.2**	5.59	**1.7**	2.52	0.76	-	-	-	-	
		75	3.63	**1.1**	2.84	0.85	-	-	-	-	-	-	
		90	1.51	0.45	-	-	-	-	-	-	-	-	
R3 / stream	0	0	-	-	11.6	**3.5**	5.2	**1.6**	2.64	0.79	-	-	1
		50	7.46	**2.2**	5.82	**1.7**	2.63	0.79	-	-	-	-	
		75	3.79	**1.1**	2.96	0.89	-	-	-	-	-	-	
		90	1.6	0.48	-	-	-	-	-	-	-	-	
R 4 / stream	0	0	-	-	8.29	**2.5**	3.73	**1.1**	1.9	0.57	-	-	1
		50	5.35	**1.6**	4.18	**1.3**	1.89	0.57	-	-	-	-	
		75	2.73	0.82	2.13	0.64	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-43: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'late' application): ERO-RAC of 3.33 µg a.s./L

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	6.74	**2.0**	3.14	0.94	-	-	-	-	1
		50	4.92	**1.5**	3.38	1.0	-	-	-	-	-	-	
		75	2.53	0.76	-	-	-	-	-	-	-	-	
D4 / stream	-	0	--	--	7.77	**2.3**	3.63	**1.1**	1.81	0.54	-	-	1
		50	4.96	**1.5**	3.91	**1.2**	1.84	0.55	-	-	-	-	
		75	2.52	0.76	1.99	0.60	-	-	-	-	-	-	
D5 / stream	-	0	--	--	8.38	**2.5**	3.91	**1.2**	1.94	0.58	-	-	1
		50	5.32	**1.6**	4.19	**1.3**	1.97	0.59	0.989	0.30	-	-	
		75	2.69	0.81	2.12	0.64	-	-	-	-	-	-	
R1 / stream	0	0	--	--	5.99	**1.8**	2.81	0.84	-	-	-	-	1
		50	3.85	**1.2**	3.04	0.91	-	-	-	-	-	-	
		75	1.98	0.59	-	-	-	-	-	-	-	-	
R2 / stream	0	0	--	--	8.04	**2.4**	3.77	**1.1**	1.89	0.57	-	-	1
		50	5.15	**1.5**	4.06	**1.2**	1.92	0.58	-	-	-	-	
		75	2.63	0.79	2.07	0.62	-	-	-	-	-	-	
R3 / stream	0	0	--	--	8.38	**2.5**	5.06	**1.5**	3.67	**1.1**	3.09	0.93	1
		50	6.07	**1.8**	5.27	**1.6**	3.68	**1.1**	2.98	0.89	-	-	
		75	4.18	**1.3**	3.78	**1.1**	2.99	0.90	-	-	-	-	
		90	3.05	0.92	2.89	0.87	-	-	-	-	-	-	
R 4 / stream	0	0	--	--	5.99	**1.8**	2.87	0.86	-	-	-	-	1
		50	3.85	**1.2**	3.04	0.91	-	-	-	-	-	-	
		75	2.87	0.86	-	-	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

The table below indicates mitigation required to be protective of the long-term risk to aquatic invertebrates

Table 10.2-44: Mitigation required to be protective of the long-term risk to aquatic invertebrates for ETO-RAC of 3.33 µg a.s./L

Scenario	1 x 375 g a.s./ha, early	3 x 375 g a.s./ha, early	1 x 375 g a.s./ha, late	3 x 375 g a.s./ha, late
D3 ditch	90% NR or 75% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 5 m DB or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 5 m DB or 10 m DB
D4 stream	90% NR or 75% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 20 m DB	90% NR or 75% NR + 5 m DB or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 10 m DB or 15 m DB
D5 stream	90% NR or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 20 m DB or 25 m DB	90% NR or 75% NR + 5 m DB or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 10 m DB or 15 m DB
R1 stream	90% NR or 75% NR + 10 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 20 m DB	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 5 m DB or 10 m DB
R2 stream	90% NR or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 20 m DB or	90% NR or 75% NR + 5 m DB or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 10 m DB or 15 m DB
R3 stream	90% NR + 5 m DB 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB	90% NR or 75% NR + 15 m DB or 50% NR + 20 m DB or 25 m DB	90% NR or 75% NR + 5 m DB or 50% NR + 10 m DB or 15 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB
R4 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	10 – 12 m VS + 90% NR + 5 m DB or 10 – 12 m VS + 75% NR + 10 m DB or 10 – 12 m VS + 50% NR + 15 m DB or 18 – 20 m VS + 20 m DB	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 5 m DB or 10 m DB

NR = drift reducing nozzles
DB = drift buffer
VS = vegetated filter strip
NS = no safe use
NA = No mitigation necessary for this scenario

Table 10.2-45: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'early' application): ERO-RAC of 4.86 µg a.s./L

Scenario	Mitigation options: Vegetative strip (m)	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction): -		5 m		10 m		15 m		20 m		Trigger
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	22.8	**4.70**	14	**2.9**	6.3	**1.3**	3.2	0.66	1
		50	14.5	**3.0**	11.4	**2.3**	7.01	**1.4**	3.15	0.65	-	-	
		75	7.26	**1.5**	5.7	**1.2**	3.5	0.72	-	-	-	-	
		90	2.90	0.60	2.28	0.47	-	-	-	-	-	-	
D4 / stream	-	0	--	--	25.5	**5.20**	15.7	**3.2**	7.06	**1.5**	3.6	0.74	1
		50	14.9	**3.10**	12.8	**2.60**	7.86	**1.6**	3.55	0.73	-	-	
		75	7.48	**1.5**	6.42	**1.3**	3.95	0.81	-	-	-	-	
		90	3.04	0.63	2.61	0.540	-	-	-	-	-	-	
D5 / stream	-	0	--	--	24.8	**5.10**	15.2	**3.1**	6.85	**1.4**	3.49	0.72	1
		50	14.4	**3.00**	12.4	**2.60**	7.62	**1.6**	3.43	0.71	-	-	
		75	7.24	**1.5**	6.21	**1.3**	3.82	0.79	-	-	-	-	
		90	2.91	0.60	2.5	0.51	-	-	-	-	-	-	
R1 / stream	0	0	0	-	20.2	**4.2**	12.4	**2.6**	5.61	**1.2**	2.86	0.59	1
		50	11.8	**2.4**	10.2	**2.1**	6.24	**1.3**	2.82	0.58	-	-	
		75	5.95	**1.2**	5.1	**1.0**	3.14	0.65	-	-	-	-	
		90	2.44	0.50	2.09	0.43	-	-	-	-	-	-	
R2 / stream	0	0	-	-	26.8	**5.5**	16.5	**3.4**	7.42	**1.5**	3.78	0.78	1
		50	15.6	**3.2**	13.4	**2.8**	8.25	**1.7**	3.73	0.77	-	-	
		75	7.85	**1.6**	6.74	**1.4**	4.15	0.85	-	-	-	-	
		90	3.18	0.65	2.73	0.56	-	-	-	-	-	-	
R3 / stream	0	0	-	-	28.6	**5.9**	17.6	**3.6**	7.9	**1.6**	4.02	0.83	1
		50	16.6	**3.4**	14.3	**2.9**	8.78	**1.8**	3.96	0.81	-	-	
		75	8.34	**1.7**	7.16	**1.5**	4.41	0.91	-	-	-	-	
		90	3.4	0.70	2.91	0.60	-	-	-	-	-	-	
R 4 / stream	0	0	-	-	20.4	**4.2**	12.5	**2.6**	5.63	**1.2**	2.87	0.59	1
		50	11.9	**2.4**	10.2	**2.1**	6.27	**1.3**	2.84	0.58	1.45	0.30	
		75	5.98	**1.20**	5.13	**1.1**	3.16	0.65	-	-	-	-	
		90	2.44	0.50	2.1	0.43	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-46: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (3 × 375 g a.s./ha for 'early' application): ERO-RAC of 4.86 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
			-		5 m		10 m		15 m		20 m		
	Vegetative strip (m)		PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	--	--	18.1	**3.7**	10.6	**2.2**	5.98	**1.2**	2.75	0.57	1
		50	11.8	**2.4**	9.04	**1.9**	5.32	**1.1**	2.99	0.62	-	-	
		75	5.87	**1.2**	4.52	0.93	2.66	0.55	-	-	-	-	
		90	2.36	0.49	-	-	-	-	-	-	-	-	
D4 / stream	-	0	--	--	20.7	**4.3**	12.2	**2.5**	6.86	**1.4**	3.16	0.65	1
		50	12.2	**2.5**	10.4	**2.1**	6.11	**1.3**	3.44	0.71	-	-	
		75	6.15	**1.3**	5.21	**1.1**	3.08	0.63	-	-	-	-	
		90	2.5	0.51	2.12	0.44	-	-	-	-	-	-	
D5 / stream	-	0	--	--	22.6	**4.7**	13.3	**2.7**	7.49	**1.5**	3.45	0.71	1
		50	13.4	**2.8**	11.3	**2.3**	6.66	**1.4**	3.75	0.77	-	-	
		75	6.68	**1.4**	5.66	**1.2**	3.33	0.69	-	-	-	-	
		90	2.7	0.56	2.29	0.47	-	-	-	-	-	-	
R1 / stream	0	0	--	--	16.1	**3.3**	9.46	**1.9**	5.33	**1.1**	2.47	0.51	1
		50	9.51	**2.0**	8.06	**1.7**	4.76	0.98	2.68	0.55	-	-	
		75	4.8	0.99	4.06	0.84	-	-	-	-	-	-	
		90	1.98	0.41	-	-	-	-	-	-	-	-	
R2 / stream	0	0	--	--	21.6	**4.4**	12.7	**2.6**	7.15	**1.5**	3.3	0.68	1
		50	12.8	**2.6**	10.8	**2.2**	6.37	**1.3**	3.59	0.74	-	-	
		75	6.42	**1.3**	5.44	**1.1**	3.22	0.66	-	-	-	-	
		90	2.63	0.54	2.22	0.46	-	-	-	-	-	-	
R3 / stream	0	0	-	-	22.6	**4.7**	13.3	**2.7**	7.47	**1.5**	3.44	0.71	1
		50	13.3	**2.7**	11.3	**2.3**	6.65	**1.4**	3.74	0.77	-	-	
		75	6.69	**1.4**	5.67	**1.2**	3.35	0.69	-	-	-	-	
		90	2.75	0.57	2.32	0.48	-	-	-	-	-	-	
R 4 / stream	0	0	--	--	16.1	**3.3**	9.46	**1.9**	5.32	**1.1**	4.47	0.92	1
		50	9.51	**2.0**	8.05	**1.7**	4.75	0.98	4.47	0.92	-	-	
		75	4.8	0.99	4.47	0.92	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-47: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ERO-RAC of 4.86 µg a.s./L

Scenario	**Mitigation options**	**Nozzle reduction (%)**	**Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**										**Trigger**
			-		**5 m**		**10 m**		**15 m**		**20 m**		
	Vegetative strip (m)		**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	**PEC_{SW} (µg/L)**	**PEC/RAC ratio**	
D3 / ditch	-	0	--	--	9.28	**1.9**	4.14	0.85	-	-	-	-	1
		50	6.87	**1.4**	4.64	0.95	2.07	0.43	-	-	-	-	
		75	3.43	0.71	-	-	-	-	-	-	-	-	
D4 / stream	-	0	-	-	10.8	**2.2**	4.81	0.99	-	-	-	-	1
		50	6.91	**1.4**	5.39	**1.1**	2.43	0.50	-	-	-	-	
		75	3.5	0.72	2.73	0.56	-	-	-	-	-	-	
D5 / stream	-	0	--	--	11.6	**2.4**	5.2	**1.1**	2.62	0.54	-	-	1
		50	7.45	**1.5**	5.81	**1.2**	2.6	0.53	-	-	-	-	
		75	3.74	0.77	2.92	0.60	-	-	-	-	-	-	
R1 / stream	0	0	--	--	8.29	**1.7**	3.73	0.77	-	-	-	-	1
		50	5.35	**1.1**	4.18	0.86	-	-	-	-	-	-	
		75	2.73	0.56	-	-	-	-	-	-	-	-	
R2 / stream	0	0	-	-	11.1	**2.3**	4.99	**1.0**	2.53	0.52			1
		50	7.16	**1.5**	5.59	**1.2**	2.52	0.52	-	-	-	-	
		75	3.63	0.75	2.84	0.58	-	-	-	-	-	-	
R3 / stream	0	0	--	--	11.6	**2.4**	5.2	**1.1**	2.64	0.54	-	-	1
		50	7.46	**1.5**	5.82	**1.2**	2.63	0.54	-	-	-	-	
		75	3.79	0.78	2.96	0.61	-	-	-	-	-	-	
R 4 / stream	0	0	--	--	8.29	**1.7**	3.73	0.77	-	-	-	-	1
		50	5.35	**1.1**	4.18	0.86	-	-	-	-	-	-	
		75	2.73	0.56	-	-	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

Table 10.2-48: Refinement of long-term risk to aquatic invertebrates using FOCUS Step 4 PECsw for pome fruit (1 × 375 g a.s./ha for 'late' application): ERO-RAC of 4.86 µg a.s./L

Scenario	Mitigation options	Nozzle reduction (%)	Non-spray buffer zone (corresponding to ≤ 95 % drift reduction)										Trigger
	Vegetative strip (m)		-		5 m		10 m		15 m		20 m		
			PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	PEC_{SW} (µg/L)	PEC/RAC ratio	
D3 / ditch	-	0	-	-	6.74	**1.4**	3.14	0.65	-	-	-	-	1
		50	4.92	**1.0**	3.38	0.70	-	-	-	-	-	-	
		75	2.53	0.52	-	-	-	-	-	-	-	-	
D4 / stream	-	0	-	-	7.77	**1.6**	3.63	0.75	-	-	-	-	1
		50	4.96	**1.0**	3.91	0.80	-	-	-	-	-	-	
		75	2.52	0.52	-	-	-	-	-	-	-	-	
D5 / stream	-	0	-	-	8.38	**1.7**	3.91	0.80	-	-	-	-	1
		50	5.32	**1.1**	4.19	0.86	-	-	-	-	-	-	
		75	2.69	0.55	-	-	-	-	-	-	-	-	
R1 / stream	0	0	--	--	5.99	**1.2**	2.81	0.58	-	-	-	-	1
		50	3.85	0.79	3.04	0.63	-	-	-	-	-	-	
R2 / stream	0	0	-	-	8.04	**1.7**	3.77	0.78	-	-			1
		50	5.15	**1.1**	4.06	0.84	-	-	-	-	-	-	
		75	2.63	0.54	-	-	-	-	-	-	-	-	
R3 / stream	0	0	--	--	8.38	**1.7**	5.06	**1.0**	3.67	0.76	-	-	1
		50	6.07	**1.2**	5.27	**1.1**	3.68	0.76	-	-	-	-	
		75	4.18	0.86	3.78	0.78	-	-	-	-	-	-	
R 4 / stream	0	0	--	--	5.99	**1.2**	2.87	0.59	-	-	-	-	1
		50	3.85	0.79	-	-	-	-	-	-	-	-	

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

The table below indicates mitigation required to be protective of the long-term risk to aquatic invertebrates

Table 10.2-49: Mitigation required to be protective of the long-term risk to aquatic invertebrates for ETO-RAC of 3.33 µg a.s./L

Scenario	1 x 375 g a.s./ha, early	3 x 375 g a.s./ha, early	1 x 375 g a.s./ha, late	3 x 375 g a.s./ha, late
D3 ditch	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 5 m DB or 50% NR + 15 m DB or 20 m DB	75% NR or 50% NR + 5 m DB or 10 m DB	75% NR or 50% NR + 5 m DB or 10 m DB
D4 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	75% NR or 10 m DB	75% NR or 50% NR + 5 m DB or 10 m DB
D5 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 5 m DB or 10 m DB
R1 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 5 m DB or 50% NR + 10 m DB or 20 m DB	75% NR or 50% NR + 5 m DB or 10 m DB	50% NR or 10 m DB
R2 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 5 m DB or 10 m DB
R3 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	75% NR or 50% NR + 10 m DB or 15 m DB	75% NR or 50% NR + 10 m DB or 15 m DB
R4 stream	90% NR or 75% NR + 10 m DB or 50% NR + 15 m DB or 20 m DB	75% NR or 50% NR + 10 m DB or 20 m DB	75% NR or 50% NR + 5 m DB or 10 m DB	50% NR or 10 m DB

NR = drift reducing nozzles
DB = drift buffer
VS = vegetated filter strip
NS = no safe use
NA = No mitigation necessary for this scenario

Long-term risk to other groups

For the risk assessment for long-term risk to fish the PEC/RAC ratios were greater than 1 for several FOCUS step 3 scenarios (please refer to Tables 10.2.15 to 10.2-18). For completeness the PEC/RAC ratios have been refined as described below.

Refinement of the long-term risk to fish

Two fish early life stage studies have been conducted with cyprodinil, one with *Cyprinodon variegates* and the other with *Pimephales promelas*. Since the endpoints for both studies are based on growth parameters it is acceptable to derive a geometric mean from the two endpoints of 40.6 and 231 µg a.s./L, respectively. Refinement has been presented in the table below.

Table 10.2-50 ~~25~~: Higher-tier long-term risk assessment for fish using an RAC of 9.68 µg a.s./L (geometric mean of 40.6 µg a.s./L [*Cyprinodon variegates*] and 231 µg a.s./L [*Pimephales promelas*]) – FOCUS Step 3 PEC_{SW}

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	29.1	**3.0**	23.5	**2.4**
	D4 pond	1.77	0.18	3.14	0.32
	D4 stream	29.6	**3.1**	24.4	**2.5**
	D5 pond	1.77	0.18	3.15	0.33
	D5 stream	28.8	**3.0**	26.7	**2.8**
	R1 pond	1.76	0.18	3.02	0.31
	R1 stream	23.5	**2.4**	18.9	**2.0**
	R2 stream	31.1	**3.2**	25.3	**2.6**
	R3 stream	33.2	**3.4**	26.6	**2.7**
	R4 stream	23.6	**2.4**	18.9	**2.0**
'Late'	D3 ditch	13.8	**1.4**	9.84	**1.0**
	D4 pond	0.615	0.06	0.948	0.10
	D4 stream	13.8	**1.4**	9.85	**1.0**
	D5 pond	0.617	0.06	0.988	0.10
	D5 stream	14.9	**1.5**	10.6	**1.1**
	R1 pond	0.616	0.06	0.977	0.10
	R1 stream	10.6	**1.1**	7.53	0.78
	R2 stream	14.1	**1.5**	10.1	**1.0**
	R3 stream	14.9	**1.5**	10.6	**1.1**
	R4 stream	10.6	**1.1**	7.53	0.78

~~Application timing~~	~~Scenario~~	~~Number of applications~~			
		~~1 × 375 g a.s./ha~~		~~3 × 375 g a.s./ha~~	
		~~PEC (µg/L)~~	~~PEC/RAC ratio~~	~~PEC (µg/L)~~	~~PEC/RAC ratio~~
~~'Early'~~	~~D3 ditch~~	~~29.1~~	**~~3.0~~**	~~23.5~~	**~~2.4~~**
	~~D4 pond~~	~~1.77~~	~~0.18~~	~~3.14~~	~~0.32~~
	~~D4 stream~~	~~29.6~~	**~~3.1~~**	~~24.4~~	**~~2.5~~**

	~~D5 pond~~	~~1.77~~	~~0.18~~	~~3.15~~	~~0.33~~
	~~D5 stream~~	~~28.8~~	**~~3.0~~**	~~26.7~~	**~~2.8~~**
	~~R1 pond~~	~~1.76~~	~~0.18~~	~~3.02~~	~~0.31~~
	~~R1 stream~~	~~23.5~~	**~~2.4~~**	~~18.9~~	**~~2.0~~**
	~~R2 stream~~	~~31.1~~	**~~3.2~~**	~~25.3~~	**~~2.6~~**
	~~R3 stream~~	~~33.2~~	**~~3.4~~**	~~26.6~~	**~~2.7~~**
	~~R4 stream~~	~~23.6~~	**~~2.4~~**	~~18.9~~	**~~2.0~~**
~~'Late'~~	~~D3 ditch~~	~~13.7~~	**~~1.4~~**	~~9.84~~	~~1.0~~
	~~D4 pond~~	~~0.615~~	~~0.064~~	~~0.948~~	~~0.10~~
	~~D4 stream~~	~~13.8~~	**~~1.4~~**	~~9.85~~	~~1.0~~
	~~D5 pond~~	~~0.616~~	~~0.06~~	~~0.988~~	~~0.10~~
	~~D5 stream~~	~~14.9~~	**~~1.5~~**	~~10.6~~	**~~1.1~~**
	~~R1 pond~~	~~0.615~~	~~0.064~~	~~0.977~~	~~0.10~~
	~~R1 stream~~	~~10.6~~	**~~1.1~~**	~~7.53~~	~~0.78~~
	~~R2 stream~~	~~14.1~~	**~~1.5~~**	~~10.1~~	~~1.0~~
	~~R3 stream~~	~~14.9~~	**~~1.5~~**	~~10.6~~	**~~1.1~~**
	~~R4 stream~~	~~10.6~~	**~~1.1~~**	~~7.53~~	~~0.78~~

Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations

The PEC/$RAC_{sw;ch}$ values are all greater than 1 for the ditch and stream scenarios, indicating the need for further consideration of the long-term risk to fish.

Further refinement of the long-term risk to fish

According to the EFSA Aquatic Guidance, the chronic risk can be refined using a default 7-d twa. However it should not be used if the following apply

- If the RAC is from studies where exposure is not maintained – *exposure was maintained throughout the study*
- When the effect is based on a developmental endpoint during a specific lifestage that may last a short time only – *the endpoint is based on growth parameters*
- When the effect is based on mortality early in the test or the acute:chronic ratio both based on mortality is <10 – *mortality did not occur early in the test*
- If latency has been demonstrated or might be expected – *there is no evidence for latency of effects*.

There is no reason not to use the 7-d twa in the chronic risk assessment. PEC/RAC values comparing the geometric mean RAC of 9.68 µg a.s./L with FOCUS Step 3 7 d TWA concentrations for the scenarios in which the ratio was >1 in the previous table are presented below.

Table 10.2-51~~26~~: Higher-tier long-term risk assessment for fish using an RAC of 9.68 µg a.s./L (geometric mean of 40.6 µg a.s./L [*Cyprinodon variegates*] and 231 µg a.s./L [*Pimephales promelas*]) – FOCUS Step 3 7 d TWA PEC$_{SW}$

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		7 d TWA PEC (µg/L)	PEC/RAC ratio	7 d TWA PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	4.63	0.48	5.70	0.59
	D4 stream	0.454	0.047	0.69	0.071
	D5 stream	0.163	0.017	1.46	0.15
	R1 stream	0.565	0.058	0.71	0.073
	R2 stream	0.36	0.037	0.38	0.039
	R3 stream	1.52	0.16	1.43	0.15
	R4 stream	0.67	0.069	0.99	0.10
'Late'	D3 ditch	3.33	0.34	5.38	0.56
	D4 stream	0.535	0.055	0.406	0.042
	D5 stream	0.813	0.084	0.581	0.060
	R1 stream	0.316	0.033	0.226	0.023
	R2 stream	0.209	0.022	0.155	0.016
	R3 stream	0.791	0.082	0.565	0.058
	R4 stream	0.315	0.033	0.703	0.073

Application timing	Scenario	Number of applications			
		1 × 375 g a.s./ha		3 × 375 g a.s./ha	
		7 d TWA PEC (µg/L)	PEC/RAC ratio	7 d TWA PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	4.66	0.48	5.72	0.59
	D4 pond	1.60	0.17	2.97	0.31
	D4 stream	0.473	0.049	0.701	0.072
	D5 pond	1.59	0.16	2.98	0.31
	D5 stream	0.179	0.018	1.48	0.15
	R1 pond	1.59	0.16	2.82	0.29
	R1 stream	0.581	0.060	0.725	0.075
	R2 stream	0.378	0.039	0.391	0.040
	R3 stream	1.54	0.16	1.45	0.15
	R4 stream	0.686	0.071	0.993	0.10
'Late'	D3 ditch	3.34	0.35	5.38	0.56
	D4 pond	0.556	0.057	0.891	0.092
	D4 stream	0.546	0.056	0.413	0.043
	D5 pond	0.56	0.058	0.934	0.096
	D5 stream	0.824	0.085	0.588	0.061
	R1 pond	0.551	0.057	0.913	0.094
	R1 stream	0.323	0.033	0.231	0.024
	R2 stream	0.218	0.023	0.161	0.017
	R3 stream	0.802	0.083	0.573	0.059
	R4 stream	0.322	0.033	0.711	0.073

All of the PEC/RAC values are below the trigger of 1 indicating acceptable long-term risk to fish following application of A8637C according to the proposed use pattern when the geometric mean endpoint is used in combination with 7 d TWA surface water concentrations.

Further refinement is presented in the table below in which the geometric mean RAC of 9.68 µg a.s./L is compared to FOCUS Step 4 PEC_{SW} values.

Table 10.2-26: Higher-tier long-term risk assessment for fish incorporating exposure mitigation options for pome fruit using a refined RAC of 9.68 µg a.s./L

Application timing	Scenario	Spray drift buffer	Number of applications			
			1 × 375 g a.s./ha		3 × 375 g a.s./ha	
			PEC (µg/L)	PEC/RAC ratio	PEC (µg/L)	PEC/RAC ratio
'Early'	D3 ditch	10 m	14.0	**1.4**	10.6	**1.1**
	D4 stream		15.7	**1.6**	12.2	**1.3**
	D5 stream		15.2	**1.6**	13.3	**1.4**
	R1 stream		12.4	**1.3**	9.43	**1.0**
	R2 stream		16.4	**1.7**	12.6	**1.3**
	R3 stream		17.5	**1.8**	13.3	**1.4**
	R4 stream		12.5	**1.3**	9.43	**1.0**
	D3 ditch	15 m	6.30	0.65	5.98	0.62
	D4 stream		7.05	0.73	6.85	0.71
	D5 stream		6.85	0.71	7.49	0.77
	R1 stream		5.57	0.58	5.30	0.55
	R2 stream		7.38	0.76	7.10	0.73
	R3 stream		7.89	0.82	7.46	0.77
	R4 stream		5.61	0.58	5.3	0.55
	D3 ditch	20 m	3.20	0.33	2.75	0.28
	D4 stream		3.59	0.37	3.16	0.33
	D5 stream		3.48	0.36	3.45	0.36
	R1 stream		2.83	0.29	2.44	0.25
	R2 stream		3.75	0.39	3.27	0.34
	R3 stream		4.01	0.41	3.43	0.35
	R4 stream		2.85	0.29	4.54	0.47
'Late'	D3 ditch	10 m	4.14	0.43	3.14	0.32
	D4 stream		4.81	0.50	3.63	0.38
	D5 stream		5.20	0.54	3.91	0.40
	R1 stream		3.68	0.38	2.77	0.29
	R2 stream		4.92	0.51	3.71	0.38
	R3 stream		5.19	0.54	5.06	0.52
	R4 stream		3.68	0.38	2.94	0.30
	D3 ditch	15 m	2.09	0.22	1.57	0.16
	D4 stream		2.44	0.25	1.81	0.19
	D5 stream		2.62	0.27	1.94	0.20
	R1 stream		1.86	0.19	1.37	0.14
	R2 stream		2.48	0.26	1.84	0.19
	R3 stream		2.62	0.27	3.66	0.38
	R4 stream		1.86	0.19	2.94	0.30
	D3 ditch	20 m	1.28	0.13	0.93	0.10
	D4 stream		1.50	0.15	1.06	0.11
	D5 stream		1.60	0.17	1.14	0.12
	R1 stream		1.19	0.12	1.35	0.14
	R2 stream		1.52	0.16	1.07	0.11

~~Application timing~~	~~Scenario~~	~~Spray drift buffer~~	~~Number of applications~~			
			~~1 × 375 g a.s./ha~~		~~3 × 375 g a.s./ha~~	
			~~PEC (µg/L)~~	~~PEC/RAC ratio~~	~~PEC (µg/L)~~	~~PEC/RAC ratio~~
	~~R3 stream~~		~~1.60~~	~~0.17~~	~~3.09~~	~~0.32~~
	~~R4 stream~~		~~1.64~~	~~0.17~~	~~2.94~~	~~0.30~~

~~Values in bold are above the trigger value of 1 and hence further consideration is needed for these taxa/scenario combinations~~
~~PEC_{SW} values have not been generated for the 'pond' scenarios as these represent least worst case.~~
~~PEC/RAC values have been generated only for those scenarios which failed at Step 3~~

~~All of the PEC/RAC values are below the trigger of 1 for the 'late' application scenario indicating acceptable long-term risk to fish following application of A8637C according to the proposed use pattern when the geometric mean endpoint is used. For the 'early' application acceptable risk would be achieved if a 15 m spray drift reduction buffer is implemented.~~

Risk assessment for cyprodinil for sediment dwelling organisms using the plateau concentration

The accumulation of cyprodinil in sediment needs to be considered in the risk assessment. The worst-case plateau concentration derived using FOCUS Step 3 modelling was estimated to be 147 µg a.s./kg. **Comparing this with the Tier 1 RAC of 8 000 µg/kg gives a PEC/RAC ratio of 0.018, indicating acceptable risk for sediment accumulation of cyprodinil following application of A8637C according to the proposed use pattern.**

Cyprodinil metabolites

The risk to aquatic organisms from the cyprodinil metabolites is presented in the table below.

Table 10.2-52 ~~27~~: Risk to aquatic organisms from cyprodinil metabolites (FOCUS Step 2)

Test organism	Substance	Tier 1-RAC (µg/L)	Max PEC_{SW} [µg/L]	PEC/RAC
Oncorhynchus mykiss	CGA249287	550	~~19.4~~ 25.9	0.035 0.047
	CGA275535	21	0.215	0.010 0.010
	CGA263208	21	~~3.93~~ 3.92	0.19
Daphnia magna	CGA249287	>1 000	~~19.4~~ 25.9	<0.019 < 0.026
	CGA275535	68	0.215	0.0032
	CGA321915	>980	~~3.24~~ 3.59	<0.0033 <0.0037
	CGA263208	206	~~3.93~~ 3.92	0.019
Chironomus riparius	CGA321915	970	~~3.24~~ 3.59	0.0033 0.0037
Chironomus riparius	CGA249287	2 560 µg/kg	~~32.4~~ 98.9 µg/kg	0.013 0.039
Psudokirchneriella subcapitata	CGA249287	>10 000	~~19.4~~ 25.9	<0.0019 <0.0026
	CGA275535	1 800	0.215	0.00012
	CGA321915	>9 900	~~3.24~~ 3.59	<0.00033 <0.00036
	CGA263208	186	~~3.93~~ 3.92	0.021

All of the PEC/RAC values are below the trigger of 1 indicating acceptable risk to aquatic organisms for metabolites of cyprodinil following application of A8637C according to the proposed use pattern.

Risk assessment for CGA249287 for sediment dwelling organisms using the plateau concentration

The accumulation of CGA249287 in sediment needs to be considered in the risk assessment. The worst-case plateau concentration derived using FOCUS Step 2 modelling was estimated to be 145 µg a.s./kg. **Comparing this with the Tier 1 RAC of 2 560 µg/kg gives a PEC/RAC ratio of 0.057, indicating acceptable risk from this metabolite for sediment accumulation following application of A8637Caccording to the proposed use pattern.**

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

All the acute aquatic studies with A8637C were previously submitted. However, for ease of reference, summaries of these studies are presented below.

Report:	K-CP 10.2.1/01 Rufli H 1996, Acute toxicity test of CGA 219417 (A8637C) to rainbow trout (*Oncorhynchus mykiss*) in the flow-through system. Report No. 953609. Ciba-Geigy Ltd., Basel, Switzerland. (Syngenta File No. CGA219417/0712)

Guidelines

OECD 203

GLP: Yes

Executive Summary

The acute toxicity of formulation A8637C to rainbow trout, *Oncorhynchus mykiss*, was determined in a flow-through test system for 96 hours. This study was run with nominal formulation concentrations of 0.76, 1.4, 2.5, 4.4 and 8.0-mg formulation/L together with a negative control.

The 96 h LC_{50} was estimated to be 6.2 mg formulation/L.

Materials

Test Material:	A8637C
Description:	Beige solid
Lot/Batch #:	P.4100096
Actual content of a.s.:	50.8% w/w cyprodinil
Stability of test compound:	To 03/96
Test concentrations:	Nominal: 0.76, 1.4, 2.5, 4.4 and 8.0-mg formulation/L
Vehicle and/or positive control:	Water vehicle and control
Analysis of test concentrations:	Yes
Test animals	
Species:	Rainbow trout *Oncorhynchus mykiss*
Source:	Charles River Aquaria, Margate, UK
Acclimatisation period:	41 days
Treatment for disease:	None
Weight and length:	Weight: range 1.54 to 2.40 g, mean 1.97 g (based on 7 control fish) Length: range 54 to 64 mm, mean 60 mm (based on 7 control fish) (Deviation from guideline: fish length based on 7 control fish was 60 mm (54 – 64 mm) instead of 50 ± 10 mm).
Feeding:	None during test

Environmental conditions

Test temperature:	12.6 – 14.0°C
pH range:	8.1 to 8.4
Dissolved oxygen:	74 – 99% saturation
Total hardness of dilution water:	112 mg $CaCO_3$/L
Lighting:	16 hours light and 8 hours dark daily with a 30 minute transition period
Length of test:	96 hours

Study Design and Methods

Experimental dates: 4th December to 16th April 1996.

Test procedure and apparatus

Test chambers were glass aquaria, of 20 L maximum capacity, filled with 15 L. The test system was flow-through. One tank was prepared for the control and each test solution, with 7 fish in each tank. Loading rate was approximately 0.15-g fish/L/day.

Preparation of test solutions

For each test concentration a single stock solution was prepared without using a solvent. An appropriate amount of each stock solution was added directly to the dilution water (3.8 L/h) by means of high precision pumps. The test medium exchange rate was adjusted to approximately 6.1 volume replacements per day.

Analytical method

Mean measured test concentrations (as cyprodinil) were determined from samples of test water collected at start of exposure and after 96 hours (or when all fish had died) and analysed by HPLC.

Observations for mortality and symptoms of toxicity

Mortalities and symptoms of toxicity were recorded after 2, 24, 48, 72 and 96 hours.

Physical and chemical parameters

Daily measurements were made of temperature, pH and dissolved oxygen. Total hardness of the water was determined at test start.

Results and Discussion

Analytical data

Concentrations varied between 105 and 116% of nominal at test start and 79 and 111% of nominal at test end. Results are given on basis of mean measured concentrations.

Biological data

Mortality data and LC_{50} values are summarised in the table below.

Table 10.2.1-1: A8637C - Acute toxicity to rainbow trout

Concentration (mg formulation/L)		Mortality 96 h (%)
Nominal	Mean measured (based on cyprodinil analysis)	
Control	< 0.04	0
0.76	0.70	0
1.4	1.5	0
2.5	2.7	0
4.4	5.0	0
8.0	7.8	100

Exposure period (hours)	LC_{50} (95% conf. interval) (mg formulation/L)
24	> 7.8 (n.a.)
48	8.1 (n.a.)
72	7.3 (n.a.)
96	6.2 (n.a.)

n.a. = not applicable

Sub-lethal effects (change in swimming behaviour, loss of equilibrium, altered respiration, change in pigmentation) were observed at the concentration levels 2.6 mg/L (light symptoms) and 4.9 mg/L (severe symptoms) during the whole test period.

Conclusions

The 96 hour LC_{50} for A8637C to rainbow trout was estimated to be 6.2 mg formulation/L, equivalent to 3.15 mg a.s./L.

(Rufli H, 1996)

Report:	K-CP 10.2.1/02 Wallace SJ 2001. CGA 219417: Acute toxicity to *Daphnia magna* of a 50 % w/w WG formulation. Report No. AJ0141/B. Brixham Environmental Laboratory, Brixham, UK. (Syngenta File No. CGA219417/1032)

Guidelines

OECD 202

GLP: Yes

Executive Summary

The acute toxicity of formulation A8637C to *Daphnia magna* was determined in a static test system for 48 hours. This study was run with nominal formulation concentrations of 0.032, 0.056, 0.10, 0.18, 0.32, 0.56 and 1.0-mg formulation/L together with a negative control.

The 48 hour EC_{50} was estimated to be 0.14 mg formulation/L (95% C.I. 0.11 – 0.17)

Materials

Test Material: A8637C
Description: Tan/brownish granules
Lot/Batch #: WM 910165
Actual content of a.s.: 50.9% w/w cyprodinil
Stability of test compound: Reanalysis 03/2003

Test concentrations: Nominal: 0.032, 0.056, 0.10, 0.18, 0.32, 0.56 and 1.0-mg formulation/L

Vehicle and/or positive control:	Vehicle = test medium (reconstituted water, Elendt's M4) Water control
Analysis of test concentrations:	Yes
Test animals	
Species:	*Daphnia magna* Straus, <24 hours old at test start
Source:	In-house culture
Acclimatisation period:	In house culture maintained in medium identical to the test medium
Treatment for disease:	None
Feeding:	None during test
Environmental conditions	
Test temperature:	20.3 – 20.9°C
pH range:	7.73 to 8.03
Dissolved oxygen:	100 – 102% saturation
Total hardness of dilution water:	215 mg $CaCO_3$/L
Conductivity:	630 $\mu S \cdot cm^{-1}$
Lighting:	16 hours light and 8 hours dark daily with a 20 minute transition period
Length of test:	48 hours

Study Design and Methods

Experimental dates: 14th to 18th May 2001.

Test procedure and apparatus

Test chambers were glass beakers, of 250 mL maximum capacity, filled with 200 mL test medium and covered with glass lids. The test system was static. Four replicate vessels were prepared for the control and each test solution, each with 5 daphnids.

Preparation of test solutions

Appropriate amounts of a stock solution (0.1 g test substance mixed into 1 L reconstituted water without additional solvent) were homogeneously distributed in the test water of each test group.

Analytical method

Samples of the test media were taken from the freshly prepared test solutions and after 48 hours for the analytical determination (HPLC) of the test concentrations (measured cyprodinil concentration is taken as a measure for the concentration of the formulation).

Observations for mortality and symptoms of toxicity

The number of dead or immobilized organisms was counted at 24 and 48 hours.

Physical and chemical parameters

Temperature was recorded automatically at 1-hour intervals in an additional water control. Dissolved oxygen and pH were measured at the start of the test. Total hardness and the conductivity of the water were determined at test start.

Results and Discussion

Analytical data

Results are given on basis of nominal concentrations since concentrations varied between 88 and 100 % of nominal at test start and 86 and 100 % of nominal at test end.

Biological data

Mortality data and EC_{50} values are summarised in the table below.

Table 10.2.1-2: A8637C - Acute toxicity to *Daphnia magna*

Concentration[a] (mg A8637C/L)			Immobilisation after 48 h (%)	Exposure period (hours)	EC_{50} [b] (95 % conf. interval) (mg A8637C/L)
Nominal	Start	End			
Control	< 0.004	< 0.004	0	24 h	0.35 (0.22 – 0.60)
0.032	0.030	0.030	0	48 h	0.14 (0.11 – 0.17)
0.056	0.051	0.051	0		
0.10	0.088	0.086	10		
0.18	0.17	0.16	80		
0.32	0.32	0.32	100		
0.56	0.52	0.54	100		
1.0	0.94	0.94	100	EC_0: 0.056 mg A8637C / L	

[a] based on measured cyprodinil concentration; [b] based on nominal concentrations

In addition to the immobilisation no toxicological effects were observed during the test period.

Conclusions

The 48 hour EC_{50} for A8637C to *Daphnia magna* was calculated to be 0.14 mg formulation/L, equivalent to 0.07 mg a.s./L

(Wallace S, 2001)

Report:	K-CP 10.2.1/03 Wallace S.J. (2001a) Toxicity to the green alga *Selenastrum capricornutum* of a 50 % w/w WG formulation. Report No. AJ0141/C. Brixham Environmental Laboratory, Brixham, UK. (Syngenta File No. CGA219417/1031)

Guidelines

OECD 201

GLP: Yes

Executive Summary

The toxicity of A8637C to the green alga *Pseudokirchneriella subcapitata* was determined over 72 hours under static conditions. The study was run with a culture medium control together with nominal concentrations of 0.56, 1.0, 1.8, 3.2, 5.6, 10, 18 and 32 mg formulation/L.

The 72 hour E_bC_{50} was estimated to be 4.1 mg formulation/L (95% C.I. 4.0 to 4.2).

Materials

Test Material	A8637C
Description:	Tan/brownish granules
Lot/Batch #:	WM 910165
Actual content of a.s.:	50.9% w/w cyprodinil
Stability of test compound:	Reanalysis 03/2003
Test concentrations:	Nominal concentrations of 0.56, 1.0, 1.8, 3.2, 5.6, 10, 18 and 32 mg formulation/L
Vehicle and/or positive control:	Culture medium
Analysis of test concentrations:	Yes
Test organisms	
Species:	Unicellular green alga, *Pseudokirchneriella subcapitata*, strain ATCC 22662
Source:	In-house culture
Environmental conditions	
Test temperature:	24 ± 1°C
pH:	7.36 to 7.45 at test start; 7.65 to 10.17 at test termination (increase in pH due to the massive growth of algae in control and low concentration groups)
Lighting:	Continuous illumination
Light intensity	Approximately 8000 Lux
Length of test:	72 hours

Study Design and Methods

Exposure dates: 14^{th} to 17^{th} May 2001

Test procedure and apparatus

The test vessels were 250 mL glass flasks, stoppered with foam bungs and held on a laboratory shaker, with 100 mL test solution per flask. Six replicate cultures of the control and triplicate cultures of each test concentration were employed. In addition to the flasks containing algae, one blank vessel per test group was incubated concurrently for analytical purposes.

Algal cell densities were measured at 24, 48 and 72 hours using an electronic cell counter. The starting cell density was approximately 10^4 cells/mL.

The test was incubated under static conditions, shaken at 160 rpm.

Preparation of test solutions

The test medium for the highest test concentration was prepared by mixing an appropriate amount of the test item into the sterile culture medium without additional solvent. The lower test concentrations were prepared via serial dilution. The 10 to 32 mg/L test solutions contained a slight suspension, while all lower concentrated solutions were clear.

Analytical method

Test item concentrations were measured (HPLC) in the remainder of each stock solution at test start and in the remaining blank medium after 72 hours.

Physical and chemical parameters

The temperature of the incubator was measured once daily, and continuously monitored (with hourly recoding). The pH was recorded at 0 h (excess medium) and 72 h (medium containing algae).

Results and Discussion

Analytical data

Samples of the test medium collected on Day 0 showed concentrations varying between 96 and 106 % of nominal, while on Day 3 concentrations varied between 75 and 103-%. Toxicity values were calculated based on the nominal concentrations.

Biological data

Table 10.2.1-3: A8637C - toxicity to *Pseudokirchneriella subcapitata*

Concentration[a] (mg A8637C /L)			Cell density after 72 hours	Inhibition (AUC) 0 - 72 h	72-h E_rC_{50}[b] (95% confid. limit)	72-h E_bC_{50}[c] (95% confid. limit)
Nominal	Measured Day 0	Measured Day 3	(cells × 10 [4]/mL)	(%)	(mg A8637C / L)	(mg A8637C / L)
Blank	< 0.016	< 0.016	248	--	7.9 (7.4 – 8.5)	4.1 (4.0 – 4.2)
0.56	0.54	0.52	225	9		
1.0	1.02	0.98	199	15 *		
1.8	1.82	1.75	187	23 *		
3.2	3.39	3.20	160	35 *		
5.6	5.77	5.77	76.2	70 *		
10	10.0	10.2	3.35	98 *		
18	18.0	17.1	1.41	99 *	NOE_rC: 1.0 mg A8637C/L	NOE_bC: 0.56 mg A8637C/L
32	32.0	24.0	2.89	99 *		

[a] Based on measured cyprodinil concentration; [b] based on nominal concentrations; * significant difference (p = 0.05) from control

Growth of cells was completely inhibited at the concentration levels 10 mg/L and above. The density of the cells in the control group increased by factor 248 during the course of the test (exponential growth), demonstrating the validity of the test system. The E_bC_{50} (72 h) of A8637C was determined to be 4.1-mg/L, equivalent to a cyprodinil concentration of 2.05-mg-ai/L.

Conclusions

The 72 hour E_bC_{50} for A8637C for *Selenastrum capricornutum* was calculated to be 4.1 mg formulation/L, equivalent to 2.05 mg a.s./L.

(Wallace S, 2001a)

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

Additional long-term or chronic studies with A8637C are not required as acute studies indicate the formulated product is no more toxic than expected on the basis of the active substance toxicity and hence risk can be adequately assessed using the chronic toxicity data for the active substance.

CP 10.2.3 Further testing on aquatic organisms

A mesocosm study was conducted using a 300 EC formulation A14325E (***Ashwell et al, 2007***) (details are provided in M-CA Section 8, CA 8.2-8) to a community typical for a lentic freshwater community, containing phyto- and zooplankton and macroinvertebrates. Intended initial concentrations were 0 – 1.5 – 5 – 10 – 20 – 50 µg a.s./L. Immediately after each of the three applications the test compound was mixed in the water layer of the microcosms. Measurements in dosing solutions and water indicated that the test systems received the intended doses. Shortly after the applications 75-80%, 119-154% and 118-156% of the target amount was measured in the water of the test systems.

MDD analysis of the available data for zooplankton demonstrated that typically small to large effects could be determined throughout the study for five parameters. As these evaluations included sensitive taxa (*Daphnia* sp.) and organisms from the three main zooplankton groups (cladocera, copepoda and rotifera), the data generated are considered robust and reliable for ETO-RAC derivation and a NOEC (class 1) of 10 µg a.s./L is recommended for zooplankton. If an NOEAEC (class 3A) is required for ERO-RAC it can be considered to be 50 µg a.s./L.

Relevant literature on further testing on aquatic organisms

Report:	K-CP 10.2.3/01 Zubrod J.P., Englert D., Feckler A., Koksharova N., Konschak M., Bundshuh R., Schnetzer N., Englert K., Shulz R. & Bundshuh M. (2015) Does the Current Fungicide Risk Assessment Provide Sufficient Protection for Key Drives in Aquatic Ecosystem Functioning? Environmental Science & Technology, 49: 1173-1181. (Syngenta File No. CGA219417_11655)

Guidelines

No guidelines available.

GLP: No.

Executive Summary

The effects of CHORUS® (A8637C) on *Gammarus* feeding behaviour and microbial decomposition in aquatic aquaria were assessed.

The NOEC within this study for aquatic microbial inhibition of decomposition is 40 µg/L. The NOEC for fungal density reduction was 8 µg/L, however bacterial densities were unaffected and the NOEC was ≥ 1 000 µg/L.

Materials

Test Material	Cyprodinil as Chorus®
Description:	Not stated
Purity	Chorus contains analytical grade cyprodinil.
Source:	Syngenta Agro
Test concentrations:	8, 40, 200 and 1 000 µg/L
Vehicle and/or positive control:	None
Analysis of test concentrations:	No.

Test animals

Species:	Aquatic bacterial and fungal communities
Source:	Leaves were added to aerated medium to produce microorganism colonies

Test design

Exposure regime:	Continuously stirred and renewed every 3 days
Aeration:	Yes
Replication:	7 per concentration

Environmental conditions

Test temperature:	16 ± 1 °C followed by 20 ± 1 °C
pH:	7.0
Dissolved oxygen:	Not stated
Hardness of dilution water:	Low hardness
Lighting:	Total darkness
Length of test:	12 days

Study Design and Methods

The effect of cyprodinil on *Gammarus* feeding behaviour and microbial decomposition in aquatic aquaria was assessed.

Black alder leaves (*Alnus glutinosa*) were used as microbial substrate. Leaves were collect in October 2011 near Landau, Germany; 49°11′ N, 8°05′ E). Five hundred leaves were suspended in fine mesh bags (0.5 mm mesh size; 10 leaves/bag) in a stream (Rodenbach near Grünstadt, Germany; 49°33′ N, 8°02′ E) and left for 14 days and then wastewater inlet for 14 days. These were further added to another 500 leaves within the laboratory and kept in total darkness at 16 ± 1 °C in 30 L of complete medium (SAM-5S; amphipod medium) for 7 days before being used as bacterial inoculum.

Sets of 4 unconditioned leaf discs (diameter = 16 mm) were dried at 60°C and weighed. Two discs per treatment were used. The treatments were either leaves added to the conditioned control or to a range of cyprodinil concentrations. Each aquarium received 10 g of inoculum. These discs were contained in 5 L litre aquaria with 4 L medium, and there were 7 replicates per treatment. The leaves were left to decompose within the aquaria exposed to either 8, 40, 200 and 100 µg/L cyprodinil or a medium control. These aquaria were continuously stirred and aerated for 12 days in total darkness at 16 ± 1 °C. After 12 days discs were removed for assessment of microbial decomposition.

Fungicide concentrations were verified using ultrahigh performance liquid chromatography−mass spectrometry (Thermo Fisher Scientific).

Mean/ median percentages of microbial decomposition inhibition and fungal and bacterial densities were reported in comparison to the medium control.

Results and Discussion

Mean measured concentrations were within 20% of nominal concentrations and nominal were used for reporting and statistical analysis.

The results presented in the publication are presented below:

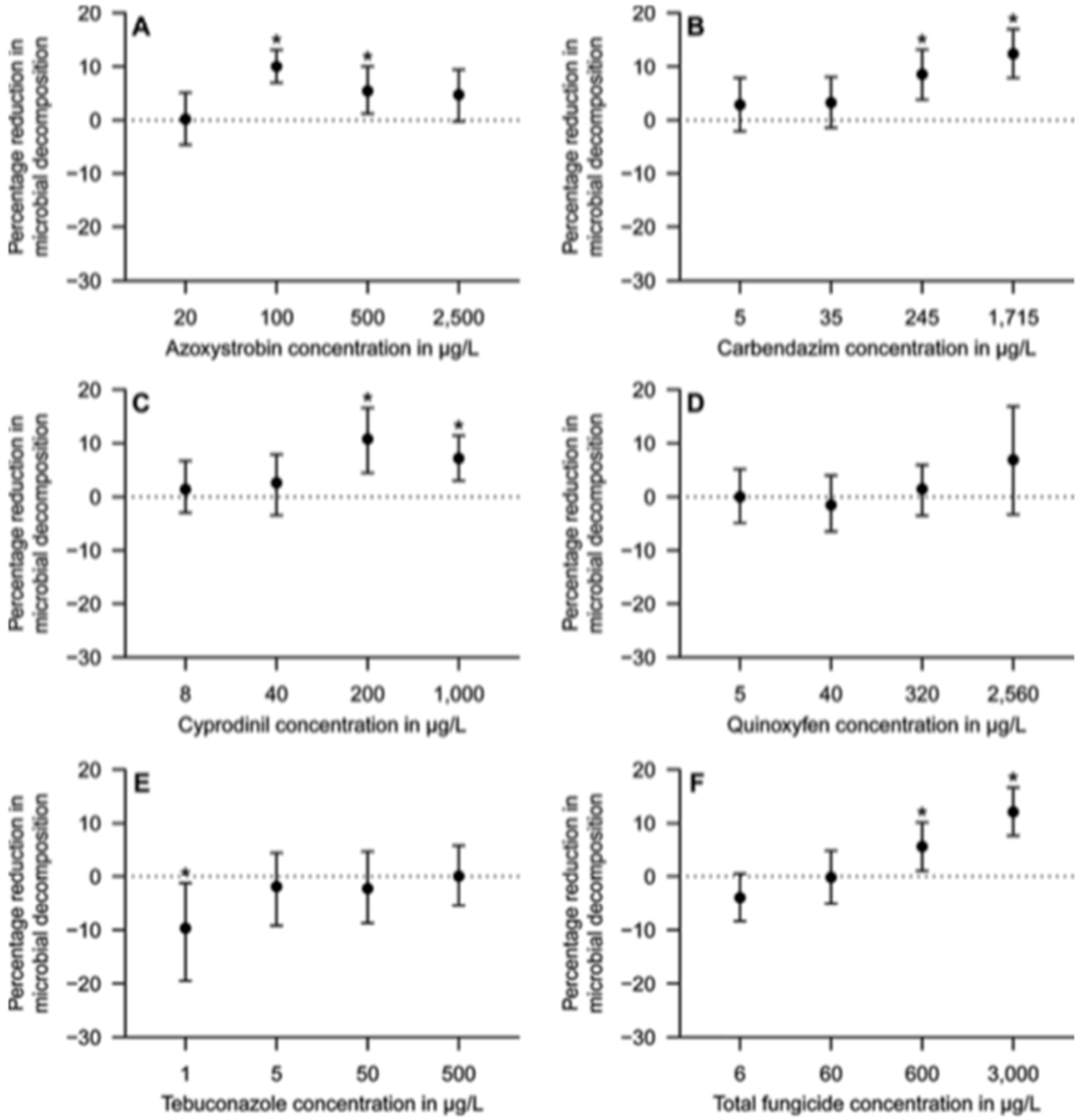

Figure 10.2.3-1. Mean or median (with 95 % C.I.) percentage reductions (compared to the respective control) in microbial decomposition of leaf material conditioned in the presence of different concentrations of (A) azoxystrobin, (B) carbendazim, **(C) cyprodinil**, (D) quinoxyfen, (E) tebuconazole, and (F) the fungicide mixture. Asterisks denote statistically significant differences compared to the respective control.

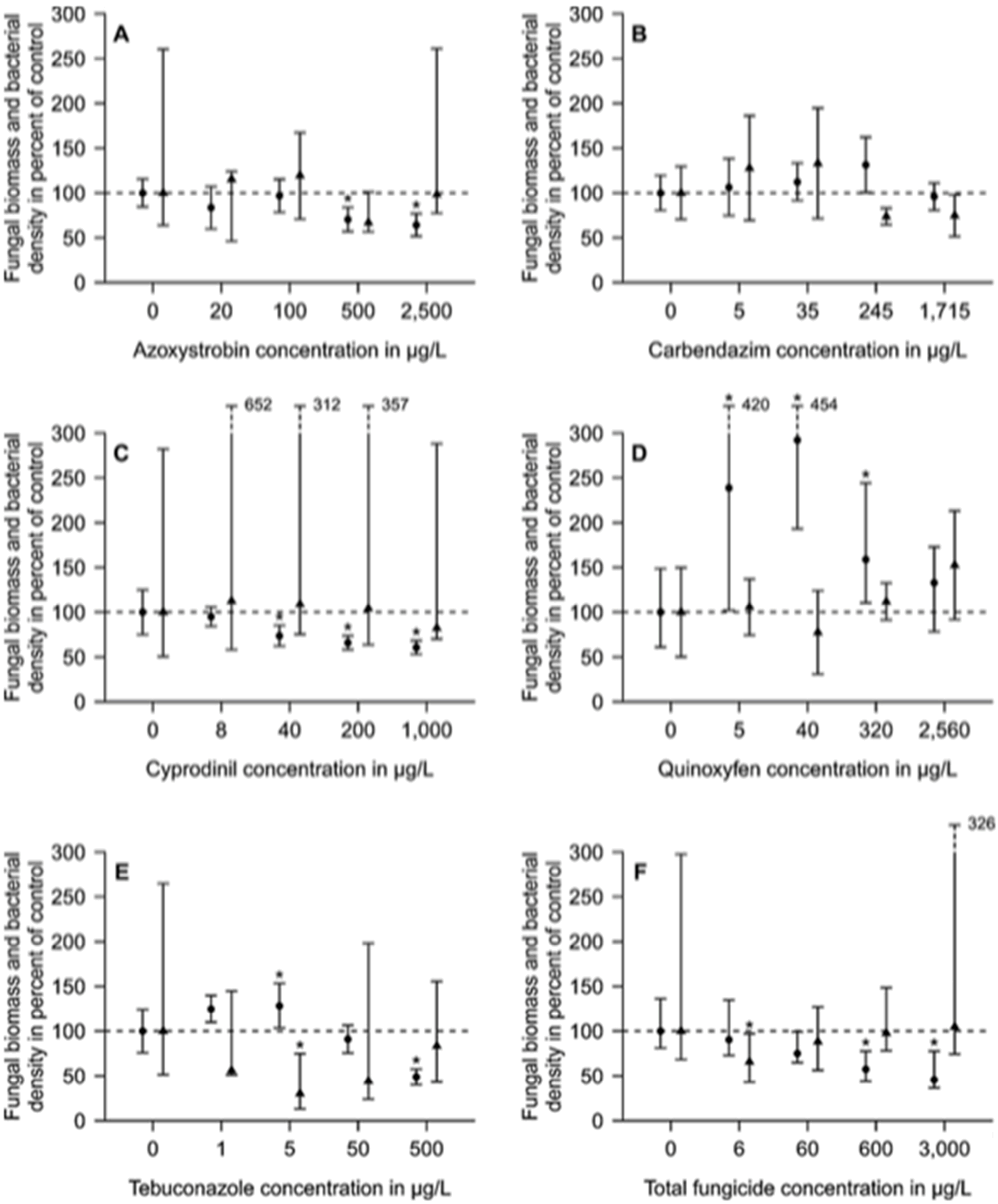

Figure 10.2.3-2. Mean or median (with 95 % CI) fungal biomass (circles) and bacterial density (triangles) relative to the respective control associated with leaf material conditioned in the presence of different concentrations of (A) azoxystrobin, (B) carbendazim, **(C) cyprodinil**, (D) quinoxyfen, (E) tebuconazole, and (F) the fungicide mixture. Asterisks denote statistically significant differences to the respective control.

Conclusions

The effects of A8637C on *Gammarus* feeding behaviour and microbial decomposition in aquatic aquaria were assessed. The NOEC for microbial inhibition was determined to be 40 µg/L. The NOECs for fungal and bacterial density were 8 and ≥ 1 000 µg/L, respectively.

References:

Study Reliability Evaluation	Yes	No	Not reported	Not applicable	Comments
Standardised test procedure followed				X	Aquatic microbe test, no guidelines are available.
Appropriate test procedure followed				X	Test methodology was previously reported by the Author, and these are well reported.
Data quality assured (GLP or equivalent)		X			
Controls appropriate	X				Controls had no contaminants/ previous contamination.
Control response acceptable, or accounted for statistically	X				Results are presented as a % of the control.
Temperature, pH & dissolved oxygen reported	X				Only dissolved oxygen is not reported.
Alkalinity and hardness reported (metals)			X		Not reported but full medium composition is.
Statistics appropriate	X				
Effect levels above analytical limit of detection/quantification	X				LOD 0.2, LOQ 0.6 µg/L
Material tested within limits of solubility, or effects above the limits of solubility sufficiently explained	X				
Analytical verification of test concentrations/doses	X				
Measurement of precipitate or undissolved material			X		
Appropriate dilution water used (e.g. not chlorinated tap, rain water etc)	X				

Study assessment	Score	Rationale
Reliability/Repeatability	Klimisch 2	Study and methodology are well reported and repeatable. Good analytics and supplementary information is thorough with raw data and all analysis.
Limitations		The endpoints currently not essential for the ERA.
Relevance	Toxicity to aquatic microbes is not relevant for ecotoxicity RA.	The endpoints are currently not essential for the ERA.
Significance	Toxicity to aquatic microbes is not suitable for use in risk assessment	The endpoint is currently not essential for the ERA.

CP 10.3 Effects on Arthropods

CP 10.3.1 Effects on bees

Toxicity

Summary of endpoints relevant for the risk assessment:

Table 10.3.1-1: Table of endpoints to assess risk from use of A8637C

Organism	Test item	Test type	Endpoint		Reference (author, date, Syngenta File No.)
Honey bee	Cyprodinil	Acute contact	EU	LD_{50} >784 µg a.s./bee	***Boeri et al. (1995d) CGA219417/0532***
	A8637C	Acute Oral	EU	Oral 72h LD_{50} >250 µg/bee (>125 µg a.s./bee)	***Candolfi (1995) CGA219417/0375***
		Acute Contact		Contact 72h LD_{50} >250 µg/bee (>125 µg a.s./bee)	
		Adult chronic	New Study	10 day LD_{50} = 112.2 µg consumed a.s./bee/day 10 day NOED = 47.3 µg consumed a.s./bee/day 10 day NOEC = 1.284 g a.s./kg food	***Ruhland (2014) A8637C_10321***
		Chronic larval	New Study	7 day NOED = 13.3 µg a.s./larva [a] 8 day NOED = 33.3 µg a.s./larva 7 day NOEC = 0.084 g a.s./kg diet 8 day NOEC = 0.211 g a.s./kg diet	***Kleebaum (2014) A8637C_10330***

[a] This value will be used in the risk assessment as it represents worst case

Exposure

Applications of pesticides can potentially result in exposure of bees either through direct over-spray, or by contact with residues on plants whilst bees are foraging for food. For cyprodinil, it is highly likely that bees will be exposed to significant residues, as A8637C is applied throughout the growing season to pome fruit, including during flowering of the trees. Therefore the in-field scenario represents a worst-case, short-term source of exposure.

Exposure through contact from drift to bees foraging in the off-field environment is a relevant exposure route; however, the level of exposure is clearly lower than in-field, and as such is covered by the in-field contact risk assessment.

In order to consider an extreme worst-case scenario and provide a conservative assessment, the maximum application rate of 375 g a.s./ha when 750 g A8637C is applied at the maximum proposed rate has been used in the risk assessment below.

Risk assessment for bees

The risk to bees has been assessed following the EPPO 2010 scheme[5] as proposed in the list of guidance documents relevant to the implementation of Regulation 1107/2009, published in the official EU Journal 2013/C 95/01 and 95/02.

Acute risk assessment

The potential acute risk from use of A8637C was assessed using the maximum single application rates and the LD_{50} values to calculate hazard quotients in accordance with the current Terrestrial Guidance Document[6] and EPPO 2010.

$$Hazard\ Quotient = \frac{Maximum\ application\ rate\ (g\ formulation/ha)}{Acute\ LD_{50}\ (\mu g/bee)}$$

Table 10.3.1-2: Risk to bees from oral exposure to A8637C

Test substance	Application rate (g/ha)	Oral LD_{50} (µg/bee)	Hazard quotient
A8637C	750	>250	<3.0
Cyprodinil	375	>125	<3.0

Both of the hazard quotients for cyprodinil and A8637C are less than 50, indicating that the risk to bees is acceptable following use of A8637C according to the proposed use pattern.

Table 10.3.1-3: Risk to bees from contact exposure to A8637C

Test substance	Application rate (g/ha)	Contact LD_{50} (µg/bee)	Hazard quotient
A8637C	750	>250	<3.0
Cyprodinil	375	>784	<0.48

Both of the hazard quotients for cyprodinil and A8637C are less than 50, indicating that the risk to bees is acceptable following use of A8637C according to the proposed use pattern.

Chronic Risk Assessment

Chronic adult and larval bee studies have been conducted according to the data requirements under 1007/2009. The endpoints from these studies have been assessed by adapting the EPPO 2010 scheme.

Larval assessment:

Following the EPPO scheme for assessing potential risks to larvae (point 4 on the scheme), the scheme suggests that effects on growth or development can be excluded when considering cyprodinil, since it is not an IGR, and shows no effects on juvenile stages in other organisms as demonstrated by the risk assessments for non-target arthropods, and soil organisms (Collembola and *Hypoaspis*). Thus cyprodinil can be categorised as posing a low risk to bees.

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[5] EPPO/OEPP (2010) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(3)). Bulletin OEPP/EPPO Bulletin 40: 323-331.

[6] Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under Council Directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

However, a chronic larval study is available and this potential low risk can be further demonstrated by carrying out a worst-case risk assessment through the calculation of a TER value as set out in the EPPO 2010 scheme (point 5 on the scheme).

A worst-case of potential exposure via residues in pollen / nectar can be estimated based on the default worst-case residue of 1 mg a.s./kg proposed in the EPPO 2010 scheme (see Note 6), based on a database of measured values from aerial plant parts as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst case data from **Rortais *et al.*, 2005**[7] as proposed in the EPPO scheme have been used to estimate the consumption by bee larvae:

Worst case: drone larvae consuming 98.2 mg sugar in 6.5 days (= 15.1 mg sugar /day).

Thus considering residues of 1 mg a.s./kg sugar × consumption of 15.1 mg sugar/bee/day

Total exposure ETE = 0.0151 µg a.s./bee/day

This value can be compared to the cyprodinil larval NOEC of 13.3 µg a.s./bee/developmental period, which is equivalent to 1.9 µg a.s./bee/day (based on 7 day study duration).

- TER = NOEL (µg a.s./bee/day)/ ETE (µg a.s./bee/day)

  = 1.9/0.0151= 126

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees. It is clear that with a TER value of 126 there is a wide safety margin, indicating that the proposed uses of cyprodinil pose an acceptable risk to bee larval development.

Adult chronic assessment:

The EPPO 2010 scheme does not recommend a chronic assessment for adults for foliar spray applications. However, as an approach is proposed as an assessment refinement for seed coatings/soil treatments (point 7 on the scheme), this approach can be adapted to provide a worst-case assessment for foliar sprays.

A worst-case of potential exposure via residues in pollen / nectar can be estimated as before based on the default worst-case value of 1 mg a.s./kg proposed in the EPPO 2010 scheme (see Note 6), based on a database of measured values from aerial plant parts as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst case data from Rortais *et al*., 2005 as proposed in the EPPO 2010 scheme have been used to estimate the consumption by bee foragers:

Worst case: forager consuming 128 mg nectar/day.

Thus considering residues of 1 mg a.s./kg sugar × consumption of 28 mg nectar/bee/day

Total exposure ETE = 0.128 µg a.s./bee/day

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[7] Agnès RORTAIS, Gérard ARNOLD, Marie-Pierre HALM, Frédérique TOUFFET-BRIENS (2005) Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36 (2005) 71–83

This value can be compared to the cyprodinil adult NOEL of 47.3 µg a.s./bee/day.

- TER = NOEL (µg a.s./bee/day)/ ETE (µg a.s./bee/day)

  = (47.3/0.128) = 370

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honey bees when a NOEL is used in this assessment. It is clear that with a TER value of 370 there is a wide safety margin, indicating that the proposed uses of cyprodinil pose an acceptable chronic risk to adult bees.

Tests on chronic toxicity and larval and brood development have been carried out in accordance with the **Annexes to Regulation 283/2013 and 284/2013**. **The results of these tests indicate that the use of cyprodinil in A8637C poses an acceptable risk to bees.**

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

A study with A8637C previously submitted in the EU was summarised in point B.9.4.1 of the DAR and a summary of this study is also presented below for ease of reference. The endpoints are summarised in Table 10.3.1-1.

Report:	K-CP 10.3.1.1.1/01 Candolfi MP 1995: CGA 219417 WG 50 (A-8637 C): laboratory oral and contact LD_{50} test with the honey bee, *Apis mellifera*. Report No. 95-053-1008. Springborn Laboratories (Europe) AG. (Syngenta file No. CGA219417/0375)

Guidelines

EPPO No. 170

GLP: Yes

Executive Summary

A single rate of A8637C was tested by oral and contact routes, 250 µg formulation/bee. Control and toxic standard were included in the test.

No toxic effects related to treatment were observed in either the contact or oral tests.

The 48-hour oral and contact LD_{50} values for A8637C were therefore >250 µg formulation/bee, the highest doses given.

Materials

Test Material:	A8637C
Description:	Light brown granules
Lot/Batch #:	P.311006
Purity:	51% w/w cyprodinil
Stability of test compound:	Not stated

Test doses:	Contact nominal 250 µg formulation/bee Oral nominal 250 µg formulation/bee
Vehicle and/or positive control:	Water with Etalfix (0.1%) for contact test; 50% w/v sucrose solution for oral test. Positive control: Dimethoate 0.16 µg dimethoate/bee.
Test animals	
Species:	*Apis mellifera*
Source:	O.Keller, Mörschwil, CH
Food:	50% w/v aqueous sucrose solution
Environmental conditions	
Temperature:	24.9 to 25.6°C
Humidity:	55% to 77%
Photoperiod:	16 h daily photoperiod of diffuse light

Study Design and Methods

Experimental dates: 11th to 20th August 1994.

Honeybees were exposed to the test substance by contact and oral routes. Oral doses were given in 50% w/v sucrose solution (approximately 100 µL per 10 bees, shared tropholactically); contact doses were given in water with Etalfix (1 µL per bee, applied to the thorax under CO_2 anaesthesia).

Test bees were collected from the hives the night prior to test initiation. Test units consisted of a PVC frame and 3 mm mesh screen walls (12.5 cm x 12.5 cm x 12.5 cm), with a removable glass sheet as the front side. Three replicate test units were maintained in each treatment and control group, with 10 bees in each. Bees were not fed for some time prior to test initiation, but had continuous access to a 50% aqueous sugar solution and water during the test.

Test units were checked for mortality and behavioural abnormalities during the first 30 minutes following treatment application, and at 6, 24, 48 and 72 hours after test initiation.

Results and Discussion

Table 10.3.1.1.1-1: A8637C: Acute toxicity to honeybees

Oral toxicity					Contact toxicity				
Treatment group	Mortality				Treatment group	Mortality			
	24 h		72 h			24 h		72 h	
	#	(%)	#	(%)		#	(%)	#	(%)
blank control	2/30	6.7	2/30	6.7	blank control	0/30	0	2/30	6.7
A8637C	3/30	10	4/30	13.3	A8637C	1/30	3.3	2/30	6.7
toxic standard	15/30	50	30/30	100	toxic standard	23/30	76.7	26/30	86.7

No toxic effects of A8637C to honey bees were noted in either test, the mortality is considered not treatment-related.

Conclusions

The LD_{50} of A8637C to honeybees was >250 µg formulation/bee (>125 µg ai/bee) for both contact and oral exposure routes.

(Candolfi MP 1995)

CP 10.3.1.1.2 Acute contact toxicity to bees

Please refer to Point CP 10.3.1.1.1.

CP 10.3.1.2 Chronic toxicity to bees

Chronic toxicity data for bees is a new data requirement under the **Annexes to Regulation 283/2013 and 284/2013**, applicable where there is a possibility that bees may be exposed. In order to minimise testing, and as the formulated product is considered to be indicative of the effects of the active substance for bees, tests have only been carried out with the formulated substance and these are summarised in M-CA Section 8, CA 8.5.1.2. The results are summarised in Table 10.3.1-1.

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

Larval and brood development data for bees is a new data requirement under the **Annexes to Regulation 283/2013 and 284/2013**, applicable where there is a possibility that bees may be exposed. In order to minimise testing, and as the formulated product is considered to be indicative of the effects of the active substance for bees, tests have only been carried out with the formulated substance and these are summarised in M-CA Section 8 Point 8.5.1.3. The results are summarised in Table 10.3.1-1.

CP 10.3.1.4 Sub-lethal effects

As the risk to bees is acceptable following use of A8637C according to the proposed use pattern, further tests are not necessary.

CP 10.3.1.5 Cage and tunnel tests

As the risk to bees is acceptable following use of A8637C according to the proposed use pattern, further tests are not necessary.

CP 10.3.1.6 Field tests with honeybees

As the risk to bees is acceptable following use of A8637C according to the proposed use pattern, further tests are not necessary.

CP 10.3.2 Effects on non-target arthropods other than bees

The toxicity of A8637C to non-target arthropods has been investigated. The testing and risk assessment strategy used here follows the approach recommended in the ESCORT 2 guidance document (**Candolfi *et al.* 2001**)[8] as proposed by **EC Guidance Document on Terrestrial Ecotoxicology** [9].

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[8] Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R, Vogt H (2000) 'Guidance Document on regulatory testing procedures for plant protection products with non-target arthropods' From the workshop, European Standard Characteristics of Non-target Arthropod Regulatory Testing (ESCORT 2) 21-23 March 2000.

Toxicity

The toxicity of A8637C to non-target arthropods has been investigated by carrying out Tier I and higher tier tests with A8637C on the non-target arthropod species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. These two species are tested, in accordance with ESCORT 2, as representative non-target arthropods since they have been found to be particularly sensitive species, and therefore can be considered as indicators of potential effects to the most sensitive non-target arthropods in the field. Additionally, testing has been carried out with a range of other NTAs. For convenience, the results of these studies are summarised below. Further details regarding the tests are provided in **M-CA Section 8, CA 8.3.2**.

Table 10.3.2-1: Table of endpoints to assess risk from use of A8637C

Species	Test type	Treatments (kg form./ha) and spray interval	Summarised results [a]	Reference (author, date, Syngenta File No.)
Aphidius rhopalosiphi	Tier 1, glass plate	1 × 0.9, 1 × 0.45, 1 × 0.09	Survival not significantly affected at any rate (LR_{50} >0.9 kg/ha); parasitisation affected at 0.9 kg/ha	***Grimm (1999) CGA219417/0925***
	Tier 1, glass plate	Rate-response 0.6, 0.9, 1.2, 1.5, 1.8	LR_{50} = 1.42 kg/ha; parasitisation affected >50% at all rates tested (0.6 and 0.9 kg/ha)	***Vinall (2001) CGA219417/1048***
	Semi-field test on wheat	4 × 0.45 (2-3 d int), 2 × 3.0 (7 d int)	No adverse effect at 4 × 0.45 kg/ha; >50% effect at 2 × 3.0 kg/ha	***Kleiner (1997) CGA219417/0813***
	Semi-field test on apple	1 × 3.0, 2 × 3.0 (7 d int)	Both parameters not affected in either treatment scenario (fecundity >control in both cases)	***Aldershof (2000) CGA219417/0965***
Typhlodromus pyri	Tier 1, glass plate	1 × 0.9, 1 × 0.45, 1 × 0.09	No effects on mortality or fecundity >50% at any treatment rate (LR_{50} >0.9 kg/ha)	***Grimm (1999) CGA219417/0923***
	Tier 1, glass plate	1 × 1.8, 1 × 0.45, 1 × 0.09	Mortality not affected at any rate (LR_{50} >1.8 kg/ha); >50% effect on fecundity at 0.45 and 1.8 kg/ha; <50% effect on fecundity at 0.09 kg/ha	***Taruza (2001) CGA219417/1057***
	Field test in apple	4 × 0.45, 4 × 0.09 (9-10 d int)	No statistically significant difference from control plot was found	***Aldershof (2000) CGA219417/0949***
	Field test in apple	4 × 0.75, 4 × 0.15 (5-8 d int)	No biologically significant difference from control plot was found	***Aldershof (2000) CGA219417/0974***
Coccinella septempunctata	Tier 1, glass plate	1 × 1.5, 1 × 0.75, 1 × 0.15	100% mortality within 4-days in all treatments	***Halsall (2000) CGA219417/0946***
	2-D extended laboratory test on bean leaves	Rate-response 0.3, 0.45, 0.60, 0.75, 0.9	LR_{50} = 0.888 kg/ha; >50% effect on reproduction at 0.9 kg/ha; no effect on fecundity at 0.75 kg/ha and below	***Halsall (2001) CGA219417/1051***
	Semi-field test on bean plants	2 × 0.6, 2 × 3.0 (7 day int); 4 × 0.09, 4 × 0.45 (7-8 d int)	Mortality >50% at 2 × 3.0 and 2 × 0.6 kg/ha; mortality <50% at 4 × 0.09 and 4 × 0.45 kg/ha. No effect on fecundity at all tested rates (4 × 0.45, 4 × 0.09, 2 × 0.6 kg/ha).	***Kleiner (1999) CGA219417/0899***

[9] EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

Species	Test type	Treatments (kg form./ha) and spray interval	Summarised results [a]	Reference (author, date, Syngenta File No.)
	Semi-field test on apple	4 × 0.45, 4 × 0.09 (7 day interval)	No effects >50%	***van. Stratum (2002) CGA219417/1066***
Chrysoperla carnea	Tier 1, glass plate	1 × 1.5, 1 × 0.75, 1 × 0.15	<50% effect on mortality at 0.15 kg/ha; >50% effect on mortality at 0.75 kg/ha (LR_{50} >0.15<0.75 kg/ha). No effect on reproduction at the two rates tested (0.15 and 0.75 kg/ha)	***Halsall (2000) CGA219417/0969***
	Semi-field test on apple	1 × 0.45; 4 × 0.45 (7 d int)	Both parameters not affected in either treatment scenario	***Bakker (2002) CGA219417/1058***
Orius laevigatus	Semi-field test on quince	2 × 3.0 (4 week int), 4 × 0.45 (7 d int)	>50% effect on mortality and fecundity at 2 × 3.0 kg/ha (unreliable fecundity result); <50% effect on mortality and fecundity at 4 × 0.45 kg/ha.	***Kleiner (1997) CGA219417/0815***
	Semi-field test on apple	2 × 0.6, 2 × 3.0 (11 d int); 4 × 0.45 (7-11 d int)	No effects >50% in any treatment [b]	***Aldershof (1999) CGA219417/0938***
Poecilus cupreus	Tier 1, on sand	1 × 0.9, 1 × 0.45, 1 × 0.09	LR_{50} >0.9 kg/ha; both parameters not affected at any treatment rate	***Grimm (1999) CGA219417/0916***

[a] Endpoints are assessed according to ESCORT 2 (***Candolfi et al. 2001***). For worst-case Tier 1 laboratory tests on inert substrates: LR_{50}/ER_{50} and 50% effect level of any sublethal effects evaluated (the latter are not strictly required by ESCORT 2). For higher tier tests: 50% effects level for lethal or sublethal effects.
[b] There was a 51% corrected mortality after a single application of 3.0 kg/ha, but only 29% mortality after 2 applications of 3.0 kg/ha, and 17% after 2 weeks ageing following application of 2 × 3.0 kg/ha.

Commemt from RMS: The results from the publication of Rogers et al. 2001 "Toxicity of pesticides to Aphelinus mali, the parasitoid of woolly apple aphid" presented in the literature data review (MCA Section 9/05) should be added to the M-CP 10.3.2 of A8637C. Indeed, even if only one rate was tested, it provides complementary information about the effects of formulation on non-target arthropods. Please also provide a detailed summary of this publication.

Response from Syngenta: A detailed summary of this publication has not been provided for the following reasons:

- The research did not follow current EU guidance (ESCORT 2) as the exposure route used in the test was not as described in the standard *Aphidius rhopalosiphi* Tier I test. Filter paper discs were used (as opposed to glass).
- The single application rate used was equivalent to approximately 126 g a.s./ha. This is far lower than that for the proposed GAP and so cannot add any useful information to the risk assessment
- The article would not have undergone a scientific peer-review as it was the derived from conference proceedings
- The geoclimatic region of the origin of *Aphidius mali* is not relevant for the EU

Risk assessment for other non-target arthropods

The risk to non-target arthropods is assessed using the approach recommended in the published ESCORT 2 document (**Candolfi et al. 2001**)[10] and the **EC Guidance Document on Terrestrial Ecotoxicology** [11].

In-field

Exposure

Non-target arthropods living in the crop can be exposed to residues from A8637C by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. A8637C is applied at a maximum rate of 750 g formulation/ha. The maximum in-field exposure (Predicted Environmental Rate, PER) to foliar-dwelling or soil-dwelling organisms is therefore 750 g formulation/ha, assuming the worst-case (contradiction) of 100% crop interception for foliar exposure and 60% crop interception for soil exposure, respectively.

The in-field exposure (predicted environmental residue, PER) is calculated according to ESCORT 2 using the following equation:

$$PER_{in-field} = Application\ \text{rate (g a.s./ha)} \times \text{MAF}$$

The maximum predicted environmental residues (PER) occurring within the field after application of A8637C at the maximum application rate are presented below.

Table 10.3.2-2: In-field PER values for application of A8637C

Crop	Application rate (g/ha)	Foliar exposure		Soil exposure		
		MAF	PER (foliar) g product/ha	MAF	Crop interception (%)	PER (soil) g product/ha
Pome fruit	750	2.3	1725	2.7	60	810

Risk Assessment

The in-field risk to non-target arthropods was assessed by calculating Hazard Quotients (HQs) for the two sensitive indicator species, *T. pyri* and *A. rhopalosiphi*, using the following equation:

$$\text{In - field HQ} = \frac{\text{PER}_{\text{in-field}}\ \text{(mL/ha)}}{\text{LR}_{50}\ \text{(mL/ha)}}$$

The resulting HQ values are presented, to 2 significant figures, in the table below. When using Tier I data the risk is considered to be acceptable if the HQ is less than 2.

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[10] Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R, Vogt H (2000) ‘Guidance Document on regulatory testing procedures for plant protection products with non-target arthropods’ From the workshop, European Standard Characteristics of Non-target Arthropod Regulatory Testing (ESCORT 2) 21-23 March 2000.

[11] EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

Table 10.3.2-3: In-field HQs for non-target arthropods

Crop	Species	LR_{50} (g/ha)	In-field foliar exposure		In-field soil exposure		Trigger value
			PER (g/ha)	HQ	PER (g/ha)	HQ	
Pome fruit	*A. rhopalosiphi*	1420	1725	1.2	810	0.57	2
	T. pyri	>1800		<0.96		<0.45	

All HQ values are below the trigger value indicating acceptable risk to the indicator species. However, although not required by ESCORT 2 guidelines, fecundity was also assessed in the Tier I tests with the standard test species. For the tier I test with *A. rhopalosiphi* there was >50% reduction of parasitism at the lowest rate of 0.6 kg/ha tested by Vinall (2001). For the Tier I test with *T. pyri*, an effect of >50% was observed at 0.45 kg/ha. Using these endpoints for the tier I risk assessment would suggest that there is the possibility of an unacceptable risk as demonstrated in the table below:

Table 10.3.2-4: In-field HQs based on fecundity endpoints for non-target arthropods

Crop	Species	ER_{50} (g/ha)	In-field foliar exposure		In-field soil exposure		Trigger value
			PER (g/ha)	HQ	PER (g/ha)	HQ	
Pome fruit	*A. rhopalosiphi*	600	1725	**2.9**	810	1.4	2
	T. pyri	450		**3.8**		1.8	

In a tier I risk assessment conducted using reproduction endpoints, it is clear that there is potential for adverse effects on foliar-dwelling non-target arthropods following application of A8637C in accordance with proposed uses. Refinement is therefore required.

Laboratory tests have been conducted with other foliar dwelling species, *Coccinella spetempunctata* and *Chrysoperla carnea*, and the soil dwelling beetle *Poecilus cupreus*. In summary:

- For *C. septempunctata* 100% mortality was observed at 150, 750 and 1500 g/ha.
- The LR_{50} for *Chrysoperla carnea* was >150 g/ha <750 g/ha. There were no effects on reproduction at 150 and 750 g/ha (the two rates tested).
- No effects on mortality or feeding behaviour were observed for *P. cupreus* at rates up to and including 900 g/ha. The LR_{50} can be therefore be considered to be >900 g A8637C/ha.

In addition, a Tier II extended laboratory test has been conducted with *C. septempunctata*. The LR_{50} was estimated to be 0.888 kg/ha.

Endpoints from the tests with the foliar dwellers demonstrate adverse effects at rates lower than the relevant PER of 1725 g/ha. Further consideration is therefore given below.

Refined in-field risk assessment

Higher tier tests have been conducted according to the requirements of ESCORT 2 and for convenience are summarised in the table below.

Table 10.3.2-5: In-field risk assessment for foliar applications of A8637C based on results from extended laboratory, semi-field and field studies

Species	Test type	Endpoints	Comments
Aphidius rhopalosiphi	Semi-field test on wheat (Kleiner, 1997)	No effects >50% on parasitisation at 4 × 0.45 kg/ha (2-3 d interval); >>50% effect at 2 × 3.0 kg/ha (7 day interval)	Cannot be used to refine the risk assessment as rates tested are either too low compared to the proposed GAP for A8637C or at the higher tested rates too few applications were made
	Semi-field test on apple (Aldershof, 2000)	No effects >50% on mortality or parasitisation at either 1 × 3 kg/ha or 2 × 3 kg/ha (7 d interval) (fecundity > control for both scenarios)	Cannot be used to refine the risk assessment as rates tested are either too low compared to the proposed GAP for A8637C or at the higher tested rates too few applications were made
Typhlodromus pyri	Field test in apple (Aldershof, 2000)	No statistically significant difference from control plot was found for either 4 × 0.45, 4 × 0.09 g/ha (9-10 d interval)	Cannot be used to refine the risk assessment as rates tested are lower than the proposed GAP for A8637C
	Field test in apple (Aldershof, 2000)	No biologically significant difference from control plot was found for either 4 × 0.75 or 4 × 0.15 (5-8 d interval)	This field test demonstrates no unacceptable effects on population of *T. pyri* when A8637C is applied as a worst case compared to the GAP
Coccinella septempunctata	Semi-field test on bean plants (Kleiner, 1999)	Mortality >50% at 2 × 3.0 and 2 × 0.6 kg/ha; mortality <50% at 4 × 0.09 and 4 × 0.45 kg/ha (7 day interval) No effect on fecundity for all tested scenarios (4 × 0.45, 4 × 0.09, 2 × 0.6 kg/ha, 7-8 day interval).	Cannot be used to refine the risk assessment as rates tested are either too low compared to the proposed GAP for A8637C or at the higher tested rates too few applications were made
	Semi-field test on apple (van. Stratum 2002)	No effects >50% for any scenario (4 × 0.45, 4 × 0.09, 7 day interval)	Cannot be used to refine the risk assessment as rates tested are lower than the proposed GAP for A8637C
Chrysoperla carnea	Semi-field test on apple (Bakker, 2002)	No effects >50% for any scenario (4 × 0.45, 1 × 0.45, 7 day interval)	Cannot be used to refine the risk assessment as rates tested are lower than the proposed GAP for A8637C
Orius laevigatus	Semi-field test on quince (Kleiner, 1997)	>50% effect on mortality and fecundity at 2 × 3.0 kg/ha (unreliable fecundity result); <50% effect on mortality and fecundity at 4 × 0.45 kg/ha (7 day interval)	Cannot be used to refine the risk assessment as rates tested are either too low compared to the proposed GAP for A8637C or at the higher tested rates too few applications were made
	Semi-field test on apple (Aldershof, 1999)	No effects >50% for any scenario 2 × 0.6, 2 × 3.0 (11 d interval); 4 × 0.45 (7-11 d interval)	Cannot be used to refine the risk assessment as rates tested are either too low compared to the proposed GAP for A8637C or at the higher tested rates too few applications were made

[a] There was a 51% corrected mortality after a single application of 3.0 kg/ha, but only 29% mortality after 2 applications of 3.0 kg/ha, and 17% after 2 weeks ageing following application of 2 × 3.0 kg/ha.

The field study conducted by Aldershof (2000), in which no significant effects were apparent following 4 applications of A8637C at 750 g/ha at 5 to 8 day intervals on populations of *T. pyri,* demonstrates no unacceptable effects for this species. As application rates in the other higher tier tests are below the PER, alternative refinement is therefore required.

Further refinement of the in-field risk assessment

According to ESCORT 2, any initial in-field effects are considered acceptable provided that the potential for recovery within one year can be demonstrated. In order to demonstrate potential for recovery, the degradation of foliar and soil residues of A8637C have been modelled using first order degradation kinetics[12], to determine the time after last application when residue levels will fall below the no-unacceptable effect rate. Since it has not been possible to refine the risk to *A. rhopalosiphi* using the higher tier data, the reproduction endpoint of 600 g A8637C could be considered to be the no-unacceptable effect rate. The foliar and soil DT_{50} values for cyprodinil are 4.5 and 284 days respectively. The times taken for foliar and soil residues to fall below the acceptable toxicity threshold of 600 g A787637C/ha are shown in the table below.

Table 10.3.2-6: A8637C effects on non-target arthropods - time taken for residues to fall to an acceptable level.

Use pattern	Exposure surface	Acceptable residue level (g/ha)	DT_{50} (days)	PER after last foliar application (g/ha)	Time after last application at which residues fall to an acceptable level (day)
Pome fruit 3 × 750 g/ha with a 7-day interval	Foliar	600	4.5	781	2

Even when considering this most sensitive endpoint and worst-case degradation, effects in-field demonstrate an acceptable potential for re-colonisation of any affected populations within the one year recovery period stipulated by ESCORT 2. Therefore, even based on this conservative assessment, and using laboratory test data, the potential for recovery is acceptable according to ESCORT 2 guidelines.

An aged residue test has been subsequently conducted with *Aphidius rholalosiphi*. French bean plants were treated at a rate of 750 g A8637C on 3 occasions separated by a 7-day spray interval. Adult wasps were exposed to fresh residues and residues which had been aged for 7 days under rain protection. No effects <50% were observed for either mortality or parasitisation success. Thus, application of A8637C according to the proposed uses resulted in an acceptable in-field risk to *A. rhopalosiphi.*

There still remains the risk to other foliar dwelling predators. There is evidence for *C. carnea*, *C. septempunctata* and *O. laevigatus* that under semi-field conditions there would not be a risk to these species. However, the rates tested (450 g product/ha) and/or the number of applications do not represent the proposed scenario for application of A8637C.

Several tests have been conducted with A8779A, a similar formulation to A8637C. Information on the detailed composition of both A8779A and A8637C can be found in the confidential dossier of this submission (**Document J**). Both formulations contain qualitatively similar ingredients. Quantitatively, A8779A contains more cyprodinil (75% w/w) and accordingly less inert ingredients than A8637C (50% w/w). Due to the low toxic potential of the auxiliaries, the toxic potential of A8637C is considered to be similar to that of A8779A.

A semi-field test was conducted with *Cocinella septempunctata* with A8779A in which broad bean plants were treated twice at a rate of 750 g a.s./ha with a 7-day interval. Bioassays were initiated with fresh residues and residues which had been aged for 14 or 28 days. Pre-imaginal mortality was 18.8, 20.0 and –

[12] $PER_{(t)} = PER_{initial}(e^{-kt})$

Where: t = time elapsed (days) ; $k = \ln(2) / DT_{50}$ in days maginal 10.0% for the 0, 14 and 28 DAT bioassays, respectively. This compares to pre-imaginal mortality in the control of 16.3, 18.0 and 12.5% for the three bioassays respectively. Clearly this demonstrates no adverse effects at a test rate of 750 g a.s./ha, twice the rate to that proposed for A8637C. Clearly from the test conducted with *A. rhopalosiphi* with A8637C, in which 3 applications were applied, there was no accumulation of toxicity.

Evidence that the toxicity does not increase with an increasing number of applications is given in the field test conducted by Oberwalder (1998). Vines were sprayed twice with 1 kg A8779A/ha (750 g a.s./ha). Mean numbers of predatory mites per leaf were 4.22 in the control and 4.60 in the test item treatment 7 days after the first application. Six days after the second application the mean number of mites per leaf were 4.22 in the control and 4.01 in the test item group.

In addition, a laboratory test was conducted with A8779A with *Episyrphus balteatus*. The test item was applied at 1500 g a.s./ha and the pre-imaginal mortality was 21.7% in the group treated with A8779A compared to control mortality of 36.7%. The LR_{50} for this test is therefore >1500 g a.s./ha which is higher than the in-field PER of 862.5 g a.s./ha for A8637C.

In addition, with high margins of safety for the HQ values compared to the trigger, no unacceptable effects are shown off-field (see below), allowing recovery from any initial effects by immigration from source off-field areas.

Conclusion

A8637C poses an acceptable in-field risk to non-target arthropods, according to the proposed use patterns.

<u>**Off-field**</u>

Exposure

Risk assessment of areas immediately surrounding the crop is considered important since these areas represent a natural reservoir for immigration, emigration and reproduction of arthropod populations and provide increased species diversity. Exposure of non-target arthropods living in off-field areas to A8637C will mainly be due to spray drift from field applications. Off-field areas are assumed to be densely vegetated and thus spray drift is unlikely to reach bare ground. Therefore, evaluation of exposure *via* soil residues in off-field areas was not considered. Off-field foliar PER values were calculated from in-field foliar PERs in conjunction with drift values published by the *BBA (2000)*[13] as shown in the following equation:

$$\text{Off-field foliar PER} = \frac{\text{Maximum in-field foliar PER x (\% drift/100)}}{\text{vegetation distribution factor}}$$

<u>Vegetation distribution factor</u>: The model used to estimate spray drift was developed for drift onto a two-dimensional water surface and, as such, does not account for interception and dilution by three-dimensional vegetation in off-crop areas. Therefore, a vegetation distribution or dilution factor is incorporated into the equation when calculating PERs to be used in conjunction with toxicity endpoints derived from two-dimensional (glass plate or leaf disc) studies. A dilution factor of 10 is recommended by ESCORT 2. For 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the

[13] 90^{th} percentile drift according to BBA (2000): Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden

dilution factor of 10 is not used, as any dilution over the 3-dimensional vegetation surface is accounted for in the study design.

The worst case drift value at 3 m distance is 23.96% of the application rate (77th percentile drift). The drift factor (% drift/100) is therefore 23.98/100 = 0.240

The resulting $PER_{off\text{-}field}$ values are shown below.

Table 10.3.2-7: Off-field foliar Predicted Environmental Rates (PER)

Maximum in-field foliar PER [a] (g product/ha)	drift factor (% drift/100)	Vegetation distribution factor	Off-field foliar PER (g product/ha)
1725	0.240	10	41.4

[a] See Table CP 10.3.2-2

Risk Assessment

The off-field risk to non-target arthropods was assessed by calculating Hazard Quotients (HQs) for the two sensitive indicator species, *T. pyri* and *A. rhopalosiphi*, using the following equation:

$$\text{Off-field HQ} = \frac{\text{PER (g/ha)}}{LR_{50}\text{(g/ha)}}$$

The resulting HQ values are presented, to 2 significant figures, in the table below. When using Tier I data the risk is considered to be acceptable if the HQ is less than 2.

Table 10.3.2-8: Off-field HQs for non-target arthropods

Crop	Species	LR_{50} (g/ha)	PER (g/ha)	HQ	Trigger value
Pome fruit	*A. rhopalosiphi*	1420	41.4	0.029	2
	T. pyri	>1800		<0.023	

Both HQ values are below the trigger value indicating acceptable risk to the indicator species. However, although not required by ESCORT 2 guidelines, fecundity was also assessed in the Tier I tests with the standard test species. For the tier I test with *A. rhopalosiphi* there was >50% reduction of parasitism at the lowest rate of 0.6 kg/ha tested by Vinall (2001). For the Tier I test with *T. pyri* of >50% were observed at 0.45 kg/ha. Comparison between these endpoints and the off-field PER is presented in the table below:

Table 10.3.2-9: Off-field HQs based on fecundity endpoints for non-target arthropods

Crop	Species	ER_{50} (g/ha)	PER (g/ha)	HQ	Trigger value
Pome fruit	*A. rhopalosiphi*	600	41.4	0.069	2
	T. pyri	450		0.092	

The off-field HQ values are below the trigger value of 2, indicating an acceptable risk.

Conclusion:

A8637C poses an acceptable off-field risk to non-target arthropods, according to the proposed use patterns.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Standard studies on non-target arthropods are routinely carried out on the representative formulation to represent the active substance, and therefore these are presented in **M-CA Section 8**. The tests have been performed with the standard species (*A. rhopalosiphi* and *T. pyri*) and endpoints are summarised in Table 10.3.2-1 above.

Summaries of laboratory studies carried out with additional species are presented below for ease of reference. All these studies with A8637C were previously submitted.

Report:	K-CP 10.3.2.1/01 Halsall N. (2000) CGA 219417 WG 50 (A8637C) – evaluation of the effects of pesticides on the ladybird beetle *Coccinella septempunctata* in the laboratory. Report No. NVR 044/994132. Huntingdon Life Sciences Ltd., Huntingdon, UK. (Syngenta file No. CGA219417/0946)

Guidelines

Pinsdorf W, BBA Guideline, VI, 23-2.1.5 (1989)

GLP: Yes.

Executive Summary

A8637C was evaluated in a definitive test at rates equivalent to 1.5 kg/ha, 0.75 kg/ha and 0.15 kg/ha, on glass substrate. These treatments were compared to a control of deionised water and a toxic reference treatment of pyrazophos 300 EC.

The test was finished after four days due to 100% mortality in all test item treatments. At this time eight larvae (= 20%) had died in the control group and 20 larvae (= 100%, within 1 day) in the toxic standard group.

A8637C residues on glass at 1.5, 0.75, and 0.25 kg/ha caused 100% mortality of *C. septempunctata* in this Tier 1 laboratory test.

Materials

Test Material:	A8637C
Description:	Brown granules
Lot/Batch #:	609025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	Expiry April 2000
Test rates:	1.5 kg/ha, 0.75 kg/ha and 0.15 kg/ha
Vehicle and control:	Water
Toxic reference:	pyrazophos 300 EC
Spray volume rate:	200 L spray solution/ha
Application method:	calibrated, automatic laboratory spraying equipment (Burkhard Manufacturing Co. Ltd., UK)

Test organisms	
Species:	*Coccinella septempunctata* L. (Coleoptera: Coccinellidae), larvae 2-3 days old at test start
Source:	In-house culture

Food:	*ad libitum* with aphids (*A. pisum*, *R. padi*) at regular intervals
Test substrate:	Glass plates (8 cm × 8 cm). Perspex sheets of the same dimensions but with a hole (∅-5.5 cm) in the centre were laid onto the treated surfaces, and a Fluon treated cylinder (∅-5-cm, 2.5 cm height) was fitted to each perspex sheet forming the test arena for one larvae

Environmental test conditions

Temperature:	20 to 22°C
Humidity:	60 to 76% relative humidity
Photoperiod:	16 h daily photoperiod (505 to 1113 lux)

Study Design and Methods

Experimental dates: 29th July to 10th August 1999.

Larvae impartially selected were individually confined over dry residues of the test item. Per treatment group 40 larvae (toxic standard 20 larvae) were individually exposed. Observations on mortality, behaviour and development were recorded daily. Due to high pre-imaginal mortality, the reproductive performance was not investigated.

Results and Discussion

The test was finished after four days due to 100% mortality in all test item treatments. At this time eight larvae (= 20%) had died in the control group and 20 larvae (= 100%, within 1 day) in the toxic standard group.

Conclusions

A8637C residues on glass at 1.5, 0.75, and 0.25 kg/ha caused 100% mortality of *C. septempunctata* in this Tier 1 laboratory test.

(Halsall N, 2000)

Report:	K-CP 10.3.2.1/02 Halsall N. (2000a) CGA 219417 WG 50 (A8637C) – evaluation of the effects of pesticides on the green lacewing *Chrysoperla carnea* in the laboratory. Report No. NVR 043/994279. Huntingdon Life Sciences Ltd., Huntingdon, UK. (Syngenta file No. CGA219417/0969)

Guidelines

Bigler F, IOBC/WPRS Bulletin XI/4, pp.71-77 (1988)

GLP: Yes.

Executive Summary

A8637C was evaluated in a definitive test at rates equivalent to 1.5 kg/ha, 0.75 kg/ha and 0.15 kg/ha, on glass substrate. These treatments were compared to a control of deionised water and a toxic reference treatment of dimethoate 400 EC.

A8637C at 0.75 and 1.5 kg/ha had a >50% effect on *C. carnea* mortality in this Tier 1 laboratory test on glass. There was no effect on reproduction at 0.75 kg/ha. A8637C at 0.15 kg/ha had no effect >50% on mortality or fecundity.

Materials

Test Material:	A8637C
Description:	Brown granules
Lot/Batch #:	609025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	Expiry April 2000
Test rates:	1.5 kg/ha, 0.75 kg/ha and 0.15 kg/ha
Vehicle and control:	Water
Toxic reference:	dimethoate 400 EC
Spray volume rate:	200 L spray solution/ha
Application method:	calibrated, automatic laboratory spraying equipment (Burkhard Manufacturing Co. Ltd., UK)
Test organisms	
Species:	*Chrysoperla carnea* Steph. (Neuroptera: Chrysopidae), larvae 1-2 days old at test start
Source:	In-house culture
Food:	Larvae were fed *ad libitum* with fresh eggs of the cereal moth *Sitotroga* at regular intervals. The adult lacewings were offered a formulated diet *ad libitum*.
Test substrate:	Glass plates (8 cm × 8 cm). Perspex sheets of the same dimensions but with a hole (∅-5.5 cm) in the centre were laid onto the treated surfaces, and a Fluon treated cylinder (∅-5-cm, 2.5 cm height) was fitted to each perspex sheet forming the test arena for one larvae
Environmental test conditions	
Temperature:	21 to 24°C
Humidity:	52 to 84% relative humidity
Photoperiod:	16 h daily photoperiod (763 to 1985 lux)

Study Design and Methods

Experimental dates: 7th July to 10th September 1999.

Larvae impartially selected were individually confined over dry residues of the test item. The test organisms stayed in the test arenas for 2 to 3 weeks, i.e. until they had finished the larval development. Per treatment group 40 larvae (toxic standard 20 larvae) were individually exposed. Observations on mortality, behaviour and development were recorded daily.

Hardened cocoons (‘pupae’) were transferred to untreated vessels for emergence, separated by treatment. Any lacewings that had not emerged within 21 days of the final pupal formation were recorded as dead. Hatched adults were assigned to untreated oviposition cages (28 × 16 × 10 cm, lined on the upper surface with a fibrous gauze sheet serving as oviposition substrate), ensuring as far as possible that equal numbers were present in each. Four replicate fecundity chambers were established for both the water and the lowest A8637C test group, and two were used for the medium A8637C treatment. Pre-imaginal mortality was too high in the upper A8637C treatment to allow a fecundity assessment. About one week after the emergence of the last adults, the oviposition period started, and then two checks were done weekly for a period of eight weeks. For each check, fresh gauze was put on top of each beaker and replaced after 24 hours. The eggs were counted and up to 100 eggs, collected from each replicate from each treatment at each fecundity assessment, were transferred to a separate box to determine the hatching rate. The viability of these eggs was assessed daily for a period of seven days. Any unhatched eggs were recorded as non-viable after that period. In order to avoid cannibalism of eggs, hatched larvae were removed from the boxes after each assessment. Immediately before introduction of each sheet and their subsequent removal, the number of adults in each box was recorded, dead adults were removed and their sex was determined.

Results and Discussion

Table 10.3.2.1-1: A8637C - effects on survival and reproductive capacity of *C. carnea* in a Tier 1 laboratory test

Treatment group	Mortality (%)	Corrected mortality (%)	Number of eggs per female per day	Fecundity as proportion of control	Number of fertile eggs per female per day	Reproduction as proportion of control	Hatch rate (%)
Control, deion. water	17.5	-	30.20	--	22.45	--	74.3
A8637C, 0.15 kg/ha	20.0	3.0	23.12	0.77	17.52	0.78	75.8
A8637C, 0.75 kg/ha	79.5	75.2	24.72	0.82	20.56	0.92	83.2
A8637C, 1.5 kg/ha	95.0	93.9	n.d.	--	--	--	--
Toxic standard	80.0	-	n.d.	--	--	--	--

n.d. = not determined

No assessment of lacewing fecundity was made for the highest A8637C treatment due to the low number of survivors. For the two lower treatment groups there was no evidence of a treatment effect on fecundity or on egg viability.

Conclusions

A8637C at 0.75 and 1.5 kg/ha had a >50% effect on *C. carnea* mortality in this Tier 1 laboratory test on glass. There was no effect on reproduction at 0.75 kg/ha. A8637C at 0.15 kg/ha had no effect >50% on mortality or fecundity.

(Halsall N, 2000a)

Report:	K-CP 10.3.2.1/03 Grimm C. (1999) Acute toxicity of CGA 219417 WG 50 (A-8637 C) to the predatory ground beetle *Poecilus cupreus* L. (Coleoptera: Carabidae). Report No. 983968. Novartis Crop Protection AG, Basel, Switzerland. (Syngenta file No. CGA219417/0916)

Guidelines

Heimbach U, IOBC/WPRS Bulletin XV/3, pp. 103-109 (1992)

GLP: Yes.

Executive Summary

A8637C was evaluated in a definitive test at a rates equivalent to 90, 450 and 900 g product/ha, on a sand substrate. This treatment was compared to a control of water and a toxic reference treatment of pyrazophos. Survival, behaviour and food consumption was assessed over 14 days.

A8637C at up to 900 g/ha had no effect on *P. cupreus* mortality or behaviour in this Tier 1 laboratory test on sand.

Materials

Test Material:	A8637C
Description:	Beige granules
Lot/Batch #:	609025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	To April 2000
Test rates:	90, 450 and 900 g product/ha
Vehicle and control:	Water
Toxic reference:	pyrazophos
Spray volume rate:	400 L spray solution/ha
Application method:	Calibrated laboratory sprayer (Schachtner)
Test organisms	
Species:	*Poecilus cupreus* L. (Carabidae, Coleoptera), adults 6-7 weeks old at test start
Source:	BTL Bio-Test Labor GmbH, Sagerheide, Germany
Food:	*Calliphora* sp. pupae (blowfly)
Test vessels:	Plastic tray: 17 × 12.5 × 6 cm, covered with a plastic lid permitting gas exchange
Test substrate:	Quartz sand (size: 0.3 to 0.8 mm; 250 g dw)
Environmental test conditions	
Temperature:	18.5 to 22.0°C
Humidity:	62 to 87%
Photoperiod:	16 h daily photoperiod (947 to 1480 lux)

Study Design and Methods

Experimental dates: 11th to 28th June 1999

Adult *Poecilus cupreus* (6 to 7 weeks old) were exposed to fresh spray residues on sand. In addition there was a control group (water) and toxic standard group. The sand was added to each chamber and moistened to 70% of the maximum water holding capacity (MWHC) before placing the beetles and food on the sand surface. Beetles and their food, fly pupae, were oversprayed with a single application. Each treatment group consisted of 5 replicate test chambers, each containing 6 beetles (3 male, 3 female).

Beetles were kept under test conditions and not fed for 3 days prior to the start of the exposure. At test initiation and on test days 2, 4, 7 and 10 the beetles were fed with one fly pupa (*Calliphora* sp.) per living beetle.

The parameters evaluated during the 14 day exposure period (days 1, 2, 4, 7, 10 & 14) were mortality, clinical symptoms and food consumption.

Results and Discussion

Table 10.3.2.1-2: A8637C - effects on *P. cupreus* in a Tier 1 laboratory test on sand

Treatment	Mortality (%)	Average number of fly pupae consumed per beetle per day	Feeding as proportion of control
Control, deionised water	0	0.07 ± 0.01	--
A8637C, 90 g/ha	0	0.08 ± 0.01	1.14

Treatment	Mortality (%)	Average number of fly pupae consumed per beetle per day	Feeding as proportion of control
A8637C, 450 g/ha	0	0.07 ± 0.01	1.0
A8637C, 900 g/ha	0	0.08 ± 0.01	1.14
Toxic standard (pyrazophos)	100	all beetles dead by day 2	--

No adverse effects of the formulation A8637C on mortality and feeding activity were observed, nor were there any behavioural changes.

Conclusions

A8637C at up to 900 g/ha had no effect on *P. cupreus* mortality or behaviour in this Tier 1 laboratory test on sand.

(Grimm C, 1999)

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

Summaries of extended laboratory studies carried out are presented below for ease of reference. All these studies with A8637C were previously submitted.

Report:	K-CP 10.3.2.2/01 Halsall N (2001). CGA219417: a rate-response laboratory test to evaluate the effects of a 500 g/kg formulation (A8637C) on the foliar-active predator, *Coccinella septempunctata*. Report No. SYN-01-31. Mambo-Tox Ltd., Southampton, UK. (Syngenta file No. CGA219417/1051)

Guidelines

Schmuck R *et al*., in: Candolfi *et al*., IOBC, Gent, 45-56 (2000)

GLP: Yes.

Executive Summary

A8637C was evaluated in a definitive test at rates equivalent to 0.90, 0.75, 0.60, 0.45 and 0.30 kg/ha, on bean leaves. These treatments were compared to a control of deionised water and a toxic reference treatment of dimethoate 400 EC.

The LR_{50} of A8637C to *C. septempunctata* on bean leaves in the laboratory was 0.888 kg/ha. Effects >50% on reproduction were observed at 0.9 kg/ha, but there were no apparent effects on fecundity at rates of 0.75 kg/ha and below.

Materials

Test Material:	A8637C
Description:	Light brown extruded granules
Lot/Batch #:	WM910165
Purity:	50.9% w/w cyprodinil
Stability of test compound:	Expiry 03/2003
Test rates:	0.90, 0.75, 0.60, 0.45 and 0.30 kg product/ha
Vehicle and control:	Water

Toxic reference:	dimethoate 400 EC
Spray volume rate:	400 L spray solution/ha
Application method:	Calibrated laboratory sprayer (Azo, NL)

Test organisms

Species:	*Coccinella septempunctata* L. (Coleoptera: Coccinellidae), I-II instar larvae 3 days old at test start
Source:	In-house culture
Food:	*ad libitum* with pea aphids at regular intervals
Test substrate:	Bean leaves. Following the treatment, a leaf was placed with the treated side upwards on a glass plate (7.5 × 7.5 cm), and a Perspex sheet of the same dimensions but with a hole (∅-5 cm) in the centre was laid on top, and a Fluon treated cylinder (∅-4.4-cm, 2.5 cm height) was fitted into the hole in the Perspex sheet, which then served as the test arena for one larvae with the leaf forming the bottom. The petiole of the leaf was wrapped in wet cotton wool to slow down wilting.

Environmental test conditions

Temperature:	21 to 26°C
Humidity:	33 to 96% relative humidity
Photoperiod:	16 h daily photoperiod (2800 to 5200 lux)

Study Design and Methods

Experimental dates: 30th May to 17th September 2001.

Impartially selected larvae were individually confined over dry residues, which had been sprayed onto bean leaves. 40 larvae were individually exposed per treatment group. Observations on mortality, behaviour and development were recorded daily through pupation of larvae. Pupae were transferred to separate untreated hatching boxes for each treatment. The number of successfully emerging beetles was recorded daily. Emerged beetles were separated from the pupae to fresh boxes, and regularly provided with food (aphids) and water.

Egg-laying was noted approximately 4 weeks after onset of adult emergence. The sex of the beetles was determined, and all available females in the control and test item treatments were placed in individual Petri dishes (∅-9-cm) with dry tissue paper offered as oviposition substrate. Beetles were fed daily with pea aphids. Males were confined with the females where numbers allowed, and were moved between the dishes once during the fecundity assessment. The egg-laying activity was then monitored daily for two weeks, and eggs laid were counted and removed to separate Petri dishes for the assessment of viability.

Results and Discussion

Table 10.3.2.2-1: A8637C - effects on mortality and fecundity of *C. septempunctata* in an extended laboratory test

Treatment	Pre-imaginal mortality (%)	Corrected mortality (%)	Eggs per female per day (mean)	Viability (%)	Viable eggs per female per day	Viable eggs as proportion of control
Water control	2.5	--	7.1	74.9	5.3	--
A8637C, 0.30 kg/ha	12.8	10.6	10.8	67.8	7.3	1.38
A8637C, 0.45 kg/ha	15.0	12.8	8.5	77.0	6.5	1.23

A8637C, 0.60 kg/ha	32.5	30.8	13.8	67.5	9.3	1.76
A8637C, 0.75 kg/ha	30.0	28.2	10.6	66.3	7.0	1.32
A8637C, 0.90 kg/ha	55.0	53.8	2.4	44.1	1.1	0.21
Toxic standard	87.5	87.2	--	--	--	--

The LR_{50} was calculated at 0.888 kg/ha (95% confidence limits 0.78 – 1.077 kg/ha). The reproductive efficiency of ladybirds was affected only in the 0.9 kg/ha treated group, compared to both the control group and the acceptability criteria given in the guideline, i.e. ≥ 2 viable eggs per female per day.

Conclusions

The LR_{50} of A8637C to *C. septempunctata* on bean leaves in the laboratory was 0.888 kg/ha. Effects >50% on reproduction were observed at 0.9 kg/ha, but there were no apparent effects on fecundity at rates of 0.75 kg/ha and below.

(Halsall N, 2001)

Report:	K-CP 10.3.2.2/02 Stevens J. (2016), Cyprodinil WG (A8637C) – Aged-residue extended laboratory tests to determine effects on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). Report Number SYN-16-40. Mambo-Tox Ltd. 2 Venture Road, University Science Park, Southampton SO16 7NP, United Kingdom (Syngenta file No. A8637C_10377).

Guideline: Mead-Briggs *et al* An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (2009)

GLP: Yes

Executive Summary

The effects of fresh and outdoor-aged residues of A8637C on the parasitic wasp, *Aphidius rhopalosiphi*, were evaluated in extended laboratory tests. Following application to french bean plants at a rate of 750 g product/ha on three occasions, with a 7-day interval between each application, bioassays were initiated on both fresh (0-day-old) and 7-day-old foliar residues. In both bioassays, A8637C resulted in < 50% effects on both the survival and reproductive capacity of the wasps.

Materials

Test Material	A8637C Cyprodinil WG (50)
Lot/Batch #:	SMO2C304
Actual content of active ingredient:	50.2% w/w (502 g/kg)
Description:	Brownish granules
Stability of test compound:	Stable under standard conditions.
Recertification date:	31 December 2016

Treatments

Test rate:	750 g product/ha
Control:	Purified water

Toxic standard:	BAS 152 11 I (nominally 400 g dimethoate/L) in purified water, applied at a rate of 60 mL product/ha in 400 L water/ha
Spray volume rate:	400 L spray solution/ha
Application method:	Laboratory track sprayer
Number of applications:	3 (times T1, T2 and T3) for A8637C and the control; 1 for the toxic reference
Spray interval:	7 days

Test organisms

Species:	*Aphidius rhopalosiphi* De Stefani-Perez. (Hymenoptera: Braconidae).
Age:	< 48 hours
Source:	Culture maintained at Test Facility (originally: Katz Biotech AG, Baruth, Germany)
Feeding:	1:3 v/v solution of honey

Test design - Mortality phase

Arenas:	Treated french bean leaf discs held in circular frames made from clear acrylic tubing (these were of approx. 5.1 cm internal diameter and 15 mm deep). Holes (8 mm diameter) had been drilled through the side wall of the frame to provide ventilation.
Replication:	4
No. of wasps/arena :	10

Test design - Fecundity phase

Arenas:	Pots containing barley seedlings (> 100 adults and nymphs of a mixed cereal aphid culture containing *M. dirhodum* and *R. padi*) The wasps were confined over the pots of plants using clear acrylic cylinders (9 cm diameter, 20 cm high), the tops of which were covered with nylon netting.
Replication:	15
No. of wasps/arena :	1
Duration of test:	13 days for each bioassay

Environmental test conditions

Temperature:	0 DAT bioassay: Mortality assessment phase: 21-22ºC 0 DAT bioassay: Fecundity assessment phase: 20-22ºC 7 DAT bioassay: Mortality/fecundity assessment phases: 21ºC
Humidity:	0 DAT bioassay: Mortality assessment phase: 65-73% 7 DAT bioassay: Mortality assessment phase: 70-76%
Photoperiod:	0 DAT bioassay: Mortality assessment phase: 16 h photoperiod (1094 lux). 0 DAT bioassay: Fecundity assessment phase: 16 h photoperiod (5514 lux). 7 DAT bioassay: Mortality assessment phase: 16 h photoperiod (1204 lux). 7 DAT bioassay: Fecundity assessment phase: 16 h photoperiod (5220 lux).

Study Design and Methods

Experimental dates: 3rd August to 6th September 2016

Treatments were applied to french bean plants. After the spray treatments had been applied, the plants were moved away from the spray area and once dry the leaves needed for the 0 DAT bioassay were removed. Treated plants were protected from rainfall by being placed under a suspended sheet of polythene permeable to most wavelengths of light including UV, once dry were used to construct the arenas.

Once residues had dried on the freshly-sprayed plants (i.e. within 1 hr of treatment for the bioassay initiated at 0 DAT), and for the 14 DAT bioassay, leaves were removed and returned to the laboratory for the preparation of the test arenas. The wasps were introduced to the arenas and their behaviour and mortality was assessed 2, 24 and 48 h later.

To assess any sub-lethal effects, reproduction assessments were then carried out for each bioassay. Female wasps were confined individually over untreated aphid-infested barley plants for 24 h, before being removed. The plants were left for a further 10 days before the number of aphid mummies that had developed on plants where wasps had been found alive after the 24-h oviposition period was recorded.

The percentage mortality of the insects in the bioassay over 48 h was calculated. Mortality was defined as the numbers of moribund and dead insects combined. The corrected percentage mortality (taking into account any control treatment losses) was derived using Abbott's formula. Where there was treatment mortality at 48 h, this was compared to the control using Fisher's Exact Test ($\alpha = 0.05$).

For each bioassay, a square root transformation was carried out on the numbers of mummies produced per female found *alive* after the 24-h parasitism period. The data from each treatment were checked for normality of distribution (Shapiro-Wilk test, $\alpha = 0.05$) and then analysed by t-test for independent samples ($\alpha = 0.05$).

Results and Discussion

Mortality and reproduction are summarised in the table below.

Table 10.3.2.2-2: Effects of fresh and aged-residues of A8763C on mortality and reproduction of *Aphidius rhopalosiphi*, when exposed under extended laboratory test conditions.

Treatment	Mean % mortality at 48 h [a]	Corrected mean % mortality at 48 h [b]	Number females successfully assessed for reproduction	Mean number mummies per surviving female [c]	% Effect on reproduction compared to control (R-value) [d]
0 DAT bioassay			-		
Control	2.5	-	14	34.9	-
A8637C, 3 x 750 g/ha	7.5	5.1	13	33.6	3.6
Toxic reference	100 *	100	-	-	-
7 DAT bioassay					
Control	0.0	-	14	19.4	
A8637C, 3 x 750 g/ha	5.0	5.0	14	21.1	-8.8

a The results for the individual treatments were compared to the control using Fisher's Exact Test ($\alpha = 0.05$). Significant differences are indicated by an asterisk (*).
b Corrected mortalities were calculated using Abbott's formula.
c For each bioassay, results for individual treatments were compared by independent samples t-test ($\alpha = 0.05$), but there were no significant differences.
d Percentage effect on reproduction. A positive value indicates a decrease, a negative value an increase, relative to the control.

Validity criteria

The validity criteria for the test were met since:

- Mortality within the control treatment at 48 hours was 2.5% for the 0 DAT bioassay and 0.0% for the 7 DAT bioassay (should not exceed 13% (i.e. 5 wasps from 40).

- Mortality within the toxic-reference treatment at 48 hours in the 0 DAT bioassay was 100 % (should exceed 50%).

Conclusions

The effects of fresh and outdoor-aged residues of A8637C on the parasitic wasp, *Aphidius rhopalosiphi*, were evaluated in extended laboratory tests. Following application to french bean plants at a rate of 750 g product/ha on three occasions, with a 7-day interval between each application, bioassays were initiated on both fresh (0-day-old) and 7-day-old foliar residues. In both bioassays, A8637C resulted in < 50% effects on both the survival and reproductive capacity of the wasps.

(Stevens J, 2016)

CP 10.3.2.3 Semi-field studies with non-target arthropods

Summaries of semi-field studies carried out are presented below for ease of reference. All these studies with A8637C were previously submitted.

Report:	K-CP 10.3.2.3/01 Kleiner R. (1997) CGA 219417 WG 50 (A-8637 C): testing toxicity to beneficial arthropods – cereal aphid parasitoid – *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) – semifield. Report No. 971048023. BioChem GmbH, Germany. (Syngenta file No. CGA219417/0813)

Guidelines

Mead-Briggs M, Aspects Appl. Biol. 31, 179-189 (1992); Mead-Briggs M, Manuscript (1994); Naton E & Hassansada MK, IOBC/WPRS Bulletin XI/4, 111-118 (1988).

GLP: Yes.

Executive Summary

Aphidius rhopalosiphi (circa 2 days old post-emergence at release time) were exposed to A8637C residues on wheat (*Triticum aestivum*) plants under semi-field conditions. The four treatment groups used were: deionised water control, toxic standard (dimethoate 400 EC, 0.85 mL/ha), 0.45 kg A8637C/ha (4 treatments at 2 to 3-day intervals), and 3.0 kg A8637C/ha (2 treatments at a 7-day interval).

A8637C at 4 × 0.45 kg/ha (2-3 day interval) had no effect on *A. rhopalosiphi* fecundity in this semi-field test on wheat. A8637C at 2 × 3.0 kg/ha (7-day interval) caused >50% (92%) reduction in fecundity.

Materials

Test Material:	A8637C
Description:	Beige granules
Lot/Batch #:	501003
Purity:	50.9% w/w cyprodinil
Stability of test compound:	Reanalysis January 1998
Test rates:	A8637C 0.45 kg/ha, 4 applications at 2-3 day intervals; A8637C 3.0 kg/ha, 2 applications at 7 day intervals.
Vehicle and control:	Water (control sprayed only on the last application date)
Toxic reference:	Dimethoate 400 g/L EC applied at 0.85 mL/ha, only at the last application date
Spray volume rate:	300 L/ha

Application method:	Calibrated plot sprayer (agrotop GmbH, D) equipped with customary nozzles
Test organisms	
Species:	*Aphidius rhopalosiphi* (Hymenoptera: Aphidiidae), adults circa 2 days old at start of test
Source:	PK Nützlingszuchten, Welzheim, Germany
Food:	None added
Test substrate:	wheat plants (*Triticum aestivum*)
Environmental test conditions	(Meteorological data obtained from a climate station in the vicinity of the test site)
Temperature:	19 to 23 °C
Humidity:	68 to 80% RH

Study Design and Methods

Experimental dates: 4^{th} to 26^{th} August 1997.

Seedlings of wheat *Triticum aestivum* L. were cultivated in plastic boxes (65 × 40 × 18 cm) filled with natural soil and were infested with cereal aphids shortly after emergence. 24 of these boxes were set up in the field in a gauze tent (4.5 × 4.5 × 2-m; mesh size 2 mm; the roof was covered with an UV-permeable plastic foil to give shelter from rainfall) at a 0.5 m distance from each other and assigned randomly to four treatment groups each comprising 4 replicates. The treatment cycle was started when plants were sufficiently infested with aphids. All applications were performed on a separate plot. Following the applications, the plants were covered with gauze cages (60 × 40 × 30 cm).

About 1 hour after the last application, 10 female and 10 male wasps were introduced into each test cage. After 48 hours, the wasps were removed, and the test cages were maintained for another 13 days in the field. Then the numbers of aphid mummies on the wheat plants of each box were counted, and the parasitisation efficiency in each treatment group was assessed. The aphid density was visually inspected every day afterwards to guarantee an optimum prey supply.

Results and Discussion

Table 10.3.2.3-1: A8637C - effects on fecundity of *A. rhopalosiphi* in a semi-field test on wheat

Treatment	Average number of mummies per female	Fecundity as proportion of control
Control, deionised water	25	--
A8637C, 4 × 0.45 kg/ha	26.2	1.05
A8637C, 2 × 3.0 kg/ha	2.0	0.08
Toxic Standard (dimethoate)	0	0

Conclusions

A8637C at 4 × 0.45 kg/ha (2-3 day interval) had no effect on *A. rhopalosiphi* fecundity in this semi-field test on wheat. A8637C at 2 × 3.0 kg/ha (7-day interval) caused >50% (92%) reduction in fecundity.

(Kleiner R, 1997)

Report:	K-CP 10.3.2.3/02 Aldershof SA. (2000) Residual effects of 2 applications of CHORUS® 50 WG (A-8637 C) on the life history of the parasitic wasp *Aphidius rhopalosiphi* (DiStefani-Perez) determined in a semi-field study on apple. Report No. N016ARS. MITOX, The Netherlands. (Syngenta file No. CGA219417/0965)

Guidelines

Mead-Briggs M, Aspects of Applied Biology 31: 179-189 (1992); Mead-Briggs M *et al*., Draft (1996); Polgar L, Bulletin IOBC/WPRS 1988/XI/4: 29-34 (1988)

GLP: Yes.

Executive Summary

Aphidius rhopalosiphi (circa 2 days old post-emergence at release time) were exposed to A8637C residues at 3.0 kg product/ha on apple trees plants under semi-field conditions. Effects were assessed after a single application and after two applications with a 7 day interval. The exposure phase lasted 2 days. At the end of the exposure period, the test units (including the encaged branch) were removed from the tree and transferred to the laboratory to assess mortality. Surviving female wasps of the control and the A8637C treatments were transferred and kept individually in the laboratory in acrylic cylinders containing untreated aphid-infested barley. Females were allowed to parasitize the aphids during a 1-day period, after which time they were removed from the cylinders. After removal of the adult wasps, the test units were maintained under controlled conditions for an additional 7 to 10 days, after which the number of parasitised aphids was counted.

A8637C at up to 2 × 3.0 kg/ha (7-day interval) had no effect on mortality or reproduction of *A. rhopalosiphi* in this semi-field test on apple.

Materials

Test Material:	A8637C
Description:	Not stated
Lot/Batch #:	609025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	Expiry April 2000
Test rates:	A8637C 3.0 kg/ha, 1 application or 2 applications at 7 day intervals.
Vehicle and control:	Water
Toxic reference:	Dimethoate 400 g/L EC
Spray volume rate:	1200 L/ha, all applications were done to the point of incipient run-off
Application method:	calibrated compression sprayer (Guarany, BRA) equipped with a hollow cone nozzle
Test organisms	
Species:	*Aphidius rhopalosiphi* (Hymenoptera: Aphidiidae), adults circa 2 days old at start of test
Source:	PK Nützlingszuchten, Welzheim, Germany
Food:	Branches pre-selected to attach the test cage were sprayed with a sugar solution (BEE FIT® HM diluted with deionized water 1:1 v/v) 2-hours before treatment in trial (i) and after treatment in trial (ii).
Test substrate:	Apple trees
Environmental test conditions	(measured regularly during the exposure period with an electronic device inside a gauze cage of one of the replicate units; in the laboratory for the

	fecundity phase)
Temperature:	Exposure (semi-field), 13 to 27 °C
	Fecundity (laboratory), 19 to 22°C
Humidity:	Exposure (semi-field), 47 to 98% RH
	Fecundity (laboratory), 69 to 75% RH
Lighting:	Fecundity (laboratory), 16 hour daily photoperiod (2800 to 3900 lux)

Study Design and Methods

Experimental dates: 13th July to 4th September 1998.

Apple trees (1.5 to 2 m height) grown in plastic containers (23 L) were used as exposure units. For each treatment group five replicate units (1 replicate unit = one tree) were used and placed in a tunnel greenhouse in the field. The tunnel (6.2 m at the base, 12 m length, 2.7 m height in the middle) was fitted with Mevolux EVA UV transparent covering (to prevent wash-off of residues from plants), and had ventilation openings (50 cm long) at 1 m height along both long sides. During warm weather the tunnel was ventilated. The actual applications were done outside the tunnel at a sheltered place.

The test organisms (impartially selected from the holding dishes) were released on fresh residues within 1 to 3 hours after the first and second application. The wasps were confined to apple tree branches in bag-shaped gauze covers (∅ 27 cm, 80 cm length; 0.3-mm mesh size; held in shape around the branch by a cylindrical iron construction) in groups of 25 individuals in 5 replicates (i.e. 125 individuals per treatment group). The exposure phase lasted 2 days. At the end of the exposure period, the test units (including the encaged branch) were removed from the tree and transferred to the laboratory to assess mortality.

Surviving female wasps of the control and the A8637C treatments were transferred and kept individually in the laboratory in acrylic cylinders containing untreated aphid-infested barley. Females were allowed to parasitize the aphids during a 1-day period, after which time they were removed from the cylinders. After removal of the adult wasps, the test units were maintained under controlled conditions for an additional 7 to 10 days, after which the number of parasitised aphids was counted.

Results and Discussion

Table 10.3.2.3-2: A8637C - effects on survival and fecundity of *A. rhopalosiphi* in a semi-field test on apple

Treatment	Mortality after 48 h (%)	Corrected mortality (%)	Average number of mummies per female	Reproduction as proportion of control
Control, deionised water	13 ± 4.0	--	9 ± 6.4	--
A8637C, 1 × 3.0 kg/ha	25 ± 15.8	13	11 ± 7.0	1.23
Toxic Standard (dimethoate)	98 ± 2.3	98	--	--
Control, deionised water	6 ± 10.8	--	5 ± 3.5	--
A8637C, 2 × 3.0 kg/ha	10 ± 6.7	4	8 ± 7.1	1.52
Toxic Standard (dimethoate)	98 ± 2.2	97	--	--

Survival of parasitic wasps exposed to A8637C was not affected by either application scenario. The same was true for the parasitic efficiency, i.e. the reproductive performance.

Conclusions

A8637C at up to 2 × 3.0 kg/ha (7-day interval) had no effect on mortality or reproduction of *A. rhopalosiphi* in this semi-field test on apple.

(Aldershof S, 2000)

Report:	K-CP 10.3.2.3/03 Kleiner R 1999. Toxicity of CGA 219417 50 WG (A8637C) to *Coccinella septempunctata* L. under semi-field conditions. Report No. 981048070. BioChem agrar, Germany. (Syngenta file No. CGA219417/0899)

Guidelines

Schmuck R *et al*., J. Appl. Ent. 121: 111-120 (1997); Bigler F & Waldburger M, IOBC/WPRS Bulletin XI/4, 127-133 (1988)

GLP: Yes.

Executive Summary

Second instar larvae of *Coccinella septempunctata* were exposed to treatments on broad bean plants in outdoor cages. The six treatment groups used were: deionised water control, toxic standard (dimethoate 400 EC, 0.85 L/ha), 0.09 kg A8637C/ha (4 treatments at 7 to 8-day intervals), 0.45 kg A8637C/ha (4 treatments at 7 to 8-day intervals), 0.6 kg A8637C/ha (2 treatments at a 7-day interval), and 3.0 kg A8637C/ha (2 treatments at a 7-day interval). The water control was treated on all the application dates, whereas the toxic standard was sprayed only on the last application date.

From the beginning of pupation the numbers of pupated larvae were recorded daily until all larvae had pupated. Afterwards the pupae were transferred to separate untreated hatching boxes for each treatment, which were placed in an environmental controlled room in the laboratory. The number of hatched beetles was counted daily, until by day 43 after start of exposure the last beetle hatched, and the total pre-imaginal mortality in each treatment group was assessed. Reproduction of surviving beetles was assessed in the laboratory.

A8637C at 2 × 0.6 and 2 × 3.0 kg/ha (7 day interval) caused >50% corrected mortality, whereas A8637C at 4 × 0.09 or 4 × 0.45 kg/ha (7-8 day interval) did not. No effects on reproduction of surviving females were observed in any of the tested treatments (4 × 0.09 kg/ha, 4 × 0.45 kg/ha, 2 × 0.6 kg/ha). The reproductive efficiency of surviving ladybirds was also above the acceptability criteria given in the test guideline, i.e. ≥-2 viable eggs per female per day.

Materials

Test Material:	A8637C
Description:	Tan granules
Lot/Batch #:	6009025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	Reanalysis April 2000
Test rates:	0.09 kg A8637C/ha (4 treatments at 7 to 8-day intervals) 0.45 kg A8637C/ha (4 treatments at 7 to 8-day intervals) 0.6 kg A8637C/ha (2 treatments at a 7-day interval) 3.0 kg A8637C/ha (2 treatments at a 7-day interval)
Vehicle and control:	Water (at each application date)

Toxic reference:	Dimethoate 400 EC at 0.85 L/ha, on the last application date only
Spray volume rate:	300 L/ha
Application method:	calibrated plot sprayer (Agrotop GmbH, D) equipped with customary nozzles
Test organisms	
Species:	*Coccinella septempunctata* L. (Coleoptera: Coccinellidae), II-instar larvae 3-4 days old at test start
Source:	in-house culture, from a field population collected in the vicinity of the laboratory in summer 1997
Food:	Pea aphids
Test substrate:	Broad bean plants (*Vicia faba*)
Environmental test conditions	
Temperature:	Exposure phase (from a nearby climate station): 3.5 to 24.6°C Reproduction phase (laboratory): 20 to 26°C
Humidity:	Exposure phase: 43 to 89% relative humidity Reproduction phase: 60 to 86% relative humidity
Rainfall:	Exposure phase: 200 mm during the entire period, 6 weeks prior to start of exposure and 6 weeks exposure time.
Photoperiod:	Reproduction phase: 16 hour daily photoperiod (circa 1300 lux)

Study Design and Methods

Experimental dates: 11th August to 26th November 1998.

Seedlings of the bean *Vicia faba* L. were cultivated in plastic boxes (65 × 40 × 18 cm) filled with natural soil. 24 of these boxes were set up in the field in a gauze tent (4.5 × 4.5 × 2-m; mesh size 2 mm; the roof was covered with an UV-permeable plastic foil to give shelter from rainfall) at a 0.5-m distance from each other, and assigned randomly to six treatment groups, each comprising 4 replicates. During the treatment and the subsequent exposure period, the bean plants were kept at a height of 20 to 25 cm by cutting new leaves and shoots before each application and thereafter at weekly intervals, taking care that all treated plant parts remained during the entire period. All applications were performed on a separate plot.

About 1 hour prior to the last application, 25 *Coccinella* larvae were introduced into each test cage. Afterwards a plastic frame (60 × 40 × 25 cm with inward sloping upper edges to prevent escape of larvae) was put on each box and pressed slightly into the soil. During the application the frame was removed. When the spray deposits had dried the bean plants were infested with pea aphids as food for the larvae. The aphid density was visually inspected every day to guarantee an optimum prey supply. From the beginning of pupation the numbers of pupated larvae were recorded daily until all larvae had pupated. Afterwards the pupae were transferred to separate untreated hatching boxes for each treatment, which were placed in an environmental controlled room in the laboratory. The number of hatched beetles was counted daily, until by day 43 after start of exposure the last beetle hatched, and the total pre-imaginal mortality in each treatment group was assessed.

Surviving beetles from each replicate were transferred to 2 L glass beakers (covered with gauze) for oviposition assessment. The sex of the beetles was determined, and if necessary for getting a similar sex ratio, males were exchanged between replicates of the same treatment. Folded strips of black plastic were added as oviposition substrates and were checked daily for eggs. Egg clutches were removed, the number of eggs was recorded, and then the eggs were transferred into separate Petri dishes in order to check the hatchability of larvae. During the 39-day oviposition period, adult beetles were fed with aphids *ad libitum*.

Results and Discussion

Table 10.3.2.3-3: A8637C - effects on mortality and fecundity of *C. septempunctata* in a semi-field test on beans

Treatment	Pre-imaginal mortality (%)	Corrected mortality (%)	Mean number of eggs per female per day	Viability (%)	Mean number of viable eggs per female per day	As proportion of control
Water control	27	--	3.8	74	2.8	--
A8637C, 4 × 0.09 kg/ha, 7-8 day interval	55	38.4	5.6	77	4.2	1.50
A8637C, 4 × 0.45 kg/ha, 7-8 day interval	60	45.2	5.9	76	4.5	1.60
A8637C, 2 × 0.60 kg/ha, 7 day interval	78	69.9	5.1	66	3.4	1.21
A8637C, 2 × 3.0 kg/ha, 7 day interval	100	100	--	--	--	--
Toxic standard	100	100	--	--	--	--

Conclusion

A8637C at 2 × 0.6 and 2 × 3.0 kg/ha (7 day interval) caused >50% corrected mortality, whereas A8637C at 4 × 0.09 or 4 × 0.45 kg/ha (7-8 day interval) did not. No effects on reproduction of surviving females were observed in any of the tested treatments (4 × 0.09 kg/ha, 4 × 0.45 kg/ha, 2 × 0.6 kg/ha). The reproductive efficiency of surviving ladybirds was also above the acceptability criteria given in the test guideline, i.e. ≥-2 viable eggs per female per day.

(Kleiner R, 1999)

Report:	K-CP 10.3.2.3/04 van Stratum P (2002). Residual effects of multiple applications of CGA219417 (A8637C) on the life history of the ladybird, *Coccinella septempunctata* (Coleoptera: Coccinellidae) determined in a semi-field study on apple. Report No. S007CSS. MITOX, The Netherlands. (Syngenta File No. CGA219417/1066)

Guidelines

Pinsdorf W, BBA Guideline, VI, 23-2.1.5 (1989); Schmuck R *et al*., in: Candolfi *et al*., IOBC, Gent, 13-27 (2000)

GLP: Yes.

Executive Summary

Second instar larvae of *Coccinella septempunctata* were exposed to treatments on apple trees under semi-field conditions. A8637C was applied four times at 0.45 and 0.09 kg product/ha with a 7 day interval. To ensure a worst-case test situation, all applications were done to the point of incipient run-off. A bioassay was initiated within 4 hours after the last application, including also a deionized water control (applied at all treatment dates) and a toxic standard (dimethoate 400 EC; rate: 1 L/ha; applied only at the last treatment date). During the exposure phase and between the four treatment applications, trees were placed in a tunnel greenhouse in the field. The exposure phase lasted for 17 days, and was terminated when the first adults were observed. Reproduction of surviving adults was assessed in the laboratory.

A8637C applied to apple trees at 4 × 0.09 or 0.45 kg/ha (7 day interval) had no effects >50% on mortality or reproduction of *C. septempunctata*.

Materials

Test Material:	A8637C
Description:	Not stated
Lot/Batch #:	WM910165
Purity:	50.9% w/w cyprodinil
Stability of test compound:	Expiry March 2003
Test rates:	0.09 kg A8637C/ha (4 treatments at 7 day intervals) 0.45 kg A8637C/ha (4 treatments at 7 day intervals)
Vehicle and control:	Water (at each application date)
Toxic reference:	Dimethoate 400 EC at 1.0 L/ha, on the last application date only
Spray volume rate:	1000 L/ha
Application method:	Calibrated compression sprayer (Breedveld Trading Holland, Mierlo, NL) equipped with a hollow cone nozzle
Test organisms	
Species:	*Coccinella septempunctata* L. (Coleoptera: Coccinellidae), I to II-instar larvae 3-4 days old at test start
Source:	PK-Nützlingszuchten, Welzheim, Germany
Food:	During the exposure time, larvae were regularly fed with heavily aphid infested bean tips, and additionally with *Ephestia* eggs that were glued with a honey dilution to small pieces of paper. During the reproduction test, they were regularly fed with aphids on bean plants, a commercial sugar solution (BeeFit® HM) and a mixture of walnut and apple pollen.
Test substrate:	Apple trees
Environmental test conditions	
Temperature:	Exposure phase (electronic device inside the tunnel): 12 to 34°C Reproduction phase (laboratory): 24.3±2°C
Humidity:	Exposure phase: 40 to 100% relative humidity Reproduction phase: 64±2% relative humidity
Photoperiod:	Reproduction phase: 16 hour daily photoperiod (2000 to 3500 lux)

Study Design and Methods

Experimental dates: 16th July to 15th November 2001.

Apple trees (1 year old) grown in plastic containers were used as exposure units. A bioassay was initiated within 4 hours after the last application. Five trees were used per treatment group except the toxic standard where 1 tree died leaving only four replicates. During the exposure phase and between the four treatment applications, trees were placed in a tunnel greenhouse in the field. The tunnel (6.2 m wide at the base, 12 m length, 2.7-m height in the middle) was fitted with Mevolux EVA UV transparent covering (to prevent wash-off of residues from plants), and had ventilation openings (50 cm long, covered with gauze) at 1 m height along both long sides. During warm weather the tunnel was ventilated. The actual applications usually were done outside the tunnel at a sheltered place, or if not possible due to technical reasons, spatial arrangements ensured that trees of different treatments were not cross-contaminated. To ensure a worst-case test situation, all applications were done to the point of incipient run-off.

The test organisms (impartially selected from the hatching dishes) were released to fresh residues within 4 hours after the last application. Thirty *C. septempunctata* larvae were confined to each apple tree, i.e. 150 individuals per treatment group. Each apple tree was covered with gauze (avoiding contact with the leaves) to prevent ladybirds from escaping, but also to keep predators out of the test system. When large 3rd instar larvae were observed for the first time, black folded papers were placed inside each test unit serving as substrate for pupation. The exposure phase lasted for 17 days, and was terminated when the first adults were observed. The adults of each treatment were transferred to separate maintenance units (to allow for mating), whereas all trees were carefully cut into small pieces and together with the black papers carrying pupae transferred to separate hatch units (10 L plastic boxes) to enable pupae to complete metamorphosis. Maintenance and hatching units were transferred to the laboratory to assess pre-imaginal mortality.

Surviving ladybirds of the control and the A8637C treatments were kept together per treatment in maintenance units. In the second week after the first eggs were observed in the control group, the sex of ladybirds was determined and they were impartially assigned to two to three replicate groups per treatment (no fertility test was performed with the toxic standard) of 4-5 females and 3-5 males per replicate. In order to assess reproduction, black filter papers were added as oviposition substrate and replaced after one day during two subsequent weeks (except Friday and weekends). The number of eggs laid as well as the number and sex of dead adults were assessed at each of these days. Egg clutches were transferred to Petri dishes and after 3 to 6 days the number of not hatched eggs was determined.

Results and Discussion

Table 10.3.2.3-4: A8637C - effects on mortality and reproduction of *C. septempunctata* in a semi-field test on apples

Treatment	Pre-imaginal mortality (% ± SD)	Corrected mortality (%)	Mean number of eggs per female per day per replicate	Viability per replicate (%)	Mean number of viable eggs per female per day per treatment	As proportion of control
Water control	30.4 ± 2.7	--	59 / 74	86/89	57	--
A8637C, 4 × 0.09 kg/ha	35.7 ± 0.9	7.5	38 / 41	90/78	35	0.61
A8637C, 4 × 0.45 kg/ha	33.0 ± 1.7	3.7	45 / 43 / 39	77/87/84	39	0.68
Toxic standard	100 ± 0	100	--	--	--	--

A8637C applied four times at 0.09 or 0.45 kg/ha (7 day interval) had no statistically significant or >50% adverse effect on the survival or reproductive capacity of ladybird beetles exposed to residues immediately after the last application. A high reproductive capacity was found for the control group in this experiment (i.e. 57 fertile eggs per female per day). Reproduction was somewhat lower in the A8637C treatments, 39 fertile eggs per female per day were found in the A8637C group treated at the maximum rate, but the mean egg production in all treatments tested was clearly above the acceptability threshold of 2 fertile eggs/female/day as given in the test guideline.

Conlusion

A8637C applied to apple trees at 4 × 0.09 or 0.45 kg/ha (7 day interval) had no effects >50% on mortality or reproduction of *C. septempunctata*.

(van Stratum P, 2002)

Report:	K-CP 10.3.2.3/05 Bakker F (2002). Residual effects of multiple applications of CGA219417 (A8637C) on the life history of the green lacewing, *Chrysoperla carnea* (Neuroptera: Chrysopidae) determined in a semi-field study on apple. Report No. S006CCS. MITOX, The Netherlands. (Syngenta file No. CGA219417/1058)

Guidelines

Bigler F, IOBC/WPRS Bulletin XI/4, pp.71-77 (1988); Vogt H *et al*. (1999), Laboratory method to test effects of pesticides on larvae of *Chrysoperla carnea*. Draft 4/9; Candolfi M *et al*. (2000), J. Pest Science 73 (6): 141-147

GLP: Yes.

Executive Summary

First to second instar larvae of *Chrysoperla carnea* were exposed to treatments on apple trees under semi-field conditions. A8637C was applied four times at 0.45 kg product/ha with a 7 day interval. To ensure a worst-case test situation, all applications were done to the point of incipient run-off. Bioassays were initiated within 3 hours of application on the days of 1st and 4th application. All bioassays included a deionized water control, and in the two tests with fresh residues a toxic standard (dimethoate 400 EC; rate: 1 L/ha) was used. Additionally, a bioassay was started 2 weeks after the last treatment to test the effect of aged residues of A8637C. During the exposure phase and during ageing of residues, trees were placed in a tunnel greenhouse in the field. The exposure phase lasted for at least three weeks, and was terminated when the first adults were observed. Reproduction of surviving adults was assessed in the laboratory.

A8637C at 4 × 0.45 kg/ha (7 day interval) had no unacceptable (>50%) effects on *C. carnea* mortality or fecundity in this semi-field test on apple.

Materials

Test Material:	A8637C
Description:	Not stated
Lot/Batch #:	WM910165
Purity:	50.9% w/w cyprodinil
Stability of test compound:	Expiry March 2003
Test rates:	0.45 kg A8637C/ha (4 treatments at 7 day intervals)
Vehicle and control:	Water (at each application date)
Toxic reference:	Dimethoate 400 EC at 1.0 L/ha
Spray volume rate:	1000 L/ha
Application method:	Calibrated compression sprayer (Breedveld Trading Holland, Mierlo, NL) equipped with a hollow cone nozzle
Test organisms	
Species:	*Chrysoperla carnea* (Chrysopidae); Age: 1st to 2nd instar larvae (3-4 days old) at start of test
Source:	Sautter & Stepper, Ammerbuch, Germany
Food:	During the exposure time, three times per week larvae were supplied with *Ephestia* eggs that were glued with a honey dilution to small pieces of paper. During the reproduction test, the lacewings were regularly fed with a species-specific formulated diet.
Test substrate:	Apple trees

Environmental test conditions

Temperature: Exposure phase (electronic device inside the tunnel): 12 to 34°C
Reproduction phase (laboratory): 24.6±0.2°C

Humidity: Exposure phase: 30 to 100% relative humidity
Reproduction phase: 56±3.9% relative humidity

Photoperiod: Reproduction phase: 16 hour daily photoperiod (400 to 1300 lux)

Study Design and Methods

Experimental dates: 9th July to 29th October 2001.

Apple trees (1 year old) grown in plastic containers were used as exposure units. In each bioassay five trees were used per treatment group. During the exposure phase and during ageing of residues, trees were placed in a tunnel greenhouse in the field. The tunnel (6.2 m wide at the base, 12 m length, 2.7-m height in the middle) was fitted with Mevolux EVA UV transparent covering (to prevent wash-off of residues from plants), and had ventilation openings (50 cm long, covered with gauze) at 1 m height along both long sides. During warm weather the tunnel was ventilated. The actual applications usually were done outside the tunnel at a sheltered place. To ensure a worst-case test situation, all applications were done to the point of incipient run-off.

The test organisms (impartially selected from the holding dishes) were released to fresh residues within 3 hours after the first and last application. Thirty *Chrysoperla* larvae were confined to each apple tree, *i.e.* 150 individuals per treatment group per bioassay. Each apple tree was covered with gauze (avoiding contact with the leaves) to prevent *Chrysoperla* from escaping, but also to keep foreign organisms out of the test system. Approximately one week after the start of exposure, corrugated cardboard was placed inside each test unit serving as substrate for pupation. The exposure phase lasted for a good three weeks, and was terminated when the first adults were observed. The adults of each tree were transferred to separate maintenance units (1.5 L plastic boxes), whereas all trees were carefully cut into small pieces and together with the cardboards carrying pupae transferred to separate hatch units (14 L plastic boxes) to enable pupae to complete metamorphosis. Maintenance and hatching units were transferred to the laboratory to assess pre-imaginal mortality.

Surviving lacewings of the control and the A8637C treatments were kept together per replicate in glass jars. About one week after the first eggs were observed in the control group, the sex of lacewings was determined and at maximum 15 females per treatment (if possible 3 from each replicate) were impartially selected and individually confined in untreated glass jars (∅ 5.8 cm, 7 cm height) for oviposition. The number of eggs laid was assessed during two subsequent 1 day periods. Egg hatch success was determined 5 to 8 days after removal of females from the oviposition substrates.

Results and Discussion

Table 10.3.2.3-5: A8637C - effects on survival and oviposition capacity of *C. carnea* in a semi-field test on apple

Test series	Treatment	Exposure Phase		Reproduction Phase		
		Pre-imaginal mortality (% ± SD)	Corrected mortality (%)	Number of eggs per female per day (mean ± SD)	Proportion of control	Hatching (%)
after 1st application	Deionised water control	48.8 ± 11.3	--	18.2 ± 0.2	--	76
	A8637C, 0.45 kg/ha	31.4 ± 10.1	- 34	18.7 ± 4.4	1.03	96

Test series	Treatment	Exposure Phase		Reproduction Phase		
		Pre-imaginal mortality (% ± SD)	Corrected mortality (%)	Number of eggs per female per day (mean ± SD)	Proportion of control	Hatching (%)
	Toxic standard	81.8 ± 9.6	65	--	--	--
after 4th application	Deionised water control	61.2 ± 14.8	--	18.4 ± 1.3	--	65
	A8637C, 4 × 0.45 kg/ha	54.8 ± 16.7	- 16	15.3 ± 2.1	0.83	78
	Toxic standard	98.6 ± 1.6	98	--	--	--
2 wks after 4th application	Deionised water control	40.0 ± 11.2	--	18.0 ± 3.5	--	86
	A8637C, 4 × 0.45 kg/ha	48.8 ± 2.7	14	18.4 ± 0.2	1.01	87

A8637C applied one or four times at 0.45 kg/ha (7 day interval) had no statistically significant or >50% adverse effect on the survival or reproductive capacity of green lacewings. Uncorrected juvenile mortality had a large non-treatment related component of individuals that could not be retrieved (escape or cannibalism), while at the same time the remaining test organisms were apparently in good condition. As the uncorrected mortality figure was below or close to the acceptability threshold of 50%, and there were no effects on reproduction, the conclusion that A8637C at 4 × 0.45 kg/ha has no unacceptable effect on *Chrysoperla carnea* is considered robust.

Conclusion

A8637C at 4 × 0.45 kg/ha (7 day interval) had no unacceptable (>50%) effects on *C. carnea* mortality or fecundity in this semi-field test on apple.

(Bakker F, 2002)

Report:	K-CP 10.3.2.3/06 Kleiner R. (1997a) CGA219417 WG 50 (A8637C): testing toxicity to beneficial arthropods – predatory bug – *Orius laevigatus* (FIEBER) – semifield. Report No. 971048022. BioChem GmbH. (Syngenta file No. CGA219417/0815)

Guidelines

Sechser, B., proposed guideline (1990)

GLP: Yes.

Executive Summary

A8637C at 2 × 3.0 kg/ha (4-week interval) had >50% on mortality and fecundity of *O. laevigatus* in this semi-field test on quince trees, though the fecundity result was considered unreliable in this treatment. A8637C at 4 × 0.45 kg/ha (7-day interval) had <50% effect on mortality and fecundity.

Materials

Test Material:	A8637C
Description:	Beige granules
Lot/Batch #:	501003
Purity:	50.9% w/w cyprodinil

Stability of test compound:	Reanalysis January 1998
Test rates:	4 × 0.45 kg product/ha, 7 day interval 2 × 3.0 kg product/ha, 4 week interval
Vehicle and control:	Water
Toxic reference:	Dimethoate 400 EC, 0.85 Lha applied on the last treatment day
Spray volume rate:	600 L/ha
Application method:	Knapsack sprayer

Test organisms

Species:	*Orius laevigatus* (FIEBER) 2nd instar nymphs (L_2) 3 to 4 days old at exposure start
Source:	Koppert, The Netherlands
Food:	*Sitotroga* spp. eggs
Test substrate:	Quince leaves

Environmental test conditions

Rainfall:	During the 5-week period there was negligible rainfall.
Temperature:	Exposure phase: 10.6 to 32.5°C Reproduction phase: 22 to 28°C
Humidity:	Exposure phase: 26 to 93% relative humidity Reproduction phase: 73 to 100% relative humidity
Photoperiod:	Reproduction phase: 16 hour daily photoperiod (circa 1000 lux)

Study Design and Methods

Experimental dates: 29th July to 7th September 1997.

Orius insidiosus were exposed under semi-field conditions to applications of A8637C on quince trees. This was compared to a control and a toxic reference treatment.

Two trees (height approximately 2.8 to 3.5 m; distance between trees ca. 3 m) were used for each treatment group. All treatments were done by means of a knapsack sprayer using a spray volume of 1.5 litres per tree, which is equivalent to an overall volume of 600 L/ha for an orchard with 400 trees/ha. Following the final treatment, five exposure cages were fixed in the top of each tree when the spray residues had dried.

The exposure cages consisted of plastic petri dishes (∅ 6 cm) with three gauze covered ventilation holes at the side and one hole on the top closed with a stopper that was used for the introduction of the test organisms and food. Each exposure cage enclosed one leaf. At the start of the test, ten *Orius* larvae were carefully introduced to each cage (i.e. a total of 100 organisms per treatment group), plus some *Sitotroga* eggs as food source. Food was replenished on days 3 and 7. On day 8, when larvae had reached the adult stage, the leaves were cut and the entire exposure cages were transferred to the laboratory where they were dismantled. All bugs alive were recorded and transferred to oviposition cages (glass cylinders: ∅ 15 cm, 20 cm height) containing an oviposition substrate (fresh green beans) and food (*Sitotroga* eggs). For a period of 11 days, the number of eggs laid was recorded daily (exchange of oviposition substrate), together with the number of dead bugs (including determination of sex). The eggs were maintained under controlled climatic conditions for the determination of the hatching rate.

Results and Discussion

Table 10.3.2.3-6: A8637C - effects on survival and oviposition capacity of *O. laevigatus* in a semi-field Test

	Exposure Phase		Fecundity Phase		
Treatment	**Mortality (%)**	**Corrected mortality (%)**	**Number of eggs per female per day**	**Proportion of control**	**Hatching (%)**
Control, water	13	--	3.33	--	83.8
A8637C, 4 × 0.45 kg/ha	43	34.5	2.43	0.73	80.5
A8637C, 2 × 3.0 kg/ha	77	73.6	1.30	0.39	77.2
Toxic standard (ethyl parathion)	100	100	--	--	--

The pre-imaginal mortality of the predatory bugs was significantly increased in both A8637C treatments, though the 50% trigger was exceeded at the 3.0 kg/ha level only. The same result appeared to occur with regard to fecundity. However, the reliability of this result is questionable as only two replicate groups (comprising 4 and 3 females) were used in the oviposition phase for the 3.0 kg/ha treatment, and for one of them the reproductive capacity was 78% in comparison to the control, whereas for the other one no eggs were laid at all.

Conclusions

A8637C at 2 × 3.0 kg/ha (4-week interval) had >50% on mortality and fecundity of *O. laevigatus* in this semi-field test on quince trees, though the fecundity result was considered unreliable in this treatment. A8637C at 4 × 0.45 kg/ha (7-day interval) had <50% effect on mortality and fecundity.

(Kleiner R 1997a)

Report:	K-CP 10.3.2.3/07 Aldershof SA. (1999) Residual effects of multiple applications of CHORUS® 50 WG (A8637C) on the life history of the predatory bug *Orius laevigatus* (Fieber) determined in a semi-field study on apple. Report No. N017OLS. MITOX, The Netherlands. (Syngenta File No. CGA219417/0938)

Guideline

Austin, H. et al. (1997). Guideline for detecting side-effects of pesticides on *Orius laevigatus* in the laboratory. Draft, 02/1997

GLP: Yes.

Executive Summary

A8637C applied to apple trees at up to 4 × 0.45 kg/ha (7-11 day interval) or 2 × 3.0 kg/ha (11 day interval) had no unacceptable (>50%) effects on mortality or fecundity of *O. laevigatus* in this semi-field test.

Materials

Test Material:	A8637C
Description:	Tan granules
Lot/Batch #:	609025

Purity:	51.3% w/w cyprodinil
Stability of test compound:	Expiry April 2000
Test rates:	(i) 4 applications with a 7 to 11-day spray interval at 0.45 kg product/ha (ii) 2 applications with an 11 day spray interval at a rate of 3.0 kg product/ha and 20% of this rate, i.e. 0.6 kg product/ha
Vehicle and control:	Water
Toxic reference:	Dimethoate 400 EC, in parallel to each application
Spray volume rate:	400 L/ha at first application, increasing linearly to 1500 L/ha at the 4th application (with decreasing spray concentration), according to common agricultural practice. To ensure a constant worst-case test situation, all applications were done to the point of incipient run-off.
Application method:	Calibrated compression sprayer equipped with a hollow cone nozzle

Test organisms

Species:	*Orius laevigatus* (FIEBER) 2nd to 3rd instar larvae at exposure start
Source:	Koppert, The Netherlands
Food:	*Ephestia kuehniella* eggs
Test substrate:	Apple leaves

Environmental test conditions

Temperature:	Exposure phase: 11 to 33°C Reproduction phase: 25 to 26°C
Humidity:	Exposure phase: 29 to 98% relative humidity Reproduction phase: 50 to 65% relative humidity
Photoperiod:	Reproduction phase: 16 hour daily photoperiod (120 to 380 lux)

Study Design and Methods

Experimental dates: 13th July to 22nd October 1998.

Test phase I (exposure): Apple trees (1 to 1.5 m height) grown in plastic containers (23 litre) were used as exposure units. For each treatment group (0.45 kg/ha, 0.60 kg/ha and 3.0 kg/ha A8637C, deionised water control; toxic standard (dimethoate 400 EC) five replicate units (1 replicate unit = three trees, except for the toxic standard = only one tree; => a total of 65 trees) were used and placed in a tunnel greenhouse in the field. The tunnel (6.2 m at the base, 12 m length, 2.7 m height in the middle) was fitted with Mevolux EVA UV transparent covering (to prevent wash-off of residues from plants), and had ventilation openings (50 cm long) at 1 m height along both long sides. During warm weather the tunnel was ventilated. The actual applications were done outside the tunnel at a sheltered place. During the aging of residues, the trees were located inside the tunnel.

The test organisms (impartially selected from the holding dishes) were released to fresh residues within 5 to 10 hours after the first and last application. Additionally, a bioassay was started 2 weeks after the last treatment to test the effect of aged residues of A8637C on the predatory bug. *Orius* larvae were confined to apple tree branches in bag shaped gauze covers (∅ 27 cm, 80 cm length; 0.3-mm mesh size; held in shape around the branch by a cylindrical iron construction) in groups of 30 individuals in 5 replicates (i.e. 150 individuals in total). The exposure phase lasted for 9 days. During that time, the bugs were supplied with fresh eggs of *Ephestia kuehniella* 3 to 4 times that were spread out over slightly moistened leaves. At the end of the exposure period, the test units (including the encaged branch) were removed from the tree and transferred to the laboratory to assess pre-imaginal mortality. Temperature and relative humidity were measured regularly during the exposure period with an electronic device inside a gauze cage of one of the replicate units.

Test phase II (reproduction): Surviving bugs of the control and the A8637C treatments were kept together per replicate in glass jars to ascertain that females were mated and developed through their pre-oviposition period. Following that a subset of females (at maximum 15 per treatment, with about equal numbers from each replicate) was transferred and confined individually over untreated cow pea leaf discs in petri-dishes for oviposition. The number of eggs laid was assessed during two subsequent 2 day periods. Egg hatch success was determined 5 to 6 days after removal of females from the oviposition substrates. During the entire time in the laboratory, the bugs were regularly fed with fresh eggs of *Ephestia kuehniella*.

Results and Discussion

Table 10.3.2.3-7: A8637C - effects on survival and oviposition capacity of *O. laevigatus* in a semi-field test

		Exposure Phase		Fecundity Phase		
Test series	**Treatment**	**Pre-imaginal mortality (% ± SD)**	**Corrected mortality (%)**	**Number of eggs per female per day (mean ± SD)**	**Proportion of control**	**Hatching (%)**
after 1st application of 4 × spray with 7-11 day interval scenario	Deionised water control	23 ± 6.8	--	10 ± 1.6	--	91 ± 15.5
	A8637C, 0.45 kg/ha	31 ± 10.5	11	8 ± 4.0	0.83	96 ± 3.6
	Toxic standard	38 ± 16.6	19	--	--	--
after 1st application of 2 × spray with 11 day interval scenario	Deionised water control	30 ± 14.2	--	8 ± 2.5	--	91 ± 9.5
	A8637C, 0.6 kg/ha	34 ± 23.1	4	7 ± 2.9	0.91	96 ± 5.6
	A8637C, 3.0 kg/ha	66 ± 12.9	51	6 ± 4.6	0.82	93 ± 7.4
	Toxic standard	58 ± 12.9	40	--	--	--
after last application	Deionised water control	27 ± 2.4	--	9 ± 3.1	--	88 ± 8.4
	A8637C, 4 × 0.45 kg/ha	25 ± 8.0	- 3	7 ± 3.7	0.71	87 ± 14.8
	A8637C, 2 × 0.6 kg/ha	29 ± 13.0	3	6 ± 3.9	0.59*	88 ± 13.8
	A8637C, 2 × 3.0 kg/ha	48 ± 12.2	29	6 ± 4.2	0.64	89 ± 5.3
	Toxic standard	55 ± 16.8	39	--	--	--
2 weeks after last application	Deionised water control	19 ± 4.8	--	10 ± 3.91	--	95 ± 5.8
	A8637C, 4 × 0.45 kg/ha	17 ± 9.5	-3	9 ± 3.0	0.95	87 ± 26.1
	A8637C, 2 × 0.6 kg/ha	22 ± 7.7	3	9 ± 4.2	0.87	93 ± 4.7
	A8637C, 2 × 3.0 kg/ha	33 ± 6.1	17	9 ± 3.5	0.92	84 ± 18

* significant @p=0.05.

A8637C applied four times at 0.45 kg/ha had no statistically significant effect on the survival or reproductive capacity of predatory bugs exposed to residues after any application. A 51% (corrected) effect on mortality occurred after one application of 3.0-kg/ha, though mortality was only 29% after 2 applications of 3.0 kg/ha and 17% after 2 weeks ageing of residues following 2 applications of 3.0 kg/ha. Thus, it is considered that no unacceptable effects on mortality would occur from this treatment rate, and the >50% (51%) effect after one application is probably an artefact. Oviposition was somewhat lower at all treatment levels in comparison to the control but there were no effects >50%.

Conclusions

Conclusion: A8637C applied to apple trees at up to 4 × 0.45 kg/ha (7-11 day interval) or 2 × 3.0 kg/ha (11 day interval) had no unacceptable (>50%) effects on mortality or fecundity of *O. laevigatus* in this semi-field test.

(Aldershof S, 1999)

CP 10.3.2.4 Field studies with non-target arthropods

Two tests in apples have been conducted to investigate the potential effects of A8637C on predatory mites under natural conditions. These studies with A8637C were previously submitted. However for ease of reference, summaries of these studies are presented below.

Report:	K-CP 10.3.2.4/01 Aldershof S. (2000a) Evaluating effects of CGA219417 WG 50 (A8637C) applications on predatory mites (Acari: Phytoseiidae) in the field (apple orchards, Netherlands). Report No. N031AFA. MITOX Consultants, Amsterdam, Netherlands. (Syngenta file No. CGA219417/0949)

Guidelines

Bakker *et al*., 5th Draft, BFL, Vienna (1999); Heimann-Detlefsen, BBA-Guideline, Teil VI, 23-2.3.4 (1991); Boller *et al*., IOBC/WPRS Bulletin XI/4, 139-143 (1988)

GLP: Yes.

Executive Summary

A8637C applied up to four times at 0.45 kg/ha with an interval of 9 to 10 days had no effect on the predatory mite population in an apple orchard.

Materials

Test Material:	A8637C
Description:	Tan granules
Lot/Batch #:	609025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	Expiry April 2000
Test rates:	A8637C (4 × 0.45 kg/ha), 9-10 day interval A8637C (4 × 0.09 kg/ha), 9-10 day interval
Vehicle and control:	Water
Toxic reference:	Dithane M45 = mancozeb 80% w/w; 2.75 kg product/ha
Spray volume rate:	Nominal 1250 L/ha (500 L/ha per m tree height, 2.5 m high trees); measured was within ±10% of nominal)
Application method:	A calibrated high pressure hydraulic sprayer (Douven™) with a hand lance fitted with a hollow cone nozzle.
Test organisms:	Field population of predatory mites
Crop:	Apple

Study Design and Methods

Experimental dates: 28th April to 20th September 1999.

Test site location: experimental station for fruit crops ”De Schuilenburg”, 4041 BK Kesteren, the Netherlands. Description of the crop: varieties – var. Golden Delicious alternating with var. Gloster. Due to the long history of IPM, the orchard contained a high natural population of phytoseiid mites, particularly *T. pyri* (98%). The tolerance spectrum of the population is limited to cholinesterase inhibitors.

The principle of this study was to apply the test substance according to practical use conditions on apple, and to assess its effect by comparing the predatory mite population in the plots treated with the test substance with the populations in the control plots (toxic standard, water). Four treatment applications were done with a 9 to 10-day interval, i.e. 28th April, 7th May, 13th May and 26th May 1999. The test substance solution was prepared and well homogenized immediately before spraying. The exact amount of spray solution sprayed was determined by measuring the volume of spray solution before and after spraying (for both the test substance and the toxic standard the applied amounts did not vary by more than ± 9% from nominal). The homogeneity of the spray cover was checked with strips of water sensitive paper distributed within each plot. The applications took place under stable weather conditions with moderate wind and no rain. In addition to the protocolled test treatments, routine maintenance measures in the crop (tillage, fertilisation, and spraying using commercial products known not to affect mites) were done according to local practice.

A completely randomized design was used to assign 6 replicate plots to each treatment group except the toxic standard with 3 replicates. Each plot comprised 3 adjacent rows of 5 adjacent trees each, separated by one buffer row. However, only the 5 central trees of each plot were used for evaluation. The population development of predatory mites was assessed in all treatment groups. Eight samplings were conducted in total, just before each application and about 1, 4, 7 and 10 weeks after the last application. At each sampling date, 180 sample items (60 per tree) were randomly selected from 3 trees in the centre of each plot. The leaves were packed in paper bags and transported to the laboratory. Samples were processed immediately or after storage for 2-7 days at 4 °C. Sample material was spread out evenly on a metal grid (mesh size about 2-3 mm) above a funnel with a vial attached to the narrow end, containing 70% ethanol solution. There was one funnel for each pooled sample. Each funnel was placed under a light bulb such that samples gradually desiccated over 3-5 days. After this time, all mites were expected to have moved down to the funnel. The funnel was then flushed with 70% ethanol. Extractions, collected either in alcohol or on the sieves, were transferred with water onto black filter paper in a Büchner funnel. When the liquid was removed, the black paper was examined under a dissection microscope and all mobile stages were counted.

Meteorological data on the dates of application were as follows: 1st application: 21-23°C, wind speed 0.4-1.1 m/sec, 30-60% clouds, 38-55% relative humidity; 2nd application: 16-20°C, wind speed 0.8-3.1 m/sec, 50-80% clouds, 74-81% relative humidity; 3rd application: 15-18°C, wind speed 0.4-1.0 m/sec, 20% clouds, 40-46% relative humidity; 4th application: 20-25°C, wind speed 0.4-1.3 m/sec, 5-20% clouds, 30-45% relative humidity.

Results and Discussion

Table 10.3.2.4-1: A8637C - effects on predatory mites in an apple orchard

Sampling	Predatory mite densities per leaf (mean ± SD)			
	Water control	A8637C 0.45 kg/ha	A8637C 0.09 kg/ha	Toxic standard
1st / just before 1st application	0.34 ± 0.07	0.27 ± 0.09	0.37 ± 0.14	0.73 ± 0.28
2nd / just before 2nd application	0.06 ± 0.01	0.05 ± 0.01	0.06 ± 0.01	0.10 ± 0.02
3rd / just before 3rd application	0.18 ± 0.04	0.17 ± 0.05	0.22 ± 0.07	0.07 ± 0.04
4th / just before 4th application	0.16 ± 0.04	0.13 ± 0.04	0.24 ± 0.09	0.14 ± 0.07
5th / ca. 1 wk after 4th application	0.27 ± 0.03	0.26 ± 0.05	0.31 ± 0.05	0.12 ± 0.04 *
6th / ca. 4 wks after 4th application	0.50 ± 0.06	0.44 ± 0.14	0.43 ± 0.06	0.16 ± 0.11 *
7th / ca. 7 wks after 4th application	1.81 ± 0.22	1.90 ± 0.32	n.d.	n.d.
8th / ca. 10 wks after 4th application	0.98 ± 0.14	0.93 ± 0.04	0.84 ± 0.08	0.41 ± 0.16 *

* significantly different from control ($p < 0.05$); n.d. = not determined

A8637C applied up to four times at 0.45 kg/ha with an interval of 9 to 10 days had no effect on the predatory mite population in an apple orchard. The mean numbers of predatory mites per leaf were similar to the normal fluctuations observed in the water control plots during the entire test period. A clear and statistically significant effect, however, was observed in the plots treated with a toxic standard, thus demonstrating the validity of the test system.

Conclusions

A8637C applied up to four times at 0.45 kg/ha with an interval of 9 to 10 days had no effect on the predatory mite population in an apple orchard.

(Aldershof SA 2000a)

Report:	K-CP 10.3.2.4/02 Aldershof SA. (2000b). Evaluating effects of CGA219417 WG 50 (A8637C) applications on predatory mites (Acari: Phytoseiidae) in the field (apple orchards, Portugal). Report No. N032AFA. MITOX Consultants, Amsterdam, Netherlands. (Syngenta File No. CGA219417/0974)

Guidelines

Bakker *et al*., 5th Draft, BFL, Vienna (1999); Heimann-Detlefsen, BBA-Guideline, Teil VI, 23-2.3.4 (1991); Boller *et al*., IOBC/WPRS Bulletin XI/4, 139-143 (1988)

GLP: Yes.

Executive Summary

A8637C applied up to four times at 0.75 kg/ha with an interval of 5 to 8 days had no biologically significant adverse effect on the predatory mite population in an apple orchard.

Materials

Test Material:	A8637C
Description:	Tan granules

Lot/Batch #:	609025
Purity:	51.3% w/w cyprodinil
Stability of test compound:	Expiry April 2000
Test rates:	A8637C (4 × 0.75 kg/ha), 5-8 day interval A8637C (4 × 0.15 kg/ha), 5-8 day interval
Vehicle and control:	Water
Toxic reference:	Dithane M45 = mancozeb 80% w/w; 2.0 kg product/ha
Spray volume rate:	Nominal 500 L/ha (500 L/ha per m tree height, 1 m high trees); measured was within ±10% of nominal)
Application method:	A calibrated compression sprayer with a hand lance fitted with a hollow cone nozzle.

Test organisms:	Field population of predatory mites
Crop:	Apple

Study Design and Methods

Experimental dates: 13th May 1999 to 28th January 2000.

Test site location: agricultural research station "Centro Experimental de Pegões", Setubal, Palmel, Portugal. Description of the crop: variety – Riscadinha de Palmela; planted in 1990, tree height 1-2 m. The orchard had a 3-year tradition of IPM. *Typhlodromus* was the dominant genus of predatory mites in this orchard (98%). In a sensitivity test, a high sensitivity of the mite population of the test site to organophosphates was demonstrated, and a moderate sensitivity to pyrethroids and dithiocarbamates.

The principle of this study was to apply the test substance according to practical use conditions on apple, and to assess its effect by comparing the predatory mite population in the plots treated with the test substance with the populations in the control plots (toxic standard, water). Four treatment applications were done with a 5 to 8-day interval, i.e. 15th May, 23rd May, 28th May and 3rd June 1999. The test substance solution was prepared and well homogenized immediately before spraying. The exact amount of spray solution sprayed was determined by measuring the volume of spray solution before and after spraying (for both the test substance and the toxic standard the applied amounts did not vary by more than ± 6 % from nominal). The homogeneity of the spray cover was checked with strips of water sensitive paper distributed within each plot. The applications took place under stable weather conditions with moderate wind and no rain. In addition to the protocolled test treatments, routine maintenance measures in the crop (tillage, fertilisation, spraying, using commercial products known not to affect mites) were done according to local practice.

A completely randomized design was used to assign 6 replicate plots to each treatment group except for the toxic standard which had 3 replicates. Each plot comprised 9 adjacent trees in one row or 2-6 adjacent trees in 2 adjacent rows. The outermost two blocks were spaced in 2 rows along the edge of the field. The number of trees in the field did not allow for untreated buffer rows. Therefore, a 3-by-6-m plastic wind screen was used during applications to avoid contamination. The population development of predatory mites was assessed in all treatment groups. Seven samplings were conducted in total, just before each application and about 1, 4 and 7 weeks after the last application. At each sampling date, 432 leaves (2 subsamples of 216 leaves each) per plot of 9 trees were randomly selected. The leaves were packed in paper bags (1 bag per subsample) and transported to the laboratory. One set of subsamples was processed immediately, whereas the other set was stored for 2-5 days at 7°C. Sample material was spread out evenly on a metal grid (mesh size about 2-3 mm) above a funnel with a vial attached to the narrow end, containing 70 % ethanol solution. There was one funnel for each pooled subsample. Each funnel was placed under a light bulb such that samples gradually desiccated over 3-5 days. After this time, all mites were expected to have moved down to the funnel. The funnel was then flushed with 70 % ethanol.

Extractions, collected either in alcohol or on the sieves, were transferred with water onto black filter paper in a Büchner funnel. When the liquid was removed, the black paper was examined under a dissection microscope and all mobile stages were counted.

Meteorological data on the dates of application were as follows: 1st application: 16-20°C, wind speed 0.6-2.9 m/sec, 10-80% clouds, 50-64% relative humidity; 2nd application: 14-27°C, wind speed 0.2-1.3 m/sec, 5-10% clouds, 48-85% relative humidity; 3rd application: 13-27°C, wind speed 0.5-2.5 m/sec, 10-30% clouds, 50-99% relative humidity; 4th application: 11-19°C, wind speed 0.4-1.2 m/sec, 0-90% clouds, 76-91% relative humidity.

Results and Discussion

Table 10.3.2.4-2: Effects of A8637C on predatory mites in an apple orchard

Sampling	Predatory mite densities per leaf (mean ± SD)			
	Water control	A8637C 0.75 kg/ha	A8637C 0.15 kg/ha	Toxic standard
1st / just before 1st application	0.092 ± 0.015	0.074 ± 0.019	0.078 ± 0.015	0.090 ± 0.026
2nd / just before 2nd application	0.088 ± 0.013	0.072 ± 0.012	0.082 ± 0.010	0.086 ± 0.026
3rd / just before 3rd application	0.125 ± 0.011	0.128 ± 0.017	0.115 ± 0.008	0.126 ± 0.016
4th / just before 4th application	0.217 ± 0.016	0.161 ± 0.016 *	0.185 ± 0.013	0.096 ± 0.011 *
5th / ca. 1 wk after 4th application	0.227 ± 0.024	0.213 ± 0.019	0.270 ± 0.036	0.132 ± 0.023 *
6th / ca. 4 wks after 4th application	0.869 ± 0.132	0.664 ± 0.114	0.623 ± 0.130	0.448 ± 0.126
7th / ca. 7 wks after 4th application	1.344 ± 0.190	1.294 ± 0.258	1.054 ± 0.148	0.939 ± 0.192

* significantly different from control ($p < 0.05$)

Though the density of predatory mites on the whole test site was quite low during the application period, it can be stated that A8637C applied up to four times at 0.75 kg/ha with an interval of 5 to 8 days had no biologically significant adverse effect on the predatory mite population in an apple orchard. The mean numbers of predatory mites per leaf were similar to the normal fluctuations observed in the water control plots during the entire test period except at the sampling time following the third application (- 26 %). The difference, however, is considered not test item related, since the density was equal to the control after the fourth application (- 6 %) and during the other post-application samplings. A clear effect, however, was observed in the plots treated with the toxic standard after the third (- 56 %) and fourth application (- 42 %), thus demonstrating the validity of the test system.

Conclusions

A8637C applied up to four times at 0.75 kg/ha with an interval of 5 to 8 days had no biologically significant adverse effect on the predatory mite population in an apple orchard.

(Aldershof S, 2000b)

CP 10.3.2.5 Other routes of exposure for non-target arthropods

No other routes of exposure are considered relevant for non-target arthropods after use of A8637C as recommended.

Relevant Literature on non-target arthropods other than bees

No relevant scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

CP 10.4 Effects on Non-Target Soil Meso- and Macrofauna

Toxicity

Summary of endpoints relevant for the risk assessment:

Table 10.4-1: Table of endpoints for earthworms

Organism	Test item	Test type	Endpoint		Endpoint used for the risk assessment	Reference (author, date, Syngenta File No.)
Earthworm	Cyprodinil (A8779A)	Chronic and reproductive	EU	NOEC = 3.75 kg a.s./ha (≅ 5 mg a.s./kg)	20 mg a.s./kg [b]	***Nienstedt (2001) CGA219417/1029 EC_{10}/EC_{20} estimate Taylor & Joyce (2015) CGA8779A_10235***
			EC_{10}/EC_{20} [a]	Not possible to estimate due to lack of a significant concentration response		
	Cyprodinil (A8779A)		EU	NOEC = 15 kg a.s./ha (≅ 20 mg a.s./kg)		***Ehlers (2001) CGA219417/1028 EC_{10}/EC_{20} estimate Taylor & Pickering (2015) CGA8779A_10237***
			EC_{10}/EC_{20} [a]	Not possible to estimate due to lack of a significant concentration response		
	CGA249287		EU	NOEC = 1.13 mg/kg soil d.w.	NOEC = 1.13 mg/kg	***Pfeifle (2001) CGA249287/0020 Taylor & Pickering (2015) CGA249287_10008***
			EC_{10}/EC_{20} [a]	Not possible to estimate due to lack of a significant concentration response		
	CGA275535		New	NOEC (reproduction) = 556 mg/kg soil d.w.; EC_{10} = 385 mg/kg; EC_{20} = 638 mg/kg	NOEC = 556 mg/kg	***Lührs (2014) CGA275535_10002***
	CGA321915			$NOEC/EC_{10}/EC_{20}$ (reproduction) = 1000 mg/kg soil d.w.	$NOEC/EC_{10}$ = 1000 mg/kg	***Lührs (2015) CGA321915_10012***

[a] Values estimated in accordance with **Commission Regulation (EU) No 283/2013**
[b] For the tests conducted by Neinstedt and Ehlers the NOEC values represent the highest concentrations tested. Therefore the endpoint of 20 mg a.s./kg derived by Ehlers 2001 will be used for the risk assessment

Table 10.4-2: Table of endpoints for non-target soil meso- and macro-fauna

Organism	Test item	Test type	Endpoint		Endpoint used for the risk assessment	Reference (author, date, Syngenta File No.)
Folsomia candida	Cyprodinil [a]	28 day chronic	New	NOEC = 29.4 mg A14325E/kg (8.67 mg a.s./kg); EC_{10} = 53.2 mg A14325E//kg (15.7 mg a.s./kg); EC_{20} = 67.7 mg A14325E (20 mg a.s./kg)[c]	NOEC = 29.4 mg a.s./kg	***Lührs (2014) A14325E_10061***
	Cyprodinil [b]			NOEC/EC_{10}/EC_{20} = 105 mg A8637C/kg (52.5 mg a.s./kg) [d, e]		***Lührs (2014) A8637C_10314***
			$EC_{10/20}$	Not possible to estimate due to lack of a significant concentration response		***EC_{10}/EC_{20} estimate Taylor & Pickering (2016) A8637C_10368***
	CGA249287		New	NOEC = 31 mg/kg soil; EC_{10} = 7.9 mg/kg; EC_{20} = 22.7 mg/kg	NOEC = 31 mg/kg	***Vinall (2012) CGA249287/10003***
	CGA275535			NOEC = 171.5 mg/kg soil [f]	NOEC = 171.5 mg/kg	***Lührs (2014) CGA275535_10004***
	CGA321915			NOEC/EC_{10}/EC_{20} = 1000 mg/kg soil d.w. [e]	NOEC/EC_{10} = 1000 mg/kg	***Lührs (2015) CGA321915_10010***
Hypoaspis aculeifer	Cyprodinil [a]	14 day chronic	New	NOEC/EC_{10}/EC_{20} = 1000 mg A14325E/kg soil (295 mg a.s./kg) [c, e]	NOEC/EC_{10} = 277.8 mg/kg	***Lührs (2014) A14325E_10062***
	Cyprodinil [b]			NOEC/EC_{10}/EC_{20} = 555.6 mg A8637C/kg (277.8 mg a.s./kg) [d, f]		***Lührs (2014) A8637C_10312***
	CGA249287			NOEC = 74 mg/kg soil; EC_{10} = 70.5 mg/kg; EC_{20} = 321.3 mg/kg	NOEC = 74 mg/kg	***Schultz (2014) CGA249287_10005***
	CGA275535			NOEC = 171.5; EC_{10} = 104.6 mg/kg; EC_{20} = 272.5 mg/kg	NOEC = 171.5 mg/kg	***Lührs (2014) CGA275535_10000***
	CGA321915			NOEC/EC_{10}/EC_{20} = 1000 mg/kg soil	NOEC/EC_{10} = 1000 mg/kg	***Lührs (2015) CGA321915_10011***

[a] Tested as A14325E
[b] Tested as A8637C
[c] Concentrations converted to active substance content based on nominal formulation composition of 295 g cyprodinil/L
[d] Concentrations converted to active substance content based on nominal formulation composition of 500 g cyprodinil/kg
[e] It was not possible to estimate EC_{10} or EC_{20} values as the NOEC was derived for the highest concentration tested
[f] It was not possible to estimate EC_{10} or EC_{20} values as a significant concentration response could not be derived

The exposure to soil organisms was estimated by calculating the maximum instantaneous predicted environmental concentrations in soil (PEC_S) (see **M-CP, Section 9**). For multiple applications, the worst-case maximum PEC_S will be immediately after the final application.

Since A8637C is rapidly broken down into its constituent parts on contact with soil and/or crop material, it was appropriate to calculate the PEC_S for A8637C following a single application only.

The PEC_S was calculated as described in the **M-CP Section 9**. The resulting PEC_S values are presented below.

Table 10.4-3: Maximum peak PEC_S values for A8637C, cyprodinil and soil metabolites following application of A8637C at 750 g product/ha to pome fruit

Formulation/ compound	$PEC_{S, initial}$ [mg/kg]	$PEC_{S, plateau}$ [mg/kg]	$PEC_{S, peak accum}$ [mg/kg]
A8637C	**0.400**	-	-
Cyprodinil	0.571	0.441	**1.012**
CGA249287	0.054	0.055	**0.070**
CGA275535	**0.130**	-	-
CGA321915	0.023	0.085	**0.108**

Numbers in bold are used for the risk assessment

CP 10.4.1 Earthworms

Risk assessment for earthworms

An acute risk assessment is no longer required in accordance with the guidance in **Annexes to Regulation 284/2013**.

The potential long-term risk of cyprodinil and relevant soil metabolites was assessed by calculating long-term TER (TER_{LT}) values by comparing the NOEC or the adjusted NOEC, if appropriate, and the PEC_S using the following equation:

$$TER_{LT} = \frac{NOEC(mg/kg)}{PEC_S\ (mg/kg)}$$

For substances with log P_{OW} values greater than 2, there was a need to reduce the NOEC by a factor of 2 in order to account for the relatively high organic matter content of the artificial test soil (10%) compared to agricultural soils in accordance with the EPPO guidelines (**EPPO, 2002**). Since the log P_{OW} values of the cyprodinil metabolites CGA249287 and CGA321915 are less than 2 (1.5 and -0.10 respectively) there was no need to reduce the NOEC by a factor of 2. The log P_{OW} values of cyprodinil and its metabolite CGA275535 are greater than 2 (4.0 and 3.3 respectively), therefore the NOECs have been reduced by a factor of 2.

The resulting TER_{LT} values are presented below:

Table 10.4.1-1: Long-term TER values for earthworms

Formulation/ compound	Endpoint [mg/kg]	$NOEC_{adjusted}$ [mg/kg]	Maximum PEC_S [mg/kg	TER_{LT}	Trigger
Cyprodinil [a]	NOEC = 20	10	1.012	9.9	5
CGA249287	NOEC = 1.13	-	0.070	16	
CGA275535	NOEC = 556	278	0.130	2 100	
CGA321915	NOEC = 1000	-	0.108	9 300	

[a] Tested as A8779A (a 750 mg/kg WG formulation)

The long-term TER values exceed the Commission Regulation (EU) No. 546/2011 long-term trigger value of 5, indicating that the long-term risk to earthworms is acceptable following use of A8637C according to the proposed use pattern.

CP 10.4.1.1 Earthworms – sub-lethal effects

Studies have not been carried out with A8637C, but with the similar formulation A8779A (75WG). These studies have not been previously submitted and are summarised below.

Report:	K-CP 10.4.1.1/01 Ehlers A. H. (2001) Effects of CGA 219417 75 WG (A8779A) on reproduction and growth of earthworms *Eisenia fetida* (Savigny 1826) in artificial soil, Report Number 10291022. IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany. (Syngenta File No. CGA219417/1028).

Guideline(s)

BBA guideline VI, 2-2 (1994)

ISO 11268-2 (1998)

GLP: Yes

Executive Summary

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A8779A at 2 000, 10 000 and 20 000 g formulation/ha, the NOEC was determined to be 20 000 g formulation/ha. Since no concentration response was observed for adult mortality or biomass, or for number of juveniles produced, the EC_{50} could not be calculated but it can be concluded that the EC_{50} is >20 000 g formulation/ha, this being the highest concentration tested.

Materials

Test Material:	A8779A
Description:	Beige to light brown solid
Lot/Batch No.:	WM 902997
Purity:	75% CGA219417
Density:	Not stated
Stability:	Expiry date November 2001
Control:	Deionised water
Toxic reference:	Derosal SC 360 g/L was tested at 3,215 g/ha, corresponding to 1 000 g a.s./ha
Test concentrations:	2 000, 10 000 and 20 000 g formulation/ha
Test organisms	
Species:	*Eisenia fetida*
Source:	In-house culture, originating from Kraut & Rubeen (Doris Haber), Zeilstraße 40, 64367 Mühltal-Frankenhausen, Germany . Acclimated to test soil for 2 days prior to testing.
Age and weight range of worms at test start:	Adult worms, about 9 months old, with clitellum. Wet weight range 345 – 545 mg
Food:	Weekly, with 5.0g dried and finely ground cattle manure
Test Design	
Test vessels:	Plastic boxes (18.3 × 13.6 × 6 cm, with approximately 190 cm^2 surface area) with a lid pervious to air. 646 g wet weight soil, corresponding to about 500 g dry weight, of artificial soil was added to each test vessel.
Test substrate:	Artificial OECD soil comprising 10% sphagnum peat, 20 % kaolinite clay,

	69.5 % industrial sand (> 50% of the particles between 50 mm and 200 µm) and 0.5% calcium carbonate (chalk)
Replication:	Four replicates per test item treatment and control, each containing 10 adult worms

Environmental test conditions

Temperature:	19 to 21^{o}C
pH of soil:	5.7 to 5.9
Water content of soil:	54.1 to 60.6% water holding capacity
Photoperiod:	16-h light, 8-h dark. Light period 407 to 700
Duration of test:	28 days adult exposure and 28 days juvenile exposure

Study Design and Methods

Experimental dates: 22nd March to 26th June 2001.

Before the start of the test the artificial soil was prepared and deionised water added to the dry soil to adjust the water content to approximately 60 % of its water holding capacity. The worms were acclimatised in a separate batch of the untreated artificial substrate for approximately 2 days before the start of the test. The test concentrations were prepared by dispersing exactly weighed amounts of A8779A (3.33g, 16.67g and 33.33g) in 1000 mL deionised water. When sprayed onto the test vessels at a rate equivalent to 600 L/ha they result in 2 000, 10 000 and 20 000 g A8779A/ha.

Once the requisite amounts of OECD soil (646 g wet weight) had been placed in each test vessel, ten pre-weighed adult worms were added to each replicate and allowed to burrow into the substrate. After the earthworms had burrowed beneath the soil surface, the solutions containing A8779A were applied to the relevant test vessels using a laboratory spray system (Fa. Schachtner, D-71640 Ludwigsburg) calibrated to deliver 6 mg of spray solution per cm^2 (equivalent to 600 L/ha). Deionised water was used for the control.

One day after application, 5 g dried cattle manure, moistened with deionised water, was added to each test vessel. The feeding interval was weekly during the first four weeks of the test. Soil moisture was measured weekly by weighing test vessels and adjusted if required by adding deionised water.

After four weeks the adult worms were removed from the test vessels and mortality and the body weight of the groups of surviving worms determined. After all of the adult worms had been removed the batches of test and control soil were returned to their respective test vessels. Four weeks later the number of surviving juvenile worms was recorded. Observations of behavioural and pathological symptoms were observed weekly.

Data for adult biomass and juvenile numbers were analysed using 2-sided Dunnett-test, (p = 0.05)

Results and Discussion

The results are summarised in the table below.

Table 10.4.1.1-1: Effect of A8779A on mortality, growth and reproduction of *Eisenia fetida*

Endpoints	Treatment groups (g A8779A/ha)				
	Control	2 000	10 000	20 000	Toxic standard
Adult mortality at 28 days (%)	0	0	0	0	0
Mean % biomass change of adults from 0-28 days (± std. dev.)	29.3 (± 4.8)	34.5 (± 4.9)	32.1 (± 14.9)	34.2 (+ 9.3)	4.0 (±12.0)
Mean number of juveniles after 8 weeks	261 (± 33)	216 (± 31)	268 (± 29)	264 (± 12)	48 (± 7)
Coefficient of variation for reproduction (cv %)	12.6	6.97	9.24	4.55	14.6
% difference in reproduction relative to the control	n.a.	-17.2	2.7	1.1	-81.6
LC_{50} (g A8779A/ha)	>20 000				
NOEC (g A8779A/ha)	20 000				

n.a. = not applicable

Mortality of the parental worms was less than 10% (0% observed). The number of juvenile worms produced in the control was greater than 30 per replicate (mean 261 observed), and the coefficient of variation for the number of control juveniles was less than 30% (12.6% observed). The result of the reference toxicant test showed a significant reduction in reproduction, compared to the control, at 1 000 g a.s./kg. These validity criteria indicate that the study was valid.

Conclusions

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A8779A the NOEC was determined to be 20 000 g formulation/ha. Since no concentration response was observed for adult mortality or biomass, or for number of juveniles produced, the EC_{50} could not be calculated but it can be concluded that the EC_{50} is >20 000 g formulation/ha, this being the highest concentration tested.

(Ehlers H, 2001)

Report:	K-CP 10.4.1.1/02 Nienstedt K M. (2001) A chronic toxicity and reproduction test exposing *Eisenia fetida*, to CGA 219417 75 WG (A-8779 A) in OECD artificial soil, Report Number 1047.094.631. Springborn Laboratories (Europe) AG, Seestrasse 21, CH-9326 Horn, Switzerland. (Syngenta File No. CGA219417/1029).

Guideline(s)

BBA guideline VI, 2-2 (1994)

ISO 11268-2 (1998)

GLP: Yes

Executive Summary

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A8779A at 1 000 and 5 000 g formulation/ha (equivalent to 750 and 3,750 g a.s./ha) the NOEC was determined to be 3 750 g a.s./ha. Since no concentration response was observed for adult mortality or biomass, or for number of juveniles produced, the EC_{50} could not be calculated but it can be concluded that the EC_{50} is >3 500 g a.s./ha, this being the highest concentration tested.

Materials

Test Material:	A8779A
Description:	Beige to light brown granules
Lot/Batch No.:	WM 902997
Purity:	75% CGA219417
Density:	Not stated
Stability:	Expiry date November 2001
Control:	Deionised water
Toxic reference:	Carbendazime S was tested at concentrations of 100, 250, 500 and 1 000 mg a.s./kg soil dry weight (separate study - No.: 7000.025.613, dated 19 August 2000).
Test concentrations:	1 000 and 5 000 g formulation/ha, equivalent to 750 and 3 750 g a.s./ha
Test organisms	
Species:	*Eisenia fetida*
Source:	In-house culture, originating from Biologische Bundesanstalt (BBA), Braunschweig, Germany on 20 September 1996. Acclimated to test soil for 7 days prior to testing.
Age and weight range of worms at test start:	Adult worms with clitellum. Wet weight range 480 – 588 mg
Food:	Weekly, with 6.0g dried cattle manure
Test Design	
Test vessels:	Plastic vessels (17 × 12.5 × 10 cm, with approximately 212.5 cm^2 surface area) with a lid pervious to air. 813.6 g wet weight soil, corresponding to about 550 g dry weight, of artificial soil was added to each test vessel.
Test substrate:	Artificial OECD soil comprising 10% sphagnum peat, 20 % kaolinite clay, 70 % industrial sand (> 50% of the particles between 50 mm and 200 µm) and 100g calcium carbonate per 30 kg dry soil
Replication:	Four replicates per test item treatment and six control replicates, each containing 10 adult worms (one replicate at 1 000 mg A8779A/ha contained 11 worms)
Environmental test conditions	
Temperature:	18.0 to 20.5°C
pH of soil:	5.8 to 7.1
Water content of soil:	60.4 to 72.3% water holding capacity
Photoperiod:	16-h light, 8-h dark. Light period 400 to 800
Duration of test:	28 days adult exposure (phase I) and 28 days juvenile exposure (phase II)

Study Design and Methods

Experimental dates: 17th February to 14th April 2000.

Before the start of the test the artificial soil was prepared and deionised water added to the dry soil to adjust the water content to approximately 60 % of its maximum water holding capacity (WHC). The worms were acclimatised in a separate batch of the untreated artificial substrate for approximately 7 days before the start of the test. The test concentrations were prepared by dispersing an exactly weighed amount of A8779A (4.1664 g) in 500 mL deionised water to make a stock solution of 6.25 g a.s./L. With an application volume of 600 L/ha, this stock solution is equivalent to 3,750 g a.s./ha. An aliquot (100 mL) of this stock solution was diluted to 500 mL with deionised water to obtain the 750 g a.s./ha application rate, when used at 600 L/ha.

Once the requisite amounts of OECD soil (813.6 g wet weight) had been placed in each test vessel, ten pre-weighed adult worms were added to each replicate and allowed to burrow into the substrate. After the earthworms had burrowed beneath the soil surface, the stock solutions were applied to the relevant test vessels using an SL Conformal Spray System (model RC-10E, Springborn Laboratories) calibrated with deionised water to deliver 6 mg of spray solution per cm^2 (equivalent to 600 L/ha). Deionised water was used for the control.

One day after application, 6 g dried cattle manure, moistened with deionised water, was added to each test vessel. The feeding interval was weekly during the first four weeks of the test. Soil moisture was measured weekly by weighing test vessels and adjusted if required by adding deionised water.

After four weeks the adult worms were removed from the test vessels and mortality and the body weight of the surviving worms determined. After all of the adult worms had been removed the batches of test and control soil were returned to their respective test vessels. Four weeks later the number of surviving juvenile worms was recorded, along with any morphological alterations observed. Observations of behavioural and pathological symptoms were observed weekly.

Fisher’s exact test was used to test for statistically significant differences in adult mortality between the control and exposure treatments. Data for adult biomass and juvenile numbers were analyses using ANOVA.

Results and Discussion

The results are summarised in the table below.

Table 10.4.1.1-2: Effect of A8779A on mortality, growth and reproduction of *Eisenia fetida*

Endpoints	Treatment groups (g A8779A/ha)		
	Control	**1 000**	**5 000**
Adult mortality at 28 days (%)	0	0	2.5 (1 in 40)
Mean % biomass change of adults from 0-28 days (± std. dev.)	53.2 (± 3.9)	52.7 (± 6.1)	48.5 (± 14.1)
Mean number of juveniles after 8 weeks	460 (± 100)	412 (± 137)	367 (± 129)
Coefficient of variation for reproduction (cv %)	21.7	33.3	35.1
% difference in reproduction relative to the control	n.a.	89.4	79.7
LC_{50} (g A8779A/ha)	>5 000		
NOEC (g A8779A/ha)	5 000		

n.a. = not applicable

Mortality of the parental worms was less than 10% (0% observed). The number of juvenile worms produced in the control was greater than 30 per replicate (mean 460 observed), and the coefficient of variation for the number of control juveniles was less than 30% (21.7% observed). The results of the reference toxicant test, where effects were found at 250 g a.s./kg and above, are in line with the range given in the draft OECD guideline (2000). These validity criteria indicate that the study was valid.

Conclusions

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A8779A the NOEC was determined to be 5,000 g formulation/ha (equivalent to 3 750 g a.s./ha). Since no concentration response was observed for adult mortality or biomass, or for number of juveniles produced, the EC_{50} could not be calculated but it can be concluded that the EC_{50} is >5 000 g formulation/ha, this being the highest concentration tested.

(Nienstedt K, 2001)

CP 10.4.1.2 Earthworms – field studies

Not required given that acceptable risk was demonstrated with laboratory data.

Relevant Literature on Earthworms

No relevant scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

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

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

The potential long-term risk of cyprodinil and relevant soil metabolites to other non-target soil meso- and macro-fauna was assessed by calculating long-term TER (TER_{LT}) values by comparing the NOEC values and the maximum instantaneous PEC_S using the following equation:

$$TER_{LT} = \frac{\text{NOEC(mg/kg)}}{\text{PEC}_S \text{ (mg/kg)}}$$

For substances with log P_{OW} values greater than 2, there was a need to reduce the NOEC by a factor of 2 in order to account for the relatively high organic matter content of the artificial test soil (10%) compared to agricultural soils in accordance with the EPPO guidelines (**EPPO, 2002**). Since the log P_{OW} values of the cyprodinil metabolites CGA249287 and CGA321915 are less than 2 (1.5 and -0.10 respectively) there was no need to reduce the NOEC by a factor of 2. The log P_{OW} values of cyprodinil and its metabolite CGA275535 are greater than 2 (4.0 and 3.3 respectively), however, all tests were conducted in artificial soil containing 5% peat so therefore there was no need to reduce the endpoint.

The resulting TER_{LT} values are presented below:

Table 10.4.2-1: Long-term TER values for other soil meso- and macro-fauna

Organism	Test substance	Endpoint (mg/kg soil)	PEC_S (mg a.s./kg soil)	TER_{LT}	Trigger value
Folsomia candida	A8637C	NOEC = 105	0.400	260	5
	Cyprodinil [a]	NOEC = 29.4	1.012	29	
	CGA249287	NOEC = 31	0.07	440	
	CGA275535	NOEC =171.5	0.130	1 300	
	CGA321915	NOEC = 1000	0.108	9 300	
Hypoaspis acuelifer	A8637C	NOEC = 555.6	0.400	1 400	
	Cyprodinil	NOEC = 277.8	1.012	270	
	CGA249287	NOEC = 74	0.070	1 000	
	CGA275535	NOEC = 171.5	0.130	1 300	
	CGA321915	NOEC = 1000	0.108	9 300	

[a] Endpoint derived for a test conducted with A14325E as this represented the worst case from tests conducted with this formulation and A8637C

The long-term TER values all exceed the Commission Regulation (EU) No. 546/2011 long-term trigger value of 5, indicating that the long-term risk to *Folsomia candida* and *Hypoaspis aculeifer* is acceptable following use of A8637C according to the proposed use pattern.

CP 10.4.2.1 Species level testing

New studies have been carried out for A8637C with *Folsomia candida* and *Hypoaspis aculeifer* to fulfil current data requirements for in Regulation 283/2013 and 284/2013. Endpoints from these studies are considered to cover effects for the active substance. The endpoints are summarised in Table 10.4-1 above. Summaries of these studies are presented in M-CA Section 8.

CP 10.4.2.2 Higher tier testing

Higher tier tests were not conducted as the risk assessment above indicates acceptable risk to soil macro- and meso-organisms other than earthworms.

Relevant literature on non-target soil meso- and macrofauna (other than earthworms)

No relevant scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

CP 10.5 Effects on Soil Nitrogen Transformation

The toxicity of A8637C, cyprodinil and metabolites to soil microbial activity in terms of nitrogen transformation is summarised below.

Table 10.5-1: Table of endpoints to assess risk from use of A8637C

Test type	Test item	Endpoint (mg/kg)		Reference (author, date, Syngenta File No.)
N-transformation	A8637C	New	NOEC = 9.96	***Hammesfahr (2014) A8637C_10317***
		LIT	NOEC = 250 mg a.s./kg for nitrification in soil/litter microcosms	***Puglisi et al. (2012) CGA219417_11654***
	Cyprodinil	EU	NOEC = 26.7	***Wütrich (1993) CGA219417/0209***
	CGA249287		NOEC = 3.33	***Grade (2000) CGA249287/010***
	CGA275535		NOEC = 1.15	***Seyfried (2001) CGA275535/020***
	CGA321915	New	NOEC = 5.10	**Hammesfahr (2015) *CGA321915_10008***

LIT = Scientific peer-reviewed literature article

Exposure

The exposure to soil organisms was estimated by calculating the maximum instantaneous predicted environmental concentrations in soil (PEC_S) as presented under CP 10.4, above (see **M-CP, Section 9** for details of PEC calculations). The PEC_s are repeated below for convenience.

Table 10.5-2: Maximum peak PEC_S values for A8637C, cyprodinil and metabolites following application of A8637C

Test substance	Maximum instantaneous PEC_S (mg/kg)	Peak accumulation PECs
A8637C	0.400	-
Cyprodinil	0.571	1.012
CGA249287	0.054	0.070
CGA275535	0.130	0.130
CGA321915	0.023	0.108

Risk assessment for Soil Nitrogen Transformation

As a worst case approach the peak accumulation PECs have been compared with the NOECs derived for nitrogen transformation by soil micro-organisms. This comparison, presented as 'Ratio of NOEC:PECs' is presented in the table below.

Table 10.5-3: Risk assessment for effects on soil micro-organisms

Test substance	NOEC (mg/kg)	PEC_S (mg a.s./kg)	Ratio of NOEC:PEC_S
A8637C	9.96	0.400	25
Cyprodinil	26.7	1.012	26

Test substance	NOEC (mg/kg)	PEC_S (mg a.s./kg)	Ratio of NOEC:PEC_S
CGA249287	3.33	0.070	48
CGA275535	1.15	0.130	8.8
CGA321915	5.10	0.108	47

[1] Initial PECs
[2] Peak accumulation PEC_S

A8637C had no significant effect on soil micro-organisms at 9.96 mg A8637C/kg. This is approximately 25 times higher than the maximum PEC_S of 0.40 mg A8637C/kg following the worst-case application. This indicates that the risk to non-target soil micro-organisms is acceptable following use of A8637C according to the proposed use pattern.

Furthermore, the NOECs for cyprodinil and all metabolites range from 8.8 to 47 times higher than the maximum soil concentrations.

Laboratory testing

A summary of a study conducted with the representative formulation has not been submitted previously and is presented below.

Report:	K-CP 10.5/01 Hammesfahr U. (2014) Cyprodinil WG (A8637C) - Effects on Activity of Soil Microflora (Carbon and Nitrogen) in the Laboratory Report Number 92771080, Institut für Biologische Analytik und Consulting, IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany (Syngenta file No. A8637C_10317).

Guidelines

OECD guidelines 216, Soil Microorganisms: Nitrogen Transformation Test (2000)

OECD guidelines 217, Soil Microorganisms: Carbon Transformation Test (2000)

GLP: Yes

Executive Summary

A8637C was applied to the soil at concentrations of 2.99 mg/kg dry soil and 9.96 mg/kg dry soil. The test item caused no adverse effects on soil nitrogen transformation (measured as NO_3-N-production) and on soil carbon transformation (measured as O_2-consumption) at the end of the 28-day incubation period.

Materials

Test Material	A8637C Cyprodinil WG
Lot/Batch #:	SMO2C304
Actual content of active ingredients:	50.2 % w/w
Description:	Brown granules
Stability of test compound:	Stable under test conditions
Reanalysis/Expiry date:	End of December 2016
Density:	Not stated

Treatments

Test rates:	2.99 and 9.96 mg /kg dry soil
Control:	Deionised water
Toxic standard:	Sodium chloride (potassium nitrate, sodium nitrate and Ammonium sulphate used as reference items for Continuous flow analysis)

Test design

Soil type:	Loamy sand
Test units:	Disposable plastic boxes; each box contained different amounts of soil for the two tests: Carbon transformation test: 750 g to 1000 g soil d.w. box size approximately 1 L, filled up to 6 cm. nitrogen transformation test: 250 g to 500 g soil (dry weight), box size approximately 0.5 L, filled up to 6 cm
Replication:	3
Duration of test:	28 days

Environmental test conditions

Temperature:	20°C ± 2°C
pH of soil:	6.8 to 7.0
Soil moisture content:	48% to 52% of WHC
Photoperiod:	Constant darkness

Study Design and Methods

Experimental dates: 14th August to 12th September 2014

Soil samples were treated with A8637C at two doses, 2.99 and 9.96 mg /kg dry soil. Test concentrations related to a soil depth of 5 cm and a soil density of 1.5-g/cm3

The test item was mixed with deionised water and the test solution was subsequently mixed with the soil in the laboratory mixer. Water was added to the soil to achieve a water content of approximately 45 % of WHC. The water content of the soil in each test vessel was determined at test start (after application) and adjusted once a week to the required range of 40 - 50 % of WHC.

Three replicate soil samples were prepared for each treatment rate and the control for the nitrogen transformation test and carbon transformation test.

Mean nitrogen content (mg NO_3/kg soil d.w.), standard deviation and coefficient of variation as well as the mean nitrogen content/day (mg NO_3/kg soil d.w./day) were calculated for each treatment group and sampling date.

For the evaluation of the results the relative deviations (%) of the test item treatment groups from the control were calculated (based on the mean nitrogen content/day) for each sampling date.

The amount of oxygen consumed by soil microorganisms was calculated based on the pressure decrease in the reaction vessel. The oxygen consumption was calculated by regression analysis of the linear part of the respiration curve over 12 hours.

Amounts of NH_4^+, NO_2^- and NO_3^- were calculated based on concentrations determined in soil extracts and the amount of extracted soil.

Data for short-term respiration and soil nitrogen contents were tested for normality and homogeneity of variance using the R/S-Test (α = 0.05) and Levene´s test (α = 0.05), respectively. The Student t-test (pair wise comparison, two-sided, α = 0.05) was used for comparison of treated and control values. The software used to conduct the statistical analysis was ToxRat Professional, Version 2.10.05

Results and Discussion

Results from the nitrogen and carbon transformation tests are summarised in the tables below.

Table 10.5-4: Effects on nitrogen transformation in soil after treatment with A8637C

Time Interval (days)	Control		2.99 mg test item/kg soil dry weight		9.96 mg test item/kg soil dry weight	
	NO_3-N [mg/kg soil d.w./day]	CV (%)	NO_3-N [mg/kg soil d.w./day]	Deviation from control [%][1)]	NO_3-N [mg/kg soil d.w./day]	Deviation from control [%][1)]
0 - 7	-1.26	-5.16	-0.97	-23.02	-0.75	-40.48
0 - 14	2.53	0.99	2.42	-4.35	2.63	3.95
0 - 28	1.87	1.66	1.82	-2.67	1.82	-2.67

The calculations were performed with non-rounded values
No statistically significant differences between the control and the test item treatments were calculated

Table 10.5-5: Effects on carbon transformation in soil after treatment with A8637C

Days after application	Control		2.99 mg test item/kg soil dry weight		9.96 mg test item/kg soil dry weight	
	O_2-consumption [mg/kg soil d.w./h]	CV (%)	O_2-consumption [mg/kg soil d.w./h]	Deviation from control [%][1)]	O_2-consumption [mg/kg soil d.w./h]	Deviation from control [%][1)]
0	11.171	0.95	11.543	-3.33	12.668	-13.40
7	8.967	8.84	8.794	1.93	9.592	-6.97
14	10.698	2.00	10.393	2.85	11.408	-6.64
28	9.614	3.23	9.734	-1.25	10.057	-4.61

Based on O_2-consumption; - = inhibition; + = stimulation
Negative values indicate an increase relative to the control
No statistically significant differences between the control and the test item treatments were calculated

The reference item sodium chloride was evaluated in a separate test (IBACON study code 30698080). For The deviation from the control for carbon transformation was 68.8% at 28 days. The deviation from the control for nitrogen transformation was 86.84% in terms of soil nitrate content and 106.84% in terms of soil nitrate formation rate.

Validity criteria

The validity criteria were fulfilled in that:

- The variation between replicate control samples should be less than ± 15% (range was 0.99 to 8.84%)
- The reference item must have a retarding or stimulating effect of more than ± 25% compared to the control at day 28 after application (68.8% for carbon transformation and 86.84 to 106.84% for nitrogen transformation).

Conclusions

There is no long-term impact of A8637C on soil microbial nitrification and respiration processes up to and including concentrations of 9.96 mg test item/kg soil dry weight.

(Hammesfahr U. 2014)

Relevant Literature on Nitrogen Transformation

Scientifically peer-reviewed open literature that was possibly relevant was found for the potential effects of A8637C on nitrification, and is summarised below:

Report:	K-CP 10.5/02 Puglisi E., Vasileiades S., Demeris K., Bassi D., Karpouzas D.G., Capri E., Cocconcelli P.S. & Trevisan M. (2012). Impact of Fungicides on the Diversity and Function of Non-target Ammonia-Oxidizing Microorganisms Residing in a Litter Soil Cover. *Microbial Ecology*, 64: 692-701 (Syngenta File No. CGA219417_11654)

Guidelines

The study does not use standard test guidelines for the microcosm study and uses guidance as previously published by Kandeler (1995) and Coppolecchia *et al.* (2010) to study nitrification in the soil litter.

GLP: No.

Executive Summary

Uncontaminated grass, vine branches and leaves were collected, as well as soil (sandy clay loam) from the same site (abandoned vineyard, Northern Italy). Nine soil-litter microcosms were prepared, covered with filter paper and left to equilibrate for 3 weeks. Moisture was kept on the top layer by wetting the filter paper. At the initiation of the test cyprodinil was applied at a rate of 10 L/ha. Samples were taken at 0, 7, 21, 56 and 100 days after test initiation and nitrification potential was analysed.

Samples were incubated for 5 hours at 26 °C at 100 rpm. At the end of the incubation period a colour reagent was added and absorbance was measured at 520 nm and compared to the controls. Cyprodinil did not significantly reduce potential nitrification over time. However, further analysis of nitrification showed that within the controls nitrification potential remained the same but within the cyprodinil this potential was significantly decreased shortly after application, however recovery was fast and within 7 days no significant changes were evident.

The NOEC can be considered to be 250 mg a.s./kg.

Materials

Test Material 1	Cyprodinil (Chorus® 500 g a.s./kg)
Source:	Syngenta Agro
Purity:	N/A
Description:	Not stated
Treatments:	0, 0.05, 0.5, 5.0, 50, 500 mg/kg of soil dry mass (dm)
Treatments	
Control:	No added fungicide macro-element medium only ((g·kg^{-1} of soil in terms of pure ingredient): N – 0.12 ($CO(NH_2)_2$], P – 0.05 (KH_2PO_4), K – 0.12 (KH_2PO_4 + KCl), Mg – 0.025 ($MgSO_4 \cdot 7H_2O$) and micro-elements (mg/kg of soil in terms of pure ingredient): Zn – 5.0 ($ZnSO_4 \cdot 7H_2O$), Cu – 5.0 ($CuSO_4 \cdot 5H_2O$), Mn –

	5.0 ($MnCl_2 \cdot 5H_2O$), Mo – 5.0 ($Na_2MoO_4 \cdot 2H_2O$), B – 0.33 (H_3BO_3).
Toxic standard:	None tested
Test design	
Soil type:	Sandy Clay Loam (29 % clay, 27 % silt, 43 % sand). Litter was grass, vine branches and leaves. All collected from the same vineyard in Northern Italy.
Duration of test:	50 days (sampled at day 10 and 50)
Bacteria:	Soil-litter nitrifying organisms
Source:	Abandoned vineyard, Northern Italy.
Environmental test conditions	
Temperature:	26 °C
pH of soil:	6.62-6.90 (KCl)
Soil moisture content:	65 % WHC
Photoperiod:	None stated
Total organic carbon:	2.1 % soil; 21 % litter
Total Nitrogen	0.81 % soil; 1.1 % litter
C/N ratio:	2.6 soil; 19:1 litter

Study Design and Methods

The absence of contamination was assessed using HPLC. The uncontaminated grass, vine branches and leaves were collected, as well as soil (sandy clay loam) from the same site (abandoned vineyard, Northern Italy). The litter was mechanically chopped to small particles (≤ 2 cm in length). The final composition of this layer was ryegrass (*Lolium perenne*): vine branches and leaves 90:10 w/w. Validity was met for quantity of organic carbon required within the sample (> 1 %, OECD test 216, 2000).

Nine soil-litter microcosms (0.176 m^2 filled with 900 g soil dw and 200 g litter, which was 2 cm thick on top of the soil) were prepared, covered with filter paper and left to equilibrate for 3 weeks. Moisture was kept on the top layer by wetting the filter paper. At the initiation of the test cyprodinil was applied at a rate of 10 L/ha. Samples (25 g) were taken at 0, 7, 21, 56 and 100 days after test initiation and nitrification potential was analysed.

Nitrification assays were conducted according to Kandeler (1995) and Coppolecchia *et al*. (2010). Briefly, 2 g of litter was placed in a flask with 8 ml of $(NH_4)_2SO_4$ (1mM) and 0.04 mL $NaClO_3$ (1.5 mM). The mixture was incubated for 5 hours at 26 °C at 100 rpm within an incubation unit. Then 2 mL of KCl was added in all flasks, the content briefly mixed and filtered. Filtrates were mixed with 0.19 M NH_4Cl (pH 8.5) solution and 0.8 mL of (*N*-(1-naphtyl)- ethylenediamine hydrochloride in phosphoric acid solution) a colour reagent. This mix was incubated for a further 15 minutes, along with non-filtrated colour controls. The absorbance of the controls and tests were compared to the non-filtrated controls at 520 nm.

Soil nitrification was measured as absorbance at 520 nm and converted to NO_2-N/g/5 h.

Results and Discussion

There were no significant effects on nitrogen transformation in the soil litter layer when cyprodinil was applied at rates above those suggested in the GAP, and this was observed over 100 days. However there was an initial decrease in nitrifying potential ($p < 0.001$) upon the initiation of the experiment, but this soon recovered and was insignificant within 7 days ($p > 0.05$).

Conclusions

The NOEC can be considered to be 250 mg a.s./kg.

Table of relevant endpoints/ toxicity data available:

Figures are unclear due to the several pesticides plotted and values not reported so data cannot be tabulated or re-plotted.

References:

Coppolecchia D, Puglisi E, Vasileiadis S, Suciu N, Hamon R, Maria Beone G, Trevisan M (2010). Relative sensitivity of different soil biological properties to zinc. *Soil Biology Biochemistry*, 43:1798–1807.

Kandeler E (1995) Potential nitrification. In: Schinner F, Ohlinger R, Kandeler E, Margesin R (eds) Methods in soil biology. Springer, Heidelberg, pp 146–149

Study Reliability Evaluation	**Yes**	**No**	**Not reported**	**Not applicable**	**Comments**
Standardised test procedure followed		**X**			The methods have been previously published but these are not a standard ecotoxicological methods as per the OECD. Please see the above references.
Appropriate test procedure followed	**X**				Methodology is reasonably well documented and scientifically acceptable with basic requirements met. However, some limitations exist.
Data quality assured (GLP or equivalent)		**X**			
Controls appropriate	**X**				Results were weighted appropriately based on the controls.
Control response acceptable, or accounted for statistically			**X**		Results were reported in comparison to controls.
Temperature, pH & dissolved oxygen reported	**X**				
Alkalinity and hardness reported (metals)	**X**				Hardness was reported but not alkalinity, full medium as reported/ referenced to.
Statistics appropriate	**X**				
Effect levels above analytical limit of detection/quantification		**X**			
Material tested within limits of solubility, or effects above the limits of solubility sufficiently explained	**X**				Soil layer, leaf layer and medium were fully elucidated within the text.
Analytical verification of test concentrations/doses				**X**	
Measurement of precipitate or undissolved material				**X**	
Appropriate dilution water used (e.g. not chlorinated tap, rain water etc)	**X**				Water

Study assessment	Score	Rationale
Reliability/Repeatability	Klimisch 2	Reliable with restrictions Non-GLP. Methodology is reasonably well documented and scientifically acceptable with basic requirements met. The test is not standard but may act as a weight of evidence.
Limitations		Recording of data mainly restricted to figures and tables, no raw data presented. Figures are crowded and unclear.
Relevance	Microbial inhibition results are relevant for ecotoxicity RA.	Study shows not adverse effects on microbial capacity for nitrification up to the loading rate tested within this study.
Significance	Microbial inhibition results are suitable for use in risk assessment	Inhibition of leaf litter microbes will be useful in a weight of evidence approach that current usage and GAP will not affect these microbes.

CP 10.6 Effects on Terrestrial Non-Target Higher Plants

Toxicity

The effect of A8637C on seedling emergence and vegetative vigour in 6 plant species was evaluated in a glasshouse study (***Wälder, 2000***). Pre- and post-emergence applications of A8637C at rates up to and including 450 g formulation /ha did not have an adverse effect on seedling emergence or subsequent shoot growth. This study was submitted previously, however for completeness, further details of the study are provided under CP 10.6.1 below.

Exposure

Effects on non-target plants are of concern in the off-crop environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the **BBA (2000)**[14] from the spray-drift predictions of ***Ganzelmeier & Rautmann (2000)***[15]. Only a single application is considered as factors such as plant growth will reduce residues per unit area between multiple applications. For a single application of A8637C, as a worst case (early application in pome fruit) 29.2% of the in-field application rate is assumed to reach areas at a minimum distance of 3 m from the edge of the orchard.

The single application rate of A8637C is 750 g product/ha, giving a maximum off-crop predicted environmental rate ($PER_{off\text{-}crop}$) of 219 g A8637C/ha.

Risk assessment for Terrestrial Non-Target Higher Plants

A8637C is a fungicide and is therefore not expected to have any significant herbicidal activity.

The potential risk of cyprodinil, formulated as A8637C, to non-target plants is evaluated by comparing toxicity with the maximum predicted residue concentration. The off-field PER of 219 g/ha is below 450 g/ha i.e. the rate which showed no ecologically relevant effects on six plant species. It is therefore considered that the proposed use of A8637C is highly unlikely to affect non-target higher plants in the off-field environment.

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[14] BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

[15] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

Conclusion

When applied in accordance with the uses supported in this submission A8637C does not pose an unacceptable risk to non-target plants.

CP 10.6.1 Summary of screening data

The effect of A8637C on seedling emergence and vegetative vigour in 6 plant species was evaluated in a glasshouse study (***Wälder, 2000***). This study was submitted previously, however for completeness, further details of the study are provided below.

Report:	K-CP 10.6.1/01 Wälder L. (2000) Herbicide profiling test to evaluate the phytotoxicity of CGA 219417 50 WG (A8637C) to terrestrial non-target higher plants. Report No. 49 / SMQ00008. Novartis Crop Protection AG, Stein, Switzerland. (Syngenta File No. CGA219417/0989)

Guideline(s)

None stated. Approximates to the OECD revised draft guideline No. 208 (seedling emergence and vegetative vigour tests), except that 3 monocotyledons and 3 dicotyledons tested; 2 replicates, each with unknown number of seeds; visual assessments only.

GLP: No. Data were generated in a manner similar to discovery efficacy screens that are not performed under GLP. However, standardised study protocols were in place at the time the data were collected and the data presented are considered to be scientifically valid.

Executive Summary

Three monocotyledons and 3 dicotyledons were tested for pre-emergent and post-emergent effects of A8637C at rates of 14.06, 28.13, 56.25, 112.5, 225 and 450 g product/ha. Effects were assessed visually, using a rating scale.

A8637C applied at rates up to 450 g formulation/ha had negligible effect on the emergence or growth of the 6 tested species of higher plants.

Materials

Test Material:	A8637C
Description:	Not stated
Lot/Batch #:	WM910165
Purity:	Nominal cyprodinil 500 g/kg
Stability of test compound:	Not stated
Test rates:	14.06, 28.13, 56.25, 112.5, 225 and 450 g formulation/ha
Vehicle and/or positive control:	Water vehicle and untreated control
Application volume:	500 L/ha
Application method:	Laboratory sprayer fitted with a Teejet 8004 nozzle
Environmental test conditions	In glasshouses
Temperature:	15-18 or 20-25°C depending on species
Photoperiod:	14 hours daily

Study Design and Methods

Experimental dates: 27th July to 22nd August 2000

Test species are shown in the table below.

Table 10.6.1-1: A8637C: Herbicide profiling test – test species

Common name	Latin name	Family
Monocotyledonae		
Maize	*Zea mays*	Graminae (Panicoidea)
Wild oat	*Avena fatua*	Graminae (Pooideae)
Onion	*Allium cepa*	Liliaceae (Allioideae)
Dicotyledonae		
Sugar beet	*Beta vulgaris*	Chenopodiaceae
Oilseed rape	*Brassica napus*	Cruciferae (Brassicaceae)
Soybean	*Glycine max*	Leguminosae (Fabaceae)

Two replicates per treatment level were sprayed, each with three to approximately 20 seeds of each species, depending on seed size.

Test units were non-porous plastic trays, 10 cm deep, with drainage holes in the bottom and containing a mineral soil. All species were sown together at intervals along one tray (= replicate). Plants were top-watered as required and a nutrient solution supplied twice a week. Plants used for the vegetative vigour test were grown for 14 or 17 days (depending on species) prior to treatment application. Plants used for the seedling emergence test were watered within 24 hours prior to the treatment application.

Seedling emergence was evaluated 21 or 26 days after application; vegetative vigour was assessed 14 days after application. Phytotoxicity was assessed visually according to a rating scale ranging from 1 (complete destruction or no emergence; 100% effect) to 9 (normal growth compared to control; 0% effect), with a rating of 5 approximating to a 50% effect on emergence or visual symptoms compared to the control.

Results and Discussion

Table 10.6.1-2: A8637C: Herbicide profiling test – seedling emergence effect ratings

Species	Application rate (g formulation/ha)					
	450	**225**	**112.5**	**56.25**	**28.13**	**14.06**
Brassica napus	9	9	9	9	9	9
Avena fatua	9	9	9	9	9	9
Beta vulgaris	9	9	9	9	9	9
Zea mays	9	9	9	9	9	9
Glycine max	9	9	9	9	9	9
Allium cepa	9	9	9	9	9	9

Table 10.6.1-3: A8637C: Herbicide profiling test – vegetative vigour effect ratings

Species	Application rate (g formulation/ha)					
	450	225	112.5	56.25	28.13	14.06
Brassica napus	9	9	9	9	9	9
Avena fatua	9	9	9	9	9	9
Beta vulgaris	9	9	9	9	9	9
Zea mays	8.5	9	9	9	9	9
Glycine max	9	9	9	9	9	9
Allium cepa	9	9	9	9	9	9

Conclusions

A8637C applied at rates up to 450 g formulation/ha had negligible effect on the emergence or growth of the 6 tested species of higher plants.

(Wälder L 2000)

CP 10.6.2 Testing on non-target plants

Further testing is not required since A8637C does not exhibit herbicidal activity.

CP 10.6.3 Extended laboratory studies on non-target plants

Extended laboratory tests were not conducted as the risk assessment above indicates acceptable risk to non-target plants.

CP 10.6.4 Semi-field and field tests on non-target plants

Semi-field or field tests were not conducted as the risk assessment above indicates acceptable risk.

Relevant Literature on Non-Target Plants

No relevant scientifically peer-reviewed open literature could be found on A8637C. Details of the literature search undertaken can be found in **M-CA Section 9**.

CP 10.7 Effects on Other Terrestrial Organisms (Flora and Fauna)

No further data on other terrestrial organisms is required.

Risk assessment for Other Terrestrial Organisms (Flora and Fauna)

No further risk assessments on other terrestrial organisms are required.

CP 10.8 Monitoring Data

There are no records of reported incidents related to use of A8637C or cyprodinil from monitoring data. No monitoring studies are needed for cyprodinil for ecotoxicological purposes as an acceptable risk has been identified for its proposed uses.