Document Title

Tier 2 Summary

of the Fate and Behaviour in the Environment

for the Plant Protection Product
Iprovalicarb & Folpet WG 65.3 (90+563 g/kg)

(Specification number 102000011659-04)

Substance(s)

IPROVALICARB
(Annex I renewal)

Data Requirements

Regulation EC/1141/2010

on the renewal of the inclusion of AIR2 active substances

in conjunction with

Directive 91/414/EEC and Regulation EC/1107/2009

According to OECD format guidance for industry data submissions
(SANCO/10387/2010 rev. 8 - on the renewal of active substances included in Annex I)

Annex IIIA
Document M
Section 5, Point 9

Date

2012-05-12

Author(s)

[redacted]

Bayer CropScience

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Table of Contents

IIIA1 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

Regulatory background

This document summarises predicted environmental concentrations for the product 'Iprovalicarb + Folpet - WG 65.3' containing the active substances iprovalicarb and folpet for the application of the product according to the use pattern provided in Table 9- 1.

This document summarises predicted environmental concentrations for the active substance iprovalicarb contained in the product 'Iprovalicarb + Folpet - WG 65.3' for the application of the product according to the use pattern provided in Table 9- 1. For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no predicted environmental concentrations of folpet are submitted here. For details please refer to the statement mentioned at page 9.

Formulants

The formulants of a preparation would not be expected to influence the environmental behaviour of an active substance (except in special formulation types such as slow release formulations). The effects of the formulants are limited to short term processes such as the formation of stable spray dispersions, sprayability and permeation into target organisms, while the impact on long-term processes such as degradation and distribution is negligible. As this formulation is not a slow release formulation the results of environmental fate studies performed with the active substance are thus valid also for the formulation.

Intended application pattern

The formulation is intended for use as a fungicide for vines. The critical use pattern for this formulation is summarised as follows. Detailed use patterns for different countries can be found in document D-2, which is enclosed with this submission.

Table 9- 1: Comparison to the actual application use pattern and the calculated use pattern for PEC calculations

Crop	Timing of application [BBCH]	Number of applications	Application interval [days]	Maximum application rate, individual treatment [kg a.s./ha]	
				Iprovalicarb	Folpet
GAP:					
vines	16 – 75	1 - 4	10 - 14	0.216	1.3512
	16 – 61	1 - 4	10 - 14	0.162	1.0134
	15 – 85	1 - 4	10 - 12	0.150	0.940
PECs:					
vines	15 - 85	4	10	216	a)

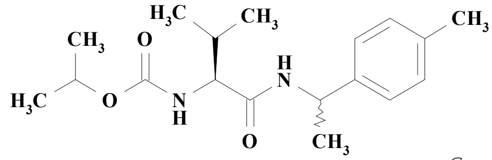
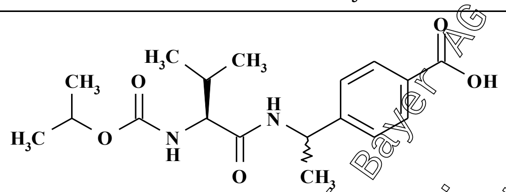
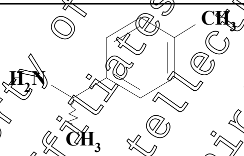
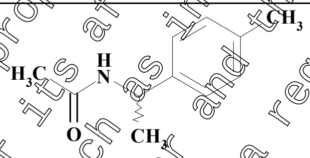
a) Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Compounds addressed in this document

Iprovalicarb

In addition to the active substance, the following metabolites were addressed in this document as they were considered important due to the amounts in which they were found during the course of environmental fate studies, or due to their specific properties. Study authors sometimes have used different names or short codes for the active substances and degradation products. In this summary, a single name for each substance is always used.

Table 9- 2: Active substance and metabolites addressed in this document

Compound (Codes)	Chemical structure	Explanation for consideration	Considered for
Iprovalicarb (SZX 0722)		active substance	PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}
SZX 0722-carboxylic acid (M03)		occurrence in - aerobic soil (10%)	PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}
PMPA (M10)		occurrence in - aerobic soil (> 10%) - water/sediment study (> 10% in water and sediment)	PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}
N-acetyl-PMPA (M15)		occurrence in - anaerobic soil (> 10%) - water/sediment study (> 10% in water)	PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sed}

Folpet

The representative formulation in the application for Annex I Renewal of iprovalicarb is a combination with folpet, which – from a Bayer perspective – is a 3rd party substance, procured from [redacted]). Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. The right to references of Bayer CropScience AG extends to all EU countries. A separate Letter of Access is included in this supplementary dossier (M-428625-01-1).

Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

IIIA1 9.1 Rate of Degradation in Soil

Specific studies on the preparation have not been performed. The results of laboratory studies performed

with the active substance iprovalicarb as provided in the Annex IIA in the context of Section 5, Point 7 submitted within the EU Basic Dossier 1998 and the Annex I Renewal Dossier 2012 are also applicable for the preparation. A short summary of the data is given in the subsections below. For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.1.1 Aerobic degradation of the preparation in soil

Specific studies on the preparation have not been performed.
The results of laboratory studies performed with the active substance iprovalicarb as provided in the Annex IIA in the context of Section 5, Point 7 submitted within the EU Basic Dossier 1998 and the Annex I Renewal Dossier 2012 are also applicable for the preparation. A short summary of the data is given in the subsections below. A short summary of the data is given in the subsections below.
For the 3rd party substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

Iprovalicarb

The degradation behaviour of iprovalicarb under laboratory conditions, in the dark, has been studied in a number of different soils at temperatures of 20 C and with one soil under 10°C.
From the studies on the route of degradation in soil, it can be concluded that iprovalicarb was thoroughly degraded in soil under aerobic conditions to the final degradation product CO_2. Three metabolites were identified in the soil along with the parent compound and $^{14}CO_2$. The major metabolites (> 10% of the applied radioactivity (AR)) were SZX 0722-carboxylic acid *(M03)* and PMPA *(M10)*. Terephthalic acid *(M23)* was found as minor metabolite. Unextractable residues reached 29.5 to 33.9% of AR at study end (valine-label, day 21) and up to 27.9% of AR and 31.5% of AR (phenyl label, day 100 / day 365).
Iprovalicarb was metabolised to the endpoint CO_2 via two routes. In one route the breakdown of the molecule started with the cleavage of the amide bond between the L valine and PMPA moieties. This led to the main metabolite PMPA *(M10)*. The other route proceeded via oxidation of the methyl group on the phenyl ring to a carboxylic group (SZX 0722-carboxylic acid *(M03)*) and further oxidation. The degradation pathway is given in Figure 9.1.1- 1.
It can be concluded from the study concerning the photodegradation of iprovalicarb on soil surfaces that photodegradation will not significantly contribute to the degradation of iprovalicarb. A total of five degradation products including CO_2 were detected in the soil extracts. Two of these degradates were identified as SZX 0722-carboxylic acid *(M03)* and PMPA *(M10)*. All individual degradates accounted for less than 5% of the applied radioactivity in the irradiated samples, with CO_2 representing 2.8% of AR following the irradiation period. The breakdown of iprovalicarb proceeded oxidation of the 4-methyl group to SZX 0722-carboxylic acid, cleavage of the amide bond to PMPA and ring cleavage followed by

formation of CO_2.

The degradation behaviour of iprovalicarb in soil under aerobic conditions was determined in laboratory studies using two different radiolabels, different soil types and different temperatures (20°C and 10°C). To derive kinetic parameters suitable for modelling purpose and environmental risk assessments a kinetic evaluation of these data was performed according to FOCUS kinetics (FOCUS, 2006[1]), for the parent compound the major soil metabolites. A summary of these data is given in Table 9.1.1- 1.

For **iprovalicarb** the non-normalised $DT_{50\ mod}$ for modelling purpose were in the range of 1.99 to 68.56 days and the normalised $DT_{50\ mod}$ in the range of 1.77 to 68.56 days (geom. mean 6.78 days). For persistence trigger evaluation (non-normalised) the $DT_{50\ initial}$ were in the range of 1.99 to 18.00 days and the $DT_{90\ initial}$ in the range of 6.62 to 252.12 days.

For **SZX 072-carboxylic acid *(M03)*** the non-normalised $DT_{50\ mod}$ for modelling purpose were in the range of 0.56 to 1.852 days and the normalised $DT_{50\ mod}$ in the range of 0.45 to 1.85 days (geom. mean 0.97 days). For persistence trigger evaluation (non-normalised) the $DT_{50\ initial}$ were in the range of 0.58 to 1.97 days and the $DT_{90\ initial}$ in the range of 1.94 to 6.53 days.

For **PMPA *(M10)*** the non-normalised $DT_{50\ mod}$ for modelling purpose were in the range of 44.28 to 187.33 days and the normalised $DT_{50\ mod}$ in the range of 39.39 to 187.4 days (geom. mean 81.08 days). For persistence trigger evaluation (non-normalised) the $DT_{50\ initial}$ were in the range of 44.28 to 239.32 days and the $DT_{90\ initial}$ in the range of 147.1 to 759.0 days.

For **N-acetyl-PMPA *(M10)*** the non-normalised $DT_{50\ mod}$ for modelling purpose were in the range of 0.422 to 0.929 days and the normalised $DT_{50\ mod}$ in the range of 0.42 to 0.93 days (geom. mean 0.72 days). For persistence trigger evaluation (non-normalised) the $DT_{50\ initial}$ were in the range of 9.0 to 22.3 hours (0.4 to 0.9 days) and the $DT_{90\ initial}$ in the range of 39.0 to 74.1 hours (1.6 to 3.1 days).

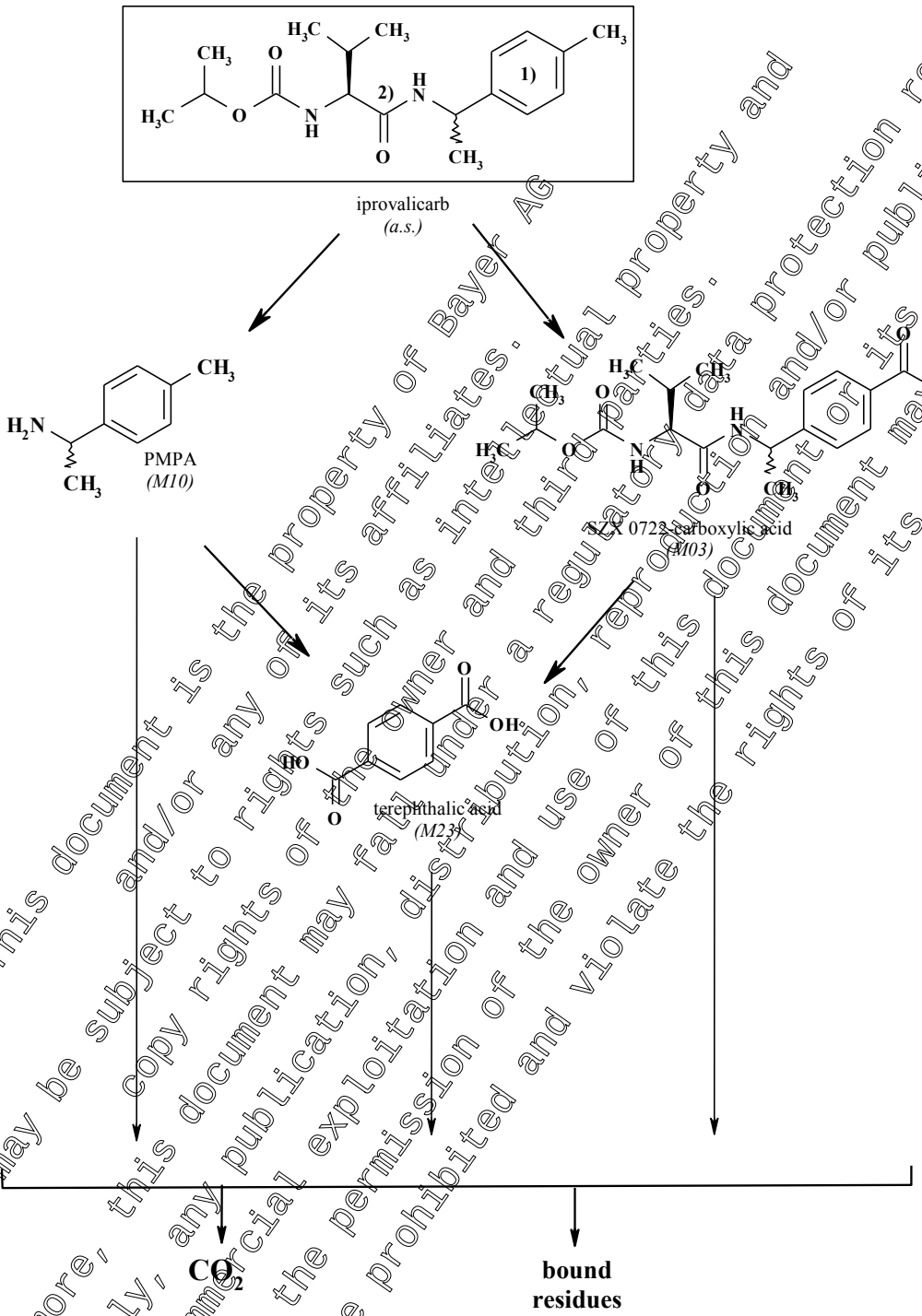
Table 9.1.1- 1: Summary of DT_{50} values of iprovalicarb and metabolites in aerobic soil studies evaluated for modelling purpose and trigger evaluation according to FOCUS kinetics (FOCUS, 2006)

Compound	range for modelling purpose			range for trigger evaluation
	$DT_{50\ mod}$ [hours]	$DT_{50\ mod}$ [days]		$DT_{50\ initial}$
	non-normalised		normalised	non-normalised
Iprovalicarb		1.99 – 68.56	1.77 – 68.6	1.99 – 18.0 days
SZX 0722-carboxylic acid *(M03)*		0.56 – 1.852	0.45 – 1.85	0.58 – 1.97 days
PMPA *(M10)*		44.28 – 187.33	39.39 – 187.3	44.28 –239.32 days
N-acetyl-PMPA *(M15)*	10.1 – 22.30	0.422 – 0.929	0.42 – 0.93	9.0 - 22.3 hours

The rate of degradation of iprovalicarb irradiated with artificial light was investigated in a soil photolysis study. It can be concluded that photodegradation will not significantly contribute to the degradation of the parent compound. The DT_{50} was 62.3 days.

[1] FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration.
Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference SANCO/10058/2005, v.2.0, June 2006

Figure 9.1.1- 1: Proposed metabolic pathway of iprovalicarb in soil under aerobic conditions



Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.1.2 Anaerobic degradation of the preparation in soil

Iprovalicarb

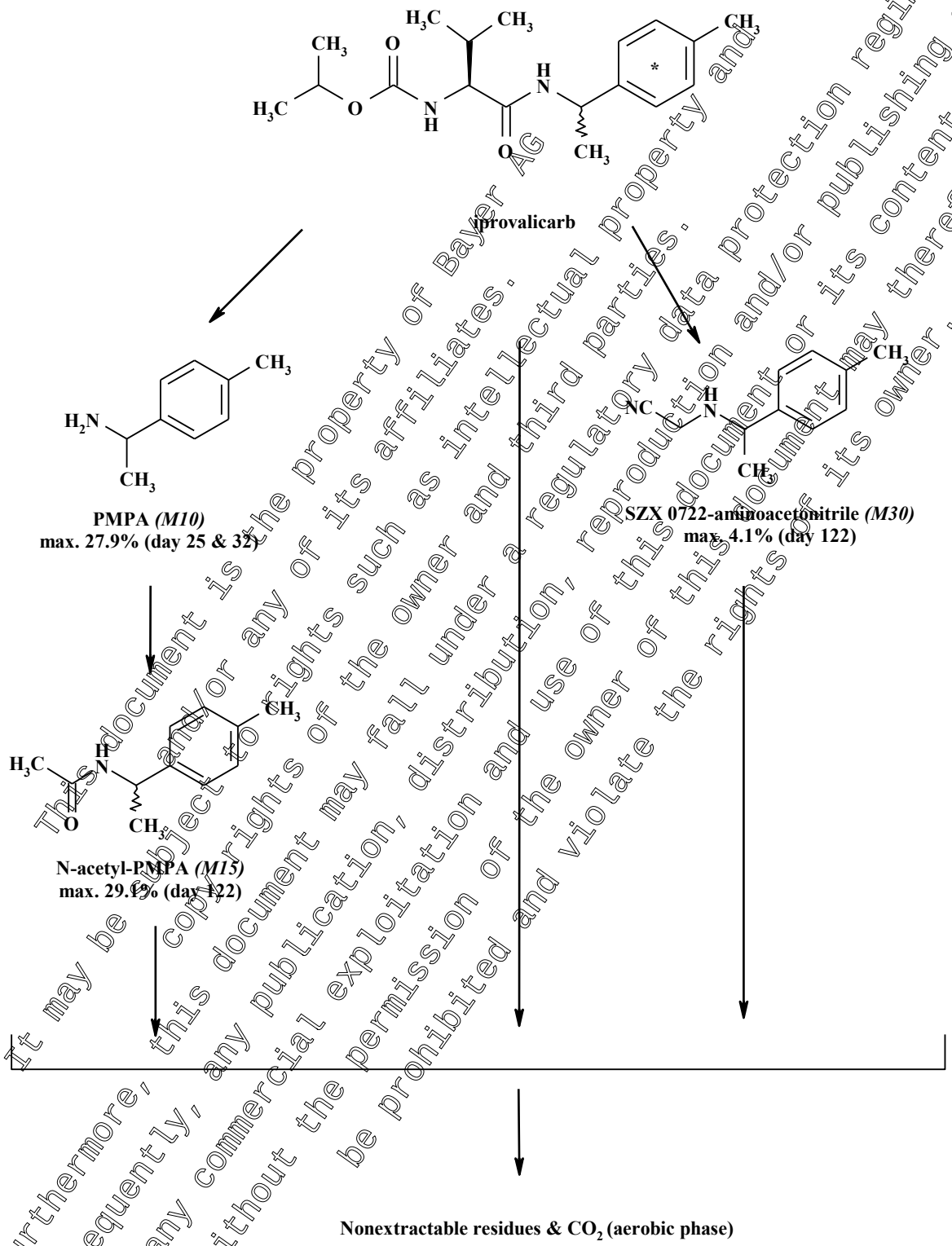
The anaerobic biotransformation of iprovalicarb has been studied in a silt soil in the dark at 20°C. During the first phase of the study, the soil was maintained under aerobic conditions for three days. Afterwards the samples were flooded with water and maintained under anaerobic conditions.
Iprovalicarb degraded to two major degradates. One major degradate, PMPA *(M10)*, was formed under aerobic conditions and increased under anaerobic conditions. During the anaerobic phase, N-acetyl-PMPA *(M15)* was also formed as major degradate. SZX 0722-aminoacetonitrile *(M30)*, was formed later in the study under anaerobic conditions as a minor degradate. Unextractable residues reached 39.8% by the end of the study. Additional CO_2 and volatile organic compounds were produced at low levels throughout the anaerobic phase of the study (≤ 4.1%). A degradation pathway is shown in Figure 9.1.2- 1.

The degradation of iprovalicarb is well described assuming SFO decay ($DT_{50\ modelling}$ = 30.8 days). The metabolites PMPA *(M10)* and N-acetyl-PMPA *(M15)* were fitted together with the parent compound, to describe best its total degradation pathways. PMPA *(M10)* shows very good to reasonable fits, assuming SFO decay (DT_{50} for modelling purpose: 38.6 days) and DFOP decay (DT_{50} for persistence endpoints: 43.1 days). N-acetyl-PMPA *(M15)* shows very good to reasonable fits, assuming SFO decay (DT_{50} for modelling purpose: 76.2 days) and DFOP decay (DT_{50} for persistence endpoints: 105.7 days). (Table 9.1.2- 1).

Table 9.1.2- 1: Laboratory anaerobic soil Deg DT_{50} values of iprovalicarb and metabolites for modelling or persistence purpose

Compound	$DT_{50\ mod}$ [days]	$DT_{50\ initial}$ [days]
Iprovalicarb	30.8	25.4
PMPA *(M10)*	38.6	43.1
N-acetyl-PMPA *(M15)*	76.2	105.7

Figure 9.1.2- 1: Proposed metabolic pathway of phenyl-labelled iprovalicarb in soil under anaerobic conditions



Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.2 Field Studies

The results of field studies performed with representative preparations of the active substances as provided in Annex II in the context of Section 5, Point 7 are also applicable for this preparation.

IIIA1 9.2.1 Soil dissipation testing on a range of representative soils

Iprovalicarb

The field dissipation of iprovalicarb was evaluated during the Annex I Inclusion. In addition a kinetic evaluation of the dissipation behaviour of iprovalicarb and its metabolite PMPA *(M10)* has been performed. A short summary of the data is given below:

The dissipation of iprovalicarb under field conditions has been investigated a number of sites in England, France and Germany. The kinetic evaluation of six field dissipation trials for persistence or trigger purpose according to FOCUS kinetics (FOCUS, 2006) resulted in non-normalised half-lives of 3.7 to12.5 days for iprovalicarb and 22.2 to 228.4 days for the metabolite PMPA *(M10)*. The corresponding DT_{90} values were in the range of 12.8 to 61.7 days and 73.6 to 7582.9 days, respectively. The non-normalised $DisT_{50}$ values for persistence or trigger purpose are summarised in Table 9.2.1- 1.

Table 9.2.1- 1: $DisT_{50, initial}$ values of iprovalicarb of iprovalicarb and its metabolite PMPA *(M10)* in field dissipation trials, for trigger purpose (not temperature or moisture normalised)

Compound	range $DisT_{50, initial}$ [days]
Iprovalicarb	3.73 – 12.45
PMPA *(M10)*	22.15 – 228.4

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.2.2 Soil residue testing

Soil residues relevant for succeeding crops can be predicted from soil dissipation data provided in

IIIA1 9.1.1 and IIIA1 9.2.1 (see also IIIA1 9.4). Therefore, no further soil residue testing with the preparation is required.

IIIA1 9.2.3 Soil accumulation testing

Iprovalicarb

Due to the use pattern of the formulation and the degradation rates of the active substance no accumulation in soil would be expected.

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.2.4 Aquatic (sediment) field dissipation

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA1 9.2.5 Forestry field dissipation

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA1 9.3 Mobility of the Plant Protection Product in Soil

Specific studies on the preparation have not been performed. The results of studies performed with the active substance provided in the Annex II Section 5, point 7 and subsequent addenda are also applicable for the preparation. Short summaries of the data are given below.

Iprovalicarb

The adsorption constants K_f for Iprovalicarb calculated by means of the Freundlich adsorption isotherm ranged from 0.60 - 4.64 mL/g. The corresponding K_{oc} were in the range of 44 - 221 mL/g with an arithmetic mean of 114 mL/g. For the major soil metabolites SZX 0722-carboxylic acid *(M03)*, PMPA *(M10)* and N-acetyl-PMPA *(M15)* the K_f values were in the range of 0.012 - 0.354 mL/g, 0.67 - 11.09 mL/g and 0.34 - 0.56 mL/g and the corresponding K_{oc} values were in the range of 0.6 - 13.1 mL/g (mean 5.2 mL/g), 117.9 - 574.6 mL/g (mean 290.2 mL/g) and 32.2 - 53.4 mL/g (mean 39.7 mL/g) respectively. The values are summarised in Table 9.3- 1.

No obvious pH dependence was observed for Iprovalicarb, PMPA *(M10)* , N-acetyl-PMPA *(M15)* but for the metabolite SZX 0722 carboxylic acid *(M03)*.

Table 9.3- 1: Adsorption properties of iprovalicarb and metabolites in soil

	K_{oc} (mean) [mL/g]	1/n (mean)
Iprovalicarb	114	0.8725
SZX 0722-carboxylic acid *(M03)*	5.2	1.0250
PMPA *(M10)*	290.2	0.8629
N-acetyl-PMPA *(M15)*	39.7	0.9025

Folpet

For the 3rd party active substance folpet, produced from [redacted])
Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Polpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.3.1 Column leaching

Iprovalicarb

The potential mobility of iprovalicarb can be determined from the adsorption/desorption studies described under section IIIA1 9.3 and no column leaching studies are reported.

Folpet

For the 3rd party active substance folpet, produced from [redacted])
Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.3.2 Lysimeter studies

Iprovalicarb

Based on the results of a lysimeter study it can be concluded with a high probability that iprovalicarb and its metabolites will not contaminate deeper soil layers or groundwater at concentrations ≥ 0.1 µg/L.

Folpet

For the 3rd party active substance folpet, produced from [redacted])
Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.3.3 Field leaching studies

Iprovalicarb

Field leaching studies have not been conducted for the active substance as sufficient information can be derived from the existing studies.

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.3.4 Volatility – laboratory study

No volatility studies on the preparation have been performed. Details of the volatility of the active substance are given in Section 1. The vapour pressures are also reported in Section IIIA1 9.9.

IIIA1 9.3.5 Volatility – field study

Iprovalicarb

Field volatility studies showed a low trend of iprovalicarb to volatilise from soil and plants under field conditions. Therefore an exposure of emission via contaminated air is not to be expected.

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.4 Predicted Environmental Concentrations in Soil (PECs) for the Active Substance

Endpoints for PEC_{soil}

Iprovalicarb

Table 9.4-1: Modelling input parameters for iprovalicarb

End-Point	Active substance: iprovalicarb Value used for modeling
DT_{50} soil [days] (lab., worst case, non-normalised)	68.56

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{soil} calculations of folpet are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

PEC_{soil} modelling approach

Calculations were based on a simple first tier approach (Excel sheet) assuming even distribution of the compound in upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed.

Crop interception data which correspond to the intended growth stages were taken from the FOCUS groundwater guidance paper (FOCUS, 2002[1]).

Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the recommendations of the FOCUS groundwater guidance paper (FOCUS, 2002) for grapes.

PEC_{soil} for iprovalicarb

Report:	**KIIA1 9.4/01, [redacted] 2012**
Title:	Predicted environmental concentrations in soil (PEC_{soil}) of iprovalicarb Use in vines, early, vines, intermediate and vines, late in Europe
Report No:	EnSa-12-0169
Document No:	M-429638-01-1
Guidelines:	Soil Persistence Models and EU registration: Report of the FOCUS Soil Modelling Work Group, 1996 EC Document Reference 7617/VI/96
GLP:	No (calculation)

Methods and Materials: The predicted environmental concentrations in soil (PEC_{soil}) of iprovalicarb were estimated using a simple first tier approach (Excel sheet). Detailed application data used for simulation of PEC_{soil} were compiled in Table 9.4- 2.

Substance Specific Parameters: PEC_{soil} calculations were based on the DT_{50} of 68.56 days (worst case of laboratory studies, non-normalised).

[1] FOCUS (2002): Generic Guidance for FOCUS Groundwater Scenarios, Version 1.1; Date: April 2002, amending FOCUS 2000

Table 9.4- 2: Comparison of actual application use pattern and the calculated use pattern used for PEC_{soil} calculations of iprovalicarb

Individual crop	FOCUS crop used for interception	Application rate per season [g a.s./ha]	interval [days]	plant interception [%]	BBCH stage	Amount reaching the soil per season application [g a.s./ha]
GAP:						
grapes	vines	1 - 4 x 216	10 - 14	60 - 85	16 - 75	1 - 4 x 32.4 - 86.4
		1 - 4 x 162	10 - 14	60 - 70	16 - 61	1 - 4 x 48.6 - 64.8
		1 - 4 x 150	10 - 12	60 - 85	15 - 85	1 - 4 x 22.5 - 60.0
Simulation:						
vines, early	vines	4 x 216	10	4 x 60	15 - 85	4 x 86.4
vines, intermediate	vines	4 x 216	10	60/70/70/70	50 - 85	86.4/64.8/64.8/64.8
vines, late	vines	4 x 216	10	70/85/85/85	80 - 85	64.8/32.4/32.4/32.4

Findings: The PEC_{soil} and the time weighted average values (TWA_{soil}) of iprovalicarb after application in vines are summarised in Table 9.4-3.

Table 9.4- 3: PEC_{soil} (actual) and TWA_{soil} of iprovalicarb

	Time [days]	vines, early PEC_{soil} [mg/kg]	vines, early TWA_{soil} [mg/kg]	vines, intermediate PEC_{soil} [mg/kg]	vines, intermediate TWA_{soil} [mg/kg]	vines, late PEC_{soil} [mg/kg]	vines, late TWA_{soil} [mg/kg]
Initial	0	0.398	-	0.320	-	0.181	-
Short term	1	0.394	0.396	0.317	0.319	0.180	0.180
	2	0.391	0.394	0.314	0.317	0.178	0.180
	4	0.383	0.391	0.307	0.314	0.174	0.178
Long term	7	0.371	0.385	0.298	0.309	0.169	0.175
	21	0.322	0.359	0.259	0.288	0.147	0.163
	28	0.300	0.347	0.241	0.279	0.137	0.158
	50	0.240	0.313	0.193	0.251	0.109	0.142
	100	0.145	0.251	0.116	0.201	0.066	0.114

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

PEC_{soil} for folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{soil} calculations of folpet are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between

applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling Comments: IIIA 9.4/01	
Agreed PEC_s (active substance): IIIA 9.4/01	

IIIA1 9.4.1 Initial PECs values

Please refer to point IIIA1 9.4.

IIIA1 9.4.2 Short-term PECs values (1-4 days after last application)

Please refer to point IIIA1 9.4.

IIIA1 9.4.3 Long-term PECs values (from 7-100 days after last application)

Please refer to point IIIA1 9.4.

IIIA1 9.5 Predicted Environmental Concentrations in Soil (PECs) for Relevant Metabolites

Predicted environmental concentrations in soil were calculated for the metabolites indicated in Table 9-2. These metabolites are not automatically "relevant" with regard to their environmental, biological, ecotoxicological or toxicological properties.

Endpoints for PEC_{soil}

Iprovalicarb

Table 9.5- 1: Modelling input parameters for iprovalicarb metabolites

End-Point	Iprovalicarb metabolites Value used for modelling
SZX 0722-carboxylic acid *(M03)*	
Molecular mass correction	1.0935
DT_{50} soil [days] (lab., worst case, non-normalised)	1.852
Maximum occurrence in soil [%]	10.0
PMPA *(M10)*	
Molecular mass correction	0.422
DT_{50} soil [days] (lab., worst case, non-normalised)	187.33
Maximum occurrence in soil [%]	50.7
N-acetyl-PMPA *(M15)*	
Molecular mass correction	0.5531
DT_{50} soil [days] (lab., worst case, non-normalised)	0.929
Maximum occurrence in anaerobic soil [%]	29.1

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{soil} calculations of folpet metabolites are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

PEC$_{soil}$ for iprovalicarb metabolites

For iprovalicarb the metabolites SZX 0722-carboxylic acid *(M03)*, PMPA *(M10)* and N-acetyl-PMPA *(M10)* were considered.

Report:	**KIIIA1 9.5 /01, [redacted] 2012**
Title:	Predicted environmental concentrations in soil (PECsoil) of iprovalicarb Use in vines, early, vines, intermediate and vines, late in Europe
Report No:	EnSa-12-0169
Document No:	M-429638-01-1
Guidelines:	Soil Persistence Models and EU registration: Report of the FOCUS Soil Modelling Work Group, 1996 EC Document Reference 7617VI/96
GLP:	No (calculation)

Methods and Materials: PEC$_{soil}$ for the metabolites were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point 9.4 (KIIIA1 9.5/01). Compound specific parameters are summarised in Table 9.5- 2.

Table 9.5- 2: Input parameters for PEC$_{soil}$ for metabolites of iprovalicarb

Compound	DT$_{50}$ soil[a] [days]	Max. occurrence in soil [%]	Molar mass [g/mol]	Molar mass correction factor
SZX 0722-carboxylic acid *(M03)*	1.852	10.0	350.41	1.0935
PMPA *(M10)*	187.33	50.7	135.21	0.422
N-acetyl-PMPA *(M15)*	0.929	29.1	177.25	0.5531

a) worst case of laboratory studies, non-normalised

Findings: The PEC$_{soil}$ and the time weighted average values (TWA$_{soil}$) of iprovalicarb metabolites SZX 0722-carboxylic acid *(M03)*, PMPA *(M10)* and N-acetyl-PMPA *(M10)* are summarised in Table 9.5- 3, Table 9.5- 4 and Table 9.5- 5, respectively.

Table 9.5- 3: PEC$_{soil}$ (actual) and TWA$_{soil}$ of SZX 0722-carboxylic acid *(M03)*

	Time [days]	vines, early		vines, intermediate		vines, late	
		PEC$_{soil}$ [mg/kg]	TWA$_{soil}$ [mg/kg]	PEC$_{soil}$ [mg/kg]	TWA$_{soil}$ [mg/kg]	PEC$_{soil}$ [mg/kg]	TWA$_{soil}$ [mg/kg]
Initial	0	0.013	-	0.013	-	0.009	-
Short term	1	0.009	0.011	0.009	0.010	0.006	0.008
	2	0.006	0.009	0.006	0.009	0.004	0.007
	4	0.003	0.007	0.003	0.006	0.002	0.005
Long term	7	< 0.001	0.005	< 0.001	0.004	< 0.001	0.003
	21	< 0.001	0.002	< 0.001	0.002	< 0.001	0.001
	28	< 0.001	0.001	< 0.001	0.001	< 0.001	< 0.001
	50	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	100	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Table 9.5- 4: PEC_{soil} (actual) and TWA_{soil} of PMPA *(M10)*

	Time [days]	vines, early		vines, intermediate		vines, late	
		PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.093	-	0.076	-	0.043	-
Short term	1	0.093	0.093	0.075	0.075	0.043	0.043
	2	0.093	0.093	0.075	0.075	0.043	0.043
	4	0.092	0.093	0.074	0.075	0.043	0.043
Long term	7	0.091	0.092	0.074	0.075	0.042	0.043
	21	0.086	0.090	0.070	0.073	0.040	0.042
	28	0.084	0.089	0.068	0.072	0.039	0.041
	50	0.078	0.085	0.063	0.069	0.036	0.040
	100	0.064	0.078	0.052	0.063	0.030	0.036

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Table 9.5- 5: PEC_{soil} (actual) and TWA_{soil} of N-acetyl-PMPA *(M15)*

	Time [days]	vines, early		vines, intermediate		vines, late	
		PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]	PEC_{soil} [mg/kg]	TWA_{soil} [mg/kg]
Initial	0	0.019	-	0.019	-	0.014	-
Short term	1	0.009	0.013	0.009	0.013	0.007	0.010
	2	0.004	0.010	0.004	0.010	0.003	0.007
	4	< 0.001	0.006	< 0.001	0.006	< 0.001	0.004
Long term	7	< 0.001	0.004	< 0.001	0.004	< 0.001	0.003
	21	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	28	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	50	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	100	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

PEC_{soil} for folpet metabolites

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{soil} calculations of folpet metabolites are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it

justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling Comments: IIIA 9.5	
Agreed PEC_s (metabolites): IIIA 9.5	

IIIA1 9.5.1 Initial PECs values

Please refer to point IIIA1 9.5.

IIIA1 9.5.2 Short-term PECs values (1-4 days after last application)

Please refer to point IIIA1 9.5.

IIIA1 9.5.3 Long-term PECs values (from 7-100 days after last application)

Please refer to point IIIA1 9.5.

IIIA1 9.6 Predicted Environmental Concentrations in Ground Water (PECgw)

Endpoints for PEC_{gw}

Iprovalicarb

Table 9.6- 1: Modelling input parameters for iprovalicarb and its major metabolites

End-Point	Active substance: iprovalicarb Value used for modelling
Iprovalicarb	
Aqueous solubility [mg/L] at 20°C	17.8
Vapour pressure [Pa] at 20°C	7.82×10^{-8}
DT_{50} soil [days] (geo-mean lab., normalised)	6.78
Adsorption data: - 1/n (arith. mean) - K_{oc} / K_{om} [L/kg] (arith. mean)	 0.8725 113.9 / 66.1
SZX 0722-carboxylic acid *(M03)*	
Molar mass correction factor	1.0935
Aqueous solubility [mg/L] at 20°C, pH 7	56000
Vapour pressure [Pa] at 20°C	8.9×10^{-6}
DT_{50} soil [days] (geo-mean lab., normalised)	0.97
Formation fraction	0.3242
Adsorption data: - 1/n (arith. mean) - PEARL input data[a)]: - K_{oc, A^-} / K_{om, A^-} [L/kg][b)] - $K_{oc, AH}$ / $K_{om, AH}$ [L/kg][c)] - PELMO input data[d)]: - K_{oc} / K_{om} at pH 7.0 [L/kg] - K_{oc} / K_{om} at pH 5.5 [L/kg]	 1.025 0.64 / 0.37 14.30 / 8.29 1.54 / 0.89 10.19 / 5.91
PMPA *(M10)*	
Molar mass correction factor	0.422
Aqueous solubility [mg/L] at 20°C, pH 11	15000
Vapour pressure [Pa] at 20°C	20
DT_{50} soil [days] (geo-mean lab., normalised)	81.08
Formation fraction	0.5061
Adsorption data: - 1/n (arith. mean) - K_{oc} / K_{om} [L/kg] (arith. mean)	 0.8629 290.2 / 168.3
N-acetyl-PMPA *(M15)*	
Molar mass correction factor	0.5531
Aqueous solubility [mg/L] at 20°C, pH 7	6600
Vapour pressure [Pa] at 20°C	2.7×10^{-3}
DT_{50} soil [days] (geo-mean lab., normalised)	0.72
Max. occurrence in anaerobic soil [%]	29.1
Adsorption data: - 1/n (arith. mean) - K_{oc} / K_{om} [L/kg] (arith. mean)	 0.9025 39.7 / 23.0

a) in PEARL, the following values were implemented: alkaline, dissociated compound K_{oc, A^-} and acidic, undissociated compound $K_{oc, HA}$, the inflection point is apparent soil pK_a of 5.88 (H_2O)
b) alkaline, dissociated K_{oc, A^-}
c) acidic, undissociated $K_{oc, AH}$
d) in PELMO, the following values were implemented: 2 different points at the Henderson-Hasselbach equation or curve, the inflection point is apparent soil pK_a of 5.88 (H_2O)

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{gw} calculations of folpet and its metabolites are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

PEC_{gw} modelling approach

The predicted environmental concentrations in groundwater (PEC_{gw}) for the active substance(s) were calculated using the simulation models PEARL and PELMO following the recommendations of the FOCUS working group on groundwater scenarios.

The leaching calculations were run over 26 years, as proposed for pesticides which may be applied every year. The first six years are a ‘warm up’ period; only the last 20 years were considered for the assessment of the leaching potential. The 80th percentile of the average annual groundwater concentrations in the percolate at 1 m depth under a treated plantation were evaluated and were taken as the relevant PEC_{gw} values. In respect to the assessment of a potential groundwater contamination this shallow depth reflects a worst case. The effective long-term groundwater concentrations will be even lower due to dilution in the groundwater layer.

According to FOCUS, the calculations were conducted based on mean soil half-lives, referenced to standard temperature and moisture conditions. Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the FOCUS recommendations (Table 9.6- 2).

Table 9.6- 2: FOCUS groundwater crop interception values

	Crop: vines				
Stage	without leaves	first leaves	leaf development	flowering	ripening
Crop interception [%]	40	50	60	70	85
	00	01 - 08	11 - 19	60 - 69	71 - 99

IIIA1 9.6.1 Active substance

PEC$_{gw}$ for iprovalicarb

Report:	**KIIIA1 9.6.1 /01, [redacted] 2012**
Title:	Predicted environmental concentrations in groundwater recharge (PEC$_{gw}$) of iprovalicarb based on FOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.3 Use in vines early, vines intermediate and vines late in Europe
Report No:	EnSa-12-0167
Document No:	M-430141-01-1
Guidelines:	FOCUS groundwater scenarios in the EU plant protection product review process. Report of the FOCUS Groundwater Scenarios Workgroup. EC Document Reference SANCO/321/2000 rev.2
GLP:	No (calculation)

Materials and Methods: The predicted environmental concentrations in groundwater (PEC$_{gw}$) for iprovalicarb were calculated using the simulation model FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 4.4.3). Detailed application data used for simulation of PEC$_{gw}$ were compiled Table 9.6.1- 1.

The use of iprovalicarb in vines early, vines intermediate and vines late in Europe was assessed according to the Good Agricultural Practice (GAP). Applications to vine are intended of 1 - 4 x 150 - 216 g a.s./ha, with 10 - 14 days application intervals, at BBCH 15 - 85. Therefore, three representative periods were chosen for the assessment (Table 9.6.1- 1): an early period to start at BBCH 15, an intermediate period to cover BBCH 50 - 61, and a late period to cover BBCH 80 - 85. The calculations were based on the maximum intended application rate together with the maximum intended number of applications per season and the minimum interval between two applications. The use of the higher use rate, lower crop interception and a shorter application interval leading to a higher of compound reaching the soil in the simulation provides a conservative estimate for the groundwater concentrations from the current formulation.

Table 9.6.1- 1: Comparison of actual application use pattern and calculated use pattern for PEC$_{gw}$ calculations of iprovalicarb

Individual crop	FOCUS crop used for interception	Application rate per season [g a.s./ha]	interval [days]	plant interception [%]	BBCH stage	Amount reaching the soil per season application [g a.s./ha]
GAP:						
grapes	vines	1 - 4 x 216 1 - 4 x 162 1 - 4 x 150	10 - 14 10 - 14 10 - 12	60 - 85 60 - 70 60 - 85	16 - 75 16 - 61 15 - 85	1 - 4 x 32.4 - 86.4 1 - 4 x 48.6 -64.8 1 - 4 x 22.5 - 60.0
Simulation:						
vines, early	vines	4 x 216	10	4 x 60	15 - 85	4 x 86.4
vines, intermediate	vines	4 x 216	10	60/70/70/70	50 - 85	86.4/64.8/64.8/64.8
vines, late	vines	4 x 216	10	70/85/85/85	80 - 85	64.8/32.4/32.4/32.4

For the metabolite SZX 0722-carboxylic acid *(M03)* a moderately significant correlation is given for the dependency of the K$_{oc}$ from soil pH. Therefore, in PEARL, the following values were implemented:

dissociated compound $K_{oc, A}$- and the undissociated compound $K_{oc, HA}$. The inflection point is apparently soil pK_a of 5.88 (H_2O). In PELMO, the following values were implemented: 2 different points at the Henderson-Hasselbach equation or curve: K_{oc} at pH 7.0 and at pH 5.5. The inflection point is apparently soil pK_a of 5.88 (H_2O).

Typically, a leaching assessment is carried out considering aerobic conditions as a common agricultural situation. Therefore, observed major aerobic metabolites were taken into account, implementing their amounts and behaviour as observed under aerobic conditions. However, in anaerobic soil, a further fast degrading mayor metabolite, N-acetyl-PMPA *(M15)*, was identified which did not occur under aerobic conditions, mainly due to fast degradation. Based on these observations, a conservative anaerobic leaching assessment was carried out for this metabolite, respectively. The aerobic degradation behaviour of this metabolite was studied separately in a laboratory study.
Anaerobic leaching scenario: Under common agricultural situations in Europe, considering e.g. climatic conditions or slope of fields, it is obviously unrealistic, that a total treated agricultural field or area turns anaerobic, each year after application and lasting for a long time period, as typically considered for aerobic leaching assessments. Such conditions would make farming effectively impossible. Therefore, two more realistic, but still very conservative scenarios have been considered here:
Scenario 1: Anaerobic conditions may occur regularly in plane fields or cropping areas, when rain water remains in small sinks and furrows with low permeability. In this case, only a relatively small percentage of the total cropped area or field would be affected.
Scenario 2: Anaerobic conditions on larger scale may occur due to flooding along rivers. Typically, this flooding will not occur regularly or each year, only with large time intervals in between.
The following assumptions have been made to address these two scenarios. Partly, additional safety factors are applied to address uncertainties in the estimation.

Further input parameters for PEC_{gw} modelling of iprovalicarb are summarised in Table 9.6.1- 2.

Table 9.6.1- 2: Substance specific and model related input parameter for PEC_{gw} calculation of iprovalicarb and its major metabolites

Parameter	Unit	Iprovalicarb	SZX 0722-carboxylic acid *(M03)*	PMPA *(M10)*	N-acetyl-PMPA *(M15)*
Molar mass	[g/mol]	320.44	350.41	135.21	177.25
Water solubility	[mg/L]	17.8	56000	15000	6600
Vapour Pressure	[Pa]	7.82 x 10^{-8}	8.9 x 10^{-6}	20	2.7 x 10^{-3}
DT_{50} soil	[days]	6.78	0.97	81.08	0.72
Formation fraction	[%]	-	0.3242	0.5061	- [b)]
K_{oc}	[L/kg]	113.9	PEARL: 0.64 / 14.3 [a)] PELMO: 1.54 / 10.19	290.2	39.7
K_{om}	[L/kg]	66.1	PEARL: 0.37 / 8.29 [a)] PELMO: 0.89 / 5.91	168.3	23.0
Freundlich exponent	[-]	0.8725	1.025	0.8629	0.9025
Molar activ. energie	[kJ/mol]	65.4	65.4	65.4	65.4
Q_{10}	[-]	2.58	2.58	2.58	2.58
Plant uptake factor	[-]	0.5	0.5	0.5	0.5

a) For the metabolite SZX 0722-carboxylic acid *(M03)* a moderately significant correlation is given for the dependency of the K_{oc} from soil pH. Therefore, in PEARL, the following values were implemented: alkaline, dissociated compound K_{oc, A^-} of 0.64 L/kg (corresponding K_{om, A^-}: 0.37 L/kg) and acidic, undissociated compound $K_{oc, HA}$ of 14.30 L/kg (corresponding $K_{om, HA}$: 8.29 L/kg). The inflection point is apparent soil pKa of 5.88 (H_2O).
In PELMO, the following values were implemented: 2 different points at the Henderson-Hasselbach equation or curve: K_{oc} of 1.54 L/kg at pH 7.0 (corresponding K_{om} 0.89 L/kg) and K_{oc} of 10.19 L/kg at pH 5.5 (corresponding K_{om} : 5.91 L/kg). The inflection point is apparent soil pKa of 5.88 (H_2O).
b) maximum occurrence in anaerobic soil: 29.1%

Findings: The 80[th] percentile concentrations of iprovalicarb and its major metabolites are given in Table 9.6.1- 3.

Table 9.6.1- 3: PEC_{gw} of iprovalicarb

Scenario	Iprovalicarb					
	Vines, early		Vines, intermediate		Vines, late	
	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]	PEARL PEC_{gw} [µg/L]	PELMO PEC_{gw} [µg/L]
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Conclusion: There are no concerns for groundwater from the use of iprovalicarb in accordance with the use pattern for the current formulation.

PEC_{gw} for folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{gw} calculations of folpet are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling Comments: IIIA 9.6.1	
Agreed PEC_{gw} (active substance): IIIA 9.6.1	

IIIA1 9.6.2 Relevant metabolites

Predicted environmental concentrations in groundwater were calculated for those soil metabolites which should be subject to further assessment according to the guidance document on the assessment of the relevance of metabolite in groundwater (SANCO/221/2000 –rev.10- final, 25 February 2003). The metabolites are not automatically relevant in groundwater in the sense of this guidance document.

PEC$_{gw}$ for iprovalicarb metabolites

For iprovalicarb metabolites SZX 0722-carboxylic acid *(M03)*, PMPA *(M10)* and N-acetyl-PMPA *(M15)* were assessed.

Report:	**KIIIA1 9.6.2 /01, [redacted].; 2012**
Title:	Predicted environmental concentrations in groundwater recharge (PEC$_{gw}$) of iprovalicarb based on FOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.3 Use in vines early, vines intermediate and vines late in Europe
Report No:	EnSa-12-0167
Document No:	M-430141-01-1
Guidelines:	FOCUS groundwater scenarios in the EU plant protection product review process. Report of the FOCUS Groundwater Scenarios Workgroup. EC Document Reference SANCO/321/2000 rev.2
GLP:	No (calculation)

Materials and Methods: PEC$_{gw}$ for the metabolites were calculated using the approach, scenarios and application described for the calculations for the parent compound in Point IIIA1 9.6.1.
Compound specific input data for the metabolites are summarised together with the data of the parent compound in KIIIA1 9.6.1 /01 and in Table 9.6.1- 2.

Findings: The PEC$_{gw}$ values for the metabolites for the different EU scenarios are presented in Table 9.6.2- 1 to Table 9.6.2- 3.

Table 9.6.2- 1: PEC$_{gw}$ of the iprovalicarb metabolite SZX 0722-carboxylic acid *(M03)*

Scenario	SZX 0722-carboxylic acid *(M03)*					
	Vines, early		Vines, intermediate		Vines, late	
	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	0.001	0.008
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.005
[redacted]	< 0.001	0.002	< 0.001	< 0.001	< 0.001	0.005
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.002
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Table 9.6.2- 2: PEC$_{gw}$ of the iprovalicarb metabolite PMPA *(M10)*

Scenario	PMPA *(M10)*					
	Vines, early		Vines, intermediate		Vines, late	
	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	0.001	< 0.001	0.001	< 0.001	< 0.001
[redacted]	< 0.001	0.001	< 0.001	0.001	< 0.001	< 0.001
[redacted]	< 0.001	0.002	< 0.001	0.001	< 0.001	0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Table 9.6.2- 3: PEC$_{gw}$ of the iprovalicarb metabolite N-acetyl-PMPA *(M15)*

Scenario	N-acetyl-PMPA *(M15)*					
	Vines, early		Vines, intermediate		Vines, late	
	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]	PEARL PEC$_{gw}$ [µg/L]	PELMO PEC$_{gw}$ [µg/L]
Scenario 1[a)]						
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Scenario 2[a)]						
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
[redacted]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval
a) anaerobic conditions considered within two different scenarios, detailed description see KIIIA1 9.6.1 /01, page 29

Conclusion: There are no concerns for groundwater from the use of iprovalicarb in accordance with the use pattern for the current formulation.

PEC_{gw} for folpet metabolites

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{gw} calculations of folpet metabolites are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling Comments: IIIA 9.6.2	
Agreed PEC_{gw} (metabolites): IIIA 9.6.2	

IIIA1 9.6.3 Additional field testing

No additional field testing was required.

IIIA1 9.6.4 Information on impact on water treatment procedures

The compounds would not be expected to reach water treatment plants in sufficient concentrations to have any impact on water treatment procedure.

IIIA1 9.7 Predicted Environmental Concentrations in Surface Water (PECsw) for the Active Substance

No specific information is available for the preparation, however the information on the active substance <u>iprovalicarb</u> as provided in the Annex IIA in the context of Section 5, Point 7 submitted within the EU Basic Dossier 1998 and the Annex I Renewal Dossier 2012 are also applicable for the preparation. A summary of this information is presented below. For the 3rd party active substance <u>folpet</u>, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80

WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

Summary of fate and behaviour of iprovalicarb in water

In sterile aquatic systems iprovalicarb was stable to hydrolysis. Under the experimental conditions no formation of hydrolysis products was observed. Considering the hydrolytic stability determined under environmental pH and temperature conditions, it is not expected that hydrolytic processes will contribute to the degradation of iprovalicarb in the environment.

The UV-VIS absorption data in the environmentally relevant pH range showed that iprovalicarb in aqueous solutions does not absorb any light at wavelengths above 281 nm. Therefore no contribution of the direct photodegradation to the overall elimination of iprovalicarb in the aqueous environment is to be expected.

Studies with iprovalicarb in four different natural water/sediment systems under aerobic conditions showed that the compound was thoroughly degraded leading to CO_2 as the end product of the mineralisation process. In parallel to mineralisation, bound residues were formed. PMPA *(M10)* was identified as major metabolite (> 10% of the applied radioactivity) in the water and sediment layers and N-acetyl-PMPA *(M15)* as major metabolite in the water layer. SZX 0722-carboxylic acid *(M03)* was found in amounts of 5.2% of the applied radioactivity in one entire system and N-acetyl-N-methyl-PMPA *(M16)* was found in very small amounts (< 0.5% of the applied radioactivity).

Iprovalicarb was metabolised to the endpoint CO_2 via several routes. In one route iprovalicarb was degraded via oxidation of the methyl group of the aromatic system yielding the SZX 0722 carboxylic acid *(M03)*. In the other route the breakdown of the molecule started with cleavage in one of the amide bonds which led to the main metabolite PMPA *(M10)*. Subsequently PMPA reacted with an activated acidic acid derivative yielding N-acetyl-PMPA *(M15)*. This metabolite was methylated in very small amounts to form N-acetyl-N-methyl-PMPA *(M16)*. Ultimately the breakdown of iprovalicarb led to total mineralisation of the aromatic nucleus in the form of carbon dioxide. The proposed pathway of iprovalicarb in water-sediment systems under aerobic conditions is given in Figure 9.7- 1.

To derive kinetic parameters suitable for modelling purpose and environmental risk assessments a kinetic evaluation of the data from the two water-sediment studies was performed according to FOCUS kinetics (FOCUS, 2006) for the parent compound the major metabolites.

For iprovalicarb the $DisT_{50}$ for modelling purpose in the water phase were in the range of 16.65 to 57.28 days (geom. mean 24.61 days) and in the range of 24.20 to 78.99 days (geom. mean 46.78 days) for the sediment phase. In the total system the $DegT_{50}$ for modelling purpose were in the range of 19.93 to 58.67 days (geom. mean 34.73 days). For persistence trigger evaluation the $DisT_{50}$ in the water phase were in the range of 14.84 to 57.28 days and in the range of 24.20 to 78.99 days for the sediment phase. In the total system the $DegT_{50}$ for persistence trigger evaluation were in the range of 19.17 to 58.67 days. The corresponding $DisT_{90}$ in the water phase were in the range of 58.2 to 190.3 days and in the range of 80.4 to 262.4 days for the sediment phase. In the total system the $DegT_{90}$ were in the range of 66.9 to

194.9 days. (see Table 9.7- 1).

Table 9.7- 1: DT50 (and DT90) values of iprovalicarb in water sediment systems for modelling purpose and trigger evaluation

Compartment	Kinetic evaluation according to FOCUS[a)] for **modelling** purpose DT_{50}[b)] [days]		for **trigger** evaluation	
	range	geo. mean	DT_{50}[b)] [days]	DT_{90}[b)] [days]
Water phase	16.65-57.28	24.61	14.84-57.28	58.2-190.3
Sediment	24.20-78.99	46.78	24.20-78.99	80.4-262.4
Total system	19.93-58.67	34.73	19.17-58.67	66.9-194.9

) Kinetic calculation by [redacted] (2012), submitted within the Anne II dossier submitted in 2012 (IIA, KIIA 7.8.3 /03) according to FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. The Final Report of the Work Group on Degradation Kinetics of FOCUS. SANCO/10058/2005, v.2.0, June 2006

b) water and sediment phase. $DisT_{50}$, total system: $DegT_{50}$

For SZX 0722-carboxylic acid *(M03)* the $DegT_{50}$ in the total systems for modelling purpose and trigger evaluation were in the range of 5.64 to 25.15 days (geom. mean 12.15 days, arith. mean 15.89 days). The corresponding $DegT_{90}$ were in the range of 18.74 to 86.85 days.
For PMPA *(M10)* a $DegT_{50}$ in the total systems for modelling purpose and trigger evaluation of 66.34 days is considered appropriate. The corresponding $DegT_{90}$ is 220.4 days.
For N-acetyl-PMPA *(M15)* no reliable and statistically significant degradation parameters could be evaluated. So, for predictive modelling, a conservative default DT_{50} of 1000 days might be assumed in a total water-sediment system for N-acetyl-PMPA. (Summary of the data of these metabolites see Table 9.7- 2.)

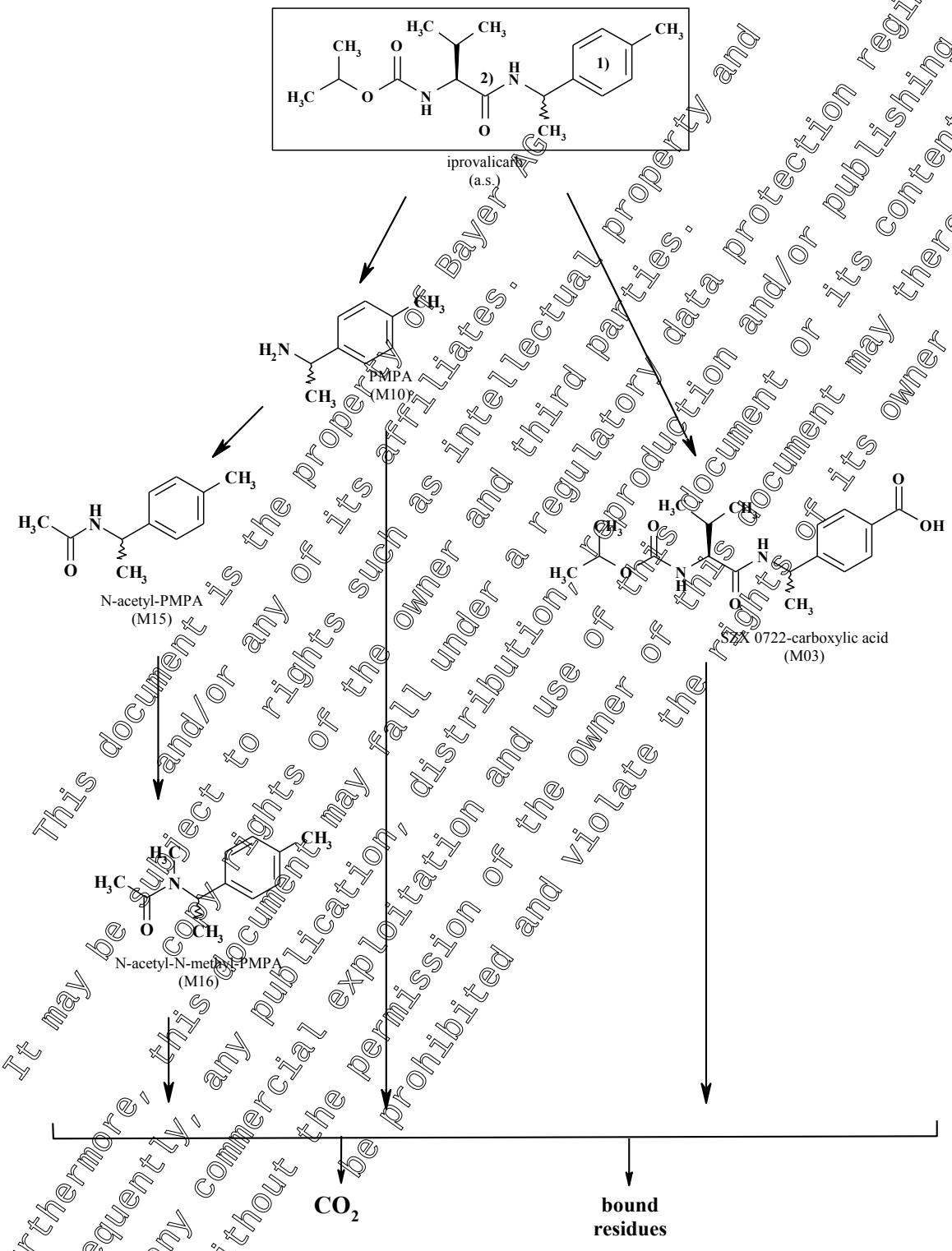
Table 9.7- 2: Evaluation for persistence and modelling endpoints of iprovalicarb in water sediment systems

Compartment	Compound	Kinetic evaluation according to FOCUS[a)] for modelling purpose and trigger evaluation $DegT_{50}$ [days]		$DegT_{90}$ [days]
		range	geo. mean/ arith. mean	
Total system	SZX 0722-carboxylic acid *(M03)*	5.64-25.15	12.15/15.89	18.74-86.85
	PMPA *(M10)*	66.34	-	220.4
	N-acetyl-PMPA *(M15)*	1000[b)]	-	-

) Kinetic calculation by [redacted] (2012), submitted within the Anne II dossier submitted in 2012 (IIA, KIIA 7.8.3 /03) according to FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. The Final Report of the Work Group on Degradation Kinetics of FOCUS. SANCO/10058/2005, v.2.0, June 2006

b) default value

Figure 9.7- 1: Proposed metabolic pathway of iprovalicarb in water-sediment systems under aerobic conditions



Summary of fate and behaviour of folpet in water

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

PEC_{sw} calculations

The following PEC_{sw} calculations are applicable to Europe and represent a worst-case use pattern.

Endpoints for PEC_{sw}

Iprovalicarb

Table 9.7- 3: Modelling input parameters for iprovalicarb

Endpoint	Values used for modelling
Aqueous solubility [mg/L] at 20°C	17.8
Vapour pressure [Pa] at 20°C	7.82×10^{-8}
DT_{50} soil [days] (lab. geo-mean, normalised)	6.78
K_{oc} / K_{om} [L/kg]	113.9 / 66.1
1/n	0.8725
DT_{50} total system water-sediment [days] (geo. mean)	34.73

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{sw} calculations of folpet are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

PEC_{sw} modelling approach

Calculation of PEC values for the active substances according to FOCUS

$FOCUS_{sw}$ is a four step tiered approach:
Step 1: In this, the most conservative step, all inputs are considered as a single loading to the water body and a worst-case PEC_{sw} and PEC_{sed} is calculated.
Step 2: A refinement is made whereby individual loadings into the water body from different entry routes are considered. Scenarios are also considered for Northern and Southern Europe separately but no specific crop scenarios are defined.
Step 3: An exposure assessment using realistic worst-case scenarios is made. The scenarios are representative of agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA.
Step 4: PEC values are refined by considering mitigation measures or specific scenario descriptions on a case-by-case basis. If step 4 calculations are required, they will be presented in the national addenda.

PEC_{sw} for iprovalicarb

Report:	**KIIIA1 9.7 /01, [redacted].; 2012**
Title:	Predicted environmental concentrations in surface water and sediment (PEC_{sw}) of iprovalicarb according to $FOCUS_{sw}$ Step 1-2 Use in vines in Europe
Report No:	EnSa-12-0168
Document No:	M-429643-01-1
Guidelines:	FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev.2.2003
GLP:	No (calculation)

Materials and Methods: Predicted environmental concentrations in surface water and sediment (PEC_{sw} and PEC_{sed}) of iprovalicarb have been calculated for the use of iprovalicarb in vines in Europe.
At FOCUS Step 2 the application period was set to March to May, calculations considered the use in Northern and Southern Europe. Details of the parameters used in the calculations are summarised in Table 9.7- 4.

Table 9.7- 4: Comparison of actual application use pattern and calculated use pattern for FOCUS Step 1 & 2 calculations of iprovalicarb

Individual crop	FOCUS crop used for interception	Application				Amount reaching the soil per season application [g a.s./ha]
		rate per season [g a.s./ha]	interval [days]	plant interception [%]	BBCH stage	
GAP:						
grapes	vines	1 - 4 x 216 1 - 4 x 162 1 - 4 x 150	10 - 14 10 - 14 10 - 12	60 - 85 60 - 70 60 - 85	16 - 75 16 - 61 15 - 85	1 - 4 x 32.4 - 86.4 1 - 4 x 48.6 - 64.8 1 - 4 x 22.5 - 60.0
Simulation:						
vines, early	vines	4 x 216	10	4 x 60	15 - 85	4 x 86.4
vines, intermediate	vines	4 x 216	10	60/70/70/70	50 - 85	86.4/64.8/64.8/64.8
vines, late	vines	4 x 216	10	70/85/85/85	80 - 85	64.8/32.4/32.4/32.4

Compound specific input data are summarised in Table 9.7- 5.

Table 9.7- 5: Substance specific and model related input parameter for PEC_{sw} calculation of iprovalicarb

Parameter	Unit	Value used in modelling
Aqueous solubility at 20°C	[mg/L]	17.8
Vapour pressure at 20°C	[Pa]	7.82×10^{-6}
DT_{50} soil (lab. geo-mean, normalised)	[days]	6.78
K_{oc} / K_{om}	[L/kg]	113.9 / 66.1
1/n	[-]	0.8725
DT_{50} total system water-sediment (geo. mean)	[days]	34.73

For an aquatic risk assessment the worst-case concentration considering either a single application or multiple applications should be considered, especially in case that the dominant entry route is via drift. Therefore, both multiple applications (in accordance with the use patterns) and single applications were considered.

Findings:

Step 1 and 2: The maximum PEC_{sw}, PEC_{sed} and $PEC_{sw\ 21d\ TWA}$ values for for Steps 1 and 2 are given in Table 9.7- 6.

Table 9.7- 6: Maximum PEC_{sw}, PEC_{sed} and $PEC_{sw,\ 21d\ TWA}$ values for iprovalicarb at Step 1 and Step 2

Crop	Step	Application scenario	Region	Iprovalicarb $PEC_{sw,\ max}$ [µg/L]	Iprovalicarb $PEC_{sw,\ 21d\ TWA}$ [µg/L]	Iprovalicarb $PEC_{sed,\ max}$ [µg/kg]
Vines, early	1			273.1	220.7	284.8
	2	Multi	N-EU	18.54	14.72	20.11
			S-EU	24.92	19.93	27.23
		Single	N-EU	8.999	7.18	9.809
			S-EU	13.15	10.57	14.45
Vines, intermediate	1			273.1	220.7	284.8
	2	Multi	N-EU	18.54	14.72	20.11
			S-EU	21.73	17.33	23.67
		Single	N-EU	8.999	7.182	9.809
			S-EU	11.08	8.879	12.13
Vines, late	1			273.1	220.7	284.8
	2	Multi	N-EU	15.99	12.64	17.26
			S-EU	17.91	14.20	19.39
		Single	N-EU	7.338	5.825	7.955
			S-EU	8.584	6.843	9.346

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

PEC_{sw} for folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{sw} calculations of folpet are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

IIIA1 9.7.1 Initial PECsw value for static water bodies

Please refer to Point IIIA1 9.7.

IIIA1 9.7.2 Initial PECsw value for slow moving water bodies

Please refer to Point IIIA1 9.7.

IIIA1 9.7.3 Short-term PECsw values for static water bodies (1-4 days after last application)

Please refer to Point IIIA1 9.7.

IIIA1 9.7.4 Short-term PECsw values for slow moving water bodies (1-4 days after last application)

Please refer to Point IIIA1 9.7.

IIIA1 9.7.5 Long-term PECsw values for static water bodies (7-42 days after last application)

Please refer to Point IIIA1 9.7.

IIIA1 9.7.6 Long-term PECsw values for slow moving water bodies (7-42 days after last application)

Please refer to Point IIIA1 9.7.

IIIA1 9.8 Predicted Environmental Concentrations in Surface Water (PECsw) for Metabolites

EU endpoints for PEC_{sw}

Iprovalicarb

Table 9.8- 1: Modelling input parameters for iprovalicarb metabolites

End-Point	Iprovalicarb metabolites Values used in modelling
SZX 0722-carboxylic acid *(M03)*	
Aqueous solubility [mg/L] at 20°C and pH 7	56000
Vapour pressure [Pa] at 20°C	8.9×10^{-6}
DT_{50} soil [days] (geo. mean lab., normalised)	0.97
Max. occurrence in soil [%]	10.0
K_{oc} / K_{om} [L/kg] (worst case alkaline soils)	0.64 / 0.37
1/n (arith. mean)	1.025
DT_{50} total system water-sediment [days] (geo. mean)	12.15
Max. occurrence in total system water-sediment [%]	5.2
PMPA *(M10)*	
Aqueous solubility [mg/L] at 20°C and pH 11	15000
Vapour pressure [Pa] at 20°C	20
DT_{50} soil [days] (geo. mean lab., normalised)	81.08
Max. occurrence in soil [%]	50.7
K_{oc}/K_{om} [L/kg] (arith. mean)	290.2 / 168.3
1/n (arith. mean)	0.8629
DT_{50} total system water-sediment [days] (n = 1)	66.34
Max. occurrence in total system water-sediment [%]	19.7
N-acetyl-PMPA *(M15)*	
Aqueous solubility [mg/L] at 20°C and pH 7	6600
Vapour pressure [Pa] at 20°C	2.7×10^{-3}
DT_{50} soil [days] (geo. mean lab., normalised)	0.72
Max. occurrence in anaerobic soil [%]	29.1
K_{oc}/K_{om} [L/kg] (arith. mean)	39.7 / 23.0
1/n (arith. mean)	0.9025
DT_{50} total system water-sediment [days] (default worst case)	1000
Max. occurrence in total system water-sediment [%]	11

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{sw} calculations of folpet metabolites are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This

is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

PEC_{sw} for iprovalicarb metabolites

For iprovalicarb metabolites SZX 0722-carboxylic acid *(M03)*, PMPA *(M10)* and N-acetyl-PMPA *(M15)* were assessed.

Report:	**KIIIA1 9.8 /01, [redacted] 2012**
Title:	Predicted environmental concentrations in surface water and sediment (PEC_{sw}) of iprovalicarb according to $FOCUS_{sw}$ Step 1-2 Use in vines in Europe
Report No:	EnSa-12-0169
Document No:	M-429638-01-1
Guidelines:	FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev2 2003
GLP:	No (calculation)

Materials and Methods: PEC_{sw} for the metabolites were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point IIIA1 9.7. Input parameters for the metabolite are described in Table 9.8- 2.

Table 9.8- 2: Substance specific and model related input parameter for PEC_{sw} calculation

Parameter	Unit	Values used in modelling
SZX 0722-carboxylic acid *(M03)*		
Aqueous solubility at 20°C and pH 7	[mg/L]	56000
Vapour pressure at 20°C	[Pa]	8.9×10^{-6}
DT_{50} soil (geo. mean lab., normalised)	[days]	0.97
Max. occurrence in soil	[%]	10.0
K_{oc} / K_{om} (worst case alkaline soils)	[L/kg]	0.64 / 0.37
1/n (arith. mean)	[-]	1.023
DT_{50} total system water-sedimen (geo. mean)	[days]	12.15
Max. occurrence in total system water-sediment	[%]	5.2
PMPA *(M10)*		
Aqueous solubility at 20°C and pH 7	[mg/L]	15000
Vapour pressure at 20°C	[Pa]	20
DT_{50} soil (geo. mean lab., normalised)	[days]	81.08
Max. occurrence in soil	[%]	50.7
K_{oc} / K_{om} (arith. mean)	[L/kg]	290.2 / 168.3
1/n (arith. mean)	[-]	0.8629
DT_{50} total system water-sedimen (n = 1)	[days]	66.34
Max. occurrence in total system water-sediment	[%]	19.7
N-acetyl-PMPA *(M15)*		
Aqueous solubility at 20°C and pH 7	[mg/L]	6600
Vapour pressure at 20°C	[Pa]	2.7 x 10-3
DT_{50} soil (geo. mean lab. normalised)	[days]	0.72
Max. occurrence in anaerobic soil	[%]	29.1
K_{oc} / K_{om} (arith. mean)	[L/kg]	39.7 / 23.0
1/n (arith. mean)	[-]	0.9025
DT_{50} total system water-sedimen (default worst case)	[days]	1000
Max. occurrence in total system water-sediment	[%]	11

Findings:

Step 1 and 2: The maximum PEC_{sw}, PEC_{sed} and $PEC_{sw\ 21d\ TWA}$ values for the metabolites of iprovalicarb at Step 1 and Step 2are given in Table 9.8- 3 to Table 9.8- 5.

Table 9.8- 3: Maximum PEC_{sw}, PEC_{sed} and $PEC_{sw,\ 21d\ TWA}$ values for metabolite SZX 0722 carboxylic acid *(M03)*

Crop	Step	Application scenario	Region	SZX 0722-carboxylic acid *(M03)* $PEC_{sw,\ max}$ [µg/L]	$PEC_{sw,\ 21d\ TWA}$ [µg/L]	$PEC_{sed,\ max}$ [µg/kg]
Vines, early	1			32.78	19.10	0.201
	2	Multi	N-EU	0.561	0.351	0.003
			S-EU	0.561	0.376	0.003
		Single	N-EU	0.329	0.216	0.002
			S-EU	0.329	0.205	0.002
Vines, intermediate	1			32.78	19.10	0.201
	2	Multi	N-EU	0.561	0.351	0.003
			S-EU	0.561	0.363	0.003
		Single	N-EU	0.329	0.216	0.002
			S-EU	0.329	0.192	0.002
Vines, late	1			32.78	19.10	0.201
	2	Multi	N-EU	0.561	0.341	0.003
			S-EU	0.561	0.349	0.003
		Single	N-EU	0.329	0.206	0.002
			S-EU	0.329	0.214	0.002

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Table 9.8- 4: Maximum PEC_{sw}, PEC_{sed} and $PEC_{sw,\ 21d\ TWA}$ values for metabolite PMPA *(M10)*

Crop	Step	Application scenario	Region	PMPA *(M10)* $PEC_{sw,\ max}$ [µg/L]	$PEC_{sw,\ 21d\ TWA}$ [µg/L]	$PEC_{sed,\ max}$ [µg/kg]
Vines, early	1			46.34	41.14	128.9
	2	Multi	N-EU	4.835	4.257	13.61
			S-EU	8.629	7.663	24.50
		Single	N-EU	1.440	1.263	4.036
			S-EU	2.513	2.223	7.119
Vines, intermediate	1			46.34	41.14	128.9
	2	Multi	N-EU	4.835	4.257	13.61
			S-EU	6.732	5.960	19.06
		Single	N-EU	1.440	1.263	4.036
			S-EU	1.976	1.745	5.577
Vines, late	1			46.34	41.14	128.9
	2	Multi	N-EU	3.318	2.895	9.250
			S-EU	4.456	3.916	12.52
		Single	N-EU	1.010	0.877	2.804
			S-EU	1.332	1.166	3.728

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Table 9.8- 5: Maximum PEC_{sw}, PEC_{sed} and $PEC_{sw, 21d\ TWA}$ values for metabolite N-acetyl-PMPA *(M15)*

Crop	Step	Application scenario	Region	N-acetyl-PMPA *(M15)*		
				$PEC_{sw, max}$ [µg/L]	$PEC_{sw, 21d\ TWA}$ [µg/L]	$PEC_{sed, max}$ [µg/kg]
Vines, early	1			45.43	45.04	17.48
	2	Multi	N-EU	1.131	1.105	0.441
			S-EU	1.155	1.128	0.451
		Single	N-EU	0.362	0.354	0.141
			S-EU	0.386	0.377	0.151
Vines, intermediate	1			45.43	45.04	17.48
	2	Multi	N-EU	1.131	1.105	0.441
			S-EU	1.143	1.117	0.446
		Single	N-EU	0.362	0.354	0.141
			S-EU	0.374	0.366	0.146
Vines, late	1			45.43	45.04	17.48
	2	Multi	N-EU	1.122	1.096	0.438
			S-EU	1.129	1.103	0.441
		Single	N-EU	0.353	0.345	0.138
			S-EU	0.360	0.352	0.141

vines, early: 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval
vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval
vines, late: 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

PEC_{sw} for folpet metabolites

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9.

No PEC_{sw} calculations of folpet metabolites are submitted here. Bayer CropScience AG is using a risk envelope approach for the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that [redacted] currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by [redacted] wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling Comments: IIIA 9.8	
Agreed PEC (metabolites): IIIA 9.8	

IIIA1 9.8.1 Initial PECsw value for static water bodies

Please refer to Point IIIA1 9.8.

IIIA1 9.8.2 Initial PECsw value for slow moving water bodies

Please refer to Point IIIA1 9.8.

IIIA1 9.8.3 Short-term PECsw values for static water bodies 1-4 days after last application)

Please refer to Point IIIA1 9.8.

IIIA1 9.8.4 Short-term PECsw values for slow moving water bodies 1-4 days after last application)

Please refer to Point IIIA1 9.8.

IIIA1 9.8.5 Long-term PECsw values for static water bodies 7-42 days after last application)

Please refer to Point IIIA1 9.8.

IIIA1 9.8.6 Long-term PECsw values for slow moving water bodies 7-42 days after last application)

Please refer to Point IIIA1 9.8.

IIIA1 9.8.7 Additional field testing

No additional field studies on the formulation have been performed or are required.

IIIA1 9.9 Fate and Behaviour in Air

Iprovalicarb

Iprovalicarb has a very low vapour pressure of 7.7 x 10^{-8} Pa. Therefore, it can be concluded that significant volatilisation of iprovalicarb is not to be expected.

In addition, estimates of the chemical lifetime in the troposphere resulted in half-lives < 1 day.

Folpet

For the 3rd party active substance folpet, produced from [redacted]) Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by [redacted] which were submitted in the EU for the support of the registration of the active

substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here. For details please refer to the statement mentioned at page 9.

IIIA1 9.9.1 Spray droplet size spectrum – laboratory studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA1 9.9.2 Drift – field evaluation

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA1 9.10 Other/Special Studies

IIIA1 9.10.1 Laboratory studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA1 9.10.2 Field studies

This is not an EC data requirement / not required by Directive 91/414/EEC.