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**IIIA19** FATE AND BEHAVIOUR IN THE ENVIRONMENT

### **Regulatory background**

(Submission for Annex I renewal)

This document summarises predicted environmental concentrations for the product 'Iprovalicate + 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 proval warb contained in the product 'Iprovalicarb + Folpet - WG (5.3' for the application of the product according @ the use pattern provided in Table 9-1. For the 3rd patty active substance folpet, produced from ) Bayer Cropscience AG has the right of reference to files, data

which were submitted in the EU for the support of studies, summaries and assessments owned by the registration of the active substance folpet and the representative formulation Folpan 80 WDG. Therefore, no predicted environmental concentrations of folges are submitted here. For details please refer Formulants The formulants of a preparation would not be expected to influence the environmental behaviour of an

active substance (except inspecial formulation to be such as slow refease 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 tong-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 thosyalid also for the formulation.

# Intended application pattern 🖄

Ő The formulation is intended for use as a fungicide for vines. The critical use pattern for this formulation is

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

# Table 9-1:Comparison to the actual application use pattern and the calculated use pattern for<br/>PEC calculations

Сгор	Timing of application [BBCH]	Number of applications	Application interval [days]	Maximum ap individual [kg a. Inrovalicarb	plication rate, treatment .s./ma]	
CAD						
GAP:				K Y		, P K
vines	16 – 75	1 - 4	10 - 14 🖒	0.216	1.3512	
	16 - 61	1 - 4	10 - 14	0.162	1.9134~0	
	15 - 85	1 - 4	10 - 12	0,150	× 0.940 ×	
PECs:						
vines	15 - 85	4	¶©‴10	2 kg		
a) Bayer (	CropScience AG	is using a risk e	kvelope approach	of the risk assessme	ent of 😡 🍾	<u> </u>
represe	ntative formulat	ion. Within the	Done of Whis supp	ementar dossier un	to Applications a	it «

representative formulation. Within the wore of this supplementaty dossier up to Applications at 1.35 kg/ha folpet are proposed as a safe use in grapes. This is much below the critical GAP that the 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, Bay CropScience AG considers it justified to the to tobe the data swned by the parameters appropriate. A tolpet-specific risk assessment is not considered necessary to defend the Antex I listing of interval case.

# 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 of short codes for the active substances and degradation products. In this summary, a single name for each substance is always used.

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Compound	Chemical structure	Explanation for	Considered for
(Codes)		consideration	
Iprovalicarb (SZX 0722)	$\begin{array}{c c} & H_3C \\ CH_3 & O \\ \downarrow & \downarrow \\ \end{array} \xrightarrow{ \begin{array}{c} H_3C \\ H_3 \\ H_3 \\ \end{array}} \xrightarrow{ \begin{array}{c} CH_3 \\ H_3 \\ CH_3 \\ H_3 \\ \end{array}} \xrightarrow{ \begin{array}{c} CH_3 \\ CH_3 \\ H_3 \\ \end{array}}$	active substance	PEC See
	$\begin{array}{c c} H_{3}C & O & N \\ H_{3}C & O & CH_{3} \end{array}$		
SZX 0722- carboxylic acid (M03)	$H_{3}C \xrightarrow{H_{3}C} CH_{3} \xrightarrow{H_{3}C} OH$	occurrence in - aerobic soil (10%) @	PECsoit PECson PECson PECson PECson
PMPA (M10)		occurrence in - Aerobic Goil (> 10%) - watet/sediment study (>40% in water and sediment)	PEC soil PEC sw PEC sw & CEC sed
N-acetyl-PMPA (M15)		of currende in 5 - anaerobic sold (> 10%) - water/sechinent stody - 10% in water	PEO _{soil} PEC _{gw} PEC _{sw} & PEC _{sed}

<b>Table 9- 2:</b>	Active substance and	metabolites addressed	in this document

# Folpet

The representative formulation in the application for Andex I Renewal of iprovalicarb is a combination with folget, which – from a Bayer perspective is a 3° party substance, procured from Seven CropScience AG has the right of reference of files, data studies, summaries and assessments owned by which were submitted in the EU for the support of the registration of the active substance folget and the representative formulation Folgan 80 WDG. The right to references of Bayer CropScience AG extends to all EC countries a separate Letter of Access is included in this supplementary dossier (M-428625-0)(-1).

Bayer CropScience AG is using orisk 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 **set of** currently defends in this crop in the EU, where 10 applications of 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, Boyer CropScience AG considers it justified to refer to folpet data owned by **set of** wherever appropriate A fotpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalitarb.

# IIIA1 2 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 parts active Bayer CropScoonce AG substance folpet, produced from

whichwere has the right of reference to files, data, studies, summaries and assessments owned by 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.

# Aerobic degradation of the preparation in soil 2 **IIIA1 9.1.1**

Specific studies on the preparation have not been performed. The results of laboratory studies performed with the active substance iprovalicarb as provider in the ... Annex IIA in the context of Section 5, Potor 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 subsection below. For the 3rd party substance folpet, poduced from ) Bayer

CropScience AG has the right reference to Mes, data, studies, summaries and sessments owned by 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 a page of

# Iprovalicarb

The degradation behaviour of iprovadicarb under laboratory conditions, in the dark, has been studied in a number of different soils at temperatures \$\$20 Cand with one soil under 10°C. From the studies on the route of degradation is soil, it can be concluded that iprovalicarb was thoroughly degraded on soil under derobic conditions to the find degradation product CO₂. Three metabolites were identified in the soil along with the parent compound and ¹⁴CO2. The major metabolites (> 10% of the applied radioactivity (AR)) were SZX 0722-carboxyl@acid (M03) and PMPA (M10). Terephthalic acid (M23) was found as migor metabolite Unextractable residues reached 29.5 to 33.9% of AR at study end (valine-label, day 210 and up to 27.9% of AR and 31.5% of AR (phenyl label, day 100 / day 365). Iprovalicarb was metabolised to the endpoint  $O_2$  via two routes. In one route the breakdown of the molecule started with the cleavage of the apoide bond between the L valine and PMPA moieties. This led to the main metabolite PMPA (Mhy). 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 9.1.0-1.

It can be conduded 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 CO₂ were detected in the soil extracts. Two of these degradates were identified as SZX 0522-carboxylic acid (M03) and PMPA (M10). All individual degradates accounted for less than 5% of the applied radioactivity in the irradiated samples, with CO₂ 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 CO₂.

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 katetic evaluation of these data was performed according to FOCUS kinetics (FOCUS, 2006¹), for the patent compound the major soil metabolites. A summary of these data is given in Table 9.1.1-4. For **iprovalicarb** the non-normalised  $DT_{50 \text{ mod}}$  for <u>modelling purpose</u> were in the range of 1.99 to 68.56 days and the normalised  $DT_{50 \text{ mod}}$  in the range of  $c_1$ .77 to 68.56 days (geom. mean 6.78 days). For  $c_1$  persistence trigger evaluation (non-normalised) the  $DT_{50 \text{ mitial}}$  were in the range of 1.99 to 18.00 days and the  $DT_{90 \text{ initial}}$  in the range of 6.62 to 252.12 days.

For SZX 072-carboxylic acid (*M03*) the non-normalised DT  $_{50 \text{ mod}}$  for <u>modelling purpose</u> were in the range of 0.56 to 1.852 days and the normalised DT  $_{50 \text{ mod}}$  in the range of 0.45 to 1.852 days (geom. mean. 0.97 days). For <u>persistence trigger evaluation</u> (non-hormalised) the DT  $_{50 \text{ initial}}$  were in the range of 0.58 to 1.97 days and the DT  $_{90 \text{ initial}}$  in the range of 0.53 days (geom. mean.

For **PMPA** (*M10*) the non-normalised  $DT_{50 \text{ mod}}$  for <u>modelling purpose</u> were in the range of 44.28 to 187.33 days and the normalised  $DT_{50 \text{ mod}}$  in the range of 39.39 to 187.4 days (geom. mean \$1.08 days). For <u>persistence trigger evaluation</u> (non-normalised) the  $DT_{50 \text{ mod}}$  were in the range of 44.28 to 239.32 days and the  $DT_{90 \text{ initia}}$  or the range of 147.1 to 759.0 days

For **N-acetyl-PMPA** (*M10*) the non-normalised  $DT_{50 \text{ mod}}$  for <u>modelling purpose</u> were in the range of 0.422 to 0.929 days and the normalised  $DT_{50 \text{ mod}}$  in the range of 0.424 to 0.935 days (geom. mean 0.72 days). For <u>persistence trigger-evaluation</u> (non-normalised) the DT_{90 initial} were in the range of 9.0 to 22.3 hours (0.4 to 0.9 days) and the DT_{90 initial} to the range of 9.0 to 74.1 hours (10 to 3.4 days).

 
 Table 9.1.1-1:
 Summary of DT-3 values of iprovalicarb and metabolities in morobic soil studies evaluated for modeling purpose and trigger evaluation according to FOCUS kinetics (FOCUS, 2006)

Compound		Difference Difference (bours)	lling purpose ØT50 mod [days]	range for trigger evaluation DT50 initial
Iprovalicarb		1.9876	68.56 1.77 – 68.6	1.99 – 18.0 days
SZX 0722-carboxy	pic acid (M03)	∞ ್ 0,56−1	.892 0.45 - 1.85	0.58 – 1.97 days
PMPA (M10)	ŐY A		87.33 39.39 – 187.3	44.28 –239.32 days
N-acetyl-PMPQ (A	M15\$	10.1-22.30 0.422	0.929 0.42 - 0.93	9.0 - 22.3 hours
.4	Or a			

The rate of degradation of iprovalicarb irradiated with artificial light was investigated in a <u>soil photolysis</u> study. It can be concluded that photodegradation will not significantly contribute to the degradation of the parent compound. The  $DT_{50}$  was 62 days

Jucgit ... Ji 50 stas 62 day.

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



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(Submission for Annex I renewal)

#### Folpet

For the 3rd party active substance folpet, produced from

all of the second secon Baver CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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.

#### Anaerobic degradation of the preparation in soil **IIIA1 9.1.2**

### **Iprovalicarb**

The anaerobic biotransformation of iprovalicarly 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 scrobic Conditions for three days. Afterwards the samples were flooded with water and maintained under an erobic conditions. Iprovalicarb degraded to two major degradates. One major degradato, PMPA (M/Q), was formed under aerobic conditions and increased under analyobic conditions. During the maerobic phase, N-acetyl-PMPA (M15) was also formed as major degradate. SZX 0722-aminoacetonitele (M30), way formed later in the study under anaerobic conditions as a minor degradate, Unextractable residues reached 39.8% by the end of the study. Additional CQ2 and vetatile organic compounds were produced allow levels throughout the anaerobic phase of the study ( $\leq 40\%$ ). A degradation oathway is shown in Figure 9.1.2-1.

The degradation of iprovalicate 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 (\$110) shows wiry good to reasonable fits, assuming SFO decay (DIG) for modelling purpose: 28% days) and DFOP decay (DT₅₀ for persistence endpoints: 43.1 days). N-acety PMPA (M15) shows very good to reasonable fits, assuming SFO decay (DT50 for modelling purpose: 76.2 days) and DEOP decay (DT₅₀ for persistence endpoints: 105.7 days). (Table \$1.2-1).

Table 9.1.2- 1:	Laboratory	anaerobi	c sốil/]	DegT	values	of iprovalicarb	and metal	bolites for modelli	ng or
	Ô. A		×	a a construction and a construct		_0×			0
	persistence	purpose	0	°~	£	, CV			

		1 Alian A	
~Ŷ	Compound in a in	DT50 mod	DT 50 initial
4		<u>[uays]</u>	[uays]
<u>A</u>	Iprovalicarb V V	30.8	25.4
	PMPA (MÍO)	38.6	43.1
, K	Nacetyk MP A M15) O'	76.2	105.7

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



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#### Folpet

For the 3rd party active substance folpet, produced from

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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 are also applicable for this preparation."

#### Soil dissipation testing on a range of representative soils **IIIA1 9.2.1**

### **Iprovalicarb**

The field dissipation of iprovalicarb oas evaluated during the Amer I Inclusion. In addition kinetic evaluation of the dissipation behaviour of iprovalicarb and its petabolite PMPA (MH) has been performed. A short summary of the data is given below:

The dissipation of iprovaliearb 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-hormalised half-lives of 3.7 to12.5 days for iprovalicarb and 202 to 228.4 days for the merabolite PMPA (M10). The corresponding DT₉₀ values were in the vange of 12.8 to 61.7 days and 73.600 7580 days respectively. The nonnormalised Dis \$250 values for persistence of frigget purpose are sommarised in Table 9.2.1-1.

Table 0 2 1 /2	Dist	, fald
1 abie 9.2. į-gz	Distis, initial values of iprovancare of iprovancare and as includente river A (M10) in	i neia
	dissingtion trials for the gas numeros and the prototo on maisture normalized)	
~~ ×	issipation triats, for trigger purpose that temperature or moisture normansed)	

	. 01	());		*	) O`	<b>%</b>	$\sim$ $\bigcirc$	
	^ر ک	ompou	ind≪J	Ő	°N	🌾 rang	ge DisT50, init	ial
~	Ş 🗌	~~	Ş	N	Å		[days]	
Ô	Å	novalie	Şarb (			, "Ş	.73 – 12.45	
	, Ôř	MPAN	M10) Û			®*22	2.15 - 228.4	
Ŷ	O	×°	$\sim$		Ś	ð		

## Folpet 🖑

For the 3rd party active substance folpet broduced from

Bayer CropScience AG has the Fight of reference to files, data, studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance forpet 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^{9/2.2.2} 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.

Liprovalicarb Due to the use pattern of the formulation and the degradation rates of the active substance not the degradation rates of the active Jn of L Jn of substance folpet and the representative formulation Falpan 80 WD Therefore, so sumpary data of folpet are submitted here. For details please tefer to the statement mentioned at page

#### Aquatic (sediment) field dissipation **IIIA1 9.2.4**

This is not an EC data requirement / not required by D

#### Forestry field dissipation **IIIA1 9.2.5**

This is not an & data requirement Onot required b

#### Mobility of the Plant Protection Broduct in Soil **IIIA1 9.3**

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

# Iprovalicarb

**Iprovalicarb** The <u>adsorption</u> constants of for provalicarb 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 mLog. For the major soil metabolites SZX 0722-carboxylic acid (M03), PMPA (M10) and S-acet PMPON (M15) the W values were in the range of 0.012 - 0.354 mL/g, 0.67 - 11  $\frac{1}{100}$  mL/g and 0.34 -  $\frac{1}{1000}$  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 39/2 mL/g prespectively 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).

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	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

39.7

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

#### Folpet

For the 3rd party active substance folpet, produced from

N-acetyl-PMPA (M15)

Bayer CropScience AG has the right of reference of files, data, studies, summaries and assessments owned by 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.

o⁴, o

## 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 eported.

### Folpet

For the 3rd party active substance folpet, produced from **Constant and State States** and assessments Bayer CropScience AG has the right of reference to files data, studies, summaries and assessments owned by **States** which were submitted in the PU 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 Uysometer 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  $\geq 0.1 \ \mu g/L$ .

## Folpet

For the 3rd party active substance folpet broduced from

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by **Sector** which were submitted in the EU for the support of the registration of the active substance to pet 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.

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#### **IIIA1 9.3.3 Field leaching studies**

### **Iprovalicarb**

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

### Folpet

For the 3rd party active substance folpet, produced from

Ullea Up 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, ho surbmary data of folpet are submitted here. For details please refer to the statement menuoned at page . Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments

No volatility studies on the preparation have been performed. Defai Is of the volatility of the active substance are given in Section 1. The vapour pressures are also reported in Section A1 3.

#### · field stud Volatilitv **IIIA1 9.3.5**

## **Iprovalicarb**

Field volatility studies showed a low trand of iprovalicarb to solatilise from soil and plants under field conditions. Therefore an exposure or emission via contaminated at is not to be expected. Ľ

# Folpet

For the 3 party active substance folget, produced from

Bayer CropScience AG has the right of reference to files, data studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance folpet and the representative formal ation Folpan 80 WDG. Therefore, no summary data of folpet are submitted here for details please refer to the statement mentioned at page 9.

#### Predicted En Concentrations in Soil (PECs) for the Active IIIA&9.4 iconmental Substance

#### Modelling inper parameters for iprovalicarb Table 9.4

DTso soil [days] (lab_worst case_non-normalised) 68.56	End-Point S	Active substance: iprovalicarb Value used for modeling
D 130 500 [augs] (augs)	^v DT ₅₀ soil [days] (lab., worst case, non-normalised)	68.56

Endpoints for PECsóu

Iprovalicarb

### Page 19 of 49 2012-05-12 Doc. M-III /Tier 2, Sec. 5, Point 9 – Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

### Folpet

For the 3rd party active substance folpet, produced from

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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 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 the Annex I tisting 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 dayer. A standard soil density of 1.5 g/cm³ was assumed. Crop interception data which correspond to the intended growth stages were taken from the FOCUS groundwater guidance paper (FOCUS, 2002¹).

taken into account depending on the growth stage at application The interception rates follow the recommendations of the FQCUS groundwater guidance paper@FOCUS, 2002) for grapes.

## PEC_{soil} for ippovalicarb

Report:	KUIA1 94 701, 2012
Title:	Predicted environmental concentrations in soil (PEC _{soil} ) of iprovalicarb
	verse in ymes, early, wres, intermediate and wines, late in Europe
Report No:	\$\San 12-0169 \sqrt{69} \sqrt{12}
Document No: @	∑ M-42963&01-1 √ √
Guidelines:	Soil Persistence Models and OU registration: Report of the FOCUS Soil Modelling
~Ç	WorkGroup, 1996 7 2
2	EC Bocuttent Reference 7617 y 4/96
GLP:	No (calcolation)

**Methods and Materials:** The predicted environmental concentrations in soil (PEC_{soil}) of iprovalicarb were estimated using a simple first tice 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 DT₅₀ of 68.56 days (worst case of laboratory studies mon-normalised).

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

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

Individual crop	FOCUS		Applio		Amount reaching	
	crop used	rate per	interval	plant	BBCH	the soil per season
	for	season	[days]	interception	stage	application
	interception	[g a.s./ha]		[%]		[g a.s./hat
GAP:	-		-	~	Ą	
grapes	vines	1 - 4 x 216	10 - 14	60 - 85 🔬	16 - 75	≪J - 4 x 32.4 - 86.4
		1 - 4 x 162	10 - 1🌮	60 - 70	16 - 61 _@	C 1 - <b>4</b> © 48.6 <b>∠-</b> 64.8 ⊀
		1 - 4 x 150	10, 12	60 - 🔊	15 - 85	1 7 x 22 5 60.0 °
Simulation:			À			
vines, early	vines	4 x 216 4	🖗 10	~4 x 60	15-85	x 4 x 86.4
vines, intermediate	vines	4 x 216 Ķ	LØ Å	\$60/70/ <b>#9</b> /70	<u>(</u> 30 - 85)	86.4/64.8/64.8/64.8
vines, late	vines	4 x 216	× 40 0	70/8585/85	80-85	€4.8/32. <u>4</u> 32.4/ <u>3</u> 2.4
		4	<u> </u>	Q ,		O Q A

Findings: The PEC_{soil} and the time work the daverage values (TWA_{soil}) of provalicarb after application in vines are summarised in Table 9.4-6 and the provalicarb after application in Table 9.4-3: PEC_{soil} (actual) and TWA_{soil} of introvalicarb

Table 9.4- 3:	PEC _{soil} (actual)	and TWAsoil	of provalicarb
---------------	------------------------------	-------------	----------------

			0	4//m .ii	- ~ /		
	Time vines, early		vines, int	ermediate	vines, late		
	[days]	PECseil	<b>WAsop</b>	PPCsoil	TWAsoil 🗞	PECsoil	TWAsoil
	2	[mg/kg]	©[mg/kg]	,∬mg/kg],∿	[mg/kg]♥	[mg/kg]	[mg/kg]
Initial	0,	<b>9</b> 5398 O		0,3 <b>20</b> °	& <del>.</del>	<u></u> 0)).181	-
	Ę.	Ø.394 🖉	Q.396 🖉	Q:317 (	0.3,19	^(م) 0.180	0.180
Short term		0.39	~~0.394 [~]	0.314	0.317	0.178	0.180
	<u>گُ</u> 4 ر	0,383	[≪] 0. <b>3</b> 9¥	0.30	0.314	0.174	0.178
. (		0.371 📡	0,385	0,298	© 0.309 [°]	0.169	0.175
) Ô	2	<i>√</i> 0.322 ^O	<b>9</b> .359 6	QZ 59	° 0 <b>2</b> 88	0.147	0.163
Long term	28	0.300	<u>1</u> 0.34	00.241	<b>0</b> ,279	0.137	0.158
	50	0,240	0.313	0.195	∾0.251	0.109	0.142
E V	1000		Q.251 C	0.146 🔩	© 0.201	0.066	0.114

216 g provalearb/har x 60% interception, 10 days application interval vines, early: x 216 g iprovaticarb/ha, 60/70/70/70/0nterception, 10 days application interval vines, intermediate 0/85/85/85% interception, 10 days application interval vines, late:

# PEC_{soil} for folpet

For the 3rd party active substance folpet, produced from

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance folget and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page 9. ~Ò

No PEC & calculations of folget 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 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 wherever appropriate. A folpet-specific risk considers it justified to refer to folpet data owned by assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling Comments: IIIA 9.4/01		Ŵ)
Agreed PEC _s (active substance): IIIA 9.4/01		
[IIA1 9.4.1 Ini	tial PECs values	
Please refer to point	IIIA19.4. $\begin{array}{c} \begin{array}{c} \begin{array}{c} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \begin{array}{c} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{} \end{array}{$	
IIA1 9.4.2 Sho	ort-term PECs values (1-4 days after last application)	
Please refer to point	IIIA1 9.4. $\begin{array}{c} \mathcal{A} \\ \mathcal{A} $	
IIA1 9.4.3 Lo	ig-term PECs values (from 7,100 days after last application)	
Please refer to point		

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

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

#### **Endpoints for PEC**soil

### **Iprovalicarb**

e	nvironmental concentrations in soil were calculated for the metabolites indicated in Type 9-2
ta	bolites are not automatically "relevant" with regard to their environmental, biological,
lc	ogical or toxicological properties.
ts	for PEC _{soil}
a	rb
1	: Modelling input parameters for iprovalizarb metabolites
	End-Point Iprovaticarb metabolites
	SZX 0722-carboxylic acid (M03)
	Molecular mass correction A & O Q 1.0935 O
	DT ₅₀ soil [days] (lab., worst case, non-normalised)
	Maximum occurrence in soil $[0^{6}]$ $[0^{7}]$ $[0^{7}]$ $[0^{7}]$ $[0^{7}]$ $[0^{7}]$
	PMPA (M10)
	Molecular mass correction of the two sets of the set of
	DT ₅₀ soil [days] (lab@worst ease, non normalised) @ 987.33
	Maximum occurrence in soil [%]
	N-acetyl-PMRA (M15)
	Molecular mass correction S S O & 0.5536
	$DT_{50}$ soil feays] (bb., worst case, non-normalised) $O = 0.929$
	Maximum occurrence manaerobic soil [%] 29.1

# Table 9.5-1:

## Folpet

For the 3rd party active substance folger, produced from

Bayer CropScience AC has the right of reference to files, data, studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the O statement mentioned at page.

No PEC_{soil} calculations of olpetmetabolites 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 currently defends in this crop in the EU, where 10 applications of up to 1.6 kg/ka have been approved, with all other parameters such as interval between applications or pre-harvest interval being intentical or very similar. Therefore, Bayer CropScience AG considers it justified to ver appropriate. A folpet-specific risk assessment ssary to defend the Annex I listing of iprovalicarb. is not considered neo

# **Bayer CropScience**

Doc. M-III /Tier 2, Sec. 5, Point 9 - Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

### 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, 2012
Title:	Predicted environmental concentrations in soil (PECsoil) of iprovalicato
	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 760 $VI/96$ $\sim$ $0^{\circ}$ $\sqrt{0^{\circ}}$ $\sqrt{0^{\circ}}$
GLP:	No (calculation)

Methods and Materials: PECsoil for the metabolites were calculated using the approach, sceparios and application rates described for the calculations for the parent compound in Point 94 **\$1**). Compound specific parameters are summarised in The 9.3

#### Input parameters for PEC soffor metabolites of ipcovalicate Table 9.5- 2:

			$\bigcirc$ $\bigcirc$ $\bigcirc$ $\bigcirc$	**
Compound	Data soil*?	Max. occurrence	Modar mass	🔬 Molar mass
	/ days	in søil	္တ [g/mol]	<b>Correction</b> factor
~	k _s ov	<i>∽ [</i> %] [∧]		
SZX 0722-carboxylic acid (2003)	) 🌵 🎉 🆧	10.0	350.41	1.0935
PMPA (M10)	187.33	S& 5	¥35.2	0.422
N-acetyl-PMPA (M15)	1.929	29.1	× 177 25	0.5531
a) worst case of laboratory studies n	on-pormalised		0 4	

Findings: The PEC, Sand the time weighted average values (TNA source fiprovalicarb metabolites SZX 0722-earboxylic acid (M03) PMPA (MIO) and Wacetyl-PMPA (M10) are summarised in 🖓 and 🖇 5, respectively 3, Table 9. Table 9 able 🎗

	[©] Time [∽]	vines 🖉	early	y vines, inte	ermediate	vines	, late
<u></u>	[daxo]	<b>PÉC</b> soil	T Asoil O	PECsoil	TWAsoil	PECsoil	TWAsoil
~Q	Ŭ,	O[mg/kg]	mg/kg	(mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]
Initial 🕰	0	0.013	÷,	0.013	-	0.009	-
	10	Q,009	QQ911 >>	0.009	0.010	0.006	0.008
Short term	~27	<u>ý</u> 0.006	@.009	0.006	0.009	0.004	0.007
$\sim$	₩4	0. <b>003</b>	Q 0.000	0.003	0.006	0.002	0.005
, and the second	_	< <u>0</u> 901	0,095	< 0.001	0.004	< 0.001	0.003
	2 2 1 ∿	Ø.001~C	Q002	< 0.001	0.002	< 0.001	0.001
Long tern	~28	\$ 0.00 ¹	Ø.001	< 0.001	0.001	< 0.001	< 0.001
Ĺ	1 250 . (	° < 0.€01	Q < 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Ú,	2 100 C	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

PEQoil (actual) and TWAS of SEX 0722-carboxylic acid (M03) Table 9.5-3:

4 x 216 gorovalicarb/ha, 4 x 60% interception, 10 days application interval vines, early

thes, intermediate x 216 y iprovalicarb/ha, 60/70/70/70% interception, 10 days application interval 4 x 216 g iprovalicarb/ha, 70/85/85/85% interception, 10 days application interval

Doc. M-III /Tier 2, Sec. 5, Point 9 - Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

	Time	vines,	, early	arly vines, intermediate			, late a °
	[days]	PEC _{soil}	TWAsoil	PEC _{soil}	TWAsoil	PEC _{soil}	TWASSI
		[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg]	[mg/kg] 6
Initial	0	0.093	-	0.076	-	0.043	<u> </u>
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	C 0.043
	4	0.092	0.093	0.074	0.075	0.043 %	<u>_0.043</u> ≪
	7	0.091	0.092	0.004	0.075	0.042	0.043
Long term	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	Q 0.069 o	£0.036	© 040 °
	100	0.064	0.078	0.052 a	0.063	~~0.030°	© 0.036

Table 0 5 4.	DEC .	(aatual)	and TWA	of DMDA	(M10)
1 able 9.3-4:	<b>FLU</b> soil	(actual)	anu I w Asoil	OI F MIFA	WIIU)

4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days apply cation paterval vines, early: vines, intermediate:  $4 \times 216$  g iprovalicarb/ha, 60/767/0/70% faterception, 10 days application interval vines, late:  $4 \times 216$  g iprovalicarb/ha, 70/89/85/85% interception, 10 days application interval.

Table 9.5- 5:	PEC _{soil} (actual) and	TWA Sil of	f N-acety	A PMPA	х¢М15)
---------------	----------------------------------	------------	-----------	--------	--------

vines, early:	4 X Z I	o g iprovalicaro	/na, 4 x 60% mi	erception, 10 ga	ays approximing		
vines, interme	diate: 4 x 21	6 g iprovalicarb	/ha, 60/7	)% Interception	, 10 days applie	ation interval	¥ *
vines, late:	4 x 21	6 g iprovalicarb	/ha, 70/89/85/8;	5% interception	, he days applic	ationointerval	A
			1	ř. Oř	Q .		D' A
			Ś, Ś		'A (		
ble 9.5- 5:	PEC _{soil} (a	ctual) and TW	Axil of N-acet	tvlæMPA	15) 👋 👌		, Å
r		, 		<u>× ~ × </u>		<u> </u>	0
	Time	vines	searly 🧳 🔍 🦧	🔰 vines, inte	apmediate	S Xines	s, late
	[days]	PECsoil	TWA _{soil} 🚿	PEC _{soil}	TWAsoil	PEC il	<b>WTWA</b> soil
		[mg/kg]	∭ mg/kĝ	ung/kgb	mg/kg O	[m͡͡͡g/kg] ំ	🎾 [mg/kg]
Initial	0	<b>A</b> 919 %	<u> </u>	0.010	<u> </u>	0.014	-
	1	≪ð.00 <u>2</u>	<b>29</b> ,013	0,009	0.093	ی 0.007 ⁰	0.010
Short term	2	õ 0.004	~0.010°	0.004	<b>~</b> ©©10 °∧	0.003	0.007
	4 %	y < 0,001	0.000	\$0.001 °	0.006	< 0.001	0.004
	7,	<.0.001 0	0.0004 2	~<0.00 [°]	l≪ 0.004 ⊂	<b>\$00</b> .001	0.003
	2¢	Ø0.001	Ø.001 🔊	< 0.001	0,001	Ç¥0.001	< 0.001
Long term	28	$\mathcal{L} < 0.00$	×\$0.001 [™]		<0.001 _@	< 0.001	< 0.001
	¢ 50 گ	P' < 0.001	×0.00x	\$¥0.004	£0.004	< 0.001	< 0.001
. (	100	$\leq 0.001$ %	< 0,001	∀<0 <u>001</u>	\$\$ ⁷ <0.00₽	< 0.001	< 0.001

4x 216 g provalicarb/ha, 4/x 60% interception, 10 days apprication interval vines, early vines, early vines, early vines, intermediate 4 x 216 g iprovaticarb/ha, 60/79/70/70% arterception, 10 theys application interval 46 g iprovalicarboad, 70/85/85/85% interception, 10 days application interval vines. late 

# PECsoil for for for metabolites

For the 3rd party active substance folpet, produced from

Bayer CropScience AQ has the right of reference of files, data, studies, summaries and assessments which were submitted in the EV for the support of the registration of the active owned by substance folpet and the representative formulation Folpan 80 WDG. For details please refer to the statement mentioned at page.

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 supplementar dossien 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 currently defends in this crop in the EU, where 10 applications of up to b 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 wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

The set of Modelling Comments:

Doc. M-III /Tier 2, Sec. 5, Point 9 – Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

#### **IIIA1 9.6** Predicted Environmental Concentrations in Ground Water (PECgw)

### **Endpoints for PEC**_{gw}

#### **Iprovalicarb**

arb	×. Š
1: Modelling input parameters for iprovali	icarb and its major metabolites
End-Point	Active substance: iprovalicars
	Value used for modelling
Inrovalicarh	
Aqueous solubility [mg/L] at 20°C	
Vanour pressure [Pa] at 20°C	$7 \frac{1}{10} \frac{1}{10}$
$DT_{50}$ soil [days] (geo-mean lab_normalised)	6789
Adsorption data:	
- 1/n (arith mean)	2 ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~
- $K_{oc} / K_{om} [L/kg]$ (arith. mean)	C 7 125.9/66.9 4 A
SZX 0722-carboxylic acid (M03)	
Molar mass correction factor	<u>1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 </u>
Aqueous solubility [mg/L] at to C, all 7	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Vapour pressure [Pa] at 20% 🖉 🔗	₩ <u></u>
DT ₅₀ soil [days] (geo-mean lab., mormalised)	<u> </u>
Formation fraction	0:3242 × ×
Adsorption data:	
- 1/n (arith. mean)	
- PEARL input data ^a :	
- K _{oc} , A ⁻ / K _{om} , A ⁻ [L/(C) ⁰ )	
- K _{oc, AH} K _{om, AH} / Kg	× 0 14.30 / 8229
- PELMO uput gata".	J. 15000 80
- $K_{oc}$ $[K_{oc}]$	$\sqrt{1.34} 0.89$
PMPA ( <i>MI</i> )	
Molar mass correction factor	² 0.422
Aqueous solubity [mg/L] at & C, pH 11	<u> </u>
Vapour pressure [Pa, at 20°C $\sim$ ]	20
DT ₅₀ soil Qays] (geo-mean lab., normalised)	81.08
Formation fraction	0.5061
Adsorption data:	
- 4(m (arith mean)	0.8629
$-K_{oc} / K_{om} [L/kg) (arithonean) $	290.2 / 168.3
N-acetyi-Pivek (M15k	0.5521
Molar mass correction factor	0.5531
Aqueous solubility [mg/h] at 2000, pH h	6600
vapour pressure [Pa] at 20°C	2./ x 10 ⁻³
D15d soil [days] (gettemean hab., nothealised)	0.72
Max. occurrence avanaerobic sou(2/%]	29.1
Adsorption data	0.0005
$= 1/n$ (arith. mean) $\bigcirc$	0.9025
- Kor Kon th/kgl (arith. mean)	39.7723.0

 a) and E Parte, the restoring values were implemented: a relative, dissociated compound K_{oc}, A and active a undissociated K_{oc}, A a) alkaline, dissociated K_{oc}, A a) acidic, undissociated K_{oc}, A a) acidic, undissociated K_{oc}, A a) in <u>PELMO</u>, 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 (H₂O)

### Folpet

For the 3rd party active substance folpet, produced from Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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 score 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 currently defends in this crop in the EU, where 40 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to folpet data owned by the rever appropriate. A folpet-specific risk assessment is not considered necessary to detend the funce.

## PEC_{gw} modelling approach

The predicted environmental concentrations in groundwater ( $PEC_{gw}$ ) for the active substance(s) were calculated using the simulation models PDARL 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 ar 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 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 soft and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the EOCUS recommendations (Table 9.6-2).

# Table 9.6.2: FOCUS groundwater crop interception values

		Crop: vines			
Stage O	without leaves	Ofirst leaves	leaf development	flowering	ripening
Crop interception [%]	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	[♥] 50	60	70	85
	\$90 [°]	01 - 08	11 - 19	60 - 69	71 - 99

# Bayer CropScience

Doc. M-III /Tier 2, Sec. 5, Point 9 – Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

### IIIA1 9.6.1 Active substance

#### **PEC**_{gw} for iprovalicarb

Report:	KIIIA1 9.6.1 /01, 2012
Title:	Predicted environmental concentrations in groundwater recharge (PECgoo of
	iprovalicarb based on FOCUS PEARL 4.4.4 and FOCUSPELMO 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. O
	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, ) for , ° iprovalicarb were calculated using the simulation model POCUS 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  $1 - 0 \times 150 - 216$  g a.s./ha, with 10 - 14 days application intervals, at BDCH 15 - 85. Therefore, three representative periods were chosen for the assessment (Table 6.1-1), an early period to start at BBCH 45, 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 lighter of compound reaching the soil in the simulation provides a conservative estimate for the groundwater concentrations from the current formulation.

					, , , <i>, , , ,</i>	0
Table 9.60 - 1:	Comparison of	actual applic	ation use p	attern and cal	culated use pattern f	ior
K.V			л» О``	$\sim$	•	
~ 2/	PECex calculati	ons of iprova	ilcarp _			
	_~)) _ ( /	×/ • ~ *	. 1	(n 4) (n		

Individual crop N FOCUS	, 7 , 0	OXpplig	cation		Amount reaching
🦉 🖉 🖉	vate per	interval	plant	BBCH	the soil per season
∅ O [∨] for	season .	Oldays	interception	stage	application
Section Vinter Ception	[g a s./ha]		[%]	-	[g a.s./ha]
A. 3			=		=
GAP:		[°]			
grapes wines	1 - 4 🔊 216 🖓	[¶] 910 - 14	60 - 85	16 - 75	1 - 4 x 32.4 - 86.4
	1 - 6 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:	J ^Y a. ^Y				
vines, early vines	AOX 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, fote S gvines	4 x 216	10	70/85/85/85	80 - 85	64.8/32.4/32.4/32.4

For the metabolite <u>SZX 0722-carboxylic acid (M03)</u> a moderately significant correlation is given for the dependency of the K_{oc} from soil pH. Therefore, in <u>PEARL</u>, 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 (H₂O). In <u>PELMO</u>, 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 (H₂O).

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 an anaerobic soil, a brither ast degrading mayor metabolite, N-acetyl-PMPA (M15), was identified, which did not occur prider acrobic O 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 of area owns 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 h plane fields or cropping areas, when rain water remains in small sinks and functives 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 scafe may occur due to flooding along fivers. Typically, this flooding will not occurregularly or each year only with large time intervals in between. The following assumptions have been made to address these two scenarios. Partly, additional safety



Table 9.6.1- 2:	Substance specific and model related input parameter for PECgw calculation of iproval	icarb
	and its major metabolites	0

Parameter	Unit Iprovalicarb SZ		SZX 0722-carboxylic	PMPA	N-acetyl-PMPA
			acid (M03) (M10)		(MIS)
Molar mass	[g/mol]	320.44	350.41	135 Ør	107.25
Water solubility	[mg/L]	17.8	56000	1 <i>5</i> 00	~660Q ~~~~
Vapour Pressure	[Pa]	7.82 x 10 ⁻⁸	8.9 x 10 ⁻⁶	₄ 20	2.7 x 10 ³
DT ₅₀ soil	[days]	6.78	0.97	\$1.08	~~~ <u>0</u> .92 ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Formation fraction	[%]	-	<b>©3</b> 242	🖓 0.5061 🦿	
Koc	[L/kg]	113.9	PEARE: 0.64 / 14.3ª	290.2	\$\$39.74 K
			PELMO: 1.54 / 10 ₪	×,	
Kom	[L/kg]	66.1	PEARL: 0.37 / 8@ ^{9a)}	· 168,3	, [∞] 23.0 , [∞]
			PELMO: 0.89/5.91	? Q'.(	
Freundlich exponent	[-]	0.8725	1.025	<b>0</b> 8629	≪_0.902€
Molar activ. energie	[kJ/mol]	65.4 📡	65.4	≪ 65.4	[™] 65.4
Q ₁₀	[-]	2.58	258	2.58	£ 258 °
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 a) For the metabolite SZX 0/22-carboxylic acid (M03) a moderately significant correlation is given for the dependency of the K_{oc} from soil pH. Therefore, in <u>PEAR</u> the following values were implemented; a kaline dissociated compound K_{oc} A- of 0.64 L/kg (corresponding K_{om} Q 0.37 D/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 appatent soil pK a of 5.88 (H2O).
In <u>PELMO</u>, the following values were implemented; 2 different points at the Henderson diasselfach equation or curve: K_{oc} of 1.54 L/kg at pH 7.0 (corresponding K_{om} 0.89 C/kg) and K_{oc} of 0.19 L/kg at pH 5.5 (corresponding K_{om} : 5.91 L/kg). The inflection point is apparent soil pK of 5.88 (H2O).
b) maximum occurrence in anaerobic soil: 29.1%

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

Table 9.6.1- 3: PECg	w of iprovalicar	ſþ,
----------------------	------------------	-----

Scenario		<u> </u>	6 Lprova	liçarb 🕡		
Ô	Vines,	çarly 🔬 👌	🍼 Viges, int	ermediate	Vines	s, late
	PEARL 👡	PEOMO	PEARL	PELMO	PEARL	PELMO
<i>K</i>	, PECgw, O	₽ĔC _{gw} ∿	<b>OPEC</b> gw	<b>©PEC</b> gw	PECgw	PECgw
•	a lug/L	[μg/Ι	[μg(L]	گ [™] [µg/L]	[µg/L]	[µg/L]
	100.0 > گرچ	¢ < 0,001	° <09001 ≳	< 0.001	< 0.001	< 0.001
(	ବ <_6001 ୍୍ର୍	° <00:001 √	£0.001	< 0.001	< 0.001	< 0.001
1	0.0010	≥0.0Q1 ^O	°~~0.0010°	< 0.001	< 0.001	< 0.001
\$	< 0.00	0.001	Q [*] < 0,001	< 0.001	< 0.001	< 0.001
	< 0.001	< 001	_≪0.001	< 0.001	< 0.001	< 0.001
	×9.001 ×	< 0.001	0.001	< 0.001	< 0.001	< 0.001
	0.00 <del>1</del>	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	××<0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 gprovalie arb/ha, 4 x 60% miterception, 10 days application interval 1 x 216 g iprovalicarb/h@60/70/49/70% interception, 10 days application interval vines, intermediate 16 g iprocalicarb/ha, 70/85/85/85% interception, 10 days application interval vines, late:

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

### **PEC**_{gw} for folpet

For the 3rd party active substance folpet, produced from

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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 PECgw calculations of folpet are submitted here. Bayer CropScience KG 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/ba folpet are proposed as a safe use in grapes. is much below the critical GAP that currently defends in the EU, where 100 applications of up to 1.6 kg/ha have been approved, with all other parameters such as interval between versions of the second -specifi -speci applications or pre-harvest interval being identical or very similar. Therefore, Bayer CropScience AG wherever appropriate. A topet-specific risk considers it justified to refer to folpet data owned by

#### **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) metabolites are not automatically relevant in groundwater in the sense of this andance document

PEC _{gw} for iproval	icarb metabolites
For iprovalicarb me	etabolites SZX 0722-carboxylic acide (M03), PMPA (M10) and V-aceto-PMPA (M15)
were assessed.	
Report:	KIIIA1 9.6.2 /01,
Title:	Predicted environmental concentrations in groundwater recharge (REC _{gy} ) of iprovalicarb based on BOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.2
	Use in vines early, Sines intermediate and vines late in Europe
Report No:	EnSa-12-0167
Document No:	$M-430141-01_{T}Q^{2}$
Guidelines:	FOCUS groundwater scenarios in the EU plant protection product review process.
	Report of the FOCUS Groundwater Scenarios Workgroup.
	EC Document Reference SANCO/324/2000aev.2
GLP:	No (calculation)

Materials and Methods: PEC for the metabolite were alculated 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 merabolites are simmarised together with the data of the parent compound in KIOA1 & 1 /01 and in Table 36.1-

Findings: The PEC_{gw} values for the metabolites for the different EU scenarios are presented in , ¢ Table 9 2-1 to Table

Scenario			ZX 0722-carbo	xylic acid (M03	)	
Q)	o [∞] Vines,	early 🔿	) ÖVine@int	ermediate	Vines	, late
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	<b>PEARD</b>	PELMO	» PEARL	PELMO	PEARL	PELMO
1	PEC [®] _{gw}	PEC w	PKC gw	PECgw	PECgw	PECgw
Į,	[µĝ/L]	[fig /L]	, [Jrg/L]	[µg/L]	[µg/L]	[µg/L]
	~~0.001 ×	≫0.001	م ^م 0.001	< 0.001	< 0.001	< 0.001
	× 0.000 ×	× 0.001 ×	© ^y < 0.001	< 0.001	0.001	0.008
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	< 0.001	< 0.001	< 0.001	0.005
L. L.	<b>₹ 0.001 ©</b> ″	~~~0.002~~~	< 0.001	< 0.001	< 0.001	0.005
	~0.00	°≪0.0@b	< 0.001	< 0.001	< 0.001	< 0.001
- C	<0_001	J < 0.9€1	< 0.001	< 0.001	< 0.001	0.002
	<ul><li>&lt; 0.001 ∩</li></ul>	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Table 9.6.2- 1:	PEQw of the i	provalicarb	metabolite SZ	X 0722-earboxylic	acid (M03)
	\$Y			•	

vines, carly: 4 x 246 g iptovalicarb/ha, 4 x 60% interception, 10 days application interval

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

Scenario		PMPA ( <i>M10</i> )						
	Vines	, early	Vines, int	ermediate	Vine	s, late 🖉 🕺		
	PEARL	PELMO	PEARL	PELMO	PEARL	<b>PÉX MO</b>		
	PEC _{gw}	PEC _{gw}	PEC _{gw}	PEC _{gw}	PECgw	<b>PEC</b>		
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	^[μg/L]	🧄 [нзАр]		
	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	× <0,001		
	< 0.001	0.001	< 0.001	0.001	< 0.001	مي¢0.001		
	< 0.001	0.001	< 0.001	0.00	< 0.00	<0.0 <b>€</b>		
	< 0.001	0.002	< 0.001	0.000	< 0.001	<b>990</b> 1		
	< 0.001	< 0.001	< 0.001	< 0,001	< 0.001	<b>0</b> .001		
	< 0.001	< 0.001	≪0,001	< 0.001 °	₩0.00K	Q 0.001		
	< 0.001	< 0.001	Q 0.001	$\sim 0.000$	°≪ 0.009	© < 0.001		
vines, early: vines, intermedi	4 x 216 g iprovali iate: 4 x 216 g iprovali	carb/ha, 4 x 60% ; carb/ha, 60/70/70	interception,°10 da	x application inte 10 days application	Bval 👌 💊			
vines, late:	4 x 216 g iprovali	carb/ha, 70/85/85	85% interception,	10 dags applicatio	on interval			
Fable 9.6.2- 3:	$\operatorname{PEC}_{\operatorname{gw}}$ of the ipp	rovalica 🕉 meta	bolite Nacetyl-	PMPACM15		Ŏ		
Scenario		_0* _×	N-acetw] ² P	$MP \mathcal{R}(M15)$		Ô		

Table 9.6.2- 2:	PECaw	of the iprovalicarb	metabolite PMPA	<i>(M10)</i>
	I LCgw	of the ipioranearb	metabolite i wii i	(1110)

<b>Fable 9.6.2- 3:</b>	PEC _{gw} of the iprovalica	metabolite Nace	tyl=PMPAQM15	
Scenario	Vines, early	Vines,	PMPA (M15) intermediate	

	Vines,	exply	Vines, int	ecmediate	🗘 🔊 Vines	, late
	PEARL	, PELNO	PEARL ,	🔊 PELMO 🗞	PEARL	PELMO
	PEC _{gw}	₽₩ <u>C</u> gw _~	PEC _{gw} &	PECgw	<b>PEC</b>	PECgw
	[µg/L] 🔊	µg/L	μg/L	~~[μg/]	<u>ک [μg/L</u>	[µg/L]
Scenario 1 ^{a)}	~~~ _3					
	< 🔍 001 🖉	ÿ _≶ Ø.001 ○	0.001 ×	\$0.004	s, <b>€</b> 0.001	< 0.001
	0.001	~~ 0.00 <i>1</i>	¢0.00 کې	< 0.0Q	≪y < 0.001	< 0.001
	\$\$< 0.06¥	~ 0.001 ~	<u>&lt;0.001</u>	<u> </u>	< 0.001	< 0.001
	~_Q.Q01 ~	× <0.001 >>	≤0.001 २	Ø.001	< 0.001	< 0.001
	£9.001 O	0.00k	×0.00	0.001	< 0.001	< 0.001
	°€0.001€	< 0.001	~~<0.0 <b>0</b> 1	O < 0.001	< 0.001	< 0.001
Solution and the second s	< 0.001	$\sqrt{3} < 0.001$	) < 0.001 @	<b>≈@</b> 001	< 0.001	< 0.001
Scenario 2 ^{a)}						
	₹ 0.001	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		< 0.001	< 0.001	< 0.001
	\$ < 0, <del>0</del> 01	< 0,001	<0.001	< 0.001	< 0.001	< 0.001
	^م ري 001.001		ر ³⁷ 0.001 ک	< 0.001	< 0.001	< 0.001
~Q	$Q_{0.00}$	$\sim 0.00$	¢¢≤0.00	< 0.001	< 0.001	< 0.001
A	< 0.001	♀ < 0.4 <b>0</b> 1 、	° <0,001	< 0.001	< 0.001	< 0.001
	< <b>0</b> 9001 Q	< 0.001	×0.001	< 0.001	< 0.001	< 0.001
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~©0.001	<b>≫</b> 0.001	s्र्¥ 0.001	< 0.001	< 0.001	< 0.001

vines, early: 4 x 216 g iprovalicato/ha, 42 60% fuerception, 10 days application interval vines, intermediate: 4 x 216 g iprovalicato/ha, 60/70/70/10% interception, 10 days application interval vines, late: 24 x 216 g iprovalicato/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

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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 score of the supplementary dossier, up to 4 applications at 1.35 kg/ha folpet are proposed as a safe us in grapes. The is much below the critical GAP that 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 wherever appropriate. A tolpet-specific risk assessment is not considered necessary to defend the Annex Misting of ippovalicarb.

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 got be expected to reach water treatment plants in sufficient concentrations to have any impact on water treatment procedure.

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

No specific information is a callable for the preparation, however the information on the active substance iprovalicate as provided in the Annex 10 in the context of Section 5, Point 7 submitted within the EU Basic Dossier 1008 and the Annex 10 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 1000 Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 1000 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 <u>hydrolysis</u>. Under the experimental conditions no formation of hydrolysis products was observed. Considering the hydrolytic stability determined and er 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 in ovalicarb in aqueous solutions does not absorb any light at wavelengths above 281 nm. Therefore no contribution of the direct <u>photodegradation</u> to the overall elimination of iprovalicarb in the aqueous environment is to be expected.

Studies with iprovalicarb in four different natural water/sectiment systems under aerobic conditions showed that the compound was thoroughly degraded leading to O_2 as the end product of the mineralisation process. In parallel to mineralisation, bound residues over formed PMPA (*M10*) was identified as major metabolite (200%) of the applied adioactivity) in the water and sectiment layers and N-acetyl-PMPA (*M15*) as major metabolite in the water/tayer. SZX 0722-carboxylic acid (*M03*) was found in amounts of 5.2% of the applied adioactivity 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 O_2 via several routes. In one route iprovalicarb was degraded via oxplation of the methyl group of the momatic system yielding the SZX 0722 carboxylic acid (M03). In the other route the breakdown of the molecule started with deavage 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 (M16). This metabolite was methylated in very small amounts to form N-acetyl-N-methyl-PMPA (M16). Otimately the breakdown of iprovalicarb led to total mineralisation of the aromatic nucleus in the form of carbor dioxide. The proposed pathway of iprovalicarb in water-sediment systems under aerobic conditions is given in Figure 9.7-1.

To derive the 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 iprovalicate 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 DegT₅₀ for modelling purpose were in the range of 19.93 to 58.67 days (geom. mean 34.73 days). For persistence trigger evaluation the DisT₅₀ 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 DegT₅₀ for persistence trigger evaluation the DisT₅₀ in the sediment phase. In the total system the DegT₅₀ for persistence trigger evaluation were in the range of 19.17 to 58.67 days. The corresponding DisT₉₀ 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 DegT₉₀ were in the range of 66.9 to

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194.9 days. (see Table 9.7-1).

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

Compartment	Kinet	tic evaluation	according to FO®	
Compartment				
	for modellin	ig purpose	for trigger	evaluation $$
	DT ₅	0 ^{b)}	$DT_{50}^{b)}$	DT ₉₀ ^b
	[day	's]	[days]	[days]
	range	geo. mean	L. L.	
Water phase	16.65-57.28	24.61	14.84457.28	582-190,5
Sediment	24.20-78.99	46.78	2 20-78.99	x80.4-2624
Total system	19.93-58.67	¢¢ 34.73	9.17-58.67	Oč6.9-194.9
) Kinetic calculation by	(2012), submitte	d within the An	ne II doscher submi	rted in 2012
(IIA, KIIA 7.8.3 /03) acco	ording to FOCUS	2006): Guidanc	Document on Est	imating Q
Persistence and Degradat	ion Kinetics from E	Invironmenta	ate Studies on Pest	icides in EU.
Registration The Final R	eport of the Work (Transin on Degra	dation Kinetics of F	FOCUS
SANCO/10058/2005 v 2	0 June 2006 \times			O L A .
b) water and sediment phase	DisTer total av	m. Dolt		O' D' A
b) water and sediment phase	. Dis 150, wiai syste	5111. Lacger 50	× A AV	
	l l l	S' O		
			0 4	
		v iv	×1 A.	

For SZX 0722-carboxylic acid (M02) the Deg T_{50} in the total systems for modeling porpose and trigger evaluation were in the range of 5.64 to 25.15 days (geom. mean 12.10 days arith. mean 15.89 days). The corresponding DegT₉₀ were in the range of 18.94 to \$6.85 days.

For PMPA (M10) a DegT₅₀ in the total systems for modelling purpose and trigger evaluation of 66.34 days is considered appropriate. The corresponding DegT₉₀ is 220.4 days.

For N-acetyl-PMPA (M15) no teliable and statistically significant degradation parameters could be evaluated. So, for predictive modelling, a conservative default DT 50 of 7000 days might be assumed in a total water-sediment system for Nacety PMPA. (Summary of the data of these metabolites see Table 9.7-2.)

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

Compartment	Compound 🔊	à ò	Kinetic e	valuation according to FO	CUS ^{a)} for
jê Ç ^a			nodel	ing purpose and trigger eva	aluation
N.				DegT ₅₀	DegT ₉₀
				[days]	[days]
Ö	PA &	× ×	range	geo. mean/ arith. mean	
Total system	SZX 0722 Carbox	dic acid (M03)	5.64 25.15	12.15/15.89	18.74-86.85
~~~	POMPA (MTO)		<u>66.34</u>	-	220.4
.1	N-acet PMRO (1	MISER 6	©1000 ^{b)}	-	-

Kinetic calculation by 2012), advinited 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 EU Registration. The Final Report of the Work Group on Degradation

Kinetics of FOCUS. SANCO/10058/2005, v.2.0 June 2006 default value.





#### Summary of fate and behaviour of folpet in water

For the 3rd party active substance folpet, produced from

Bayer CropScience AG has the right of reference to files, data, studies, summaries and assessments owned by 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 places refer to the

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.
$\mathbf{PEC} = \mathbf{colorizations} \qquad \qquad$
PEC _{sw} calculations
The following PEC _{sw} calculations are applicable to Europe and represent a worst-case use pattern
Endpoints for PEC _{sw}
Incovalicarb $\mathcal{A} \rightarrow \mathcal{A} \rightarrow \mathcal$
Table 9.7-3: Modelling input parameters for iprovalicarby 20 20 20 20 20 20
Endpoint 🖉 🖓 🗸 Values used for modelling
Aqueous solubility $[mg/L]$ at 20° $6$ $6$ $6$ $7$ $17.8$ $7$
Vapour pressure [Pa] at $\mathfrak{W}^{\circ}$ $\mathfrak{C}$ $\mathfrak{V}$
DT ₅₀ soil [days] (lab. geo-mean, normatised)
$K_{oc} / K_{om} [L/kg]$
$DT_{50}$ total system water stediment [days] (geo tean) $O' = \frac{34033}{34033}$

### Folpet

For the 3rd party active substance folpet, produced from

Bayer CropScience AG has the right opreference to files, data, studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance folpet and the representative formulation Forpan 80 WDG. For details please refer to the statement mentioned at page 95

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

# Bayer CropScience

Doc. M-III /Tier 2, Sec. 5, Point 9 – Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 *(Submission for Annex I renewal)* 

#### 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 heading 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, dop and different waterbodies. Simulations use the models PRZM, MACRO and TOSSWA

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, the will be presented in the national addenda

## PEC_{sw} for iprovalicarb

Report:	KIIIA1.9.7/01; <b>1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1</b>
Title:	Predicted environmental concentrations in surface water and sediment (PEC _{sw} ) of
	iprovalicarbaccording to CUSsw Step 1-2
	Use in vines in Europe & S & S
Report No:	EnSa-12-0168
Document No:	∭.429643-0€71 ,
Guidelines:	FOGUS Sarrace Water Scenarios in the EU Evoluation Process under 91/414/EC.
Č,	Report of the FQCUS Working Group on Surface Water Scenarios. EC Document
ð	Reference SANCO/4802/2001-rev 22003
GLP:	"No (calculation)
0, -V	

**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.

Doc. M-III /Tier 2, Sec. 5, Point 9 - Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

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

Individual crop	FOCUS		Applic	_	Amount reaching	
	crop used	rate per	interval	plant	BBCH	the soil per/season
	for	season	[days]	interception	stage	application
	interception	[g a.s./ha]		[%]		[g a.s./hat
GAP:				~	Ą	
grapes	vines	1 - 4 x 216	10 - 14Ô	60 - 85 న	16 - 75	≪J [*] -4 x 32.4 - 86.4
		1 - 4 x 162	10 - 14	60 - 70	16 - 61 🭙	0 1 - 4⊚ 48.6⊱64.8 ↓
		1 - 4 x 150	10, 12	60 - 🔊	15 - 85	1 7 x 22 5 60.0 0
Simulation:						
vines, early	vines	4 x 216	♥ 10	~4 x 60	15 - 85	√ <b>x 86</b> €
vines, intermediate	vines	4 x 216 🗶	ĽØ Š	£60/70/79/70	<u>(</u> ,50 - 85)	86.4/64.8/64.8/64.8
vines, late	vines	4 x 216	× 90	70/85/85/85	80- <b>8</b> 5	£4.8/32£(32.4/32.4

Compound specific input data are summarised in Table

#### Substance specific and model related input parameter for BECs. estculation of inpovalicarb Table 9.7- 5:

Parameter	Q,	Ô	Ô	ð	Ugit	<b>Walue</b>	sed in modelling
Aqueous solubility	at 20°C .	<i>S</i>	<i>©</i>		[mg/L]	)» O	19 <del>5</del> 8 €.,
Vapour pressure at	20°C	¥	1	0	[™] [Pa] [©]		7,82 x 10 ^{-®}
DT ₅₀ soil (lab. geo-	mean no	rmalisec	l) 💦	Ô	[days]	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	6.780
Koc / Kom	A	Ċ,	K K	Å	[[4/kg]		13.9 206.1
1/n	à l	ħ (		Ű.	Õ[-] &	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	08725
DT ₅₀ total system (	pater-sedi	ment (g	eo. mea	in) 🔬	[≫] [days¶″	×	34.73
<u> </u>			Ś.			0	- ¥

For an aquatic rist assessment the worst-case concentration considering other a single application or multiple applications, Pould be considered, Especially in case that the dominant entry route is via drift.

multiple applications should be considered, especially incase that the dominant entry route is via drift. Therefore, both multiple applications (in accordance with the use patterns) and single applications were considered.

Doc. M-III /Tier 2, Sec. 5, Point 9 – Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

### 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.

Crop	Step	Application	Region		Iprovalicarb	
		scenario		PECsw, max	PECsw, 21d TWA	PECked, max
			A	[µg/L] 🕺	/ [µg/L] 🍾	∘ <b>∬</b> ¤g/kgĮ∕√
Vines, early	1			273.1	220.7	284.8
	2	Multi	N-ĘU [™]	18.5 <b>4</b>	14.02	20M1 A
			S₋ĘU	24.92	19.93 Q	ð 1.23 S
		Single	A, EU	° _م 999§يې	<i>√</i> 7.18 <i>√</i>	O 9.809
			S-EU	~_13.1₅°©́́	~%10. <b></b> ≨⊅″	© 14. <b>C</b> 5
Vines, intermediate	1	6	, ko	273 J	) 🖉 22 🎯 🔬	284.8
	2	Multi 🔊	NÆU	18,54	¥.72	₃ 20.11
		. 1	S-EU	<u>4</u> 1.73 °	17.33	23.6 <b>V</b>
		Singlo	Ŋ <b>N-ĘÔ</b> Ŋ	<u>≈</u> [∞] 8.9 <b>2</b> Q	7,182	\$ 2,809
			S-FU	11,08	🔊 🔏 🕉 🔨 🌾	2.13
Vines, late	1	Q V		2739.1	<b>2</b> 0.7	284.8
	2	Multi	°∽Ni-EU©	~¶5.99~	£ 12.64€	<i>Q</i> 17.26
			S-EU	× 17.90	14≈ <b>2</b> 0 ≈	19.39
	(	, Single 🔗	NÆU	0,7 <b>7</b> 938 (	S.825	7.955
	Ś		S-EU 🐇	8.584	6.84	9.346

Table 9.7-6: Maximum PECsw, PECsed and PECsw, 21d TWA values for iprovalication Step 1 and Step 2

vines, early:  $4 \times 216$  g iprovalicate/ha,  $4 \times 6\%$  interception, 10 days application interval vines, intermediate:  $4 \times 216$  g iprovalicate/ha, 6670/70/76% interception, 10 days application interval vines, late:  $4 \times 216$  g iprovalicate/ha, 70/85/85% interception, 10 days application interval vines, late:  $4 \times 216$  g iprovalicate/ha, 70/85/85% interception, 10 days application interval

## PEC_{sw} for folpet

For the 3rd party active substance folget, produced from Bayer CropScience & G has the right of reference to files, data, studie, summaries and assessments owned by which were submitted in the EU for the support of the registration of the active substance folget and the representative formulation Folgar 80 WPG. For details please refer to the statement mentioned at page 9.

No PEC_{sw} calculations of folpec are submitted here. Bayer GopScience 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 135 kg/ba folpet are proposed as a safe use in grapes. This is much below the critical GAP that **Example approved**, with all other parameters such as interval between applications of up to 4.6 kg/ba have been approved, with all other parameters such as interval between applications or pre-harves interval being identical or very similar. Therefore, Bayer CropScience AG considers it justified to refer to tolpet data of ned by **Example** wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

**III 9.7 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

strong at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodies (1-14 days after last at the state water bodi

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#### **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 inrovalicarh metabolites

Metabolites	
admaints for PEC	
alicarb	
0.8.1. Modelling input peremeters for inrovalizarh metabol	litos
y.o- 1. Woodening input parameters for iprovancarb inclasor	
End-Point	Iprovalicarb metabolites
	Salues used in model ling
SZX 0722-carboxylic acid (M03)	
Aqueous solubility [mg/L] at 20°C and pH 7	۲ <u>کې ۲</u> ۳6000 ۲
Vapour pressure [Pa] at 20°C	8.9 x 10 ⁻⁶
DT ₅₀ soil [days] (geo. mean lab., normalised)	L L 297 ~ L
Max. occurrence in soil [%]	
$K_{oc} / K_{om} [L/kg]$ (worst case alkaline solits) $\mathcal{O}$	<u>Q.64 / 007</u>
1/n (arith. mean)	<u> </u>
DT ₅₀ total system water-sediment (days) (geo. metal)	
Max. occurrence in total system stater-sediment [*]	<u><u> </u></u>
A quaque aclubility [ma/L Rat 2008] bind m 1 1	
Venour procesure [Do] at 20°C	
DT soil [days] (geo mean law normalised)	20 3
Max occurrence in spil [%]	× × × × × × × × × × × × × × × × × × ×
$K_{aa}/K_{am}$ [I/kg] (arith mean)	2968 / 168 3
1/n (arith mean)	× ( ² 0.8629
$DT_{50}$ total system water-sedment [days] (n $rac{1}{2}$ )	66.34
Max. occurrence in Qotal system water-sediment 128	19.7
N-acetol-PMFX (M15)	Ø)
Aqueous solubility [mg/L] @ 20°C and pH 7 0	<i>š</i> 6600
Vapour pressure [Pa] at 20°C	2.7 x 10 ⁻³
DI 50 soil [days @geo, mean lab., normalised] O V V .	0.72
Max. occurrence in anderobic soil [%]	29.1
$K_{oc}/K_{om}$ [LAg] (arith. means $V$	39.7 / 23.0
1/n (arith. řínean)	0.9025
DI ₅₀ total system water sediment [days] (default worst case)	1000
Max. occurrence in oral system water-sediment [%]	11

## Folpet

For the 3rd party Cactive substance folget, produced from

Bayer Cropsoence AG has the right of reference to files, data, studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance folger and the representative formulation Folpan 80 WDG. For details please refer to the statement montioned at page 9.

NoPEC_s, calculations of folpet metabolites are submitted here. Bayer CropScience AG is using a risk enveloge 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 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 G considers it justified to refer to folpet data owned by **sector** wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iproval carb.

#### **PEC**_{sw} for iprovalicarb metabolites

(M10) and N-acetyl-PMPA (M75) For iprovalicarb metabolites SZX 0722-carboxylic acid (M03), PM were assessed.

Panart.	
Keport.	$\mathbf{XIIIAI 9.8} / 01, 202 0 01 0^{Y} 0^{Y}$
Title:	Predicted environmental concentrations in surface water and sediment PEC of
	iprovalicarb according to POCUS Step 1-2 2 2 2 2
	Use in vines in Europe 2 2 2 2 2 2 2 2 0
Report No:	EnSa-12-0169 $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$ $\checkmark$
Document No:	M-429638-00-1 & & & & & & & & & & & & & & & & & & &
Guidelines:	FOCUS Surface Water Scenaries in the EU Evaluation Process under 91/414/EC.
	Report of the FOCUS Working Group on Sudface Water Scenarios EC Document
	Reference SANCO/4802/2001-rev22003
GLP:	No calculation) of the

Materials and Methods: PECsw for the metabolities were calculated using the approach, scenarios and application rates described for the valculations for the parent compound in Point IIIA1 9.7. Input

# Bayer CropScience

Doc. M-III /Tier 2, Sec. 5, Point 9 – Fate and behavior in the Environment - Iprovalicarb + Folpet WG 65.3 (Submission for Annex I renewal)

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

Parameter	Unit	Values used in modelling
SZV 0777 aarbarulia aaid (M02)		
Aqueous solubility at 20°C and pH 7	[mg/I]	36000
Vapour pressure at 20°C	[Hig/L]	<b>9 x</b> 10 ⁻⁶
DT _{co} soil (geo mean lab normalised)	[dave]	
Max occurrence in soil	[04y3]	
$K_{\rm c}/K_{\rm c}$ (worst case alkaline soils)	[/v] [⁄/[/kg]	
1/n (arith mean)		
$DT_{50}$ total system water-sedimen (geo mean)	[davs]	0 ¹ 1845 0 5
Max. occurrence in total system water-sediment	[%]	
PMPA ( <i>M10</i> )		
Aqueous solubility at 20°C and pH 7	[mg/L]	LEV00 × ×
Vapour pressure at 20°C	Ĉ[Pa] Ø	
DT ₅₀ soil (geo. mean lab., normalised)	¶ [dayś]≶	<u> </u>
Max. occurrence in soil	, jŵj	<u>~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~</u>
$K_{oc} / K_{om}$ (arith. mean)	°{[Ĵ/kg]	<u> </u>
1/n (arith. mean)	19 [-] Ø	\$1.862 <u>9</u>
$DT_{50}$ total system water-sedimen (n = 4)	[days]	<u> </u>
Max. occurrence in total system water-sedificent	D D	
	~ <i>6</i> ;	
N-acetyl-PMPA (M15)	Time/I	× × × ×
Venous solubility at 20°C and ph 5	≤ [mg/L]	× × 0000
DT	(Fa)	2 (3 10-3 00 72
Max accurrence in an archite will	^δ ^q uays	201
$\frac{1}{1}$ $\frac{1}$	/ [70] / [[ <i>t</i> ]///	29.1
$\frac{\mathbf{K}_{oc}}{1/n}$ (arith mean).		0.9025
DT _{co} total system water-sedimen (default worst case)	Idays/	× 1000
Max accurrence in total system water sediment		
		× · · · ·
		/
	w _v oʻ	
	, A	
	ð	
	S	
	103	
A & Y Y		
A C C C C C C C C C C C C C C C C C C C		

(Submission for Annex I renewal)

### **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.

Maximum PECsw, PECsed and PECsw, 21d TWA values for metabolite Sex 0722 carboxylic acid Table 9.8-3: (M03) S

Crop	Step	Application	Region	SZX 0722 carboxylic acid (M03		
1		scenario		PECsw, max 🐉	PECsw, 21d TWA	PECsed, max
				🎾 [µg/L] 🧷	[µg/L]	∭yμg/kg
Vines, early	1		¥	32.78-Q	19.10	SY 0.201 €
	2	Multi	N-EL	0.561	<b>0</b> ,351 4	Q 0 <del>0</del> 03 %
			S₊₫Ŭ	Ø\$61	° \$0.376	Ø.003
		Single	<b>∂\$</b> ² ÉU	~0.329 <i>©</i> ⁴	~%0.2 <b>↓</b> ©″	© 0.002
			, Š-EU ∘	0.329	<i>,</i> ⊘° 0. <b>29</b> 5 ∘	0,002
Vines, intermediate	1	(	Ď.Ű	32.48	19910	0.201
	2	Multi , 🔨	N-₽U	0.561 O	0.351	0.003 L
		, S	°∧S-EU ∽	0.561	0.363	0.00
		Single	N-EU	رمن 0.3 <b>2</b> %	°∽ 0,2,16 _*	0.002
		Q. (%	S-KU	× Q329 ~	Ø.192 S	0.002
Vines, late	1			× <u>3</u> 2.78	Š19.10	Q 0.201
	2	Multi	Ň-EU	ۍ ^م 0.56	0.341	0.003
			S-EQ	0.561	<u>ک</u> ک	0.003
	4	Single	N-EU	\$ \$329	Ø.206	0.002
	*	Y & .0 ^y	S-EU @	×0.329	0.214	0.002

 $\cap$ 

vines, early: 4 x 216 g provalicarb/ha, 4 x 60% inferception, 10 days application interval vines, intermediate: 4 x 216 g/provalicarb/ha, 60/70/70% inferception, 10 days application interval vines, late: 4 x 216 g iprovalicarb/ha, 70/85085/85% interception, 10 days application interval L

#### PECser and PECsw, 24d TWA values for metabolite PMPA (M10) Table 9.8-4: Maximum PEC

Crop 🔊	Step	Application	Region		[®] PMPA <i>(M10)</i>	
		scenario		PECsw, mar	PECsw, 21d TWA [µg/L]	PECsed, max [µg/kg]
Vines carly	ÛĬ (	S.S.	S.	\$ 46.84	41.14	128.9
Ky 3	2 👡	Multi 🔊	∘"Ŋ-EU	^~,	4.257	13.61
~Ç	° 4'		‰S-EU	8.629	7.663	24.50
l S	A	Single 🔬	N-EU	1.440	1.263	4.036
~	Q" s	S de S	S EU	2.513	2.223	7.119
Vines, intermediate				46.34	41.14	128.9
.4	20	Multre	N-E	4.835	4.257	13.61
and the second s	à	N 6 5	∑. <b>*£</b> Ŭ	6.732	5.960	19.06
Å.		🗸 "Single 🖉	<b>∧ð</b> -EU	1.440	1.263	4.036
			<b>Š∕S-</b> EU	1.976	1.745	5.577
Vines, late	E.		$\mathcal{D}_{\mathcal{F}}$	46.34	41.14	128.9
<u>"</u> Q"	2	🛇 Manti 🔗	N-EU	3.318	2.895	9.250
	A` E		S-EU	4.456	3.916	12.52
		, Single	N-EU	1.010	0.877	2.804
	õ	S Y	S-EU	1.332	1.166	3.728

vines, and vines 4 x 216 g iprovalicarb/ha, 4 x 60% interception, 10 days application interval vines, htermodate: 4, 216 g.pp/valicarb/ha, 60/70/70/70% interception, 10 days application interval A 216 sprovalicarb/ha, 70/85/85% interception, 10 days application interval vines, late

Crop	Step	Application	Region	N-a	ncetyl-PMPA <i>(M</i>	(15) _{@,° &amp;}
-	-	scenario	0	PECsw, max	PECsw, 21d TWA	PEC ad, max
				[µg/L]	[µg/L]	[ûg/kg] 🔗
Vines, early	1			45.43	<b>\$</b> .04	@17.48
	2	Multi	N-EU	1.131	î.105	[™] Q.4Q1
			S-EU	1.155	1.128	× 0,451
		Single	N-EU	0.362 🔬	0.354 🔊	<u> </u>
			S-EU_Ô	0.386	0.37	~~~~ 0.1 <b>5</b>
Vines, intermediate	1		· As	45.43Q	45.04	9 17:48
	2	Multi	N-EU	1.191	Ľ¥05 Q	<b>3?</b> .441 (c)
			SEU	QI43 °	L.117	© 0.446
		Single	<b>⊘</b> M-EU	~0.362	Q, 0.3,5⊕ [∞]	© 0.141
			S-EU.	0.374	₯ 0,3,06 ू×	<b>0</b> ,946
Vines, late	1	×		° 45.43 ~	4\$04	17.48
	2	Multi	₩EU C	Ø.122 O	1.096	→ 0.438°
		× A	°∼S-Elo	1.129	\$ 1.103	© 0, <b>@</b> 41
		Single	א N-É₽	0.353	0345	0.138
			Stell 🏻	y Q.360 ×	Ø.352 S	©0.141

Table 9.8- 5:	Maximum PEC _{sw}	, PEC _{sed} and PEC _{sw,}	21d TWA values for me	tabolite N-acetyl-PMPA (M15)
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vines, early: 4 x 216 g iprovalicarb/h0 4 x 6% interception, b days application intervals vines, intermediate: 4 x 216 g iprovalicarb/ha, 60/70/70/70% interception, 10 days application intervals vines, late: 4 x 216 g iprovalicarb/ha, 70%5/85/85% interception, 40 days application intervals

### PECsw for folpet metabolites

For the 3rd party active substance forpet, produced from. Bayer CropScience AG has the right of reference to files, date studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by substance folger and the representative formulation Folger 80 WDG. For details please refer to the statement montioned at page 9. m No PEC Calculations of folget metabolites are substitted here. Bayer CropScience AG is using a risk envelope approach to the risk assessment of the representative formulation. Within the scope of this supplementary dossier, up to 4 applications at \$35 kg/ha folget are proposed as a safe use in grapes. This currently defends in this crop in the EU, where 10 is much below the critical GAP that applications of up to .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 folget data wined by wherever appropriate. A folpet-specific risk assessment is not considered necessary to defend the Annex I listing of iprovalicarb.

Modelling
Comments of 5
Agreed/PECs
(metabolites) of N
IIIA 9.8 2
$\mathcal{O}^{\mathcal{O}}$

#### **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.

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

Please refer to Point IIIA1 9.8.

#### ocfies **IIIA1 9.8.4** Short-term PECsw value application)

Please refer to Point IIIA1 9.8.

w values for static water bodies Long-term PE atter last **IIIA1 9.8.5** application)

Please refer to Point IIIA

#### moving water bodies 7-42 days after last slow long-term PEC **IIIA1 9.8.6** (application)

Please refer to Point

#### Additional field testing **IIIA1 9.8.7**

e been performed or are required. No additional field studies formu ation h

#### **IIIA1 9.** Fate and B

# **Iprovalicarb**

Iprovalicarb  $\sqrt{2}$   $\sqrt{2}$   $\sqrt{2}$   $\sqrt{2}$   $\sqrt{2}$  Iprovalicarb has a very low vapour pressure of  $\sqrt{2}$ .7 x 10⁻⁸ Pa. Therefore, it can be concluded that significant volatilisation of iprovalicate is not to be expected.

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

## Folper

For the 3rd party active substance folpet, produced from

Bayer CopScience AG has the right of reference to files, data, studies, summaries and assessments which were submitted in the EU for the support of the registration of the active owned by

. Later of the second s substance folpet and the representative formulation Folpan 80 WDG. Therefore, no summary data of