

Renewal Assessment Report

Dimethenamid-P

BAS 830 01 H

**Volume 3 – B.8 Environmental fate and behaviour
and environmental exposure assessment**

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**Rapporteur Member State: Germany
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B.8 Environmental fate and behaviour and environmental exposure assessment

B.8.1 Fate and behaviour in soil

B.8.1.1 Rate of degradation in soil

No studies were performed with the formulation BAS 830 01 H. For studies performed with the active substance dimethenamid-P please refer to Volume 3 CA, B.8 of dimethenamid-P.

B.8.1.2 Mobility in soil

No studies were performed with the formulation BAS 830 01 H. For studies performed with the active substance dimethenamid-P please refer to Volume 3 CA, B.8 of dimethenamid-P.

B.8.2 Predicted environmental concentrations in soil (PECs)

B.8.2.1 Dimethenamid-P and its metabolites:

KCP 9.1.3/ 1 – Maleri, 2014a

Author:	Maleri,M.
Title:	Predicted environmental concentrations in soil, groundwater, surface water and sediment of dimethenamid-p and its metabolites after application of BAS 656 12 H and 830 01 H
Date:	28.02.2014
Doc ID:	BASF DocID 2014/1000682
Guidelines:	FOCUS groundwater (2009): SANCO/13144/2010 v1.0, Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2012) version 2.1, SANCO/4802/2001 rev. 2 (FOCUS surface water scenarios) May 2003, FOCUS Surface Water (2012) Generic guidance for FOCUS surface water scenarios v 1.1, FOCUS (2007): Landscape And Mitigation Factors Volume
GLP:	No
Validity:	Partly acceptable

Material and Methods

Predicted environmental concentrations in soil (PEC_{soil}) were calculated for dimethenamid-P, active substance in the formulated product BAS 830 01 H, and its soil metabolites M656PH023 (= M23 in this study), M656PH027 (= M27 in this study) and M656PH031 (= M31 in this study).

Calculations were only carried out for the worst-case application scenario, i.e one pre-emergence application of 500 g dimethenamid-P per hectare (representing winter oilseed rape with the highest yearly soil load in BAS 830 01 H). Post-emergence applications and lower application rates within a product were not calculated since they are covered by the highest pre-emergence applications.

Table B.8.2-1 summarises the worst-case application scenario of dimethenamid-P applied to bare soil.

Table B.8.2-1: Worst-case application scenario of dimethenamid-P applied to winter oilseed rape considered for the PEC_{soil} calculations

Crop	Winter oilseed rape, pre-emergence (representing highest soil load)
Growth stage at first application [BBCH]	00
Application rate [g as ha⁻¹]	500
No. of applications [-]	1
Interception [%]	0
Total yearly soil load [g as ha⁻¹]	500

The degradation behaviour of dimethenamid-P was studied in six laboratory soils with 6 different soils in total. A re-evaluation of Krueger and Bade (1990) was not performed in full extent due to deficiencies of the study design on the one hand, and the original peer-reviewed DT₅₀ being more conservative on the other hand (kinetic evaluation of the parent (including the total mass balance) produced a DT₅₀ slightly below the present DT₅₀ of 38). Therefore the present, more conservative DT₅₀, was considered in the selection of parameters when required.

Additionally, the dissipation rate of dimethenamid was investigated in the 9 field trials. The field degradation rate of dimethenamid-P according to EFSA (2014) guidance was determined in 6 trials throughout Europe.

The non-normalised DT₅₀ values of dimethenamid-P obtained in the laboratory are summarised in Table B.8.2-2. The non-normalised of dimethenamid-P obtained in the field dissipation trials and in the field degradation trials are summarised in Table B.8.2-3.

Table B.8.2-2: Non-normalised laboratory half-lives of dimethenamid-P

Soil	Soil texture	pH	Temp. [°C] / moisture	DT ₅₀ at study cond. [d]	Method of calculation	Reference
Flaach	sandy clay loam	7.5	20 / 40 %MWHC	7.7	SFO	König (1996), Platz (2008)*
BBA 2.2	loamy sand	5.8	20 / 40 %MWHC	12.8	SFO	König (1995), Platz (2008)*
BBA 2.3	sandy loam	6.6	20 / 40 %MWHC	13.3	SFO	König (1995), Platz (2008)*
Kenyon	loam	6.0	25 / 75 % FC	38	SFO	Krueger and Bade (1990)
Elliot DS1	clay loam	6.4	23 / 75 % FC	9.40	SFO	Wendt (1997), Bronner (2010)*
Elliot DS2	clay loam	6.4	23 / 75 % FC	9.32	SFO	Wendt (1997), Bronner (2010)*
Maximum				38		-

* kinetic re-evaluation

Table B.8.2-3: Non-normalised half-lives of dimethenamid-P in the field dissipation and field degradation trials

Field location	Soil texture	DT ₅₀ at study cond. [d]	Reference
Field dissipation trials			
Budrio (ITALY)	sandy loam	9.8	Carrier (1997)
Mezzolara (ITALY)	sandy loam	8.9	Carrier (1997)
Argenta (ITALY)	loam	15.2	Carrier (1997)
Vergoignan (FRANCE)	loam	16.3	Carrier and Blanz (1997)
Cestas (FRANCE)	sand	16.0	Carrier and Blanz (1997)
Niederaula (GER)	loamy sand	4.7	Fricker and Hertl (1995a)
Niedergoslar (GER)	Silty loam	3.9	Fricker and Hertl (1995a)
Morbihan (FRANCE)	sandy loam	3.2	Fricker and Hertl (1995b)
Sarthe (FRANCE)	silt loam	34.7	Fricker and Hertl (1995b)
Field degradation trials according to EFSA (2014)			
L110061 Goch-Nierswalde, (GER)	silt loam	20.4	Bayer and Marwitz 2014a), Wiedemann (2014a) *
L110062 Alsace, (FR)	silt loam	17.6	Bayer and Marwitz 2014a), Wiedemann (2014a) *
L110063 Meauzac, (FR)	sandy loam	14.5	Bayer and Marwitz 2014a), Wiedemann (2014a) *
L110064 Utrera, (ES)	sand	16.5	Bayer and Marwitz 2014a), Wiedemann (2014a) *
L110481 Derbyshire, (UK)	silt loam	17.6	Bayer and Marwitz 2014b), Wiedemann (2014a) *
L110482 Brunne, (GER)	sandy loam	10.2	Bayer and Marwitz 2014b), Wiedemann (2014a) *
Maximum		34.7	

* kinetic re-evaluation

The formation and degradation behaviour of M656H023, M656H027 and M656PH031 was studied in the six laboratory soils performed with dimethenamid and/or dimethenamid-P with 6 different soils in total.

Additionally, the formation and dissipation rate of M656H023 and M656H027 was also investigated in the 9 field trials performed with dimethenamid. In the field degradation studies with dimethenamid-P according to EFSA (2014) guidance, all three metabolites M656H023, M656H027 and M656PH031 were investigated, however no statistical valid degradation and formation parameters could be acquired. Additionally, four field degradation trials with M656H027 were performed according to EFSA (2014) guidance.

The non-normalised DT₅₀ values of M656H023, M656H027 and M656PH031 obtained in the laboratory are summarised in Table B.8.2-4. The non-normalised of M656H023 and M656H027 obtained in the field dissipation trials and in the field degradation trials are summarised in Table B.8.2-5.

Table B.8.2-4: Non-normalised laboratory half-lives of M656H023, M656H027 and M656PH031

Soil	Soil texture	Temp. [°C] / moisture	M656H023	M656H027	M656PH031	Ref.
			DT ₅₀ at study cond. [d]	DT ₅₀ at study cond. [d]	DT ₅₀ at study cond. [d]	
Flaach	sandy clay loam	20 / 40 %MWHC	24.1	33.1	37.7	König (1996), Platz (2008)*
BBA 2.2	loamy sand	20 / 40 %MWHC	41.0	60.6	61.3	König (1995), Platz (2008)*
BBA 2.3	sandy loam	20 / 40 %MWHC	23.8	43.5	39.4	König (1995), Platz (2008)*
Elliot DS1	clay loam	23 / 75 % FC	30.1	49.4	63.6	Wendt (1997), Bronner (2010)*
Elliot DS2	clay loam	23 / 75 % FC	26.2	45.6	55.9	Wendt (1997), Bronner (2010)*
Maximum			41.0	60.6	63.6	

Table B.8.2-5: Non-normalised half-lives of M656H023 and M656H027 in the field dissipation and field degradation trials

Field location	Soil texture	M656H023	M656H027	Reference
		DT ₅₀ at study cond. [d]	DT ₅₀ at study cond. [d]	
Budrio (ITALY)	sandy loam	97.8	24.4	Carrier (1997)
Mezzolara (ITALY)	sandy loam	52.8	74.1	Carrier (1997)
Argenta (ITALY)	loam	158.5	136.6	Carrier (1997)
Vergoignan (FRANCE)	loam	n.d.	n.d.	Carrier and Blanz (1997)
Cestas (FRANCE)	sand	n.d.	n.d.	Carrier and Blanz (1997)
Niederaula (GER)	loamy sand	45.0	76.0	Fricker and Hertl (1995a)
Niedergoslar (GER)	silty loam	18.0	22.0	Fricker and Hertl (1995a)
Morbihan (FRANCE)	sandy loam	n.d.	25.4	Fricker and Hertl (1995b)
Sarthe (FRANCE)	silt loam	41.5	41.7	Fricker and Hertl (1995b)
L110330 Goch-Nierswalde, (GER)	silt loam	-	31.4	Bayer and Marwitz 2014c), Wiedemann (2014a)
L110331 Alsace, (FR)	silt loam	-	12.0	Bayer and Marwitz 2014c), Wiedemann (2014a)
L110332 Meauzac, (FR)	loam	-	19.4	Bayer and Marwitz 2014c), Wiedemann (2014a)
L110333 Utrera, (ES)	loamy sand	-	23.7	Bayer and Marwitz 2014c), Wiedemann (2014a)
Maximum		158.5	136.6	

The maximum observed amounts of the metabolites M656H023 and M656H027 in the laboratory studies were 14.8 % (Krueger & Bade, 1990) and 12.7 % (Koenig, 1995), respectively. Metabolite M656PH031 was found with a maximum occurrence in soil of 6.9 % (Wendt, 1997).

In the field dissipation and field degradation trials, the metabolites M656H023 and M656H027 were found with maxima of 9.4 % in Sarthe, France (Fricker & Hertl, 1995b) and 8.1 % in Niedergoslar, Germany (Fricker & Hertl, 1995a), respectively.

The final endpoints used for PEC_{soil} calculation of dimethenamid-P and its soil metabolites M656H023, M656H027 and M656PH031 are summarised in Table B.8.2-6.

Table B.8.2-6: Summary of substance parameters for dimethenamid-P and its metabolites used for PEC_{soil} calculations

Parameter	Dimethenamid-P	M656H023	M656H027	M656PH031
Molar mass (g mol ⁻¹)	275.8	271	321.4	347
Molar correction factor (-)	-	0.983	1.165	1.258
DT ₅₀ in soil for PEC _{soil} [d]	38 ^F	158.5 ^G	136.6 ^G	63.6 ^F
Max. occurrence in soil for PEC _{soil} [%]	100	9.4 ^H	8.1 ^H	6.9 ^H

F longest, non-normalised DT₅₀ from laboratory studies

G longest, non-normalised DT₅₀ from field studies

H from field studies, including molar correction

The maximum PEC values in soil (PEC_{soil,max}) were calculated considering the respective application rate, a soil bulk density of 1.5 g cm⁻³ and a thickness of the soil layer of 5 cm (Equation B.8.2.1-1).

Equation B.8.2.1-1: Calculation of the maximum PEC_{soil}

$$PEC_{soil,max} = \frac{A \cdot (1 - f_{int})}{100 \cdot d \cdot bd_{soil}} \cdot f_{mol} \cdot f_{max,occ}$$

with:	PEC _{soil,max}	maximum concentration in soil [mg kg ⁻¹]
	A	application rate [g as ha ⁻¹]
	f _{int}	fraction intercepted by plant cover (here: 0) [-]
	d	depth of soil layer (5 cm) [cm]
	bd _{soil}	soil bulk density (1.5 g cm ⁻³) [g cm ⁻³]
	f _{mol}	molar correction factor for the metabolite (set to 1 for the parent) [-]
	f _{max,occ}	maximum occurrence in soil (set to 1 for the parent) [-]

The actual concentration in soil (PEC_{soil,act}) was calculated for different time points t = 1, 2, 4, 7, 14, 21, 28, 50 and 100 days after the occurrence of the maximum concentration according to Equation B.8.2.1-2.

Equation B.8.2.1-2: Calculation of the actual PEC_{soil}

$$PEC_{soil,act} = PEC_{soil,max} \cdot e^{-k \cdot t}$$

with:	PEC _{soil,act}	actual concentration in soil [mg kg ⁻¹]
	PEC _{soil,max}	maximum concentration in soil [mg kg ⁻¹]
	k	degradation rate (= ln (2) / DT ₅₀) [d ⁻¹]
	t	time after last application [d]

The maximum time weighted average concentrations ($PEC_{\text{soil, twa}}$) for exposure periods (Δt) of 1, 2, 4, 7, 14, 21, 28, 50 and 100 days calculated according to

Equation B.8.2.1-3: Calculation of the time-weighted average PEC_{soil}

$$PEC_{\text{soil, twa}}(\Delta t) = PEC_{\text{soil, max}} \cdot \frac{1}{k \cdot \Delta t} \cdot (1 - e^{-k \cdot \Delta t})$$

with: $PEC_{\text{soil, twa}}$ time-weighted average concentration for time interval Δt [mg kg^{-1}]
 $PEC_{\text{soil, max}}$ maximum concentration in soil [mg kg^{-1}]
 Δt time interval [d]
 k degradation rate ($= \ln(2) / DT_{50}$) [d^{-1}]

Since the maximum DT_{50} values of the metabolites M23 and M27 in soil exceed 90 days, the potential of accumulation of these metabolites in soil was assessed. For this purpose, the plateau concentration in soil at steady state ($PEC_{\text{soil, plateau}}$) and the overall accumulation PEC in soil ($PEC_{\text{soil, accu}}$) after application of dimethenamid-P over many years were determined.

The plateau concentration at steady state ($PEC_{\text{soil, plateau}}$) is defined as the level of residues in soil after the winter regeneration period immediately before the first seasonal application and is calculated according to Equation B.8.2.1-1. A soil layer depth of 20 cm was considered as a conservative assumption for the distribution of the substances in soil after crop cultivation over many years.

The maximum concentration ($PEC_{\text{soil, max}}$) of the substance after the last application is derived for a soil layer of 20 cm using Equation B.8.2.1-4.

Equation B.8.2.1-4: Calculation of the plateau PEC_{soil}

$$PEC_{\text{soil, plateau}} = \frac{PEC_{\text{soil, max}}}{1 - e^{-k \cdot t}} \cdot e^{-k \cdot t}$$

with: $PEC_{\text{soil, plateau}}$ plateau concentration at steady state [mg kg^{-1}]
 $PEC_{\text{soil, max}}$ maximum concentration in soil (depth: 20 cm) [mg kg^{-1}]
 t interval between application seasons (365 days) [d]
 k degradation rate ($= \ln(2) / DT_{50}$) [d^{-1}]

The overall accumulation PEC in soil ($PEC_{\text{soil, accu}}$) represents the highest potential soil concentration considering the multi-year accumulation load as background concentration plus the maximum concentration ($PEC_{\text{soil, max}}$) after application in the top soil layer. For this purpose, the $PEC_{\text{soil, plateau}}$ and the $PEC_{\text{soil, max}}$ in the top 5 cm soil layer are added (Equation B.8.2.1-5).

Equation B.8.2.1-5: Calculation of the overall accumulation PEC_{soil}

$$PEC_{\text{soil, accu}} = PEC_{\text{soil, plateau}} + PEC_{\text{soil, max}}$$

with: $PEC_{\text{soil, accu}}$ maximum concentration in soil
for the accumulation risk assessment [mg kg^{-1}]
 $PEC_{\text{soil, plateau}}$ plateau concentration at steady state [mg kg^{-1}]
 $PEC_{\text{soil, max}}$ maximum concentration in soil (depth: 5 cm) [mg kg^{-1}]

Results and Discussion

The maximum, actual and time weighted average PEC_{soil} values of dimethenamid-P and the metabolites for a soil layer depth of 5 cm are shown in Table B.8.2-7.

Table B.8.2-7: PEC_{soil} of dimethenamid-P and the metabolites M656H023, M656H027 and M656PH031 after application of 500 g dimethenamid-P ha^{-1}

	Time * [d]	PEC_{soil} [mg kg^{-1}]							
		Dimethenamid-P		M656H023		M656H027		M656PH031	
		Act	TWA	Act	TWA	Act	TWA	Act	TWA
Global maximum	0	0.667	-	0.063	-	0.054	-	0.058	-
Short-term	1	0.655	0.661	0.062	0.063	0.054	0.054	0.057	0.058
	2	0.643	0.655	0.062	0.062	0.053	0.054	0.057	0.057
	4	0.620	0.643	0.062	0.062	0.053	0.053	0.055	0.057
Long-term	7	0.587	0.626	0.061	0.062	0.052	0.053	0.054	0.056
	14	0.516	0.588	0.059	0.061	0.050	0.052	0.050	0.054
	21	0.455	0.554	0.057	0.060	0.049	0.051	0.046	0.052
	28	0.400	0.522	0.055	0.059	0.047	0.050	0.043	0.050
	50	0.268	0.437	0.050	0.056	0.042	0.048	0.034	0.045
	100	0.108	0.307	0.040	0.051	0.033	0.042	0.019	0.035

* Time: days after maximum concentration ($PEC_{soil,act}$) or time interval ($PEC_{soil,twa}$)

$PEC_{soil,accu}$ of the metabolites M656H023 and M656H027 after application for a period of many years are given in Table B.8.2-8.

Table B.8.2-8: $PEC_{soil,accu}$ of M656H023 and M656H027 after multi-year application of 500 g dimethenamid-P ha^{-1}

Metabolite	$PEC_{soil,max}$ [mg kg^{-1}]	$PEC_{soil, plateau}$ [mg kg^{-1}]	$PEC_{soil,accu}$ (= $PEC_{soil,plateau} + PEC_{soil,max}$) [mg kg^{-1}]
	0 – 5 cm depth	0 – 20 cm depth	0 – 5 cm depth
M656H023	0.063	0.004	0.067
M656H027	0.054	0.003	0.057*

* calculated with unrounded value

Conclusion

The worst case application rate of 500 g/ha dimethenamid-P used for PEC_{soil} calculations is considered acceptable by the RMS.

The same is true for the calculation methods used by the applicant.

However, during the evaluation process of the laboratory studies, the study Krueger & Bade (1990) was considered not acceptable anymore. Besides, a new kinetic evaluation was performed of the 9 field dissipation trials of the studies Fricker & Hertl, 1995a &b, Carrier & Blanz, 1997 & Carrier, 1997. In this process, new dissipation half lives were obtained for dimethenamid-P and no statistically valid dissipation half lives could be obtained anymore for the metabolites M656H023 and M656H027. Besides, different maximum occurrences for the metabolites M656H023 and M656H027 were derived by the RMS from the field dissipation studies Fricker & Hertl, 1995a &b, Carrier & Blanz, 1997 &

Carrier, 1997. Even so molecular correction was also considered (see Table 2.8.1-7 of Volume 1, Level 2.8.1).

Thus, the PEC_{soil} calculations were repeated by the RMS using the newly derived endpoints as summarised in Table B.8.2-9. They were chosen from the summary tables on degradation route and rate of dimethenamid-P under aerobic conditions provided in Volume 1, Level 2.8.1 of this document.

Table B.8.2-9: Summary of substance parameters for dimethenamid-P and its metabolites used for PEC_{soil} calculations (re-calculation of the RMS)

Parameter	Dimethenamid-P	M656H023	M656H027	M656PH031
Molar mass (g mol ⁻¹)	275.8	271	321.4	347
Molar correction factor (-)	-	0.983	1.165	1.258
DT ₅₀ in soil for PEC_{soil} [d]	35.1 (SFO) ^F	63.94 (SFO) ^H	31.3 (SFO) ^F	103.3 (SFO) ^H
Max. occurrence in soil for PEC_{soil} [%]	100	13.44 ^I	13.32 ^J	10.34 ^J
Application rate (g/ha) assuming direct application	500	66.0	77.6	65.0

F longest, non-normalised DT₅₀ from field studies

H longest, non-normalised DT₅₀ from laboratory studies

I maximum occurrence in field studies

J maximum occurrence in laboratory studies

The maximum, actual and time weighted average PEC_{soil} values of dimethenamid-P and the metabolites for a soil layer depth of 5 cm are shown in Table B.8.2-10.

Table B.8.2-10: PEC_{soil} of dimethenamid-P and the metabolites M656H023, M656H027 and M656PH031 after application of 500 g dimethenamid-P ha⁻¹* (re-calculation of the RMS)

	Time * [d]	PEC_{soil} [mg kg ⁻¹]							
		Dimethenamid-P		M656H023		M656H027		M656PH031	
		Act	TWA	Act	TWA	Act	TWA	Act	TWA
Global maximum	0	0.6667	-	0.0880	-	0.1035	-	0.0867	-
Short-term	1	0.6536	0.6601	0.0871	0.0875	0.1012	0.1023	0.0861	0.0864
	2	0.6408	0.6537	0.0861	0.0871	0.0990	0.1012	0.0855	0.0855
	4	0.6160	0.6410	0.0843	0.0861	0.0947	0.0990	0.0844	0.0844
Long-term	7	0.5806	0.6227	0.0816	0.0847	0.0886	0.0958	0.0827	0.0827
	14	0.5056	0.5825	0.0756	0.0816	0.0759	0.0890	0.0789	0.0789
	21	0.4404	0.5457	0.0701	0.0787	0.0650	0.0827	0.0753	0.0753
	28	0.3835	0.5121	0.0650	0.0759	0.0557	0.0771	0.0718	0.0718
	42	0.2909	0.4531	0.0558	0.0707	0.0408	0.0674	0.0654	0.0654
	50	0.2484	0.4237	0.0512	0.0679	0.0342	0.0626	0.0620	0.0620
	100	0.0925	0.2907	0.0298	0.05379	0.0113	0.0416	0.0443	0.0443

* Time: days after maximum concentration ($PEC_{soil,act}$) or time interval ($PEC_{soil,twa}$)

$PEC_{soil,accu}$ were obtained for the metabolites M656H023 and M656H031 after application for a period of many years. They are given in Table B.8.2-11.

Table B.8.2-11: $PEC_{soil,accu}$ of M656H023 and M656H031 after multi-year application of 500 g dimethenamid-P ha^{-1}

Metabolite	$PEC_{soil,max}$ [mg kg^{-1}] 0 – 5 cm depth	$PEC_{soil, plateau}$ [mg kg^{-1}] 0 – 20 cm depth	$PEC_{soil,accu}$ (= $PEC_{soil,plateau} + PEC_{soil,max}$) [mg kg^{-1}] 0 – 5 cm depth
M656H023	0.0880	0.0004	0.0884
M656H031	0.0867	0.0035	0.0902

B.8.2.2 Quinmerac and its metabolites:

No study on PEC_{soil} values of quinmerac and its major soil metabolites BH 518-2 (29.1 % maximum formation) and BH 518-5 (27.2 % max. maximum formation) in the representative formulation BAS 830 01 H were submitted, but additional PEC_{soil} values of these substances were provided in the dossier of the applicant.

However, since this document concerns the EU approval of the active substance dimethenamid-P and not of quinmerac, which was already approved on 01/05/2011, we believe that the PEC_{soil} values presented here for quinmerac and its metabolites BH 518-2 and BH 518-5 should be the same as the values provided in the List of Endpoints (LoEP) of quinmerac (drafted in April 2007, last updated in November 2009) in order to not repeat the approval process for quinmerac.

Material and Methods

PEC_{soil} calculations of quinmerac and its metabolites for EU approval were performed for the application scenario provided in Table B.8.2-12.

Table B.8.2-12: Application scenario of quinmerac applied to winter oilseed rape considered for the PEC_{soil} calculations (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

Crop	Pre-emergence
Growth stage at first application [BBCH]	00
Application rate [g as ha^{-1}]	250
No. of applications [-]	1
Interception [%]	0
Total yearly soil load [g as ha^{-1}]	250

This application scenario is also considered sufficient to cover the application of 1.5 L BAS 830 01 H containing 250 g/ha quinmerac to winter oilseed rape (pre- and post emergence application).

Results and Discussion

The maximum PEC_{soil} values of quinmerac and its soil metabolites BH 518-2 and BH 518-5 taken from the LoEP (Nov 2009) of quinmerac are presented in Table B.8.2-13.

Table B.8.2-13: Maximum PEC_{soil} of quinmerac and its metabolites BH 518-2 and BH 518-5 after application of 250 g quinmerac ha⁻¹ (5 cm soil depth, 20 cm tillage depth)

Active substance/ metabolite	PEC _{ini} (mg/kg)	PEC _{accu} (mg/kg)
Quinmerac	0.333	No accumulation
Metabolite BH 518-2	0.160	No accumulation
Metabolite BH 518-5	0.124	0.130 (in third year of application)

Conclusion

The application window chosen for EU approval of quinmerac, also covers the application of the representative formulation BAS 830 01 H.

The PEC_{soil} values of quinmerac and its metabolites BH 518-2 and BH 518-5 derived for EU approval of quinmerac are considered acceptable by the RMS to be used for risk assessment also for BAS 830 01 H.

B.8.3 Predicted environmental concentrations in groundwater (PEC_{GW})

B.8.3.1 Dimethenamid-P and its metabolites:

KCP 9.2.2/ 1– Maleri, 2014a

Author:	Maleri, M.
Title:	Predicted environmental concentrations in soil, groundwater, surface water and sediment of dimethenamid-p and its metabolites after application of BAS 656 12 H and 830 01 H
Date:	28.02.2014
Doc ID:	BASF DocID 2014/1000682
Guidelines:	FOCUS groundwater (2009): SANCO/13144/2010 v1.0, Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2012) version 2.1, SANCO/4802/2001 rev. 2 (FOCUS surface water scenarios) May 2003, FOCUS Surface Water (2012) Generic guidance for FOCUS surface water scenarios v 1.1, FOCUS (2007): Landscape And Mitigation Factors Volume
GLP:	No
Validity:	Partly acceptable

Material and Methods

In this study, predicted environmental concentrations in groundwater (PEC_{GW}) of dimethenamid-P and its metabolites M656PH003 (= M3 in this study), M656PH010 (= M10 in this study), M656PH023 (= M23 in this study), M656PH027 (= M27 in this study), M656PH031 (= M31 in this study), M656PH032 (= M32 in this study), M656PH043 (= M43 in this study), M656PH045 (= M45 in this study), M656PH047 (= M47 in this study), M656PH049 (= M49 in this study), M656PH050 (= M50 in this study), M656PH051 (= M51 in this study), M656PH052 (= M52 in this study), M656PH053 (= M53 in this study), M656PH054 (= M54 in this study), M656H055 (= M55 in this study), M656PH059 (= M59 in this study) and M656PH062 (= M62 in this study) following application of BAS 830 01 H to winter oilseed rape were calculated in accordance with the guidance of the FOCUS groundwater scenarios work group (2009).

Groundwater leaching was assessed using a tiered approach following FOCUS (2009):

Tier 1:

- Basic laboratory and/or field data for dimethenamid-P and the aerobic soil metabolites M23, M27 and M31 using a plant uptake factor (PUF) of 0.5 for dimethenamid-P and a default PUF of 0 for the soil metabolites.
- Newly elucidated metabolites (M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62) from lysimeter leachate – derivation of PEC_{GW} from lysimeter leachate (Tier 3c) of the lysimeter study Burgener (1996) using transfer factors.

Tier 2a:

- PUF of 0.5 for dimethenamid-P and for the metabolites M23, M27 and M31 based on experimental data.
- Newly elucidated metabolites (M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62) from lysimeter leachate – derivation of PEC_{GW} from lysimeter leachate (Tier 3c) of the lysimeter study Burgener (1996) using transfer factors.

Tier 3c:

- Lysimeter data for PEC_{GW} for all soil and lysimeter leachate metabolites. Derivation of transfer factors for the newly elucidated metabolites to obtain Tier1/2a PEC_{GW} .

Tier 4:

- Monitoring data for soil and lysimeter leachate metabolites.

Tier 1 & 2a groundwater leaching assessment:

The metabolites M23, M27 and M31 were found in aerobic soil studies with dimethenamid-P in concentrations > 10 %. Besides, the metabolites M23 and M27 were found in the lysimeter leachate of the Burgener (1996) in concentrations > 0.1 $\mu\text{g L}^{-1}$. Tier 1 and 2a PEC_{gw} of dimethenamid-P and the soil metabolites M23, M27 and M31 were calculated with the models FOCUS-PEARL 4.4.4 and FOCUS-PELMO 5.5.3 for all available FOCUS scenarios of maize (pre- and post-emergence), soybeans (pre-emergence), sugar beets (post-emergence) and sunflowers (pre-emergence) with an annual application pattern (continuous cropping over a period of 26 years).

The remaining metabolites M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 were present in lysimeter leachates of the study Burgener, 1996 and were identified in the study Staudenmaier (2014b) both described in Volume 3 CA, B 8.1.4.2 of the active substance. Since these metabolites were not identified and found in aerobic soil metabolism studies, there is not enough substance specific information for direct PEC calculations of these metabolites (e.g. no available formation fractions). Therefore, an alternative concept, the so called transfer factor concept, was applied to derive lower tier PEC_{GW} concentrations from higher Tier PEC_{GW} concentrations.

The worst application scenarios for groundwater assessment (tier 1 and 2a) of dimethenamid-P in the formulation BAS 830 01 H are given in Table B.8.3-1.

Table B.8.3-1: Worst-case application scenarios for groundwater assessment (tier 1 and 2a) of dimethenamid-P in the formulation BAS 830 01 H

Crop	Winter oilseed rape	
Crop growth stage [BBCH]	00 – 09	10-16
Max. no. of applications	1	1
Application rate [g as ha ⁻¹]	500	500
Interception [%] accord. to FOCUS GW	0	40
Total yearly soil load [g as ha ⁻¹]	500	300

The application dates were set to seven days before and after the pre-defined crop emergence of the respective FOCUS locations for pre-emergent and post-emergent application, respectively. The emergence and application dates for all relevant FOCUS scenarios are shown in Table B.8.3-2.

Table B.8.3-2: FOCUS emergence dates and application dates used for groundwater assessment (tier 1 and 2a) of dimethenamid-P in the formulation BAS 830 01 H

Scenario	Winter oilseed rape, 500 g ha ⁻¹		
	Emergence date according to FOCUS	Application date, pre-emergence	Application date, post-emergence
Châteaudun	07-Sep	31-Aug	14-Sep
Hamburg	02-Sep	26-Aug	09-Sep
Kremsmünster	02-Sep	26-Aug	09-Sep
Okehampton	14-Aug	07-Aug	21-Aug
Piacenza	05-Oct	28-Sep	12-Oct
Porto	07-Sep	31-Aug	14-Sep

An overview over the substance specific input parameter of dimethenamid-P used for tier 1 and 2a groundwater modelling is given in Table B.8.3-3. An overview over the substance specific input parameter of the metabolites M23, M27 and M31 used for tier 1 and 2a groundwater modelling is given in Table B.8.3-4.

Table B.8.3-3: Summary of input parameters of dimethenamid-P used for tier 1 and 2a groundwater modelling with FOCUS-PEARL and FOCUS-PELMO

Input parameter	Unit	Dimethenamid-P	Default value
Physico-chemical parameters			
Molecular weight	[g mol ⁻¹]	275.8	-
Water solubility	[mg L ⁻¹]	1449 (25 °C)	-
Molar enthalpy of dissolution (PEARL)	[kJ mol ⁻¹]	-	27
Saturated vapor pressure	[Pa]	2.51 x 10 ⁻³ (25 °C)	-
Molar enthalpy of vaporisation (PEARL)	[kJ mol ⁻¹]	-	95
Diffusion coefficient in water (PEARL)	[m ² d ⁻¹]	-	4.3 x 10 ⁻⁵ (20 °C)
Diffusion coefficient in air (PEARL)	[m ² d ⁻¹]	-	0.43 (20 °C)
Diffusion coefficient in air (PELMO)	[cm ² s ⁻¹]	-	0.05 (20 °C)
Degradation parameters			
Half-life at reference conditions (PEARL)	[d]	11.3 ^A	-
Transformation rate (k) to M23 (PELMO)	[d ⁻¹]	0.0087103	-
Transformation rate (k) to M27 (PELMO)	[d ⁻¹]	0.0079743	-
Transformation rate (k) to M31 (PELMO)	[d ⁻¹]	0.0051526	-
Transformation rate (k) to CO ₂ (PELMO)	[d ⁻¹]	0.0395033	-
Molar activation energy (PEARL)	[kJ mol ⁻¹]	-	65.4
Q ₁₀ (PELMO)	[-]	-	2.58
Exponent of moisture correction function	[-]	-	0.7
Sorption parameters			
K _{f,oc} value (PELMO)	[mL g ⁻¹]	167.4 ^B	-
K _{f,om} value* (PEARL)	[mL g ⁻¹]	97.1	-
Freundlich exponent 1/n	[-]	0.985 ^B	-
Method of subroutine description	[-]	-	pH-independent
Crop related parameters			
TSCF (crop uptake)	[-]	-	0.5

* $K_{f,om} = K_{f,oc} / 1.724$ ^A Geometric mean of normalised (20 °C and pF2) laboratory and field DT₅₀ values (n=12)^B Median of K_{f,oc} / 1/n values (n=10)

Table B.8.3-4: Summary of input parameters of the metabolites M23, M27 and M31 used for groundwater modelling with FOCUS-PEARL and FOCUS-PELMO (tier 1 and 2a)

Input parameter	Unit	M23	M27	M31
Physico-chemical parameters				
Molecular weight	[g mol ⁻¹]	271	321.4	347
Water solubility	[mg L ⁻¹]	1000 (20 °C) ^A	1000 (20 °C) ^A	1000 (20 °C) ^A
Saturated vapor pressure	[Pa]	10 ⁻¹⁰ (20 °C) ^A	10 ⁻¹⁰ (20 °C) ^A	10 ⁻¹⁰ (20 °C) ^A
Degradation parameters				
Half-life at reference conditions (PEARL)	[d]	24.6 ^B	14.3 ^C	43.6 ^B
Transformation rate (k) to M27 (PELMO)	[d ⁻¹]	-	-	0.0158979
Transformation rate (k) to CO ₂ (PELMO)	[d ⁻¹]	0.0281767	0.0484718	-
Formation fraction (PEARL)	[-]	0.142 from parent ^H	0.130 from parent ^H 1 from M31 ^I	0.084 from parent ^H
Sorption parameters				
K _{f,oc} value (PELMO)	[mL g ⁻¹]	11.86 ^D	9.27 ^E	4.38 ^F
K _{f,om} value* (PEARL)	[mL g ⁻¹]	6.9	5.4	2.5
Freundlich exponent 1/n	[-]	0.722 ^D	1.0 ^E	0.930 ^F
Crop related parameters				
TSCF (crop uptake)	[-]	0 / 0.5 ^G	0 / 0.5 ^G	0 / 0.5 ^G

* K_{f,om} = K_{f,oc} / 1.724

A Conservative default value

B Geometric mean of normalised (20 °C, pF2) laboratory values (n=5)

C Geometric mean of normalised (20 °C, pF2) field values (n=4)

D Arithmetic mean of K_{f,oc} values (n=5)E Arithmetic mean of K_{f,oc} values (n=5)F Arithmetic mean of K_{f,oc} values (n=5)G Conservative default value of 0 in Tier 1; crop uptake of 0.5 selected in Tier 2a based on *Gourlay (2013a)*

H Arithmetic mean of laboratory formation fractions (n=5)

I worst-case default

The remaining metabolites M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 were present in lysimeter leachate of the study Burgener, 1996 but were not formed in the soil metabolism studies with dimethenamid-P. Due to the lack of substance specific information for direct PEC calculations of these metabolites a different concept, called “transfer factor concept”, was developed. This concept relates concentrations of the lysimeter leachate of the newly elucidated metabolites to metabolite M27, which was detected both in the lysimeter leachate and in the soil metabolism studies with dimethenamid-P thus allowing groundwater modelling with FOCUS-PEARL and FOCUS-PELMO.

In order to obtain lower Tier PEC_{GW} values for the newly elucidated metabolites, transfer factors were derived from the leachate concentrations in the lysimeter study by setting M27 as reference metabolite. M27 was chosen since this metabolite occurred as a single identified component in the leachate, while the other soil aerobic metabolites M23 and M31 were not uniquely definable from HPLC peak analyses (for more details see Staudenmaier, 2014b in , Vol. 3 CA, B.8.1.4.2 of the active substance).

The transfer factors were derived applying Equation 8.3.1-1 for all relevant FOCUS Scenarios of FOCUS-PEARL and FOCUS-PELMO.

$$Transferfactor = \frac{M27_{calc}}{M27_{meas}}$$

$$MX_{calc} = MX_{meas} \cdot Transferfactor$$

M27 _{calc}	=	Concentration of metabolite M27 measured in lysimeter leachate adapted to application rate according to crop scenario
M27 _{meas}	=	Tier 1 and Tier 2a PEC _{GW} of metabolite M27 calculated for each FOCUS PEARL and FOCUS PELMO scenario
MX _{calc}	=	Concentration of metabolite in question measured in lysimeter leachate adapted to application rate according to crop scenario
MX _{meas}	=	Tier 1 and Tier 2a PEC _{GW} of metabolite in question only found in lysimeter leachate for the respective FOCUS PEARL and FOCUS PELMO scenario

Equation 8.3.1-1 Calculation of PEC_{GW} for dimethenamid-p metabolites only found in lysimeter leachate for all relevant FOCUS PEARL and FOCUS PELMO scenarios

Tier 3c groundwater leaching assessment:

A lysimeter study is one of the study types that belong to a Tier 3c assessment for groundwater, under the condition that representativeness of the lysimeter can be shown (FOCUS, 2009). A lysimeter study Burgener (1996) with dimethenamid was performed for Annex I inclusion. The study was further elucidated by Fent (2008), Staudenmaier (2009 with amendment 2014a) and Staudenmaier (2014b). These studies are summarised in more detail in Volume 3 CA, B.8.1.4.2 of the active substance.

A vulnerability analysis for the EU was performed in Haering (2013). In this study, the main parameters influencing leaching were firstly evaluated for the lysimeter versus the agricultural areas in Europe (using GIS tools) and show that the lysimeter is highly vulnerable. Secondly, relative leachate concentrations obtained from a meta-model (METAPearl) show the vulnerability of the lysimeter with respect to the groundwater scenarios developed in the framework of FOCUS and the agricultural area in Europe. The study is also summarised in more detail in Volume 3 CA, B.8.1.4.2 of the active substance.

Since the vulnerability of the lysimeter for Europe is demonstrated and the breakthrough of the metabolites was obtained within the experimental period (which is mainly influenced by the short degradation of dimethenamid and dimethenamid-P combined with the low sorption and fast degradation of the soil metabolites), the lysimeter study is considered appropriate for the Tier 3 risk assessment to groundwater.

Tier 4 groundwater leaching assessment:

Groundwater monitoring was performed in Germany (Schmidt et al (2010), Schmidt & Schulz (2012), Schmidt & Schneider (2013), Class (2013), Mewis (2014a)) and in the Netherlands (Mewis, 2014b). The groundwater monitoring studies are summarised in more detail in Volume 3 CA, B.8.4.1 of the active substance. The German and Dutch monitoring sites were analysed for their suitability as monitoring sites for dimethenamid-P and for their representativeness for the EU in the study Haering & Miles, 2013, which is also summarised in Volume 3 CA, B.8.4.1 of the active substance.

Haering & Miles (2013) show that the German monitoring sites can be regarded as representative for most of Europe's agricultural areas and that the data is valid for the metabolites of dimethenamid-P in a retro- and prospective way. With respect to the 80 Dutch monitoring wells and the sampling period, a single analysis for the dimethenamid-P metabolites provides a representative snapshot of the

situation in an area with shallow groundwater and high levels of maize production at a time when both groundwater recharge and groundwater levels are expected to be around their annual maxima.

As a consequence, groundwater monitoring samples from both, the German and Dutch monitoring sites, can be used to evaluate the concentration in groundwater in a realistic way. Especially the German sites are characterised in depth with respect to their vulnerability in Europe and are thus suitable as Tier 4 PEC_{GW} values.

Results and Discussion

Tier 1 groundwater leaching assessment:

The modelled tier 1 PEC_{GW} for dimethenamid-P and the metabolites M23, M27 and M31 using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 after application of BAS 830 01 H to winter oilseed rape are presented in Table B.8.3-5 and Table B.8.3-6.

Table B.8.3-5: 80th percentile of annual leachate concentrations of dimethenamid-P and the metabolites M23, M27 and M31 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS - PELMO 5.5.3 – Tier 1

Scenario	PEC _{GW} [$\mu\text{g L}^{-1}$]			
	Dimethenamid-P	M23	M27	M31
Winter oilseed rape, pre-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.098	3.004	6.138
Hamburg	0.002	0.995	6.510	9.827
Kremsmünster	0.001	0.494	3.707	6.233
Okehampton	0.002	0.853	3.597	5.730
Piacenza	0.005	0.809	4.297	6.197
Porto	0.002	0.773	3.342	5.528
Winter oilseed rape, post-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.028	1.865	3.716
Hamburg	0.001	0.416	4.428	6.378
Kremsmünster	0.001	0.217	2.428	3.778
Okehampton	0.002	0.431	2.603	3.826
Piacenza	0.002	0.176	2.493	3.409
Porto	0.002	0.360	2.357	3.391

Table B.8.3-6: 80th percentile of annual leachate concentrations of dimethenamid-P and the metabolites M23, M27 and M31 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS - PEARL 4.4.3 – Tier 1

Scenario	PEC _{GW} [$\mu\text{g L}^{-1}$]			
	Dimethenamid-P	M23	M27	M31
Winter oilseed rape, pre-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.181	3.686	7.706
Hamburg	0.002	1.166	6.656	12.053
Kremsmünster	0.001	0.529	3.434	5.810
Okehampton	0.001	0.718	3.553	5.543
Piacenza	0.002	0.600	3.789	5.336
Porto	0.001	0.842	4.050	6.831
Winter oilseed rape, post-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.065	2.307	4.572
Hamburg	0.001	0.476	4.072	7.159
Kremsmünster	<0.001	0.206	2.086	3.531
Okehampton	0.001	0.360	2.434	3.759
Piacenza	0.001	0.188	1.946	2.945
Porto	0.001	0.358	2.463	4.131

FOCUS-PEARL generally provides more conservative PEC_{GW} concentrations for dimethenamid-P and its soil metabolites than FOCUS-PELMO. In the results below, M31 provides the highest concentrations, with one exceedance over the 10 $\mu\text{g/L}$ threshold value for non-relevant metabolites.

The transfer factors based on M27 for each crop scenario (application rate adapted) and FOCUS scenario (ratio of calculated to measured M27 in the lysimeter leachate) can be found in Table B.8.3-7.

Table B.8.3-7: Transfer factors for M27 derived from ratio of M27_{calc}*/M27_{meas} - Tier 1**

Scenario	Winter oilseed rape, pre-emergence	Winter oilseed rape, post-emergence
	M27 calculated with FOCUS-PELMO 5.5.3	
Châteaudun	1.3	0.9
Hamburg	3.2	2.2
Kremsmünster	1.8	1.2
Okehampton	1.8	1.4
Piacenza	2.8	1.6
Porto	1.7	1.4
M27 calculated with FOCUS-PEARL 4.4.4		
Châteaudun	2.0	1.2
Hamburg	4.0	2.4
Kremsmünster	2.1	1.3
Okehampton	2.4	1.6
Piacenza	2.7	1.3
Porto	2.6	1.6

* calculated according to FOCUS using FOCUS-PELMO 5.5.3 and FOCUS-PEARL 4.4.4 (Tier 1)

** measured in lysimeter study, adapted for application rate according to crop scenario (Table 9.2.4-27)

The estimated PEC_{GW} values for the metabolites that were only found in the lysimeter leachate are presented exemplary after pre-emergence application of dimethenamid-P to winter oilseed rape are presented in Table B.8.3-8 and Table B.8.3-9.

Table B.8.3-8: Estimated PEC_{gw} after pre-emergence application of dimethenamid-P to winter oilseed rape – based on Tier 1 PEC_{GW} results calculated with FOCUS-PELMO 5.5.3

Winter oilseed rape, pre-emergence, 500 g ha ⁻¹									
Scenario	PEC _{GW} [µg L ⁻¹]								
	M3	M10	M32	M43 (rota 1+2)	M45 (rota 1+2)	M47 (rota 1+2)	M49	M50	M51
Châteaudun	0.07	0.05	1.1	0.9	1.5	0.9	0.7	0.4	0.8
Hamburg	0.16	0.11	2.4	1.9	3.2	2.0	1.6	0.8	1.8
Kremsmünster	0.09	0.06	1.4	1.1	1.8	1.1	0.9	0.5	1.0
Okehampton	0.09	0.06	1.3	1.1	1.8	1.1	0.9	0.4	1.0
Piacenza	0.11	0.07	1.6	1.3	2.1	1.3	1.1	0.5	1.2
Porto	0.08	0.06	1.3	1.0	1.7	1.0	0.8	0.4	0.9
Scenario	M52	M53 iso 1	M53 iso 2	M54 (rota 1+2)	M55	M59 iso 1	M59 iso 2	M59 iso 3	M62
Châteaudun	0.6	1.2	1.5	2.4	0.5	0.6	0.3	1.2	1.5
Hamburg	1.4	2.6	3.2	5.3	1.1	1.4	0.6	2.6	3.2
Kremsmünster	0.8	1.5	1.8	3	0.6	0.8	0.4	1.5	1.8
Okehampton	0.8	1.4	1.8	2.9	0.6	0.8	0.4	1.4	1.8
Piacenza	0.9	1.7	2.1	3.5	0.7	0.9	0.4	1.7	2.1
Porto	0.7	1.3	1.6	2.7	0.6	0.7	0.3	1.3	1.6

iso isomer, rota rotamere

Table B.8.3-9: Estimated PEC_{GW} after pre-emergence application of dimethenamid-P to winter oilseed rape – based on Tier 1 PEC_{gw} results calculated with FOCUS-PEARL 4.4.3

Winter oilseed rape, pre-emergence, 500 g ha ⁻¹									
Scenario	PEC _{GW} [µg L ⁻¹]								
	M3	M10	M32	M43 (rota 1+2)	M45 (rota 1+2)	M47 (rota 1+2)	M49	M50	M51
Châteaudun	0.09	0.06	1.4	1.1	1.8	1.1	0.9	0.5	1.0
Hamburg	0.16	0.11	2.5	2.0	3.3	2.1	1.6	0.8	1.8
Kremsmünster	0.08	0.06	1.3	1.0	1.7	1.1	0.8	0.4	0.9
Okehampton	0.09	0.06	1.3	1.1	1.8	1.1	0.9	0.4	1.0
Piacenza	0.09	0.06	1.4	1.1	1.9	1.2	0.9	0.5	1.0
Porto	0.1	0.07	1.5	1.2	2	1.3	1.0	0.5	1.1
Scenario	M52	M53 iso 1	M53 iso 2	M54 (rota 1+2)	M55	M59 iso 1	M59 iso 2	M59 iso 3	M62
Châteaudun	0.8	1.5	1.8	3.0	0.6	0.8	0.4	1.5	1.8
Hamburg	1.4	2.6	3.2	5.4	1.1	1.4	0.7	2.6	3.2
Kremsmünster	0.7	1.4	1.7	2.8	0.6	0.7	0.3	1.4	1.7
Okehampton	0.8	1.4	1.7	2.9	0.6	0.7	0.4	1.4	1.7
Piacenza	0.8	1.5	1.8	3.1	0.6	0.8	0.4	1.5	1.8
Porto	0.9	1.6	2.0	3.3	0.7	0.9	0.4	1.6	2.0

iso isomer, rota rotamere

Tier 2a groundwater leaching assessment:

The modelled tier 1 PEC_{GW} for dimethenamid-P and the metabolites M23, M27 and M31 using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 after application of BAS 830 01 H to winter

oilseed rape are presented in Table B.8.3-10 and Table B.8.3-11.

Table B.8.3-10: 80th percentile of annual leachate concentrations of dimethenamid-P and the metabolites M23, M27 and M31 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS - PELMO 5.5.3 – Tier 2a

Scenario	PEC _{GW} [µg L ⁻¹]			
	Dimethenamid-P	M23	M27	M31
Winter oilseed rape, pre-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.045	1.750	3.423
Hamburg	0.002	0.620	4.462	6.712
Kremsmünster	0.001	0.296	2.479	3.834
Okehampton	0.002	0.530	2.535	3.587
Piacenza	0.005	0.670	3.879	5.200
Porto	0.002	0.564	2.363	3.746
Winter oilseed rape, post-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.013	1.188	2.248
Hamburg	0.001	0.285	3.100	4.513
Kremsmünster	0.001	0.152	1.605	2.402
Okehampton	0.002	0.285	1.990	2.686
Piacenza	0.002	0.146	2.237	2.798
Porto	0.002	0.276	1.937	2.560

Table B.8.3-11: 80th percentile of annual leachate concentrations of dimethenamid-P and the metabolites M23, M27 and M31 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS - PEARL 4.4.3 – Tier 2a

Scenario	PEC _{GW} [µg L ⁻¹]			
	Dimethenamid-P	M23	M27	M31
Winter oilseed rape, pre-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.139	2.779	5.556
Hamburg	0.002	0.929	5.515	9.076
Kremsmünster	0.001	0.436	2.890	4.649
Okehampton	0.001	0.643	3.359	5.243
Piacenza	0.002	0.580	3.736	5.073
Porto	0.001	0.703	3.594	5.272
Winter oilseed rape, post-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.050	1.728	3.349
Hamburg	0.001	0.383	3.389	5.181
Kremsmünster	<0.001	0.167	1.801	2.855
Okehampton	0.001	0.312	2.280	3.460
Piacenza	0.001	0.170	1.864	2.838
Porto	0.001	0.296	2.284	3.154

FOCUS-PEARL generally provides more conservative PEC_{GW} concentrations for dimethenamid-P and its soil metabolites than FOCUS-PELMO. In the results below, M31 provides the highest concentrations but remains below the 10 µg/L threshold value for non-relevant metabolites.

The estimated PEC_{GW} values for the metabolites that were only found in the lysimeter leachate are presented exemplary after pre-emergence application of dimethenamid-P to winter oilseed rape are presented in Table B.8.3-12 and Table B.8.3-13.

Table B.8.3-12: Estimated PEC_{GW} after pre-emergence application of dimethenamid-P to winter oilseed rape – based on Tier 2a PEC_{gw} results calculated with FOCUS-PELMO 5.5.3

Winter oilseed rape, pre-emergence, 500 g ha ⁻¹									
Scenario	PEC _{GW} [µg L ⁻¹]								
	M3	M10	M32	M43 (rota 1+2)	M45 (rota 1+2)	M47 (rota 1+2)	M49	M50	M51
Châteaudun	0.04	0.03	0.7	0.5	0.9	0.5	0.4	0.2	0.5
Hamburg	0.11	0.07	1.7	1.3	2.2	1.4	1.1	0.6	1.2
Kremsmünster	0.06	0.04	0.9	0.7	1.2	0.8	0.6	0.3	0.7
Okehampton	0.06	0.04	1.0	0.8	1.3	0.8	0.6	0.3	0.7
Piacenza	0.1	0.06	1.5	1.2	1.9	1.2	1	0.5	1.1
Porto	0.06	0.04	0.9	0.7	1.2	0.7	0.6	0.3	0.6
Scenario	M52	M53 iso 1	M53 iso 2	M54 (rota 1+2)	M55	M59 iso 1	M59 iso 2	M59 iso 3	M62
Châteaudun	0.4	0.7	0.9	1.4	0.3	0.4	0.2	0.7	0.9
Hamburg	1.0	1.8	2.2	3.6	0.7	0.9	0.4	1.8	2.2
Kremsmünster	0.5	1.0	1.2	2.0	0.4	0.5	0.2	1.0	1.2
Okehampton	0.5	1.0	1.2	2.1	0.4	0.5	0.3	1.0	1.2
Piacenza	0.8	1.5	1.9	3.2	0.6	0.8	0.4	1.5	1.9
Porto	0.5	0.9	1.2	1.9	0.4	0.5	0.2	0.9	1.2

iso isomer, rota rotamere

Table B.8.3-13: Estimated PEC_{GW} after pre-emergence application of dimethenamid-P to winter oilseed rape – based on Tier 2a PEC_{gw} results calculated with FOCUS-PEARL 4.4.3

Winter oilseed rape, pre-emergence, 500 g ha ⁻¹									
Scenario	PEC _{GW} [µg L ⁻¹]								
	M3	M10	M32	M43 (rota 1+2)	M45 (rota 1+2)	M47 (rota 1+2)	M49	M50	M51
Châteaudun	0.05	1.0	0.8	1.4	0.9	0.7	0.3	0.8	0.05
Hamburg	0.09	2.1	1.6	2.7	1.7	1.4	0.7	1.5	0.09
Kremsmünster	0.05	1.1	0.9	1.4	0.9	0.7	0.4	0.8	0.05
Okehampton	0.06	1.3	1.0	1.7	1.0	0.8	0.4	0.9	0.06
Piacenza	0.06	1.4	1.1	1.8	1.2	0.9	0.5	1.0	0.06
Porto	0.06	1.3	1.1	1.8	1.1	0.9	0.4	1.0	0.06
Scenario	M52	M53 iso 1	M53 iso 2	M54 (rota 1+2)	M55	M59 iso 1	M59 iso 2	M59 iso 3	M62
Châteaudun	0.6	1.1	1.4	2.3	0.5	0.6	0.3	1.1	1.4
Hamburg	1.2	2.2	2.7	4.5	0.9	1.2	0.5	2.2	2.7
Kremsmünster	0.6	1.1	1.4	2.3	0.5	0.6	0.3	1.1	1.4
Okehampton	0.7	1.3	1.6	2.7	0.6	0.7	0.3	1.3	1.6
Piacenza	0.8	1.5	1.8	3.0	0.6	0.8	0.4	1.5	1.8
Porto	0.8	1.4	1.8	2.9	0.6	0.8	0.4	1.4	1.8

iso isomer, rota rotamere

Tier 3c groundwater leaching assessment:

The maximum annual average concentration of the dimethenamid-P metabolites found in the leachate of the three-year lysimeter study Burgener (1996) They are based on the HPLC peak analysis of

Staudenmaier (2014b) are presented in Table B.8.3-14. The active substance dimethenamid-P remained at concentrations $<0.05 \mu\text{g L}^{-1}$ in the leachate and is thus not presented here. For details on the lysimeter study and the additional analysis of the leachate please refer to Volume 3 CA, B 8.1.4.2 of the active substance. Additionally, adapted leachate concentrations of the metabolites for the reduced application rates for maize, soybeans, sunflowers and sugar beet are presented in Table B.8.3-14.

Table B.8.3-14: Maximum annual average concentrations of the dimethenamid-P metabolites in the leachate of the lysimeter study Burgener (1996) following pre-emergence application of dimethenamid to maize and adjusted concentrations based on the actual application rates for the representative uses

Metabolite	Maximum annual average concentration in leachate of lysimeter study (1440 g dimethenamid/ha) [$\mu\text{g L}^{-1}$]	Adjusted concentrations to
		Winter oilseed rape (500 g as ha^{-1})
M3	0.10	0.03
M10	0.07	0.02
M23	1.0	0.3
M27 (rotamer 1+2)	4.0	1.4
M31	0.10	0.03
M32	1.5	0.5
M43 (rotamer 1+2)	1.2	0.4
M45 (rotamer 1+2)	2.0	0.7
M47 (rotamer 1+2)	1.2	0.4
M49	1.0	0.3
M50	0.5	0.2
M51	1.1	0.4
M52	0.9	0.3
M53 iso 1	1.6	0.6
M53 iso 2	2.0	0.7
M54 (rotamer 1+2)	3.3	1.1
M55	0.7	0.2
M59 iso 1	0.8	0.3
M59 iso 2	0.4	0.1
M59 iso 3	1.6	0.6
M62	2.0	0.7

The maximum concentration for Tier 3 was identified for metabolite M27. Metabolite M31 was found in the lysimeter leachate in concentrations $< 0.1 \mu\text{g L}^{-1}$.

The results of the vulnerability analysis of the lysimeter study performed by Haering (2014) are summarised in Volume 3 CA, B 8.1.4.2 of dimethenamid-P.

Tier 4 groundwater leaching assessment:

20 German monitoring sites and 80 g monitoring samples obtained from the Netherlands were analysed for their representativeness for the EU were analysed for their suitability as monitoring sites for dimethenamid-P and for their representativeness for the EU by Haering & Miles (2014). The study is summarised in Volume 3 CA, B 8.4.1 of dimethenamid-P.

Haering & Miles (2014) show that the German monitoring sites can be regarded as representative for

most of Europe's agricultural areas and that the data are valid for the metabolites of dimethenamid-P in a retro- and prospective way. With respect to the Dutch monitoring wells and the sampling period, a single analysis for the dimethenamid-P metabolites provides a representative snapshot of the situation in an area with shallow groundwater and high levels of maize production at a time when both groundwater recharge and groundwater levels are expected to be around their annual maxima.

As a consequence, groundwater monitoring samples from both, the German and Dutch monitoring sites, can be used to evaluate the concentration in groundwater in a realistic way. Especially the German sites are characterised in depth with respect to their vulnerability in Europe and are thus suitable as Tier 4 PEC_{GW} values.

Conclusion

Acceptability of Tier 1 & 2a groundwater leaching assessment:

Application scenario (Tier 1 & 2a):

The application scenarios chosen by the applicant for the application of BAS 830 01 H to winter oilseed rape are considered acceptable by the RMS.

Substance related input parameters (Tier 1 & 2a):

Regarding the substance related input parameter for dimethenamid-P in tier 1 & 2a modelling, using the combined DT₅₀ values of laboratory data and field degradation studies is considered acceptable by the RMS. The final geometric mean of the DT₅₀ value derived by the RMS is, however, with 11.5 d slightly higher. Besides, the applicant used the median of the K_{foc} values and the Freundlich exponents for groundwater modelling of dimethenamid-P instead of the arithmetic mean. This is justifiable for the K_{foc} values, since a sufficient number of ten values is available and the resulting median is smaller and thus more conservative for the resulting PEC_{GW} values. For the Freundlich exponent, the arithmetic mean of 0.994 should have been used instead. Besides, different formation fractions were obtained by the RMS for the metabolites M23, M27 and M31 resulting in different transformation rates. The remaining input parameters of dimethenamid-P are considered acceptable by the RMS.

Regarding the substance related input parameter of the metabolite M23 in tier 1 & 2a modelling, the evaluation of the laboratory degradation studies by the RMS resulted in a different DT₅₀ endpoint and a different formation fraction from the parent. The K_{foc} value and Freundlich exponent used by the applicant are considered acceptable.

Regarding the substance related input parameter of the metabolite M31 in tier 1 & 2a modelling, the evaluation of the laboratory degradation studies by the RMS resulted in a different DT₅₀ endpoint and a different formation fraction from the parent. Besides, as described in more detail in Volume 3 CA, B.8.1.3 of the active substance under the conclusion of the studies Class (2011a) and Sacchi (2013), the adsorption of M31 to soil is so poor, that an accurate determination of acceptable adsorption parameters was not possible. Since the data show, that at least some adsorption took place in the six investigated soils, the RMS considers a worst case defaults of 1 for the K_{foc} and 0.9 for the Freundlich exponent the most appropriate.

To describe the degradation rate of the metabolite M27 in tier 1 & 2a modelling, the applicant used the geometric mean of the field degradation studies. Since the t-test showed that the laboratory and the field data are from different populations this is in general possible. The applicant combined the DT₅₀ geometric mean of the field studies with formation fractions from the laboratory studies performed with dimethenamid-P. In the special case of dimethenamid-P and M27 this is considered acceptable by the RMS: The t-test showed, that dimethenamid-P degrades at the same rate in laboratory and field studies, thus also the formation of M27 should occur at the same rate and thus at the same ratio both in laboratory and field studies. Only the metabolite M27 degrades faster under field conditions, which should result in smaller and narrower concentration peaks of M27 under field conditions. To decide, whether the combination of formation fraction determined under laboratory conditions and DT₅₀ values of M27 under field conditions really describe the M27 occurrence observed under field conditions is indeed valid, the RMS plotted all M27 residues observed in the field studies performed

with dimethenamid-P (see study summaries Bayer & Marwitz, 2014a & c in Vol. 3 CA, B.8.1.2.6 of the active substance) against the time corrected for temperature and moisture normalisation (see study summary Wiedemann, 2014b in Vol. 3 CA, B.8.1.2.6 of the active substance) together with a modelled M27 peak when using its DT_{50} endpoint of 14.4 d (geometric mean, normalised field data) together with the arithmetic mean of the formation fractions (arithmetic mean, normalised laboratory data) of 0.1062. Parallel all M27 residues observed in the laboratory studies with dimethenamid-P (see study summaries Unsworth, 2014, Staudenmaier, 2009, Wendt, 1997, Koenig, 1996 and Koenig, 1995 in Vol. 3 CA, B.8.1.1 of the active substance) against time together with a modelled M27 peak when using its DT_{50} endpoint of 52.4 d (geometric mean, normalised laboratory data) together with the arithmetic mean of the formation fractions of 0.1062 (arithmetic mean, normalised laboratory data). The results are shown Figure B.8.3-1 and Figure B.8.3-2.

As can be seen from the Figures, using DT_{50} endpoint of 14.3 d (geometric mean, normalised field data) together with the arithmetic mean of the formation fractions (laboratory data) of 0.1062 describes the M27 concentration peak under field conditions as well as the DT_{50} endpoint of 52.4 (geometric mean, normalised laboratory data) of the laboratory studies together with the arithmetic mean of the formation fractions of 0.1062 (laboratory data) describes the M27 concentration peak under laboratory conditions. This is the case even so neither the DT_{50} values nor the formation fractions were actually obtained in the field studies with dimethenamid-P, where the plotted residues were measured, but either in separate field studies with directly applied metabolite or in the laboratory studies with dimethenamid-P. Thus the RMS considers it acceptable to use the DT_{50} endpoint of 14.3 d together with the formation fractions of 0.1062 for groundwater modelling of M27.

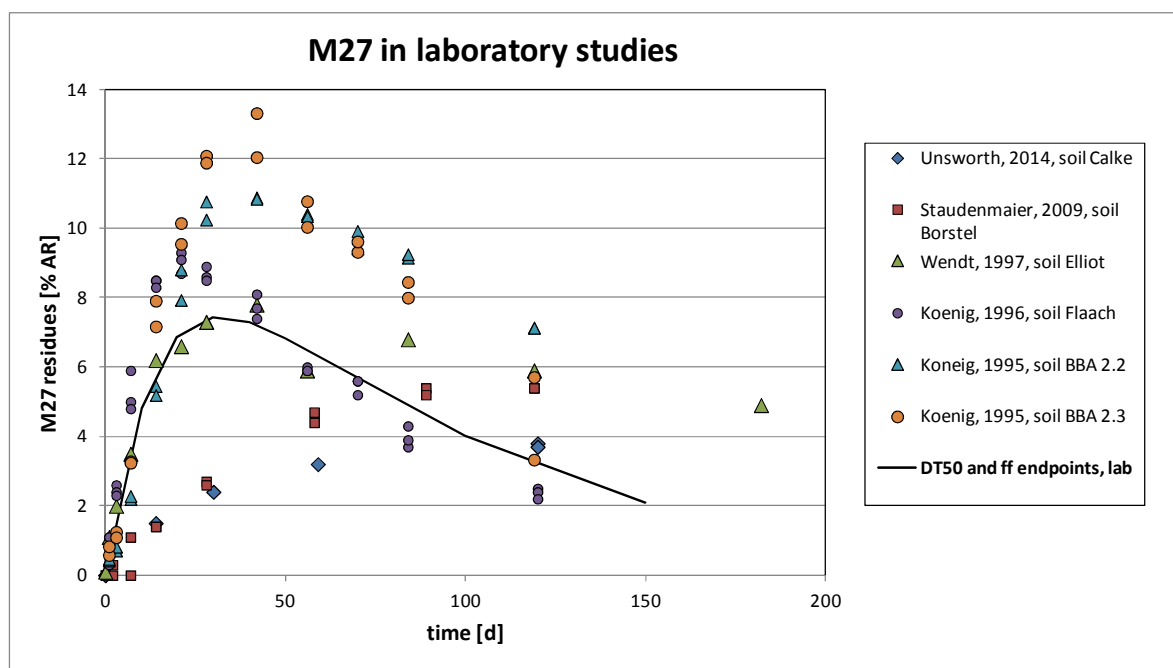


Figure B.8.3-1: Residues of the metabolite M27 observed in aerobic laboratory studies with dimethenamid-P and theoretical concentration peak of M27 when using the DT_{50} geometric mean 52.4 d together with the arithmetic mean of the formation fractions, 0.1062, from the laboratory studies

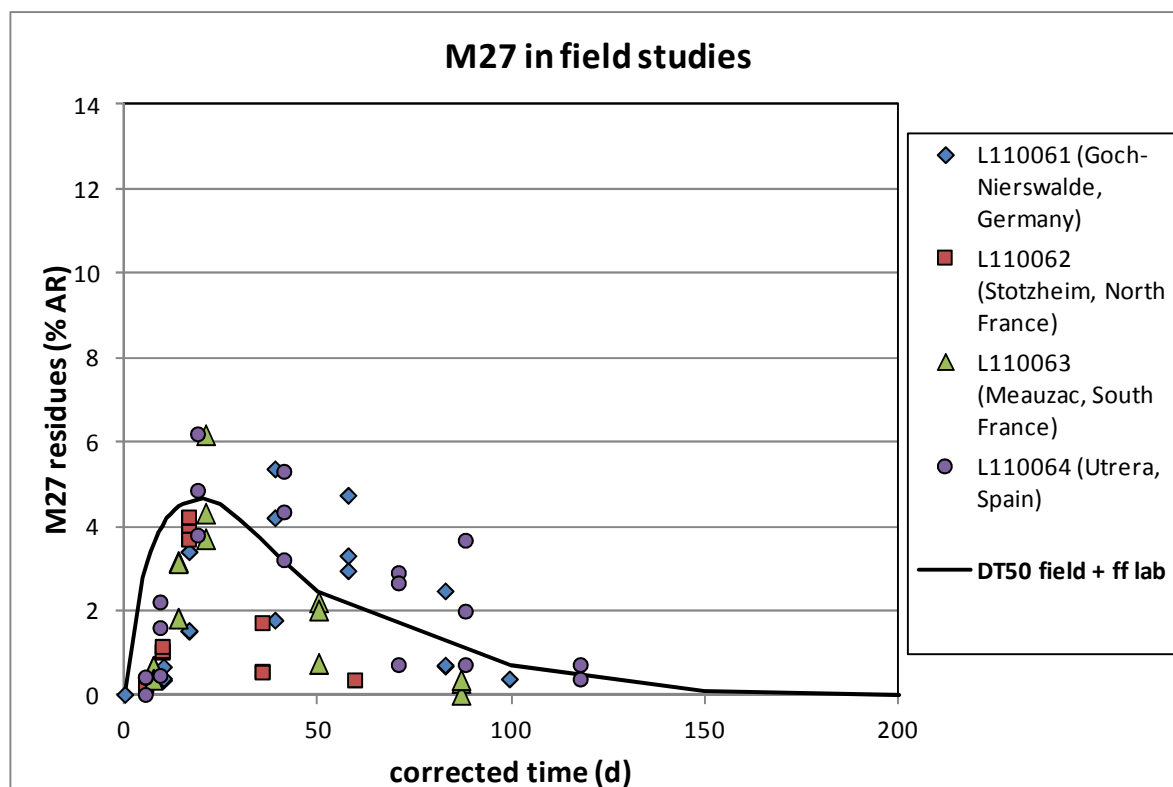


Figure B.8.3-2: Residues of the metabolite M27 observed in field degradation studies with dimethenamid-P and theoretical concentration peak of M27 when using the DT_{50} geometric mean, 14.3 d, from the field studies together with the arithmetic mean of the formation fractions, 0.1062, from the laboratory studies

In the opinion of the RMS, trying to reproduce the complex metabolism scheme of dimethenamid-P including the metabolites M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 that were only found in the lysimeter leachate is beyond the possibilities of the current groundwater models and would result in very high, unrealistic and very uncertain concentrations for all metabolites, since default values would need to be used for a lot of parameters like most of the formation fractions. Thus, the transfer factors are considered a possible option to at least estimate the potential of groundwater leaching for the dimethenamid-P metabolites that were only found in the lysimeter leachate.

However, the method bears some major problems that are listed below. The metabolism scheme of dimethenamid-P proposed by the applicant and shown in Volume 3 CA, B.8 in the study Staudenmaier (2014) and in Volume 1, Level 2.8.1 is very complex and divides into different independent degradation branches. The metabolism scheme was sorted by the RMS according to the main soil metabolites as shown in Table B.8.3-15.

The assumption that the concentration pattern of these dimethenamid-P metabolites at groundwater level will always be the same regardless of metabolism branch and the different soil and climate conditions is of course very simplistic.

Table B.8.3-15: Position of all metabolites in the metabolism scheme of dimethenamid-P in soil

Metabolite only found in lysimeter leachate	Position in metabolism scheme of dimethenamid-P
M3, M62	Directly formed from dimethenamid-P
M10 M31 M32 M51	M31 branch
M23 M43 (rotamer 1+2) M45 (rotamer 1+2) M49 M50	M23 branch
M27 M47 (rotamer 1+2) M52, M53 iso 1 M53 iso 2 M54 (rotamer 1+2) M55 M59 iso 1 M59 iso 2 M59 iso 3	M27 branch

And indeed, the concentration ratios of three main soil metabolites M23, M27 and M31 in the different modelled FOCUS scenarios vary: When comparing the concentration ratios of the metabolites M23 and M27 measured in the lysimeter and modelled with FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 as shown in Table B.8.3-16 for tier 1 pre-emergence application of dimethenamid-P to maize, only in the FOCUS Scenario Okehampton, a similar concentration ratio for M23 and M27 as found in the lysimeter leachate was modelled. For the metabolite M31, the problematic is even more severe, since the metabolite was not found in the lysimeter leachate at all while it was modelled in the highest concentrations of all three metabolites in the FOCUS models.

Table B.8.3-16: Concentration ratios of M23 to M27 measured in the lysimeter leachate and modelled in the groundwater for tier 1 pre-emergence application of dimethenamid-P to maize

M23/M27 concentration ratio			
FOCUS Scenario	Modelled with FOCUS PELMO 5.5.3	Modelled with FOCUS PEARL 4.4.3	Measured in lysimeter
Châteaudun	0.07	0.10	0.25
Hamburg	0.13	0.14	
Kremsmünster	0.15	0.17	
Okehampton	0.23	0.24	
Piacenza	0.15	0.12	
Porto	0.07	0.05	
Sevilla	0.002	0.002	
Thiva	0.02	0.04	

However, several of the dimethenamid-P metabolites were also investigated in two groundwater monitoring studies in Germany and the Netherlands which are described in more detail in Mewis, 2014a & b in Vol. 3 CA, B.8.4 of the active substance. The resulting maximum concentrations are shown in Table B.8.3-17.

Table B.8.3-17: Maximum concentrations of dimethenamid-P metabolites investigated in groundwater monitoring studies

Groundwater monitoring study in Germany	
Metabolites investigated	Max. concentration [$\mu\text{g L}^{-1}$]
M3	<0.025
M10	<0.025
M27	1.680
M23	0.379
M31	<0.025
M32	<0.025
M43	<0.025
M45	0.045
M47	0.161
M54	0.049
Groundwater monitoring study in the Netherlands	
Metabolites investigated	Max. concentration [$\mu\text{g L}^{-1}$]
M3	<0.025
M10	0.033
M27	1.509
M23	0.810
M31	0.042
M32	<0.025
M43	<0.025
M45	0.213
M47	0.459
M54	0.076

The results of the monitoring studies actually confirm the trends observed in the lysimeter leachate but they did not confirm the trend of the FOCUS modelling for the metabolites M23, M27 and M31. M31 was not detected above the LOQ in the German monitoring studies and were found only in very small concentrations in the Netherlands. The ratio of the maximum M23 to M27 concentrations found in the German monitoring studies was with 0.23 almost similar to the concentration ratio in the lysimeter. In the groundwater monitoring studies of the Netherlands, the ratio was with 0.54 even higher than in the lysimeter study and not lower as suggested from the FOCUS modelling.

The main explanation for these differences between modelling and actual measurements could be that also the metabolites M23 and M31 also degrade faster under field conditions than under laboratory conditions as was shown for M27. This implies that the FOCUS modelling results of M27, where a DT_{50} endpoint from field studies was used, are likely the most realistic modelled concentrations of the three metabolites M23, M27 and M31. This supports the use of transfer factors for all lysimeter metabolites based only on M27 leachate concentrations.

However, the RMS also tested a different approach dividing the metabolites in the different degradation branches shown in Table B.8.3-15. After this scheme transfer factors derived from M27 should only be used for the metabolites M47, M52, M53, M54, M55 and M59.

The metabolites M43, M45, M49 and M50 of the M23 degradation branch can be modelled using

transfer factors derived using M23 concentrations in the leachate and in the FOCUS models.

To assess groundwater leaching of the metabolites M3 and M62, direct modelling from dimethenamid-P using worst case default values was performed since their degradation does depend neither on M23 nor on M27 formation.

For M10, M32 and M51, two different options were tested: First the potential concentrations in groundwater were estimated using transfer factors from M31. However, since M31 was not detected in the lysimeter leachate but could have been present in small amounts in the M23 peak (see Staudenmaier, 2014 for more details), it is not clear, which M31 concentrations should be used. Using the assumed $0.1 \mu\text{g L}^{-1}$ leachate concentration for M31 chosen by the applicant would actually be a best case for M10, M32 and M51, however, it led already to very high concentrations for M10, M32 and M51. As a second possible approach, the metabolite M32 directly formed from dimethenamid-P was modelled using worst case default values. Afterwards, transfer factors calculated from M32 were used to estimate of PEC_{GW} values also for M10 and M51.

While this approach of the RMS would work for the metabolites M47, M52, M53, M54, M55 and M59 of the M27 metabolism branch and for the metabolites M43, M45, M49 and M50 of the M23 degradation branch, the resulting concentrations of M3, M10, M32 and M51, M62 were unrealistically high and well above the threshold of $10 \mu\text{g L}^{-1}$ for all metabolites except M3.

Thus, after consideration of all available information and especially fact, that the DT_{50} values of M27 for obtained from field degradation studies and can be thus considered more realistic than the laboratory DT_{50} values of M23 and M31, the RMS believes that estimating the concentrations of all lysimeter metabolites using transfer factors derived from M27 is the best possible approach. Thus the approach of the applicant is accepted by the RMS.

As an additional small issue, it is not clear to the RMS, why the concentrations of M27 in the leachate were corrected for different application rates of dimethenamid-P before deriving transfer factors (see Table B.8.3-7) together with another similar correction of the metabolite concentrations only found in the lysimeter leachate. Since the transfer factors only describe the ratio of M27 concentration in comparison to the other metabolite concentrations, such an adaption to the application rate is not necessary and does not lead to different results. Besides, as already pointed out in the conclusion of the study Staudenmaier (2014b) in Vol. 3 CA, B.8.1.4.2, the adjustment of the metabolite concentrations in the lysimeter leachate to the actual application rate of 864 g/ha (and 720 g/ha) by multiplying all estimated concentrations with a factor of 0.6 (and 0.5) is considered oversimplified by the RMS. While it can be assumed that metabolite concentrations in the leachate will be smaller when reducing the application rates of dimethenamid-P, the experimental set-up is too complex to assume a simple reduction of 0.6 or 0.5. Wherever possible, such oversimplified assumptions should be avoided.

The RMS therefore provided different transfer factors for M27 in their own re-calculations using the original lysimeter concentrations as determined by Staudenmaier (2014b) without correction for the application rate and additionally provided transfer factors for M23.

Finally as described in more detail in Volume 3 CA, B.8.1.4.4 of the active substance, the study Gourlay (2013) was not considered acceptable by the RMS. Thus, using a plant uptake factor of 0.5 for the metabolites as a tier 2a groundwater assessment is not accepted by the RMS.

PEC_{GW} values (Tier 1 & 2a):

All tier 1 PEC_{GW} calculations were repeated by the RMS using the new input parameters for dimethenamid-P, M27, M23 and M31. Afterwards new PEC_{GW} were estimated for the lysimeter metabolites M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62. The calculations are described in more detail below.

Acceptability of Tier 3c groundwater leaching assessment:

The lysimeter study Burgener (1996) and the additional work performed in the studies Fent (2008), Staudenmaier (2009a) with amendment no. 1 Staudenmaier, (2014a), Staudenmaier & Kuhnke, 2014

and Staudenmaier (2014b) are summarised and discussed already in Volume 3 CA, B.8.1.4.2 of dimethenamid-P. The lysimeter study and the additional work performed to elucidate the unknown lysimeter fractions is considered acceptable by the RMS.

The approach to adapt the concentrations found in the leachate of the lysimeter to the application rate of the representative uses is actually suggested in the FOCUS groundwater report (2009, 2014) under 'Post-processing approaches of higher tier experimental leaching data'. Thus, the adaption of the leachate concentrations presented in Table B.8.3-10 is acceptable for maize although the RMS considers such an approach over-simplistic. Since the lysimeter was cropped with maize, the RMS believes, that the correction should also only be performed for maize, which then can be used as worst case for application of BAS 830 01 H to winter oilseed rape.

The vulnerability of the conditions of the lysimeter study compared to the conditions in the whole agricultural area in Europe was performed in the study Haering (2014) which is also summarised and discussed in Volume 3 CA, B.8.1.4.2 of dimethenamid-P.

Only the first part of the study was considered acceptable by the RMS. The results show, that the annual average precipitation at the lysimeter study location over the three years of the lysimeter study (= 1046.5 mm/a) is higher than 98.1 % of the annual average precipitation of the whole agricultural area of Europe (although it was not stated which years of precipitation were used for comparison). The results further indicate that the organic matter content in the top 30 cm of the lysimeter soil (0.0181 kg/kg) is lower than 81.4 % of the agricultural area of Europe. Besides, the Borstel soil exhibits a more coarse soil texture than the majority of the European soils.

Thus the results indicate that the site characteristics of the lysimeter study over the three years study duration represent vulnerable conditions regarding groundwater leaching also for the whole area of Europe. Still it is not clear, if really all vulnerable regions in Europe are covered by the lysimeter study. Thus, the RMS believes that the results of the lysimeter study should not overwrite the results of the groundwater modelling but should be considered as additional information providing important information on the expected metabolite pattern in groundwater under natural conditions.

As discussed already early, the concentrations of M27 measured in the lysimeter and modelled in the FOCUS scenarios agree well while lower concentrations of M23 and M31 were found in the lysimeter leachate than modelled for the FOCUS scenarios. The reason for these differences between modelling and actual measurements could be that also the metabolites M23 and M31 also degrade faster under field conditions than under laboratory conditions as was shown for M27 and that the concentrations of these metabolites in the lysimeter are therefore more realistic for M23 and M31 than the concentrations modelled in the FOCUS scenarios.

Acceptability of Tier 4 groundwater leaching assessment:

The vulnerability assessment of the German groundwater monitoring sites compared to the conditions in the whole agricultural area in Europe was performed in the study Haering & Miles (2014) which is also summarised and discussed in Volume 3 CA, B.8.4.1 of dimethenamid-P. The groundwater sampling of the Dutch monitoring wells is described in the study Mewis, 2014b which is also described in Volume 3 CA, B.8.4.1.

From all 100 sampled groundwater wells, only 16 German wells fulfill all 6 quality criteria for groundwater monitoring listed in the FOCUS groundwater report (2009, 2014), which is not considered a sufficient number to use groundwater monitoring for higher tier groundwater assessment (at least 20 acceptable wells specifically targeted to the pesticide of interest are required according to page 184, FOCUS (2011)). However, also the results of the monitoring studies can be considered as additional information providing important information on the expected metabolite pattern in groundwater under natural conditions. The results of the monitoring studies actually confirm the trends observed in the lysimeter leachate although lower concentrations were found for all investigated metabolites. Groundwater concentrations found in both the German and the Dutch monitoring studies were highest for M27, followed by M23. M31 in the other hand was not detected above the LOQ in the German monitoring studies and were found only in very small concentrations in the Netherlands.

Besides, the spatial modelling performed by Haering & Miles, 2014 to assess the vulnerability of the

groundwater sites with regard to the whole European agricultural area was not considered acceptable by the RMS.

Thus, the groundwater monitoring performed by the applicant is not considered acceptable by the RMS to be used for higher tier groundwater assessment.

Both the results of the lysimeter and of the groundwater monitoring of the dimethenamid-P metabolites indicate that under natural environmental conditions throughout Europe, M27 will be expected to be found in the highest concentrations in groundwater with lower concentrations of M23. Concentrations of M31 in groundwater on the other hand will likely be negligible.

Besides, the RMS believes that the higher tier leaching based on lysimeter or groundwater monitoring data should be discussed among the European experts, since the use of these approaches for EU approval are uncommon and there is not much experience on the evaluation of such studies.

PEC_{GW} of dimethenamid-P and its metabolites (Re-calculations of the RMS)

Material and Methods

Tier 1 groundwater leaching assessment:

The same application scenarios for groundwater assessment of dimethenamid-P as already given in Table B.8.3-1 were used.

An overview over the substance specific input parameter of dimethenamid-P used for tier 1 groundwater modelling is given in Table B.8.3-18. An overview over the substance specific input parameter of the metabolites M23, M27 and M31 used for tier 1 groundwater modelling is given in Table B.8.3-19, Table B.8.3-20 and Table B.8.3-21.

Table B.8.3-18: Summary of input parameters of dimethenamid-P used for tier 1 groundwater modelling with FOCUS-PEARL and FOCUS-PELMO (re-calculations of the RMS)

Input parameter	Unit	Dimethenamid-P	Remarks
Physico-chemical parameters			
Molecular weight	[g mol ⁻¹]	275.8	-
Water solubility	[mg L ⁻¹]	1449 (25 °C)	-
Molar enthalpy of dissolution (PEARL)	[kJ mol ⁻¹]	27	default
Saturated vapor pressure	[Pa]	2.51 x 10 ⁻³ (25 °C)	-
Molar enthalpy of vaporisation (PEARL)	[kJ mol ⁻¹]	-	95
Diffusion coefficient in water (PEARL)	[m ² d ⁻¹]	4.3 x 10 ⁻⁵ (20 °C)	default
Diffusion coefficient in air (PEARL)	[m ² d ⁻¹]	0.43 (20 °C)	default
Diffusion coefficient in air (PELMO)	[cm ² s ⁻¹]	0.05 (20 °C)	default
Degradation parameters			
Half-life at reference conditions (PEARL)	[d]	11.3	Geometric mean, n=12, normalised combined laboratory and field data
Formation fraction from dimethenamid-P to CO ₂	[-]	0.6807	
Transformation rate (k) to CO ₂ (PELMO)	[d ⁻¹]	0.041028	-
Molar activation energy (PEARL)	[kJ mol ⁻¹]	65.4	default
Q ₁₀ (PELMO)	[-]	2.58	default
Exponent of moisture correction function	[-]	0.7	default
Sorption parameters			
K _{f,oc} value (PELMO)	[mL g ⁻¹]	167.4	Median, n=10
K _{f,om} value (PEARL)*	[mL g ⁻¹]	97.1	Median, n=10
Freundlich exponent 1/n	[-]	0.994	Arithmetic mean, n=10
Method of subroutine description	[-]	pH-independent	
Crop related parameters			
TSCF (crop uptake)	[-]	-	0.5

* $K_{f,om} = K_{f,oc} / 1.724$

Table B.8.3-19: Summary of input parameters of the metabolite M23 used for groundwater modelling with FOCUS-PEARL and FOCUS-PELMO (re-calculations of the RMS)

Input parameter	Unit	M23	Remarks
Physico-chemical parameters			
Molecular weight	[g mol ⁻¹]	271	
Water solubility	[mg L ⁻¹]	1000 (20 °C) ^A	default
Saturated vapor pressure	[Pa]	10 ⁻¹⁰ (20 °C) ^A	default
Degradation parameters			
Half-life at reference conditions (PEARL)	[d]	28.2	Geometric mean, lab data (n= 5)
Formation fraction from dimethenamid-P to M23	[-]	0.138	Arithmetic mean, lab data (n = 5)
Sorption parameters			
K _{f,oc} value (PELMO)	[mL g ⁻¹]	11.9	Arithmetic mean (n=5)
K _{f,om} value* (PEARL)	[mL g ⁻¹]	6.9	Arithmetic mean (n=5)
Freundlich exponent 1/n	[-]	0.722 ^D	Arithmetic mean (n=5)
Crop related parameters			
TSCF (crop uptake)	[-]	0	Default

* $K_{f,om} = K_{f,oc} / 1.724$

Table B.8.3-20: Summary of input parameters of the metabolite M31 used for groundwater modelling with FOCUS-PEARL and FOCUS-PELMO (re-calculations of the RMS)

Input parameter	Unit	M31	Remarks
Physico-chemical parameters			
Molecular weight	[g mol ⁻¹]	347	
Water solubility	[mg L ⁻¹]	1000 (20 °C) ^A	default
Saturated vapor pressure	[Pa]	10 ⁻¹⁰ (20 °C) ^A	default
Degradation parameters			
Half-life at reference conditions (PEARL)	[d]	51.9	Geometric mean, lab data (n= 6)
Formation fraction from dimethenamid-P to M31	[-]	0.0751	Arithmetic mean, lab data (n = 6)
Sorption parameters			
K _{f,oc} value (PELMO)	[mL g ⁻¹]	1	default
K _{f,om} value* (PEARL)	[mL g ⁻¹]	0.58	default
Freundlich exponent 1/n	[-]	0.9	default
Crop related parameters			
TSCF (crop uptake)	[-]	0	default

* $K_{f,om} = K_{f,oc} / 1.724$

Table B.8.3-21: Summary of input parameters of the metabolite M27 used for groundwater modelling with FOCUS-PEARL and FOCUS-PELMO (re-calculations of the RMS)

Input parameter	Unit	M27	Remarks
Physico-chemical parameters			
Molecular weight	[g mol ⁻¹]	321.4	
Water solubility	[mg L ⁻¹]	1000 (20 °C) ^A	default
Saturated vapor pressure	[Pa]	10 ⁻¹⁰ (20 °C) ^A	default
Degradation parameters			
Half-life at reference conditions (PEARL)	[d]	14.3	Geometric mean, field data (n= 4)
Formation fraction from dimethenamid-P to M27	[-]	0.1062	Arithmetic mean, lab data (n = 6)
Formation fraction from M31 to M27	[-]	1	default
Sorption parameters			
K _{f,oc} value (PELMO)	[mL g ⁻¹]	7.0	Arithmetic mean (n=5)
K _{f,om} value* (PEARL)	[mL g ⁻¹]	4.06	Arithmetic mean (n=5)
Freundlich exponent 1/n	[-]	0.979	Arithmetic mean (n=5)
Crop related parameters			
TSCF (crop uptake)	[-]	0	Default

* K_{f,om} = K_{f,oc} / 1.724

To assess the groundwater leaching potential of the metabolites M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 that were only found in the lysimeter leachate, transfer factors were derived from the leachate concentrations in the lysimeter study by setting M27 as reference metabolite. The transfer factors were derived according to Equation B.8.3.1-2.

$$Transferfactor = \frac{M27_{calc}}{M27_{meas}}$$

$$MX_{calc} = MX_{meas} \cdot Transferfactor$$

M _{ref, calc}	=	Concentration of reference metabolite M27 measured in lysimeter leachate
M _{ref, meas}	=	Tier 1 and Tier 2a PEC _{GW} of reference metabolite M27 calculated for each FOCUS PEARL and FOCUS PELMO scenario
MX _{calc}	=	Concentration of metabolite in question measured in lysimeter leachate
MX _{meas}	=	Tier 1 and Tier 2a PEC _{GW} of metabolite in question only found in lysimeter leachate for the respective FOCUS PEARL and FOCUS PELMO scenario

Equation B.8.3.1-2: Calculation of PEC_{GW} for the dimethenamid-P metabolites only found in lysimeter leachate for all relevant FOCUS PEARL and FOCUS PELMO scenarios

Results and Discussion

Tier 1 groundwater leaching assessment:

The modelled PEC_{GW} for dimethenamid-P and the metabolites M23, M27 and M31 using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 after application of BAS 830 01 H to winter oilseed rape are presented in Table B.8.3-22.

Table B.8.3-22: 80th percentile of annual leachate concentrations of dimethenamid-P and the metabolites M23, M27 and M31 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS- PELMO 5.5.3 (re-calculations of the RMS)

Scenario	PEC _{GW} [µg L ⁻¹]			
	Dimethenamid-P	M23	M27	M31
Winter oilseed rape, pre-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.249	3.272	9.327
Hamburg	0.003	1.608	6.347	12.285
Kremsmünster	0.002	0.788	3.255	7.561
Okehampton	0.003	1.287	3.277	7.133
Piacenza	0.008	1.285	4.180	8.250
Porto	0.005	1.285	3.193	7.428
Winter oilseed rape, post-emergence, 500 g ha⁻¹				
Châteaudun	<0.001	0.087	1.967	5.488
Hamburg	0.002	0.738	3.937	7.548
Kremsmünster	0.001	0.344	2.147	4.741
Okehampton	0.003	0.664	2.272	4.593
Piacenza	0.003	0.384	2.333	4.342
Porto	0.005	0.684	2.304	4.632

The Transfer factors based on M27 for each crop scenario (application rate adapted) and FOCUS scenario (ratio of calculated to measured M27 in the lysimeter leachate) can be found in Table B.8.3-23.

Table B.8.3-23: Transfer factors for M27 derived from ratio of M27_{calc}*/ M27_{meas} (re-calculations of the RMS)**

Scenario	Winter oilseed rape, pre-emergence	Winter oilseed rape, post-emergence
	Transfer factors calculated for FOCUS-PELMO 5.5.3	
Châteaudun	0.8	0.5
Hamburg	1.6	1.0
Kremsmünster	0.8	0.5
Okehampton	0.8	0.6
Piacenza	1.0	0.6
Porto	0.8	0.6

* calculated according to FOCUS using FOCUS-PELMO 5.5.3 (re-calculation of the RMS)

** measured in lysimeter study (Table B.8.3-14)

The estimated PEC_{GW} values for the metabolites that were only found in the lysimeter leachate after pre & post -emergence application of dimethenamid-P to winter oilseed rape are presented in Table B.8.3-24 and Table B.8.3-25.

Table B.8.3-24: Estimated PEC_{GW} after pre-emergence application of dimethenamid-P to winter oilseed rape– based PEC_{GW} results calculated with FOCUS-PELMO 5.5.3 (re-calculations of the RMS)

Winter oilseed rape, pre-emergence, 500 g ha ⁻¹									
Scenario	PEC _{GW} [µg L ⁻¹]								
	M3	M10	M32	M43 (rota 1+2)	M45 (rota 1+2)	M47 (rota 1+2)	M49	M50	M51
Châteaudun	0.08	0.06	1.2	1.0	1.6	1.0	0.8	0.4	0.9
Hamburg	0.16	0.11	2.4	1.9	3.2	1.9	1.6	0.8	1.7
Kremsmünster	0.08	0.06	1.2	1.0	1.6	1.0	0.8	0.4	0.9
Okehampton	0.08	0.06	1.2	1.0	1.6	1.0	0.8	0.4	0.9
Piacenza	0.10	0.07	1.6	1.2	2.1	1.2	1.0	0.5	1.1
Porto	0.08	0.06	1.2	1.0	1.6	1.0	0.8	0.4	0.9
Scenario	M52	M53 iso 1	M53 iso 2	M54 (rota 1+2)	M55	M59 iso 1	M59 iso 2	M59 iso 3	M62
Châteaudun	0.7	1.3	1.6	2.7	0.6	0.7	0.3	1.3	1.6
Hamburg	1.4	2.5	3.2	5.2	1.1	1.3	0.6	2.5	3.2
Kremsmünster	0.7	1.3	1.6	2.7	0.6	0.7	0.3	1.3	1.6
Okehampton	0.7	1.3	1.6	2.7	0.6	0.7	0.3	1.3	1.6
Piacenza	0.9	1.7	2.1	3.4	0.7	0.8	0.4	1.7	2.1
Porto	0.7	1.3	1.6	2.6	0.6	0.6	0.3	1.3	1.6

iso isomer, rota rotamere

Table B.8.3-25: Estimated PEC_{GW} after post-emergence application of dimethenamid-P to winter oilseed rape– based PEC_{GW} results calculated with FOCUS-PELMO 5.5.3 (re-calculations of the RMS)

Winter oilseed rape, post-emergence, 500 g ha ⁻¹									
Scenario	PEC _{GW} [µg L ⁻¹]								
	M3	M10	M32	M43 (rota 1+2)	M45 (rota 1+2)	M47 (rota 1+2)	M49	M50	M51
Châteaudun	0.05	0.03	0.7	0.6	1.0	0.6	0.5	0.2	0.5
Hamburg	0.10	0.07	1.5	1.2	2.0	1.2	1.0	0.5	1.1
Kremsmünster	0.05	0.04	0.8	0.6	1.1	0.6	0.5	0.3	0.6
Okehampton	0.06	0.04	0.9	0.7	1.1	0.7	0.6	0.3	0.6
Piacenza	0.06	0.04	0.9	0.7	1.2	0.7	0.6	0.3	0.6
Porto	0.06	0.04	0.9	0.7	1.2	0.7	0.6	0.3	0.6
Scenario	M52	M53 iso 1	M53 iso 2	M54 (rota 1+2)	M55	M59 iso 1	M59 iso 2	M59 iso 3	M62
Châteaudun	0.4	0.8	1.0	1.6	0.3	0.4	0.2	0.8	1.0
Hamburg	0.9	1.6	2.0	3.2	0.7	0.8	0.4	1.6	2.0
Kremsmünster	0.5	0.9	1.1	1.8	0.4	0.4	0.2	0.9	1.1
Okehampton	0.5	0.9	1.1	1.9	0.4	0.5	0.2	0.9	1.1
Piacenza	0.5	0.9	1.2	1.9	0.4	0.5	0.2	0.9	1.2
Porto	0.5	0.9	1.2	1.9	0.4	0.5	0.2	0.9	1.2

iso isomer, rota rotamere

Conclusion

The re-calculated PEC_{GW} values of dimethenamid-P and its metabolites M23, M27 and M31 are considered acceptable to be used for groundwater risk assessment of dimethenamid-P in BAS 830 01 H.

The active substance dimethenamid-P is not expected to exceed groundwater concentrations $> 0.1 \mu\text{g L}^{-1}$ in any of the modelled crop or FOCUS scenarios. The metabolites M23, M27 and M31 were mostly modelled in groundwater concentrations $> 0.1 \mu\text{g L}^{-1}$. The metabolite M31 also exceeded the $10 \mu\text{g L}^{-1}$ threshold in the FOCUS scenario Hamburg for pre-emergence application of dimethenamid-P to winter oilseed rape. Maximum concentrations of M23, M27 and M31 for all representative uses of BAS 830 01 H are summarised in Table B.8.3-26.

Table B.8.3-26: Maxima of the 80th percentile annual leachate concentrations of the metabolites M23, M27 and M31 calculated with FOCUS - PELMO 5.5.3 for all representative uses of BAS 830 01 H (re-calculations of the RMS)

Metabolite	Maximum concentration [$\mu\text{g L}^{-1}$]	FOCUS scenario	Crop and application scenario
M23	1.6	Hamburg	Pre-emergence application to winter oilseed rape
M27	6.4		
M31	12.3		

The re-estimated PEC_{GW} values of the lysimeter metabolites M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 are also considered acceptable to be used for groundwater risk assessment.

The metabolites M3 and M10 were mostly estimated in groundwater concentrations $\leq 0.1 \mu\text{g L}^{-1}$ and exceed the $0.1 \mu\text{g L}^{-1}$ only for some crops and some FOCUS scenarios.

The remaining metabolites M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 were mostly estimated in groundwater concentrations $> 0.1 \mu\text{g L}^{-1}$.

Maximum concentrations of M3, M10, M32, M43, M45, M47, M49, M50, M51, M52, M53, M54, M55, M59 and M62 of all representative uses of BAS 830 01 H are summarised in Table B.8.3-27.

Table B.8.3-27: Maxima of the 80th percentile annual leachate concentrations of the metabolites only found in the lysimeter leachate for all representative uses of BAS 830 01 H (re-calculations of the RMS)

Metabolite	Maximum concentrations [µg L ⁻¹]	FOCUS scenario	Crop and application scenario
M3	0.2	Hamburg	Pre-emergence application to winter oilseed rape
M10	0.1		
M32	2.4		
M43	1.9		
M45	3.2		
M47	1.9		
M49	1.6		
M50	0.8		
M51	1.7		
M52	1.4		
M53 (iso 1)	2.5		
M53 (iso 2)	3.2		
M54	5.2		
M55	1.1		
M59 (iso 1)	1.3		
M59 (iso 2)	0.6		
M59 (iso 3)	2.5		
M62	3.2		

B.8.3.2 Qinmerac and its metabolites:

No study on PEC_{GW} values of quinmerac and its major soil metabolites BH 518-2 (29.1 % maximum formation) and BH 518-5 (27.2 % max. maximum formation) in the representative formulation BAS 830 01 H was submitted, but additional tier 1 PEC_{GW} values of these substances were provided in the dossier of the applicant.

However, since this document concerns the EU approval of the active substance dimethenamid-P and not of quinmerac, which was already approved on 01/05/2011, we believe that the PEC_{GW} values presented here for quinmerac and its metabolites BH 518-2 and BH 518-5 should be the same as the values provided in the List of Endpoints (LoEP) of quinmerac (drafted in April 2007, last updated in November 2009) in order to not repeat the approval process for quinmerac.

Material and Methods

PEC_{GW} calculations of quinmerac and its metabolites for EU approval were performed for the application scenario provided in Table B.8.3-28.

The groundwater assessment for EU approval of quinmerac was performed using the FOCUS model versions FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3.

Table B.8.3-28: Application scenario of quinmerac applied to winter oilseed rape considered for the PEC_{GW} calculations (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

Crop	Winter oilseed rape
Growth stage at first application [BBCH]	BBCH 0 (pre-emergence)
Application rate [g as ha⁻¹]	250
No. of applications [-]	1
Interception [%]	0
Total yearly soil load [g as ha⁻¹]	1

The application dates were set to 6 days before crop emergence

This application scenario is also considered sufficient to cover the application of 1.5 L BAS 830 01 H containing 250 g/ha quinmerac to winter oilseed rape (pre- and post emergence application).

The substance related input parameter used for PEC_{GW} calculations of quinmerac and its metabolites can be found in the LoEP (Nov 2009).

Results and Discussion

The resulting PEC_{GW} values of quinmerac and its metabolites BH 518-2 and BH 518-5 after modelling with FOCUS PELMO 3.3.2 taken from the LoEP (Nov 2009) of quinmerac are presented in Table B.8.3-29. The PEC_{GW} values derived with FOCUS PEARL 3.3.3 and presented in Table B.8.3-30 were not listed in the LoEP, thus they were extracted from the additional report to the RAR, Vol 3. B.8 (June 2009) of quinmerac.

Table B.8.3-29: 80th percentile of annual leachate concentrations of quinmerac and the metabolites BH 518-2 and BH518-5 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS - PELMO 3.3.2 (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

Scenario	PEC _{GW} [µg L ⁻¹]		
	Quinmerac	BH 518-2	BH 518-5
Winter oilseed rape, pre-emergence, 250 g ha ⁻¹			
Châteaudun	<0.001	0.265	2.675
Hamburg	0.001	0.970	2.580
Kremsmünster	<0.001	0.518	2.083
Okehampton	0.001	0.773	1.854
Piacenza	0.200	2.147	2.935
Porto	<0.001	0.032	0.587

Table B.8.3-30: 80th percentile of annual leachate concentrations of quinmerac and the metabolites BH 518-2 and BH518-5 after application of BAS 830 01 H to winter oilseed rape calculated with FOCUS - PEARL 3.3.3

Scenario	PEC _{GW} [µg L ⁻¹]		
	Quinmerac	BH 518-2	BH 518-5
Winter oilseed rape, pre-emergence, 250 g ha ⁻¹			
Châteaudun	<0.001	0.563	3.215
Hamburg	<0.001	1.257	2.683
Kremsmünster	0.008	0.728	2.204
Okehampton	<0.001	0.919	2.010
Piacenza	0.211	2.143	2.629
Porto	<0.001	0.055	0.617

Conclusion

The application window chosen for EU approval of quinmerac, also covers the application of the representative formulation BAS 830 01 H.

The PEC_{GW} values of quinmerac and its metabolites BH 518-2 and BH 518-5 derived for EU approval of quinmerac are considered acceptable by the RMS to be used for risk assessment also for BAS 830 01 H.

B.8.4 Fate and behaviour in water and sediment

B.8.4.1 Aerobic mineralisation in surface water

No studies were performed with the formulation BAS 830 01 H. For studies performed with the active substance dimethenamid-P please refer to Volume 3 CA, B.8 of dimethenamid-P.

B.8.4.2 Water/sediment study

No studies were performed with the formulation BAS 830 01 H. For studies performed with the active substance dimethenamid-P please refer to Volume 3 CA, B.8 of dimethenamid-P.

B.8.4.3 Irradiated water/sediment study

No studies were performed with the formulation BAS 830 01 H. For studies performed with the active substance dimethenamid-P please refer to Volume 3 CA, B.8 of dimethenamid-P.

B.8.5 Predicted environmental concentrations in surface water and sediment (PEC_{SW} , PEC_{SD})

B.8.5.1 Dimethenamid-P and its metabolites:

KCP 9.2.5/ 1 – Maleri, 2014a

Author:	Maleri, M.
Title:	Predicted environmental concentrations in soil, groundwater, surface water and sediment of dimethenamid-P and its metabolites after application of BAS 656 12 H and 830 01 H
Date:	28.02.2014
Doc ID:	BASF DocID 2014/1000682
Guidelines:	FOCUS groundwater (2009): SANCO/13144/2010 v1.0, Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2012) version 2.1, SANCO/4802/2001 rev. 2 (FOCUS surface water scenarios) May 2003, FOCUS Surface Water (2012) Generic guidance for FOCUS surface water scenarios v 1.1, FOCUS (2007): Landscape And Mitigation Factors Volume
GLP:	No
Validity:	Partly acceptable

Material and Methods

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) were calculated for dimethenamid-P, active substance in the formulated product BAS 830 01 H, its soil metabolites M656H023 (= M23 in this study), M656H027 (= M27 in this study) and M656PH031 (= M31 in this study) and the metabolite M656H003 (= M3 in this study) formed in the water/sediment studies with dimethenamid-P, after one pre- and/or post- emergence spray application of

dimethenamid-P to oilseed rape. Global maximum, actual and time-weighted average environmental concentrations in surface water ($PEC_{SW,max}$, $PEC_{SW,act}$, $PEC_{SW,tna}$) as well as maximum concentrations in sediment ($PEC_{SED,max}$) were calculated for dimethenamid-P. For the metabolites M23, M27, M31 and M3, only maximum concentrations in surface water and sediment were calculated.

The calculations were carried out according to the recommendations of the FOCUS working group on surface water scenarios (FOCUS, 2001) considering the entry pathways spray drift (M23, M27 and M3), drainage and runoff (M23, M27 and M31).

At Step 1 and Step 2, the model STEPS1-2 in FOCUS, version 2.1, is used for exposure calculation.

At Step 3, calculations are performed with the software tool SWASH version 3.1. Within SWASH, the model versions FOCUS-PRZM 3.1.1 and FOCUS-MACRO 4.4.2 together with FOCUS-TOXSWA 3.3.1 were used.

The application scenarios for step 1 and step 2 modelling are shown in Table B.8.5-1.

Table B.8.5-1: Selected application scenarios for FOCUS Step 1 and 2 simulations

Crop	Winter oilseed rape	
Number of applications	1	1
Application rate	500	500
Region [#]	North and South Europe	North and South Europe
Growth stage	00-09	10-18
Crop interception	No interception	Minimal crop cover
Application period [#]	Jun-Sep and Oct-Feb	Jun-Sep and Oct-Feb

[#] only relevant for Step 2

The application scenario for Step 3 modelling is presented in Table B.8.5-2.

Table B.8.5-2: Selected application scenario for FOCUS Step 3 simulations

FOCUS _{sw} crop	Relevant FOCUS _{sw} scenarios	Application type
Winter oilseed rape	D2, D3, D4, D5, R1, R3	Ground spray

The appropriate start dates for the application window were selected relative to the emergence dates of the crops as specified by FOCUS [FOCUS (2001)]. For the pre-emergence applications, the beginning of the 31-days application interval required by SWASH was set to 30 days before the scenario specific emergence date. Thus, the last possible day for the pre-emergence application was the day of emergence. The beginning of the application window for the post-emergence scenarios was set to the first day after emergence. The detailed application timing used for the calculations is shown in Table B.8.5-3.

Table B.8.5-3: Application timing for dimethenamid-P in the relevant scenario (Step 3 and Step 4)

Scenario	Winter oilseed rape, 500 g ha ⁻¹			
	Pre-emergence application		Post-emergence application	
	Application window	Application date chosen by Swash	Application window	Application date chosen by Swash
D 2 - Brimstone	16 th Aug – 15 th Sep	3 rd Sep	16 th Sep – 16 th Oct	9 th Oct
D 3 – Vreedepeel	3 rd Aug – 2 nd Sep	2 nd Aug	3 rd Sep – 3 rd Oct	26 th Sep
D 4 – Skousbo	4 th Aug – 3 rd Sep	27 th Aug	4 th Sep – 4 th Oct	10 th Sep
D 5 – La Jailliere	21 st Aug – 20 th Sep	27 th Aug	21 st Sep – 21 st Oct	21 st Sep
R 1 – Weiherbach	5 th Aug – 4 th Sep	20 th Aug	5 th Sep – 5 th Oct	17 th Sep
R 3 – Bologna	5 th Sep – 5 th Oct	23 rd Sep	6 th Oct – 5 th Nov	27 th Oct

As Step 4 scenarios, the mitigation methods 5 m non-sprayed buffer zone (drift reduction), 10 m non-sprayed and vegetated buffer zone (drift + runoff reduction), and 20 m non-sprayed and vegetated buffer zone (drift + runoff) buffer zone were selected. The reduction factors for runoff and erosion applying of 10 m and 20 m non-sprayed and vegetated buffer zones were chosen according to Table B.8.5-4 following FOCUS (2007).

Table B.8.5-4: Reduction values applying of 10 m and 20 m non-sprayed and vegetated buffer zones for the SWAN calculations (Step 4)

	10 m distance	20 m distance
Reduction in volume of runoff water	60 %	80 %
Reduction in mass of pesticide transported in aqueous phase	60 %	80 %
Reduction in mass of eroded sediment	85 %	95 %
Reduction in mass of pesticide transported in sediment phase	85 %	95 %

Since dimethenamid-P is a semi-volatile substance, deposition on the water surface after volatilisation from the soil has to be considered. This was done in the Step 4 calculations using the deposition rates after 0 to 24 hours estimated by Winkler and Koch (2005) for the Excel Programme EVA 2.1 for different buffer distances. The estimated deposition rates calculated with EVA 2.1 are presented in Table B.8.5-5.

For the edge-of-field calculations, the deposition values for 1 m distance were applied. Deposition values differ between pre- and post-emergence application since volatilisation from plant surfaces is higher than from the soil surface.

Table B.8.5-5: Deposition rates due to volatilisation after different times [mg m⁻² h⁻¹] calculated with EVA 2.1 and used in STEP 4

Time [h]	1 m distance	5 m distance	10 m distance	20 m distance
1 x 500 g ha⁻¹, pre-emergence				
0-4	0.0033	0.0027	0.0020	0.0012
4-12	0.0017	0.0013	0.0010	0.0006
12-24	0.0008	0.0007	0.0005	0.0003
1 x 500 g ha⁻¹, post-emergence				
0-4	0.0060	0.0048	0.0037	0.0021
4-12	0.0030	0.0024	0.0018	0.0011
12-24	0.0015	0.0012	0.0009	0.0005

An overview over the substance specific input parameter of dimethenamid-P used for Step 1, 2, 3 and 4 calculations is given in Table B.8.5-6. An overview over the substance specific input parameter of the metabolites M656H003, M656H023, M656H027 and M656PH031 and the metabolite used for Step 1 and 2 calculations is given in Table B.8.5-7, Table B.8.5-8, Table B.8.5-9 and Table B.8.5-10.

Table B.8.5-6: Summary of FOCUS Step 1 - 4 input parameters for dimethenamid-P

Parameter	Value	Remarks
Entry routes into surface water	Spray drift Runoff Drainage	--
Molecular weight [g mol ⁻¹]	275.8	Phys.-chem. properties
Water solubility (at 25 °C) [mg L ⁻¹]	1449	Phys.-chem. properties
Vapour pressure (at 25 °C) [Pa]	2.51 x 10 ⁻³	Phys.-chem. properties
Degradation in soil		
DT ₅₀ (soil) [d]	11.3	Geometric mean of normalised (pF 2, 20 °C) laboratory and field DT ₅₀ (n = 12)
Temperature correction function		
Reference temperature [°C]	20	FOCUS recommendation
MACRO: gamma exponent [K-1]	0.095	EFSA opinion [EFSA (2007)]
PRZM: Q ₁₀ [-]	2.58	EFSA opinion [EFSA (2007)]
Moisture correction function		
Reference moisture [-]	pF 2	FOCUS recommendation
PRZM / MACRO: moisture exponent [-]	0.7	
Sorption to soil		
K _{f,oc} [L kg ⁻¹]	167.4	Median (n = 10)
1/n [-]	0.985	Median (n = 10)
Degradation in aquatic systems		
DegT ₅₀ water [d] (Step 1 - 4)	26.9	Geomean, whole system (n = 3)
DT ₅₀ sediment [d] (Step 1 - 4)	1000	Default value [FOCUS (2006)]
DegT ₅₀ total system [d] (Step 1 - 2)	26.9	Geomean, whole system (n = 3)
DT ₅₀ crop [d] (Step 3 – 4)	Tier 1: 10 Tier 2: 1*	FOCUS recommendation / FRIEDEMANN, TERESIAK (2014 a and b)
Temperature correction function		
Reference temperature [°C]	20	FOCUS recommendation
TOXSWA: activation energy [J mol ⁻¹]	65400	EFSA opinion [EFSA (2007)]
Management related parameters		
Crop uptake factor [-]	0.5	FOCUS recommendation
Wash off coefficient		
PRZM: [cm ⁻¹]	0.5	FOCUS recommendation:
MACRO: [mm ⁻¹]	0.05	

* Foliar DT₅₀ value of 1 selected in Tier 2 based on the studies Friedemann & Teresiak (2014 a and b)

Table B.8.5-7: Summary of FOCUS Step 1 - 2 input parameters for M656H003

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent	--
Molecular weight [g mol ⁻¹]	241.4	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1000	Default value
Degradation in soil		
DT ₅₀ soil [d]	1000	Default value
Max. observed occurrence in soil [%]	0*	Metabolite is not formed in soil
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	10 / 10000	Default values (worst cases for water / sediment)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	14.3	9.1 % TAR in water phase and 5.2 % TAR in sediment

* Set to 0.001 in STEPS 1-2, because it is not possible to enter zero.

Table B.8.5-8: Summary of FOCUS Step 1 - 2 input parameters for M656H023

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent; run-off and drainage of the metabolite	--
Molecular weight [g mol ⁻¹]	271	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1000	Default value
Degradation in soil		
DT ₅₀ soil [d]	24.6	Geometric mean of normalised (pF 2, 20 °C) laboratory DT ₅₀ (n = 5)
Max. observed occurrence in soil [%]	14.8	Maximum occurrence in laboratory studies
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	11.9	Arithmetic mean (n = 5)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	11.4	9.6 % TAR in the water phase + 1.8 % TAR in the sediment

Table B.8.5-9: Summary of FOCUS Step 1 - 2 input parameters for M656H027

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent; run-off and drainage of the metabolite	--
Molecular weight [g mol ⁻¹]	321.4	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1000	Default value
Degradation in soil		
DT ₅₀ soil [d]	14.3	Geometric mean of normalised (pF 2, 20 °C) field DT ₅₀ (n = 4)
Max. observed occurrence in soil [%]	12.7	Maximum occurrence in laboratory studies
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	9.27	Arithmetic mean (n = 6)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	6.3	6.3 % TAR in the water phase

Table B.8.5-10: Summary of FOCUS Step 1 - 2 input parameters for M656H031

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent	--
Molecular weight [g mol ⁻¹]	347	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1000	Default value
Degradation in soil		
DT ₅₀ soil [d]	43.6	Geometric mean of normalised (pF 2, 20 °C) laboratory DT ₅₀ (n = 5)
Max. observed occurrence in soil [%]	6.9	Maximum occurrence in laboratory studies
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	4.38	Arithmetic mean (n = 5)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	0*	Metabolite was not found >5 % TAR in water/sediment studies

* Set to 0.001 in STEPS 1-2, because it is not possible to enter zero.

Additionally, a program called Exposure Pattern Analysis Tool (EPAT) was used to further analyse the concentrations of dimethenamid-P in surface water derived in the FOCUS_{SW} Step 3 and 4 calculations. The model version of EPAT used for these analyses was not provided.

Results and Discussion

Global maximum PEC_{sw} values – dimethenamid-P

The global maximum Step 1 and 2 PEC_{sw} values of dimethenamid-P following pre- and post application to oilseed rape are summarised in Table B.8.5-11.

The tier 1 modelling global maximum Step 3 PEC_{sw} values of dimethenamid-P following pre- and post-emergence application to oilseed rape are summarised in Table B.8.5-12.

The tier 1 modelling global maximum Step 4 PEC_{SW} values of dimethenamid-P following pre- and post-emergence application to oilseed rape are summarised in Table B.8.5-14 and Table B.8.5-15.

The tier 2 modelling global maximum Step 3 PEC_{SW} values of dimethenamid-P following post-emergence application to oilseed rape are summarised in Table B.8.5-13.

The tier 2 modelling global maximum Step 4 PEC_{SW} values of dimethenamid-P following post-emergence application to oilseed rape are summarised in Table B.8.5-16.

Table B.8.5-11: Step 1 and 2: Global maximum PEC_{SW} values of dimethenamid-P following application to winter oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	140.853	24.967	35.628
	Oct-Feb	140.853	56.949	46.288
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	140.853	16.438	22.835
	Oct-Feb	140.853	35.628	29.231

Table B.8.5-12: Step 3 global maximum PEC_{SW} of dimethenamid-P following pre- and post-emergence to winter oilseed rape (tier 1 modelling)

Location	Water body		PEC _{SW} [µg L ⁻¹]	
			Winter oilseed rape, 500 µg L ⁻¹	
			pre-emergence	post-emergence
D2	ditch	PEC _{SW,max} [µg L ⁻¹]	8.318	20.377
		main entry route	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	5.206	12.707
		main entry route	Drainage	Drainage
D3	ditch	PEC _{SW,max} [µg L ⁻¹]	3.191	3.181
		main entry route	Drift	Drift
D4	pond	PEC _{SW,max} [µg L ⁻¹]	0.427	0.787
		main entry route	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	2.743	2.747
		main entry route	Drift	Drift
D5	pond	PEC _{SW,max} [µg L ⁻¹]	0.207	0.306
		main entry route	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	2.959	2.960
		main entry route	Drift	Drift
R1	pond	PEC _{SW,max} [µg L ⁻¹]	0.122	0.136
		main entry route	Runoff	Runoff
	stream	PEC _{SW,max} [µg L ⁻¹]	2.096	2.096
		main entry route	Drift	Drift
R3	stream	PEC _{SW,max} [µg L ⁻¹]	6.044	11.180
		main entry route	Runoff	Runoff

Table B.8.5-13: Step 3 global maximum PEC_{SW} of dimethenamid-P following post-emergence to winter oilseed rape (tier 2 modelling)

Location	Water body		PEC _{SW} [$\mu\text{g L}^{-1}$]
			Winter oilseed rape, 864 $\mu\text{g L}^{-1}$
			post-emergence
D2	ditch	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	19.833
		main entry route	Drainage
	stream	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	12.371
		main entry route	Drainage
D3	ditch	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	3.181
		main entry route	Drift
D4	pond	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	0.781
		main entry route	Drainage
	stream	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	2.747
		main entry route	Drift
D5	pond	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	0.306
		main entry route	Drainage
	stream	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	2.960
		main entry route	Drift
R1	pond	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	0.136
		main entry route	Runoff
	stream	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	2.096
		main entry route	Drift
R3	stream	PEC _{SW,max} [$\mu\text{g L}^{-1}$]	10.161
		main entry route	Runoff

Table B.8.5-14: Step 4: Global maximum PEC_{SW} of dimethenamid-P following pre-emergence application of 1 x 500 g ha⁻¹ to oilseed rape (tier 1 modelling)

Location	Water body		FOCUS mitigation				
			5 m D	10 m D	20 m D	10 m D + R	20 m D + R
D2	ditch	PEC _{SW,max} [µg L ⁻¹]	8.318	8.318	8.318	8.318	8.318
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	5.206	5.206	5.206	5.206	5.206
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
D3	ditch	PEC _{SW,max} [µg L ⁻¹]	0.870	0.472	0.249	0.472	0.249
		main entry route	Drift	Drift	Drift	Drift	Drift
D4	pond	PEC _{SW,max} [µg L ⁻¹]	0.425	0.420	0.416	0.420	0.416
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	1.005	0.710	0.710	0.710	0.710
		main entry route	Drift	Drainage	Drainage	Drainage	Drainage
D5	pond	PEC _{SW,max} [µg L ⁻¹]	0.207	0.207	0.207	0.207	0.207
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	1.082	0.574	0.300	0.574	0.300
		main entry route	Drift	Drift	Drift	Drift	Drift
R1	pond	PEC _{SW,max} [µg L ⁻¹]	0.104	0.075	0.050	0.075	0.050
		main entry route	Runoff	Runoff	Runoff	Runoff	Runoff
	stream	PEC _{SW,max} [µg L ⁻¹]	0.766	0.406	0.211	0.406	0.211
		main entry route	Drift	Drift	Drift	Drift	Drift
R3	stream	PEC _{SW,max} [µg L ⁻¹]	6.044	6.044	6.044	2.754	1.445
		main entry route	Runoff	Runoff	Runoff	Runoff	Runoff

D Drift mitigation using no-spray buffer zones

R Runoff mitigation using vegetated filter strips

Table B.8.5-15: Step 4: Global maximum PEC_{SW} of dimethenamid-P following post-emergence application of 1 x 500 g ha⁻¹ to oilseed rape (tier 1 modelling)

Location	Water body		FOCUS mitigation				
			5 m D	10 m D	20 m D	10 m D + R	20 m D + R
D2	ditch	PEC _{SW,max} [µg L ⁻¹]	20.377	20.377	20.377	20.377	20.377
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	12.707	12.707	12.707	12.707	12.707
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
D3	ditch	PEC _{SW,max} [µg L ⁻¹]	0.876	0.485	0.258	0.485	0.258
		main entry route	Drift	Drift	Drift	Drift	Drift
D4	pond	PEC _{SW,max} [µg L ⁻¹]	0.783	0.776	0.770	0.776	0.770
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	1.342	1.342	1.342	1.342	1.342
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
D5	pond	PEC _{SW,max} [µg L ⁻¹]	0.306	0.306	0.306	0.306	0.306
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	1.089	0.584	0.342	0.584	0.342
		main entry route	Drift	Drift	Drainage	Drift	Drainage
R1	pond	PEC _{SW,max} [µg L ⁻¹]	0.116	0.084	0.055	0.084	0.055
		main entry route	Runoff	Runoff	Runoff	Runoff	Runoff
	stream	PEC _{SW,max} [µg L ⁻¹]	0.877	0.877	0.877	0.406	0.211
		main entry route	Runoff	Runoff	Runoff	Drift	Drift
R3	stream	PEC _{SW,max} [µg L ⁻¹]	11.180	11.180	11.180	5.095	2.671
		main entry route	Runoff	Runoff	Runoff	Runoff	Runoff

D Drift mitigation using no-spray buffer zones

R Runoff mitigation using vegetated filter strips

Table B.8.5-16: Step 4: Global maximum PEC_{SW} of dimethenamid-P following post-emergence application of 1 x 500 g ha⁻¹ to oilseed rape (tier 2 modelling)

Location	Water body		FOCUS mitigation				
			5 m D	10 m D	20 m D	10 m D + R	20 m D + R
D2	ditch	PEC _{SW,max} [µg L ⁻¹]	19.833	19.833	19.833	19.833	19.833
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	12.371	12.371	12.371	12.371	12.371
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
D3	ditch	PEC _{SW,max} [µg L ⁻¹]	0.876	0.485	0.258	0.485	0.258
		main entry route	Drift	Drift	Drift	Drift	Drift
D4	pond	PEC _{SW,max} [µg L ⁻¹]	0.777	0.770	0.764	0.770	0.764
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	1.332	1.332	1.332	1.332	1.332
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
D5	pond	PEC _{SW,max} [µg L ⁻¹]	0.306	0.306	0.306	0.306	0.306
		main entry route	Drainage	Drainage	Drainage	Drainage	Drainage
	stream	PEC _{SW,max} [µg L ⁻¹]	1.089	0.584	0.342	0.584	0.342
		main entry route	Drift	Drift	Drainage	Drift	Drainage
R1	pond	PEC _{SW,max} [µg L ⁻¹]	0.116	0.084	0.055	0.084	0.055
		main entry route	Runoff	Runoff	Runoff	Runoff	Runoff
	stream	PEC _{SW,max} [µg L ⁻¹]	0.830	0.830	0.830	0.406	0.211
		main entry route	Runoff	Runoff	Runoff	Drift	Drift
R3	stream	PEC _{SW,max} [µg L ⁻¹]	10.161	10.161	10.161	4.631	2.428
		main entry route	Runoff	Runoff	Runoff	Runoff	Runoff

D Drift mitigation using no-spray buffer zones

R Runoff mitigation using vegetated filter strips

Global maximum PEC_{sw} values– metabolites

The global maximum Step 1 and 2 PEC_{SW} values of the metabolites M656H003, M656H023, M656H027 and M656PH031 following application to oilseed rape are summarised in Table B.8.5-17.

Table B.8.5-17: Step 1 and 2 Global maximum PEC_{SW} of M656H003 following one application of dimethenamid-P to oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	0.577	0.576	0.576
	Oct-Feb	0.577	0.576	0.576
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	0.577	0.576	0.576
	Oct-Feb	0.577	0.576	0.576

Table B.8.5-18: Step 1 and 2 Global maximum PEC_{SW} of M656H023 following one application of dimethenamid-P to oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	24.374	4.771	6.903
	Oct-Feb	24.374	11.166	9.035
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	24.374	3.066	4.345
	Oct-Feb	24.374	6.903	5.624

Table B.8.5-19: Step 1 and 2 Global maximum PEC_{SW} of M656H027 following one application of dimethenamid-P to oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	24.703	4.348	6.355
	Oct-Feb	24.703	10.369	8.362
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	24.703	2.742	3.947
	Oct-Feb	24.703	6.355	5.151

Table B.8.5-20: Step 1 and 2 Global maximum PEC_{SW} of M656H031 following one application of dimethenamid-P to oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	14.385	2.700	4.050
	Oct-Feb	14385	6.749	5.400
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	14.385	1.620	2.430
	Oct-Feb	14385	4.050	3.240

Actual and time-weighted average PEC_{SW} values – dimethenamid-P

The actual and time-weighted average PEC_{SW} of dimethenamid-P are not presented here since there were not used for aquatic risk assessment of dimethenamid-P (see Volume 3 CP, B9 for BAS 830 01 H). The actual and time-weighted average concentrations PEC_{SW} for of dimethenamid-P after application to oilseed rape can be found in Table A 117 to Table A 122 of the original study report.

The additional EPAT analyses of the concentration course of dimethenamid-P in the water phase after application to oilseed rape are shown in Table A 130 to Table A 132 of the original study report Maneri (2014). The analyses includes figures and tables showing and listing up properties like peak

duration, maximum peak concentration, area under the curve, time between peaks etc. for peaks above the threshold value of 1.57 and 5.445 $\mu\text{g L}^{-1}$.

The concentration course of dimethenamid-P in the water bodies in mg L^{-1} of all FOCUS SW scenarios for the respective modelled climate year is shown exemplary after pre-emergence application of dimethenamid-P to winter oilseed rape in Figure B.8.5-1 and Figure B.8.5-2.

The duration and extent of concentration peaks and the integrated concentration peaks over time calculated with EPAT after pre-emergence application of dimethenamid-P to winter oilseed rape are presented in Table B.8.5-21.

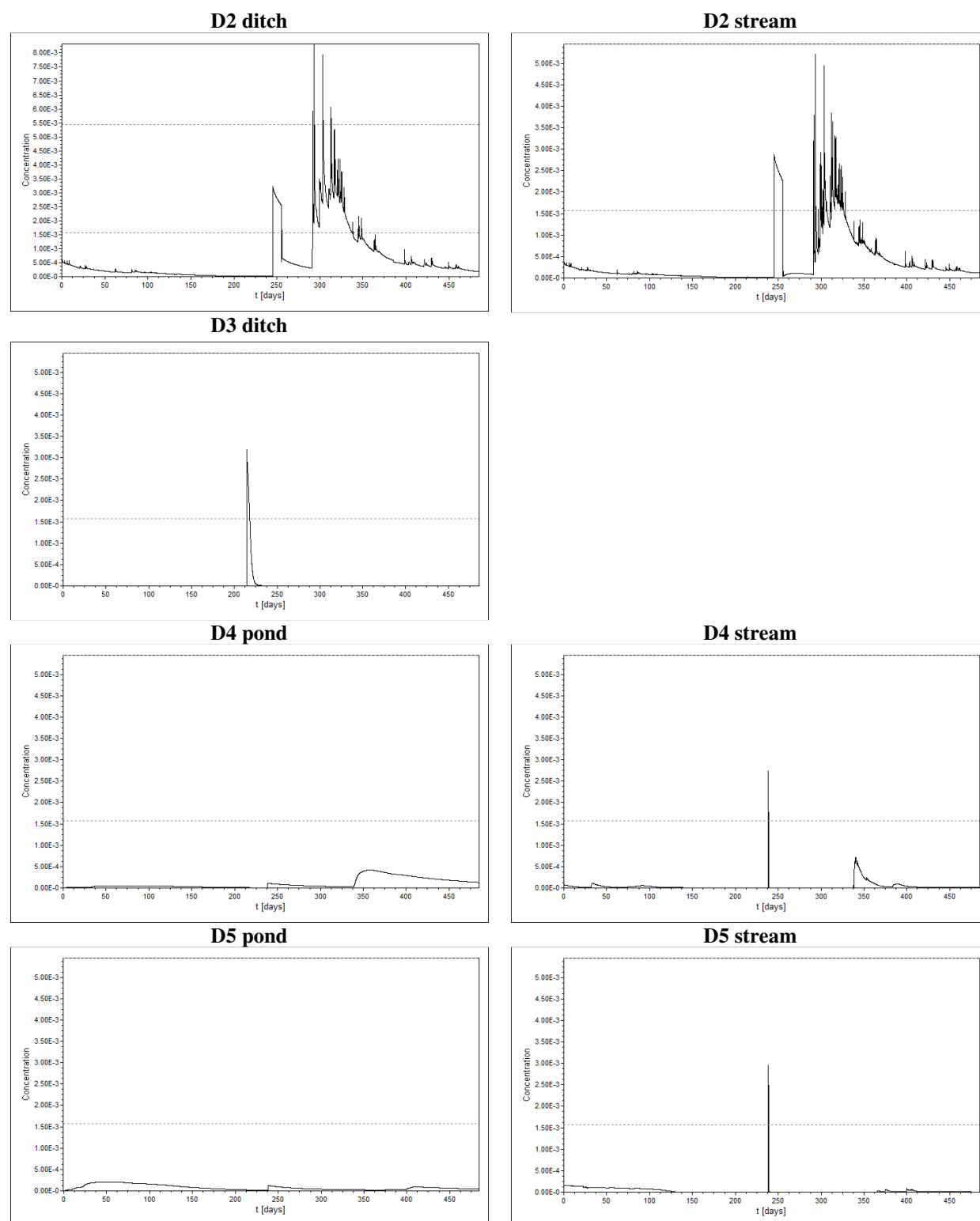


Figure B.8.5-1: Concentration course of dimethenamid-P in the water bodies in mg L⁻¹ of all FOCUS SW scenarios after pre-emergence application of dimethenamid-P to winter oilseed rape - D scenarios

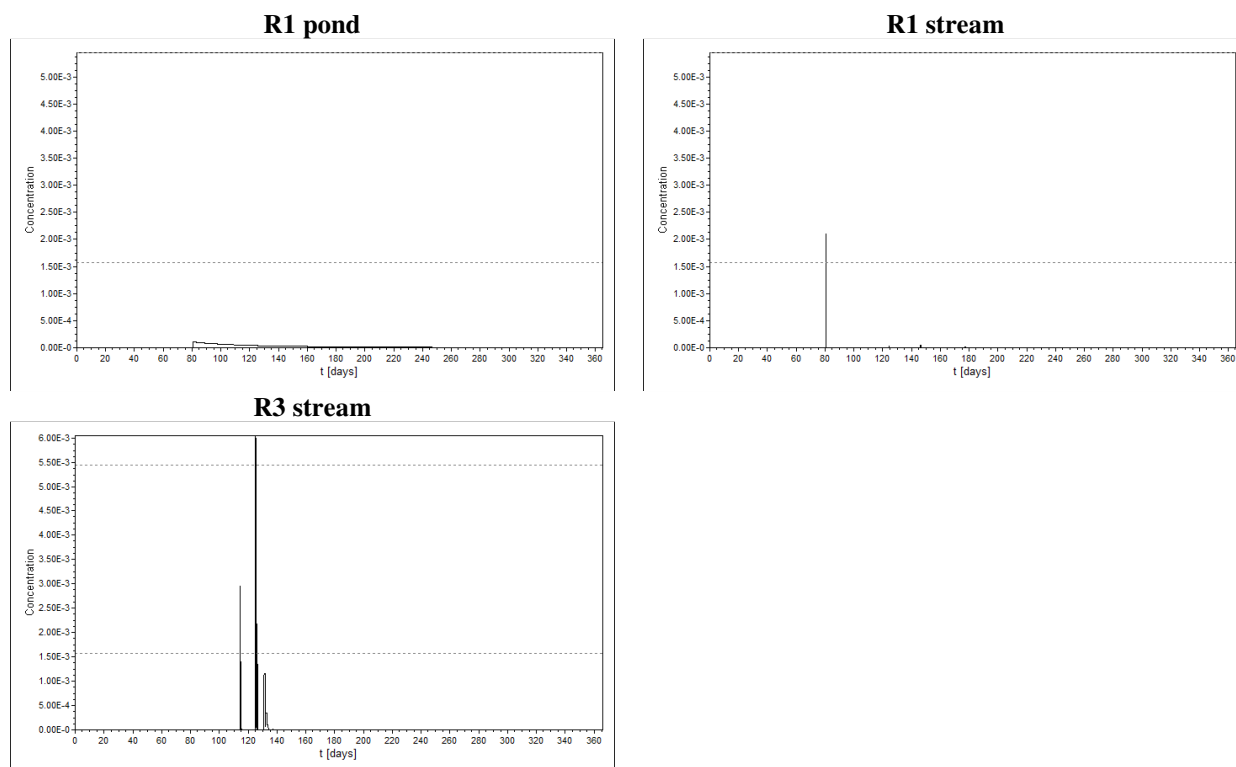


Figure B.8.5-2: Concentration course of dimethenamid-P in the water bodies in mg L⁻¹ of all FOCUS SW scenarios after after pre-emergence application of dimethenamid-P to winter oilseed rape – R scenarios

Table B.8.5-21: Duration, extent of concentration peaks and the integrated concentration peaks over time calculated with EPAT after pre-emergence application of dimethenamid-P to maize

Concentration level [µg L ⁻¹]	Peak number	Start date	Duration of the peak [d]	Maximum concentration [µg L ⁻¹]	Area under the curve [µg L ⁻¹ * d]	Interval between peaks [d]
D2 ditch						
1.57	1	03/09/1986	9.92	3.230	668.1	-
	2	13/09/1986	0.21	2.504	10.96	0.17
	3	19/10/1986	46.13	8.319	3219	35.63
	4	05/12/1986	0.38	1.948	15.81	0.75
	5	11/12/1986	0.25	1.703	9.933	5.67
	6	12/12/1986	0.58	2.167	25.49	0.67
	7	15/12/1986	0.50	2.084	22.15	2.46
5.445	1	19/10/1986	0.17	5.927	22.78	-
	2	21/10/1986	0.38	8.319	64.09	1.58
	3	31/10/1986	0.46	7.935	75.03	9.63
	4	09/11/1986	0.13	6.071	17.81	8.54
	5	10/11/1986	0.04	5.657	5.657	0.88
D2 stream						
1.57	1	03/09/1986	9.83	2.877	591	-
	2	13/09/1986	0.04	1.680	1.68	0.29
	3	19/10/1986	0.42	3.798	29.14	35.71
	4	21/10/1986	0.71	5.207	53.89	1.46
	5	24/10/1986	0.08	1.610	3.205	2.38
	6	27/10/1986	0.63	2.932	33.11	2.83
	7	28/10/1986	0.67	2.619	32.78	0.38
	8	30/10/1986	0.54	2.074	23.98	1.38
	9	31/10/1986	2.92	4.950	169.3	0.42
	10	03/11/1986	0.58	1.766	23.78	0.17
	11	07/11/1986	1.33	2.385	58.7	3.33
	12	09/11/1986	14.04	3.835	671.1	0.67
	13	25/11/1986	0.25	2.005	11.22	1.96
5.445	no peaks above 5.445 µg/L					
D3 ditch						
1.57	1	02/08/1992	3.67	3.191	214.5	-
5.445	no peaks above 5.445 µg/L					
D4 pond						
1.57	no peaks above 1.57 µg/L					
5.445	no peaks above 5.445 µg/L					
D4 stream						
1.57	1	27/08/1985	0.25	2.742	15.29	-
5.445	no peaks above 5.445 µg/L					
D5 pond						
1.57	no peaks above 1.57 µg/L					
5.445	no peaks above 5.445 µg/L					

Concentration level [µg L ⁻¹]	Peak number	Start date	Duration of the peak [d]	Maximum concentration [µg L ⁻¹]	Area under the curve [µg L ⁻¹ * d]	Interval between peaks [d]
D5 stream						
1.57	1	27/08/1978	0.38	2.958	23.25	-
5.445	no peaks above 5.445 µg/L					
R1 pond						
1.57	no peaks above 1.57 µg/L					
5.445	no peaks above 5.445 µg/L					
R1 stream						
1.57	1	20/08/1978	0.17	2.096	8.143	-
5.445	no peaks above 5.445 µg/L					
R3 stream						
1.57	1	23/09/1975	0.33	2.947	20.46	-
	2	04/10/1975	0.54	6.045	70.27	10.33
	3	05/10/1975	0.29	2.170	14.04	0.54
5.445	1	04/10/1975	0.46	6.045	65.44	-

Global maximum PEC_{SED} values – dimethenamid-P

The global maximum Step 1 and 2 PEC_{SED} values of dimethenamid-P following application to oilseed rape are summarised in Table B.8.5-22.

The tier 1 modelling global maximum Step 3 PEC_{SED} values of dimethenamid-P following pre- and/or post-emergence application to oilseed rape are summarised in Table B.8.5-23.

The tier 2 modelling global maximum Step 3 PEC_{SED} values of dimethenamid-P following post-emergence application to maize and sugar-beets are summarised in Table B.8.5-24.

Table B.8.5-22: Step 1 and 2: Global maximum PEC_{SED} values of dimethenamid-P following application to oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	228.421	41.414	59.248
	Oct-Feb	228.421	94.916	77.082
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	228.421	27.147	37.848
	Oct-Feb	228.421	59.248	48.548

Table B.8.5-23: Step 3 global maximum PEC_{SED} of dimethenamid-P following pre- and post-emergence to oilseed rape (tier 1 modelling)

Location	Water body		PEC _{SED} [$\mu\text{g kg}^{-1}$]	
			Winter oilseed rape, 500 g ha ⁻¹	
			pre-emergence	post-emergence
D2	ditch	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	6.796	15.351
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	3.882	8.999
D3	ditch	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	1.339	0.936
D4	pond	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.964	1.728
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.463	0.860
D5	pond	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.523	0.764
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.525	0.521
R1	pond	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.138	0.181
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.203	0.203
R3	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	1.270	2.728

Table B.8.5-24: Step 3 global maximum PEC_{SED} of dimethenamid-P following pre- and post-emergence to oilseed rape (tier 2 modelling)

Location	Water body		PEC _{SED} [$\mu\text{g kg}^{-1}$]
			Winter oilseed rape, 500 g ha ⁻¹
			post-emergence
D2	ditch	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	15.065
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	8.837
D3	ditch	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.936
D4	pond	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	1.716
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.854
D5	pond	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.764
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.521
R1	pond	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.180
	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	0.203
R3	stream	PEC _{SED,max} [$\mu\text{g kg}^{-1}$]	2.475

Global maximum PEC_{SED} values– metabolites

The global maximum Step 1 and 2 PEC_{SED} values of the metabolites M656H003, M656H023, M656H027 and M656PH031 following application to oilseed rape are summarised in Table B.8.5-25, Table B.8.5-26, Table B.8.5-27 and Table B.8.5-28.

Table B.8.5-25: Step 1 and 2 Global maximum PEC_{SED} of M656H003 following one application of dimethenamid-P to winter oilseed rape

Crop	Application time	Step 1	Step 2	
		PEC _{SED,max} [µg kg ⁻¹]	Europe North	Europe South
			PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha⁻¹, pre-emergence				
Winter oilseed rape	Jun-Sep	2.898	0.567	0.821
	Oct-Feb	2.898	1.328	1.074
1 x 500 g ha⁻¹, post-emergence				
Winter oilseed rape	Jun-Sep	2.898	0.364	0.516
	Oct-Feb	2.898	0.821	0.669

Table B.8.5-26: Step 1 and 2 Global maximum PEC_{SED} of M656H023 following one application of dimethenamid-P to winter oilseed rape

Crop	Application time	Step 1	Step 2	
		PEC _{SED,max} [µg kg ⁻¹]	Europe North	Europe South
			PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha⁻¹, pre-emergence				
Winter oilseed rape	Jun-Sep	2.898	0.567	0.821
	Oct-Feb	2.898	1.328	1.074
1 x 500 g ha⁻¹, post-emergence				
Winter oilseed rape	Jun-Sep	2.898	0.364	0.516
	Oct-Feb	2.898	0.821	0.669

Table B.8.5-27: Step 1 and 2 Global maximum PEC_{SED} of M656H027 following one application of dimethenamid-P to winter oilseed rape

Crop	Application time	Step 1	Step 2	
		PEC _{SED,max} [µg kg ⁻¹]	Europe North	Europe South
			PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha⁻¹, pre-emergence				
Winter oilseed rape	Jun-Sep	2.288	0.403	0.589
	Oct-Feb	2.288	0.960	0.775
1 x 500 g ha⁻¹, post-emergence				
Winter oilseed rape	Jun-Sep	2.288	0.254	0.366
	Oct-Feb	2.288	0.589	0.477

Table B.8.5-28: Step 1 and 2 Global maximum PEC_{SED} of M656H031 following one application of dimethenamid-P to winter oilseed rape

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	0.630	0.118	0.177
	Oct-Feb	0.630	0.296	0.237
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	0.630	0.071	0.106
	Oct-Feb	0.630	0.177	0.142

Conclusion

Acceptability of application scenario:

The application scenarios chosen by the applicant for the application of BAS 830 01 H to winter oilseed rape are considered acceptable by the RMS.

Acceptability of substance related input parameters - dimethenamid-P:

Regarding the substance related input parameter for dimethenamid-P in tier 1 modelling, using the combined DT₅₀ values of laboratory data and field degradation studies is considered acceptable by the RMS. The final geometric mean of the DT₅₀ value derived by the RMS is, however, with 11.5 d slightly higher. This small difference of 0.2 days is considered to have only a marginal influence on the resulting PEC_{SW} and PEC_{SED} values. Besides, the applicant used the median of the K_{foc} values and the Freundlich exponents for FOCUS SW simulation instead of the arithmetic mean. This is justifiable for the K_{foc} values, since a sufficient number of ten values is available and the resulting median is smaller and thus more conservative for the resulting PEC_{SW} values. For the Freundlich exponent the arithmetic mean of 0.994 should have been used instead. However, since both the median of 0.985 as well as the arithmetic mean of 0.994 are implemented in SWASH as 0.99, no difference is expected in the resulting PEC_{SW} and PEC_{SED} values.

The crop uptake factor of 0.5 is considered acceptable by the RMS, since there is enough evidence on the uptake of dimethenamid-P by plants. This is described in more detail in the RAR, Volume 3 CA, B.8.1.4.4 of the active substance dimethenamid-P.

The foliar DT₅₀ value used by the applicant in tier 2 simulations is not considered acceptable, since the studies Friedemann & Teresiak, 2014a & b were not accepted by the RMS. The shortcomings of the studies are listed in the RAR, Volume 3 CA, B.8.1.4.4 for the active substance dimethenamid-P. The use of a refined foliar DisT₅₀ which includes loss via volatilisation appears appropriate in this case, since the apparent increase in surface water and sediment concentrations caused by the path volatilisation of active substances from soil and plant surface with subsequent deposition was added to the derived Step 3 PEC_{SW} and PEC_{SED} values (although this was not described in the study report, see RMS conclusion on the acceptability of the PEC_{SW} and PEC_{SED} values). Without considering this additional pathway also a foliar DisT₅₀ partly or mainly driven by volatilisation should not be used for FOCUS surface water Step 3 modelling.

Acceptability of PEC_{SW} and PEC_{SED} values – dimethenamid-P:

Even though the RMS considered the application scenarios for application to oilseed rape and the input parameter of dimethenamid-P, the RMS was at first not able to reproduce the results at Step 3 level even when using the same input parameters and the same model versions. Instead the values produced by the applicant were slightly higher for some scenarios than the values derived by the RMS. Therefore the RMS performed additional Step 4 modelling applying the deposition rates after volatilisation of the active substance derived by EVA 2.1 (Table B.8.5-5) for 1 m distance without implementing any mitigation measures. Using this approach the Step 3 values derived by the applicant

could be exactly reproduced. Thus, it appears as if the applicant did not list the pure Step 3 PEC_{SW} and PEC_{SED} values, but Step 3 PEC_{SW} and PEC_{SED} values including the additional contribution of volatilisation with subsequent deposition of the active substance. Since this is indeed a possible entry pathway for dimethenamid-P to surface water and since it leads to more conservative Step 3 PEC_{SW} and PEC_{SED} values for dimethenamid-P, the approach is considered acceptable by the RMS.

Thus, the Step 1-2, Step 3 and Step 4 PEC_{SW} and PEC_{SED} values (tier 1 modelling) for dimethenamid-P in winter oilseed rape are considered acceptable by the RMS. The Step 3 and Step 4 PEC_{SW} and PEC_{SED} values (tier 2 modelling) for dimethenamid-P in winter oilseed rape are not considered acceptable.

The analyses performed with EPAT[Jwö1] provide additional parameters like the number of peaks, the duration of the peak, the interval between peaks and the area under the peak out of the concentration pattern modelled by FOCUS SW. However, no guidance is so far available how to use these additional parameters in ecotoxicological risk assessment. Besides, it should be noted that this additional calculations only work due to the major shortcoming of FOCUS SW Step 3 calculations: Since only one year was modelled, only one concentration pattern per FOCUS scenario is provided. If 20 years had been modelled, as would be desirable and is planned for future model versions, there would be 20 different peaks and different concentration pattern of peaks per scenario. It would then be necessary to define a worst case for each of the additional parameters or to define an overall worst case concentration pattern for each scenario which might well be different for different species with different life cycles. Thus, the RMS does not believe that the provision of additional parameters out of concentration patterns is currently of any use.

Besides, for the BAS 830 01 H different with EPAT derived values were provided by the applicant for the B.8 and the B.9 part. In Table 10.2-28 of the dossier for the Ecotoxicology Vol. 8, B.9 part values for post-emergence application of BAS 830 01 H to winter oilseed rapes were presented including values for the 'peak area under the curve' while values for pre-emergence application to winter oilseed rapes including 'area under the curve values' were provided for the Environmental Fate Volume 3, B.8 part. We believe, that in the B8 part the values should be presented that were actually used for ecotoxicological risk assessment. A correct evaluation of the surface water concentrations used for aquatic risk assessment is otherwise not possible.

Acceptability of substance related input parameters - metabolites:

Regarding the water solubility of the metabolites, a default water solubility of 1000 mg L^{-1} was used, although the water solubility of the parent is with 1449 mg L^{-1} actually higher. It would have been more suitable to use the water solubility of the parent also for the metabolites. However, repeating the calculations for the metabolites using a water solubility of 1449 mg L^{-1} did not result in different PEC_{SW} and PEC_{SED} values for the metabolites.

Regarding the remaining substance related input parameter for the metabolite M656H003, the default values used to describe the degradation in soil and water/sediment systems and the not observed formation in soil are considered acceptable by the RMS. However, a default K_{foc} of 10 for the water phase is not considered worst case by the RMS. Instead zero should have been used as worst case, especially since other metabolites (M656H031, M656H043, M656H047 and M656H054) of dimethenamid-P where the adsorption parameters were determined exhibit very poor adsorption properties to soil. A default K_{foc} of 10000 is considered acceptable as worst case for the sediment. Regarding the maximum occurrence of M656H003 in the water/sediment system, 14.4 % were derived by the RMS instead of the 14.3 % used in the simulations.

Regarding the remaining substance related input parameter for the metabolite M656H023, the default values used to describe the degradation in water/sediment systems, the maximum occurrence in water/sediment systems and the chosen K_{foc} value are considered acceptable by the RMS. However, during the evaluation of the aerobic soil degradation studies, a different DT_{50} geometric mean of 32.4 d to describe degradation of M656H023 in soil was derived. Besides, the maximum occurrence in

soil of this metabolite is now with 13.4 % slightly lower as the 14.8 % used by the applicant. The remaining input parameter for M656H023 are considered acceptable.

Regarding the remaining substance related input parameter for the metabolite M656H027, the default values used to describe the degradation in water/sediment systems, the DT_{50} soil and the maximum occurrence in water/sediment systems are considered acceptable by the RMS. However, during the evaluation of the adsorption studies with M656H027, a different K_{foc} arithmetic mean of 7.0 was derived. Besides, the maximum occurrence in soil of this metabolite is with 13.32 % slightly higher than the concentration used by the applicant.

Regarding the remaining substance related input parameter for the metabolite M656H031, the default values used to describe the degradation in water/sediment systems and the not observed formation in water/sediment systems are considered acceptable by the RMS. However, during the evaluation of the adsorption studies with M656H031, it was concluded, that the adsorption of M656H031 is too poor for accurate determination. Thus, as a realistic worst case K_{foc} , a default K_{foc} of 1 should be used (from the study results it can be concluded that while a K_{foc} of 0 for some soils cannot be ruled out, it is unlikely that an arithmetic mean of all K_{foc} values would be below 1). Additionally a longer DT_{50} soil geometric mean of 51.9 d was derived and the maximum occurrence of M656H031 in soil reaches 10.34 %.

Thus, the Step 1 & 2 calculations for the metabolites M656H003, M656H023, M656H027 and M656H031 were repeated by the RMS using different substance related input parameters. This is described below.

Global maximum PEC_{SW} and PEC_{SED} values – metabolites (re-calculations of the RMS)

The same application scenarios as shown in Table B.8.5-1 were used for Step 1 and 2 calculations for the metabolites M656H003, M656H023, M656H027 and M656PH031.

The substance specific input parameters of the metabolites M656H003, M656H023, M656H027 and M656PH031 used for Step 1 and 2 calculations is given in Table B.8.5-29, Table B.8.5-30, Table B.8.5-31 and Table B.8.5-32.

The re-calculated modelling global maximum Step 1 and 2 PEC_{SW} values of the metabolites M656H003, M656H023, M656H027 and M656PH031 following application to winter oilseed rape are summarised in Table B.8.5-33, Table B.8.5-34, Table B.8.5-35 and Table B.8.5-36.

The re-calculated modelling global maximum Step 1 and 2 PEC_{SED} values of the metabolites M656H003, M656H023, M656H027 and M656PH031 following application to winter oilseed rape are summarised in Table B.8.5-37, Table B.8.5-38, Table B.8.5-39 and Table B.8.5-40.

Table B.8.5-29: Summary of FOCUS Step 1 - 2 input parameters for M656H003 (re-calculation of the RMS)

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent	--
Molecular weight [g mol ⁻¹]	241.4	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1449	Water solubility of parent (at 25 °C)
Degradation in soil		
DT ₅₀ soil [d]	1000	Default value
Max. observed occurrence in soil [%]	0*	Metabolite is not formed in soil
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	0 / 10000	Default values (worst cases for water / sediment)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	14.4	9.1 % TAR in water phase and 5.3 % TAR in sediment

* Set to 0.001 in STEPS 1-2, because it is not possible to enter zero.

Table B.8.5-30: Summary of FOCUS Step 1 - 2 input parameters for M656H023 (re-calculation of the RMS)

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent; run-off and drainage of the metabolite	--
Molecular weight [g mol ⁻¹]	271	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1449	Water solubility of parent (at 25 °C)
Degradation in soil		
DT ₅₀ soil [d]	28.2	Geometric mean of normalised (pF 2, 20 °C) laboratory DT ₅₀ (n = 5)
Max. observed occurrence in soil [%]	13.4	Maximum occurrence in laboratory studies
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	11.9	Arithmetic mean (n = 5)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	11.4	9.6 % TAR in the water phase + 1.8 % TAR in the sediment

Table B.8.5-31: Summary of FOCUS Step 1 - 2 input parameters for M656H027 (re-calculation of the RMS)

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent; run-off and drainage of the metabolite	--
Molecular weight [g mol ⁻¹]	321.4	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1449	Water solubility of parent (at 25 °C)
Degradation in soil		
DT ₅₀ soil [d]	14.3	Geometric mean of normalised (pF 2, 20 °C) field DT ₅₀ (n = 4)
Max. observed occurrence in soil [%]	13.3	Maximum occurrence in laboratory studies
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	7.0	Arithmetic mean (n = 6)
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	6.3	6.3 % TAR in the water phase

Table B.8.5-32: Summary of FOCUS Step 1 - 2 input parameters for M656H031 (re-calculation of the RMS)

Parameter	Value	Remarks
Entry routes into surface water	Spray drift, runoff and drainage of the parent	--
Molecular weight [g mol ⁻¹]	347	Phys.-chem. properties
Water solubility [mg L ⁻¹]	1449	Water solubility of parent (at 25 °C)
Degradation in soil		
DT ₅₀ soil [d]	51.9	Geometric mean of normalised (pF 2, 20 °C) laboratory DT ₅₀ (n = 5)
Max. observed occurrence in soil [%]	10.34	Maximum occurrence in laboratory studies
Sorption to soil		
K _{f,oc} [mL g ⁻¹]	1	Worst case
Degradation in aquatic systems		
DT ₅₀ total system [d]	1000	Default value – not relevant, since only initial concentrations were regarded
DT ₅₀ water [d]	1000	
DT ₅₀ sediment [d]	1000	
Maximum observed concentration in water/sediment [%]	0*	Metabolite was not found >5 % TAR in water/sediment studies

* Set to 0.001 in STEPS 1-2, because it is not possible to enter zero.

Table B.8.5-33: Step 1 and 2 global maximum PEC_{SW} of M656H003 following one application of dimethenamid-P to oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	0.580	0.580	0.580
	Oct-Feb			
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	0.580	0.580	0.580
	Oct-Feb			

Table B.8.5-34: Step 1 and 2 global maximum PEC_{SW} of M656H023 following one application of dimethenamid-P to oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	22.117	4.424	6.382
	Oct-Feb		10.298	8.340
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	22.117	2.858	4.033
	Oct-Feb		6.382	5.207

Table B.8.5-35: Step 1 and 2 global maximum PEC_{SW} of M656H027 following one application of dimethenamid-P to oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	25.767	4.523	4.523
	Oct-Feb		10.807	8.712
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	25.767	2.847	4.104
	Oct-Feb		6.617	5.361

Table B.8.5-36: Step 1 and 2 global maximum PEC_{SW} of M656H031 following one application of dimethenamid-P to oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	21.654	4.106	8.211
	Oct-Feb		10.264	6.158
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	21.654	2.463	4.926
	Oct-Feb		6.158	3.695

Table B.8.5-37: Step 1 and 2 global maximum PEC_{SED} of M656H003 following one application of dimethenamid-P to winter oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	2.482	2.475	2.475
	Oct-Feb			
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	2.482	2.475	2.475
	Oct-Feb			

Table B.8.5-38: Step 1 and 2 global maximum PEC_{SED} of M656H023 following one application of dimethenamid-P to winter oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	2.571	0.526	0.759
	Oct-Feb		1.224	0.991
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	2.571	0.340	0.479
	Oct-Feb		0.759	0.619

Table B.8.5-39: Step 1 and 2 global maximum PEC_{SED} of M656H027 following one application of dimethenamid-P to winter oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	3.026	0.538	0.538
	Oct-Feb		1.285	1.036
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	3.026	0.338	0.488
	Oct-Feb		0.787	0.637

Table B.8.5-40: Step 1 and 2 global maximum PEC_{SED} of M656H031 following one application of dimethenamid-P to winter oilseed rape (recalculations of the RMS)

Crop	Application time	Step 1	Step 2	
			Europe North	Europe South
		PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]	PEC _{SED,max} [µg kg ⁻¹]
1 x 500 g ha ⁻¹ , pre-emergence				
Winter oilseed rape	Jun-Sep	0.217	0.041	0.082
	Oct-Feb		0.103	0.062
1 x 500 g ha ⁻¹ , post-emergence				
Winter oilseed rape	Jun-Sep	0.217	0.025	0.049
	Oct-Feb		0.062	0.037

B.8.5.2 Qinmerac and its metabolites:

No study on PEC_{SW} and PEC_{SED} values of quinmerac and its major metabolites BH 518-2 (29.1 % maximum formation in soil, 13.1 % maximum formation in water/sediment system) and BH 518-5 (27.2 % maximum formation in soil) in the representative formulation BAS 830 01 H were submitted, but additional Step 3 PEC_{SW} and PEC_{SED} values of quinmerac were provided in the dossier of the applicant.

Since this document concerns the EU approval of the active substance dimethenamid-P and not of quinmerac, which was already approved on 01/05/2011, we believe that the PEC_{SW} and PEC_{SED} values presented here for quinmerac and its metabolites BH 518-2 and BH 518-5 should be the same as the values provided in the List of Endpoints (LoEP) of quinmerac (drafted in April 2007, last updated in November 2009) in order to not repeat the approval process for quinmerac.

Material and Methods

For EU approval of quinmerac, PEC_{SW} and PEC_{SED} calculations of quinmerac and its metabolites BH 518-2 and BH 518-5 were performed for the spring and winter oilseed rape. The application scenario used to derive Step 1 and 2 PEC_{SW} and PEC_{SED} values for application of quinmerac to winter oilseed rape is given in Table B.8.5-41.

Table B.8.5-41: Selected application scenarios for FOCUS Step 1 and 2 simulations
(see *LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523*)

Crop	Winter oilseed rape
Number of applications	1
Application rate	250
Region[#]	North and South Europe
Crop interception	No interception*
Application period[#]	Jun-Sep*

[#] only relevant for Step 2

* not stated in LoEP of quinmerac, thus taken from additional report Vol.3, B.1, B.6, B.8 of quinmerac (June 2009)

For quinmerac, additional FOCUS SW Step 3 calculations were performed for its EU approval. For the application to winter oilseed rape, the emergence date for oilseed rape minus a time span of 6 days, as a conservative worst case estimation, was assumed as the earliest date for application of quinmerac to oilseed rape. The detailed application timing taken from the LoEP of quinmerac (Nov 2009) used for the calculations is shown in Table B.8.5-42.

Table B.8.5-42: Application timing for quinmerac in the relevant FOCUS SW Step 3 scenario (see *LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523*)

Scenario	Winter oilseed rape, 250 g ha ⁻¹	
	Application window	
D 2 - Brimstone	9 th September	9 th October
D 3 – Vreedepeel	27 th August	26 th September
D 4 – Skousbo	28 th August	27 th September
D 5 – La Jailliere	14 th September	14 th October
R 1 – Weiherbach	29 th August	28 th September
R 3 – Bologna	29 th September	29 th October

The substance related input parameter used for PEC_{SW} and PEC_{SED} calculations of quinmerac and its metabolites can be found in the LoEP (Nov 2009).

Results and Discussion

The maximum FOCUS SW Step 1 & 2 PEC_{SW} values of quinmerac and its metabolites BH 518-2 and BH 518-5 taken from the LoEP (Nov 2009) of quinmerac are presented in Table B.8.5-43, Table B.8.5-44 and Table B.8.5-45. No FOCUS SW Step 1 & 2 PEC_{SED} values of quinmerac and its metabolites BH 518-2 and BH 518-5 were reported in the LoEP (Nov 2009) or in additional report Vol. 3, B.1, B.6 and B.8 of quinmerac (June 2009) since they were not required for risk assessment.

Table B.8.5-43: Step 1 and 2: Global maximum PEC_{SW} values of quinmerac following application of 250 g/ha of quinmerac to winter oilseed rape (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

Crop	Step 1	Step 2	
		Europe North	Europe South
	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
Winter oilseed rape	81.91	14.83	21.15

Table B.8.5-44: Step 1 and 2: Global maximum PEC_{SW} values of BH 518-2 following application of 250 g/ha of quinmerac to winter oilseed rape (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

Crop	Step 1	Step 2	
		Europe North	Europe South
	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
Winter oilseed rape	39.01	7.38	10.90

Table B.8.5-45: Step 1 and 2: Global maximum PEC_{SW} values of BH 518-5 following application of 250 g/ha of quinmerac to winter oilseed rape (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

Crop	Step 1	Step 2	
		Europe North	Europe South
	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]	PEC _{SW,max} [µg L ⁻¹]
Winter oilseed rape	29.89	5.95	8.93

Table B.8.5-46: Step 3: Global maximum PEC_{SW} and PEC_{SED} values of quinmerac following application of 250 g/ha of quinmerac to winter oilseed rape (see LoEP quinmerac - Nov 2009 and EFSA conclusion – 2010; 8(3):1523)

FOCUS STEP 3 Quinmerac	PEC _{SW} (µg/L)	PEC _{SED} (µg/kg)
	Actual	Actual
Winter Oilseed rape		
D2 ditch	30.639	10.542
D2 stream	19.377	3.609
D3 ditch	1.600	0.535
D4 pond	0.292	0.760
D4 stream	1.371	0.259
D5 pond	0.189	0.471
D5 stream	1.479	0.255
R1 pond	0.055	0.088
R1 stream	1.048	0.085
R3 stream	7.177	0.800

Conclusion

It should be noted, that the Step 1 & 2 PEC_{SW} values of quinmerac and its metabolites BH 518-2 and BH 518-5 listed in the LoEP (Nov 2009) of quinmerac only cover pre-emergence application to winter oilseed rape but not post-emergence application. The application window used for Step 3 calculations for quinmerac on the other hand only covers an application window of 30 days, while for dimethenamid-P 60 days were chosen by performing two separate runs (post- and pre emergence application). The application dates chosen by Swash for post-emergence application of dimethenamid-P (see Table B.8.5-3) were always within the application window chosen for quinmerac. Thus, the Step 3 PEC_{SW} values listed in the LoEP of quinmerac only cover post-emergence application but not pre-emergence application.

However, since the toxicological risk assessment of BAS 830 01 H for aquatic risk assessment is driven by the toxicology of dimethenamid-P and not quinmerac (see Vol. 3 CP, B.9 of the formulation BAS 830 01 H), the PEC_{SW} and PEC_{SED} of quinmerac and its metabolites BH 518-2 and BH 518-5 listed in the LoEP (Nov 2009) of quinmerac are also considered to be sufficient by the RMS for risk assessment of the representative formulation BAS 830 01 H.

B.8.6 Fate and behaviour in air

B.8.6.1 Route and rate of degradation in air and transport via air

No studies were performed with the formulation BAS 830 01 H. For studies performed with the active substance dimethenamid-P please refer to Volume 3 CA, B.8 of dimethenamid-P.

B.8.6.2 Predicted environmental concentrations from airborne transport

No risk assessment of dimethenamid-P in the formulation BAS 830 01 H for air was performed by the applicant.

Dimethenamid-P has a vapour pressure: 3.47×10^{-3} Pa (20 °C). Hence dimethenamid-P is regarded as semivolatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by dimethenamid-P due to volatilisation with subsequent deposition should be considered. For surface water this path was considered as described in more detail under B.8.5 of this document.

The calculated photochemical oxidative degradation half life of dimethenamid-P is with 0.2 d (12-hr day, $1.5 \times 10^6 \text{ cm}^{-3}$ OH radicals). Distribution of the active substance via long range transport through the atmosphere is therefore not expected.

The fate and behaviour of quinmerac in air has already been performed for EU approval of quinmerac.

B.8.7 Predicted environmental concentrations from other routes of exposure

No other routes of exposure are considered relevant for the representative uses of dimethenamid-P in the formulation BAS 830 01 H.

B.8.8 References relied on

Data Point EU as of 2014	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N If yes, old data point
KCP 9.1.3/1	Maleri M.	2014	Predicted environmental concentrations in soil, groundwater, surface water and sediment of dimethenamid-p and its metabolites after application of BAS 656 12 H and 830 01 H 2014/1000682 BASF SE, Limburgerhof, Germany Fed.Rep. Not GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 9.1.3
KCP 9.2.4/1	Maleri M.	2014	Predicted environmental concentrations in soil, groundwater, surface water and sediment of dimethenamid-p and its metabolites after application of BAS 656 12 H and 830 01 H 2014/1000682 BASF SE, Limburgerhof, Germany Fed.Rep. Not GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 9.2.1
KCP 9.2.5/1	Maleri M.	2014	Predicted environmental concentrations in soil, groundwater, surface water and sediment of dimethenamid-p and its metabolites after application of BAS 656 12 H and 830 01 H 2014/1000682 BASF SE, Limburgerhof, Germany Fed.Rep. Not GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 9.2.3