Renewal Assessment Report

Dimethenamid-P

BAS 830 01 H

Volume 3 – B.9 Ecotoxicology data and assessment of risks for non-target species

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When	What
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B Summary, evaluation and assessment of the data and information

B.9 Ecotoxicology data and assessment of risks for non-target species

A search for open literature which included papers in peer-reviewed journals and reports from government and other agencies in the EU and several other countries was performed by the applicant. The literature search was done via databases such as PubMed, Agricola, and SciFinder using the key-word “dimethenamid” or “dimethenamid-P” and the CAS Numbers 87674-68-8 and 163515-14-8, respectively. The initial search was a net cast as wide as possible to ensure complete coverage of the literature. The references were then reviewed and, on the basis of the title and the abstract, a subset was retained for use in the characterisation. Priority was given to papers published since 2003 and, where possible, copies of these were obtained for more detailed review. No additional open-literature studies concerning ecotoxicology of dimethenamid-P were found helpful for risk assessment purposes.

Study summaries of all listed studies are provided below.

The final results of all acceptable studies regarding the fate and behaviour of dimethenamid-P and its metabolites in water and soil are summarised in Volume 1 under 2.9.

The representative formulation BAS 830 01 H contains two active substances, dimethenamid-P and quinmerac. The overall assessment is intended to provide a basis for the decision on a possible renewal of the approval of the active substance dimethenamid-P. Hence, priority is given to assessing the risk due to this compound. Since a specific risk assessment for the second representative formulation is not foreseen in the relevant Guidance Document SANCO/4145/2000, TER values are also provided for the second active substance quinmerac. However, these data are considered supplementary in nature. Parameters used in refined risk assessments for quinmerac are thus not considered to be an integral part of the assessment of the active substance dimethenamid-P. Additional parameters required for calculating exposure levels of quinmerac were taken from the endpoint list contained in the EFSA Scientific Report (Conclusion on the peer review of quinmerac, EFSA Journal 2010; 8(3):1523) without reassessment.

In cases where the risk assessment for the formulation cannot be based on actual studies with the formulation, a calculation approach is used to address the possible combined action of several active substances on non-target organisms. The model used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Loewe & Muischneck, 1926, frequently referred to as ‘Finney’s equation’).
The following formula is used to derive a surrogate LC_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$LC_{50}(\text{mix}) = \left(\sum_i \frac{X(\text{a.s.}_i)}{LC_{50}(\text{a.s.}_i)} \right)^{-1}$$

where:
X(a.s. i) = fraction of active substance (i) in the mixture
LC_{50}(a.s. i) = acute toxicity value for active substance (i)
Because of the direct proportionality of the calculated TER to the LC_{50} (or any other relevant toxicity value), it is also possible to calculate a TER(mix) with the following formula:

$$\text{TER(mix)} = \left(\sum_i \frac{1}{\text{TER(a.s.}_i\text{)}} \right)^{-1}$$

where:
TER(a.s.i) = calculated TER for the active substance i

Calculation of a TER(mix) is also the recommended approach for long-term/chronic risk assessments. Due to the dependency of NOEC values from experimental dose-spacing and due to the diversity of

biological endpoints in long-term/chronic toxicity tests, a calculated NOEC(mix) is unlikely to constitute a reliable measure of toxicity. Against that background, the calculated TER(mix) for a long-term/chronic risk is only applied in the assessment in combination with additional considerations on its possible relevance in terms of actual risk.

B.9.1 Effects on birds and other terrestrial vertebrates

B.9.1.1 Effects on birds

B.9.1.1.1 Acute oral toxicity to birds

No studies submitted, not required.

B.9.1.1.2 Higher tier data on birds

No studies submitted, not required.

B.9.1.2 Effects on terrestrial vertebrates other than birds

B.9.1.2.1 Acute oral toxicity to mammals

No studies submitted, not required.

B.9.1.2.2 Higher tier data on mammals

No studies submitted, not required.

B.9.1.2.3 Effects on other vertebrate wildlife (reptiles and amphibians)

No studies submitted, not required.

B.9.2 Risk assessment for birds and other terrestrial vertebrates

Effects on birds of BAS 830 01 H were not evaluated as part of the EU assessment of dimethenamid-P. No studies have been submitted with the formulation BAS 830 01 H. Avian toxicity studies have been carried out with the active substance dimethenamid-P or with with racemic dimethenamid and with the active substance quinmerac. Full details of these studies are provided in Volume 3 CA of this document for dimethenamid-P, and in the respective EU DAR and related documents for quinmerac. The risk assessment is based on the studies with the active substances and on mixture toxicity calculation of the active substances.

According to current guidance, a specific risk assessment for short-term risks from dietary uptake is not triggered for dimethenamid-P, since there are no indications for delayed action or accumulation of the compound leading to mortality on a short-term time scale.

Table B.9.2-1: Proposed avian and mammalian toxicity endpoints for use in risk assessment

Species	Test substance	Time scale	End point (mg/kg bw per day)	Reference
Birds				
Colinus virginianus	Dimethenamid-P	Acute	LD_{50} = 1068 mg/kg bw	[redacted] 03.06.1996 131-187; BASF RegDoc #1996/5419 *1)
Colinus virginianus	Dimethenamid-racemate	Long-term	NOEC = 900 ppm NOEL = 114 mg a.s./kg bw/d 3)	[redacted] 06.05.1994 131-177; BASF RegDoc # 1994/11900 *1)
Mammals				
Rat	Dimethenamid-P	Acute	LD_{50} = 429 mg/kg bw (male) LD_{50} = 531 mg/kg bw (female) LD_{50} = **466 mg/kg** bw (combined) **LD_{50} = 477 mg/kg** bw **(geomean)**	[redacted] 17.07.1996 94-1404; BASF RegDoc # 1996/11087*1)
Rat	Dimethenamid-racemate Keto-enol process Undiluted, no carrier	Acute	LD_{50} = 397 mg/kg bw 90 % at 600 mg/kg bw; 10 % at 300 mg/kg bw 0 % at 150 mg/kg bw	[redacted] 1991 1991/11940; BASF RegDoc# 1991/11940 4)
Rat	Dimethenamid-racemate	Long-term (2-generation-study)	NOAEL = 500 mg a.s./kg diet NOAEL **= 33.3 mg/kg bw/day** 3)	[redacted] 17.05.1989 2012065; BASF Doc# 1990/11140 *2) 4)

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003
1) For summary and evaluation of the study please refer to dimethenamid-P_RAR_11_Volume_3CA_B-9
2) For summary and evaluation of the study please refer to dimethenamid-P_RAR_08_Volume_3CA_B-6.
3) Daily Dose [mg/kg b.w./d] calculated based on study data for food consumption and body weight.
4) Endpoint from EFSA Scientific Report (2005) 53, 1-73, Conclusion on the peer review of dimethenamid.

B.9.2.1 Risk for birds and mammals from dietary exposure

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

The calculation of Tier-1 TER values for dietary exposure for acute and for long-term/reproductive toxicity is documented in Table B.9.2-2 for birds and Table B.9.2-3 for mammals.

B.9.2.1.1 First-tier assessment (screening/generic focal species)

No studies were submitted with the formulation BAS 830 01 H. Therefore, additionally to calculating the risk of the active substance dimethenamid-P, a calculational approach was performed to address the possible combined action of the active substances on non-target organisms.

According to EFSA/2009/1438, Appendix B mixture toxicity needs to be considered for the risk assessment unless one active substance can be identified that drives the risk. Therefore, 'tox per fractions' quotients should be derived for each active substance of the mixture, and should be compared with the surrogate LD_{50} of the mixture. If the "tox per fraction of one of the active substances" and surrogate LD_{50} ("tox per fraction (mix)") deviates by ≤ 10 %, this indicates that this

active substance will contribute to ≥ 90 % to the toxicity of the mixture, while the other components of the mixture will only have a marginal impact on the predicted risk. Consequently, in such cases the risk assessment could be performed for the most toxic active substance alone and no mixture toxicity risk assessment is necessary.

Table B.9.2-2: Calculation of surrogate LD_{50} values for acute dietary risk assessment based on acute endpoints of active substances

Active substance	**LD_{50} [mg a.s./kg .w.]**	**Fraction of a.s. in product: X (a.s.$_i$)**	**X (a.s.$_i$)/$LD_{50\ i}$**	**Sum[1)]**	**Surrogate LD_{50} [2)] [mg a.s./kg b.w.]**
Birds					
Dimethenamid-P	1068	0.67	0.00062	0.00079	1264.9
Quinmerac	2000	0.33	0.00017		
Mammals					
Dimethenamid-P	466	0.67	0.00143	0.0015	668.5
Quinmerac	>5000	0.33	0.00007		

[1)] $\sum$ (X (a.s.$_i$)/$LD_{50\ i}$)
[2)] $LD_{50\ (mix)}$ (= surrogate LD_{50}) = 1/($\sum$ X (a.s.$_i$)/$LD_{50\ of\ a.s.}$)

For the avian acute endpoint, the surrogate LD_{50}, or LD_{50} (mix), for the mixture of active substances in BAS 830 01 H is 1264.9 mg a.s./kg bw As discribed in EFSA/2009/1438 Appendix B the 'tox per fractions' quotients ($\sum LD_{50\ i}$/ (X (as_i)) were derived for each active substance of the mixture, and compared with the corresponding quotient of the mixture (tox per fraction(mix) = $LD_{50\ (mix)}$ /$\sum$ X (as_i)).

The 'tox per fraction' for quinmerac deviates by 379 % to the 'tox per fraction' of the mixture. In contrast, the 'tox per fraction' for dimethenamid-P deviates by 26 % to the 'tox per fraction' of the mixture. Hence, a mixture toxicity assessment is necessary for acute risk for birds.

For the mammalian acute endpoint, the surrogate LD_{50}, or LD_{50} (mix), for the mixture of active substances in BAS 830 01 H is 668.5 mg a.s./kg bw. The 'tox per fraction' for quinmerac deviates by 2166 % to the 'tox per fraction' of the mixture. In contrast, the 'tox per fraction' for dimethenamid-P deviates only by 4 % to the 'tox per fraction' of the mixture. Following EFSA/2009/1438, this indicates that quinmerac will only have a marginal impact on the predicted risk while dimethenamid-P will contribute to more than 90 % to the toxicity of the mixture. Hence, dimethenamid-P is driving the acute risk and no additional mixture toxicity assessment is necessary to adress the acute risk for mammals.

For the long-term risk assessment of the formulation TER-mix was calculated.

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table B.9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of BAS 830 01 H in winter oilseed rape

Intended use	**1, 2**				
Active substance/product	**BAS 830 01 H**				
Application rate (g/ha)	**1 x 500** [1)] **1 x 250** [2)]				
Acute toxicity (mg/kg bw)	a) LD_{50} = 1068 b) LD_{50} > 2000 [1)] LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$ = 1265				
TER criterion	10				
Crop scenario Growth stage	**generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH 00-09	Small granivorous bird "finch"	24.7	1	a) 12.35 b) 6.2	a) 86.5 b) 323
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				68.3
Bare soil BBCH 00-09	Small omnivorous bird "lark"	17.4	1	a) 8.7 b) 4.35	a) 123 b) 460
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				96.9
Bare soil BBCH 00-09	Small insectivorous bird "wagtail"	10.9	1	a) 5.45 b) 2.73	a) 196 b) 733
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				155
Oilseed rape BBCH 10-18 (shoots)	Large herbivorous bird "goose"	39.0	1	a) 19.5 b) 9.75	a) 54.8 b) 205
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				43.2
Oilseed rape BBCH 10-18	Small omnivorous bird "lark"	24.0	1	a) 12 b) 6	a) 89.0 b) 333
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				70.3
Oilseed rape BBCH 10-18	Medium herbivorous/granivorous bird "pigeon"	55.6	1	a) 27.8 b) 13.9	a) 38.4 b) 144
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				30.3
Oilseed rape BBCH 10-18	Small insectivorous bird "wagtail"	10.9	1	a) 5.45 b) 2.73	a) 196 b) 734
	LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$				154.7
Reprod. toxicity (mg/kg bw/d)	**a) LD_{50} / 10 = 106.8 b) 173**				
TER criterion	**5**				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soil BBCH 00-09	Small granivorous bird "finch"	11.4	0.53	a) 3.02 b) 1.51	a) 35.4 b) 115
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				27.1
Bare soil BBCH 00-09	Small insectivorous bird "wagtail"	5.9	0.53	a) 1.56 b) 0.78	a) 68.5 b) 222
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				52.3

Intended use	**1, 2**
Active substance/product	**BAS 830 01 H**
Application rate (g/ha)	**1 x 500** [1)] **1 x 250** [2)]
Acute toxicity (mg/kg bw)	a) LD_{50} = 1068 b) LD_{50} > 2000 [1)] LD_{50} (mix) = $[\sum(X\ (as_i)/\ LD_{50(as\ i)})]^{-1}$ = 1265
TER criterion	10

Crop scenario Growth stage	**generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH 00-09	Small omnivorous bird “lark”	8.2	0.53	a) 2.17 b) 1.09	a) 49.2 b) 159
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				37.6
Oilseed rape BBCH 10-18 (shoots)	Large herbivorous bird "goose"	15.9	0.53	a) 4.21 b) 2.11	a) 25.4 b) 82.1
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				19.4
Oilseed rape BBCH 10-18	Small omnivorous bird “lark”	10.9	0.53	a) 2.89 b) 1.44	a) 37.0 b) 120
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				28.3
Oilseed rape BBCH 10-18	Medium herbivorous/granivorous bird "pigeon"	22.7	0.53	a) 6.02 b) 3.01	a) 17.7 b) 57.5
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				13.5
Oilseed rape BBCH 10-18	Small insectivorous bird “wagtail”	5.9	0.53	a) 1.56 b) 0.78	a) 68.5 b) 221
	TER(mix) = $[\sum(1/TER_i)]^{-1}$				52.3

TER values shown **in bold** fall below the relevant trigger.

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

a) Active substance dimethenamid-P

b) Active substance quinmerac

[1)] EFSA conclusion on quinmerac, EFSA Journal 2010; 8(3):1523)

Table B.9.2-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of BAS 830 01 H in winter oilseed rape

Intended use	**1, 2**				
Active substance/product	**BAS 830 01 H**				
Application rate (g/ha)	**1 x 500** [1)] **1 x 250** [2)]				
Acute toxicity (mg/kg bw)	a) LD_{50} = 466 (sexes combined) b) LD_{50} > 5000 [1)]				
TER criterion	10				
Crop scenario Growth stage	**Generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Bare soil BBCH 00-09	Small omnivorous mammal “mouse”	14.3	1	a) 7.15 b) 3.58	a) 65 b)1399
Oilseed rape BBCH 10-19	Small insectivorous mammal “shrew”	7.6	1	a) 3.8 b) 1.9	a) 122 b) 2632
Oilseed rape (all season)	Large herbivorous mammal "largomorph"	35.1	1	a) 17.6 b) 8.78	a) 26.6 b) 570
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse”	17.2	1	a) 8.6 b) 4.3	a) 54.2 b) 1163
Reprod. toxicity (mg/kg bw/d)	a) NOAEL = 33.3 b) 100 (rabbit)				
TER criterion	5				
Crop scenario Growth stage	**Generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Bare soil BBCH 00-09	Small omnivorous mammal “mouse”	5.7	0.53	a) 1.51 b) 0.76	a) 22 b) 132
	TER(mix) = $[\sum(1/TERi)]^{-1}$				18.9
Oilseed rape BBCH 10-19	Small insectivorous mammal “shrew”	4.2	0.53	a) 1.11 b) 0.56	a) 29.9 b) 179
	TER(mix) = $[\sum(1/TERi)]^{-1}$				25.6
Oilseed rape (all season)	Large herbivorous mammal "largomorph"	14.3	0.53	a) 3.79 b) 1.89	a) 8.79 b) 52.9
	TER(mix) = $[\sum(1/TERi)]^{-1}$				7.54
Oilseed rape BBCH 10-29	Small omnivorous mammal “mouse”	7.8	0.53	a) 2.07 b) 1.03	a) 16.1 b) 79.1
	TER(mix) = $[\sum(1/TERi)]^{-1}$				13.4

TER values shown **in bold** fall below the relevant trigger.
SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
a) Active substance dimethenamid-P
b) Active substance quinmerac
[1)] EFSA conclusion on quinmerac, EFSA Journal 2010; 8(3):1523)

For avian and mammalian acute and long-term risk assessment TER values are above the relevant trigger value. To address the toxicity of the formulation, TER values based on calculated $LD_{50\ mix}$ were calculated for acute avian risk assessment and TER_{mix} for the long-term risk assessment for birds and mammals as a worst-case approach.

B.9.2.2 Risk for birds and mammals from exposure to contaminated drinking water

In addition to their diet, birds and mammals may also be exposed to dimethenamid-P via drinking water. Only the scenario of puddles formed on soil needs to be considered in this case. As pointed out in the EFSA Guidance document, specific calculations of exposure and TER values are only necessary when the ratio of effective application rate (in g as/ha) to relevant endpoint (in mg as/kg bw/d) exceeds 50 in the case of less sorptive (K_{OC} < 500 L/kg) or 3000 in the case of more sorptive (K_{OC} ≥ 500 L/kg) substances. For dimethenamid-P, the Koc is 227 L/kg. The ratio of highest application rate (500 g as/ha) to lowest relevant avian endpoint (LD_{50}/10 = 106.8 mg as/kg bw/d) is 4.6; therefore, the risk for birds can be considered acceptable without the need for further calculations. The ratio of highest application rate (500 g as/ha) to lowest relevant mammalian endpoint (NOEL = 33.3 mg as/kg bw/d) is 15; therefore, the risk for mammals can be considered acceptable without the need for further calculations.

B.9.2.3 Risk assessment for metabolites

Plant material may serve as potential food item for herbivorous/granivorous birds and mammals. Several metabolites of dimethenamid-P have been detected in plant metabolism studies.

The metabolites M27 (sulfonate) and M30 (sulfoxide of thioactic acid) were found in edible crop parts up to 7.4 % and 17.9 % of parent level. Both metabolites also occurred in laying hens, rats and mice.

Since mammalian testing does not indicate that they are more toxic than the parent, it can be concluded that the risk to mammals will be covered by the parent compound and no further quantitative risk assessment is conducted.

B.9.2.4 Bioaccumulation and food chain behaviour for birds and mammals

According to the EFSA Guidance Document, substances with a log P_{OW} ≥ 3 are likely to possess a potential for bioaccumulation that might result in unacceptable risks for organisms at higher trophic levels. Hence, a specific risk assessment ('secondary poisoning') must be performed for these substances. The log P_{OW} for dimethenamid-P and quinmerac is 1.89 and - 1.41, respectively. Therefore, an assessment of the potential risk of secondary poisoning is not triggered and due to the low lipophilicity no risk of bioaccumulation is assumed.

B.9.2.5 Overall conclusions

Dietary risk assessment

TER values for birds were calculated, taking into account the relevant toxicity data for dimethenamid-P and calculated exposure levels for dietary exposure, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. To assess the toxicity of the formulation, the risk based on mixture toxicity was calculated for the formulation BAS 830 01 H. The calculated TER values do achieve the acceptability criterion TER ≥ 10 for acute effects as well as the acceptability criterion TER ≥ 5 for long-term/reproductive effects, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1. The results of the assessment indicate an acceptable risk for birds due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

TER values mammals were calculated, taking into account the relevant toxicity data for dimethenamid-P and calculated exposure levels for dietary exposure, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. To assess the toxicity of the formulation, the risk based on mixture toxicity was calculated for the formulation BAS 830 01 H. The calculated TER values do achieve the acceptability criterion TER ≥ 10 for acute effects as well as the acceptability criterion TER ≥ 5 for long-term/reproductive effects, according to Commission Regulation (EU) No

546/2011, Annex, Part I C, point 2.5.2.1. The results of the assessment indicate an acceptable risk for mammals due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

Risk assessment for exposure via drinking water

The ratio of highest application rate to lowest relevant endpoint for birds and mammals were calculated, taking into account the relevant toxicity data for dimethenamid-P and calculated exposure levels for exposure via drinking water, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. The calculated ratios are below the trigger of 50 for less sorptive (KOC < 500 L/kg) substances. The results of the assessment indicate an acceptable risk for birds and mammals due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

Risk assessment for exposure via secondary poisoning

The log P_{OW} for dimethenamid-P and quinmerac is 1.89 and - 1.41, respectively. Therefore an assessment of the potential risk of secondary poisoning is not triggered and due to the low lipophilicity no risk of bioaccumulation is assumed.

B.9.3 Effects on aquatic organisms

B.9.3.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

KCP 10.2.1/1 (new study, submitted with renewal dossier)

Author: [redacted]
Title: BAS 830 01 H: Toxicity to the rainbow trout *Oncorhynchus mykiss* under laboratory conditions (acute toxicity test - static)
Date: 07.10.2013
Doc ID: 2013/1168360
Guidelines: OECD 203 (1992)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008; content of a.s.: dimethenamid-P (BAS 656 H, Reg. no. 363 851): 347.7 g/L (nominal: 333.0 g/L); quinmerac (BAS 518 H, Reg.no. 168 526): 173.0 g/L (nominal: 167.0 g/L); density: 1.135 g/cm³.

Test species: Rainbow trout (*Oncorhynchus mykiss*); mean body length 4.3 cm (4.0 - 5.4 cm); mean body weight 0.72 g (0.49 - 1.42 g); supplied by Forellenzucht am Kocherursprung, Oberkochen, Germany.

Test design: Static system (96 hours); 10 fish per aquarium (loading 0.48 g fish/L) and per concentration; assessment of mortality and symptoms of toxicity 0, 3, 6, 24, 48, 72 and 96 hours after start of exposure.

Endpoints: LC_{50}, NOEC, mortality and sub-lethal effects.

Test concentrations: 0 (control), 6.0, 8.8, 13.0, 19.0 and 28.0 mg BAS 830 01 H/L (nominal).

Test conditions: 25 L glass aquaria, test volume: 15 L, non-chlorinated tap water and deionised water; temperature: 15.6 - 16.5 °C; pH 8.20 - 8.37; oxygen saturation: 94 % - 102 %; total hardness: about 161 mg $CaCO_3$/L; photoperiod: 16 h light: 8 h dark; continuous aeration; no feeding.

Analytics: Analytical verification of the test item was conducted using an HPLC-method with MS/MS-detection.

Statistics: Descriptive statistics; Spearman-Kärber method for calculation of LC_{50}.

Results and Discussion

Analytical measurements: Analytical verification of test item concentrations was conducted in each concentration at the beginning and at the end of the test. The analysed contents of dimethenamid-P ranged from 98 % to 110 % of nominal at test initiation and from 93 % to 103 % of nominal at test termination. Measured concentrations of quinmerac were between 97 % and 108 % of the nominal concentrations in samples taken at test initiation and between 90 % and 102 % of nominal at test termination. As measured concentrations confirmed the correct application of the test item, the following biological results are based on nominal concentrations.

Biological results: After 96 hours of exposure no mortality was observed in the control and at test item concentrations up to and including 13.0 mg BAS 830 01 H/L, whereas 40 % mortality occurred at 19.0 mg/L. At the highest test item concentration of 28.0 mg/L all fish were found dead after 96 h. No sublethal effects were observed for surviving fish in the control and at test item concentrations up to and including 13.0 mg/L. After 96 hours of exposure, some fish showed reduced activity and dark pigmentation in the 19.0 mg/L test item treatment. The results are summarised in Table B.9.3-1:

Table B.9.3-1: Acute toxicity (96 h) of BAS 830 01 H on rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L] (nominal)	**Control**	**6.0**	**8.8**	**13.0**	**19.0**	**28.0**
Mortality [%]	0	0	0	0	40	100
Symptoms *	none	none	none	none	A, P	n.d.
Endpoints [mg BAS 830 01 H /L] (nominal)						
LC_{50} (96 h)	19.8 (95 % confidence limits: 17.5 - 22.4)					
NOEC (96 h)	13.0					

n.d. = not determined; all fish dead
* Symptoms after 96 h: A = reduced activity, P = dark pigmentation

Conclusions

In a static acute toxicity study with rainbow trout the LC_{50} (96 h) of BAS 830 01 H was 19.8 mg/L based on nominal concentrations. The NOEC (96 h) was determined to be 13.0 mg/L (nominal).

KCP 10.2.1/2 (new study, submitted with renewal dossier)

Author: Zawadsky, C.
Title: BAS 830 01 H: Toxicity to the Water Flea *Daphnia magna* STRAUS under laboratory conditions (acute immobilisation test - static)
Date: 08.08.2013
Doc ID: 2013/1168361
Guidelines: OECD 202 (2004)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008; content of a.s.: dimethenamid-P (BAS 656 H, Reg. no. 363 851): 347.7 g/L (nominal: 333.0 g/L); quinmerac (BAS 518 H, Reg.no. 168 526): 173.0 g/L (nominal: 167.0 g/L); density: 1.135 g/cm³.

Test species: Water flea (*Daphnia magna* STRAUS), neonates collected from in-house culture (originally obtained from Umweltbundesamt, Berlin, Germany), less than 24 hours old at test initiation.

Test design: Static system (48 hours), 5 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility after 24 and 48 hours.

Endpoints: NOEC, EC_{50} based on immobility of daphnids.

Test concentrations: Control, 9.53, 17.1, 30.9, 55.6 and 100 mg BAS 830 01 H/L (nominal).

Test conditions: 100 mL glass beakers, test volume 50 mL, dilution water: "M4" (Elendt medium); pH 7.52 - 7.90; oxygen saturation: 86 % - 101 %; total hardness: 268 mg $CaCO_3$/L at test initiation; temperature: 18.5 °C - 21.2 °C; photoperiod: 16 h light : 8 h dark; light intensity: about 550 lux; no feeding, no aeration.

Analytics: Analytical verification of test item concentrations was conducted using an HPLC-method with MS/MS-detection.

Statistics: Descriptive statistics; probit analysis for determination of the EC_{50} values.

Results and Discussion

Analytical measurements: Analytical verification of test item concentrations was conducted in each concentration at the beginning and at the end of the test. The analysed contents of dimethenamid-P ranged from 96 % to 103 % of nominal at test initiation and from 91 % to 104 % of nominal at test termination. Measured concentrations of quinmerac were between 93 % and 98 % of the nominal concentrations in samples taken at test initiation and between 91 % and 96 % of nominal at test termination. As measured concentrations confirmed the correct application of the test item, the following biological results are based on nominal concentrations.

Biological results: After 48 hours of exposure, no immobility of the daphnids was observed in the control and at concentrations of up to and including 30.9 mg BAS 830 01 H/L, whereas 5 % and 100 % mortality was observed at the two highest test item concentrations of 55.6 and 100 mg/L, respectively. No other sublethal effects were observed during the test. For results see Table B.9.3-2.

Table B.9.3-2: Effects of BAS 830 01 H on *Daphnia magna* immobility

Concentration [mg/L] (nominal)	**Control**	**9.53**	**17.1**	**30.9**	**55.6**	**100**
Immobility (24 h) [%]	0	0	0	0	0	40
Immobility (48 h) [%]	0	0	0	0	5	100
Endpoints [mg BAS 830 01 H/L] (nominal)						
EC_{50} (48 h)	58.7 (95 % confidence limits: 57.8 - 59.7)					
NOEC (48 h)	55.6					

Conclusions

In a 48-hour static acute toxicity study with *Daphnia magna* the EC_{50} of BAS 830 01 H was 58.7 mg/L based on nominal concentrations. The NOEC was determined to be 55.6 mg/L (nominal).

KCP 10.2.1/3 (new study, submitted with renewal dossier)

Author: Backfisch, K.
Title: Effect of BAS 830 01 H on the growth of the green alga *Pseudokirchneriella subcapitata*
Date: 17.10.2013
Doc ID: 2013/1311299
Guidelines: OECD 201, EPA 850.5400
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008; content of a.s.: dimethenamid-P (BAS 656 H, Reg. no. 363 851): 347.7 g/L (nominal: 333.0 g/L); quinmerac (BAS 518 H, Reg.no. 168 526): 173.0 g/L (nominal: 167.0 g/L); density: 1.135 g/cm³

Test species: Unicellular fresh water green alga, *Pseudokirchneriella subcapitata* (Reinsch) Korshikov (syn. *Selenastrum capricornutum* Prinz), SAG 61.81; stock obtained from the "Sammlung von Algenkulturen" Göttingen, Germany

Test design: Static system; test duration 72 hours; 6 test concentrations, each with 5 replicates per treatment plus a control with 10 replicates; daily assessment of growth

Endpoints: EC_{10} and EC_{50} with respect to growth rate and yield after exposure over 72 hours

Test concentrations: 0 (control), 0.01, 0.02, 0.04, 0.08, 0.16 and 0.32 mg BAS 830 01 H/L (nominal)

Test conditions: 100 mL Erlenmeyer dimple flasks; test volume 60 mL; pH 8.1 at test initiation, pH 7.48 - 7.75 at test termination; temperature: 22 ± 1 °C; initial cell densities 1 x 10^4 cells/mL; continuous light at about 8000 lux; continuous shaking

Analytics: Analytical verification of the test item was conducted using an HPLC-method with MS-detection.

Statistics: Descriptive statistics; probit analysis for determination of EC_x values for growth rate and yield

Results and Discussion

Analytical measurements: Analytical verification of test item concentrations was conducted in each concentration at the beginning and at the end of the test. Measured values at test initiation were between 81 % and 92 % of nominal for dimethenamid-P and between 98 % and 107 % of nominal for quinmerac. At test termination analysed contents ranged from 63 % to 97 % of nominal for dimethenamid-P and from 100 % to 109 % for quinmerac. As the initially measured concentrations confirmed the correct application of the test item, the following biological results are based on nominal concentrations.

Biological results: No morphological effects on algae were observed in the control group and at any of the test item concentrations. The effects on algal growth rate and yield are summarised in Table B.9.3-3.

Table B.9.3-3: Effect of BAS 830 01 H on the growth of green alga *P. subcapitata*

Concentration [mg/L] (nominal)	**Control**	**0.01**	**0.02**	**0.04**	**0.08**	**0.16**	**0.32**
Inhibition in 72 h (growth rate) [%]	--	0.4	0.4	1.6	25.2	56.5	66.6
Inhibition in 72 h (yield) [%]	--	1.5	1.3	7.6	71.3	94.0	96.9
Endpoints [mg BAS 830 01 H/L] (nominal)							
E_rC_{50} (72 h)	0.1661 (95 % confidence limits: 0.1507 - 0.1842)						
E_rC_{10} (72 h)	0.0429 (95 % confidence limits: 0.0336 - 0.0517)						
E_yC_{50} (72 h)	0.0656 (95 % confidence limits: 0.0619 - 0.0691)						
E_yC_{10} (72 h)	0.0411 (95 % confidence limits: 0.0356 - 0.0455)						

Conclusions

In a 72-hour algae test with *Pseudokirchneriella subcapitata* the E_rC_{50} for BAS 830 01 H was determined to be 0.1661 mg/L, the E_yC_{50} was 0.0656 mg/L based on nominal concentrations.

KCP 10.2.1/4 (new study, submitted with renewal dossier)

Author: Turek, T.
Title: BAS 830 01 H - Lemna gibba CPCC 310 growth inhibition test
Date: 14.10.2013
Doc ID: 2013/1250860
Guidelines: OECD (221)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008; content of a.s.: dimethenamid-P (BAS 656 H, Reg. no. 363 851): 347.7 g/L (nominal: 333.0 g/L); quinmerac (BAS 518 H, Reg.no. 168 526): 173.0 g/L (nominal: 167.0 g/L); density: 1.135 g/cm³.

Test species: Duckweed (*Lemna gibba* CPCC 310), inocula 7 days old cultures; cultures maintained in-house (Institute of Industrial Organic Chemistry, Branch Pszczyna); stock obtained from Canadian Phycological Culture Centre, Department of Biology, University of Waterloo, Canada.

Test design: Static system (7 days); 7 treatment groups (6 test item concentrations, control) with 3 replicates for the test item treatments and 6 replicates for the control; 3 plants with 3 fronds, total number of fronds at test initiation: 9 per replicate; assessment of growth and other effects on days 3, 5 and 7. The dry weight of a representative sample of the duckweed culture used as the inoculum was determined at the exposure initiation.

Endpoints: EC_x and NOEC with respect to growth rate and yield after exposure over 7 days

Test concentrations: 0 (control), 0.0033, 0.01, 0.03, 0.09, 0.27 and 0.81 mg BAS 830 01 H/L (nominal)

Test conditions:	600 mL glass beakers, test volume 400 mL, 20x-AAP nutrient medium, pH 7.58 - 7.77 at test initiation and pH 9.28 – 9.43 at test termination; water temperature: 23.3 °C - 24.5 °C, continuous light, light intensity: 8285 - 9173 lux
Analytics:	Analytical verification of the test item was conducted using a liquid chromatographic method with DAD.
Statistics:	Descriptive statistics; probit method for determination of the EC_x values, Williams Multiple Sequential t-test for determination of the NOEC values

Results and Discussion

Analytical measurements: Analytical verification of test item concentrations was conducted in each test concentration except for the lowest concentration of 0.00333 mg/L (which is below the limit of quantification (LoQ)) at the beginning and at the end of the test. Measured contents of dimethenamid-P were between 96.97 % and 103.41 % of nominal at test initiation and between 98.11 % and 104.17 % of nominal at test termination. The analysed contents of quinmerac ranged from 96.76 % to 101.22 % of nominal at test initiation and from 97.73 % to 101.46 % of nominal at test termination. As the analytical data confirmed the correct application of the test item, the following biological results are based on nominal concentrations.

Biological results: The duckweed population in the control vessels showed sufficient growth, increasing from 9 fronds per vessel to an average of 65.2 fronds per vessel, corresponding to a 7.2 x multiplication. The dry weight increased to an average of 15.5 mg per vessel in the control at test termination. Statistically significant (inhibitory) effects on the growth of *Lemna gibba* compared to the control were observed at all tested concentration after exposure over 7 d based on growth rate related to frond numbers and based on yield related to frond numbers and dry weight (Williams Multiple Sequential t-test, $\alpha = 0.05$). Based on growth rate related to dry weight, statistically significant differences in plant growth compared to the control were detected at 0.010 mg/L and at all higher concentrations. No morphological changes were observed for the plants in controls and at the test item concentrations of up to and including 0.03 mg/L over the whole study duration. At the three highest tested concentrations of 0.09, 0.27 and 0.81 mg/L, symptoms like overlapping fronds, bending colonies, and smaller fronds with spots of chlorosis or necrosis were observed. The number of spots was increased with the test concentrations. Effects on growth rate and yield are summarised in Table B.9.3-4.

Table B.9.3-4: Effect of BAS 830 01 H on the growth of duckweed *Lemna gibba*

Concentration [mg/L] (nominal)	**0.0033**	**0.01**	**0.03**	**0.09**	**0.27**	**0.81**
Inhibition after 7 d [%] (growth rate based on frond no.)	5.85 *	12.74 *	17.21 *	30.48 *	42.69 *	52.80 *
Inhibition after 7 d [%] (yield based on frond no.)	12.76 *	25.82 *	33.53 *	52.52 *	66.17 *	75.07 *
Inhibition after 7 d [%] (growth rate based on dry weight)	5.23	17.06 *	20.54 *	27.76 *	31.74 *	39.60 *
Inhibition after 7 d [%] (yield based on dry weight)	11.89 *	33.79 *	39.10 *	49.63 *	54.84 *	63.69 *
	Endpoints [mg BAS 830 01 H/L] (nominal)					
E_rC_{50} (7 d) based on frond no.	0.573 (95 % confidence limits: 0.443 - 0.780)					
E_rC_{10} (7 d) based on frond no.	0.0073 (95 % confidence limits: 0.0043 - 0.0111)					
E_yC_{50} (7 d) based on frond no.	0.0863 (95 % confidence limits: 0.0673 - 0.112)					
E_yC_{10} (7 d) based on frond no.	0.0018 (95 % confidence limits: 0.0009 - 0.0031)					
NOE_rC / NOE_yC (7 d) based on frond no.	≤ 0.0033					
E_rC_{50} (7 d) based on dry weight	n.d. (> 0.810)					
E_rC_{10} (7 d) based on dry weight	0.0032 (95 % confidence limits: 0.0003 - 0.0010)					
E_yC_{50} (7 d) based on dry weight	0.1302 (95 % confidence limits: 0.0598 - 0.388)					
E_yC_{10} (7 d) based on dry weight	n.d. (< 0.0033)					
NOE_rC (7 d) based on dry weight.	0.0033					
NOE_yC (7 d) based on dry weight.	≤ 0.0033					

n.d. = not determined

* Statistically significant differences in growth rate / yield data compared to the control (Williams Multiple Sequential t-test, $\alpha = 0.05$).

Conclusions

In a 7-day aquatic plant test with *Lemna gibba* the E_rC_{50} of BAS 830 01 H was determined to be 0.573 mg/L based on frond number and > 0.810 mg/L based on dry weight (nominal). The E_yC_{50} of BAS 830 01 H was determined to be 0.0863 mg/L based on frond number and 0.130 mg/L based on dry weight (nominal). The overall NOEC was ≤ 0.0033 mg BAS 830 01 H /L (nominal).

B.9.3.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Marine or estuarine organisms

Studies on marine or estuarine species are not required according to the relevant EU documents and no studies have been conducted with the formulation BAS 830 01 H on marine or estuarine organisms. The contamination of estuarine and marine environments is considered to be minimal compared to freshwater habitats adjacent to agricultural land according to the use pattern, the potential route of contamination and the dissipation of the active substances. Thus, the risk to those habitats is covered by the risk assessment for freshwater ecosystems.

Marine sediment invertebrates

Studies on marine or estuarine species are not required according to the relevant EU documents and no studies have been conducted with the formulation BAS 830 01 H on marine or estuarine organisms. The contamination of estuarine and marine environments is considered to be minimal compared to

freshwater habitats adjacent to agricultural land according to the use pattern, the potential route of contamination and the dissipation of the active substances. Thus, the risk to those habitats is covered by the risk assessment for freshwater ecosystems.

Microcosm or mesocosm study

No microcosm or mesocosm study has been performed with the formulated product BAS 830 01 H or dimethenamid-P, since the data available are sufficient for risk assessment.

Residue data in fish

The log P_{OW} of the active substance dimethenamid-P was determined to be < 2 (BASF DocID 1998/5071). Hence, the accumulation potential of dimethenamid-P in aquatic organisms is considered to be low.

Thus, residues of dimethenamid-P in fish are of no concern and no accumulation in the food chain is to be expected.

Chronic toxicity to fish and aquatic invertebrates

The results obtained in the acute study on *O. mykiss* and *D. magna* with the formulated product BAS 830 01 H are in good agreement with the results expected from the data with the active substances dimethenamid-P and quinmerac (see above). Furthermore, the results obtained with the formulated product are in good agreement with the results expected from the data with the active substance dimethenamid-P, which basically determines the toxicity of the product to aquatic organisms whereas quinmerac contributes only minor to the overall toxicity of the product. This demonstrates that the formulation does not cause significant unexpected (additional) toxicity to fish and daphnids. Therefore, the studies conducted with the active substances can be used to assess the chronic risk resulting from BAS 830 01 H applications according to the proposed uses. No further testing with the product is indicated.

Accumulation in aquatic non-target organisms

Bioaccumulation of the active substance dimethenamid-P under natural conditions is not expected to occur (see "Residue data in fish" above); additional studies are not required or necessary to determine bioaccumulation in aquatic non-target organisms.

B.9.3.3 Further testing on aquatic organisms

No further studies submitted.

B.9.4 Risk assessment for aquatic organisms

In Volume 1, section 2.9.2 an overview of the available toxicity endpoints for aquatic organisms is presented.

Toxicity exposure ratios

The following TER calculations were conducted based on application of BAS 830 01 H according to the proposed uses in winter oilseed rape. The initial risk assessments were carried out by comparing the PECsw values with the acute and long-term toxicity endpoints.

For evaluation of potential synergistic / antagonistic effects of the compounds in the formulation as well as for chronic cumulative toxicity calculations, the EU agreed endpoints for the second active substance quinmerac (BAS 656 H) are considered (see Draft Assessment Report (Vol. 3, Annex B.9,

August 2007) and EFSA Conclusion (8 (3):1523; 2010) of quinmerac).

The studies performed with the formulated product BAS 830 01 H indicate no significantly higher (or unexpected) toxicity than predicted based on the results of the active substances. Furthermore, the results obtained with the formulated product are in good agreement with the results expected from the data with the active substance dimethenamid-P, which basically determines the toxicity of the product to aquatic organisms whereas quinmerac contributes only minor to the overall toxicity of the product. Therefore, the risk assessment presented for the active substance dimethenamid-P also covers the risk to aquatic organisms following the proposed uses of BAS 830 01 H.
Nevertheless, to proof acceptable risk after application of the formulation, in the following additional TER calculations based on the results with the formulated product and the PECsw values resulting from drift entry were performed.

Although chronic exposure to different active substances at fixed and constant levels is highly unlikely, the respective chronic cumulative assessment for fish and *Daphnia* is provided in the following as no chronic studies were performed with the formulation for these groups of organisms. For algae and aquatic plants reference is made to the studies conducted with the formulation BAS 830 01 H and the respective TER calculations.

The following calculations of chronic mixture toxicity of the formulated product BAS 830 01 H have been conducted based on the model of concentration addition using the following equation:

$$\text{"Trigger}_A\text{"-value / TER}_A + \text{"Trigger}_B\text{"-value / TER}_B + \ldots = SUM$$

Where:"Trigger"-value represents the uncertainty factor of chemical A, B etc. according to the Commission regulation (EU) 546/2011. If SUM is below 1 the risk assessment is acceptable.

Respective calculations were conducted based on the worst-case FOCUS Step 2 PEC values for the active substances and the relevant chronic endpoints for fish and *Daphnia* and are presented below.

Cumulative assessment of BAS 830 01 H to fish
The chronic cumulative assessment of BAS 830 01 H to fish is based on the worst-case FOCUS Step 2 $PEC_{sw, max}$ values for the active substances (and the relevant chronic NOEC values for fish obtained in the studies with the active substances (see Table B.9.4-1 and the DAR (Vol. 3, Annex B.9, August 2007) and EFSA Conclusion (8 (3):1523; 2010) of quinmerac). For quinmerac, only one chronic fish study was performed, *i.e.* a 28-day standard chronic flow-through study on *O. mykiss.* In order to compare the results of same types of studies for the assessment of chronic, combined toxicity to fish, the endpoint obtained in the 21-day standard flow-through study with dimethenamid-P on *O. mykiss* (NOEC = 630 µg a.s./L; BASF DocID 1991/11906) is considered to be more appropriate than the 90-days NOEC obtained in the ELS study and is thus, used in the following assessment.

Table B.9.4-1: Cumulative assessment of the chronic mixture toxicity of BAS 830 01 H to fish using worst-case FOCUS Step 2 $PEC_{sw, max}$ values for dimethenamid-P and quinmerac

Organism	Test substance	NOEC [µg/L]	FOCUS Step (FOCUS scenarios)	$PEC_{sw, max}$ [µg/L]	TER_{LT}	Trigger value	Ratio (Trigger value/ TER)
pre-emergence application							
O. mykiss	dimethenamid-P	630	Step 2 (EU North)	56.949	11	10	0.909
	quinmerac	3160	Step 2 (EU South) #	21.15	149	10	0.067
	SUM						0.976
post-emergence application							
O. mykiss	dimethenamid-P	630	Step 2 (EU North)	35.628	18	10	0.556
	quinmerac	3160	Step 2 (EU South) #	21.15	149	10	0.067
	SUM						0.623

PEC values for quinmerac have been calculated for pre-emergence application only, also covering post-emergence application.

The calculated SUM values for the chronic toxicity of the formulated product BAS 830 01 H to fish are below the required trigger of 1 based on FOCUS Step 2 PEC values, demonstrating low chronic combined toxicity to fish following the proposed uses of BAS 830 01 H in winter oilseed rape with no need for additional mitigation measures.

Cumulative assessment of BAS 830 01 H to *Daphnia*

The chronic cumulative assessment of BAS 830 01 H to aquatic invertebrates is based on the worst-case FOCUS Step 2 $PEC_{sw, max}$ values for the active substances and the relevant chronic NOEC values for *D. magna* obtained in the studies with the active substances (see table below). For toxicity data for quinmerac reference is made to the DAR (Vol. 3, Annex B.9, August 2007) and the EFSA Conclusion (8 (3):1523; 2010) of quinmerac.

Table B.9.4-2: Cumulative assessment of the chronic mixture toxicity of BAS 830 01 H to aquatic invertebrates using worst-case FOCUS Step 2 $PEC_{sw, max}$ values for dimethenamid-P and quinmerac

Organism	Test substance	NOEC [µg/L]	FOCUS Step (FOCUS scenarios)	$PEC_{sw, max}$ [µg/L]	TER_{LT}	Trigger value	Ratio (Trigger value/ TER)
pre-emergence application							
D. magna	dimethenamid-P	680	Step 2 (EU North)	56.949	12	10	0.833
	quinmerac	100000	Step 2 (EU South) #	21.15	4728	10	0.0021
	SUM						0.835
post-emergence application							
D. magna	dimethenamid-P	680	Step 2 (EU North)	35.628	19	10	0.526
	quinmerac	100000	Step 2 (EU South) #	21.15	4728	10	0.0021
	SUM						0.528

PEC values for quinmerac have been calculated for pre-emergence application only, also covering post-emergence application

The calculated SUM values for the chronic toxicity of the formulated product BAS 830 01 H to *D. magna* are below the required trigger of 1 based on FOCUS Step 2 PEC values, demonstrating low

chronic combined toxicity to aquatic invertebrates with no need for additional mitigation measures for the proposed uses of BAS 830 01 H in winter oilseed rape.

B.9.4.1 Lower tier acute and chronic risk assessment

The acute and chronic TER values calculated by the RMS are presented in the tables below

Table B.9.4-3: Maximum PEC_{SW} values (FOCUS Step 1 and 2) and TER values for dimethenamid-P following one application of BAS 830 01 H in winter oilseed rape

Scenario FOCUS	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
Step 1							
	140.85	18.46	0.85	22.72	4.83	**0.05**	**0.04**
Step 2 *							
N. Europe	56.95	45.65	2.11	56.19	11.94	**0.12**	**0.11**
S. Europe	46.29	56.17	2.59	69.13	14.69	**0.14**	**0.13**
Step 2 +							
N. Europe	35.63	72.97	3.37	89.81	19.09	**0.19**	**0.17**
S. Europe	29.23	88.95	4.11	109.48	23.26	**0.23**	**0.20**
TER criterion		100	10	100	10	10	10

TERs shown in **bold** fall below the relevant trigger
* based on a single application in pre-emergence winter oilseed rape (worst case application during Oct-Feb)
+ based on a single application in post-emergence winter oilseed rape (worst case application during Oct-Feb)

The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger value of 10 and 100 based on FOCUS Step 1 and 2 calculations for application in winter oilseed rape, indicating high aquatic risk. Therefore, additional TER calculations considering more realistic Step 3 PEC_{sw} values are presented in the Tables below.

Table B.9.4-4: Maximum PEC_{SW} values (FOCUS Step 3) and TER values for dimethenamid-P following pre- and post-emergence application in winter oilseed rape (OSR)

Scenario FOCUS	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
Step 3, pre-emergence OSR							
D2/ditch	8.318	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.206	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	3.191	814.79	37.61	1002.82	213.10	**2.07**	**1.88**
D4/pond	0.427	6088.99	281.03	7494.15	1592.51	15.46	14.03
D4/stream	2.743	947.87	43.75	1166.61	247.90	**2.41**	**2.18**
D5/pond	0.207	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	2.959	878.68	40.55	1081.45	229.81	**2.23**	**2.02**
R1/pond	0.122	21311.48	983.61	26229.51	5573.77	54.10	49.10
R1/stream	2.096	1240.46	57.25	1526.72	324.43	**3.15**	**2.86**
R3/stream	6.044	430.18	19.85	529.45	112.51	**1.09**	**0.99**
Step 3, post-emergence OSR							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**
D3/ditch	3.181	817.35	37.72	1005.97	213.77	**2.07**	**1.88**
D4/pond	0.787	3303.68	152.48	4066.07	864.04	**8.39**	**7.61**
D4/stream	2.747	946.49	43.68	1164.91	247.54	**2.40**	**2.18**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	2.96	878.38	40.54	1081.08	229.73	**2.23**	**2.02**
R1/pond	0.136	19117.65	882.35	23529.41	5000.00	48.53	44.04
R1/stream	2.096	1240.46	57.25	1526.72	324.43	**3.15**	**2.86**
R3/stream	11.18	232.56	10.73	286.23	60.82	**0.59**	**0.54**
TER criterion		100	10	100	10	10	10

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

Based on FOCUS Step 3, an acceptable risk has been demonstrated for 3 out of 10 FOCUS scenarios in the pre-emergence oilseed rape (OSR) use (D4/pond, D5/pond and R1/pond), whereas only 2 FOCUS scenarios are indicating low risk in the post-emergence OSR use (D5/pond and R1/pond).
The TER values for dimethenamid-P do not exceed the Commission regulation (EU) 546/2011 trigger value of 10 and 100 based on FOCUS Step 1 and 2 calculations for the remaining FOCUS scenarios in winter OSR, indicating high risk to algae and macrophytes, driving the risk assessment. Therefore, TER-calculations based on FOCUS Step 4 including risk mitigating measures are presented in the Tables below.

Table B.9.4-5: Maximum PEC_{SW} values (FOCUS Step 4) and TER values for dimethenamid-P following one application [1 x 500 g a.s./ha] in winter oil seed rape (OSR) pre-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhyn-chus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 pre-emergence OSR: 5 m drift mitigation							
D2/ditch	8.32	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.21	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	0.87	2988.51	137.93	3678.16	781.61	**7.59**	**6.89**
D4/pond	0.43	6117.65	282.35	7529.41	1600.00	15.53	14.09
D4/stream	1.01	2587.06	119.40	3184.08	676.62	**6.57**	**5.96**
D5/pond	0.21	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	1.08	2402.96	110.91	2957.49	628.47	**6.10**	**5.54**
R1/pond	0.10	25000.00	1153.85	30769.23	6538.46	63.46	57.60
R1/stream	0.77	3394.26	156.66	4177.55	887.73	**8.62**	**7.82**
R3/stream	6.04	430.18	19.85	529.45	112.51	**1.09**	**0.99**
step 4 pre-emergence OSR: 10 m drift mitigation							
D2/ditch	8.32	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.21	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	0.47	5508.47	254.24	6779.66	1440.68	13.98	12.69
D4/pond	0.42	6190.48	285.71	7619.05	1619.05	15.71	14.26
D4/stream	0.71	3661.97	169.01	4507.04	957.75	**9.30**	**8.44**
D5/pond	0.21	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	0.57	4529.62	209.06	5574.91	1184.67	11.50	10.44
R1/pond	0.08	34666.67	1600.00	42666.67	9066.67	88.00	79.87
R1/stream	0.41	6403.94	295.57	7881.77	1674.88	16.26	14.75
R3/stream	6.04	430.18	19.85	529.45	112.51	**1.09**	**0.99**
step 4 pre-emergence OSR: 20 m drift mitigation							
D2/ditch	8.32	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.21	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	0.25	10441.77	481.93	12851.41	2730.92	26.51	24.06
D4/pond	0.42	6250.00	288.46	7692.31	1634.62	15.87	14.40
D4/stream	0.71	3661.97	169.01	4507.04	957.75	**9.30**	**8.44**
D5/pond	0.21	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	0.30	8666.67	400.00	10666.67	2266.67	22.00	19.97
R1/pond	0.05	52000.00	2400.00	64000.00	13600.00	132.00	119.80
R1/stream	0.21	12322.27	568.72	15165.88	3222.75	31.28	28.39
R3/stream	6.04	430.18	19.85	529.45	112.51	**1.09**	**0.99**

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhyn-chus mykiss	*Oncorhyn-chus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 pre-emergence OSR: 10 m drift + runoff mitigation							
D2/ditch	8.32	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.21	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	0.47	5508.47	254.24	6779.66	1440.68	13.98	12.69
D4/pond	0.42	6190.48	285.71	7619.05	1619.05	15.71	14.26
D4/stream	0.71	3661.97	169.01	4507.04	957.75	**9.30**	**8.44**
D5/pond	0.21	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	0.57	4529.62	209.06	5574.91	1184.67	11.50	10.44
R1/pond	0.08	34666.67	1600.00	42666.67	9066.67	88.00	79.87
R1/stream	0.41	6403.94	295.57	7881.77	1674.88	16.26	14.75
R3/stream	2.75	944.08	43.57	1161.95	246.91	**2.40**	**2.18**
step 4 pre-emergence OSR: 20 m drift + runoff mitigation							
D2/ditch	8.32	312.58	14.43	384.71	81.75	**0.79**	**0.72**
D2/stream	5.21	499.42	23.05	614.68	130.62	**1.27**	**1.15**
D3/ditch	0.25	10441.77	481.93	12851.41	2730.92	26.51	24.06
D4/pond	0.42	6250.00	288.46	7692.31	1634.62	15.87	14.40
D4/stream	0.71	3661.97	169.01	4507.04	957.75	**9.30**	**8.44**
D5/pond	0.21	12560.39	579.71	15458.94	3285.02	31.88	28.94
D5/stream	0.30	8666.67	400.00	10666.67	2266.67	22.00	19.97
R1/pond	0.05	52000.00	2400.00	64000.00	13600.00	132.00	119.80
R1/stream	0.21	12322.27	568.72	15165.88	3222.75	31.28	28.39
R3/stream	1.45	1799.31	83.04	2214.53	470.59	**4.57**	**4.15**
TER criterion		100	10	100	10	10	10

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

Based on FOCUS step 4 scenarios considering risk mitigating measures, the number of safe scenarios considerably increases. TER values for all scenarios indicate an acceptable risk to aquatic organisms except the D2 (ditch/stream), D4 (stream) and R3 (stream) scenarios when considering drift mitigation ≥10 m (with or without runoff mitigation).

Table B.9.4-6: Maximum PEC_{SW} values (Focus Step 4) and TER values for dimethenamid-P following one application [1 x 500 g a.s./ha] in winter oilseed rape (OSR) post-emergence

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 post-emergence OSR: 5 m drift mitigation							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**
D3/ditch	0.876	2968.04	136.99	3652.97	776.26	**7.53**	**6.84**
D4/pond	0.783	3320.56	153.26	4086.85	868.45	**8.43**	**7.65**
D4/stream	1.342	1937.41	89.42	2384.50	506.71	**4.92**	**4.46**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	1.089	2387.51	110.19	2938.48	624.43	**6.06**	**5.50**
R1/pond	0.116	22413.79	1034.48	27586.21	5862.07	56.90	51.64
R1/stream	0.877	2964.65	136.83	3648.80	775.37	**7.53**	**6.83**
R3/stream	11.18	232.56	10.73	286.23	60.82	**0.59**	**0.54**
step 4 post-emergence OSR: 10 m drift mitigation							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**
D3/ditch	0.485	5360.82	247.42	6597.94	1402.06	13.61	12.35
D4/pond	0.776	3350.52	154.64	4123.71	876.29	**8.51**	**7.72**
D4/stream	1.342	1937.41	89.42	2384.50	506.71	**4.92**	**4.46**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	0.584	4452.05	205.48	5479.45	1164.38	11.30	10.26
R1/pond	0.084	30952.38	1428.57	38095.24	8095.24	78.57	71.31
R1/stream	0.877	2964.65	136.83	3648.80	775.37	**7.53**	**6.83**
R3/stream	11.18	232.56	10.73	286.23	60.82	**0.59**	**0.54**
step 4 post-emergence OSR: 20 m drift mitigation							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**
D3/ditch	0.258	10077.52	465.12	12403.10	2635.66	25.58	23.22
D4/pond	0.77	3376.62	155.84	4155.84	883.12	**8.57**	**7.78**
D4/stream	1.342	1937.41	89.42	2384.50	506.71	**4.92**	**4.46**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	0.342	7602.34	350.88	9356.73	1988.30	19.30	17.51
R1/pond	0.055	47272.73	2181.82	58181.82	12363.64	120.00	108.91
R1/stream	0.877	2964.65	136.83	3648.80	775.37	**7.53**	**6.83**
R3/stream	11.18	232.56	10.73	286.23	60.82	**0.59**	**0.54**

FOCUS Scenario / water body	PEC global max (µg/L)	Fish acute	Fish ELS	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic plant
		Oncorhynchus mykiss	*Oncorhynchus mykiss*	*Americamysis bahia*	*Daphnia magna*	*Monoraphidium griffithii*	*Lemna gibba*
		LC_{50} (µg/L)	NOEC (µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	E_yC_{50} (µg/L)	E_bC_{50} (µg/L)
		2600	120	3200	680	6.60	5.99
step 4 post-emergence OSR: 10 m drift + runoff mitigation							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**
D3/ditch	0.485	5360.82	247.42	6597.94	1402.06	13.61	12.35
D4/pond	0.776	3350.52	154.64	4123.71	876.29	**8.51**	**7.72**
D4/stream	1.342	1937.41	89.42	2384.50	506.71	**4.92**	**4.46**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	0.584	4452.05	205.48	5479.45	1164.38	11.30	10.26
R1/pond	0.084	30952.38	1428.57	38095.24	8095.24	78.57	71.31
R1/stream	0.406	6403.94	295.57	7881.77	1674.88	16.26	14.75
R3/stream	5.095	510.30	23.55	628.07	133.46	**1.30**	**1.18**
step 4 post-emergence OSR: 20 m drift + runoff mitigation							
D2/ditch	20.377	127.59	**5.89**	157.04	33.37	**0.32**	**0.29**
D2/stream	12.707	204.61	**9.44**	251.83	53.51	**0.52**	**0.47**
D3/ditch	0.258	10077.52	465.12	12403.10	2635.66	25.58	23.22
D4/pond	0.77	3376.62	155.84	4155.84	883.12	**8.57**	**7.78**
D4/stream	1.342	1937.41	89.42	2384.50	506.71	**4.92**	**4.46**
D5/pond	0.306	8496.73	392.16	10457.52	2222.22	21.57	19.58
D5/stream	0.342	7602.34	350.88	9356.73	1988.30	19.30	17.51
R1/pond	0.055	47272.73	2181.82	58181.82	12363.64	120.00	108.91
R1/stream	0.211	12322.27	568.72	15165.88	3222.75	31.28	28.39
R3/stream	2.671	973.42	44.93	1198.05	254.59	**2.47**	**2.24**
TER criterion		100	10	100	10	10	10

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

Based on FOCUS step 4 scenarios considering risk mitigating measures, the number of safe scenarios considerably increases. TER values for all scenarios indicate an acceptable risk to aquatic organisms except the D2 (ditch/stream), D4 (pond/stream) and R3 (stream) scenarios when considering 10 m or 20 m drift and runoff mitigation.

Metabolites of dimethenamid-P

The acute and long-term TER values for the metabolites of dimethenamid-P are presented in the tables below.

Table B.9.4-7: Fish acute TER values for the metabolites M656H003, M656H023 and M656H027 using the worst-case FOCUS Step 1 $PEC_{sw, max}$ values

Application scenario	Test substance	Test organism	96 h LC_{50} [µg/L]	FOCUS Step	$PEC_{sw, max}$ [µg/L]	TER_A	Trigger value
pre- and post-emergence	M656H003	*O. mykiss*	60800	1	0.577	105373	100
	M656H023	*O. mykiss*	> 87000	1	22.117	> 3934	100
	M656H027	*O. mykiss*	> 100000	1	24.703	> 4048	100

The TER_A values for the dimethenamid-P metabolites M656H003, M656H023 and M656H027 exceed the required trigger value of 100 based on worst-case FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

Table B.9.4-8: Acute TER values for *D. magna* exposed to metabolites M656H003, M656H023, M656H027 and M656H031 using the worst-case FOCUS Step 1 $PEC_{sw, max}$ values

Application scenario	Test substance	Test organism	48 h EC_{50} [µg/L]	FOCUS Step	$PEC_{sw, max}$ [µg/L]	TER_A	Trigger value
pre- and post-emergence	M656H003	*D. magna*	> 101600	1	0.577	> 176083	100
	M656H023	*D. magna*	> 95000	1	22.117	> 4295	100
	M656H027	*D. magna*	> 100000	1	24.703	> 4048	100
	M656H031	*D. magna*	> 100000	1	14.385	> 6952	100

The TER_A values for the metabolites M656H003, M656H023, M656H027 and M656H031 exceed the required trigger value of 100 based on worst-case FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

Table B.9.4-9: TER values for algae[1)] exposed to major metabolites using worst-case FOCUS Step 1 $PEC_{sw, max}$ values

Application scenario	Test substance	Test organism	72 h E_bC_{50} [µg/L]	FOCUS Step	$PEC_{sw, max}$ [µg/L]	TER	Trigger value
pre- & post-emergence	M656H003	*D. subspicatus*	97400	1	0.577	168804	10
	M656H023	*P. subcapitata*	> 100000	1	22.117	> 4521	10
	M656H027	*P. subcapitata*	> 208000	1	24.703	> 8420	10
	M656H031	*P. subcapitata*	> 100000	1	14.385	> 6952	10

[1)] Where several endpoints are available for the same group or where several endpoints are available for one study based on different effect parameters, the lowest (most sensitive) endpoint is used in the TER calculations.

The TER values for the dimethenamid-P metabolites M656H003, M656H023, M656H027 and M656H031 exceed the required trigger value of 10 based on FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

Table B.9.4-10: Long-term TER values for the aquatic plant *Lemna gibba*[1)] exposed to metabolites M656H031, M656H062, M656PH043 and M656H055 using worst-case FOCUS Step 1 $PEC_{sw, max}$ values

Application scenario	Test substance	Test organism	7 d E_yC_{50} [µg/L]	FOCUS Step	$PEC_{sw, max}$ [µg/L]	TER_{LT}	Trigger value
pre- & post-emergence	M656H031	*L. gibba*	> 100000	1	14.385	> 6952	10
	M656H062 +	*L. gibba*	> 100000	1	140.853 #	> 710	10
	M656PH043	*L. gibba*	> 100000	1	140.853 #	> 710	10
	M656H055	*L. gibba*	> 143000	1	140.853 #	> 1015	10

1) Where several endpoints are available for the same group or where several endpoints are available for one study based on different effect parameters, the lowest (most sensitive) endpoint is used in the TER calculations.

For the metabolites M656H062 (tested with Reg. No. 403 121; for details see above), M656PH043 and M656H055, the worst-case Step 1 PEC value for the active substance is used for TER calculations (for justifications see above)

The TER_{LT} values for the dimethenamid-P metabolites M656H031, M656H062, M656PH043 and M656H055 exceed the required trigger value of 10 based on FOCUS Step 1 calculations, indicating low ecotoxicological relevance of the metabolites.

B.9.4.2 Refined risk assessment

Since additional laboratory toxicity tests are available for the most sensitive organisms group "primary producers" (algae/macrophytes) a tier 2 effect assessment is performed below.

According to the EFSA Aquatic Guidance Document (EFSA, 2013) it is recommended to preferably apply the species-sensitivity-distribution (SSD) approach if more than eight algae/macrophyte endpoints are available. Nevertheless, the geomean approach could also be applied if, for example, the SSD is deemed inappropriate (e.g. goodness-of-fit tests not passed).

The present SSD analysis for algae and macrophytes, respectively, differs from the applicant in the following way:

- The median HC_5 (based on EC_{50} data) for both algae and macrophytes is calculated and used separately in the risk assessment as the presence of sediment in all macrophyte studies may have affected bioavailability, and thus, toxicity when compared to sediment-free algal test systems.
- Only E_bC_{50} or E_yC_{50} values were considered in the present risk assessment as the proposed change from biomass/yield to growth rate endpoints would lead to a significant decrease of the protection level for both algae and macrophytes if no specific corrections in the assessment factors were made (for further details, see Vol. 1, chapter 2.9.2, algae and macrophytes).
- Geometric mean of measured test concentrations were considered in studies with recovery <80 % of nominal over the entire study period.
- Geometric mean (instead of arithmetic mean) EC_{50} values if more than one study is available for the same species.
- In accordance with the EFSA GD (2013), unbound values ("greater-than" values) in the SSD were excluded from the SSD unless "greater-than" values corresponded to the highest toxicity value.
- Several algae tests were excluded from the SSD analysis as the validity criterion (cv % for section-by-section specific growth rate ≤35 %) were not met (see Volume 3 CA B-9 for further details).

The SSD analysis presented below was performed with the software ETX 2.0 (Van Vlaardingen et al., 2004).

SSD for algae (Tier 2B):

Table B.9.4-11: Species sensitivity distribution (SSD) for algae

Data no	Toxicity data [µg/L]	Species
1	6.6	*Monoraphidium griffithii*
2	9.7	*Ankistrodesmus bibraianus*
3	13.9	*Pseudokirchneriella subcapitata* (geometric mean, n=2)
4	18.3	*Desmodesmus subspicatus*
5	85.4	*Chlamydomonas reinhardtii*
6	111	*Planktosphaeria botryoides*
7	127	*Schroederia setigera*
8	154	*Navicula pelliculosa*
9	368	*Neochloris aquatica*

Table B.9.4-12: Results of the goodness-of-fit test

Anderson-Darling test for normality			
Sign. level	**Critical**	**Normal?**	**AD Statistic: 0.466**
0.1	0.631	Accepted	**n: 9**
0.05	0.752	Accepted	
0.025	0.873	Accepted	
0.01	1.035	Accepted	

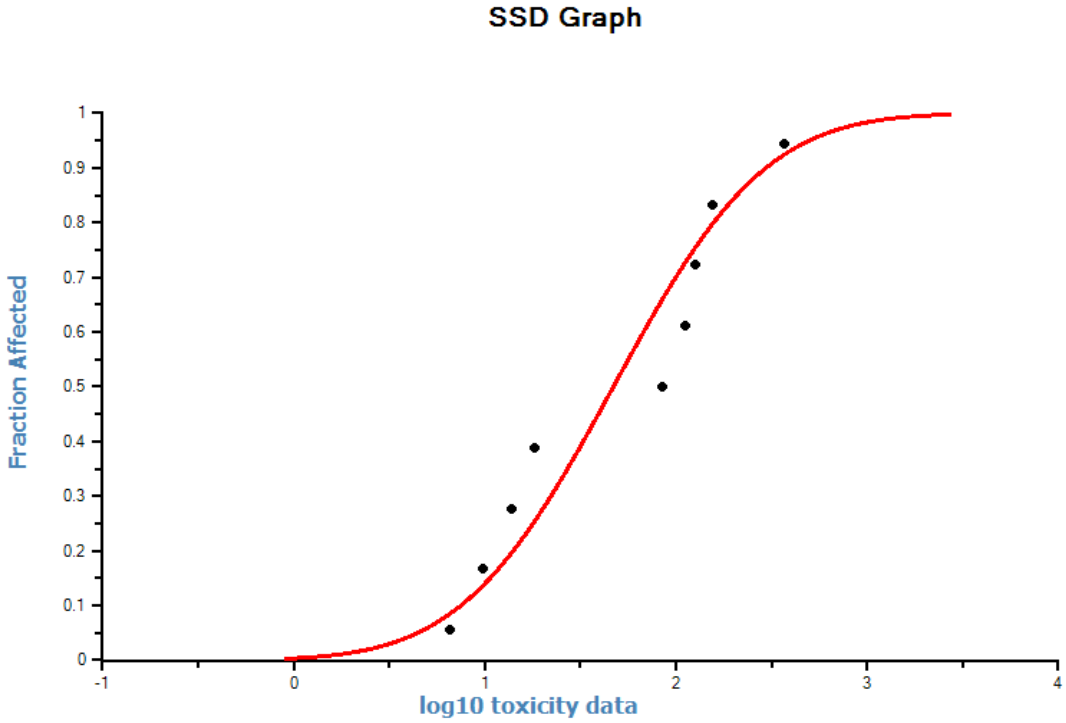

Figure B.9.4-1: SSD graph for algae

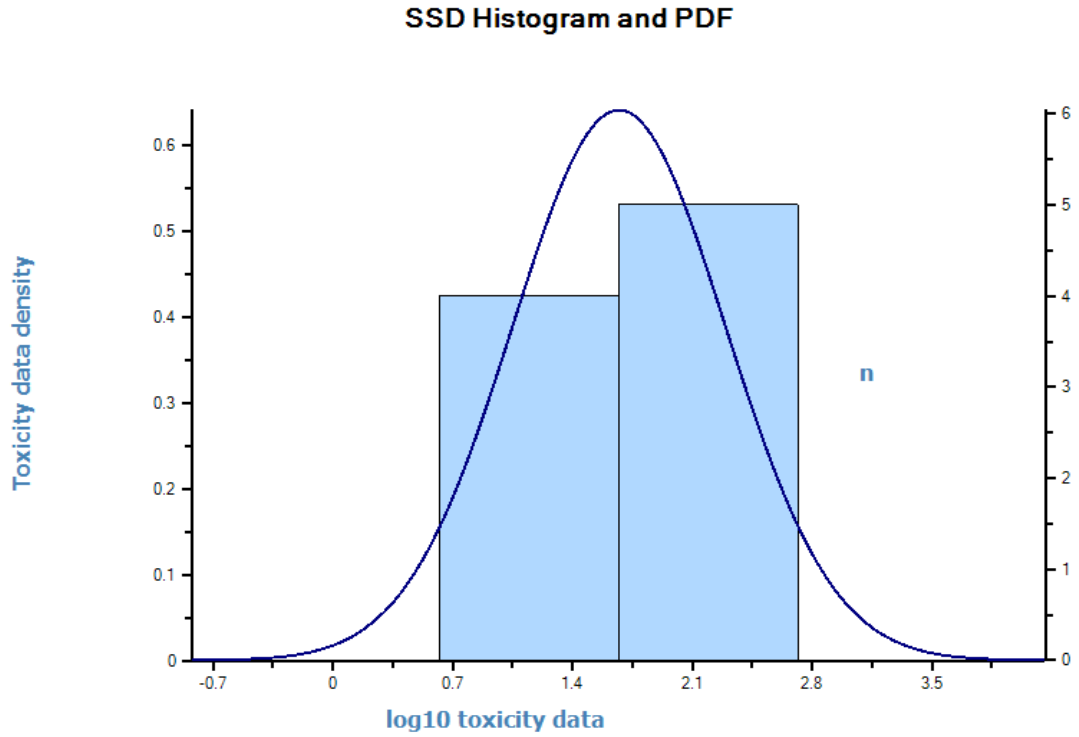

Figure B.9.4-2: SSD histogram and PDF for algae

Table B.9.4-13: Parameters of the normal distribution

Name	Value	Description
mean	1.672	mean of the log toxicity values
s.d.	0.623	sample standard deviation
n	9	sample size

Table B.9.4-14: HC5 results

Name	Value [µg/L]	log10(Value)	Description
LL HC5	0.609	-0.216	lower estimate of the HC5
HC5	**4.051**	**0.608**	**median estimate of the HC5**
UL HC5	11.360	1.055	upper estimate of the HC5
sprHC5	18.667	1.271	spread of the HC5 estimate

SSD for macrophytes (Tier 2B):

Table B.9.4-15: Species sensitivity distribution (SSD) for aquatic plants

Data no	Toxicity data [µg/L]	Species [1)]
1	13.3	*Ceratophyllum demersum*
2	25.5	*Lemna gibba* [2)]
3	33.5	*Ludwigia palustris*
4	86.5	*Crassula recurva*
5	88.4	*Myriophyllum spicatum*
6	104	*Veronica beccabunga*
7	109	*Glyceria maxima*
8	154	*Iris pseudoacorus*
9	174	*Potamogeton crispus*
10	206	*Mentha aquatica*
11	208	*Elodea densa*
12	373	*Sparganium erectum*
13	>1314	*Acorus calamus*

[1)]Vallisneria spiralis E_yC_{50} >269 µg/L was excluded from the SSD analysis as it is not recommended to include unbound values (greater-than or lower-than values) in the SSD (see EFSA GD, 2013).
[2)] The Lemna study with sediment was used in order to increase comparability among the remaining macrophyte endpoints.

Table B.9.4-16: Results of the goodness-of-fit test

Anderson-Darling test for normality			
Sign. level	**Critical**	**Normal?**	**AD Statistic: 0.318**
0.1	0.631	Accepted	**n: 13**
0.05	0.752	Accepted	
0.025	0.873	Accepted	
0.01	1.035	Accepted	

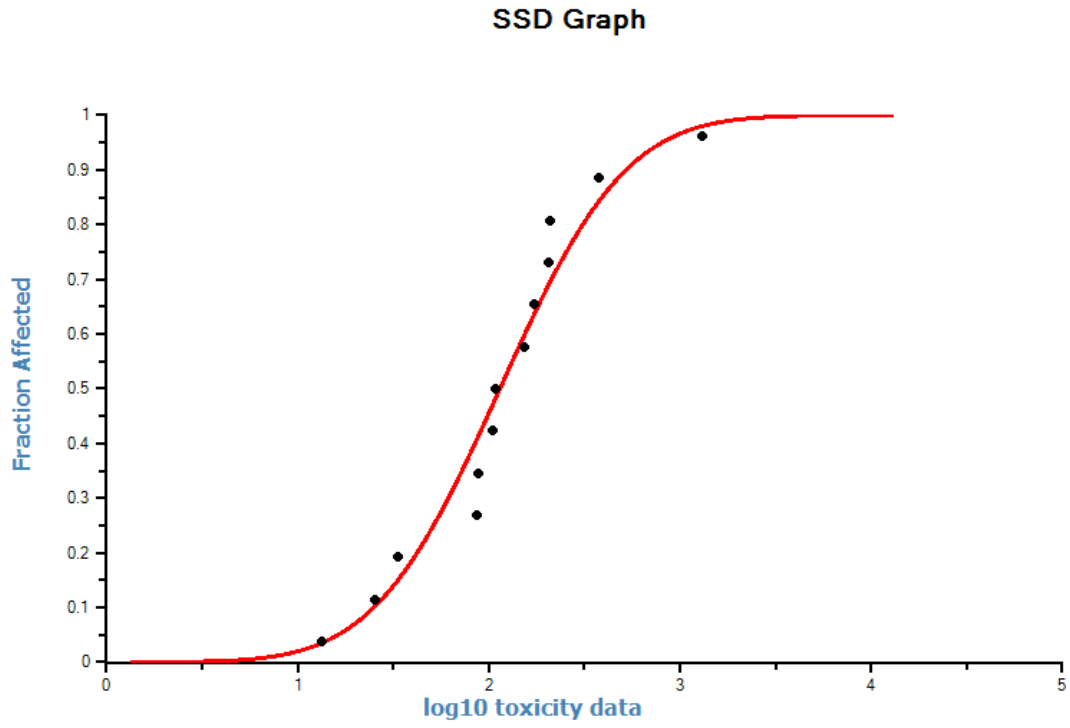

Figure B.9.4-3: SSD graph for macrophytes

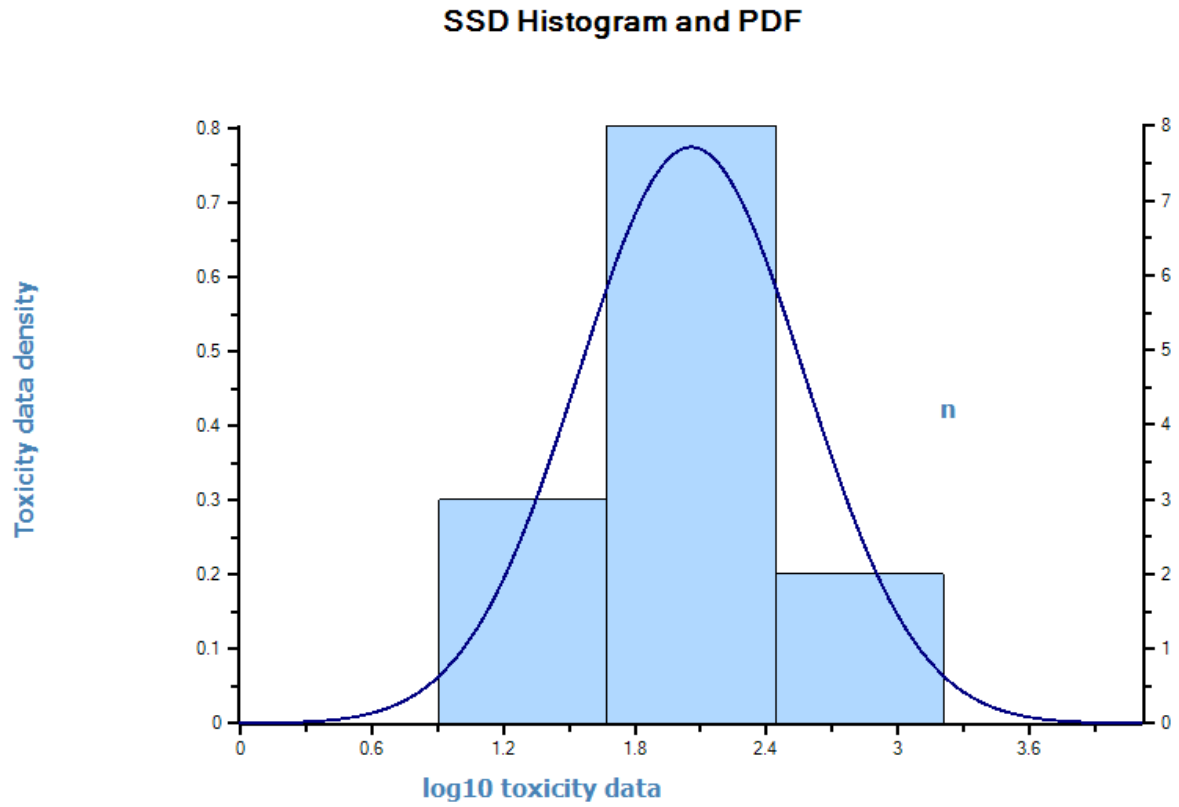

Figure B.9.4-4: SSD histogram and PDF for macrophytes

Table B.9.4-17: Parameters of the normal distribution

Name	Value	Description
mean	2.057	mean of the log toxicity values
s.d.	0.515	sample standard deviation
n	13	sample size

Table B.9.4-18: HC5 results

Name	Value [µg/L]	log10(Value)	Description
LL HC5	4.808	0.682	lower estimate of the HC5
HC5	**15.43**	**1.188**	**median estimate of the HC5**
UL HC5	31.64	1.500	upper estimate of the HC5
sprHC5	6.581	0.818	spread of the HC5 estimate

Conclusion on the SSD analysis:
HC_5 values were 4.05 and 15.4 µg a.s./L for algae and macropyhtes, respectively. For the risk assessment, the lowest corresponding **RAC of 1.35 µ a.s.g/L** will be used, taking into account an AF of 3 for primary producers in line with the EFSA GD (2013).

Refined Risk Assessment:
The TER values calculated by the RMS for the respective representative uses are presented in the tables below.

Table B.9.4-19: TER (FOCUS step 4) calculations considering the algae SSD-RAC in the refined risk assessment for dimethenamid-P following one application [1 x 500 g a.s./ha] in pre-emergence and post-emergence winter oilseed rape

FOCUS Scenarios	Algae SSD-RAC [µg a.s./L]	FOCUS Step 4 – Oil seed rape (pre-emergence)		FOCUS Step 4 – Oil seed rape (post-emergence)	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
5 m drift mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.87	1.55	0.876	1.54
D4/pond		0.43	3.14	0.783	1.72
D4/stream		1.01	1.34	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		1.08	1.25	1.089	1.24
R1/pond		0.1	13.50	0.116	11.64
R1/stream		0.77	1.75	0.877	1.54
R3/stream		6.04	**0.22**	11.18	**0.12**
10 m drift mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.47	2.87	0.876	1.54
D4/pond		0.42	3.21	0.783	1.72
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.57	2.37	1.089	1.24
R1/pond		0.08	16.88	0.116	11.64
R1/stream		0.41	3.29	0.877	1.54
R3/stream		6.04	**0.22**	11.18	**0.12**
20 m drift mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.25	5.40	0.258	5.23
D4/pond		0.42	3.21	0.77	1.75
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.3	4.50	0.342	3.95
R1/pond		0.05	27.00	0.055	24.55
R1/stream		0.21	6.43	0.877	1.54
R3/stream		6.04	**0.22**	11.18	**0.12**
10 m drift + runoff mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.47	2.87	0.485	2.78
D4/pond		0.42	3.21	0.776	1.74
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41
D5/stream		0.57	2.37	0.584	2.31
R1/pond		0.08	16.88	0.084	16.07
R1/stream		0.41	3.29	0.406	3.33
R3/stream		2.75	**0.49**	5.095	**0.26**
20 m drift + runoff mitigation					
D2/ditch	1.35	8.32	**0.16**	20.377	**0.07**
D2/stream		5.21	**0.26**	12.707	**0.11**
D3/ditch		0.25	5.40	0.258	5.23
D4/pond		0.42	3.21	0.77	1.75
D4/stream		0.71	1.90	1.342	1.01
D5/pond		0.21	6.43	0.306	4.41

FOCUS Scenarios	Algae SSD-RAC [µg a.s./L]	FOCUS Step 4 – Oil seed rape (pre-emergence)		FOCUS Step 4 – Oil seed rape (post-emergence)	
		$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)	$PEC_{sw.\ max}$ [µg/L]	TER (RAC/PEC)
D5/stream		0.3	4.50	0.342	3.95
R1/pond		0.05	27.00	0.055	24.55
R1/stream		0.21	6.43	0.211	6.40
R3/stream		1.45	**0.93**	2.671	**0.51**

TERs shown in **bold** indicate high risk (PEC > SSD-RAC).

Based on FOCUS step 4 scenarios considering risk mitigating measures and the algae SSD-RAC in the refined risk assessment for dimethenamid-P, TER values for all scenarios indicate an acceptable risk to aquatic organisms except the D2 (ditch/stream) and R3 (stream) scenarios when considering drift mitigation ≥5 m (regardless of runoff mitigation).

Tier 2C: The refined exposure laboratory test AF approach

In support of the higher tier risk assessment, the applicant has submitted refined exposure laboratory tests ("time-to-effect/event" (TTE) studies) on the sensitive aquatic plant species *L. gibba* and *C. demersum* as well as on two alga species *P. subcapitata* and *M. griffithii* with dimethenamid-P using exposure duration derived from exposure scenarios representative for moving water bodies like streams and ditches (see Table below).

Table B.9.4-20:Summary of the results of the time-to-effect/event studies on aquatic primary producers and the proposed use for refined risk assessment of dimethenamid-P

Test organism	Exposure scenario	E_rC_{50} / $E_{y/b}C_{50}$ (duration) [µg a.s./L] *	TTE-AUC [µg a.s./L*d] #	AF	covered peak conc. (duration) [µg a.s./L] *	covered peak AUC [µg a.s./L*d]
M. griffithii	single peak exposure over 6 & 24 h (+ 72 h growth phase)	> 2400 / > 2400 (6 h)	> 600	10	≤ 240 (6 h)	≤ 60.0
		> 1200 / > 1200 (24 h)	> 1200	10	≤ 120 (24 h)	≤ 120
P. subcapitata	single peak exposure over 6 & 24 h (+ 72 h growth phase)	> 1200 / 1200 (6 h)	> 300	10	≤ 120 (6 h)	≤ 30.0
		> 1200 / 388 (24 h)	120 / 388	10	≤ 38.8 (24 h)	≤ 38.8
L. gibba	Scenario A: single peak exposure over 12, 24 & 36 h (+ 7 d growth phase)	> 500 (12 h)	> 250	10	≤ 50 (12 h)	≤ 25.0
		> 500 (24 h)	> 500	10	≤ 50 (24 h)	≤ 50.0
		458 / 253 (36 h)	687 / 380	10	≤ 25.3 (36 h)	≤ 38.0
	Scenario B: two consecutive peaks with decreasing conc. separated by a 13 h non-exposure period (+ 7 d growth phase)	> 500-350-100-0-180-100 (5-4-3-13-6-3 h)	--	--	n.c.	n.c.
		≥ 250-175-50-0-90-50 (5-4-3-13-6-3 h)	--	--	n.c.	n.c.
C. demersum	single peak exposure over 24 & 48 h (+ 7 d growth phase)	> 3000 (24 h)	> 3000	10	≤ 300 (24 h)	≤ 300
		> 3000 (48 h)	> 6000	10	≤ 300 (48 h)	≤ 600

TTE = Time-To-Effect/Event; AF = Assessment Factor; n.c. = not calculated

For details on AUC (= Area Under the Curve) calculation and its use for refined risk assessment see text below.

* Only valid for respective short-term exposure peaks (duration given in brackets).

Generally, the aim of TTE-studies is to mimic short exposure durations, which might result from running water bodies like streams or ditches in order to demonstrate that these exposure patterns elicit lower impacts on sensitive aquatic primary producers in comparison to long-term exposure durations simulated in the standard studies (Tier 1). In the present case, the results of the TTE studies simulating realistic short pulse exposure scenarios suggest that exposure durations strongly influence the toxicity of dimethenamid-P to aquatic primary producers.

According to the applicant, the results of these studies may directly be used for TER calculation since exposure patterns in the studies are comparable to the predicted exposure patterns that should be representative for streams and ditches used for calculation of PECs as proposed by the ELink workshop (Brock et al., 2009).

In order to define if the peak concentrations of short-term exposure profiles for dimethenamid-P are covered by the results of the TTE studies, for each exposure peak higher than a critical threshold level, a detailed characterisation of the exposure profile in the relevant FOCUS surface water stream scenarios has been performed by the applicant in the dossier using the Exposure Pattern Analysis Tool (EPAT; Wang, 2010). This was done by comparing Area-under-the-curve concentrations (AUC)

derived for respective peak durations from the simulated exposure profiles to the AUCs obtained from the TTE-studies.

However, EPAT-generated PEC values in conjunction with TTE studies are shown to be unsuitable for the higher tier assessment for several reasons:

i) The underlying concept of EPAT, for which no EU guidance is available so far, does not consider multiple years of application and consequently, an overall worst case concentration pattern for each scenario could not be defined (for further information, see also conclusions in chapter B.8.5, annex point KCP 9.2., Acceptability of PECsw and PECsed values – dimethenamid-P‘)

ii) Furthermore, an increase of effects over time (“carry-over of effects”) occurred in the TTE studies during the growth phase (see chapter B.9.5, annex point KCA 8.2.7/1 for more information), which supports the conclusion that repeated exposures are not ecotoxicologically independent.

Overall, it can be concluded that considerable uncertainties remain with regard to both the TTE-derived toxicity values and exposure modelling approaches such as EPAT, and therefore, the respective risk refinement approaches were not further presented in the renewal assessment report.

Conclusion on the aquatic risk assessment:
Based on the results above, taking into account SSD analysis for primary producers, acceptable risk for aquatic organisms is supported ($PEC_{sw;max} < RAC_{sw;ch}$) for the proposed pre-emergence as well as post-emergence applications in winter oilseed rape, taking into account risk mitigation measures such as ≥ 5 m drift mitigation.

B.9.5 Effects on arthropods

B.9.5.1 Effects on bees

BAS 830 01 H is a suspo-emulsion formulation (SE) supported for renewing the approval of dimethenamid-P containing 333 g dimethenamid-P/L and 167 g quinmerac/L. Effects of BAS 830 01 H on bees were not evaluated as part of the first EU review of the active substance dimethenamid-P. Therefore all relevant data and assessments are provided here and are considered adequate.

B.9.5.1.1 Acute toxicity (KCP 10.3.1.1)

Acute oral (KCA 10.3.1.1.1) and contact (KCA 10.3.1.1.2) toxicity

Report:	CP 9.5.1.1/1 Franke M., 2013a Acute toxicity of BAS 830 01 H to the honeybee *Apis mellifera* L. under laboratory conditions 2013/1132519
Guidelines:	OECD 213 (1998)
GLP:	yes
Validity:	Acceptable

Executive Summary
In an oral toxicity test, honeybees (young adult worker honeybees of *Apis mellifera*) were exposed to BAS 830 01 H. The toxicity of the test item was determined at nominal concentrations of 28.4, 56.8, 113.5, 227.0 and 454.0 µg BAS 830 01 H/bee, resulting in an actual uptake of 28.4, 56.8, 113.5, 197.8 and 416.2 µg BAS 830 01 H/bee. Additionally, honeybees were treated with Dimethoate EC 400 as

reference item at concentrations ranging from 0.054 to 0.250 µg dimethoate/bee and with an aqueous sugar solution as control.

After 48 hours of oral exposure, 0.0 % mortality was observed in the control. Statistically significant effects of 30.0 % and 96.7 % on survival were observed in the two highest test item treatment groups of 197.8 and 416.2 µg BAS 830 01 H/bee after 48 hours, respectively. The LD_{50} value (48 h) was determined to be 233.9 µg BAS 830 01 H/bee.
Effects on behaviour of surviving honeybees occurred at consumed dose rates of 197.8 and 416.2 µg BAS 830 01 H/bee at the 4-hour assessment, after 24 hours no behavioural effects occurred at all. Major behavioural abnormalities observed were hyperactivity, impaired locomotion and moribund symptoms.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 830 01 H; batch no. 451008; content of active substance: quinmerac (BAS 518 H, Reg. No. 168 526): 167.0 g/L (nominal), 173.0 g/L (analysed); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 333.0 g/L (nominal), 347.7 g/L (analysed); density: 1.135 g/cm^3.

B. STUDY DESIGN

Test species: *Apis mellifera carnica* (honeybee), young adult worker honeybees (3 - 5 weeks old); deriving from a healthy and queen-right colony; source: Bienenfarm Kern GmbH, Leipzig, Germany; collected in the morning prior to use.

Test design: In a 48 hour test young adult worker honeybees of *Apis mellifera* were exposed to BAS 830 01 H via food (50 % (w/v) aqueous sucrose solution). In total, 3 treatment groups were set up (5 concentrations of the test item, one untreated control and 4 concentrations of the reference item) with 3 replicates each and 10 honeybees per replicate. Assessment of honeybee mortality and behavioural effects was done after 4, 24 and 48 hours.

Endpoint: Mortality, behavioural impairments.

Reference item: Dimethoate EC 400 (dimethoate, 411.7 g/L analysed).

Test concentrations: Control, 28.4, 56.8, 113.5, 227.0 and 454.0 µg BAS 830 01 H/bee (nominal), corresponding to an actual uptake of 28.4, 56.8, 113.5, 197.8 and 416.2 µg BAS 830 01 H/bee; reference item: 0.054, 0.090, 0.150 and 0.250 µg dimethoate/bee.

Test conditions: Temperature: 24.8 °C – 26.0 °C; relative humidity: 53 % - 63 %; photoperiod: 24 h darkness; food: 50 % (w/v) aqueous sucrose solution.

Statistics: Descriptive statistics; Fisher's Exact Binominal Test with Bonferroni Correction for mortality data (one-sided greater, $\alpha = 0.05$); Probit-analysis for calculation of LD_{50} for the reference item.

II. RESULTS AND DISCUSSION

After 48 hours of oral exposure, 0.0 % mortality was observed in the control. Statistically significant effects of 30.0 % and 96.7 % on survival were observed in the two highest test item treatment groups

of 197.8 and 416.2 µg BAS 830 01 H/bee after 48 hours, respectively (Fisher's Exact Binominal Test, $\alpha = 0.05$). The LD_{50} value (48 h) was determined to be 233.9 µg BAS 830 01 H/bee.
Effects on behaviour of surviving honeybees occurred at consumed dose rates of 197.8 and 416.2 µg BAS 830 01 H/bee at the 4-hour assessment, after 24 hours no effects on behavior occurred at all. Major behavioural abnormalities observed were hyperactivity, impaired locomotion and moribund symptoms. The results are summarised in Table B.9.5-1.

Table B.9.5-1: Toxicity of BAS 830 01 H to *Apis mellifera* (honeybee) in an oral toxicity test

Treatment	**Uptake of test item**	**Mortality [%]**	
[µg BAS 830 01 H/bee]		**24 h**	**48 h**
Control	-	0.0	0.0
28.4	28.4	0.0	0.0
56.8	56.8	0.0	0.0
113.5	113.5	0.0	0.0
227.0	197.8	20.0 *	30.0 *
454.0	416.2	86.7 *	96.7 *
	Endpoint [µg BAS 830 01 H/bee]		
LD_{50} (95 % CL) (48 h)	233.9 (207.4 – 263.8)		

* Statistically significantly different compared to the control (Fisher's Exact Binominal Test, $\alpha = 0.05$).

The LD_{50} value (24 h) for the reference item was 0.153 µg dimethoate/bee.

Conclusion:
In an acute oral toxicity test with BAS 830 01 H on honeybees the LD_{50} value (48 h) was determined to be 233.9 µg BAS 830 01 H/bee.
The study is considered valid and acceptable for the risk assessment.

Report: CP 9.5.1.1/2
Franke M., 2013a
Acute toxicity of BAS 830 01 H to the honeybee *Apis mellifera* L. under laboratory conditions
2013/1132519
Guidelines: OECD 214 (1998)
GLP: yes
Validity: Acceptable

Executive Summary

In a contact toxicity test, honeybees (young adult worker honeybees of *Apis mellifera*) were exposed to BAS 830 01 H. The toxicity of the test item was determined at nominal concentrations of 109.0, 155.7, 222.5, 317.8 and 454.0 µg BAS 830 01 H/bee. Additionally, honeybees were treated with Dimethoate EC 400 as reference item at concentrations ranging from 0.086 to 0.250 µg dimethoate/bee and with deionised water and tween solution as controls.

After 48 hours of contact exposure, 0.0 % mortality was observed in the controls. After 48 hours of exposure a mortality of 3.3 % was recorded at 454.0 µg BAS 830 01 H/bee, which was not statistically significantly different to the control. The LD_{50} value (48 h) was determined to be > 454.0 µg

BAS 830 01 H/bee.
Effects on behaviour of surviving honeybees occurred at application rates of 317.8 and 454.0 µg BAS 830 01 H/bee at the 24-h and 48-h assessment. The majority of honeybees with deviations to the normal behaviour were recognised as affected by impaired locomotion.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 830 01 H; batch no. 451008; content of active substance: quinmerac (BAS 518 H, Reg. No. 168 526): 167.0 g/L (nominal), 173.0 g/L (analysed); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 333.0 g/L (nominal), 347.7 g/L (analysed); density: 1.135 g/cm^3.

B. STUDY DESIGN

Test species: *Apis mellifera carnica* (honeybee), young adult worker honeybees (3 - 5 weeks old); deriving from a healthy and queen-right colony; source: Bienenfarm Kern GmbH, Leipzig, Germany; collected in the morning prior to use.

Test design: In a 48 hour test young adult worker honeybees of *Apis mellifera* were exposed to BAS 830 01 H in an appropriate carrier (1.0 % (v/v) tween 80® solution) placed on the dorsal honeybee thorax. In total, 3 treatment groups were set up (5 concentrations of the test item, two untreated control groups and 4 concentrations of the reference item) with 3 replicates each and 10 honeybees per replicate. Assessment of honeybee mortality and behavioural effects was done after 4, 24 and 48 hours.

Endpoint: Mortality, behavioural impairments.

Reference item: Dimethoate EC 400 (dimethoate, 411.7 g/L analysed).

Test concentrations: Water control (deionised water), tween control (1.0 % (v/v) tween 80® solution), test item: 109.0, 155.7, 222.5, 317.8 and 454.0 µg BAS 830 01 H/bee (nominal); reference item: 0.086, 0.123, 0.175 and 0.250 µg dimethoate/bee.

Test conditions: Temperature: 24.8 °C - 26.0 °C; relative humidity: 53 % - 63 %; photoperiod: 24 h darkness; food: 50 % (w/v) aqueous sucrose solution.

Statistics: Descriptive statistics; Fisher's Exact Binominal Test with Bonferroni Correction for mortality data (one-sided greater, $\alpha = 0.05$); Probit-analysis for calculation of LD_{50} for the reference item.

II. RESULTS AND DISCUSSION

After 48 hours of contact exposure, 0.0 % mortality was observed in the controls. After 48 hours of exposure a mortality of 3.3 % was recorded at 454.0 µg BAS 830 01 H/bee, which was not statistically significantly different to the control. The LD_{50} value (48 h) was determined to be > 454.0 µg BAS 830 01 H/bee.
Effects on behaviour of surviving honeybees occurred at application rates of 317.8 and 454.0 µg BAS 830 01 H/bee at the 24-h and 48-h assessment. The majority of honeybees with deviations to the normal behaviour were recognised as affected by impaired locomotion. The results are summarised in Table B.9.5-2.

Table B.9.5-2: Toxicity of BAS 830 01 H to *Apis mellifera* (honeybee) in a contact toxicity test

Treatment [µg BAS 830 01 H/bee]	**Mortality [%]**	
	24 h	**48 h**
Water control	0.0	0.0
Tween control	0.0	0.0
109.0	0.0	0.0
155.7	0.0	0.0
222.5	0.0	0.0
317.8	0.0	0.0
454.0	0.0	3.3
Endpoint [µg BAS 830 01 H/bee]		
LD_{50} (48 h)	> 454.0	

The LD_{50} value (24 h) for the reference item was 0.187 µg dimethoate/bee.

Conclusion
In a contact toxicity test with BAS 830 01 H on honeybees the LD_{50} value (48 h) was determined to be > 454.0 µg BAS 830 01 H/bee.
This study is considered valid and acceptable for the risk assessment.

B.9.5.1.2 Chronic toxicity (KCP 10.3.1.2)

As BAS 830 01 H does not pose an unacceptable risk to honeybees, further tests are not necessary.

B.9.5.1.3 Effects on honeybee brood (KCP 10.3.1.3)

Tests regarding effects on honeybee brood are not required since BAS 830 01 H is not an IGR. However, a laboratory honeybee brood toxicity test with the active substance dimethenamid-P was presented (please refer to Kleebaum K. 2014, CA 9.3.1.3/1).

B.9.5.1.4 Sublethal effects (KCP 10.3.1.4)

As BAS 830 01 H does not pose an unacceptable risk to honeybees, further tests are not necessary.

B.9.5.1.5 Cage and tunnel tests (KCP 10.3.1.5)

As BAS 830 01 H does not pose an unacceptable risk to honeybees, further tests are not necessary.

B.9.5.1.6 Field tests (KCP 10.3.1.6)

As BAS 830 01 H does not pose an unacceptable risk to honeybees, further tests are not necessary.

B.9.5.1.7 Summary of effects on honeybees

Due to the results of laboratory tests BAS 656 12 H is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. Additionally, a laboratory honeybee brood toxicity test with the active substance dimethenamid-P showed no indication of increased honeybee brood toxicity.

B.9.5.1.8 Risk assessment for honeybees

Toxicity
Table B.9.5-3 presents a summary of all studies submitted for the risk assessment. Further details regarding studies with BAS 830 01 H are provided in section B.9.5.1.1.

Table B.9.5-3: Toxicity of BAS 830 01 H to bees

Test substance	Test species	Endpoint	Value	Reference
BAS 830 01 H	adult honeybees	48 h acute oral LD_{50}	233.9 µg product/bee (103.0 µg as/bee)	Franke M., 2013 131048061 B
		48 h acute contact LD_{50}	> 454.0 µg product/bee (>200.0 µg as/bee)	
Dimethenamid-P (BAS 656 H)	adult honeybees	24 h acute oral LD_{50}	> 1000 µg as/bee	Donat H.J, 1986 1986/11170
		24 h acute contact LD_{50}	94 µg as/bee	
	adult honeybees	48 h acute oral LD_{50}	118.8 µg as/bee	Zenker K., 2011** Study no. 2010/1126065
		48 h acute contact LD_{50}	93.8 µg as/bee	
	honeybee larvae	96 h oral LD_{50} 96 h oral LC_{50}	69.6 µg as/larva 2.054 g as/kg food	Kleebaum K., 2014** Study no. 2013/1132510
	bumblebee	48 h acute oral LD_{50}	> 158 µg as/bumblebee	Roehlig U., 2014** Study no. 2013/1275562
		48 h acute contact LD_{50}	> 200 µg as/bumblebee	

** new study submitted for the re-evaluate of dimethenamid-P (BAS 656 H)

Exposure
Applications of pesticides can potentially result in exposure of honeybees either through direct over-spray, or by contact with residues on plants whilst honeybees are foraging for food. However, as the crops are not flowering during application time, they are of low attractiveness to foraging honeybees. However, in order to consider a worst-case scenario, the maximum recommended use rates are used for the risk assessment.

Table B.9.5-4: Proposed use pattern

Crop	Application time (BBCH growth stage)	Number of applications	Application rate per treatment		
			quinmerac [kg as/ha]	dimethenamid-P [kg as/ha]	BAS 830 01 H [L/ha]
Winter oilseed rape	00 - 09 10 - 18	1	0.25	0.5	1.5

Hazard quotients

The acute risk to honeybees from the use of BAS 830 01 H was assessed using the maximum single application rate and the respective LD_{50} values to calculate hazard quotients (HQ) (*EPPO/OEPP, 2003: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145*)) as follows:

Hazard Quotient = max. application rate [g product/ha] / LD_{50} [µg product/bee]

HQs for honeybees were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to BAS 830 01 H. An HQ < 50 indicates low risk to honeybees in the field. For bumblebees no risk assessment scheme currently exists.

Table B.9.5-5: Risk to honeybees and bumblebees from exposure to dimethenamid-P and BAS 830 01 H using the worst-case application rate

Test substance	Application rate [g/ha]	Endpoint	LD_{50}	Hazard quotient HQ	Trigger
honeybee					
dimethenamid-P (BAS 656 H)	500	48 h acute, oral	118.8 µg as/bee	4.2	50
		48 h acute, contact	93.8 µg as/bee	5.3	
BAS 830 01 H	1702.5 *	48 h acute, oral	233.9 µg product/bee	7.3	
		48 h acute, contact	> 454.0 µg product/bee	< 3.8	
bumblebee					
dimethenamid-P (BAS 656 H)	500	48 h oral	> 158 as/bee	-- [1)]	
		48 h contact	> 200 as/bee		

* taking into account the density of BAS 830 01 H of 1.135 g/cm³.
[1)] HQvalues are not validated for bumblebees.

Due to the results of laboratory tests BAS 830 01 H is considered practically non-toxic to honey bees. All HQs are considerably below the trigger value of 50, indicating that the intended use poses a low risk to bees in the field. Additionally, a laboratory honeybee brood toxicity test with the active substance dimethenamid-P showed no indication of increased honeybee brood toxicity.

Regarding bumblebees no risk assessment scheme exists. However, the endpoints obtained for acute oral and acute contact exposure to BAS 656 H (dimethenamid-P) on bumble bees did not indicate increased sensitivity to dimethenamid-P compared to the toxicity endpoints for honey bees.

Conclusion

The proposed uses of BAS 830 01 H according to good agricultural practice present a low risk to bees and bee colonies.

B.9.5.2 Effects on non-target arthropods other than bees

B.9.5.2.1 Standard laboratory testing for non-target arthropods

Two new studies on the acute toxicity of the formulation BAS 830 01 H to the standard species *Aphidius rhapalosiphi* and *Typhlodromus pyri* were submitted with the renewal dossier and are summarised below. In these studies only the effects on mortality were investigated.

KCP 10.3.2.1/1 Röhlig, 2013a (new study, submitted with the renewal dossier)

Author:	Röhlig, U.
Title:	Effects of BAS 830 01 H on the predatory mite *Typhlodromus pyri* SCHEUTEN in a laboratory test - Rate-response-test (LR_{50})
Date:	09.09.2013
Doc ID:	13 10 48 033A; BASF RegDoc# 2013/1132521
Guidelines:	IOBC (Blümel *et al.* 2000)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 830 01 H; batch no. 451008; content of a.s.: quinmerac (BAS 518 H, Reg. No. 168 526): 167.0 g/L (nominal), 173.0 g/L (analysed); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 333.0 g/L (nominal), 347.7 g/L (analysed); density: 1.135 g/cm^3

Test species: *Typhlodromus pyri* Scheuten (predatory mite), protonymphs, < 24 hours old; source (in the stage of eggs): Katz Biotech AG, Baruth, Germany

Test design: Exposure of protonymphs was reached via air-dried residues on treated glass plates. Based on an initial range finding test, 7 treatments (5 test item rates, water treated control, reference item) were set up each with 5 replicates; each replicate contained 20 protonymphs. Mortality assessments were carried out 3 and 7 days after treatment.

Endpoint: Mortality after 7 days

Reference item: Dimethoate EC 400 (dimethoate, 400 g/L nominal, 411.7 g/L analysed)

Test rates: Control (deionised water); 188, 375, 750, 1500 and 3000 mL BAS 830 01 H/ha; reference item: 15 mL dimethoate/ha; all substances applied in 200 L water/ha. The substances were sprayed onto glass plates via a laboratory spraying equipment and air dried afterwards.

Test conditions: Temperature: 23 °C - 31 °C, increase to 31 °C for 4 h at day 3 of exposure (impact on all treatments, therefore not considered to have an impact on the test results); relative humidity: 68 % - 90 %; photoperiod: 16 h light : 8 h dark; light intensity: 1960 lux; food: pollen of pine and birch (1 : 1)

Statistics: Descriptive statistics; Fisher's Exact Binominal Test with Bonferroni correction (test item) for mortality ($\alpha = 0.05$) and Fisher's Exact Binominal Test (reference item) for mortality ($\alpha = 0.05$)

Results and Discussion

After 7 days, the mortality in the different treatment groups ranged between 0 % and 5.0 % in comparison to 0 % in the control. No statistically significant differences on mortality compared to the control were observed. The LR_{50} was determined to be > 3000 mL BAS 830 01 H/ha, the highest rate tested. The results are summarised in Table B.9.5-6.

Table B.9.5-6: Effects on predatory mites (*Typhlodromus pyri*) after 7 days of exposure to BAS 830 01 H in a laboratory trial

Treatment	Rate [mL BAS 830 01 H/ha]	Mortality [%]	Corrected mortality [1)] [%]
Control	--	0	--
BAS 830 01 H	188	1.0	1.0
	375	0	0
	750	2.0	2.0
	1500	4.0	4.0
	3000	5.0	5.0
	Endpoint [mL BAS 830 01 H/ha]		
LR_{50}	> 3000		

1) Corrected mortality according to Abbott (1925).

The reference item caused a corrected mortality of 81.0 %.

Conclusion

The study is acceptable. In a laboratory study with BAS 830 01 H the LR_{50} for *Typhlodromus pyri* was > 3000 mL BAS 830 01 H/ha in 200 L water/ha. No impact on reproduction was evaluated in this study.

KCP 10.3.2.1/2 Röhlig, 2013b (new study, submitted with the renewal dossier)

Author: Röhlig, U.
Title: Effects of BAS 830 01 H on the parasitic wasp *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) in a laboratory test - rate-response-test (LR_{50})
Date: 28.10.2013
Doc ID: 13 10 48 032 A; BASF RegDoc#2013/1132522
Guidelines: IOBC, Mead-Briggs M. et al. (2000)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H; batch no. 451008; content of a.s.: quinmerac (BAS 518 H, Reg. No. 168 526): 167.0 g/L (nominal), 173.0 g/L (analysed); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 333.0 g/L (nominal), 347.7 g/L (analysed); density: 1.135 g/cm^3.

Test species: Parasitic wasp *Aphidius rhopalosiphi*, adults, age: < 48 hours old; source (in the stage of mummies): Katz Biotech AG, Baruth, Germany.

Test design: Exposure of the adults via air-dried residues on treated glass plates, 7 treatment groups (5 test item rates, water treated control, reference item); 4 replicates per treatment; each with 10 wasps (7 females and 3 males); assessment of mortality 2, 24 and 48 hours after test initiation

Endpoint: Mortality (LR_{50}) after 48 hours

Reference item: Dimethoate EC 400 (dimethoate 411.7 g/L (analysed)

Test rates: Control (deionised water), BAS 830 01 H: 12.5, 25, 50, 75 and 100 mL/ha (nom.); reference item: 0.3 mL dimethoate/ha; all substances were applied in 200 L water/ha; spraying onto glass plates via laboratory spraying equipment and air dried afterwards

Test conditions: Temperature: 19 °C - 22 °C; relative humidity: 68 % - 72 %; photoperiod: 16 h light: 8 h dark; light intensity: 2020 lux; food: 25 % w/w aqueous fructose solution

Statistics: Descriptive statistics; Fisher's Exact Binominal Test with Bonferroni correction ($\alpha = 0.05$), Probit analysis for LR_{50} calculation

Results and Discussion

After 48 hours, a mortality of 2.5 % was observed in the water-treated control. In the test item treatments, the corrected mortality ranged between -2.6 % and 100 %. Statistically significant effects on mortality of 43.6 %, 69.2 %, 87.2 % and 100 % were observed for the test item concentrations of 25, 50, 75 and 100 mL BAS 830 01 H/ha, respectively (Fisher's Exact Binominal Test, $\alpha = 0.05$). No statistically significant effects on mortality were determined at a rate of 12.5 mL BAS 830 01 H/ha. The LR_{50} was 33.6 mL BAS 830 01 H/ha in 200 L water/ha. The results are summarised in Table B.9.5-7.

Table B.9.5-7: Effects on parasitic wasps (*Aphidius rhopalosiphi*) after 48 hours of exposure to BAS 830 01 H in a laboratory trial

Treatment rate [mL BAS 830 01 H/ha]	**Mortality [%]**	**Corrected mortality [1)] [%]**
Control	2.5	--
12.5	0	-2.6
25	45.0 *	43.6
50	70.0 *	69.2
75	87.5 *	87.2
100	100 *	100
Endpoint [mL BAS 830 01 H/ha]		
LR_{50} (95 % CL)	33.6 (23.3 – 48.4)	

* Statistically significantly different compared to the control (Fisher's Exact Binominal Test, $\alpha = 0.05$).
1) Corrected mortality according to Abbott (1925).
CL: Confidence limits.

The reference item caused a corrected mortality of 100 % of exposed wasps.

Conclusion

The study is acceptable. In a laboratory study with BAS 830 01 H the LR_{50} for *Aphidius rhopalosiphi* was determined to be 33.6 mL BAS 830 01 H/ha in 200 L water/ha. No impact on reproduction was evaluated in this study.

B.9.5.2.2 Extended laboratory testing, aged residues studies with non-target arthropods

Two new extended laboratory studies on the toxicity of the formulation BAS 830 01 H to the standard species *Aphidius rhapalosiphi* and *Aleochara bilineata* were submitted with the renewal dossier and are summarised below.

KCP 10.3.2.2/1 Stevens, 2013 (new study, submitted with the renewal dossier)

Author:	Stevens, J.
Title:	A rate-response extended laboratory test to determine the effects of BAS 830 01 H on the parasitic wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae)
Date:	02.09.2013
Doc ID:	702505; BASF RegDoc# 2013/1132523
Guidelines:	Mead-Briggs, M.A. et al. (2009)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 830 01 H (SE); batch no. 451008; content of a.s.: quinmerac (BAS 518 H, Reg. No. 168 526): 167.0 g/L (nominal), 173.0 g/L (analysed); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 333.0 g/L (nominal), 347.7 g/L (analysed); density: 1.135 g/cm^3.

Test species: Parasitoid *Aphidius rhopalosiphi*, adults, age: less than 48 h; source: in-house culture.

Test design: Exposure of adult female parasitoids was reached via air-dried residues on treated seedling barley plants (*Hordeum vulgare)*. The study included 7 treatment groups (5 test item rates, water treated control and reference item) with 6 replicates per treatment, each containing 5 wasps.

Assessments of the repellence of wasps from the freshly-treated plants were made during the first 3 h after their release and also at 24 and 48 hours. Wasp mortality was assessed 2, 24 and 48 hours after test initiation. After 48 hours, surviving wasps (n = 15 females per treatment) were removed and their reproductive capacity was assessed. Assessments were made for control and the three highest treatment rates of test item that resulted in ≤ 60 % corrected mortality. The adult wasps were removed after 24 h and the aphid-infested plants left for a further 10 days before the number of aphid mummies that had developed was assessed.

Endpoints: Mortality after 48 hours of exposure and reproduction (number of parasitised aphids) after a parasitisation phase of 24 hours

Reference item: BAS 152 11 I (dimethoate, nominal 400.0 g/L)

Test rates: Control (purified water), 0.1875, 0.375, 0.75, 1.5 and 3.0 L BAS 830 01 H/ha, reference item: 10 mL BAS 152 11 I/ha. All treatments were applied in 400 L water/ha

The treatments were sprayed onto barley plants via laboratory track-sprayer (Schachtner, Germany) and residues then left to dry.

Test conditions: Exposure of adults: temperature: 21 °C; relative humidity: 69 % – 78 %; photoperiod: 16 h light : 8 h dark; light intensity: 1224 lux.
Reproduction assessments: temperature: 20 °C – 21 °C; photoperiod: 16 h light : 8 h dark; light intensity: 4910 lux.
Food: 10 % w/v solution of fructose in water sprayed onto test plants.

Statistics: Descriptive statistics; Fisher's Exact Test ($\alpha = 0.05$) performed on mortality data; one-way analysis of variance (ANOVA, $\alpha = 0.05$) on the square root-transformed

reproduction data.

Results and Discussion

In the water-treated control no mortality of was observed. In the test item treatments corrected mortality ranged between 0.0 % and 6.7 %. No statistically significant effect on mortality was determined in all test item treatment groups (Fisher's Exact Test, $\alpha = 0.05$). The LR_{50} was > 3.0 L BAS 830 01 H/ha in 400 L water/ha. The mean number of mummies per female in the test item treatment groups was between 32.7 and 36.9 mummies/female in comparison to the control with 35.7 mummies per female. There were no statistically significant effects on reproduction at rates up to and including 3.0 L BAS 830 01 H/ha. The results are summarised in Table B.9.5-8.

Table B.9.5-8: Effects of BAS 830 01 H on parasitic wasps (*Aphidius rhopalosiphi*) under extended laboratory conditions

Treatment rate [L BAS 830 01 H/ha]	Mortality [%]	Corrected mortality [1] [%]	Reproduction [2] [mummies/ female]	Effects on reproduction [%]
Control	0.0	--	35.7	--
0.1875	0.0	0.0	~	~
0.375	3.3	3.3	~	~
0.750	0.0	0.0	33.9	5.1
1.5	0.0	0.0	36.9	-3.5
3.0	6.7	6.7	32.7	8.2
Endpoints				
LR_{50}	> 3.0 [L BAS 830 01 H/ha]			
ER_{50}	> 3.0 [L BAS 830 01 H/ha]			

1) Corrected mortality according to Abbott's formula.
2) Reproduction: mean number of parasitised aphids/surviving female (ANOVA, $\alpha = 0.05$).
~ Treatment not evaluated.

The reference item caused a corrected mortality of 100 % of the exposed organisms after 48 hours.

Conclusion

The study is acceptable. The LR_{50} of BAS 830 01 H on *Aphidius rhopalosiphi* under extended laboratory conditions was > 3.0 L BAS 830 01 H/ha in 400 L water/ha. The ER_{50} for reproduction was > 3.0 L BAS 830 01 H/ha in 400 L water/ha.

KCP 10.3.2.2/2 Röhlig, 2013c (new study, submitted with the renewal dossier)

Author: Röhlig, U.
Title: Effects of BAS 830 01 H on the rove beetle *Aleochara bilineata* GYLL. under extended laboratory conditions
Date: 04.11.2013
Doc ID: 13 10 48 034 A; BASF RegDoc#2013/1132520
Guidelines: IOBC; Grimm et al. (2000)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H; batch no. 451008; content of a.s.: quinmerac (BAS 518 H, Reg. No. 168 526): 167.0 g/L (nominal), 173.0 g/L (analysed); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 333.0 g/L (nominal), 347.7 g/L (analysed); density: 1.135 g/cm^3

Test species: *Aleochara bilineata* (rove beetle), adults (1 to 7 days old); source: in-house culture

Test design: The exposure of the beetles was reached via sandy soil (LUFA 2.1) that was treated with the test item rates via laboratory spraying equipment (track sprayer) on the soil surface, the same for control and reference item. 4 treatment groups (2 test item rates, water treated control, reference item) with 4 replicates each and 20 individuals (10 male and 10 female beetles) per replicate were set up. On day 7, 14 and 21, approx. 500 pupae of *Delia antiqua* were buried in the sandy soil to be parasitised by larvae of the beetles. On day 28 the adults were separated from the soil and the soil with the pupae was allowed to dry for 7 days. On day 35 the pupae were removed from the soil by a sieve and transferred into a hatching unit. The reproductive capacitiy (average number of hatched beetles of the F_1 generation) was daily assessed during 5 weeks.

Endpoints: Reproduction capacity.

Reference item: Dimethoate EC 400 (dimethoate 411.7 g/L (analysed).

Test rates: Control (deionised water), 1.5 and 3.0 L BAS 830 01 H/ha. The reference item was applied at a rate of 1.5 L/ha. All substances were applied in 400 L/ha water. The substances were sprayed onto the sandy soil surface using laboratory spraying equipment and air-dried afterwards.

Test conditions: Temperature: 19 °C - 30 °C, increase to 31 °C for 3 h at day 43 of exposure (impact on all treatments, therefore not considered to have an impact on the test results); relative humidity: 64 % - 96 %; photoperiod: 16 h light : 8 h dark, light intensity: 1060 lux; food: *Chironomus* spp. larvae

Statistics: Descriptive statistics, Williams-t-test for the test item ($\alpha = 0.05$) and Student-t-test for the reference item ($\alpha = 0.05$)

Results and Discussion

In the water-treated control the mean number of hatched beetles of the F_1 generation per replicate was 591, in the treatment rates of 1.5 and 3.0 L BAS 830 01 H/ha it was 542 and 454, respectively. This resulted in an effect on reproduction of 8.3 % and 23.3 %, respectively. No statistical significant differences in reproduction were observed at a rate of 1.5 L BAS 830 01 H/ha (Williams-t-test, $\alpha = 0.05$). The results are summarised in Table B.9.5-9.

Table B.9.5-9: Effects on *Aleochara bilineata* exposed to BAS 830 01 H under worst-case laboratory conditions

Treatment	**Rate [L BAS 830 01 H/ha]**	**Number of hatched beetles (mean per replicate)**	**Effect on reproduction [%]**
Control	--	591	--
BAS 830 01 H	1.5	542	8.3
	3.0	454 *	23.3
Endpoint [L BAS 830 01 H/ha]			
ER_{50}	> 3.0		

* Statistically significantly different compared to the control (Williams-t-test, $\alpha = 0.05$).

The reference item resulted in a reduction of reproduction of 91.1 % compared to the control.

Conclusion

The study is acceptable. The ER_{50} of BAS 830 01 H for reproduction on *Aleochara bilineata* under extended laboratory conditions was > 3.0 L BAS 830 01 H/ha in 400 L water/ha.

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B.9.5.2.3 Semi-field studies with non-target arthropods

No studies with the representative formulation BAS 830 01 H were submitted for the renewal assessment.

B.9.5.2.4 Field studies with non-target arthropods

No studies with the representative formulation BAS 830 01 H were submitted for the renewal assessment.

B.9.5.2.5 Other routes of exposure for non-target arthropods

No studies with the representative formulation BAS 830 01 H were submitted for the renewal assessment.

B.9.6 Risk assessment for arthropods

BAS 830 01 H was not a representative formulation in the first EU review of dimethenamid-P. It is a representative formulation supporting the application for renewing the approval of dimethenamid-P. BAS 830 01 H is a suspo-emulsion formulation (SE) containing 333 g dimethenamid-P/L and 167 g quinmerac/L.

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

The correction factor is intended to cover uncertainty with regard to species sensitivity, the default value is 10 when the two standard species are tested (Tier 1). The default value in higher tier testing is 5 when 'higher-tier studies on the 'affected species and two additional species with different biologies are conducted. Since only two species were tested in extended laboratory studies with BAS 830 01 H, the correction factor used in tier II risk assessment should remain 10.

Table B.9.6-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Test substance	Exposure System	Results	Reference
Tier I				
Typhlodromus pyri (protonymphs)	BAS 830 01 H	Laboratory test glass plates, 2D	LR_{50} > 3 L prep. /ha	Röhlig, U. 09.09.2013 13 10 48 033A; BASF RegDoc# 2013/1132521
Aphidius rhopalosiphi (adults)	BAS 830 01 H	Laboratory test glass plates, 2D	LR_{50} = 0.0336 L prep./ha	Röhlig, U. 28.10.2013 13 10 48 032 A; BASF RegDoc#2013/1132522
Tier II				
Aphidius rhopalosiphi (adults)	BAS 830 01 H	Extended laboratory test, barley seedlings, 3D	LR_{50} > 3 L prep./ha ER_{50} > 3 L prep./ha	Stevens, J. 02.09.2013 702505; BASF RegDoc# 2013/1132523
Aleochara bilineata	BAS 830 01 H	Extended laboratory test, sandy soil (LUFA 2.1), 2D	ER_{50} > 3.0 L prep./ha	Röhlig, U. 04.11.2013 13 10 48 034 A; BASF RegDoc#2013/1132520

B.9.6.1 Risk assessment for in-field exposure

Table B.9.6-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of BAS 830 01 H in winter oilseed rape

Intended use	1		
Active substance/product	BAS 830 01 H		
Application rate (g/ha)	1 × 1.5 L prep./ha		
MAF	1		
Test species Tier I	**LR_{50} (lab.) (mL prod./ha)**	**$PER_{in\text{-}field}$ (mL prod./ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	3 000	1500	0.5
Aphidius rhopalosiphi	33.6		**44.6**
Test species Higher-tier	**Rate with ≤ 50 % effect* (mL prod.//ha)**	**$PER_{in\text{-}field}$ (mL prod.//ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	3 000	1500	yes
Aleochara bilineata	3 000	1500	yes

HQ values shown in **bold** are above the relevant trigger.
MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

B.9.6.2 Risk assessment for off-field exposure

Table B.9.6-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of BAS 830 01 H in winter oilseed rape

Intended use	1				
Active substance/product	BAS 830 01 H				
Application rate (g/ha)	1 × 1.5 L prep./ha				
MAF	1				
vdf	10[1)]* with 2D test setups and 1[2)] with 3D test setups				
Test species Tier I	**LR_{50} (lab.) (mL prod./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (mL prod./ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	3 000	4.155	4.155 [1)]	10	0.01385
Aphidius rhopalosiphi	33.6				1.2366
Test species Higher-tier	**Rate with ≤ 50 % effect** (mL prod./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (mL prod./ha)**	**CF**	**corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Aphidius rhopalosiphi	3 000	4.155	41.55 [2)]	5	yes
Aleochara bilineata	3 000	4.155	4.155 [1)]	5	yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* For formal reasons, the numerical value of 10 from the ESCORT 2 is taken, although doubts on its reliability are already mentioned in the Guidance Document on Terrestrial Ecotoxicology. In the RMS´ opinion, experimental data only support a vdf of 5 for a standard assessment. However, the changed value would not affect the overall outcome of the risk assessment.
** If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

B.9.6.3 Overall conclusions

In-field

Based on the calculated rates of BAS 830 01 H in in-field areas, the calculated HQ values describing the risk resulting from an exposure of non-target arthropods to BAS 830 01 H according to the GAP of the formulation BAS 830 01 H achieve the acceptability criteria "corr. $PER_{off\text{-}field}$ below rate with ≤ 50 % effect (higher Tier)", according to the Commission Implementing Regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

Off-field

Based on the calculated rates of BAS 830 01 H in off-field, the calculated HQ values describing the risk resulting from an exposure of non-target arthropods to BAS 830 01 H according to the GAP of the formulation BAS 830 01 H achieve the acceptability criteria HQ ≤ 2, according to the Commission Implementing Regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of BAS 830 01 H H in winter oilseed rape according to the label.

B.9.7 Effects on non-target soil meso- and macrofauna

B.9.7.1 Earthworms

B.9.7.1.1 Earthworms – sub-lethal effects

One new chronic laboratory study on the toxicity of the formulation BAS 830 01 H to *Eisenia fetida* was submitted with the renewal dossier and is summarised below.

KCP 10.4.1/1 Friedrich, 2013a (new study, submitted with renewal dossier)

Author:	Friedrich, S.
Title:	Sublethal toxicity of BAS 830 01 H to the earthworm *Eisenia fetida* in artificial soil
Date:	30.10.2013
Doc ID:	13 10 48 148 S; BASF RegDoc# 2013/1132513
Guidelines:	OECD 222 (2004)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item:	BAS 830 01 H, batch no. 451008, content of a.s.: quinmerac (BAS 518 H, Reg. No 168 526): 173.0 g/L (nominal: 167.0 g/L); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 347.7 g/L (nominal: 333.0 g/L); density: 1.135 g/cm^3
Test species:	*Eisenia fetida* (earthworm); adult worms with clitellum and weight of 280-464 mg, approximately 3 months old; source: in-house culture
Test design:	56-day test in treated artificial soil according to OECD 222 (10 % peat), different concentrations of the test item were mixed homogeneously into the soil, 6 treatment groups were set up (5 concentrations of the test item, untreated control) with 4 replicates for the test item treatment groups and 8 replicates for the control and 10 worms per replicate, assessment of worm mortality, behavioural effects and biomass development after 28 days of exposure; after an additional 28 days (56 days after application) reproduction (number of juveniles) was assessed.

Endpoints: NOEC, EC_{50}.

Reference item: Nutdazim 50 FLOW (carbendazim, SC 500). The effects of the reference item were investigated in a separate study. There, inhibition of reproduction was observed by 72.7 % and 98.8 % compared to control at 5 and 10 mg product/kg dry soil.

Test concentrations: Control, 11.125, 22.25, 44.5, 89 and 178 mg BAS 830 01 H/kg dry soil

Test conditions: Artificial soil according to OECD 222 with 10 % peat; pH 6.15 - 6.17 at test initiation, pH 5.77 - 5.88 at test termination; water content 55.5 % - 55.8 % of max. water holding capacity (WHC) at test initiation and 54.5 % - 55.3 % of WHC at test termination; temperature: 18.0 °C - 21.9 °C; photoperiod: 16 hours light: 8 hours dark, light intensity: 530 lux, food: horse manure

Statistics: Descriptive statistics. Fisher's Exact Binominal Test with Bonferroni Correction for mortality data ($\alpha = 0.05$, one-sided greater) and Williams-t-test for weight change and reproduction data ($\alpha = 0.05$, one-sided smaller)

Results and Discussion

BAS 830 01 H did not show any statistically significant differences on mortality and body weight compared to the control (Fisher's Exact Binominal Test with Bonferroni Correction, $\alpha = 0.05$, one-sided greater). The mortality of adult worms ranged between 0 and 2.5 % in the treated variants and was 0 % in the control group. The weight change of adult worms ranged between 34.0 and 41.6 % in the treated variants and was 39.5 % in the control group.
The reproduction rate was statistically significantly different compared to the control at a concentration of 178 mg BAS 830 01 H/kg dry soil (Williams-t-test, $\alpha = 0.05$, one-sided smaller). No behavioural abnormalities were observed in any of the treatment groups. The feeding activity in all the treated groups was comparable to the control. The results are summarised in the following table.

Table B.9.7-1: Effects of BAS 830 01 H on *Eisenia fetida* in a 56-day reproduction study

BAS 830 01 H [mg/kg dry soil]	**Control**	**11.125**	**22.25**	**44.5**	**89**	**178**
Mortality (28 d) [%]	0.0	2.5	0.0	0.0	0.0	2.5
Weight change (28 d) [%]	39.5	41.6	39.2	37.0	38.3	34.0
Number of juveniles (56 d)	139.0	135.8	153.5	134.5	120.5	83.8 *
Reproduction [% of control] (56 d)	100.0	97.7	110.4	96.8	86.7	60.3
	Endpoints [mg BAS 830 01 H/kg dry soil]					
NOEC (28 d, mortality)	≥ 178					
NOEC (56 d, reproduction)	89					
EC_{50} [1)] (day 56)	225 (95 % confidence limits 154 to 329)					

* Statistically significant differences compared to the control (Williams-t-test, $\alpha = 0.05$, one-sided smaller).
[1)] based on estimation of the data

Conclusion

The study is acceptable. In a 56-day reproduction study with BAS 830 01 H on earthworms, the overall NOEC was determined to be 89 mg BAS 830 01 H/kg dry soil. The test substance was incorporated in artificial soil (10 % peat).

B.9.7.1.2 Earthworms – field studies

No studies submitted, not required.

B.9.7.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Two new chronic laboratory studies on the toxicity of the formulation BAS 830 01 H to the species *Folsomia candida* and *Hypoaspis aculeifer* were submitted with the renewal dossier and are summarised below.

B.9.7.2.1 Species level testing

KCP 10.4.2.1/1 Schulz, 2013a (new study, submitted with the renewal dossier)

Author:	Schulz, L.
Title:	Effects of BAS 830 01 H on the reproduction of the predatory mite *Hypoaspis aculeifer*
Date:	30.10.2013
Doc ID:	13 10 48 150 S; BASF RegDoc#2013/1132515
Guidelines:	OECD 226 (2008)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item:	BAS 830 01 H, batch no. 451008, content of a.s.: quinmerac (BAS 518 H, Reg. No 168 526): 173.0 g/L (nominal: 167.0 g/L); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 347.7 g/L (nominal: 333.0 g/L); density: 1.135 g/cm^3.
Test species:	*Hypoaspis aculeifer* (CANESTRINI), adult female predatory mites (age difference 2 days); source: in-house culture.
Test design:	14-day chronic laboratory test (according to OECD 226) on effects of BAS 830 01 H on mortality and reproduction of soil mites. 5 different concentrations of the test item were homogenously mixed into artificial soil (5 % peat) which was then filled in glass vessels before the soil mites were introduced on top of the soil; 6 treatment groups (5 test item concentrations, control); 8 replicates for the control and 4 replicates for test item treatments, each with 10 soil mites; assessment of adult mortality and reproduction effects (number of juveniles) after 14 days.
Endpoints:	Mortality and reproduction rate after 14 days
Reference item:	Dimethoate EC 400 (411.7 g analysed). The effects of the reference item were investigated in a separate study. There, EC_{50} was calculated to be 6.64 mg as/kg dry soil.
Test rates:	Control, 62.5, 125, 250, 500 and 1000 mg BAS 830 01 H/kg dry soil
Test conditions:	Artificial soil according to OECD 226; pH 5.9 – pH 6.1 at test initiation, pH 5.7 - 5.8 at test termination; water content at test initiation 48.99 % - 51.59 % of maximum water holding capacity (WHC) and 45.72 % - 49.78 % of maximum WHC at test termination; temperature: 19.5 °C - 20.9 °C; photoperiod: 16 h light : 8 h dark; light intensity: 529 lux; food: cheese mites (*Tyrophagus putrescentiae*) supplied 2-3 times a week
Statistics:	Descriptive statistics; Fisher's Exact Binominal Test with Bonferroni Correction for mortality (α = 0.05, one-sided greater), Dunnett-t-test for reproduction (α = 0.05, one-sided smaller)

Results and Discussion

Mortality rates of 0.0 - 10.0 % were recorded in the test item treatment groups. In the control group the mortality rate was 10.0 %. The observed mortality rates for adult mortality in the test item treatment groups compared to control were not statistically significantly different (Fisher's Exact Binomial Test with Bonferroni Correction, α = 0.05, one-sided greater). Differences between the behaviour and the morphology of the mites in the control and the test item treatment groups could not be observed.
Reproduction rates in the 62.5, 125, 250, 500 and 1000 mg BAS 830 01 H/kg dry soil were 309.3, 303.8, 307.0, 326.3 and 293.5 juveniles, respectively. The mean reproduction in the control reached 295.8 juveniles. BAS 830 01 H showed no statistically significantly differences on reproduction at all tested concentrations (Dunnett-t-test, α = 0.05, one-sided smaller). The results are summarised in the following table.

Table B.9.7-2: Effects of BAS 830 01 H on predatory mites (*Hypoaspis aculeifer*) in a 14-day reproduction study

BAS 830 01 H [mg/kg dry soil]	**Control**	**62.5**	**125**	**250**	**500**	**1000**
Mortality (day 14) [%]	10.0	2.5	5.0	10.0	5.0	0.0
No. of juveniles (day 14)	295.8	309.3	303.8	307.0	326.3	293.5
Reproduction [% of control] (day 14)	--	105	103	104	110	99
	Endpoint [mg BAS 830 01 H/kg dry soil]					
NOEC mortality	≥ 1000					
NOEC reproduction	≥ 1000					
LC_{50}	> 1000					
EC_{50}	> 1000					

Conclusion

The study is acceptable.In a 14-day reproduction study with BAS 830 01 H on predatory soil mites (*Hypoaspis aculeifer*), the NOEC for mortality and reproduction was determined to be 1000 mg/kg dry soil, the highest concentration tested. The test substance was incorporated in artificial soil (5 % peat).

KCP 10.4.2.1/2 Friedrich, 2013b (new study, submitted with renewal dossier)

Author: Friedrich, S.
Title: Effects of BAS 830 01 H on the reproduction of the collembolan *Folsomia candida*
Date: 08.10.2013
Doc ID: 13 10 48 149 S; BASF RegDoc#2013/1132514
Guidelines: OECD 232 (2009), ISO 11267 (1999)
GLP: Yes
Validity: Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008, content of a.s.: quinmerac (BAS 518 H, Reg. No 168 526): 173.0 g/L (nominal: 167.0 g/L); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 347.7 g/L (nominal: 333.0 g/L); density: 1.135 g/cm^3

Test species:	*Folsomia candida* (springtails), juveniles, 9 - 12 days old; source: in-house culture
Test design:	28-day exposure in treated artificial soil (5 % peat) according to OECD 232 and ISO 11267; different concentrations of the test item were mixed homogeneously into the soil, which was filled in glass vessels before the springtails were introduced on top of the soil surface. 6 treatment groups were set up (5 concentrations of the test item, untreated control) with 4 replicates for the test item treatments and 8 replicates for the control with 10 collembolans per replicate. Assessment of adult mortality, behavioural effects and reproduction (number of juveniles) was done after 28 days.
Endpoints:	NOEC, LC_{50}, EC_{50}
Reference item:	Boric acid (100 % analysed). The effects of the reference item were investigated in a separate study. There, EC_{50} was calculated to be 108 mg as/kg dry soil.
Test concentrations:	Control 9.375, 18.75, 37.5, 75 and 150 mg BAS 830 01 H/kg dry soil
Test conditions:	Artificial soil according to OECD 232 with a peat content of 5 %; pH 6.10 - 6.14 at test initiation and pH 5.77 - 5.84 at test termination; water content at study initiation 58.0 % - 58.3 % of the maximum water holding capacity (WHC) and 56.9 % - 58.0 % of max. WHC at test termination; temperature: 18.0 °C - 21.9 °C; photoperiod: 16 h light : 8 h dark, light intensity: 490 lux; food: granulated dry yeast, supplied twice a week
Statistics:	Descriptive statistics; Fisher's Exact Binominal Test for mortality data ($\alpha = 0.05$, one-sided greater) and Williams-t-test for reproduction data ($\alpha = 0.05$, one-sided smaller)

Results and Discussion

After 28 days of exposure, mortality rates of 0 % - 37.5 % were recorded in the test item treatment groups compared to 5.0 % in the control. Statistically significant differences on mortality compared to the control were observed at a concentration of 150 mg BAS 830 01 H/kg dry soil (Fisher`s Exact Binomial Test with Bonferroni Correction, $\alpha = 0.05$, one-sided greater).

The mean reproduction in the untreated control reached 1061 juveniles. Reproduction rates in 9.375, 18.75, 37.5, 75 and 150 mg BAS 830 01 H/kg dry soil were 1094, 1056, 1038, 1069 and 523 juveniles, respectively. Statistically significant differences on the number of juveniles compared to the control group were recorded at a concentration of 150 mg test item/kg dry soil (Williams-t-test, $\alpha = 0.05$, one-sided smaller). No behavioural abnormalities were observed at any tested concentration. The results are summarised in the following table.

Table B.9.7-3: Effect of BAS 830 01 H on *Folsomia candida* in a 28-day reproduction study

BAS 830 01 H [mg/kg dry soil]	**Control**	**9.375**	**18.75**	**37.5**	**75**	**150**
Mortality (day 28) [%]	5.0	5.0	0.0	0.0	5.0	37.5 *
No. of juveniles (day 28)	1061	1094	1056	1038	1069	523 *
Reproduction [% of control] (day 28)	--	103	100	98	101	49
	Endpoints [mg BAS 830 01 H/kg dry soil]					
NOEC (mortality/ reproduction)	75					
LC_{50} (mortality)	> 150					
EC_{50} [1)]	149 (138 - 161)					

* Statistically significant differences compared to the control (Fisher's Exact Binominal Test for mortality data and Williams-t-test for reproduction, $\alpha = 0.05$).

1) based on Probit analysis.

Conclusion

The study is acceptable. In a 28-day collembolan reproduction study with BAS 830 01 H the overall NOEC was determined to be 75 mg BAS 830 01 H/kg dry soil. The test substance was incorporated in artificial soil (5 % peat).

B.9.7.2.2 Higher tier testing

No studies with the representative formulation BAS 830 01 H were submitted for the renewal assessment.

B.9.8 Risk assessment for non-target soil meso- and macrofauna

Table B.9.8-1: Proposed toxicity endpoints of soil meso- and macrofauna for use in risk assessment

Species	Test substance	Exposure System	Results	Reference
Earthworm acute				
Eisenia foetida	Dimethenamid-racemate	Acute, 14 d; Incorporated/ 10 % peat	LC_{50} = 294.4 mg/kg dw	Van Dijk, A. 22.06.1988 204614*
Eisenia foetida	M 23	Acute, 14 d; Incorporated/ 10 % peat	LC_{50} > 1264 mg/kg dw $LC_{50\ corr.}$ > 632 mg/kg dw [1) 2)]	Krieg, W. 19.03.1998 47842*
Eisenia foetida	M 27	Acute, 14 d; Incorporated/ 10 % peat	LC_{50} > 1264 mg/kg dw $LC_{50\ corr.}$ > 632 mg/kg dw [1) 2)]	Krieg, W. 20.03.1998 47843*
Eisenia fetida	M 31	Acute, 14 d; Incorporated/ 10 % peat	LC_{50} > 1000 mg/kg dw $LC_{50\ corr.}$> 500 mg/kg dw [1) 2)]	Krome, K. 26.09.2008 RRA 12620
Earthworm chronic				
Eisenia foetida	Dimethenamid-P	Chronic; Incorporated/ 5 % peat	NOEC = 25.4 mg as/kg dw Reproduction, biomass, mortality	Friedrich S. 06.11.2007 12 10 48 093 S; BASF RegDoc# 2012/1129456
Eisenia foetida	M 23	Chronic; Incorporated/ 5 % peat	NOEC = 8.32 mg as/kg dw [2)] Reproduction, biomass, mortality	Lührs, U. 08.11.2007 37431022; BASF RegDoc# 2007/1037731
Eisenia foetida	M 27	Chronic; Incorporated/ 5 % peat	NOEC = 10.56 mg as/kg dw [2)] Reproduction, biomass, mortality	Lührs, U. 08.11.2007 37421022; BASF RegDoc# 2007/1037732
Eisenia fetida	M 31	Chronic; Incorporated/ 5 % peat	NOEC = 100 mg as/kg dw [2)] Reproduction, biomass, mortality	Lührs, U. 08.01.2009 46551022; BASF RegDoc# 2008/1070910
Eisenia foetida	BAS 830 01 H	Chronic; Incorporated/ 10 % peat	NOEC = **89** mg prep. /kg dw [3)] Reproduction, biomass, mortality	Friedrich S. 30.10.2013 13 10 48 148 S; BASF RegDoc# 2013/1132513

Species	Test substance	Exposure System	Results	Reference
Mesofauna chronic				
Folsomia candida	Dimethenamid-P	Chronic; Incorporated/ 5 % peat	NOEC = **12.5** mg as/kg dw mortality NOEC = 25 mg as/kg dw reproduction EC_{50} = 41.6 mg as/kg dw reproduction LC_{50} = 118.3 mg as/kg dw Mortality	Friedrich, S. 29.03.2011 11 10 48 015 S; BASF RegDoc# 2011/1000481S
Hypoaspis aculeifer	Dimethenamid-P	Chronic; Incorporated/ 5 % peat	NOEC = 1000 mg as/kg dw (mortality) NOEC = 500 mg as/kg dw (reproduction)	Schulz, L. 05.11.2012 12 10 48 097 S; BASF RegDoc# 2012/1129457
Folsomia candida	M 23	Chronic; Incorporated/ 5 % peat	NOEC = 200 mg as/kg dw [2)] (mortality, reproduction)	Friedrich, S. 18.12.2012 12 10 48 101 S; BASF RegDoc# 2012/1129536
Hypoaspis aculeifer	M 23	Chronic; Incorporated/ 5 % peat	NOEC = 200 mg as/kg dw [2)] (mortality) NOEC = 100 mg as/kg dw (reproduction)	Schulz, L. 20.12.2012 12 10 48 101 S; BASF RegDoc# 2012/1129538*
Folsomia candida	M 27	Chronic; Incorporated/ 5 % peat	NOEC = 200 mg as/kg dw [2)] (mortality, reproduction)	Friedrich, S. 26.11.2012 12 10 48 105 S; BASF RegDoc# 2012/1129537
Hypoaspis aculeifer	M 27	Chronic; Incorporated/ 5 % peat	NOEC = 200 mg as/kg dw [2)] (mortality, reproduction)	Schulz, L. 20.12.2012 12 10 48 102 S; BASF RegDoc# 2012/1129539
Folsomia candida	M 31	Chronic; Incorporated/ 5 % peat	NOEC = 200 mg as/kg dw [2)] Mortality &	Friedrich, S. 13.01.2011 10 10 48 110 S; BASF RegDoc# 2011/1000222
Hypoaspis aculeifer	M 31	Chronic; Incorporated/ 5 % peat	NOEC = 500 mg as/kg dw [2)] (mortality, reproduction)	Schulz, L. 06.01.2014 13 10 48 113 S; BASF RegDoc# 2013/1103674
Folsomia candida	BAS 830 01 H	Chronic; Incorporated/ 5 % peat	NOEC = 75 mg prep./kg dw (reproduction)	Friedrich, S. 08.10.2013 13 10 48 149 S; BASF RegDoc#2013/1132514
Hypoaspis aculeifer	BAS 830 01 H	Chronic; Incorporated/ 5 % peat	NOEC = 1000 mg prep./kg dw [2)] (reproduction)	Friedrich, S. 30.10.2013 13 10 48 150 S; BASF RegDoc#2013/1132515

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003

[1)] According to the EPPO risk assessment scheme the toxicity data from tests with artificial soil are divided by the factor of 2 because logPow for the active substance is greater than 2 (No study on log POW of the metabolite has been provided by the applicant. According to the dossier of the applicant the log POW is >2).

[2)] Highest concentration tested

[3)] Based on a density of 1.135 g/cm^3

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section B.8 (Environmental Fate), Chapter 8.5.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for dimethenamid-P and its metabolite M 27 but for the metabolites M 23 and M 31.

The results of the risk assessment are summarised in the following table.

Table B.9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of BAS 830 01 H in winter oilseed rape (use 1 covering also use 2)

Intended use	**1, 2**		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Dimethenamid-P	294.4	0.667	441
M 23	> 632 [1)]	0.0884 *	> 7149
M 27	> 632 [1)]	0.104	6077
M 31	> 500[1)]	0.0902 *	> 5543
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dimethenamid-P	25.4	0.667	38
BAS 830 01 H	89 [2)]	1.5 L prep./ha (corresponding to 2.27 mg prep./kg dw)	39
M 23	8.32	0.0884 *	94
M 27	10.56	0.104	102
M 31	100	0.0902 *	1109
Chronic effects on other soil macro- and mesofauna; *Folsomia candida*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dimethenamid-P	12.5	0.667	19
BAS 830 01 H	75	1.5 L prep./ha (corresponding to 2.27 mg prep./kg dw)	33
M 23	200	0.0884 *	2262
M 27	200	0.104	1923
M 31	200	0.0902 *	2217
Chronic effects on other soil macro- and mesofauna; *Hypoaspis aculeifer*			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
Dimethenamid-P	500	0.667	750
BAS 830 01 H	1000	1.5 L prep./ha (corresponding to 2.27 mg prep./kg dw)	440
M 23	100	0.0884 *	1131
M 27	200	0.104	1923
M 31	500	0.0902 *	5543

TER values shown in **bold** fall below the relevant trigger.

* PECsoil accu (pease refer to Section B.8 (Environmental Fate), Chapter 8.5.2.

[1)] Toxicity endpoint is re-adjusted using a soil factor of 2 to address the organic content of the soil, since the log P_{ow} of the substance is > 2.

[2)] Based on a density of 1.135 g/cm^3

B.9.8.1 Overall conclusions

Earthworms

TER values for earthworms were calculated, taking into account the relevant toxicity data for dimethenamid-P / BAS 830 01 H and calculated exposure concentrations in soil, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. The calculated TER values do achieve the acceptability criterion TER ≥ 10 for acute effects / the acceptability criterion TER ≥ 5 for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

Other organisms of the soil macro- and mesofauna

TER values for other organisms of the soil macro- and mesofauna were calculated, taking into account the relevant toxicity data for dimethenamid-P / BAS 830 01 H and calculated exposure concentrations in soil, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. The calculated TER values do achieve the acceptability criterion TER ≥ 5 for chronic effects (as adopted from the risk assessment for earthworms) on other organisms of the soil macro- and mesofauna, according to the Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for other organisms of the soil macro- and mesofauna due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

B.9.9 Effects on soil nitrogen transformation

One new study on the toxicity of the formulation BAS 830 01 H to soil microflora (nitrogen transformation test) was submitted with the renewal dossier and is summarised below.

KCP 10.5/1 Schulz, 2013b (new study, submitted with renewal dossier)

Author:	Schulz, L.
Title:	Effects of BAS 830 01 H on the activity of soil microflora (nitrogen transformation test)
Date:	17.10.2013
Doc ID:	13 10 48 100 N; BASF RegDoc#2013/1132512
Guidelines:	OECD 216 (2000)
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item:	BAS 830 01 H, batch no. 451008, content of a.s.: quinmerac (BAS 518 H, Reg. No 168 526): 173.0 g/L (nominal: 167.0 g/L); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 347.7 g/L (nominal: 333.0 g/L); density: 1.135 g/cm^3
Test species:	Biologically active agricultural soil: loamy sand (DIN 4220) / sandy loam (USDA); pH 6.5, 1.49 % C_{org}, 35.17 % WHC
Test design:	Determination of the N-transformation (NO_3-nitrogen production) in soil enriched with lucerne meal (concentration in soil 0.5 %). Comparison of test item treated soil with a non-treated soil. NH_4-nitrogen formed from organically bound nitrogen in the soil and NO_3-nitrogen from the nitrification process was determined by using an Autoanalyser II (Bran and Luebbe). Sampling scheme: 0, 7, 14 and 28 days after treatment, sub-samples (3 replicates) were withdrawn from the bulk batches and subjected

to measurement.

Endpoints: Effects on the NO_3-nitrogen production

Test concentrations: Control, 2.27 and 22.7 mg BAS 830 01 H/kg dry soil (corresponding to an application rate of 1.5 and 15.0 L BAS 830 01 H/ha)

Reference item: Dinoterb (purity: 98.0 % ±0.5 analysed). The reference item was tested in a separate study at rates of 6.80, 16.00 and 27.00 mg/kg dry soil.

Test conditions: Temperature: 19.4 °C - 21.2 °C; pH 6.3 - 6.4; soil moisture: approx. 45 % of its maximum water holding capacity, measured water content: 14.72 - 15.34 g/100 g dry soil. Soil samples were incubated while stored in glass flasks in the dark.

Statistics: Descriptive statistics

Results and Discussion

No effects > 25 % of BAS 830 01 H on nitrogen transformation could be observed at both test concentrations after 28 days. Deviations from the control of +20.4 % after 7 days, and only +8.1 % after 28 days at the maximum test concentration of 22.7 mg BAS 830 01 H/kg dry soil were measured. The results are summarised in the following table.

Table B.9.9-1: Effects BAS 830 01 H on soil micro-organisms (nitrogen transformation) on days 7, 14 and 28 of incubation

Soil (days)	Control	2.27 mg BAS 830 01 H/kg dry soil, equivalent to 1.5 L/ha		22.7 mg BAS 830 01 H/kg dry soil, equivalent to 15.0 L/ha	
	NO_3-N [mg/kg dry soil]	NO_3-N [mg/kg dry soil]	% Deviation from the control [1)]	NO_3-N [mg/kg dry soil]	% Deviation from the control [1)]
loamy sand / sandy loam (0-7 d)	22.67	25.80	+13.8	27.30	+20.4
loamy sand / sandy loam (0-14 d)	34.90	30.77	-11.8	35.87	+2.8
loamy sand / sandy loam (0-28 d)	49.17	49.07	-0.2	53.13	+8.1

1) Based on NO_3-nitrogen production; - = inhibition; + = stimulation

In a separate study the reference item dinoterb produced a stimulation of nitrogen transformation of +33.7 % and +42.6 % at 16.00 mg and 27.00 mg/kg dry soil, respectively, 28 days after application.

Conclusion

The study is acceptable. Effects + 8.1 % on nitrogen transformation after 28 days in the field soil tested at 22.7 mg BAS 830 01 H/kg dry soil, equivalent to a field application rate of 15.0 L BAS 830 01 H/ha .

B.9.10 Risk assessment for soil nitrogen transformation

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section B.8 (Environmental Fate), Chapter 8.5.2 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see chapter B.9.7.2 of this document).

Table B.9.10-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	SAN 582 H (dimethenamid-racemate), 2.4 mg/kg, 12 mg/kg (5 x)	28 d	The study is not valid. No nitrification occurred. 28 d (1x: NH_4^+ +30.8 %, NO_3^- +42.9 %, total-N +36.4 %; 5 x: NH_4^+ +27.5 %, NO_3^- +49.6 %, Total-N +37.6 %	Danneberg, G. 01.08.1991 BE-S-7-91-01; TDS BS 2451
C-mineralisation	SAN 582 H (dimethenamid-racemate), 2.4 mg/kg, 12 mg/kg (5 x)	Dehydrogenase activity; BBA 1-1 (C) 28 d loamy sand; clay silt	< 25 % 1.8 kg as/ ha and 9.0 kg as/ ha The study it is not considered valid anymore since plastic bags are used.	Danneberg, G. 01.08.1991 BE-S-7-91-01; TDS BS 2451; BE-S-7-91-01-DEH-01; BMF1999-42; BMF96-00042; BASF DocID# 91/11908 *(only the endpoint on C-mineralisation)
N-mineralisation	M 23 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 062 C; BASF RegDoc# 2008/1065116
C-mineralisation	M 23 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 062 N; BASF RegDoc# 2008/1065117
N-mineralisation	M 27 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 063 N; BASF RegDoc# 2008/1065119*
C-mineralisation	M 27 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 063 C; BASF RegDoc# 2008/1065118
N-mineralisation	M 31 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 064 N; BASF RegDoc# 2008/1065115
C-mineralisation	M 31 (metabolite of dimethenamid-P)	28 d aerob	< 25 % difference from the control at **0.2 and 1 mg as/kg dw**	Schulz, L. 19.12.2008 08 10 48 064 C; BASF RegDoc# 2008/1065109
N-mineralisation	BAS 830 01 H	28 d aerob	< 25 % difference from the control at 22.7 mg prod./kg	Schulz, L. 17.10.2013 13 10 48 100 N; BASF RegDoc#2013/1132512

Endpoint	Substance	Exposure System	Results	Reference
			dry soil, equivalent to **15.0 L prod./ha.**	
N-mineralisation	BAS 656 07 H	28 d Aerob; loamy sand	< 25 % difference from the control at 1.4 and **7.0 L Prod/ha** Equivalent to 0.99 **and 4.93 kg as/ha,** respectively	Krieg, W. 1999 49223; BMF1999-49; BMF1999-48; BASF RegDoc# 99/10134[*1)]
C-mineralisation	BAS 656 07 H	28 d Aerob; loamy sand	< 25 % difference from the control at 1.4 and **7.0 L prod./ha** equivalent to 0.99 and **4.93 kg as/ha**, respectively	Krieg, W. 1999 49223; BMF1999-49; BMF1999-48; BASF RegDoc# 99/10134[*1)]

* Endpoint from Review report for the active substance dimethenamid-P, SANCO/1402/2001-Final, July 2003

1) Study was carried out with BAS 656 07 H (a similar formulation to BAS 656 12 H from the EU review of dimethenamid-P).

2) 1.87 µL BAS 656 07 H per kg soil (corresponding to a field application rate of 1.4 L BAS 656 07 H per ha) and 9.33 µL BAS 656 07 H per kg soil corresponding to an field application rate of 7.0 L BAS 656 07 H per ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3).

Studies with the technical substance submitted during the first evaluation process of dimethenamid-P and dimethenamid (racemate) were considered not valid since no nitrification occurred.
Since no valid study on N-transformation is available with the active substance dimethenamid-P, the study conducted with the mono-formulation BAS 656 07 H (720 g as/L) was used as surrogate.

Table B.9.10-2: Assessment of the risk for effects on soil micro-organisms due to the use of BAS 830 01 H H in (use 1 covering also use 2)

Intended use	**1**		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Dimethenamid-P tested as formulation BAS 656 07 H	4.93 kg as/ha	0.5 kg as/ha	Yes
M23	1.00	0.0893 *	Yes
M27	1.00	0.0593	Yes
M31	1.00	0.0738 *	Yes
BAS 830 01 H	22.7 corresponding to 15 L prod./ha	1.5 L prep./ha	Yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Dimethenamid-P tested as formulation BAS 656 07 H	4.93 kg as/ha	0.5 kg as/ha	Yes
M23	1.00	0.0893 *	Yes
M27	1.00	0.0593	Yes
M31	1.00	0.0738 *	Yes

* PECsoil accu: pease refer to Section B.8 (Environmental Fate), Chapter 8.5.2.

B.9.10.1 Overall conclusions

Concentrations of dimethenamid-P metabolites M23, M27 and M31 in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. Concentrations of BAS 830 01 H in soil were determined where effects on nitrogen mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BAS 830 01 H in winter oilseed rape. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended use of BAS 830 01 H in winter oilseed rape according to the label.

B.9.11 Effects on terrestrial non-target higher plants

B.9.11.1 Summary of screening data

No studies with the representative formulation BAS 830 01 H were submitted for the renewal assessment.

B.9.11.2 Testing on non-target plants

Two new studies on the toxicity of the representative formulation BAS 830 01 H to terrestrial non-target plants species were submitted with the renewal dossier: one vegetative vigour study and one on seedling emergence. Both are summarised below.

KCP 10.6.2/1 Strömel, 2013a (new study, submitted with renewal dossier)

Author:	Strömel, C. et al.
Title:	Effect of BAS 830 01 H on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions
Date:	30.10.2013
Doc ID:	AC/BASF/13/18; BASF RegDoc#2013/1134946
Guidelines:	OECD 208 (2006) - Seedling Emergence and Seedling Growth Test, EPA 850.4100, EPA 712-C-012
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008, content of a.s.: quinmerac (BAS 518 H, Reg. No 168 526): 173.0 g/L (nominal: 167.0 g/L); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 347.7 g/L (nominal: 333.0 g/L); density: 1.135 g/cm^3

Test species: Carrot (*Daucus carota L.*), lettuce (*Lactuca sativa* L.), oilseed rape (*Brassica napus* L. *ssp. napus*), cabbage *(Brassica oleracea L. var. capitata L.),* soybean *(Glycine max L.),* tomato *(Lycopersicon esculentum Mill.),* onion *(Allium cepa L.),* ryegrass *(Lolium multiflorum L.),* oat *(Avena sativa L.),* corn *(Zea mays L.)*

Test design: Dose-response design; 10 treatment groups (9 test item rates, water-treated control); 1 - 2 pots/replicate comprising one pot with 5 to 10 seeds/pot; greenhouse cultivation; pre-emergence application of test item shortly after seeding in 232 L water/ha using a laboratory spray cabin; assessment of plant damage and plant survival 7, 14 and 21 days (for carrot and onion 14, 21 and 28 days) after application (DAA); shoot dry weight and plant height were determined at study termination 21 DAA (28 days for carrot and onion).

Endpoints: NOER, ER_{25}, ER_{50}

Test rates: Control (tap water), 0.006, 0.012, 0.023, 0.047, 0.094, 0.188, 0.375, 0.750 and 1.500 L BAS 830 01 H/ha, applied in 232 L water/ha

Treatment	Rate BAS 830 01 H [L/ha]	Plant species
1	control	all
2	0.006	ryegrass
3	0.012	carrot, lettuce, ryegrass
4	0.023	carrot, lettuce, tomato, ryegrass
5	0.047	carrot, lettuce, tomato, ryegrass
6	0.094	all
7	0.188	carrot, lettuce, oilseed rape, cabbage, soybean, tomato, onion, oat, corn
8	0.375	oilseed rape, cabbage, soybean, tomato, onion, oat, corn
9	0.750	oilseed rape, cabbage, soybean, onion, oat, corn
10	1.500	oilseed rape, cabbage, soybean, onion, oat, corn

Test conditions: Greenhouse conditions: daily average temperature: 20.9 °C – 30.5 °C, extremes; daily mean relative humidity: 45.1 % - 67.0 %; photoperiod: day length ≥16 hours; additional light supply automatically when outdoor illumination was less than 10 klux.

Statistics: Descriptive statistics. Welch-t test with Bonferroni adjustment, Dunnett's t-test ($\alpha = 0.05$).

Results and Discussion

No control mortality and no other adverse effects on control plants were observed.

After exposure to BAS 830 01 H none of the tested plant species were affected concerning seedling emergence and survival.

No statistically significantly plant length reduction was observed for carrot, oilseed rape, soybean, onion, ryegrass and corn. Slight influence on plant length was detected after application of BAS 830 01 H for lettuce at a rate of 0.188 L/ha, for cabbage at rates ≥ 0.375 L/ha, for tomato at a rate of 0.375 L/ha and for oat at rates ≥ 0.750 L/ha. The application of the highest tested rate dependent on plant species caused up to 10 % reduction for lettuce and cabbage, 16 % reduction for tomato and 24 % reduction for oat.

The plant biomass (shoot dry weight) was determined 21 DAT (28 DAT for carrot and onion). No statistical significant influence of BAS 830 01 H on plant dry weight was observed in all tested plant species except lettuce and oat. In carrot significantly reduced plant dry weight was found at a rate of 0.023 L product/ha, but not at the higher tested rates, indicating that the difference at 0.023 L/ha was not test item related. Oat showed a 24 % biomass reduction after application of 1.500 L BAS 830 01 H/ha. The most severe impact of BAS 830 01 H on dry biomass was found for lettuce with a statistically significant reduction of 39 % after application of 0.094 L BAS 830 01 H/ha (Welch-t test with Bonferroni adjustment, $\alpha = 0.05$). The highest tested rate of 0.188 L BAS 830 01 H/ha reduced biomass of lettuce by 62 %.

The results are summarised in the following tables.

Table B.9.11-1: Effects of BAS 830 01 H on seedling emergence, plant biomass, plant height and plant survival 21 DAA

Treatment [L/ha]	carrot#	lettuce	oilseed rape	cabbage	soybean	tomato	onion#	ryegrass	oat	corn
Plant survival [% to control]										
control	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.006	--	--	--	--	--	--	--	94.6	--	--
0.012	88.9	102.7	--	--	--	--	--	94.6	--	--
0.023	91.7	100.0	--	--	--	100.0	--	94.6	--	--
0.047	105.6	94.6	--	--	--	102.6	--	91.9	--	--
0.094	108.3	100.0	91.9	105.6	100.0	102.6	102.7	97.3	105.3	97.5
0.188	105.6	83.8	105.4	105.6	102.6	100.0	91.9	--	102.6	97.5
0.375	--	--	100.0	105.6	102.6	97.4	97.3	--	102.6	100.0
0.750	--	--	105.4	100.0	97.4	--	100.0	--	102.6	97.5
1.500	--	--	105.4	102.8	102.6	--	105.4	--	102.6	100.0
Seedling emergence rate [%]										
control	90	93	93	90	98	95	93	93	95	100
0.006	--	--	--	--	--	--	--	88	--	--
0.012	80	95	--	--	--	--	--	88	--	--
0.023	83	93	--	--	--	95	--	88	--	--
0.047	95	88	--	--	--	98	--	85	--	--
0.094	98	93	85	95	98	98	95	90	100	98
0.188	95	78	98	95	100	95	85	--	98	98
0.375	--	--	93	95	100	93	90	--	98	100
0.750	--	--	98	90	95	--	93	--	98	98
1.500	--	--	98	93	100	--	98	--	98	100
Biomass [% to control]										
control	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.006	--	--	--	--	--	--	--	104.9	--	--
0.012	86.9	103.0	--	--	--	--	--	89.0	--	--
0.023	85.6 *	106.8	--	--	--	95.6	--	106.8	--	--
0.047	94.9	81.7	--	--	--	99.6	--	108.1	--	--
0.094	94.9	60.8 **	101.0	98.0	99.9	101.0	120.2	94.9	100.7	97.6
0.188	95.0	38.5 **	111.1	103.5	110.3	100.1	105.8	--	96.9	97.5
0.375	--	--	109.9	103.7	107.0	78.2	112.5	--	92.9	97.8
0.750	--	--	116.0	88.6	91.4	--	115.1	--	86.0	96.2
1.500	--	--	108.0	92.8	94.7	--	125.8	--	76.3*	95.1
Mean plant height [% to control]										
control	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0.006	--	--	--	--	--	--	--	101.0	--	--
0.012	98.9	99.0	--	--	--	--	--	101.4	--	--
0.023	95.0	104.1	--	--	--	101.5	--	112.7	--	--
0.047	95.0	99.6	--	--	--	102.3	--	109.5	--	--
0.094	99.4	106.0	102.4	97.8	101.9	106.6	108.9	108.3	104.8	101.6
0.188	93.8	90.0 **	99.2	97.4	98.6	101.0	106.3	--	100.3	102.5
0.375	--	--	98.9	94.8*	98.9	84.4**	107.1	--	99.9	100.8
0.750	--	--	96.3	92.2*	98.5	--	102.5	--	88.1**	99.2
1.500	--	--	99.8	90.1*	96.0	--	103.8	--	76.3**	98.4

* statistically significantly different compared to the control (Dunnett's t-test, $\alpha = 0.05$)

** statistically significantly different compared to the control (Welch-t test with Bonferroni adjustment, α = 0.05)
# onion and carrot 28 DAA (14,21 and 28 DAA for seedling emergence)

Table B.9.11-2: NOER, ER_{25} and ER_{50} of BAS 830 01 H [L/ha] for non-target plants 21 DAA

End points [L/ha]	carrot#	lettuce	oilseed rape	cabbage	soybean	tomato	onion#	ryegrass	oat	corn
Plant survival										
NOER	≥ 0.188	≥ 0.188	≥ 1.500	≥ 1.500	≥ 1.500	≥ 0.375	≥ 1.500	≥ 0.094	≥ 1.500	≥ 1.500
ER_{25}	> 0.188	> 0.188	> 1.500	> 1.500	> 1.500	> 0.375	> 1.500	> 0.094	> 1.500	> 1.500
ER_{50}	> 0.188	> 0.188	> 1.500	> 1.500	> 1.500	> 0.375	> 1.500	> 0.094	> 1.500	> 1.500
Seedling emergence										
NOER	≥ 0.188	≥ 0.188	≥ 1.500	≥ 1.500	≥ 1.500	≥ 0.375	≥ 1.500	≥ 0.094	≥ 1.500	≥ 1.500
ER_{25}	> 0.188	> 0.188	> 1.500	> 1.500	> 1.500	> 0.375	> 1.500	> 0.094	> 1.500	> 1.500
ER_{50}	> 0.188	> 0.188	> 1.500	> 1.500	> 1.500	> 0.375	> 1.500	> 0.094	> 1.500	> 1.500
Plant height										
NOER	≥ 0.188	0.094	≥ 1.500	0.188	≥ 1.500	0.188	≥ 1.500	≥ 0.094	0.375	≥ 1.500
ER_{25}	> 0.188	> 0.188	> 1.500	> 1.500	> 1.500	> 1.500	> 1.500	> 0.094	> 1.500	> 1.500
ER_{50}	> 0.188	> 0.188	> 1.500	> 1.500	> 1.500	> 1.500	> 1.500	> 0.094	> 1.500	> 1.500
Biomass reduction										
NOER	≥ 0.188	0.047	≥ 1.500	≥ 1.500	≥ 1.500	≥ 0.375	≥ 1.500	≥ 0.094	0.750	≥ 1.500
ER_{25}	> 0.188	0.065	> 1.500	> 1.500	> 1.500	> 0.375	> 1.500	> 0.094	> 1.500	> 1.500
ER_{50}	> 0.188	0.132	> 1.500	> 1.500	> 1.500	> 0.375	> 1.500	> 0.094	> 1.500	> 1.500

onion and carrot 28 DAA

Conclusion

The seedling emergence and survival of all tested plant species were not influenced within the tested rates of BAS 830 01 H. Also, on plant height and biomass no negative impact of BAS 830 01 H was found in carrot, oilseed rape, soybean, onion, ryegrass and corn within the tested rates. Slight plant length reduction could be assessed for lettuce, cabbage, tomato and oat. Slight biomass reduction of 24 % occurred in oat and a clear effect on biomass was found in lettuce (*Lactuca sativa*) resulting in an ER_{50} value of 0.132 L BAS 830 01 H/ha.

Due to test design the most sensitive plant species was lettuce (*Lactuca sativa*) comparing the effects at 0.094 L BAS 830 01 H /ha test concentration. For lettuce (*Lactuca sativa*) an ER_{50} value of 0.132 L BAS 830 01 H/ha for biomass reduction could be determined, whereas the ER_{50} value for ryegras (*Lolium multiflorum)* could not be determined due to lack of data at concentrations > 0.094 L BAS 830 01 H/ha. Since *Lolium multiflorum* is very sensitive to dimethenamid-P an ER_{50} > 0.094 L BAS 830 01 H is used for risk assessment.

KCP 10.6.2/2 Strömel, 2013b (new study, submitted with the renewal dossier)

Author:	Strömel, C. et al.
Title:	Effect of BAS 830 01 H on vegetative vigour of ten species of terrestrial plants under greenhouse conditions
Date:	06.11.2013
Doc ID:	AC/BASF/13/19; BASF RegDoc#2013/1134947
Guidelines:	OECD 227 July 2006, EPA 850.4150, EPA 712-C-011
GLP:	Yes
Validity:	Acceptable

Material and Methods

Test item: BAS 830 01 H, batch no. 451008, content of a.s.: quinmerac (BAS 518 H, Reg. No 168 526): 173.0 g/L (nominal: 167.0 g/L); dimethenamid-P (BAS 656 H, Reg. No. 363 851): 347.7 g/L (nominal: 333.0 g/L); density: 1.135 g/cm^3

Test species: Carrot (*Daucus carota L.*), lettuce (*Lactuca sativa L.*), oilseed rape (*Brassica napus L. ssp. napus*), cabbage *(Brassica oleracea L. var. capitata L.),* soybean *(Glycine max L.),* tomato *(Lycopersicon esculentum Mill.),* onion *(Allium cepa L.),* ryegrass *(Lolium multiflorum L.),* oat *(Avena sativa L.),* corn *(Zea mays L.)*

Test design: Dose-response design; 8 treatment groups (7 test item rates, water-treated control); 5 replicates/treatment, with 1 - 2 pots/replicate with 3 - 10 plants/pot (depending on plant species); greenhouse cultivation; post-emergence application of test item at growth stage BBCH 12 - 14 in 235 L water/ha using a laboratory spray cabin; assessments of plant damage and plant survival were done 7, 14 and 21 days after application (DAA); shoot dry weight and plant height was determined at study termination 21 DAA.

Endpoints: NOER, ER_{25}, ER_{50}

Test rates: Control (tap water), 0.047, 0.094, 0.188, 0.375, 0.750 and 1.500 L BAS 830 01 H/ha, applied in 235 L water/ha

Treatment	Rate BAS 830 01 H [L/ha]	Plant species
1	Control	all
2	0.047	carrot, soybean, tomato
3	0.094	carrot, soybean, tomato
4	0.125	all
5	0.188	all
6	0.375	all
7	0.750	all
8	1.500	lettuce, oilseed rape, cabbage, onion, ryegrass, oat, corn

Test conditions: Greenhouse conditions: daily average temperature: 17.5 °C – 24.7 °C; daily mean relative humidity: 45.7 % - 81.1 %; photoperiod: day length ≥16 hours; additional light supply automatically when outdoor illumination was less than 10 klux.

Statistics: Descriptive statistics. Welch-t test with Bonferroni adjustment, Dunnett's t-test ($\alpha = 0.05$).

Results and Discussion

No control mortality and no other adverse effects on control plants were observed.

After exposure to BAS 830 01 H none of the tested plant species was affected concerning survival.

Plant length was not influenced by BAS 830 01 H in carrots and soybean up to 0.750 L/ha and in onion and corn up to 1.500 L/ha. Slight reduction in plant length occurred in oilseed rape, cabbage and oat with less than 10 %. Lettuce and ryegrass length was reduced by 33 % and 38 % following the application of 1.500 L BAS 830 01 H/ha. Statistically significant effects could be found at rates ≥ 0.375 L/ha for lettuce and ≥ 0.188 L/ha for ryegrass (Welch-t test with Bonferroni adjustment, α = 0.05).

No influence of BAS 830 01 H on plant weight was observed in carrot, oilseed rape, cabbage, soybean, onion and corn. Oat and tomato dry weight showed a negative influence of BAS 830 01 H at rates ≥ 0.750 L/ha with a reduction of 21 % for oat at 1.500 L/ha and of 30 % for tomato at 0.750 L/ha. In lettuce significant biomass reduction occurred at rates ≥ 0.750 L/ha with up to 62 % at 1.500 L/ha. Response of ryegrass could be found at rates ≥ 0.188 L/ha with biomass reductions between 25 % and 73 %.

The results are summarised in Table B.9.11-3 and Table B.9.11-4.

Table B.9.11-3: Effect of BAS 830 01 H on plant biomass, plant height and plant condition 21 DAA

Treatment [L/ha]	carrot	lettuce	oilseed rape	cabbage	soybean	tomato	onion	ryegrass	oat	corn
Plant survival [% to control]										
control	100	100	100	100	100	100	100	100	100	100
0.047	100	--	--	--	100	100	--	--	--	--
0.094	100	--	--	--	100	100	--	--	--	--
0.125	100	100	100	100	100	100	100	100	100	100
0.188	100	100	100	100	100	100	100	100	100	100
0.375	100	100	100	100	100	100	100	100	100	100
0.750	100	100	100	100	100	100	100	100	100	100
1.500	--	97	100	100	--	--	100	100	100	100
Biomass [% to control]										
control	100	100	100	100	100	100	100	100	100	100
0.047	97.8	--	--	--	100.4	96.2	--	--	--	--
0.094	99.6	--	--	--	98.7	97.4	--	--	--	--
0.125	104.4	102.0	99.0	104.1	98.2	95.4	92.5	98.8	107.9	102.9
0.188	103.5	98.8	104.0	102.9	94.0	92.0	92.4	74.5*	98.1	107.8
0.375	106.1	94.3	101.1	101.2	94.5	88.3	102.1	50.3*	100.8	111.4
0.750	92.6	72.3**	102.2	98.4	92.0	70.3*	90.3	40.9*	75.6*	105.5
1.500	--	37.9**	99.9	98.9	--	--	94.5	26.7*	78.7*	100.2
Mean plant height [% to control]										
control	100	100	100	100	100	100	100	100	100	100
0.047	97.5	--	--	--	94.7	100.3	--	--	--	--
0.094	101.7	--	--	--	96.4	96.8	--	--	--	--
0.125	99.5	97.3	99.2	96.8	105.4	98.7	98.4	103.7	102.1	101.5
0.188	99.8	101.9	96.7	99.5	98.9	99.5	100.2	91.4**	99.9	103.0
0.375	102.9	92.8**	94.6*	96.9**	102.6	93.3**	101.4	84.3**	101.6	104.0
0.750	94.4	82.2**	97.4	92.9**	99.0	97.5	99.0	69.5**	94.1*	103.5
1.500	--	67.3**	94.7*	91.2**	--	--	99.0	62.1**	92.0*	101.2

* statistically significantly different compared to the control (Dunnett's t-test, α = 0.05)

** statistically significantly different compared to the control (Welch-t test with Bonferroni adjustment, α = 0.05)

Table B.9.11-4: NOER, ER_{25} and ER_{50} of BAS 830 01 H [L/ha] for non-target plants 21 DAA

End points [L/ha]	carrot	lettuce	oilseed rape	cabbage	soybean	tomato	onion	ryegrass	oat	corn
Plant survival										
NOER	≥ 0.750	≥ 1.500	≥ 1.500	≥ 1.500	≥ 0.750	≥ 0.750	≥ 1.500	≥ 1.500	≥ 1.500	≥ 1.500
ER_{25}	> 0.750	> 1.500	> 1.500	> 1.500	> 0.750	> 0.750	> 1.500	> 1.500	> 1.500	> 1.500
ER_{50}	> 0.750	> 1.500	> 1.500	> 1.500	> 0.750	> 0.750	> 1.500	> 1.500	> 1.500	> 1.500
Biomass reduction										
NOER	≥ 0.750	0.375	≥ 1.500	≥ 1.500	≥ 0.750	0.375	≥ 1.500	0.125	0.375	≥ 1.500
ER_{25}	> 0.750	0.711	> 1.500	> 1.500	> 0.750	0.644	> 1.500	0.215	> 1.500	> 1.500
ER_{50}	> 0.750	1.185	> 1.500	> 1.500	> 0.750	> 0.750	> 1.500	0.527	> 1.500	> 1.500
Plant height										
NOER	≥ 0.750	0.188	0.750	0.188	≥ 0.750	≥ 0.750	≥ 1.500	0.125	0.375	≥ 1.500
ER_{25}	> 0.750	1.092	> 1.500	> 1.500	> 0.750	> 0.750	> 1.500	0.694	> 1.500	> 1.500
ER_{50}	> 0.750	>1.500	> 1.500	> 1.500	> 0.750	> 0.750	> 1.500	> 1.500	> 1.500	> 1.500

Conclusion

Based on the results of this study, conducted under worst-case greenhouse conditions, it can be concluded that post-emergence application of BAS 830 01 H with rates up to 1.500 L/ha did not cause adverse effects to plant mortality of all tested plant species. Plant weight was not affected for carrot, oilseed rape, cabbage, soybean onion and corn within the test species specific range of tested rates. Tomato and oat showed biomass reductions with significant responses at rates ≥ 0.750 L BAS 830 01 H/ha.

The most sensitive plant species was found to be ryegrass (*Lolium multiflorum*) with an ER_{50} for dry biomass reduction of 0.527 L BAS 830 01 H/ha.

B.9.11.3 Extended laboratory studies on non-target plants

No studies submitted, not required.

B.9.11.4 Semi-field and field tests on non-target plants

No studies submitted, not required.

B.9.12 Risk assessment for terrestrial non-target higher plants

Table B.9.12-1: Endpoints and effect values relevant for the risk assessment for non-target plants

Species	Substance	Exposure System	Results	Reference
Daucus carota L.; d *Lactuca sativa L.; d* *Brassica napus L. ssp. napus, d* *Brassica oleracea L. var. capitata L.; d* *Glycine max L.; d* *Lycopersicon esculentum Mill.; d* *Allium cepa L.; m* ***Lolium multiflorum L.;*** *m* *Avena sativa L.; m* *Zea mays L.; m*	BAS 830 01 H	21 d Seedling emergence	ER_{50} > 0.094 L prod./ha	Strömel, C. et al. 30.10.2013 AC/BASF/13/18; BASF RegDoc#2013/1134946
Daucus carota L.; d *Lactuca sativa L.; d* *Brassica napus L. ssp. napus, d* *Brassica oleracea L. var. capitata L.; d* *Glycine max L.; d* *Lycopersicon esculentum Mill.; d* *Allium cepa L.; m* ***Lolium multiflorum L.****; m* *Avena sativa L.; m* *Zea mays L.; m*	BAS 830 01 H	21 d Vegetative vigour	ER_{50} = 0.527 L prod./ha	Strömel, C. et al. 06.11.2013 AC/BASF/13/19; BASF RegDoc#2013/1134947
Digitaria sanguinalis, m *Setaria viridis, m* *Lolium multiflorum, m* *Setaria faberi, m* *Echinocloa crus-galli, m* *Poa annua, m* *Capsella bursa-pastoris, d* *Chenopodium album, d* *Matricaria inodora, d* *Stellaria media, d*	M 31	21 d, pre-emergence screening, 684 and 1008 g as/ha	no herbicidal effects (visual observation) ER_{50} >1008 g metabolite/ha	Dutillie, H. und Sack, D. 26.09.2008 353446*
Avena fatua, m *Bromus tectorum, m* *Echinochloa crus-galli, m* *Setaria viridis, m* *Abutilon theophrasti, d* *Amaranthus retroflexus, d* *Sinapis alba, d* *Solanum nigrum, d*	M 23 and M 27	Pre- and post emergence 250 und 1000 g metabolite/ha Parent 0.16 g as/ha	no herbicidal effects (visual observation) ER_{50} >1000 g metabolite/ha ER_{50} >0.16 g as/ha	Kaethner, M. 30.01.1995 TDS-BS5094; PFL2002-227 and PFL2002-228*

Bromus inermis, m *Echinochloa crus-galli, m* *Setaria viridis, m* *Lolium multiflorum, m* *Geranium dissectum, d* *Chenopodium album, d*	soil metabolites M656PH023, M656PH030, M656PH031, M656PH032, M656PH043, M656PH045, M656PH047, M656PH054, M656H055, the Na salt of M656PH027 and the ethylester derivate for M656PH062 parent dimethenamid-P BAS 656 12 H	21 d; Pre- and post emergence Blank formulation + 4 rates Blank formulation, 43.2; 86.4; 172.8, and 864 g ai / ha Blank formulation, 60, 120, 240, and 1200 mL prep. / ha	no herbicidal effects (visual observation) Effects on Lolium multiflorum based on phytotoxicity (at day 21): ER50 (SE) < 43.2 g as/ha (80 % effect) ER50 (VV) = 93.3 g as/ha (Probit analysis) ER50 (SE) < 43.2 g as/ha (96 % effect) ER50 (VV) = 62.3 g as/ha (Probit analysis)	N.N. (Document N4 of the dossier; Doc ID 2014/ 1101480) (study can only be used subject to the submission of the document and to the evaluation by the RMS)

m: monocotyledonous; d: dicotyledonous

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

B.9.12.1.1 Tier-1 risk assessment (based on screening data)

Not relevant.

B.9.12.1.2 Tier-2 risk assessment (based on dose-response data)

Table B.9.12-2: Assessment of the risk for non-target plants due to the use of BAS 830 01 H in (use 1 covering also use 2)

Intended use	1
Active substance/product	BAS 830 01 H
Application rate (g/ha)	1 × 1.5 L prod./ha
MAF	1

Test species	**ER_{50} (mL prod./ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (mL prod.//ha)**	**TER criterion: TER ≥ 5**
Lolium multiflorum	> 94	2.77 %	41.55	**2.3**
Lolium multiflorum	527	2.77 %	41.55	13

TER values shown in **bold** fall below the relevant trigger.
MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

B.9.12.1.3 Higher-tier risk assessment

Not relevant.

B.9.12.1.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures should be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table B.9.12-3: Risk assessment for non-target terrestrial plants due to the use of BAS 830 01 H in winter oilseed rape. (use 1 covering also use 2) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use **Active substance/product** **Application rate (g/ha)** **MAF**		1 BAS 830 01 H 1 × 1.5 L prod./ha 1			
Buffer strip (m)	**Drift rate (%)**	**$PER_{off\text{-}field}$ (mL/ha)**	**$PER_{off\text{-}field}$ 50 % drift red. (mL /ha)**	**$PER_{off\text{-}field}$ 75 % drift red. (mL /ha)**	**$PER_{off\text{-}field}$ 90 % drift red. (mL /ha)**
1	2.77	41.55	20.775	10.39	4.155
5	0.57	8.55	4.275	2.14	0.855
Toxicity value (SE) ER_{50} = > 94 mL prod./ha		**TER** **criterion: TER ≥ 5**			
1		**2.3**	**4.5**	**9.0**	22.6
5		11	22	44	110

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio.
Criteria values shown **in bold** breach the relevant trigger.

B.9.12.2 Overall conclusions

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for BAS 830 01 H and calculated exposure concentrations in off-field habitats, according to the intended uses of the product dimethenamid-P in winter oilseed rape. The calculated TER values do achieve the acceptability criterion TER ≥ 5 for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 that amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.

While the assessment based on standard exposure estimates does not indicate an acceptable risk for non-target terrestrial plants, the TER acceptability criterion can be achieved when risk mitigation measures for reducing entries via spray drift in off-field habitats are applied (75 % drift reduction or 5 m buffer strip). It has to be evaluated on Member State level, whether those or equivalent risk mitigation measures are also available in the respective Member State.

B.9.13 Effects on other terrestrial organisms (flora and fauna)

No studies submitted.

B.9.14 Risk assessment for other terrestrial organisms (flora and fauna)

No studies submitted, not required.

B.9.15 References relied on

A search for open literature which included papers in peer-reviewed journals and reports from government and other agencies in the EU and several other countries was performed by the applicant. The literature search was done via databases such as PubMed, Agricola, and SciFinder using the key-word "Dimethenamid" or "Dimethenamid-P" and the CAS Numbers 87674-68-8 and 163515-14-8, respectively. The initial search was a net cast as wide as possible to ensure complete coverage of the literature. The references were then reviewed and, on the basis of the title and the abstract, a subset was retained for use in the characterisation. Priority was given to papers published since 2003 and, where possible, copies of these were obtained for more detailed review. No additional open-literature studies concerning ecotoxicology of dimethenamid-P were found helpful for risk assessment purposes.

For details please refer to the Appendix to Dimethenamid-P_RAR_11_Volume_3CA_B-9.

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 10.2	Brock T.C.M., Alix A., Brown C.D., Capri E., Gottes-bueren B.F.F., Heimbach F., Lythgo C.M., Schulz R., Streloke M. eds.	2009	Linking Aquatic Exposure and Effects: Risk Assessment of Pesticides. SETAC Press\CRC Press, Boca Raton\Pensacola (FL), USA: 440 pp. Not GLP, published	N	N	-	LIT	N
KCP 10.2	Wang, W., Erzgräber, B. and Gottesbü-ren, B.	2010	EPAT – An Exposure Pattern Analysis Tool RIFCON GmbH Report No. R08270 Not GLP, published	N	N	-	LIT	N
KCP 10.2	Van Vlaardingen PLA, Traas TP, Wintersen AM, Aldenberg T.	2004	ETX 2.0. A program to calculate hazardous concentrations and fraction affected, based on normally distributed toxicity data. Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 601501028/2004, 68 pp. Not GLP, published	N	N	-	LIT	N
KCP 10.2.1/1	[redacted]	2013	BAS 830 01 H: Toxicity to the rainbow trout Oncorhynchus mykiss under laboratory conditions (acute toxicity test - static) 2013/1168360 [redacted] GLP, unpublished	Y	Y	New data for AIR3 renewal	BASF	N III A 10.2

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KCP 10.2.1/2	Zawadsky C.	2013	BAS 830 01 H: Toxicity to the flea Daphnia magna STRAUS under laboratory conditions (acute immobilisation test - static) 2013/1168361 Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.2
KCP 10.2.1/3	Backfisch K.	2013	Effect of BAS 830 01 H on the growth of the green alga Pseudokirchneriella subcapitata 2013/1311299 BASF SE, Limburgerhof, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.2
KCP 10.2.1/4	Turek T.	2013	BAS 830 01 H - Lemna gibba CPCC 310 growth inhibition test 2013/1250860 Institute of Industrial Organic Chemistry, Pszczyna, Poland GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.2
KCP 10.3.1.1.1/1	Franke M.	2013	Acute toxicity of BAS 830 01 H to the honeybee Apis mellifera L. under laboratory conditions 2013/1132519 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.4.1
KCP 10.3.1.1.2/1	Franke M.	2013	Acute toxicity of BAS 830 01 H to the honeybee Apis mellifera L. under laboratory conditions 2013/1132519 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.4.1
KCP 10.3.2.1/1	Roehlig U.	2013	Effects of BAS 830 01 H on the predatory mite Typhlodromus pyri SCHEUTEN in a laboratory test - Rate-response-test (LR_{50}) 2013/1132521 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.5.1
KCP 10.3.2.1/2	Roehlig U.	2013	Effects of BAS 830 01 H on the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) in a laboratory test - rate-response-test (LR_{50}) 2013/1132522 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.5.1

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KCP 10.3.2.2/1	Stevens J.	2013	A rate-response extended laboratory test to determine the effects of BAS 830 01 H on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera: Braconidae) 2013/1132523 Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.5.1
KCP 10.3.2.2/2	Roehlig U.	2013	Effects of BAS 830 01 H on the rove beetle Aleochara bilineata GYLL. under extended laboratory conditions 2013/1132520 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.5.1
KCP 10.4.1.1/1	Friedrich S.	2013	Sublethal toxicity of BAS 830 01 H to the earthworm Eisenia fetida in artificial soil 2013/1132513 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.6.1.2
KCP 10.4.2.1/1	Schulz L.	2013	Effects of BAS 830 01 H on the reproductionof the predatory mite Hypoaspis aculeifer 2013/1132515 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.6.2
KCP 10.4.2.1/2	Friedrich S.	2013	Effects of BAS 830 01 H on the reproduction of the collembolan Folsomia candida 2013/1132514 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.6.2
KCP 10.5/1	Schulz L.	2013	Effects of BAS 830 01 H on the activity of soil microflora (nitrogen transformation test) 2013/1132512 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.7
KCP 10.6.2/1	Stroemel C. et al.	2013	Effect of BAS 830 01 H on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions 2013/1134946 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.8

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KCP 10.6.2/2	Stroemel C. et al.	2013	Effect of BAS 830 01 H on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2013/1134947 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. GLP, unpublished	N	Y	New data for AIR3 renewal	BASF	N III A 10.8