Renewal Assessment Report

Dimethenamid-P

BAS 830 01 H

Volume 3 – B.6 Toxicology and metabolism data and assessment of risks for humans

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B Summary, evaluation and assessment of the data and information

B.6 Toxicology and metabolism data and assessment of risks for humans

This document reviews the toxicological studies for the product BAS 830 01 H containing the active substances dimethenamid-P and quinmerac in the context of the renewal of the approval of the active substance dimethenamid-P. A full risk assessment according to Uniform Principles is provided for both active substances contained which demonstrates that the product is safe for operators, workers and bystanders.
BAS 830 01 H, the representative formulation of dimethenamid-P, is a new product that is currently evaluated according to Uniform Principles (submission to zonal rapporteur UK in central zone and FR in the southern zone). A complete set of new studies on the product was submitted for this renewal assessment of dimethenamid-P.

B.6.1 Acute toxicity of plant protection product

The studies on acute oral, dermal and inhalation toxicity, skin and eye irritation as well as on skin sensitisation were conducted with BAS 830 01 H. A summary of the toxicological evaluation for BAS 830 01 H is given in Table B.6.1-1. The individual studies are presented under B.6.1.1 to B.6.1.6.

Table B.6.1-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for BAS 830 01 H

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Dir. 67/548/EEC)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	>2000 mg/kg bw	Yes	None	None	[redacted] 2013a, ASB2014-8512
LD_{50} dermal, rat (OECD 402)	>5000 mg/kg bw	Yes	None	None	[redacted] 2013b, ASB2014-8513
LC_{50} inhalation, rat (OECD 403)	>4.8 mg/L air	Yes	None	None	[redacted] 2013, ASB2014-8514
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	[redacted] 2013c, ASB2014-8516
Eye irritation, rabbit (OECD 405)	Irritant	Yes	R36	H319	[redacted] 2013d, ASB2014-8519
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes	R43	H317	[redacted] 2014, ASB2014-8476

Based on the results for acute toxicity, BAS 830 01 H is considered to be of no acute oral, dermal and

inhalation toxicity. It is not skin irritating but irritating to the rabbit eye. Based on the results of a LLNA, BAS 830 01 H has to be classified as skin sensitiser.

B.6.1.1 Oral toxicity

Reference: 7.1.1
Report: BAS 830 01 H - Acute oral toxicity study in rats, [redacted], 2013a, 2013/1276068, ASB2014-8512
Guideline(s): OECD 423 (2001), 440/2008/EEC, EPA OPPTS 870.1100, JMAFF 8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 830 01 H (Batch No. 451009)
Species	Rat, Wistar, Crl:WI (HAN) SPF
No. of animals (group size)	2 x 3 females (nulliparous, non-pregnant)
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table B.6.1-2: Results of acute oral toxicity study in rats of BAS 830 01 H

Dose [mg/kg bw]	Toxicological results[1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Female rats				
2000	0/3/3	day 1	--	>2000
2000	1/3/3	day 1 – day 8	day 1	>2000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table B.6.1-3: Summary of findings of acute oral toxicity study in rats of BAS 830 01 H

Mortality:	One female of the second administration group died on study day 1.
Clinical signs:	Clinical signs in the first 2000 mg/kg test group revealed impaired general state and piloerection from hour 2 until hour 3 after administration in all animals. Dyspnoea was noted from hour 2 until hour 3 in one animal, and at hour 2 only in the two other animals. Clinical signs in the second 2000 mg/kg bw test group revealed salivation at hour 0 after administration and impaired general state as well as piloerection on days 7 and 8 in the first animal. The second animal, which died, showed salivation at hour 0 after administration and impaired general state, piloerection, dyspnoea and a cowering position from hour 2 until hour 5. No clinical signs were observed in the third animal.
Body weight:	Two animals of the first test group showed stagnation of body weight during the second week. One animal of the second test group showed body weight loss during the first week post-administration, but gained body weight during the second week after administration. The mean body weight of the other surviving animals increased within the normal range throughout the study period.
Macroscopic examination:	Whitish discoloration of the stomach contents, reddish discoloration of the mall intestine contents and light spotted discoloration of the liver were found in the female that died. No abnormalities were observed at gross necropsy in surviving animals.

Conclusion

Under the experimental conditions, the oral LD_{50} of BAS 830 01 H is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

B.6.1.2 Dermal toxicity

Reference: 7.1.2
Report: BAS 830 01 H: Acute dermal toxicity study in rats, [redacted]., 2013b, 2013/1276069, ASB2014-8513
Guideline(s): OECD 402 (1987), 440/2008/EEC, EPA OPPTS 870.1200, JMAFF 8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 830 01 H (Batch No. 451009)
Species	Rat, Wistar, Crl:WI (HAN) SPF
No. of animals (group size)	5 males and 5 females (nulliparous, non-pregnant)
Dose(s)	5000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table B.6.1-4: Results of acute dermal toxicity study in rats of BAS 830 01 H

Dose [mg/kg bw]	Toxicological results[1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Male rats				
5000	0/0/5	--	--	>5000
Female rats				
5000	0/0/5	--	--	>5000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table B.6.1-5: Summary of findings of acute dermal toxicity study in rats of BAS 830 01 H

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	The mean body weight of the animals increased within the normal range throughout the study period with one exception in the female group. One female did not gain weight during the first week, but the body weight was within the normal range during the second week.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of BAS 830 01 H is higher than 5000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

B.6.1.3 Inhalation toxicity

Reference:	7.1.3
Report	BAS 830 01 H: 4-hour acute inhalation toxicity study in the rat, [redacted] 2013, 2013/1276073, ASB2014-8514
Guideline(s):	OECD 403 (2009), 440/2008/EEC, EPA OPPTS 870.1300, JMAFF 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 830 01 H (Batch No. 451009)
Species	Rat, Wistar, RccHan™:WIST(SPF)
No. of animals (group size)	5 rats/sex/dose
Concentration(s)	5 mg/L
Exposure	4 hours (nose only)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	Exposure was interrupted four times for a total of 18 min for cleaning purposes. Nevertheless, the animals were exposed for a period of 4 hours as those interruptions were accounted for. Gravimetric aerosol concentration (3.1 mg/L air) differed from chemical aerosol concentration (4.8 mg/L air). The difference was considered to be due to the evaporation of solvent.

Results and discussions

Table B.6.1-6: Concentration(s) and exposure conditions

Target conc. [mg/L air]	Nominal conc. [mg/L air]	Actual conc. [mg/L air]	MMAD[1)] [µm]	GSD[2)] [µm]
5	13.7	4.8	3.36-4.07	2.41-2.43

1) MMAD = Mass Median Aerodynamic Diameter
2) GSD = Geometric Standard Deviation

Table B.6.1-7: Results of acute inhalation toxicity study in rats of BAS 830 01 H

Concentration [mg/L air]	Toxicological results[1)]	Duration of signs	Time of death	LC_{50} [mg/L air] (14 days)
Male rats				
4.8	0/5/5	day 1	--	>4.8
Female rats				
4.8	0/5/5	day 1	--	>4.8

1) Number of animals which died/number of animals with clinical signs/number of animals used

Table B.6.1-8: Summary of findings of acute inhalation toxicity study in rats of BAS 830 01 H

Mortality:	No mortality occurred.
Clinical signs:	Clinical signs were limited to the day of exposure and consisted of slight to moderate salivation during exposure and slightly ruffled fur immediately and one hour after exposure. Some males additionally showed decreased activity and/or tachypnea immediately and/or one hour after exposure. From test day 2 onwards, all animals were free from clinical signs.
Body weight:	Between test days 1 and 2, slight body weight loss was noted in all animals. One female also showed slight body weight loss between test days 2 and 4. Thereafter, normal body weight development was observed in all animals.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the inhalation LC_{50} of BAS 830 01 H is higher than 4.8 mg/L air in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

B.6.1.4 Skin irritation

Reference: 7.1.4.
Report: BAS 830 01 H: Acute dermal irritation / corrosion in rabbits, [redacted] 2013c, 2013/1276070, ASB2014-8516
Guideline(s): OECD 404 (2002), 440/2008/EEC, EPA OPPTS 870.2500, JMAFF 8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 830 01 H (Batch No. 451009)
Species	Rabbit, New Zealand White, Crl:KBL (NZW)
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	An EpiDerm™ skin corrosion/irritation test was conducted before the animal testing. Based on the observed results it was concluded that BAS 830 01 H shows a skin irirtation potential under the test conditions chosen ([redacted] 2013a; ASB2014-8515).

Results and discussions

Table B.6.1-9: Skin irritation of BAS 830 01 H

Animal No.		Scores after treatment[1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	2 2	2 1	1 0	0 0	1.0 0.3	3 2
2	Erythema Oedema	2 1	2 1	2 0	2 0	2.0 0.3	14 2
3	Erythema Oedema	2 2	2 0	1 0	1 0	1.3 0.0	7 1

1) scores in the range of 0 to 4

Clinical signs:	None

Conclusion

Under the experimental conditions, BAS 830 01 H is not a skin irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

B.6.1.5 Eye irritation

Reference: 7.1.5
Report: BAS 830 01 H: Acute eye irritation in rabbits, [redacted] 2013d, 2013/1276071, ASB2014-8519
Guideline(s): OECD 405 (2002), 440/2008/EEC, EPA OPPTS 870.2400, JMAFF 8147
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 830 01 H (Batch No. 451009)
Species	Rabbit, New Zealand White, Crl:KBL(NZW)
No. of animals (group size)	3 females
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation into conjunctival sac)
Irrigation (time point)	Yes (24 hours after application with tap water)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	An EpiOcular™ eye irritation test and a Bovine Corneal Opacity and Permeability test (BCOP test) were conducted before the animal testing. Based on the observed results it was concluded that BAS 830 01 H does not show an eye irritation potential in both test systems under the test conditions chosen [redacted] 2013b; ASB2014-8518 / [redacted] 2013c; ASB2014-8517).

Results and discussions

Table B.6.1-10: Eye irritation of BAS 830 01 H

Animal No.		Scores after treatment[1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	2	2	0	1.3	3
	Iritis	0	1	0	0	0.3	2
	Redness conjunctivae	1	1	1	0	0.7	3
	Chemosis conjunctivae	1	2	1	0	1.0	3
2	Corneal opacity	0	1	1	1	1.0	7
	Iritis	0	1	1	1	1.0	7
	Redness conjunctivae	1	2	2	1	1.7	7
	Chemosis conjunctivae	1	2	2	1	1.7	7
3	Corneal opacity	0	1	1	1	1.0	7
	Iritis	0	1	1	1	1.0	7
	Redness conjunctivae	1	2	2	2	2.0	7
	Chemosis conjunctivae	3	3	3	3	3.0	14

[1)] scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	None

Conclusion

Under the experimental conditions, BAS 830 01 H is an eye irritant. Thus, classification is required as Xi; R36 according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations and as Cat. 2; H319 according to Regulation (EC) No. 1272/2008.

B.6.1.6 Skin sensitisation

Reference: 7.1.6
Report: BAS 830 01 H: Skin sensitisation local lymph node assay, [redacted] 2014, 2013/1276072, ASB2014-8476
Guideline(s): OECD 429 (2010), 440/2008/EEC B. 42
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 830 01 H (Batch No. 451009)
Species	Mouse, CBA/CaOlaHsd
No. of animals (group size)	Test substance group: 3 x 5 females (nulliparous and non-pregnant) Vehicle control goup: 5 females (nulliparous and non-pregnant)
Range finding:	Yes
Exposure (concentration(s), no. of applications)	25, 50 and 100 %
Vehicle	1 % aqueous Pluronic
Reliability check	alpha-Hexylcinnamaldehyde (5, 10 and 25 %)
Remarks	A statistically signifiacnt increase in ear weights was observed for the test groups treated with 50 % test item (ratio control to test group: 1.1) and 100 % test item (ratio control to test group: 1.4). The threshhold value of 25 % increase in ear weights for excessive local irritation mentioned in OECD guideline 429 was exceeded in the test group treated with 100 % test item.

Results and discussions

Table B.6.1-11: Results of skin sensitisation study of BAS 830 01 H

	No. of animals	**Concentration [%]**	**DPM/group**	**Stimulation index (SI)**
BAS 830 01 H	5	25	876.2	1.07
	5	50	4165.6	5.11
	5	100	6279.8	7.70
Test Vehicle Control Group	5	0	815.4	1.00
Positive control		5	437.3	1.6
		10	653.9	2.4
		25	1611.9	5.9

Clinical signs:	None

Conclusion

Under the experimental conditions, BAS 830 01 H is a skin sensitiser. Thus, classification is required as Xi; R43 according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations and as Cat. 1; H317 according to Regulation (EC) No. 1272/2008.

B.6.1.7 Supplementary studies on the plant protection product

No supplementary studies were conducted.

B.6.1.8 Supplementary studies for combinations of plant protection products

No studies for combinations of BAS 830 01 H with other plant protection products were conducted.

B.6.2 Dermal absorption

Dimethenamid-P

An *in vitro* dermal penetration study through human skin was performed with dimethenamid-P formulated in BAS 830 01 H. The results are summarised in Table B.6.2-1. These values were derived according to the latest Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665, ASB2012-6959).

Table B.6.2-1: Results of submitted dermal absorption studies for dimethenamid-P formulated as BAS 830 01 H

Test	Concentrate	Spray dilution (1:267)	Reference
In vitro (human)	2 %	43 %	Fabian, E., Landsiedel, R., (2013) 2013/1389063 (ASB2014-8520)

Quinmerac

No dermal absorption study for quinmerac applied within the product BAS 830 01 H was submitted. An *in vitro* dermal penetration study formulated as BAS 773 00 H through human skin was submitted. The results are summarised in Table B.6.2-2. These values were derived according to the latest Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665, ASB2012-6959).

Table B.6.2-2: Results of submitted dermal absorption studies for quinmerac formulated as BAS 773 00 H

Test	% of applied dose		Reference
	Concentrate 100 g/L	**Spray dilution 0.5 g/L**	
In vitro (human)	1 %	5 % (1:200)	Guth, K., Landsiedel, R., (2013) 2013/1287780 (ASB2014-8521)

Studies submitted with the dossier for the Renewal Assessment Report:

Data point:	IIA 7.3.1
Report:	Fabian E., Landsiedel R., 2013a (ASB2014-8520) ^{14}C-BAS 656 PH in BAS 830 01 H - Study of penetration through human skin *in vitro* 2013/1389063 Experimental work from September 2013 – November 2013
Guideline(s):	OECD Guideline for testing of chemicals No. 428 (Skin absorption: *In vitro* method (2004)), OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)
Deviations:	No relevant deviations
GLP:	Yes (certified by Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	The study is considered to be acceptable.

Materials and methods:

Test Material:	a) ^{14}C-BAS 656 PH b) BAS 830 01 H c) BAS 656-PH (dimethenamid-P)
Lot/Batch #:	a) 824-7101 b) 451007 c) L74-120
Purity:	a) radiochemical purity: >98 %; specific activity: 7.58 MBq/mg b) Content, nominal: 333 g/L dimethenamid-P, 167 g/L quinmerac c) 96.5 %
Stability of test compound:	a) The stability of the test article was confirmed by HPLC analysis prior to and after the study. b) The test article is stable in the formulation; the expiry date of the formulation was May 2014. c) Stability guaranteed until July 2016.
Vehicle:	Tap water
Skin preparations:	
Source:	Across Barriers GmbH, Science Park 1, Saarbrücken, Germany
Preparation:	Dermatomed human skin membranes with a thickness of 286-424 µm were supplied frozen.
Storage of skin samples:	Max. storage time of 3 days in a refrigerator or 12 months at -20 °C.
Reagents:	
Receptor fluid:	Tap water
Extraction media:	Soluene®-350, ethanol, 90 % ethanol solution in tap water
Washing solution:	Texapon® N 70 (sodium-laurylsulfate), 1:140 w/w in tap water

Radiolabelled dimethenamid-P (^{14}C-BAS 656 PH (Batch 824-7107, Radiochemical purity >98 %, Specific activity 7.58 MBq/mg)) and the organic solvent based EC formulation BAS 830 01 H (Batch 451009; quinmerac (BAS 518 H): analytical/nominal value: 168/167 g/L; dimethenamid-P (BAS 656 H): analytical/nominal value: 332/333 g/L) were used to prepare a homogenously radiolabelled BAS 830 01 H formulation concentrate by spiking appropriate amounts of radioactive dimethenamid-P to the non-radioactive formulation. The 1:267 (1.25 g/L) spray dilution was prepared accordingly, however water was added to obtain the dilution.

The penetration of dimethenamid-P formulated as BAS 830 01 H through human skin was determined using a modified Franz cell under static conditions equipped with dermatomed human skin at a thickness of 286 - 424 µm. Skin from 3 donors was used in this study. Eight cells each for the formulation concentrate and the 1:267 were used. Each cell was loaded with 10 µL of dosing solutions. Target and actual application rates are given in Table B.6.2-3. The test was performed under semi-occlusive conditions. In order to guarantee sufficient solubility of dimethenamid-P in the receptor fluid, tap water with was used as receptor fluid for all dose groups. The test substance is soluble in tap water with 1.4 g/L. After 8 hours the skin surface was washed twice using approximately 250 µL Texapon® N70 diluted 1:140 (w/w) in tap water and once about 250 µL tap water. The skin was then wiped dry using cotton swabs. Thereafter the semi-occlusive cover of the cells was renewed and the penetration experiment continued for another 16 hours. Samples of the receptor fluid were withdrawn 1, 2, 4, 6, 8, 12 and 24 hours after application. The removed volume was replaced by fresh receptor fluid. After the last sampling of receptor fluid, the contents of the individual receptor compartments was sampled and - like the receptor fluid samples taken during the course of the experiment - retained for analysis. The total volume of receptor medium was 8.2 mL (4 mL receptor chamber + 4.2 mL sampled and subsequently replaced volume). The diffusion cells were dismantled and all parts were extracted. The skin was removed and washed a second time. As before, the cotton swabs and the washing solutions were retained for analysis. After the skin surface had dried, the stratum corneum was removed by tape stripping using Scotch Crystal Clear Tape 600. The tapes were pooled into two samples (first 2 tapes and the remaining 4 tapes) for analysis. The remaining skin and the tape strips were analysed separately.

Results and discussions:

The stability, homogeneity and content of dimethenamid-P in the application medium were confirmed by analysis. Details are available in the raw-data.
The mean total recovery was 93.36 and 98.70 % for the high (333 g/L) and low dose (1.25 g/L), respectively (see Table B.6.2-3). With regard to the high dose group, the mean total recovery was below 95 % (93.36 %) with individual values ranging from 91.94 to 97.07 %. Six cells which displayed an insufficient recovery of <95 %, were corrected by normalisation of absorption estimate to 100 % recovery. As group mean total recovery for the low dose group was >95 %, no adjustment of the dermal penetration values was necessary. The individual recovery was in the range of 93.73 - 102.55 %. In detail, one cell was below 95 % (93.73 %). As the dermal penetration estimates of this cell with less than 95 % recovery was well within the range of the cells with greater than 95 % recovery (45.16 % vs. 12.82 - 49.80 %), no adjustment of individual cell values was considered to be justified.
In both dose groups absorption was essentially complete as already after 12 hours 93 or 97 % of the total penetrated radioactivity, respectively, was recovered in the receptor media (see Table B.6.2-4). Accordingly, neither the first two nor the following four tape strips were added to the absorption estimate.
For both dose groups the standard deviations of the absorption estimates were >25 % of the means. Accordingly, one standard deviation was added to the mean absorption estimate. When rounded to the requested number of significant digits, dermal absorption estimates of 2 and 43 % were determined for the formulation concentrate and the 1:267 spray dilution, respectively.
The total amount of dimethenamid-P recovered in the receptor media after 24 hours was 35.06 and 3.89 µg for the formulation concentrate and the 1:267 spray dilution, respectively. When compared to the maximum solubilisation capacity 1400 µg/mL i.e. 11480 µg in the total receptor medium volume of 8.2 mL the solubility in the receptor media was 327- and 2951-fold higher than actually needed for the formulation concentrate and the 1:267 spray dilution, respectively. Even if the receptor chamber volume of 4 mL is considered only, the solubility was at least 160-fold higher than actually needed.
Evaluation according to Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665), Consideration of stratum corneum and application site residues *in vitro* (ASB2012-6959):

- Is study duration up to 24 hours? Yes
- Did >=75 % of the absorption occur in the first half of the study?
  High dose: Yes
  Low dose: Yes

→ Exclude all tape strips from absorption calculation →
Dermal absorption =
% in receptor fluid + % in receptor chamber wash + % in skin sample (excluding all tape strips)

Table B.6.2-3: *In-vitro* dermal penetration of dimethenamid-P formulated as BAS 830 01 H through human skin - Recovery data

Dose group		High dose		Low dose	
		(Formulation concentrate)		(Spray dilution 1:267)	
Target concentration	[mg/mL]	333		1.25	
Target dose	[µg/cm²]	3330		12.5	
Mean actual applied dose	[µg/cm²]	3672		13.3	
Number of cells used/Valid cells		8/8		8/8	
		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.
Unabsorbed dose					
Skin washing after 8 hours		92.13	1.85	63.36	12.97
Skin washing after 24 hours		0.15	0.20	1.63	1.21
Donor chamber		0.00	0.01	2.24	0.97
Dose associated to skin					
Tape strips: 1st sample, strips 1 + 2		0.01	0.01	0.30	0.22
Tape strips: 2nd sample; strips 3 - 6		0.02	0.04	0.39	0.23
Skin preparation		0.08	0.04	1.54	0.97
Absorbed dose					
Sum receptor samples incl. wash out		0.35	0.25	9.95	3.64
Receptor fluid		0.36	0.23	6.42	2.29
Receptor chamber wash		0.25	0.28	12.88	5.71
Total recovery#		93.36	2.09	98.70	2.66
Absorption essentially complete at end of study (>75 % absorption within half the study duration)		Yes		Yes	
Absorption estimates when absorption not essentially completed (= absorbed dose + dose associated to skin + tape strips sample 2)[a]		NA		NA	
Absorption estimates when absorption essentially completed (= absorbed dose + dose associated to skin)		1.04	0.78	30.79	12.06
Absorption estimate normalised[b]		1.09	0.79	NA	
Dermal absorption rate[c]		2		43	

values may not calculate exactly due to rounding of figures

a Grouping is different than in the report: In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to 6th tape strip) is considered potentially absorbable if less than 75 % of the absorption occurred in the first half of the study (see Table B.6.2-4). Finally, the skin preparation is also considered potentially absorbable.

b Cells with insufficient recovery (mean <95 %) were corrected by normalisation of absorption estimate to 100 % recovery.

c In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) one standard deviation was added to the mean % dermal penetration in cases where the standard deviation was ≥25 % of the mean value. This value was then rounded to the required number of significant figures.

NA: not applicable

Table B.6.2-4: *In-vitro* dermal penetration of dimethenamid-P formulated as BAS 830 01 H through human skin - Penetration kinetics

Dose group	**High dose**		**Low dose**	
	(Formulation concentrate)		**(Spray dilution 1:267)**	
Target concentration [mg/mL]	333		1.25	
Target dose [µg/cm²]	3330		12.5	
Mean actual applied dose [µg/cm²]	3672		13.3	
Number of cells used/Valid cells	8/8		8/8	
	Mean cumulative absorption		Mean cumulative absorption	
	[µg]	[%]	[µg]	[%]
Sample time [h]				
1	1.19	0.03	0.65	4.85
2	3.98	0.11	1.45	10.91
4	9.88	0.27	1.87	14.11
6	15.27	0.42	2.02	15.20
8	19.12	0.52	2.16	16.25
12	22.68	0.62	2.29	17.20
24	24.30	0.67	2.36	17.77
Kp [*10^{-5} cm/h]	1.31		66.33	
Absorption rate [µg/cm^2·h]	3.87		0.92	
Lag time [h]	1.60		0.34	
% absorbed within 12 hours	93 %		97 %	

Conclusion:

A slow to moderate penetration of dimethenamid-P formulated as BAS 830 01 H through human dermatomed skin was observed *in vitro*. The estimated dermal absorption rate within 24 hours was determined to be 1.09 ± 0.79 % and 30.79 ± 12.06 % for the formulation concentrate and the 1:267 aqueous spray dilution, respectively. In summary, under the conditions of this study, the dermal penetration rates were 2 and 43 % for the formulation concentrate (333 g/L) and the 1.25 g/L aqueous spray dilution, respectively.

Data point: IIA 7.3.1

Report: Guth, K., Landsiedel, R., 2013a (ASB2014-8521)
3H-BAS 518 H in BAS 773 00 H - Study of penetration through human skin *in vitro*
2013/1287780
Experimental work from 10 April 2013 – 27 May 2013

Guideline(s): OECD Guideline for testing of chemicals No. 428 (Skin absorption: *In vitro* method (2004)), OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)

Deviations:	No relevant deviations
GLP:	Yes (certified by Landesamt für Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	The study is considered to be acceptable.

Materials and methods:

Test Material:	a) 3H-BAS 518 H b) 3H-BAS 773 00 H c) BAS 518 H (quinmerac)
Lot/Batch #:	a) 1056-2001 b) 13/0016-1 c) COD-001621
Purity:	a) radiochemical purity: >95 %; specific activity: 13.8 MBq/mg b) Content, nominal: 100 g/L quinmerac, 200 g/L dimethenamid-P, 200 g/L metazachlor c) 99.9 %
Stability of test compound:	a) The stability of the test article was confirmed by HPLC analysis prior to and after the study. b) The test article is stable in the formulation. c) Stability guaranteed until Dec 2018.
Vehicle:	Tap water
Skin preparations:	
Source:	Across Barriers GmbH, Science Park 1, Saarbrücken, Germany and BIOPREDIC International, Saint-Grégoire, France
Preparation:	Dermatomed human skin membranes with a thickness of 353-416 µm were supplied frozen.
Storage of skin samples:	Max. storage time of 3 days in a refrigerator or 12 months at -20 °C.
Reagents:	
Receptor fluid:	Tap water adjusted to pH 9
Extraction media:	Soluene®-350, ethanol, 90 % ethanol solution in tap water
Washing solution:	Texapon® N 70 (sodium-laurylsulfate), 1:140 w/w in tap water

[^{3}H]-BAS 518 H (Batch 1056-2001, Radiochemical purity >95 %, Specific activity 13.8 MBq/mg as), was used to prepare 3H-BAS 773 00 H (formulation concentrate, 100 g/L quinmerac), as well as a 1:200 (0.5 g/L) aqueous spray dilution.
For the concentrate the radiolabelled preparation (3H-BAS 773 00 H, specific activity 200 MBq/mL (target amount), 100 g/L quinmerac) was applied undiluted. For the spray dilute the radiolabelled preparation above (3H-BAS 773 00 H) was diluted with tap water in a ratio of 1:200 (v:v) (about 1.3 MBq/mL specific activity, about 0.51 g/L quinmerac)
The penetration of quinmerac formulated as BAS 773 00 H through human split thickness skin preparations was determined using a modified Franz cell under static conditions equipped with dermatomed human skin at a thickness of 353-416 µm. The area of skin membrane exposed to the donor chamber was about 1 cm^2. The dermal penetration study was performed at a temperature of 32 ± 1 °C. The skin of a total of at 3 donors was used for this experiment. Within each group skin of 3 different donors was employed. Prior to the dermal penetration study, the integrity of the skin was determined by measuring electrical resistance. In addition, the skin preparation integrity was checked by visual inspection. In the study 8 diffusion cells were used for the high dose and for the low dose and 8 cells for the high and 7 cells for the low dose group were assessed to yield valid results.
The test was performed under semi-occlusive conditions. In order to guarantee sufficient solubility of quinmerac in the receptor fluid, tap water served as receptor fluid. After 8 hours the skin surface was washed twice using about 250 µL of Texapon® N70 diluted 1:140 (w/w) in tap water and once with about 250 µL of tap water. Afterwards, the skin was wiped dry using cotton swabs. The washing solutions, water pipette tips, and cotton swabs were stored for analysis. Thereafter, the semi-occlusive cover of the cells was renewed and the penetration experiment continued for another 16 hours.

Samples of the receptor fluid were withdrawn 1, 2, 4, 6, 8, 12, and 24 hours after application. The removed volume was replaced by fresh receptor fluid. After the last sampling of receptor fluid, the contents of the individual receptor compartments was sampled and - like the receptor fluid samples taken during the course of the experiment - retained for analysis. The diffusion cells were dismantled and all parts were extracted in ethanol or Soluene®-350 (donor and receptor chamber were extracted only if necessary). The skin was removed and washed a second time as described above. As before, the cotton swabs and the washing solutions were retained for analysis. Upon skin surface drying, the stratum corneum was removed by tape stripping (6 tape strips; Scotch Crystal Clear Tape 600). The tapes were pooled into two samples (first 2 tapes and the remaining 4 tapes) for analysis. The remaining skin and the tape strips were analysed separately.

Results and discussions:

The stability, homogeneity and content of quinmerac in the application medium were confirmed by analysis. Details are available in the raw-data.
The mean total and individual recovery was in the range of 95.65 and 102.7 % (see Table B.6.2-5) and 91.83 to 104.63 %, respectively. Accordingly, as group mean total recovery for all dose groups was >95 %, no adjustment of the dermal penetration values was necessary. In two cells of the low dose group, the total recovery measured was below 95 %. Even though the results of these cells fitted well into the overall range of measurements of recovery from skin and receptor compartment as well as kinetics, the dermal absorption estimates were normalised regarding the recovery.
Absorption was essentially complete after 12 hours (see Table B.6.2-5) as already 93 % in the high dose and 76 % in the low dose group (>75 %) of the total penetrated radioactivity was recovered in the receptor media after 12 hours. Therefore, all tape strips were excluded from the absorbed dose.
In both dose group the standard deviation of the absorption estimates was >25 % of the means. Accordingly, one standard deviation was added to the mean absorption estimate. When rounded to the requested number of significant digits, dermal absorption estimates of 1 % for the formulation concentrate and 5 % for the 1:200 dilution were obtained.
The total amount of quinmerac (BAS 518 H) recovered in the receptor media was 2.06, and 0.03 µg/cm² for the formulation concentrate and the 1:200 spray dilution, respectively (see Table B.6.2-5). The maximum solubility of quinmerac in water amounts to 240 g/L. Thus, the amount recovered in the receptor medium (total volume of 7.6 mL) is well below the solubility limit for quinmerac.
Evaluation according to Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665), Consideration of stratum corneum and application site residues *in vitro* (ASB2012-6959):

- Is study duration up to 24 hours? Yes
- Did ≥ 75 % of the absorption occur in the first half of the study?
  High dose: Yes
  Low dose: Yes

→ Exclude all tape strips from absorption calculation → Dermal absorption = % in receptor fluid + % in receptor chamber wash + % in skin sample (excluding all tape strips)

Table B.6.2-5: *In-vitro* dermal penetration of quinmerac formulated as BAS 773 00 H through human skin - Recovery data

Dose group		High dose (Concentrate)		Low dose (Spray dilution 1:200)	
Target concentration	[mg/mL]	100		0.5	
Target dose	[µg/cm²]	1000		5.00	
Mean actual applied dose	[µg/cm²]	1017		6	
Number of cells used/Valid cells		8/8		8/7	
		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.
Unabsorbed dose					
Skin washing after 8 hours		102.10	1.69	73.09	6.55
Skin washing after 24 hours		0.24	0.15	13.53	6.50
Donor chamber		0.02	0.02	0.02	0.03
Dose associated to skin					
Tape strip (1st pool, strips 1 - 2)		0.02	0.03	1.92	1.27
Tape strips (2nd pool; further strips)		0.06	0.07	4.62	3.58
Skin preparation		0.08	0.09	1.92	1.63
Absorbed dose					
Sum receptor samples incl. wash out		0.10	0.15	0.25	0.50
Receptor fluid		0.09	0.11	0.28	0.49
Receptor chamber wash		0.01	0.01	0.01	0.03
Total recovery[#]		102.7	1.73	95.65	2.13
Absorption essentially complete at end of study (>75 % absorption within half the study duration)		Yes		Yes	
Absorption estimates when absorption not essentially completed (= absorbed dose + skin preparation + tape strips 2nd pool)[a]		n.a.	n.a.	n.a.	n.a.
Absorption estimates when absorption essentially completed (= absorbed dose + skin preparation)		0.28	0.36	2.46	2.65
Relevant absorption estimate		0.64		5.11	
Dermal absorption rate[b]		1.0		5	

[#] values may not calculate exactly due to rounding of figures

[a] Grouping is different than in the report: In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to 6th tape strip) is considered potentially absorbable if less than 75 % of the absorption occurred in the first half of the study (see Table B.6.2-6). Finally, the skin preparation is also considered potentially absorbable.

[b] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) one standard deviation was added to the mean % dermal penetration in cases where the standard deviation was ≥ 25 % of the mean value. This value was then rounded to the required number of significant figures.

n.a. not applicable

Table B.6.2-6: *In vitro* dermal penetration of quinmerac formulated as BAS 773 00 H through human skin - Penetration kinetics

Dose group		**High dose**		**Mid dose**	
		(Concentrate)		**(Spray dilution 1:200)**	
Target concentration	[g/L]	100		0.5	
Target dose	[µg/cm²]	1000		5	
Mean actual applied dose	[µg/cm²]	1017		6.00	
		Mean cumulative absorption		Mean cumulative absorption	
Penetration within		[µg/cm²]	[%]	[µg/cm²]	[%]
8 hours		1.46	0.14	0.04	0.28
12 hours		1.83	0.18	0.05	0.35
24 hours		1.96	0.19	0.06	0.46
Absorption rate	[µg/cm²·h]	0.306		0.0238	
% absorbed within 12 hours		93 %		76 %	

Conclusion:

A slow penetration of quinmerac (BAS 518 H) formulated as BAS 773 00 H through human dermatomed skin was observed *in vitro*. The amount of the applied dose potentially penetrating within 24 hours was determined to be 0.64, and 5.11 % for the formulation concentrate and 1:200 aqueous spray dilution, respectively. In summary, under the conditions of the study, the dermal absorption rates were 1 and 5 % for the formulation concentrate and the 1:200 aqueous spray dilution, respectively.

B.6.3 Available toxicological data relating to co-formulants

Toxicological information on the co-formulants is presented in Vol. 4. No additional labelling of the product with respect to the toxicological properties of the co-formulants is required.

B.6.4 Exposure data

The representative Plant Protection Product BAS 830 01 H containing 333 g/L dimethenamid-P and 167 g/L quinmerac is intended to be used as an herbicide on oilseed rape. A summary of the critical uses and the overall conclusion regarding exposure for operators, workers, bystanders and residents is presented in B.6.5 Appendix 1.
Exposure assessment is presented for both active substances to demonstrate that the product is safe. The calculations for dimethenamid-P and quinmerac are based on the parameters and endpoints given in Table B.6.4-1 Appendix 1.

Table B.6.4-1: Product information and toxicological reference values used for exposure assessment

Product name and code	BAS 830 01 H	
Formulation type	Suspo-emulsion (SE)	
Category	Herbicide	
Container size(s), short description	0.15-1 L bottle (42 mm opening), 1-10 L container (54 mm opening), 50 L container (52 mm opening)	
Active substance(s) (incl. content)	Dimethenamid-P 333 g/L	Quinmerac 167 g/L
AOEL systemic	0.04 mg/kg bw/d	0.08 mg/kg bw/d (EFSA Journal 2010; 8(3):1523)
Inhalative absorption	100 %	100 %
Oral absorption	100 %	100 %
Dermal absorption	Concentrate: 2 % (332 g/L) Dilution: 43 % (1.25 g/L) based on BAS 830 01 H	Concentrate: 1 % (100 g/L) Dilution: 5 % (0.5 g/L) based on BAS 773 00 H

B.6.4.1 Operator exposure

B.6.4.1.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to dimethenamid-P during application of BAS 830 01 H according to the critical uses is presented in Table B.6.4-2. Outcome of the estimation is presented in Table B.6.4-3. Detailed calculations are given in Appendix 1.

Table B.6.4-2: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 1.5 L product/ha)
Model(s)	German model [Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992]
	UK POEM (revised) [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992. ("UK model")]
	AOEM (not yet implemented in the EU, proposed by the applicant for a refinement of the UK POEM) [Joint development of a new Agricultural Operator Exposure Model – Project Report, BfR Wissenschaft 07/2013, Berlin 2013 (http://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf)]

Table B.6.4-3: Estimated operator exposure

		Dimethenamid-P		Quinmerac	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.5 kg dimethenamid-P/ha + 0.25 kg quinmerac/ha					
German Model Body weight: 70 kg	no PPE[1)]	0.1324	331.0	0.0091	11.4
	+ gloves during mixing/loading and coverall and sturdy footwear during application	0.0322	80.6	0.0020	2.5
UK POEM Application volume: 100 L/ha Container: 10 L, 63 mm closure[3)] Body weight: 60 kg	no PPE[2)]	1.5368	3842.0	0.1004	125.5
	+ gloves during mixing/loading and appl.	0.2381	595.3	0.0165	20.7
AOEM Body weight: 60 kg	with workwear	0.0735	183.8	0.0119	14.9
	+ gloves during mixing/loading	0.0286	71.5	0.0020	2.5

1) no PPE: Operator wearing T-shirt and shorts
2) no PPE: Operator wearing long sleeved shirt, long trousers (“permeable”) but no gloves
3) realistic worst-case for the treatment of 50 ha

B.6.4.1.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

B.6.4.2 Bystander and resident exposure

B.6.4.2.1 Estimation of bystander and resident exposure

Table B.6.4-4 shows the exposure model used for estimation of bystander and resident exposure to dimethenamid-P. The outcome of the estimation is presented in Table B.6.4-5. Detailed calculations are shown in Appendix 1.

Table B.6.4-4: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 1 x 1.5 L product/ha)
Model	Martin, S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76

Table B.6.4-5: Estimated bystander and resident exposure

	Dimethenamid-P		Quinmerac	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 1 x 0.5 kg dimethenamid-p/ha + 1 x 0.25 kg quinmerac/ha				
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0099	24.8	0.0006	0.7
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.0077	19.4	0.0005	0.6
Residents (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.0007	1.8	0.00004	0.05
Residents (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.0012	2.9	0.0002	0.2

B.6.4.2.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for dimethenamid-P will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

B.6.4.3 Worker exposure

B.6.4.3.1 Estimation of worker exposure

Table B.6.4-6 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BAS 830 01 H according to the critical use(s). The outcome of the estimation is presented in Table B.6.4-7. Detailed calculations are shown in Appendix 1.

Table B.6.4-6: Exposure models for intended uses

Critical use(s)	Winter oilseed rape (max. 1 x 1.5 L product/ha)
Model	German re-entry model, Krebs et al. (2000) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]

Table B.6.4-7: Estimated worker exposure

		Dimethenamid-P		Quinmerac	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate: 1 x 0.5 kg dimethenamid-P/ha + 1 x 0.25 kg quinmerac/ha					
2 h/day[1)], DFR: 1 µg/cm^2/kg as TC: 1500 cm^2/person/h[2)] Body weight: 60 kg	no PPE[3)]	0.0108[4)]	26.9[4)]	0.0006[5)]	0.8[5)]

1) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.

2) US-EPA policy paper [EPA, Science Advisory Council for Exposure; 2000; Agricultural Default Transfer Coefficients, Policy # 003.1, May 7 1998 revised 7 August 2000]

3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves

4) for a DFR of 3 µg/cm^2/kg as the estimated worker exposure towards dimethenamid-P would amount to 0.0323 mg/kg bw/day or 80.6 % of the systemic AOEL without PPE

4) for a DFR of 3 µg/cm^2/kg as the estimated worker exposure towards quinmerac would amount to 0.0019 mg/kg bw/day or 2.3 % of the systemic AOEL without PPE

B.6.4.3.2 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

B.6.5 Exposure and risk assessment

The risk assessment has shown that according to the German model (and the AOEM) the estimated exposure for operators will not exceed the systemic AOEL of dimethenamid-P and the systemic AOEL of quinmerac if PPE is worn. With respect to the German model the PPE comprises protective gloves during mixing/loading and protective clothing and sturdy footwear during application. No safe use could be demonstrated when exposure was calculated according to the UK POEM.
For workers, bystanders and residents no unacceptable risk was identified when the product is used as intended.
A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in Table B.6.5-1.

Table B.6.5-1: Critical uses and overall conclusion of exposure assessment

Crops[1] and situation (e.g. growth stage of crop)	F/G or I[2]	Application		Application rate		Remarks: (e.g. surfactant (L/ha)) critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]	Acceptability of exposure assessment			
		Method/Kind (incl. application technique[3])	Max. number (min. interval between applications) a) per use b) per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		Operator	Worker	Bystander	Residents
Winter oilseed rape	F	Foliar spray, tractor-mounted boom sprayers	a) 1 b) 1	a) 0.5 kg dimethenamid-P; 0.25 kg quinmerac b) 0.5 kg dimethenamid-P; 0.25 kg quinmerac	100- 400	German model UK POEM (AOEM)				

	Exposure acceptable without PPE / risk mitigation measures
	Further refinement and/or risk mitigation measures required
	Exposure not acceptable/ Evaluation not possible

[1] Pooled critical GAPS with the same max. application rate per application and using the same application technique
[2] F: field or outdoor application, G: greenhouse application, I: indoor application

B.6.6 References relied on

Data Point EU as of 2014	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N If yes, old data point
KCP 7.1.1/1	[redacted]	2013	BAS 830 01 H - Acute oral toxicity study in rats 2013/1276068 [redacted] GLP, unpublished BVL-2630759 ASB2014-8512	Y	Y	New data for AIR3 renewal	BASF	N III A 7.1.1
KCP 7.1.2/1	[redacted]	2013	BAS 830 01 H - Acute dermal toxicity study in rats 2013/1276069 [redacted] GLP, unpublished BVL-2630761 ASB2014-8513	Y	Y	New data for AIR3 renewal	BASF	N III A 7.1.2
KCP 7.1.3/1	[redacted]	2013	BAS 830 01 H: 4-hour acute inhalation toxicity study in the rat 2013/1276073 [redacted] GLP, unpublished BVL-2630763 ASB2014-8514	Y	Y	New data for AIR3 renewal	BASF	N III A 7.1.3
KCP 7.1.4/1	[redacted]	2013	Summary report - BAS 830 01 H - EpiDerm skin corrosion / irritation test 2013/1311292 BASF SE, [redacted] Not GLP, unpublished BVL-2630765 ASB2014-8515	N	Y	New data for AIR3 renewal	BASF	N III A 7.1.4
KCP 7.1.4/2	[redacted]	2013	BAS 830 01 H - Acute dermal irritation/corrosion in rabbits 2013/1276070 [redacted] GLP, unpublished BVL-2630767 ASB2014-8516	Y	Y	New data for AIR3 renewal	BASF	N III A 7.1.4

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 7.1.5/1	[redacted]	2013	Summary report - BAS 830 01 H - Bovine corneal opacity and permeability test (BCOP test) 2013/1311294 BASF SE, [redacted] Not GLP, unpublished BVL-2630769 ASB2014-8517	N	Y	New data for AIR3 renewal	BASF	N III A 7.1.5
KCP 7.1.5/2	[redacted]	2013	Summary report - BAS 830 01 H - EpiOcular eye irritation test 2013/1311293 [redacted]. Not GLP, unpublished BVL-2630771 ASB2014-8518	N	Y	New data for AIR3 renewal	BASF	N III A 7.1.5
KCP 7.1.5/3	[redacted]	2013	BAS 830 01 H - Acute eye irritation in rabbits 2013/1276071 [redacted] GLP, unpublished BVL-2630773 ASB2014-8519	Y	Y	New data for AIR3 renewal	BASF	N III A 7.1.5
KCP 7.1.6/1	[redacted]	2014	BAS 830 01 H - Skin sensitisation local lymph node assay 2013/1276072 [redacted]. GLP, unpublished BVL-2630775 ASB2014-8476	Y	Y	New data for AIR3 renewal	BASF	N III A 7.1.6
KCP 7.3/1	Fabian E., Landsiedel R.	2013	^{14}C-BAS 656 PH in BAS 830 01 H - Study of penetration through human skin *in vitro* 2013/1389063 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. GLP, unpublished BVL-2630777 ASB2014-8520	N	Y	New data for AIR3 renewal	BASF	N III A 7.3
KCP 7.3/2	Guth K., Landsiedel R.	2013	3H-BAS 518 H in BAS 773 00 H - Study of penetration through human skin *in vitro* 2013/1287780 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. GLP, unpublished BVL-2630779 ASB2014-8521	N	Y	New data for AIR3 renewal	BASF	N III A 7.3

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
7.6.2	EFSA	2012	Guidance on dermal absorption - EFSA Panel on Plant Protection Products and their Residues (PPR) EFSA Journal 2012;10(4):2665 ! EFSA-Q-2010-01324 BVL-2716916, ASB2012-6959	N	N	-	LIT	-

Appendix 1 Exposure calculations

A 1.1 Operator exposure

A 1.1.1 Dimethenamid-P

Table A 1: Input parameters considered for the estimation of operator exposure with the German model

Formulation type:	SE		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.5	kg as/ha			
Area treated per day (A):	20	ha	**Dermal hands m/L ($D_{M(H)}$):**	2.4	mg/person/kg as
Dermal absorption (DA):	2	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg as
	43	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg as
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg as
Body weight (BW):	70	kg/person	**Inhalation m/L (I_M):**	0.0006	mg/person/kg as
AOEL	0.04	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg as

Table A 2: Estimation of operator exposure towards dimethenamid-P using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in winter oilseed rape					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(2.4 x 0.5 x 20 x 2 %) / 70			(2.4 x 0.5 x 20 x 0.01 x 2 %) / 70		
External dermal exposure	24	mg/person	External dermal exposure	0.24	mg/person
External dermal exposure	0.342857	mg/kg bw/d	External dermal exposure	0.003429	mg/kg bw/d
Systemic dermal exposure	**0.006857**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000069**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.5 x 20 x 43 %) / 70			(0.38 x 0.5 x 20 x 1 x 43 %) / 70		
External dermal exposure	3.8	mg/person	External dermal exposure	3.8	mg/person
External dermal exposure	0.054286	mg/kg bw/d	External dermal exposure	0.054286	mg/kg bw/d
Systemic dermal exposure	**0.023343**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.023343**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE$ [2)] $\times DA) / BW$		
(1.6 x 0.5 x 20 x 43 %) / 70			(1.6 x 0.5 x 20 x 0.05 x 43 %) / 70		
External dermal exposure	16	mg/person	External dermal exposure	0.8	mg/person
External dermal exposure	0.228571	mg/kg bw/d	External dermal exposure	0.011429	mg/kg bw/d
Systemic dermal exposure	**0.098286**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.004914**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.5 x 20 x 43 %) / 70			(0.06 x 0.5 x 20 x 1 x 43 %) / 70		
External dermal exposure	0.6	mg/person	External dermal exposure	0.6	mg/person
External dermal exposure	0.008571	mg/kg bw/d	External dermal exposure	0.008571	mg/kg bw/d
Systemic dermal exposure	**0.003686**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.003686**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	44.4	mg/person	Total external dermal exposure	5.44	mg/person
Total external dermal exposure	0.634286	mg/kg bw/d	Total external dermal exposure	0.077714	mg/kg bw/d
Total systemic dermal exposure	**0.132171**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.032011**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in winter oilseed rape					
Inhalation exposure during mixing/loading					

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in winter oilseed rape					
$SIE_{OM} = (I_M \times AR \times A \times IA) / BW$			$SIE_{OM} = (I_M \times AR \times A \times PPE \times IA) / BW$		
(0.0006 x 0.5 x 20 x 100 %) / 70			(0.0006 x 0.5 x 20 x 1 x 100 %) / 70		
External inhalation exposure	0.006	mg/person	External inhalation exposure	0.006	mg/person
External inhalation exposure	0.000086	mg/kg bw/d	External inhalation exposure	0.000086	mg/kg bw/d
Systemic inhalation exposure	**0.000086**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000086**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 0.5 x 20 x 100 %) / 70			(0.001 x 0.5 x 20 x 1 x 100 %) / 70		
External inhalation exposure	0.01	mg/person	External inhalation exposure	0.01	mg/person
External inhalation exposure	0.000143	mg/kg bw/d	External inhalation exposure	0.000143	mg/kg bw/d
Systemic inhalation exposure	**0.000143**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000143**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.016	mg/person	Total external inhalation exposure	0.016	mg/person
Total external inhalation exposure	0.000229	mg/kg bw/d	Total external inhalation exposure	0.000229	mg/kg bw/d
Total systemic inhalation exposure	**0.000229**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000229**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	9.268	mg/person	Total systemic exposure	2.2568	mg/person
Total systemic exposure	**0.1324**	**mg/kg bw/d**	**Total systemic exposure**	**0.03224**	**mg/kg bw/d**
% of AOEL	**331.0**	**%**	**% of AOEL**	**80.6**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

[2)] reduction factor for protective garment is 0.05 (professional appl.)

Table A 3: Estimation of operator exposure towards dimethenamid-P using the UK-POEM (without PPE)

Active substance	**dimethenamid-P**		
Product	BAS 830 01 H		
Formulation type	water-based		
Concentration of a.s.	333	mg/mL	
Dose	1.5	L preparation/ha	(0.5 kg as/ha)
Application volume	100	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	10 litres 63 mm closure		
Work rate/day	50	ha	
Duration of spraying	6	h	
PPE during mix./loading	None		
PPE during application	None		
Dermal absorption from product	2	%	
Dermal absorption from spray	43	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	10	Litres	
Hand contamination/operation	0,05	mL	
Application dose	1.5	Litres product/ha	
Work rate	50	ha/day	
Number of operations	8	/day	
Hand contamination	0.4	mL/day	
Protective clothing	None		
Transmission to skin	100	%	
Dermal exposure to formulation	0.4	mL/day	
DERMAL EXPOSURE DURING SPRAY APPLICATION			
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Application volume	100	spray/ha	
Volume of surface contamination	10	mL/h	
Distribution	Hands	Trunk	Legs
	65 %	10 %	25 %
Clothing	None	Permeable	Permeable

Penetration	100 %		5 %	15 %	
Dermal exposure	6.5		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	41.55	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.4	mL/day		41.55	mL/day
Concen. of a.s. product or spray	333	mg/mL		4.995	mg/mL
Dermal exposure to a.s.	133.2	mg/day		207.542	mg/day
Percent absorbed	2	%		43	%
Absorbed dose	2.664	mg/day		89.243	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	4.995	mg/mL			
Inhalation exposure to a.s.	0.3	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.3	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	92.207	mg/day			
Operator body weight	60	kg			
Operator exposure	1.537	mg/kg bw/day			
Amount of AOEL	**3842.0**	**%**			

Table A 4: Estimation of operator exposure towards dimethenamid-P using the UK-POEM (with gloves during mixing/loading and application)

Active substance	**dimethenamid-P**				
Product	BAS 830 01 H				
Formulation type	water-based				
Concentration of a.s.	333	mg/mL			
Dose	1.5	L preparation/ha	(0.5 kg as/ha)		
Application volume	100	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	10 litres 63 mm closure				
Work rate/day	50	ha			
Duration of spraying	6	h			
PPE during mix./loading	Gloves				
PPE during application	Gloves				
Dermal absorption from product	2	%			
Dermal absorption from spray	43	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,05	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	8	/day			
Hand contamination	0.4	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.02	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65 %		10 %	25 %	
Clothing	Gloves		Permeable	Permeable	
Penetration	10 %		5 %	15 %	

Dermal exposure	0.65		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	6.45	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.02	mL/day		6.45	mL/day
Concen. of a.s. product or spray	333	mg/mL		4.995	mg/mL
Dermal exposure to a.s.	6.66	mg/day		32.218	mg/day
Percent absorbed	2	%		43	%
Absorbed dose	0.133	mg/day		13.854	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	4.995	mg/mL			
Inhalation exposure to a.s.	0.3	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.3	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	14.287	mg/day			
Operator body weight	60	kg			
Operator exposure	0.238	mg/kg bw/day			
Amount of AOEL	**595.3**	**%**			

Table A 5: Input parameters considered for the estimation of operator exposure towards dimethenamid-P with the AOEM

Active substance:	dimethenamid-P		**Dermal hands m/L ($D_{M(H)}$):**	57881	µg/person
Product:	BAS 830 01 H		**Dermal hands prot. m/L ($D_{M(Hp)}$):**	280	µg/person
Application technique:	Low Crop Tractor Mounted (LCTM)		**Dermal body m/L ($D_{M(B)}$):**	34276	µg/person
			Dermal body prot. m/L ($D_{M(Bp)}$):	412	µg/person
Crop type:	winter oilseed rape		**Dermal head m/L ($D_{M(C)}$):**	1297	µg/person
Formulation type:	Liquid		**Dermal head prot. m/L ($D_{M(Cp)}$):**	21	µg/person
Application rate (AR):	0.5	kg as/ha	**Dermal hands appl. ($D_{A(H)}$):**	3708	µg/person
Area treated per day (A):	50	ha	**Dermal hands prot. appl. ($D_{A(Hp)}$):**	243	µg/person
Dermal absorption (DA):	2	% (concen.)	**Dermal body appl. ($D_{A(B)}$):**	2073	µg/person
	43	% (dilution)	**Dermal body prot. appl. ($D_{A(Bp)}$):**	57	µg/person
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	98	µg/person
Body weight (BW):	60	kg/person	**Inhalation m/L (I_M):**	10	µg/person
AOEL	0.04	mg/kg bw/d	**Inhalation appl. (I_A):**	5	µg/person

Table A 6: Estimation of operator exposure towards dimethenamid-P using the AOEM

Potential exposure			**With workwear and PPE (gloves m/L)**		
Systemic exposure dermal route					
Dermal exposure during mixing/loading					
$SDE_{OM(H)} = (D_{M(H)} \times DA) / BW$			$SDE_{OM(H(p))} = (D_{M(H(p))} \times DA) / BW$		
(57881 x 2 %) / 60			(280 x 2 %) / 60		
Systemic hands exposure	**19.2937**	**µg/kg bw/d**	**Systemic hands exposure**	**0.0932631**	**µg/kg bw/d**
$SDE_{OM(B)} = (D_{M(B)} \times DA) / BW$			$SDE_{OM(B(p))} = (D_{M(B(p))} \times DA) / BW$		
(34276 x 2 %) / 60			(412 x 2 %) / 60		
Systemic body exposure	**11.4252**	**µg/kg bw/d**	**Systemic body exposure**	**0.1373918**	**µg/kg bw/d**
$SDE_{OM(C)} = (D_{M(C)} \times DA) / BW$			$SDE_{OM(C(p))} = (D_{M(C(p))} \times DA) / BW$		
(1297 x 2 %) / 60			(1297 x 2 %) / 60		
Systemic head exposure	**0.43236**	**µg/kg bw/d**	**Systemic head exposure**	**0.4323632**	**µg/kg bw/d**
Dermal exposure during application					

Potential exposure			**With workwear and PPE (gloves m/L)**		
Systemic exposure dermal route					
$SDE_{OA(H)} = (D_{A(H)} \times DA) / BW$			$SDE_{OA(H(p))} = (D_{A(H(p))} \times DA) / BW$		
(3708 x 43 %) / 60			(3708 x 43 %) / 60		
Systemic hands exposure	**26.5747**	**µg/kg bw/d**	**Systemic hands exposure**	**26.574714**	**µg/kg bw/d**
$SDE_{OA(B)} = (D_{A(B)} \times DA) / BW$			$SDE_{OA(B(p))} = (D_{A(B(p))} \times DA) / BW$		
(2073 x 43 %) / 60			(57 x 43 %) / 60		
Systemic body exposure	**14.8589**	**µg/kg bw/d**	**Systemic body exposure**	**0.4076042**	**µg/kg bw/d**
$SDE_{OA(C)} = (D_{A(C)} \times DA) / BW$			$SDE_{OA(C(p))} = (D_{A(C(p))} \times (PPE) \times DA) / BW$		
(98 x 43 %) / 60			(98 x 43 %) / 60		
Systemic head exposure	**0.70228**	**µg/kg bw/d**	**Systemic head exposure**	**0.7022754**	**µg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDEOM_{(B)} + SDEOM_{(C)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H(p))} + SDEOM_{(Bp)} + SDEOM_{(C(p))} + SDE_{OA(H(p))} + SDE_{OA(Bp)} + SDE_{OA(C(p))}$		
Total systemic dermal exposure	**73.2871**	**µg/kg bw/d**	**Total systemic dermal exposure**	**28.347612**	**µg/kg bw/d**
Systemic exposure inhalation route					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times IA) / BW$			$SIE_{OM} = (I_M \times (PPE) \times IA) / BW$		
(10 x 100 %) / 60			(10 x 100 %) / 60		
Systemic inhalation exposure	**0.1608**	**µg/kg bw/d**	**Systemic inhalation exposure**	**0.1607962**	**µg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times IA) / BW$			$SIE_{OA} = (I_A \times (PPE) \times IA) / BW$		
(5 x 100 %) / 60			(5 x 100 %) / 60		
Systemic inhalation exposure	**0.08658**	**µg/kg bw/d**	**Systemic inhalation exposure**	**0.0865776**	**µg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total systemic inhalation exposure	**0.24737**	**µg/kg bw/d**	**Total systemic inhalation exposure**	**0.2473738**	**µg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			**Total systemic exposure: $SE_O = SDE_O + SIE_O$**		
Total systemic exposure	**4.41207**	**mg/person**	**Total systemic exposure**	**1.7156991**	**mg/person**
Total systemic exposure	**0.07353**	**mg/kg bw/d**	**Total systemic exposure**	**0.028595**	**mg/kg bw/d**
% of AOEL	**183.8**	**%**	**% of AOEL**	**71.5**	**%**

A 1.1.2 Quinmerac

Table A 7: Input parameters considered for the estimation of operator exposure with the German model

Formulation type:	SE		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.25	kg as/ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg as
Dermal absorption (DA):	1	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg as
	5	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg as
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg as
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg as
AOEL	0.08	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg as

Table A 8: Estimation of operator exposure towards quinmerac using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in winter oilseed rape					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE$ [1)] $\times DA) / BW$		
(2.4 x 0.25 x 20 x 1 %) / 70			(2.4 x 0.25 x 20 x 0.01 x 1 %) / 70		
External dermal exposure	12	mg/person	External dermal exposure	0.12	mg/person
External dermal exposure	0.171429	mg/kg bw/d	External dermal exposure	0.001714	mg/kg bw/d
Systemic dermal exposure	**0.001714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000017**	**mg/kg bw/d**
Dermal exposure during application					

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in winter oilseed rape					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE x DA) / BW		
(0.38 x 0.25 x 20 x 5 %) / 70			(0.38 x 0.25 x 20 x 1 x 5 %) / 70		
External dermal exposure	1.9	mg/person	External dermal exposure	1.9	mg/person
External dermal exposure	0.027143	mg/kg bw/d	External dermal exposure	0.027143	mg/kg bw/d
Systemic dermal exposure	**0.001357**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001357**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE [2] x DA) / BW		
(1.6 x 0.25 x 20 x 5 %) / 70			(1.6 x 0.25 x 20 x 0.05 x 5 %) / 70		
External dermal exposure	8	mg/person	External dermal exposure	0.4	mg/person
External dermal exposure	0.114286	mg/kg bw/d	External dermal exposure	0.005714	mg/kg bw/d
Systemic dermal exposure	**0.005714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000286**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x PPE x DA) / BW		
(0.06 x 0.25 x 20 x 5 %) / 70			(0.06 x 0.25 x 20 x 1 x 5 %) / 70		
External dermal exposure	0.3	mg/person	External dermal exposure	0.3	mg/person
External dermal exposure	0.004286	mg/kg bw/d	External dermal exposure	0.004286	mg/kg bw/d
Systemic dermal exposure	**0.000214**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000214**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	22.2	mg/person	Total external dermal exposure	2.72	mg/person
Total external dermal exposure	0.317143	mg/kg bw/d	Total external dermal exposure	0.038857	mg/kg bw/d
Total systemic dermal exposure	**0.009**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.001874**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in winter oilseed rape					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x PPE x IA) / BW		
(0.0006 x 0.25 x 20 x 100 %) / 70			(0.0006 x 0.25 x 20 x 1 x 100 %) / 70		
External inhalation exposure	0.003	mg/person	External inhalation exposure	0.003	mg/person
External inhalation exposure	0.000043	mg/kg bw/d	External inhalation exposure	0.000043	mg/kg bw/d
Systemic inhalation exposure	**0.000043**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000043**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x PPE x IA) / BW		
(0.001 x 0.25 x 20 x 100 %) / 70			(0.001 x 0.25 x 20 x 1 x 100 %) / 70		
External inhalation exposure	0.005	mg/person	External inhalation exposure	0.005	mg/person
External inhalation exposure	0.000071	mg/kg bw/d	External inhalation exposure	0.000071	mg/kg bw/d
Systemic inhalation exposure	**0.000071**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000071**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.008	mg/person	Total external inhalation exposure	0.008	mg/person
Total external inhalation exposure	0.000114	mg/kg bw/d	Total external inhalation exposure	0.000114	mg/kg bw/d
Total systemic inhalation exposure	**0.000114**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000114**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.638	mg/person	Total systemic exposure	0.1392	mg/person
Total systemic exposure	**0.009114**	**mg/kg bw/d**	**Total systemic exposure**	**0.001989**	**mg/kg bw/d**
% of AOEL	**11.4**	**%**	**% of AOEL**	**2.5**	**%**

[1] reduction factor for gloves is 0.01 (professional appl.)

[2] reduction factor for protective garment is 0.05 (professional appl.)

Table A 9: Estimation of operator exposure towards quinmerac using the UK-POEM (without PPE)

Active substance	**quinmerac**				
Product	BAS 830 01 H				
Formulation type	water-based				
Concentration of a.s.	167	mg/mL			
Dose	1.5	L preparation/ha	(0.25 kg as/ha)		
Application volume	100	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	10 litres 63 mm closure				
Work rate/day	50	ha			
Duration of spraying	6	h			
PPE during mix./loading	None				
PPE during application	None				
Dermal absorption from product	1	%			
Dermal absorption from spray	5	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,05	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	8	/day			
Hand contamination	0.4	mL/day			
Protective clothing	None				
Transmission to skin	100	%			
Dermal exposure to formulation	0.4	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65 %		10 %	25 %	
Clothing	None		Permeable	Permeable	
Penetration	100 %		5 %	15 %	
Dermal exposure	6.5		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	41.55	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.4	mL/day		41.55	mL/day
Concen. of a.s. product or spray	167	mg/mL		2.505	mg/mL
Dermal exposure to a.s.	66.8	mg/day		104.083	mg/day
Percent absorbed	1	%		5	%
Absorbed dose	0.668	mg/day		5.204	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	2.505	mg/mL			
Inhalation exposure to a.s.	0.15	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.15	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	6.022	mg/day			
Operator body weight	60	kg			
Operator exposure	0.1	mg/kg bw/day			
Amount of AOEL	**125.5**	**%**			

Table A 10: Estimation of operator exposure towards quinmerac using the UK-POEM (with gloves during mixing/loading and application)

Active substance	**quinmerac**				
Product	BAS 830 01 H				
Formulation type	water-based				
Concentration of a.s.	167	mg/mL			
Dose	1.5	L preparation/ha	(0.25 kg as/ha)		
Application volume	100	L/ha			
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Container	10 litres 63 mm closure				
Work rate/day	50	ha			
Duration of spraying	6	h			
PPE during mix./loading	Gloves				
PPE during application	Gloves				
Dermal absorption from product	1	%			
Dermal absorption from spray	5	%			
EXPOSURE DURING MIXING AND LOADING					
Container size	10	Litres			
Hand contamination/operation	0,05	mL			
Application dose	1.5	Litres product/ha			
Work rate	50	ha/day			
Number of operations	8	/day			
Hand contamination	0.4	mL/day			
Protective clothing	Gloves				
Transmission to skin	5	%			
Dermal exposure to formulation	0.02	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	100	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65 %		10 %	25 %	
Clothing	Gloves		Permeable	Permeable	
Penetration	10 %		5 %	15 %	
Dermal exposure	0.65		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	6.45	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.02	mL/day		6.45	mL/day
Concen. of a.s. product or spray	167	mg/mL		2.505	mg/mL
Dermal exposure to a.s.	3.34	mg/day		16.157	mg/day
Percent absorbed	1	%		5	%
Absorbed dose	0.033	mg/day		0.808	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	2.505	mg/mL			
Inhalation exposure to a.s.	0.15	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.15	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	0.992	mg/day			
Operator body weight	60	kg			
Operator exposure	0.017	mg/kg bw/day			
Amount of AOEL	**20.7**	**%**			

Table A 11: Input parameters considered for the estimation of operator exposure towards quinmerac with the AOEM

Active substance:	quinmerac		**Dermal hands m/L ($D_{M(H)}$):**	33946	µg/person
Product:	BAS 830 01 H		**Dermal hands prot. m/L ($D_{M(Hp)}$):**	178	µg/person
Application technique:	Low Crop Tractor Mounted (LCTM)		**Dermal body m/L ($D_{M(B)}$):**	21056	µg/person
			Dermal body prot. m/L ($D_{M(Bp)}$):	223	µg/person
Crop type:	winter oilseed rape		**Dermal head m/L ($D_{M(C)}$):**	649	µg/person
Formulation type:	Liquid		**Dermal head prot. m/L ($D_{M(Cp)}$):**	10	µg/person
Application rate (AR):	0.25	kg as/ha	**Dermal hands appl. ($D_{A(H)}$):**	1854	µg/person
Area treated per day (A):	50	ha	**Dermal hands prot. appl. ($D_{A(Hp)}$):**	167	µg/person
Dermal absorption (DA):	1	% (concen.)	**Dermal body appl. ($D_{A(B)}$):**	1037	µg/person
	5	% (dilution)	**Dermal body prot. appl. ($D_{A(Bp)}$):**	28	µg/person
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	49	µg/person
Body weight (BW):	60	kg/person	**Inhalation m/L (I_M):**	8	µg/person
AOEL	0.08	mg/kg bw/d	**Inhalation appl. (I_A):**	4	µg/person

Table A 12: Estimation of operator exposure towards quinmerac using the AOEM

Potential exposure			**With workwear and PPE (gloves m/l)**		
Systemic exposure dermal route					
Dermal exposure during mixing/loading					
$SDE_{OM(H)} = (D_{M(H)} \times DA) / BW$			$SDE_{OM(H(p))} = (D_{M(H(p))} \times DA) / BW$		
(33946 x 1 %) / 60			(178 x 1 %) / 60		
Systemic hands exposure	**5.65774**	**µg/kg bw/d**	**Systemic hands exposure**	**0.0296993**	**µg/kg bw/d**
$SDE_{OM(B)} = (D_{M(B)} \times DA) / BW$			$SDE_{OM(B(p))} = (D_{M(B(p))} \times DA) / BW$		
(21056 x 1 %) / 60			(223 x 1 %) / 60		
Systemic body exposure	**3.50937**	**µg/kg bw/d**	**Systemic body exposure**	**0.0371627**	**µg/kg bw/d**
$SDE_{OM(C)} = (D_{M(C)} \times DA) / BW$			$SDE_{OM(C(p))} = (D_{M(C(p))} \times DA) / BW$		
(649 x 1 %) / 60			(649 x 1 %) / 60		
Systemic head exposure	**0.10809**	**µg/kg bw/d**	**Systemic head exposure**	**0.1080908**	**µg/kg bw/d**
Dermal exposure during application					
$SDE_{OA(H)} = (D_{A(H)} \times DA) / BW$			$SDE_{OA(H(p))} = (D_{A(H(p))} \times DA) / BW$		
(1854 x 5 %) / 60			(1854 x 5 %) / 60		
Systemic hands exposure	**1.54504**	**µg/kg bw/d**	**Systemic hands exposure**	**1.5450415**	**µg/kg bw/d**
$SDE_{OA(B)} = (D_{A(B)} \times DA) / BW$			$SDE_{OA(B(p))} = (D_{A(B(p))} \times DA) / BW$		
(1037 x 5 %) / 60			(28 x 5 %) / 60		
Systemic body exposure	**0.86389**	**µg/kg bw/d**	**Systemic body exposure**	**0.0236979**	**µg/kg bw/d**
$SDE_{OA(C)} = (D_{A(C)} \times DA) / BW$			$SDE_{OA(C(p))} = (D_{A(C(p))} \times (PPE) \times DA) / BW$		
(49 x 5 %) / 60			(49 x 5 %) / 60		
Systemic head exposure	**0.04083**	**µg/kg bw/d**	**Systemic head exposure**	**0.04083**	**µg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDEOM_{(B)} + SDEOM_{(C)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H(p))} + SDEOM_{(Bp)} + SDEOM_{(C(p))} + SDE_{OA(H(p))} + SDE_{OA(Bp)} + SDE_{OA(C(p))}$		
Total systemic dermal exposure	**11.725**	**µg/kg bw/d**	**Total systemic dermal exposure**	**1.7845221**	**µg/kg bw/d**
Systemic exposure inhalation route					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M \times IA) / BW$			$SIE_{OM} = (I_M \times (PPE) \times IA) / BW$		
(8 x 100 %) / 60			(8 x 100 %) / 60		
Systemic inhalation exposure	**0.13082**	**µg/kg bw/d**	**Systemic inhalation exposure**	**0.1308245**	**µg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times IA) / BW$			$SIE_{OA} = (I_A \times (PPE) \times IA) / BW$		
(4 x 100 %) / 60			(4 x 100 %) / 60		
Systemic inhalation exposure	**0.06118**	**µg/kg bw/d**	**Systemic inhalation exposure**	**0.0611774**	**µg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total systemic inhalation exposure	**0.192**	**µg/kg bw/d**	**Total systemic inhalation exposure**	**0.1920019**	**µg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			**Total systemic exposure: $SE_O = SDE_O + SIE_O$**		
Total systemic exposure	**0.71502**	**mg/person**	**Total systemic exposure**	**0.1185914**	**mg/person**

Potential exposure			**With workwear and PPE (gloves m/l)**		
Systemic exposure dermal route					
Total systemic exposure	**0.01192**	**mg/kg bw/d**	**Total systemic exposure**	**0.0019765**	**mg/kg bw/d**
% of AOEL	**14.9**	**%**	**% of AOEL**	**2.5**	**%**

A 1.2 Bystander and resident exposure

A 1.2.1 Dimethenamid-P

Table A 13: Input parameters considered for the estimation of bystander exposure

Intended use(s):	winter oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.5	kg as/ha	**Exposed body surface area (BSA):**	1	m² (adults)
	50	mg/m^2		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I*$_A$):**	0.001	mg/kg as (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg as (6 hours, children)
Dermal absorption (DA):	43	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.04	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 14: Estimation of bystander exposure towards dimethenamid-P

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(50 x 2.77 % x 1 x 43 %) / 60			(50 x 2.77 % x 0.21 x 43 %) / 16.15		
External dermal exposure	1.385	mg/person	External dermal exposure	0.29085	mg/person
External dermal exposure	0.023083	mg/kg bw/d	External dermal exposure	0.018009	mg/kg bw/d
Systemic dermal exposure	**0.009926**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.007744**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.5 x 20 x 5 x 100 %) / 60			(0.000575 / 360 x 0.5 x 20 x 5 x 100 %) / 16.15		
External inhalation exposure	0.000139	mg/person	External inhalation exposure	0.00008	mg/person
External inhalation exposure	0.000002	mg/kg bw/d	External inhalation exposure	0.000005	mg/kg bw/d
Systemic inhalation exposure	**0.000002**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000005**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.595689	mg/person	Total systemic exposure	0.125145	mg/person
Total systemic exposure	**0.009928**	**mg/kg bw/d**	**Total systemic exposure**	**0.007749**	**mg/kg bw/d**
% of AOEL	**24.82**	**%**	**% of AOEL**	**19.37**	**%**

Table A 15: Input parameters considered for the estimation of resident exposure

Intended use(s):	winter oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.5	kg as/ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.005	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	43	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.04	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%

Intended use(s):	winter oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 16: Estimation of resident exposure towards dimethenamid-P

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.005 x 1 x 2.77 % x 5 % x 7300 x 2 x 43 %) / 60			(0.005 x 1 x 2.77 % x 5 % x 2600 x 2 x 43 %) / 16.15		
External dermal exposure	0.101105	mg/person	External dermal exposure	0.03601	mg/person
External dermal exposure	0.001685	mg/kg bw/d	External dermal exposure	0.00223	mg/kg bw/d
Systemic dermal exposure	**0.000725**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000959**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100 %) / 60			(0 x 8.31 x 100 %) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.005 x 1 x % x 5 % x 50 % x 20 x 20 x 2 x 100 %) / 16.15		
			External oral exposure	0.00277	mg/person
			External oral exposure	0.000172	mg/kg bw/d
			Systemic oral exposure	**0.000172**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.005 x 1 x % x 20 % x 25 x 100 %) / 16.15		
			External oral exposure	0.000693	mg/person
			External oral exposure	0.000043	mg/kg bw/d
			Systemic oral exposure	**0.000043**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.043475	mg/person	Total systemic exposure	0.018947	mg/person
Total systemic exposure	**0.000725**	**mg/kg bw/d**	**Total systemic exposure**	**0.001173**	**mg/kg bw/d**
% of AOEL	**1.81**	**%**	**% of AOEL**	**2.93**	**%**

A 1.2.2 Quinmerac

Table A 17: Input parameters considered for the estimation of bystander exposure

Intended use(s):	winter oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.25	kg as/ha	**Exposed body surface area (BSA):**	1	m² (adults)
	25	mg/m^2		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg as (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg as (6 hours, children)
Dermal absorption (DA):	5	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.08	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 18: Estimation of bystander exposure towards quinmerac

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(25 x 2.77 % x 1 x 5 %) / 60			(25 x 2.77 % x 0.21 x 5 %) / 16.15		
External dermal exposure	0.6925	mg/person	External dermal exposure	0.145425	mg/person
External dermal exposure	0.011542	mg/kg bw/d	External dermal exposure	0.009005	mg/kg bw/d
Systemic dermal exposure	**0.000577**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00045**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application (via spray drift)					

Adults			**Children**		
$SIE_B = (I^*_A$ x AR x A x T x IA) / BW			$SIE_B = (I^*_A$ x AR x A x T x IA) / BW		
(0.001 / 360 x 0.25 x 20 x 5 x 100 %) / 60			(0.000575 / 360 x 0.25 x 20 x 5 x 100 %) / 16.15		
External inhalation exposure	0.000069	mg/person	External inhalation exposure	0.00004	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.034694	mg/person	Total systemic exposure	0.007311	mg/person
Total systemic exposure	**0.000578**	**mg/kg bw/d**	**Total systemic exposure**	**0.000453**	**mg/kg bw/d**
% of AOEL	**0.72**	**%**	**% of AOEL**	**0.57**	**%**

Table A 19: Input parameters considered for the estimation of resident exposure

Intended use(s):	winter oilseed rape		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.25	kg as/ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.0025	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	5	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.08	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 20: Estimation of resident exposure towards quinmerac

Adults			**Children**		
Residents: Systemic dermal exposure after application (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.0025 x 1 x 2.77 % x 5 % x 7300 x 2 x 5 %) / 60			(0.0025 x 1 x 2.77 % x 5 % x 2600 x 2 x 5 %) / 16.15		
External dermal exposure	0.050553	mg/person	External dermal exposure	0.018005	mg/person
External dermal exposure	0.000843	mg/kg bw/d	External dermal exposure	0.001115	mg/kg bw/d
Systemic dermal exposure	**0.000042**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000056**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application (via vapour)					
$SIE_R = (AC_V$ x IR x IA) / BW			$SIE_R = (AC_V$ x IR x IA) / BW		
(0 x 16.57 x 100 %) / 60			(0 x 8.31 x 100 %) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.0025 x 1 x % x 5 % x 50 % x 20 x 20 x 2 x 100 %) / 16.15		
			External oral exposure	0.001385	mg/person
			External oral exposure	0.000086	mg/kg bw/d
			Systemic oral exposure	**0.000086**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.0025 x 1 x % x 20 % x 25 x 100 %) / 16.15		
			External oral exposure	0.000346	mg/person
			External oral exposure	0.000021	mg/kg bw/d
			Systemic oral exposure	**0.000021**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.002528	mg/person	Total systemic exposure	0.002632	mg/person
Total systemic exposure	**0.000042**	**mg/kg bw/d**	**Total systemic exposure**	**0.000163**	**mg/kg bw/d**
% of AOEL	**0.05**	**%**	**% of AOEL**	**0.20**	**%**

A 1.3 Worker exposure

A 1.3.1 Dimethenamid-P

Table A 21: Input parameters considered for the estimation of worker exposure

Intended use(s):	winter oilseed rape		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg as
Application rate (AR):	0.5	kg as/ha	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	43	% ('worst case')			
AOEL	0.04	mg/kg bw/d			

Table A 22: Estimation of worker exposure towards dimethenamid-P using the German re-entry model

Without PPE [1)]			**With PPE (gloves, workwear)**		
Worker (re-entry): Systemic dermal exposure after application in winter oilseed rape					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 1500 x 2 x 0.5 x 1 x 43 %) / 60			(1 x 1500 x 2 x 0.5 x 1 x 5 % x 43 %) / 60		
External dermal exposure	1.5	mg/person	External dermal exposure	0.075	mg/person
External dermal exposure	0.025	mg/kg bw/d	External dermal exposure	0.00125	mg/kg bw/d
Total systemic exposure	0.645	mg/person	Total systemic exposure	0.03225	mg/person
Total systemic exposure	**0.01075**	**mg/kg bw/d**	**Total systemic exposure**	**0.000538**	**mg/kg bw/d**
% of AOEL	**26.9**	**%**	**% of AOEL**	**1.3**	**%**

A 1.3.2 Quinmerac

Table A 23: Input parameters considered for the estimation of worker exposure

Intended use(s):	winter oilseed rape		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg as
Application rate (AR):	0.25	kg as/ha	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	1		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	5	% ('worst case')			
AOEL	0.08	mg/kg bw/d			

Table A 24: Estimation of worker exposure towards quinmerac using the German re-entry model

Without PPE [1)]			**With PPE (gloves, workwear)**		
Worker (re-entry): Systemic dermal exposure after application in winter oilseed rape					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 1500 x 2 x 0.25 x 1 x 5 %) / 60			(1 x 1500 x 2 x 0.25 x 1 x 5 % x 5 %) / 60		
External dermal exposure	0.75	mg/person	External dermal exposure	0.0375	mg/person
External dermal exposure	0.0125	mg/kg bw/d	External dermal exposure	0.000625	mg/kg bw/d
Total systemic exposure	0.0375	mg/person	Total systemic exposure	0.001875	mg/person
Total systemic exposure	**0.000625**	**mg/kg bw/d**	**Total systemic exposure**	**0.000031**	**mg/kg bw/d**
% of AOEL	**0.8**	**%**	**% of AOEL**	**0.04**	**%**