

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CHR/H/DIK 480 SL

Product name(s): Macamba 480 SL, Dikambin 480 SL

Chemical active substance(s):

Dicamba, 480 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 08/2022

MS Finalisation date: 16/06/2023

CHR/H/DIK 480 SL/ Macamba 480 SL, Dikambin 480 SL
Part B – Section 8 - Core Assessment
Applicant version

Version history

When	What
01/2023	Dossier sent for evaluation
03/2023	Applicant update
04/2023	zRMS evaluation of dRR
06/2023	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

In the following document, data for active substances - dicamba - was described during its inclusion on Annex 1 process in respectively 2009. Where reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I

PPP (product name/code):		CHR/H/DIK 480 SL	Formulation type:	SC SL ^(a, b)
Active substance 1:	dicamba	Conc. of as 1:	480 g/L ^(c)	
Active substance 2:	-	Conc. of as 2:	- ^(c)	
Active substance 3:	-	Conc. of as 3:	- ^(c)	
Safener:	-	Conc. of safener:	- ^(c)	
Synergist:	-	Conc. of synergist:	- ^(c)	
Applicant:	Innvigo Sp. z o.o.	Professional use:	<input checked="" type="checkbox"/>	
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>	
Verified by MS:	no-yes			

Field of use: herbicide

[illegible]

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Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
3														
4														
Minor uses according to Article 51 (zonal uses)														
5														
6														
Minor uses according to Article 51 (interzonal uses)														
7														
8														

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

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Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

Table 8.1-1: Assessed (critical) uses during approval of Dicamba concerning the Section Environmental Fate (Dicamba EFSA Journal 2011;9(1):1965)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	kg a.s./hL min-max	Water L/ha min-max	kg a.s./ha min-max		
Maize	EU (N & S)	Bamvel 480 SL	F	Dicotyledon weeds incl. <i>Chenopodium</i> spp. <i>Convolvulus</i> spp. <i>Polygonum</i> spp.	SL	480 g/L	overall spray	Post-emergence until BBCH 16	1	-	-	100-500	0.360	-	Period between treatment and harvest is > 100 days, no PHI is applicable [1] [2]
Pasture	EU (N & S)	Bamvel 480 SL	F	Dicotyledon weeds incl. <i>Chenopodium</i> spp. <i>Convolvulus</i> spp. <i>Polygonum</i> spp.	SL	480 g/L	overall spray	Spring/summer	1 - 2	6 weeks	-	100-500	0.480	14	[1] [2][3]

[1] Dicamba has the potential for long-range transport through the atmosphere.

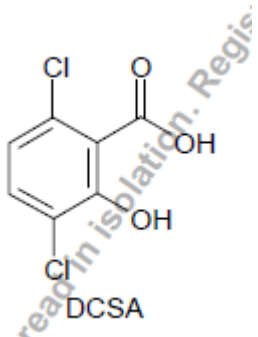
[2] A detailed quantification of a group of unidentified transformation products, found in one soil incubation, was not available, therefore there are no assessments for the environmental compartments for any potentially formed soil transformation products from this group.

[3] The environmental exposure and risk assessment available for pasture covers only those situations when the pasture is already established.

<p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. * For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account, where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GFAF Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p>	<p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> <p>(i) g/kg or g/L</p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) PHI - minimum pre-harvest interval</p> <p>(m) Remarks</p>

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Dicamba potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
DCSA	207		Total Water and Sediment: 31.4% Soil: 24.275% molar basis with respect to the parent	PECsoil, PECgw, PECsw

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in:

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.3.1.1 Dicamba and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for Dicamba - laboratory studies

Laboratory studies ‡

Dicamba	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C & pF2	Chi ²	Method of calculation
Loamy sand (BBA 2.2)	5.5	20 ± 2°C / 40%	3.2/10.8	3.2	13.0	SFO
Loam (Gartenacker)	7.3	20 ± 2°C / 40%	3.3/11.0	3.3	13.1	SFO
Sandy loam (Pappelacker)	7.4	20 ± 2°C / 40%	4.2/13.9	4.1	10.1	SFO
Loamy sand (Borstel)	5.8	20 ± 2°C / 40%	5.5/18.4	4.6	9.7	SFO
Silt loam (Elliot)	5.1	23 ± 1°C /75% FC	3.9/12.8	4.9	16.2	SFO
Geometric mean				4.0		

Table 8.3-2: Summary of aerobic degradation rates for DCSA - laboratory studies

DCSA	Aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C & pF2	f.f.	r ²	Method of calculation
Loamy sand (BBA 2.2)	5.5	20 ± 2°C / 40%	10.5	10.5	0.84	0.99	SFO - kinetic*

*: kinetically derived considering continuous formation from the parent

Data gap for kinetic assessments for formation and degradation of DCSA in the rest of the available soil incubations. Peak-down calculations, calculated from the day when the maximum of DCSA was measured, are included in the following table.

DCSA	Aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C & pF2	Chi ²	Method of calculation
Loamy sand (BBA 2.2)	5.5	20 ± 2°C / 40%	12/ 39.8*	12	9.5	SFO*
Loam (Gartenacker)	7.3	20 ± 2°C / 40%	9.0/30.1*	9.0	21.4	SFO*
Sandy loam (Pappelacker)	7.4	20 ± 2°C / 40%	6.4/21.3*	6.3	7.6	SFO*
Loamy sand (Borstel)	5.8	20 ± 2°C / 40%	10.8/35.9*	9.1	9.9	SFO*
Silt loam (Elliot)	5.1	23 ± 1°C / 75% FC	9.7/32.3*	12.1	8.9	SFO*
Geometric mean				9.4		

*Calculated from day of maximum formation (peak-down)

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.3.2.1 Dicamba and its metabolites

Table 8.3-4: Summary of anaerobic degradation route for Dicamba - laboratory studies

Laboratory studies ‡

Parent	Anaerobic conditions – No data submitted – not required
DCSA	Anaerobic conditions – No data submitted– not required

8.4 Field studies (KCP 9.1.1.2)

Studies on field degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I

inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

No data submitted – not required.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Studies on accumulation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.4.2.1 Dicamba – soil accumulation testing

Table 8.4.2-1: Summary of soil accumulation testing for Dicamba

Soil accumulation and plateau concentration ‡

No data submitted – not required

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.5.1 Dicamba and its metabolites

Table 8.5-1: Summary of soil adsorption/desorption for Dicamba

Dicamba (on 22°C)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam (Kenyon)	2.2	7.1	-	-	0.16	7.27	0.74
Clay loam (Cook)	2.9	6.9	-	-	0.10	3.45	0.62
Silt loam (Champaign)	2.5	5.1	-	-	0.53	21.2	0.80
Sediment loam (Winters)	1.2	7.3	-	-	0.21	17.5	0.8
Arithmetic mean (n= 4)					0.25	12.36	0.74
pH dependence, Yes or No			No				

Table 8.5-2: Summary of soil adsorption/desorption for metabolite DCSA

DCSA (on 22°C)							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loam (Kenyon)	2.2	7.1	-	-	31.5	1432	0.72
Clay loam (Cook)	2.9	6.9	-	-	7.0	242	0.80
Silt loam (Champaign)	2.5	5.1	-	-	20.3	812	0.93
Sandy loam (Huron)	0.4	8.1	-	-	2.5	628	0.79
Sediment loam (Winters)	1.2	7.3			35.2	2930	0.77
Arithmetic mean (n=5)					19.3	1209	0.80
pH dependence (yes or no)				No			

8.5.2 Column leaching (KCP 9.1.2.1)

Studies on column leaching with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

Column leaching ‡

Elution (mm): 200 mm
Time period (d): 2 d (48 hours)
Leachate: < 0.2 - 0.68 % dicamba equivalents < 0.12-0.48 µg/L dicamba equivalents

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Studies on lysimeter with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.5.3.1 Dicamba and metabolites.

Aged residues leaching ‡

Aged for (d): 40.5 d
Time period (d): 2 d (48 hours)
Elution (mm): 200 mm
Analysis of soil residues post ageing was not conducted
Leachate: Dicamba: 0.22-0.94 %, 0.39 - 1.7 µg/L DCSA: < 0.06-0.31 %, <0.1 - 0.53 µg/L

8.5.4 Field leaching studies (KCP 9.1.2.3)

Field leaching study was performed for Dicamba and evaluated during EU review, according to the EFSA Journal 2011;9(1):1965.

Lysimeter/ field leaching studies ‡

Location: Hamburg, Germany
 Study type (e.g.lysimeter, field): lysimeter study
 Soil properties (0-30 cm): texture, pH = 6.1-6.2, OC= 1.1-1.3, MWHC = 29.7-40.4
 Dates of application: 8 June 1990, 3 July 1991

Crop: Maize (interception not reported)
 Number of applications: 1 application per year for 2 years
 Duration: 2 years (lysimeter 3), 3 years (lysimeter 4)
 Application rate: 360 g a.s./ha/year
 Average annual precipitation (incl. irrigation) (mm): 922 mm (year 1-2)
 Average annual leachate volume (mm): 445 L (year 1-2)
 % radioactivity in leachate (maximum/year): 0.19 % AR
 Individual annual maximum concentrations (year 1-2): 0.17 µg/L dicamba equivalents. Annual mean 0.11-0.12 dicamba equivalents.
 No dicamba or DCSA identified in leachates. No specific components (besides ¹⁴CO₂) identified, all < 0.026 µg/L.
 Amount of radioactivity in the soils at the end of the study = 24.7-26.8 % AR. No dicamba or DCSA identified in the soil residues.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.6.1 Dicamba and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of Dicamba

Dicamba		Rhine: Max. 5.5% in sediment day 7 Pond: Max. 6% in sediment day 7								
Water / sed. system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole sys. (d)	St. (r ²)	DT ₅₀ -DT ₉₀ Water (d)	St. (r ²)	DT ₅₀ - DT ₉₀ Sed (d)	St. (r ²)	Method of calculation
Rhine	8.3	7.6	20± 2	38/125*	0.93					SFO
Pond	8.3	7.4	20± 2	45/151*	0.98					SFO
Geometric mean				41/137*						

* The values are considered as uncertain

Table 8.6-2: Summary of degradation in water/sediment of metabolite DCSA

DCSA	Rhine: Max. 26.9% in water and 4.5% in sediment (whole system 31.4%) at day 60 Pond: Max. 12.5% in water and 3.4% in sediment (whole system 15.9%) at day 60									
Water/sed. system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole sys. (d)	St. (r ²)	DT ₅₀ -DT ₉₀ Water (d)	St. (r ²)	DT ₅₀ -DT ₉₀ sed. (d)	St. (r ²)	Method of calculation
Rhine	8.3	7.6	20±2	57.7/192*	0.89	No reliable data – not needed for the risk assessment				SFO – linear regression
Pond	8.3	7.4	20±2	58.2/193*	0.77					SFO – linear regression
Geometric mean				57.9/193*				-		-

* No lag phase included – notifier has used DT₅₀ values of 53.7 d and 45.1 d (mean 49.4 d) based on a lag phase of 7 and 14 days, respectively, for Rhine and pond in the FOCUSsw modelling. However, these values are considered as uncertain.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

zRMS Comments:	<p>Calculations of PEC_{SOIL} for active substance dicamba, its metabolite DCSA and formulation CHR/H/DIK 480 SL were accepted.</p> <p>With according EFSA Journal 2011;9(1):1965 only initial PEC_{SOIL} values were calculated. The crop interception of 25% was taken into consideration.</p> <p>The maximum initial PEC_{SOIL} values for active substance and its metabolite for single application are presented in following table:</p> <table border="1"> <tr> <th>Application rate g a.s./ha</th><th>1 x 288.0</th></tr> <tr> <th>Compound</th><th>PEC_{SOIL}, ini mg a.s./kg</th></tr> <tr> <td>dicamba</td><td>0.288</td></tr> <tr> <td>DCSA</td><td>0.203</td></tr> </table> <p>For formulation PEC_{SOIL} = 0.6943 mg/kg soil.</p> <p>These values will be used in further risk assessment.</p>	Application rate g a.s./ha	1 x 288.0	Compound	PEC _{SOIL} , ini mg a.s./kg	dicamba	0.288	DCSA	0.203
Application rate g a.s./ha	1 x 288.0								
Compound	PEC _{SOIL} , ini mg a.s./kg								
dicamba	0.288								
DCSA	0.203								

8.7.1 Justification for new endpoints

All endpoints used for PEC soil calculations are EU approved and were evaluated on EU level and presented in:

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.7.2 Active substance(s) and relevant metabolite(s)

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1
Crop	Sugar beet Maize
Application rate (g a.s./ha)	288 g a.s./ha
Number of applications/interval	1 / -

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Crop interception (%)	25 %
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Dicamba	221	-	-	EFSA Journal 2011;9(1):1965
DCSA	207	75%	-	EFSA Journal 2011;9(1):1965

According to EFSA Journal 2011;9(1):1965 DT50 for dicamba and DCSA not used in PEC_{soil} calculation. Therefore, the PEC_{soil} value was calculated using formula below:

$$\text{Initial PEC}_{\text{soil}} \text{ (mg/kg)} = \frac{A \text{ (g/ha)}}{100 \times d \text{ (cm)} \times \rho \text{ (g/cm}^3\text{)}}$$

where: A = application rate (216 a.s./ha and 152.3 g metabolite/ha using 25% crop interception for maize)

d = depth of soil layer (5 cm)

ρ = soil bulk density (1.5 g/cm³)

8.7.2.1 Dicamba and its metabolites

Table 8.7-3: PEC_{soil} for Dicamba on maize

PEC _{soil} (mg/kg)		Sugar beets-Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.288	-	█	█
Short term	24h	-	-	█	█
	2d	-	-	█	█
	4d	-	-	█	█
Long term	7d	-	-	█	█
	14d	-	-	█	█
	21d	-	-	█	█
	28d	-	-	█	█
	50d	-	-	█	█
	100d	-	-	█	█

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Plateau concentration (5 cm) after year 10	-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})	0.288	-	-	-

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for DCSA on maize

PEC _{soil} (mg/kg)		Sugar beets Maize			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.203	-	-	-
Short term	24h	-	-	-	-
	2d	-	-	-	-
	4d	-	-	-	-
Long term	7d	-	-	-	-
	14d	-	-	-	-
	21d	-	-	-	-
	28d	-	-	-	-
	50d	-	-	-	-
	100d	-	-	-	-
Plateau concentration (5 cm) after year 10		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.203	-	-	-

8.7.2.2 PEC_{soil} of CHR/H/DIK 480 SL

The PEC_{soil} immediately after the first application was calculated for formulation as follows:

$$\text{Initial PEC}_{\text{soil}} \text{ (mg/kg)} = \frac{A \text{ (g/ha)}}{100 \times d \text{ (cm)} \times \rho \text{ (g/cm}^3\text{)}}$$

where: A = application rate (694.32 g formulation/ha – density of product: 1.1572 g/ml, volume: 600 ml)

d = depth of soil layer (5 cm)

ρ = soil bulk density (1.5 g/cm³)

Table 8.7-5: PEC_{soil} for CHR/H/DIK 480 SL on maize

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{tw21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
CHR/H/DIK 480 SL	694.32	0.6943	-	5	0.6943	0.6943

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

zRMS Comments:	<p>Presented calculations PEC_{GW} for active substance dicamba and its metabolite DCSA were accepted.</p> <p>Calculations of PEC_{GW} were provided in with PUF = 0.0.</p> <p>Modelling was conducted using PEARL and PELMO models for a single maximum application rate for maize in all relevant scenarios.</p> <p>Following the current EU guidance, EFSA (2014), the geometric mean of the sorption coefficient (K_{foc}) was used. This approach was accepted.</p> <p>The maximum PEC_{GW} values for active substance dicamba and its metabolite DCSA are below the trigger value of 0.1 µg/L.</p>
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8.8.1 Justification for new endpoints

All endpoints used for PEC ground water calculations are EU approved and were evaluated on EU level and presented in:

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1
Crop	maize
Application rate (g as/ha)	288 g as/ha
Number of applications/interval (d)	1/-
Relative application date	1 day after emergence (worst case scenario)
Crop interception (%)	25%
Frequency of application	Every year
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4

8.8.2.1 Dicamba and its metabolites

Table 8.8-2: Input parameters related to active substance Dicamba and metabolite(s) for PEC_{gw} calculations

Compound	Dicamba	NC8493-DCSA	Value in accordance with EU endpoint y/n
Molecular mass (g/mol)	221	207	EFSA Journal 2011;9(1):1965
Solubility in water (mg/L) at 20°C	6600	88000	EFSA Journal 2011;9(1):1965
Saturated vapour pressure (Pa)	0 at pH 7 and 20°C	0 at pH 7 and 20°C	EFSA Journal 2011;9(1):1965 Worst case
DT ₅₀ in soil (d) (geometric mean, normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	4 d	9.4 d	EFSA Journal 2011;9(1):1965
K _{foc} (mL/g) (geometric mean)	12.36 mL/g 9.82	1208 mL/g 877	EFSA Journal 2011;9(1):1965
K _{fom} (mL/g)	7.17 mL/g 5.70	700.69 mL/g 508.7	Calculated from K _{foc} (K _{fom} = K _{foc} /1.724) EFSA Journal 2011;9(1):1965
1/n (arithmetic mean)	0.74	0.08-0.80	EFSA Journal 2011;9(1):1965
Plant uptake factor	0	0	EFSA Journal 2011;9(1):1965
Formation fraction	-	0.75	EFSA Journal 2011;9(1):1965

Table 8.8-3: PEC_{gw} for Dicamba and metabolite(s) on ~~sugar beets~~ maize (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Dicamba	DCSA
Maize	Châteaudun	0.040014 <0.0001	<0.0001
	Hamburg	0.01618 <0.0001	<0.0001
	Jokioinen *	0.001068 <0.0001	<0.0001
	Kremsmünster	0.010372 <0.0001	<0.0001
	Okehampton	0.018098 <0.0001	<0.0001
	Piacenza	0.020410 <0.0001	<0.0001

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	Porto	0.002276 <0.0001	<0.0001
	Sevilla	0.000722 <0.0001	<0.0001
	Thiva	0.000553 <0.0001	<0.0001

* No scenario for maize

Table 8.8-4: PEC_{gw} for Dicamba and metabolite(s) on ~~sugar beets~~ maize (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Dicamba	DCSA
Maize	Châteaudun	<0.001	<0.001
	Hamburg	<0.001	<0.001
	Jokioinen *	<0.001	<0.001
	Kremsmünster	<0.001	<0.001
	Okehampton	<0.001	<0.001
	Piacenza	<0.001	<0.001
	Porto	<0.001	<0.001
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001

* No scenario for maize

Assessment of relevance of ground water metabolites is performed and presented in section b10 of dRR.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

<div>zRMS</div> <div>Comments:</div>	<div>The submitted PEC_{SW} and PEC_{SED} calculations were accepted. Following the current EU guidance, EFSA (2014), the geometric mean of the sorption coefficient (K_{foc}) was used. This approach was accepted.</div> <div>The recommended FOCUS models were used: FOCUS Step 1 & 2.</div> <div>The maximum PEC_{SW} for active substance dicamba and its metabolite DCSA are presented in the table below:</div> <table><tr><th>Crop</th><th>Dicamba</th><th>DCSA</th></tr><tr><td rowspan="3">maize 288.0 g a.s./ha</td><td>Step 2</td><td>Step 2</td></tr><tr><td colspan="2">Max PEC_{SW} (µg/L)</td></tr><tr><td>9.56</td><td>4.12</td></tr></table> <div>PEC_{SW} for the formulation CHR/H/DIK 480 SL for 694.32 g prod./ha in maize is 3.6882 µg/L.</div> <div>The relevant mitigation measure will be recommended in ecotoxicological section.</div>	Crop	Dicamba	DCSA	maize 288.0 g a.s./ha	Step 2	Step 2	Max PEC _{SW} (µg/L)		9.56	4.12
Crop	Dicamba	DCSA									
maize 288.0 g a.s./ha	Step 2	Step 2									
	Max PEC _{SW} (µg/L)										
	9.56	4.12									

8.9.1 Justification for new endpoints

All endpoints used for PEC surface water calculations are EU approved and were evaluated on EU level and presented in:

- **Dicamba** - EFSA Journal 2011;9(1):1965

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for PEC_{SW/SED} calculations

Plant protection product	CHR/H/DIK
Use No.	1
Crop	Maize
Application rate (kg as/ha)	0.288
Number of applications/interval (d)	1/-
Application method	sprayer
Models used for calculation	STEPS 1-2 ver.3.2, FOCUS SWASH v 5.3, 3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/SED} calculations for the application of CHR/H/DIK 480 SL

Not relevant

8.9.2.1 Dicamba and its metabolites

Table 8.9-3: Input parameters related to active substance Dicamba and metabolite(s) for PEC_{sw/SED} calculations STEP 1/2 and 3(4)

Compound	Dicamba	DCSA	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	221	207	EFSA Journal 2011;9(1):1965
Saturated vapour pressure (Pa)	not required for Step 1+2	not required for Step 1+2	EFSA Journal 2011;9(1):1965
Diffusion coefficient in water (m ² /d)	not required for Step 1+2	not required for Step 1+2/	default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2	not required for Step 1+2	default
Water solubility (mg/L)	6600 at pH 7 and 25°C	88000 at pH 7 and 25°C	EFSA Journal 2011;9(1):1965
K _{foc} (mL/g) (geometric mean)	12.36 9.82	1209 877	EFSA Journal 2011;9(1):1965

Compound	Dicamba	DCSA	Value in accordance to EU end-point y/n/ Reference
Plant Uptake	not required for Step 1+2	not required for Step 1+2	default
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	not required for Step 1+2/	default
DT _{50,soil} (d)	4	9.4	EFSA Journal 2011;9(1):1965
DT _{50,water} (d)	41	49.4	EFSA Journal 2011;9(1):1965
DT _{50,sed} (d)	1000 (worst case)	1000 (worst case)	
DT _{50,whole system} (d)	41	49.4	
Maximum occurrence observed (% molar basis with respect to the parent)	-	Maximum occurrence observed in soil: 58.8 % Maximum occurrence observed in water/sediment: 31.4 %	EFSA Journal 2011;9(1):1965

Table 8.9-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Dicamba following multiple single application(s) of CHR/H/DIK 480 SL to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	97.09 97.41	drainage/run off	81.69 81.97	11.79 9.40
Step 2	---	9.53 9.56	drainage/run off	8.03 8.06	1.18 0.94
Northern Europe	March-May	9.53 9.56	drainage/run off	8.03 8.06	1.18 0.94

* single applications should be marked.

** twa-time as required by ecotox

According to EFSA Journal 2011;9(1):1965, for Dicamba Regulatory Acceptable Concentration RAC=45 µg a.s./L and it is set by *Myriophyllum spicatum* study on the basis of NOEC=0.45 mg a.s./L (nominal).

Metabolite(s) of Dicamba

Table 8.9-6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for DCSA following multiple single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	31.83 38.17	drainage/run off	27.16 32.70	375.41 327.89
Step 2	---	3.43 4.12	drainage/run off	3.14 3.74	40.60 35.45

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Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- PEC_{sw, twa} (µg/L)**	Max PEC_{sed} (µg/kg)*
Northern Europe	March-May	3.43 4.12	drainage/run off	3.14 3.74	40.60 35.45

* single applications should be marked.

** twa-time as required by ecotox

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PEC_{sw/sed} of CHR/H/DIK 480 SL

Method of calculation

Drift calculator in SWASH tool calculating instantaneous PEC_{sw} at a single drift event 1 m from the field

Application rate maize

1 x 694.32 g [prod]/ha

Resulting PEC_{sw} ~~sugar beets~~ maize

3.6882 µg[prod]/L

Calculation of drift loading into surface water

✕

Input

Application Rate (g ai/ha): 694.32 Crop: Maize

Number of Applications: 1 Waterbody: focus_ditch

Use FOCUS (step 3) or mitigation distances (m)? FOCUS values

Info: Dimensions of receiving water body and field site (m)

Width: 1 Depth: 0.30 Length: 100

Distance: Crop <- 0.80 --> Top of bank <- 0.50 --> Water

Info: Drift regression terms to provide overall 90th percentile drift data

Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778

Distance for change in regression (m) 1.0

Output: Drift deposition in water body per drift event

Drift percentile per event 90 based on a total of 1 applications.

	at edge nearest field	farthest from field	areic mean
Distance from crop: (m)	1.30	2.30	
% of application rate:	2.1349	1.2221	1.5936

Output: Drift loading onto water body

Mass loading per drift event: 1.1064 mg per m2 of water surface area.

Nominal concentration in water, resulting from drift event: 3.6882 ug/L (for comparison with modelling result)

Data sources:

Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
 Calculations of percentile drift are from spreadsheet of Travis, (1998).
 Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).

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8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1 Summary of atmospheric degradation and behaviour

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Direct photolysis in air ‡	Not studied - no data required
Quantum yield of direct phototransformation	No data – not required
Photochemical oxidative degradation in air ‡	DT ₅₀ of 3.6 days were derived by the Atmospheric Oxidation Programme (AOP, ver 1.85) based on Atkinson model. OH (12 h) concentration assumed = 1.5×10^6 [OH x cm ⁻³]
Volatilisation ‡	from plant surfaces (BBA guideline): 0.12 % after 24 hours (negligible)
	from soil surfaces (BBA guideline): 0.07 - 1.15 % after 24 hours (negligible)
Metabolites	None
PEC (air)	
Method of calculation	Expert judgement based on volatilisation from plants and soil.
PEC_(a)	
Maximum concentration	Negligible

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4, KCP 9.2.5	-	2023	CHR/H/DIK 480 SL Predicted environmental concentration of dicamba and its metabolite in ground water and surface water. Innvigo Sp. z o.o. Non GLP Unpublished	N	Innvigo

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1/01	Figge, K.	1993	Aerobic Soil Metabolism of 14C-Dicamba Novartis Crop Protection AG, Basel, Switzerland Natec Institut, Hamburg, Germany, Report No NA 919358 GLP Not Published Syngenta File N° SAN837/5334	N	SYN
KCP 9.1/02	Glänzel, A.	2000	Rate of degradation of 14C-Phenyl labelled SAN 837 H (Dicamba) in various soils under laboratory conditions at 20°C Syngenta Crop Protection AG, Basel, Switzerland, Report No 99AG08 GLP Not Published	N	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Syngenta File N° SAN837/5965		
KCP 9.1/03	Sen, P.K., Yu, C.C., Ekdawi, M.L.	1993	Dicamba: Photodegradation Study on Soil Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Inc., Des Plaines, United States, Report No 480065-23 GLP Not Published Syngenta File N° SAN837/5294	N	SYN
KCP 9.1/04	Wendt, D.R.	1994	Aerobic Soil Metabolism of Dicamba Acid Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Inc., Des Plaines, United States, Report No 480065-26 GLP Not Published Syngenta File N° SAN837/5284	N	SYN
KCP 9.1/05	Ellgehausen, H.	2000	Calculation of the Degradation Kinetics of Soil Metabolite 3,6-Dichlorosalicylic Acid (3,6-DCSA) in various soils Syngenta Crop Protection AG, Basel, Switzerland, Report No 00EH02 GLP Not Published Syngenta File N° NOA414746/0016	N	SYN
KCP 9.1/06	Glänzel, A.	1994	Degradation of 3,6-Dichlorosalicylic Acid in BBA Standard Soil 2.2 Novartis Crop Protection AG, Basel, Switzerland Sandoz AG, Basel, Switzerland, Report No TDS BS 4261 GLP Not Published Syngenta File N° NOA414746/0002	N	SYN
KCP 9.1/07	Tribolet, R.	2003	Soil dissipation study with Dicamba (SAN837) in or on Bare Ground in Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Report No 307/01 GLP	N	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not Published Syngenta File N° SAN837/6048		
KCP 9.1/08	Morgenroth, U.	2000	Adsorption / desorption of Phenyl-U-14C SAN 837 H in various soils Novartis Crop Protection AG, Basel, Switzerland, Report No 99MO01 GLP Not Published Syngenta File N° SAN837/5935	N	SYN
KCP 9.1/09	Tong, T.R.	1993	Soil Adsorption and Desorption of Dicamba, Unaged, by the Batch Equilibrium Method Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Inc., Des Plaines, United States, Report No 480065 GLP Not Published Syngenta File N° SAN837/5319	N	SYN
KCP 9.1/10	Tong, T.R.	1993	Soil Adsorption and Desorption of the Major Soil Metabolite of Dicamba, 3,6-dichlorosalicylic acid (3,6-DCSA), by the Batch Equilibrium Method Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Inc., Des Plaines, United States, Report No 480065 GLP Not Published Syngenta File N° NOA414746/0006	N	SYN
KCP 9.1/11	Figge, K.	1992	Quantitative investigation of the degradation and percolation behaviour of the test substance Dicamba in an agriculturally utilized soil - Lysimeter Study Novartis Crop Protection AG, Basel, Switzerland Natec Institut, Hamburg, Germany, Report No NA 89 9716 GLP Not Published Syngenta File N° SAN837/5326	N	SYN
KCP	Ochsenbein, U.	1989	Leaching characteristics of aged residues of Dicamba techn. in two soils	N	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.1/12			Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 222265 GLP Not Published Syngenta File N° SAN837/6035		
KCP 9.2/01	Buckel, T.	2001	Hydrolysis of [Phenyl-U-14C]-NOA414746 under Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland, Report No 01TB02 GLP Not Published Syngenta File N° NOA414746/0012	N	SYN
KCP 9.2/02	Galicia, H.	1990	Degradation of 14C-Dicamba techn. in 2 aquatic systems under aerobic conditions Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, Report No 223986 GLP Not Published Syngenta File N° SAN837/5317	N	SyN
KCP 9.2/03	Morgenroth, U.	2000	Hydrolysis of Phenyl-U-14C-SAN 837 H under laboratory conditions Novartis Crop Protection AG, Basel, Switzerland, Report No 99MO04 GLP Not Published Syngenta File N° SAN837/5956	N	SyN
KCP 9.2/04	Schmidt, E.	2002	Direct Phototransformation of Dicamba (SAN837) in Water Syngenta Crop Protection AG, Basel, Switzerland Solvias AG, Basel, Switzerland, Report No L01-006791 GLP Not Published Syngenta File N° SAN837/5995	N	SYN
KCP	Sen, P.K., Yu, C.C.,	1993	Dicamba: Photodegradation Study in pH 7 Aqueous Solution	N	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
9.2/05	Ekdawi, M.L.		Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Inc., Des Plaines, United States, Report No 480065-19 GLP Not Published Syngenta File N° SAN837/5295		
KCP 9.2/06	Wallace, S.J., Daniel, M.	2001	SAN837A: Determination of 28 day ready biodegradability Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, Report No BL7173/B GLP Not Published Syngenta File N° SAN837/5987	N	SYN
KCP 9.3/01	Jonas, W.	1994	Evaporation behaviour from soil (model chamber) Novartis Crop Protection AG, Basel, Switzerland Natec Institut, Hamburg, Germany, Report No NA 93 9837 GLP Not Published Syngenta File N° SAN1214/5245	N	SYN
KCP 9.3/02	Jonas, W.	1997	Evaporation behaviour of the test substance 14C-Dicamba from soil and plants (model chamber) Novartis Crop Protection AG, Basel, Switzerland Natec Institut, Hamburg, Germany, Report No NA 96 9408/1 GLP Not Published Syngenta File N° SAN837/0005	N	SYN
KCP 9.3/03	Müller, M.	1994	Berechnung des atmosphärischen Abbaus von Dicamba Novartis Crop Protection AG, Basel, Switzerland ITA Fraunhofer-Inst., Hannover, Germany GLP Not Published	N	SYN

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Syngenta File N° SAN837/5329		
KCP 9.3/04	Stamm, E.	1998	Atmospheric oxidation of Dicamba SAN 837 H by hydroxyl radicals; rate estimation Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No 98SM17 GLP Not Published Syngenta File N° SAN837/0417	N	SYN

Appendix 2 Detailed evaluation of the new Annex II studies

Not required