

# **FINAL REGISTRATION REPORT**

## **Part B**

### **Section 5**

#### **Analytical Methods**

Detailed summary of the risk assessment

Product code: CHR/H/DIK 480 SL

Product name(s): Dicambin 480 SL, Makamba 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**

## Version history

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

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**zRMS comments:**

This report has been completed by the Applicant.  
The text highlighted in grey was provided by the zRMS.

In the following document, data for active substances - dicamba - was described during its inclusion on Annex 1 process in respectively 2009. Were 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

## **5.1 Conclusion and summary of assessment**

Sufficiently sensitive and selective analytical methods are available for the active substance(s) and relevant impurities in the plant protection product.

Noticed data gaps are:

-none

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- A primary and confirmatory method for the determination of dicamba in body fluids.

The identified data gap also applies to the active substance and should be supplemented at the stage of on-going re-evaluation of the substance. Dicamba is not classified as toxic or very toxic.

Commodity/crop	Supported/ Not supported
Maize	Supported

## **5.2 Methods used for the generation of pre-authorization data (KCP 5.1)**

### **5.2.1 Analysis of the plant protection product (KCP 5.1.1)**

#### **5.2.1.1 Determination of active substance and/or variant in the plant protection product (KCP 5.1.1)**

An overview on the acceptable methods and possible data gaps for analysis of dicamba in plant protection product is provided as follows:

zRMS Comments:	This method is acceptable according EEC guideline SANCO/3030/99 rev. 5 and can be used for analysing a.s. in the PPP.
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Reference: KCP 5.1

Report Validation of analytical method for CHR/H/DIK 480 SL for determination of dicamba, I. Knapik, Study code: ICB/75/2021

Guideline(s): Conducting of analytical method validation – own Standard Operational Procedure SPB/179.

Deviations: No

GLP: Yes

Acceptability: Yes

## **Materials and methods:**

Validation was carried out according to Standard Operational Procedure SPB/179. Content of dicamba at a level of 480 g/L in the test item was accordingly determined by liquid chromatography with diode array detection (HPLC-DAD).

- acetonitrile HPLC (VWR),
- 85% phosphoric acid (Merck),
- placebo,
- dicamba standard; Sigma Aldrich; batch BCCB1194,
- standard stock solution of dicamba in acetonitrile, for calibration
- working standard solutions of dicamba in acetonitrile, for calibration
- standard stock solution of dicamba in acetonitrile, for determination of recovery
- analytical balance – accuracy 0.0001 g, WP/16 (Ohaus, Switzerland),
- liquid chromatograph with diode array detection, WP/19 (Shimadzu, Japan),
- chromatography column type C18, 250 mm x 4.6 mm; 5 µm (Zorbax Eclipse Plus, Agilent), K/10/HPLC,
- liquid chromatograph with diode array detection, WP/42 (Shimadzu, Japan),
- chromatography column type C18 100Å, 150 mm x 4.6 mm; 5 µm (Luna Omega Polar, Phenomenex), K/15/HPLC,
- chromatographic vials 1.5 ml with septa buthyl/Teflon,
- volumetric flasks A class 10 mL,
- pipette 2 mL,
- measuring syringes 10 µL, 100 µL, 250 µL, 500 µL, 1000 µL.

Validation was carried out according to Standard Operational Procedure SPB/179. Content of dicamba at a level of 480 g/L in the test item was accordingly determined by liquid chromatography with diode array detection (HPLC-DAD).).

## Validation - Results and discussions

**Table 5.2-1: Methods suitable for the determination of active substances dicamba in plant protection product CHR/H/DIK 480 SL**

	dicamba
<b>Author(s), year</b>	M. Patrzalek, 2019
<b>Principle of method</b>	HPLC-DAD
<b>Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)</b>	In order to check the linearity of dicamba, calibration curve was prepared using standard solutions with concentrations contained in Table 3. A graph of the peak area to the concentration of dicamba was plotted. The resulting curve is linear in the tested concentrations. Linearity range of dicamba is from 1.021 to 99.900 µg/mL. Correlation coefficient R2 is 0.9998015 (Figure 2) and the linear regression is described by equation: $f(x)=5.28970 \cdot 10^{-5}x+0,00561055$ for primary chromatographic system. Correlation coefficient R2 is 0.9997857 (Figure 9) and the linear regression is described by equation: $f(x)=5.35495 \cdot 10^{-5}x+0,0102451$ for secondary chromatographic system.
<b>Precision – Repeatability Mean n = 5 (%RSD)</b>	

	<b>dicamba</b>					
	Results for primary chromatographic system.					
	Active ingredient			Linearity		
	dicamba			R <sup>2</sup> =0.9998015		
	Validation level	Active ingredient	Precision [%]	Horwitz ratio	Recovery [%]	Standard addition [%]
	100% without standard addition	dicamba	0.85	0.55	-	-
	100% with standard addition (20-30%)	dicamba	-	-	97.17-98.42	24.82
	LOQ	dicamba	0.72	0.26	99.6 (average)	-
	ULOQ	dicamba	0.85	0.58	100.2 (average)	-
	Results for secondary chromatographic system.					
	Active ingredient			Linearity		
	dicamba			R <sup>2</sup> =0.9997857		
	Validation level	Active ingredient	Precision [%]	Horwitz ratio	Recovery [%]	Standard addition [%]
	100% without standard addition	dicamba	0.80	0.52	-	-
	100% with standard addition (20-30%)	dicamba	-	-	97.01-99.28	24.81
	LOQ	dicamba	0.77	0.28	97.3 (average)	-
	ULOQ	dicamba	0.78	0.53	99.9 (average)	-

	<b>dicamba</b>
<b>Accuracy</b> <b>n = 5</b> <b>(% Recovery)</b>	<div>Results for primary chromatographic system.</div> <div> <div>Active ingredient</div> <div>Linearity</div> <div>dicamba</div> <div><math>R^2=0.9998015</math></div> </div> <div> <div>Validation level</div> <div>Active ingredient</div> <div>Precision [%]</div> <div>Horwitz ratio</div> <div>Recovery [%]</div> <div>Standard addition [%]</div> </div> <div> <div>100% without standard addition</div> <div>dicamba</div> <div>0.85</div> <div>0.55</div> <div>-</div> <div>-</div> </div> <div> <div>100% with standard addition (20-30%)</div> <div>dicamba</div> <div>-</div> <div>-</div> <div>97.17-98.42</div> <div>24.82</div> </div> <div> <div>LOQ</div> <div>dicamba</div> <div>0.72</div> <div>0.26</div> <div>99.6 (average)</div> <div>-</div> </div> <div> <div>ULOQ</div> <div>dicamba</div> <div>0.85</div> <div>0.58</div> <div>100.2 (average)</div> <div>-</div> </div>
	<div>Results for secondary chromatographic system.</div> <div> <div>Active ingredient</div> <div>Linearity</div> <div>dicamba</div> <div><math>R^2=0.9997857</math></div> </div> <div> <div>Validation level</div> <div>Active ingredient</div> <div>Precision [%]</div> <div>Horwitz ratio</div> <div>Recovery [%]</div> <div>Standard addition [%]</div> </div> <div> <div>100% without standard addition</div> <div>dicamba</div> <div>0.80</div> <div>0.52</div> <div>-</div> <div>-</div> </div> <div> <div>100% with standard addition (20-30%)</div> <div>dicamba</div> <div>-</div> <div>-</div> <div>97.01-99.28</div> <div>24.81</div> </div> <div> <div>LOQ</div> <div>dicamba</div> <div>0.77</div> <div>0.28</div> <div>97.3 (average)</div> <div>-</div> </div> <div> <div>ULOQ</div> <div>dicamba</div> <div>0.78</div> <div>0.53</div> <div>99.9 (average)</div> <div>-</div> </div>
<b>Interference/ Specificity</b>	Specificity of the method was evaluated based on the analysis of chromatograms for placebo and samples against chromatograms of standard dicamba and peak purity. Analysis showed no overlapping of determined ingredient signal with the signals of matrix components under method conditions, hence method specificity criterion is fulfilled.
<b>Comment</b>	

## Conclusion

It was confirmed that the method is specific. There were no peaks from placebo interfering with determined compounds. The validation parameters (specificity, linearity, instrument precision, repeatability and accuracy) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.5

### 5.2.1.2 Description of analytical methods for the determination of relevant impurities (KCP 5.1.1)

Not required.

### 5.2.1.3 Description of analytical methods for the determination of formulants (KCP 5.1.1)

Please refer to PART C – Confidential data.

### 5.2.1.4 Applicability of existing CIPAC methods (KCP 5.1.1)

Analytical methods for determination of dicamba impurities and relevance of CIPAC methods in

CHR/H/DIK 480 SL were not evaluated as part of the EU review. Therefore, all relevant data are provided and are considered adequate.

## 5.2.2 Methods for the determination of residues (KCP 5.1.2)

An overview on the acceptable methods and possible data gaps for analysis of residues of dicamba for the generation of pre-authorization data is given in the following table. For the detailed evaluation of additional studies it is referred to Appendix 2.

**Table 5.2-2: Validated methods for the generation of pre-authorization data**

Component of residue definition: Dicamba and DCSA for soil, water and air Dicamba + 5-OH-dicamba, free and conjugated for plants				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
Plants, plant products,...	Primary	0.01 mg/kg	GC-MSD	REM 193.01 Gasser, A. (1998)
	Confirmatory (if required)	Not required		
Soil	Primary	0.01 mg/kg	GC-MSD	Gasser, A. (2000)
	Confirmatory (if required)	Not required		
Water	Primary	0.1 µg/L	GC-MSD	Gasser, A. (2000)
	Confirmatory (if required)	Not required		
Air	Primary	21 µg a.i. /m <sup>3</sup>	HPLC-UV	Kettner, R. and Karapally, J. (1993).
	Confirmatory (if required)	Not required		
Animal substrates	Primary	0.001	GC-MSD	AM-0938-0994-0 Formanski L.J., (1994)
	Confirmatory (if required)	Not required		

## 5.3 Methods for post-authorization control and monitoring purposes (KCP 5.2)

Data provided on Annex I inclusion is sufficient for post-authorizations methods. All data is described in EU approved documents for :

- Methods are described and presented in Table 5.2-3 in point KCP 5.1.2.

### 5.3.1 Analysis of the plant protection product (KCP 5.2)

Analytical methods for the determination of the active substance and relevant impurities in the plant protection product shall be submitted, unless the applicant shows that these methods already submitted in accordance with the requirements set out in point 5.2.1 can be applied.

### 5.3.2 Description of analytical methods for the determination of residues Dicamba (KCP 5.2)

#### 5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the



current legal residue definition is identical.

**Table 5.3-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required**

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high protein/high starch content (dry commodities)	Dicamba	0.01 mg/kg 0.05 mg/kg	Gasser, A. (1998) Reg. (EU) 2015/845
Muscle	Dicamba, DCSA	0.01 mg/kg 0.02 mg/kg	Formanski L.J., (1994) Reg. (EU) 2015/845
Milk		0.01 mg/kg 0.2 mg/kg	Formanski L.J., (1994) Reg. (EU) 2015/845
Liver, kidney		0.01 mg/kg 0.07 mg/kg	Formanski L.J., (1994) Reg. (EU) 2015/845
Fat		0.04 mg/kg	Reg. (EU) 2015/845
Eggs		0.05 mg/kg	Reg. (EU) 2015/845
Soil (Ecotoxicology)	Dicamba, DCSA and their salts	0.1 mg/kg 0.016 mg/kg	Gasser, A. 2000 based on ER50 for beta vulgaris of 24.4 g a.s./ha EFSA Journal 2011;9(1):1965
Drinking water (Human toxicology)	Dicamba, DCSA and their salts	0.1 µg/L	general limit for drinking water
Surface water (Ecotoxicology)	Dicamba, DCSA and their salts	0.01 µg/L 450 µg/L (dicamba) 11900 µg/L (DCSA)	Gasser, A. 2000 based on EbC <sub>50</sub> Myriophyllum spicatum, EbC <sub>50</sub> Lemna gibba EFSA Journal 2011;9(1):1965
Air	Dicamba	21 µg/m <sup>3</sup> 90 µg/m <sup>3</sup>	Kettner, R. and Karapally, J. (1993). AOEL sys: 0.3 mg/kg bw/d EFSA Journal 2011;9(1):1965
Tissue (meat or liver)	Dicamba DCSA	0.01 mg/kg	notclassified as T / T+ required according to Reg. (EU) No 283/2013
Body fluids		not required-0.01mg/kg	notclassified as T / T+ required according to Reg. (EU) No 283/2013

### 5.3.2.2 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of dicamba in plant matrices is given in the following tables. For the detailed evaluation of additional studies it is referred to Appendix 2.

**Table 5.3-2: Validated methods for food and feed of plant origin (required for all matrix types, “difficult” matrix only when indicated by intended GAP)**

Component of residue definition: Dicamba and 5-OH-dicamba				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing / EU agreed
High protein/high starch content (dry)	Primary	0.01 mg/kg	HPLC-MS/MS	Gasser, A. (1998) Validation: Gasser, A. (1997) Validation in corn, rape seed, pasture and orange: Maffezoni, M.
	ILV	0.01 mg/kg	GC-MS	Steinhauer, S., 2004)
	Confirmatory (if required)	Not required		
High water content	Primary: REM 193.01	0.01 mg/kg	GC-MS	Gasser A., 1998 EU Agreed (Denmark, 2007)
	ILV: ADE-0402V			Steinhauer, S., 2004 EU Agreed (Denmark, 2007)

For any special comments or remarkable points concerning the analytical methods for the determination of residues in plant matrices, please refer to Appendix 2.

**Table 5.3-3: Statement on extraction efficiency**

	Method for products of plant origin
Not required, because:	Residues below LOQ

### 5.3.2.3 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of dicamba in animal matrices is given in the following tables.

**Table 5.3-4: Validated methods for food and feed of animal origin (if appropriate)**

Component of residue definition: Dicamba				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Milk	Primary	0.03 mg/kg	HPLC-MS/MS	Formanski, L.J., 1994).
	Confirmatory (if required)	-		
	ILV	0.03 mg/kg	GC-ECD	Baldi, B.G., 1994)
Egg	Primary	0.01 mg/kg	HPLC-MS/MS	Formanski, L.J., 1994).
	Confirmatory (if required)	-		
	ILV	0.01 mg/kg	GC-ECD	Baldi, B.G., 1994)
Meat	Primary	0.01 mg/kg	HPLC-MS/MS	Formanski, L.J., 1994).

Component of residue definition: Dicamba				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Liver, fat	Confirmatory (if required)	-		
	ILV	0.01 mg/kg	GC-ECD	Baldi, B.G., 1994)
	Primary	0.05 mg/kg	HPLC-MS/MS	Formanski, L.J., 1994).
Kidney	Confirmatory (if required)	-		
	ILV	0.05 mg/kg	GC-ECD	Baldi, B.G., 1994)
	Primary	0.05 mg/kg	HPLC-MS/MS	Formanski, L.J., 1994).

For any special comments or remarkable points concerning the analytical methods for the determination of residues in animal matrices, please refer to Appendix 2.

**Table 5.3-5: Statement on extraction efficiency**

	Method for products of animal origin
Not required, because:	Residue below LOQ

### 5.3.2.4 Description of methods for the analysis of soil (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of dicamba in soil is given in the following tables.

**Table 5.3-6: Validated methods for soil (if appropriate)**

Component of residue definition: Dicamba and DCSA			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	0.01 mg/kg	GC- MSD	Gasser, A, (2000)
Confirmatory	-		

### 5.3.2.5 Description of methods for the analysis of water (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of dicambaa in surface and drinking water is given in the following tables.

**Table 5.3-7: Validated methods for water (if appropriate)**

Component of residue definition: Dicamba and DCSA				
Matrix type	Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Drinking water	Primary	0.05 µg/L	GC-MSD	Gasser, A. (2000)
	ILV	-		
	Confirmatory	Not required		
Surface water	Primary	0.1 µg/L	GC-MSD	Gasser, A. (2000)
	Confirmatory	Not required		

### 5.3.2.6 Description of methods for the analysis of air (KCP 5.2)

An overview on the acceptable methods and possible data gaps for analysis of Dicamba in air is given in the following tables.

**Table 5.3-8: Validated methods for air (if appropriate)**

Component of residue definition: DICAMBA			
Method type	Method LOQ	Principle of method (i.e. GC-MS or HPLC-UV)	Author(s), year / missing
Primary	21 µg a.i. m3	HPLC-UV	Kettner, R. and Karapally, J. (1993).
Confirmatory	Not required		

For any special comments or remarkable points concerning the analytical methods for air it is referred to Appendix 2.

### 5.3.2.7 Description of methods for the analysis of body fluids and tissues (KCP 5.2)

Dicamba is not classified as toxic or highly toxic, therefore analytical methods to study residues in body fluids and tissues are not required..

#### zRMS comments:

In the opinion of zRMS, the methods are required according to Reg. (UE) 283/2013. However, at the stage of substance evaluation, these methods were not required (according to EFSA Journal 2011;9(1):1965: Not required as the active substance is not classified as toxic or very toxic). The identified data gap should be addressed at the stage of on-going re-evaluation of the substance.

### 5.3.2.8 Other studies/ information

Not required

## 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 5.1./01	I. Knapik	2021	Validation of analytical method for CHR/H/DIK 480 SL for determination of dicamba Study code: ICB/75/2021 ICB Pharma, ul. Lema 10, 43-600, Jaworzno, POLAND GLP Unpublished	N	Chemirol Sp. z o.o.

### 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 5/01	Gasser, A.	1998	Dicamba (SAN 837): Determination of Parent Compound and Metabolite 5-Hydroxy Dicamba by Gas Chromatography (MSD), Plant Material Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, Report No REM 193.01 GLP Not Published Syngenta File N° SAN837/0401	N	SYN
KCP 5/02	Gasser, A.	1997	Laboratory Validation of an Analytical Method for the Determination of Residues of Dicamba and its Metabolite 5-Hydroxy Dicamba in Corn, 1997 Novartis Crop Protection AG, Basel, Switzerland Novartis Agro Europe, ACES, Huningue, France, Report No R97-003 GLP Not Published Syngenta File N° SAN837/0199	N	SYN

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP 5/03	Maffezoni, M.	2004	Dicamba (SAN 837): Validation of Residue Method REM 193.01 in Corn, Rape Seed, Pasture and Oranges Syngenta Crop Protection AG, Basel, Switzerland ADME - Bioanalyses, Vergèze, France, Report No SYN/DIC/03041 GLP Not Published Syngenta File N° SAN837/6146	N	SYN
KCP 5/04	Steinhauer, S.	2004	Dicamba (SAN 837): Independent Laboratory Validation of Residue Method REM 193.01 for the determination of Dicamba (SAN837) and 5-OH Dicamba (NOA 405873) in Maize (Grain) and Pasture Syngenta Crop Protection AG, Basel, Switzerland Dr. Specht & Partner Chem. Laboratorien GmbH, Hamburg, Germany, Report No ADE-0402V Az. G04-0039 GLP Not Published Syngenta File N° SAN837/6260	N	SYN
KCP 5/05	Formanski, L.J.	1994	Determination of Dicamba and Dichlorosalicylic Acid Residues in Beef Tissues (GC) Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Inc., Des Plaines, United States, Report No AM-0938-0994-0 GLP Not Published Syngenta File N° SAN837/5887	N	SYN
KCP 5/06	Baldi, B.G.	1994	CONFIRMATORY METHOD TRIAL OF THE RESIDUE METHOD, AM-0938-0994-0, "DETERMINATION OF DICAMBA AND DICHLOROSALICYLIC ACID RESIDUES IN BEEF TISSUES )GC)" Novartis Crop Protection AG, Basel, Switzerland EnCas Analytical Lab., Winston-Salem, United States, Report No 09/94/AM GLP Not Published Syngenta File N° SAN837/5378	N	SYN
KCP 5/07	Gasser, A.	2000	Determination of Parent Compound Dicamba and Metabolite Dichlorosalicylic Acid by Gas	N	SYN

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Chromatography (MSD) Novartis Crop Protection AG, Basel, Switzerland, Report No REM 193.02 GLP Not Published Syngenta File N° SAN837/5927		
KCP 5/08	Gasser, A.	2000	Validation of Method REM 193.02 : Validation by Analysis of Soil Specimens Fortified with Dicamba (SAN 837) and its metabolite Dichlorosalicylic Acid (DCSA) and determination of Recoveries Novartis Crop Protection AG, Basel, Switzerland, Report No 301/00 GLP Not Published Syngenta File N° SAN837/5928	N	SYN
KCP 5/08	Gasser, A.	2000	Dicamba (SAN 837) - Determination of parent compound and metabolites dichlorosalicylic acid and 5-hydroxy dicamba by gas chromatography (MSD) Novartis Crop Protection AG, Basel, Switzerland, Report No REM 193.03 Not GLP Not Published Syngenta File N° SAN837/5944	N	SYN
KCP 5/09	Gasser, A.	2000	Validation of method REM 193.03 Novartis Crop Protection AG, Basel, Switzerland, Report No 302/00 GLP Not Published Syngenta File N° SAN837/5945	N	SYN
KCP 5/10	Kettner, R., Karapally, J.C.	1993	Determination of Dicamba in Air Novartis Crop Protection AG, Basel, Switzerland Sandoz AG, Basel, Switzerland, Report No 21401 GLP Not Published Syngenta File N° SAN837/5366	N	SYN

## **Appendix 2 Detailed evaluation of submitted analytical methods**

### **A 2.1 Analytical methods for Dicamba**

#### **A 2.1.1 Methods used for the generation of pre-authorization data (KCP 5.1)**

No new or additional studies have been submitted

#### **A 2.1.2 Methods for post-authorization control and monitoring purposes (KCP 5.2)**

##### **A 2.1.2.1 Description of analytical methods for the determination of residues in plant matrices (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.2 Description of analytical methods for the determination of residues in animal matrices (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.3 Description of Methods for the Analysis of Soil (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.4 Description of Methods for the Analysis of Water (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.5 Description of Methods for the Analysis of Air (KCP 5.2)**

No new or additional studies have been submitted

##### **A 2.1.2.6 Description of Methods for the Analysis of Body Fluids and Tissues (KCP 5.2)**

No new or additional studies have been submitted.

##### **A 2.1.2.7 A.2.A.9 Other Studies/ Information**

No new or additional studies have been submitted