

# REGISTRATION REPORT

## **Part A**

### **Risk Management**

Product code: ADM.4651.H.1.A (former A18032E)

Product name(s): NIKITA

Chemical active substances:

Dicamba: 312.5 g/kg

Mesotrione: 150 g/kg

Nicosulfuron: 100 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## NATIONAL ASSESSMENT

Poland

Sponsor: ADAMA

Applicant: ADAMA

Submission date: June 2020

MS Finalisation date: March 2022 (initial National Assessment)

June 2022 (final National Assessment)

### Version history

When	What
February 2021	Initial dRR – ADAMA
March 2022	Initial zRMS assessment  In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern <del>is struck through and shaded</del> .
June 2022	Final report (National Assessment updated following the commenting period).  Auto-correction by zRMS: Appendix 2: Copy of the product label, p. 35: removing of the redundant reference to tables that were withdrawn, from the commenting box preceding the text of national label, already at the evaluation stage. <b>The amendment marked by yellow highlighting.</b>

ADAMA use the code ADM.4651.H.1.A for the formulation but for consistency the former Syngenta code A18032E is used throughout the dRR.

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# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

#### **1.1 Application background**

This application was submitted by ADAMA. Poland was the zRMS for the evaluation.

The application was for approval of 'NIKITA' (A18032E), a water dispersible granule (WG) product containing 312.5 g/kg dicamba, 150 g/kg mesotrione and 100 g/kg nicosulfuron for use as herbicide in maize to control annual and perennial broad leaved weeds and grass weeds.

The product ownership was transferred to ADAMA from Syngenta in 2018.

Our application includes a complete dRR developed to meet the requirements after the renewal of the active substance mesotrione. Art 43 is pending in several member states in central and southern EU. The central submission was made in September 2019 and Slovakia is the zRMS. The mesotrione confirmatory data has not yet be concluded, - but we are of the opinion that the request is addressed and further requirements should not block any local evaluation.

#### **1.2 Letters of Access**

Where Syngenta relies on data belonging to a third party that are not included in the dossier, then a letter of access to that data or reference to such is provided in Appendix 3 of this document.

Where Syngenta relies on data belonging to a third party that are included in the dossier, then the ownership of the data is indicated in Appendix 4 of this document and also in the corresponding reference lists in Appendix 1 of the Registration Report, Part B Sections 1-10 and a letter of access to that data or reference to such is provided in Appendix 3 of this document.

#### **1.3 Justification for submission of tests and studies**

All reports submitted are needed for the first registration of A18032E in accordance to the data requirements laid down in Regulation (EC) No. 284/2013.

Art. 33 (3) c Justification of steps taken to avoid animal testing and duplication of such testing:

There is no repetition of studies involving vertebrates. Animal studies were only performed where there were no data available to address an endpoint, no extrapolation to existing data possible or the available data were not done according to modern guidelines. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Art. 33 (3) d Reasons for submission of tests and study reports:

Since this product was previously registered there have been changes to active substance endpoints and test, study and assessment guidelines; therefore where necessary in order to obtain re-approval new tests and study reports are provided.

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of A18032E, in accordance with Article 59 of Regulation (EC) No. 1107/2009, it is indicated in **Appendix 4** of this document.

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	ADM-4651.H.1.A = A18032E
Product name in Poland	NIKITA
Authorization number	New product
Applicant	ADAMA Polska Sp. z o.o.
Function	Herbicide
Active substances (incl. content)	dicamba; 312.5 g/kg mesotrione; 150 g/kg nicosulfuron; 100 g/kg
Formulation type	formulation type [Code: WG] Water dispersible Granule
Packaging SK	HDPE Canisters: 0,25 kg, 0,5 kg, 1 kg, 5 kg All professional user
Coformulants of concern for national authorizations	There are no coformulants of concern in A18032E
Restrictions related to identity	Not applicable
Mandatory tank mixtures	The product A18032E is not recommended as tank mix with other plant protection products.  This product must be used in conjunction with a non-ionic surfactant or an oil based adjuvant at recommended use rates (see label)
Recommended tank mixtures	The dossier does not include recommendations for specific mixing of the preparation with any other product. Consult registration holder about mixing options.  This product must be used in conjunction with a non-ionic surfactant or an oil based adjuvant at recommended use rates (see label) (see label)

### 2.2 Conclusion

The evaluation of the application for A18032E / NIKITA resulted in the decision to grant the authorization for application every third year.

### 2.3 Substances of concern for national monitoring

According to national monitoring data, mesotrione is not a substance of concern.


## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye irritation	Category 2
	Reproductive toxicity	Category 2
	STOT RE 2	
	Acute aquatic toxicity	Category 1
	Chronic aquatic toxicity	Category 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H319 Causes serious eye irritation.</b> <b>H361d Suspected of damaging the unborn child</b> <b>H373 May cause damage to organs (eyes; nervous system)</b> H400 Very toxic to aquatic life <b>H410 Very toxic to aquatic life with long lasting effects</b>
Precautionary statement(s):	<b>P102 Keep out of reach of children</b> <b>P273 Avoid release to the environment</b> <b>P260 Do not breathe spray</b> <b>P280 Wear protective gloves/ protective clothing/ eye protection</b> <b>P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</b> P337 + P313 If eye irritation persists: Get medical advice/ attention. <b>P308+P313 IF exposed or concerned: Get medical advice/attention.</b> <b>P391 Collect spillage</b> <b>P501 Dispose of contents/ container to an approved waste disposal plant.</b>
Supplemental information :	<b>EUH401 To avoid risks to human health and the environment, comply with the instructions for use</b> <b>EUH208 Contains disodium maleate. May produce an allergic reaction</b>

Special rule for labelling of plant protection product (PPP):	
<b>EUH401</b>	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
None	

**See Part C for justifications of the classification and labelling proposals.**

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
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## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

	Refer to national product label
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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
None	Not required
Worker protection:	
None	Not required
Integrated pest management (IPM)/sustainable use:	
None	n/a
Environmental protection	
SPe 3	To <u>protect aquatic organisms</u> , respect vegetated filter strip of 5 m to surface water bodies.  To <u>protect non-target terrestrial plants</u> , respect an unsprayed buffer zone of 5 m to non-agricultural land or reduce the spray drift by 90% using appropriate drift reducing techniques.
SPe 1	To <u>protect groundwater</u> do not apply this or any other product containing nicosulfuron more than once every third year.
Other specific restrictions	
None	n/a

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
None	n/a



## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
None	n/a	n/a
Environmental protection:		Relevant for use no.
None	n/a	n/a

## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	CALLISTO TURBO /A18032E
Active substance 1:	Dicamba
Active substance 2:	Mesotrione
Active substance 3:	Nicosulfuron
Safener:	None
Synergist:	None
Applicant:	ADAMA
Zone(s):	Central <sup>(d)</sup>
Verified by MS:	Yes
Field of use:	Herbicide

Formulation type:	GAP, date: 2022-06-30 WG <sup>(a, b)</sup>
Conc. of as 1:	312.5 g/kg <sup>(c)</sup>
Conc. of as 2:	150 g/kg
Conc. of as 2:	100 g/kg
Conc. of safener:	Not applicable
Conc. of synergist:	Not applicable
Professional use:	<input checked="" type="checkbox"/>
Non professional use:	<input type="checkbox"/>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha ( <sup>(1)</sup> )	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	Poland	Maize (ZEAMX)	F	Annual/perennial grass and broadleaved weeds	Foliar, spraying, overall	- / BBCH 12-14 Spring	a) 1 b) 1	n.a.	a) 0.4 b) 0.4	1) Mesotrione a) 60 b) 60  2) Dicamba a) 125 b) 125  3) Nicosulfuron a) 40 b) 40	200-300	n.a.	Tank-mixed adjuvant needed (e.g. Adigor: 1.0 - 1.5 L/ha, Olejan: 1.5 L/ha, Styk (Insert): 0,2 L )  Application every 3 years	A	A	A	A	R	R Aquatics NTTP  A Remaining species	A	A
2	Poland	Maize (ZEAMX)	F	Annual/perennial grass and broadleaved weeds	Foliar, spraying, overall	- / BBCH 12-14 Spring	a) 1 b) 1	n.a.	a) 0.4 b) 0.4	1) Mesotrione a) 60 b) 60  2) Dicamba a) 125 b) 125  3) Nicosulfuron a) 40 b) 40	200-300	n.a.	Application in tank mix with 0.8 L/ha Efica 960 EC  Application every 3 years  Risk mitigation measures identified for Efica 960 EC must be combined with RMM identified for A18032E	A	A	A	A	R	R Aquatics NTTP  A Remaining species	A	A
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)																					
None.																					
Minor uses according to Article 51 (zonal uses)																					

None.		
<b>Minor uses according to Article 51 (interzonal uses)</b>		
None.		
<b>Remarks table heading:</b>	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (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.
<b>Remarks columns:</b>	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 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) 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 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. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”. 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions 15 Overall conclusions - explanation for the column 15 is below*

**\* Explanation for column 15 “Overall conclusions”**

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

### **3 Background of authorization decision and risk management**

#### **3.1 Physical and chemical properties (Part B, Section 2)**

The product A18032E is a water dispersible granule [Code: WG] formulation.

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Physical chemistry studies that involve dilution in water have been conducted at concentrations appropriate to those stated in the GAP document.

The appearance of the product is that of a beige solid. It is not explosive, has no oxidising properties. In aqueous solution, it has a pH value around 4.5 (1% suspension in water).

The active ingredient contents and physical properties remain unchanged after high temperature storage (14 days at 54°C) demonstrating no significant effect of high temperatures.

The ambient temperature shelf-life study (two years at 20°C) show no significant change in physical properties or active ingredient content and therefore the product A18032E will have a shelf-life of at least two years at ambient temperature (HDPE).

The technical characteristics of A18032E are acceptable for a water dispersible granule formulation.

The intended concentration of use is 0.1% to 0.5%.

The product A18032E is recommended as tank mix.

#### **Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only**

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of A18032E.

#### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of product A18032E.

#### **Compliance with FAO specifications:**

There is no FAO specification for A18032E.

#### **Formulation used for tests:**

All physico-chemical endpoints were measured using A18032E. Thus, no bridging to other formulations is required.

### **3.2 Efficacy (Part B, Section 3)**

ADM.4651.H.1.A is a water dispersible granule formulation containing 31.25% of dicamba, 15% of mesotrione and 10% of nicosulfuron for use on maize. The efficacy spectrum of the product is broad and includes annual as well as perennial broadleaf and grass weed species. The product is applied post emergence of the weeds, at crop BBCH 12-14.

The proposed application pattern of product is:

Tank-mix with adjuvants:

ADM.4651.H.1.A (0,4 kg/ha) + Olejan 85 EC (1,5 L/ha)

ADM.4651.H.1.A (0,4 kg/ha) + Adigor 440 EC (1,0-1,5 L/ha)

ADM.4651.H.1.A (0,4 kg/ha) + Styk (Insert) (0,2 L/ha)

Tank - mix with product Efica 960 EC

ADM.4651.H.1.A(0,4 kg/ha) + Effic 960 EC (Dual Gold 960 EC) - S-metolachlor 960 g/L (0,8 L/ha)

### **3.3 Efficacy data**

A total of 21 efficacy trials have been submitted, carried out in 2018-2020 in Poland (North-Eastern zone) and in the Czech Republic (Maritime zone). The reliable efficacy of the test item has been demonstrated in control of majority of the tested dicotyledone and monocotyledone target weed species, as the result of the joint application of ADM.4651.H.1.A with the adjuvants Adigor 440 EC or Olejan 85 EC, or with the tank-mix partner herbicide, Efica 960 EC, at their dose rates as specified (3.2, above). The comprehensive efficacy summary is provided in the part B3 of the dRR.

#### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

The resistance risk inherent in the actives of the test item has been assessed as being medium to high for nicosulfuron, low to medium for dicamba and low for mesotrione. Single application is proposed and the product is intended for exclusive application with tank-mix adjuvants or the partner herbicide Efica 960 EC. Provided that, next to the specific label recommendations the standard IPM practice is implemented too, to the opinion of zRMS there is no need for any additional risk modifiers. The unmodified resistance risk is acceptable.

#### **3.3.2 Adverse effects on treated crops**

Within 21 field efficacy trials conducted in 2018-2020, weak symptoms of necrosis (<5%) were observed only in one trial, in all experimental treatments including standard reference product. No phytotoxic symptoms were observed in any other efficacy trials. In 10 selectivity trials conducted in 2019 and 2020 no phytotoxic effects were observed either.

#### **3.3.3 Observations on other undesirable or unintended side-effects**

No data other than those from the efficacy trials and from the proper selectivity trials (see above) has been submitted, concerning undesirable or unintended effects.

### 3.4 Methods of analysis (Part B, Section 5)

#### 3.4.1 Analytical method for the formulation

An analytical method has been developed for the determination of the active substances dicamba, mesotrione and nicosulfuron in A18032E. Mesotrione, dicamba and nicosulfuron are determined in A18032E using liquid chromatography using a reversed phase column, an acetonitrile: water (1% phosphoric acid) eluent and UV detection at 260 nm. Quantification is achieved by comparison of ratios of peak areas to those of a standard solution (internal standard method). Full validation of the method has been conducted. The method SF-568/1 is suitable for the specific, accurate and precise determination of mesotrione, dicamba and nicosulfuron in product A18032E.

An overview of the acceptable methods and possible data gaps for analysis of relevant impurities in the plant protection product A18032E is provided. A18032E contains the active substance mesotrione which contain relevant impurities.

Methods for mesotrione relevant impurities:

- Analytical method SD-977/2 has been developed for the determination of the relevant impurity R287431 (6-methanesulfonyl-7-nitro-9-oxo-9H-xanthene-1-carbonitrile) in A18032E.
- Analytical method SD-1990/1 has been developed for the determination of the relevant impurity R287432 (6-methanesulfonyl-9-oxo-9H-xanthene-1-carbonitrile) in A18032E.
- Analytical method SD-1973/1 has been developed for the determination of the relevant impurity 1,2-dichloroethane (DCE) in A18032E.

Validations of these methods are provided and are considered adequate.

There are no relevant formulants in A18032E therefore no methods are required.

There is no CIPAC method available for the determination of mesotrione, nicosulfuron, and dicamba in mixed WG formulations such as A18032E.

#### 3.4.2 Analytical methods for residues

##### Dicamba

The analytical methods were evaluated by RMS-Denmark (2007).

According to the EFSA Journal 2011;9(1):1965:

*“A GC-MS method is available for plants that claims to analyse both free and conjugated dicamba, however the hydrolysis step is not validated, therefore a data gap has been identified. A method of analysis for animal products is not available and a data gap is identified as MRLs are proposed. For soil a GC-MS method is available to analyse for dicamba and DCSA. In water GC-MS methods are available for dicamba, DCSA and 5-OH-dicamba. It should be noted however, that as the methods for plants and soil contain a hydrolysis step they are not specific for dicamba and its salts as they will also hydrolyse esters if dicamba had been applied in an ester form. The air method is not fully validated, therefore a data gap has been identified. A method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.”*

##### Analytical methods for residues (Regulation (Annex IIA, point 4.2)

##### Residue definitions for monitoring purposes

Food of plant origin

Food of animal origin

Soil

Water surface

drinking/ground

Air

Dicamba and its salts and conjugated dicamba expressed as dicamba
Dicamba and its salts and conjugated dicamba expressed as dicamba
Dicamba, DCSA and their salts
Dicamba, DCSA and their salts
Dicamba, DCSA and their salts
Dicamba

### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

REM 193.01: Extraction was performed with 1 N hydrochloric acid and the extract was brought to > pH 8 by addition of 4 N potassium hydroxide. After centrifugation an aliquot is acidified and partitioned with diethyl ether. Dicamba is converted to dicamba methyl derivative by methylation with iodomethane. Extracts were cleaned-up using a silica gel column. Determination was performed by GC-MS using SIM. LOQ was 0.01 mg/kg for maize. Open for validation of the hydrolysis step.

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

Open

Soil (analytical technique and LOQ)

Dicamba: GC-MS (LOQ: 0.01 mg/kg)  
DCSA: GC-MS (LOQ: 0.01 mg/kg)

Water (analytical technique and LOQ)

Drinking water:  
Dicamba: GC-MS (LOQ: 0.05 g/L)  
DCSA: GC-MS (LOQ: 0.05 g/L)  
5-OH-dicamba: GC-MS (LOQ: 0.05 g/L)\*

Surface water:  
Dicamba: GC-MS (LOQ: 0.1 g/L)  
DCSA: GC-MS (LOQ: 0.1 g/L)  
5-OH-dicamba: GC-MS (LOQ: 0.1 g/L)\*

\* Not a part of the residue definition for monitoring

Air (analytical technique and LOQ)

Open

Body fluids and tissues (analytical technique and LOQ)

Not required as the active substance is not classified as toxic or very toxic.

Analytical methods for the determination of residues of dicamba and its metabolites in plant matrices are available and have been presented in the draft Assessment Report for dicamba (Vol.3, Section B.5.2, February 2007) and in the addendum to DAR (Vol.3, Section B.5.2, November 2010). During the peer review under Directive 91/414/EEC, the residue method REM 193.01 was demonstrated to be suitable for the determination of dicamba and its conjugates and was validated in high water- (pasture, maize plant), high starch- (maize grain), high oil- (rape seed), high acid-content matrices (orange) and dry matrices (maize straw), achieving a LOQ of 0.01 mg/kg. Suitable ILV data were provided for high water- (pasture) and high starch-content matrices (maize grain).

New analytical methods for the determination of

- dicamba residues in animal matrices,
- dicamba and NOA414746 residues in soil,
- dicamba and dicamba metabolite NOA414746 (DCSA) in water samples
- dicamba in air

have been provided by Applicant. These data are currently under evaluation for the renewal of approval of the active substance, dicamba. For the detailed evaluation of new studies it is referred to Appendix 2 of Part B5.

The studies are acceptable.

According to the EFSA Journal 2011;9(1):1965 a method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

However in Commission Regulation (EU) No 283/2013 it is stated that “...methods, with a full description, shall be submitted for the analysis in body fluids and tissues for active substance and relevant metabolites”. In our opinion the analytical method for the determination of residues in body fluids and tissues is required and should be provided at the renewal of the active substance.

### Mesotrione

The analytical methods were evaluated and validated in the RAR (2015).

The residue definition for enforcement and risk assessment is proposed as mesotrione only in cereal grains and pulses and oilseeds.



The residue definitions for animal commodities are provisionally not required for the representative use on maize.

In the EFSA Journal 2016;14(3):4419 - “*Peer review of the pesticide risk assessment of the active substance mesotrione*” it was concluded that mesotrione residues can be monitored in food and feed of plant origin by the QuEChERS method (LC-MS/MS) with LOQs of 0.01 mg/kg in each commodity group. Residue monitoring method for food of animal origin is not required as no MRLs were set, however mesotrione can be determined in food and feed of animal origin by the QuEChERS method (LC-MS/MS) with LOQs of 0.01 mg/kg in all animal matrices.

Residues of mesotrione and its metabolites AMBA and MNBA in soil can be monitored by LC-MS/MS with LOQs of 0.002 mg/kg for all three compounds. Appropriate LC-MS/MS method exists for monitoring residues of mesotrione and its metabolites AMBA and MNBA in ground water and surface water with a LOQ of 0.05 µg/L for all compounds. It should be mentioned however, that pending on the final residue definition for monitoring for the environmental compartment, additional data might be required. Residues of mesotrione in air can be monitored by LC-MS/MS with a LOQ of 0.45 µg/m<sup>3</sup>.

The QuEChERS method (LC-MS/MS) can be used for monitoring mesotrione residues in blood with a LOQ of 0.01 mg/kg.

#### Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

##### Residue definitions for monitoring purposes

Food of plant origin  
Food of animal origin  
Soil  
Sediment  
Water surface  
drinking/ground  
Air  
Body fluids and tissues

Mesotrione
Not required (provisional)
Mesotrione and metabolite A (open)
Mesotrione and metabolite A (open)
Mesotrione and metabolite A (open)
Mesotrione and metabolite A (open)
Mesotrione
Mesotrione

##### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

Soil (analytical technique and LOQ)

Water (analytical technique and LOQ)

Air (analytical technique and LOQ)

Body fluids and tissues (analytical technique and LOQ)

QuEChERS LC-MS/MS (LOQ 0.01 mg/kg) Maize forage (high water), maize kernel (dry), oilseed rape (high oil) and orange (high acid) ILV in maize forage (high water) and maize kernel (dry) LC-MS/MS
QuEChERS LC-MS/MS (LOQ 0.01 mg/kg) in all animal matrices
Single method LC-MS/MS: Mesotrione: LOQ 0.002 mg/kg MNBA: LOQ 0.002 mg/kg AMBA: LOQ 0.002 mg/kg
Single method LC-MS/MS (surface and ground water, ILV available for drinking water) Mesotrione: LOQ 0.05 µg/L MNBA: LOQ 0.05 µg/L AMBA: LOQ 0.05 µg/L
LC-MS/MS Mesotrione: LOQ 0.45 µg/m <sup>3</sup>
QuEChERS LC-MS/MS (LOQ 0.01 mg/kg in blood)

Additional analytical methods for mesotrione have been evaluated in Appendix 2 of Part B5.

## Conclusions:

Sufficiently validated analytical methods are available to control mesotrione and metabolites in plant matrices, animal matrices, in soil, in water, in air and in human tissues and body fluids according to the definitions.

## Nicosulfuron

The analytical methods were validated and evaluated by United Kingdom, 2007.

The residue definition for enforcement and risk assessment is proposed as nicosulfuron.

The residue definitions for animal commodities are unable to propose, however not required for representative use.

According to the EFSA Journal 2011;9(1):1965: *“Adequate analytical methods are available for the determination of nicosulfuron residues in food of plant origin (in grain and fodder maize), soil, water and air. As the residue definition for all matrices is nicosulfuron, further methods of analysis and validation data for impurities and metabolites are not required.”*

*For the determination of residues of nicosulfuron in maize shoots (sprouts), grain and whole plants, a series of multistage methods based on extraction, partition and clean-up were used. Either HPLC or GC determination methods were used, with either LC/MS or GC/MS being used for confirmatory determination. Acceptable validation data were submitted for analysis of active substance, the validation data submitted for metabolite analysis were less satisfactory, however the residue definition for plant and products is ‘parent nicosulfuron’, therefore the lack of validation data in these cases is not a critical issue. Recovery data were obtained for nicosulfuron at levels between 0.01 and 0.10 mg/kg with acceptable mean recoveries and RSD values. Only single methods for the determination of residues are available.”*

In EFSA Journal 2012;10(12):3048 it is stated that *“During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS, and its ILV were evaluated and validated for the determination of parent nicosulfuron in plant matrices with an LOQ of 0.01 mg/kg in dry commodities (maize corn) and in maize straw (United Kingdom, 2007). Although this analytical method was previously considered acceptable by EFSA (2007b), the method was now re-evaluated according to the current guidelines. As this analytical method was validated only for one mass transition, the analytical method was not confirmed and confirmatory data are required.”*

*The multi-residue QuEChERS using diatomaceous earth clean up in combination with LC-MS/MS method, as described by CEN (2008), is also available to analyse the parent nicosulfuron in dry commodities. Nevertheless, the validation data reported are too limited to conclude on the validity of this analytical method (EURL, 2012).*

*Hence it is concluded that nicosulfuron can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in dry commodities but confirmatory data are still required. Additionally, an analytical method, an ILV and a confirmatory method fully validated in high water content commodities are required.*

### Methods for enforcement of residues in food of animal origin

*During the peer review under Directive 91/414/EEC, an analytical method using HPLC-UV for the determination of parent nicosulfuron was evaluated in food of animal origin but no validation data were submitted (United Kingdom, 2005).*

*However, considering that there is no significant intake of residues by livestock, no residue definition and no MRLs are proposed for commodities of animal origin (section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary.”*

## Analytical methods for residues (Regulation (Annex IIA, point 4.2))

### Residue definitions for monitoring purposes

Food of plant origin	Nicosulfuron
Food of animal origin	Not proposed
Soil	Nicosulfuron
Sediment	Nicosulfuron
Water surface	Nicosulfuron
drinking/ground	Nicosulfuron
Air	Nicosulfuron
Body fluids and tissues	Nicosulfuron

### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS, LOQ = 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Nicosulfuron: LC/MS, LOQ = 0.05 µg/kg
Water (analytical technique and LOQ)	Nicosulfuron: HPLC/UV, LOQ = 0.05 µg/L Confirmatory method: LC-DAD, LOQ = 0.05 µg/L
Air (analytical technique and LOQ)	Nicosulfuron: HPLC/UV, LOQ = 1.2 µg/m <sup>3</sup>
Body fluids and tissues (analytical technique and LOQ)	Not required

EFSA concluded (EFSA, 2012) that all tentative MRLs still need to be confirmed by the following data:

- Confirmatory data for the HPLC-MS/MS method with an LOQ of 0.01 mg/kg in dry commodities;
- An analytical method, its ILV and a confirmatory method fully validated for the determination of parent nicosulfuron in high water content commodities.

Applicant submitted new analytical methods to address these EFSA requirements. For the detailed evaluation of new studies it is referred to Appendix 2 of Part B5. These data are currently under evaluation for the renewal of approval of the active substance, nicosulfuron. The studies are acceptable.

## 3.5 Mammalian toxicology (Part B, Section 6)

### 3.5.1 Acute toxicity

A summary of the toxicological evaluation for A18032E is given in the following table:

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)
LD <sub>50</sub> oral, rat (OECD 425)	> 2000 mg/kg bw	Yes	None
LD <sub>50</sub> dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None
LC <sub>50</sub> inhalation, rat (OECD 403)	5.05 mg/L air	Yes	None
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None
Eye irritation, rabbit (OECD 405)	Irritant	Yes	H319
Skin sensitisation, guinea pig (OECD 406, Buehler (9 applications))	Non-sensitising	Yes	None
Supplementary studies for combinations of plant protection proucts	No data – not required	--	

Data and toxicological studies on dicamba, mesotrione and nicosulfuron metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were evaluated during the EU review and are considered acceptable.

The relevance assessment of the metabolites is reported in Part B.10.

Proposed dermal absorption rates for dicamba and mesotrione are based on a dermal absorption studies conducted with the current formulation. No data on dermal absorption for nicosulfuron in A18032E are available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2012; 10(4):2665) are presented.

### 3.5.2 Operator exposure

Operator exposure for use of A18032E was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the operator A18032E on maize is anticipated to be acceptable **with no PPE**.

### 3.5.3 Worker exposure

Worker exposure for A18032E was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the worker A18032E on maize is anticipated to be acceptable **with no PPE**.

### 3.5.4 Bystander and resident exposure

According to EC guidance document SANTE-10832-2015, the (EFSA Guidance) risk assessment on residents and bystanders cannot be fully considered until a procedure for the derivation of the AAOEL and higher risk assessment schemes, identified as missing by the Standing Committee, are available.

Consequently, this evaluation provides a first tier assessment based on the EFSA guidance for longer term exposures to residents' only, using 75th percentile data and comparing with the relevant AOEL. This assessment is equally applicable to longer term exposures for bystanders.

Bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for dicamba, mesotrione and nicosulfuron will not be exceeded under conditions of intended uses.

### 3.5.5 Combined Exposure and Risk Assessment

The product is a mixture of three active substances.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL/RVNAS. This is equivalent to the predicted exposure as % of systemic AOEL/RVNAS to decimal. The Hazard Index (HI) is the sum of the individual HQs.

**Table 3.5.5-1: Acute risk assessment from combined exposure**

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ) <sup>3</sup>
<i>Operators, with no PPE.</i> For details please refer to 6.6.2. Only the worst case scenario as herbicide in maize is presented	dicamba	0.073
	mesotrione	0.24
	nicosulfuron	0.025
	<b>Cumulative risk Operators (HI)<sup>2</sup></b>	<b>0.34</b>
<i>Workers</i> For details please refer to 6.6.3. Only the worst case scenario as herbicide in maize is presented	dicamba	0.06
	mesotrione	0.02
	nicosulfuron	0.008
	<b>Cumulative risk Workers (HI)<sup>2</sup></b>	<b>0.088</b>
<i>Bystander– Adult<sup>1</sup></i> For details please refer to 6.6.5. Only the worst case scenario as herbicide in maize is presented	Since no AAOEL has been determined for a.s. included in the product, estimated exposure for residents cover, exposure for bystanders. Refer Refer point 4.1 table 2 p. 9 EFSA (European Food Safety Authority), 2014. <i>Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp.,</i>	
<i>Bystander – Child<sup>1</sup></i> For details please refer to 6.6.5. Only the worst case scenario as herbicide in maize is presented	Since no AAOEL has been determined for a.s. included in the product, estimated exposure for residents cover, exposure for bystanders. Refer point 4.1 table 2 p. 9 EFSA (European Food Safety Authority), 2014. <i>Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp.,</i>	
<i>Resident – Adult<sup>1</sup></i> For details please refer to 6.6.5. Only the worst case scenario as herbicide in maize is presented	dicamba	0.056
	mesotrione	0.06
	nicosulfuron	0.0068
	<b>Cumulative risk Resident – Adult (HI)<sup>2</sup></b>	<b>0.12</b>

Application scenario	Active Substance	Estimated exposure / AOEL (RVNAS) (HQ) <sup>3</sup>
<i>Resident – Child<sup>1</sup></i> For details please refer to 6.6.5. Only the worst case scenario as herbicide in maize is presented	dicamba	0.15
	mesotrione	0.28
	nicosulfuron	0.02
	<b>Cumulative risk Resident – Child (HI)<sup>2</sup></b>	<b>0.45</b>

<sup>1</sup> The higher exposure value either from the 75<sup>th</sup> percentile of each of the four pathways (spray drift, vapour, surface deposits, entry into treated crops) or the sum of the mean exposure values is taken into consideration

<sup>2</sup> HI =Hazard Index

<sup>3</sup> HQ = Hazard Quotient

The Hazard Index is < 1. Thus combined exposure to all active substances in A18032E/NIKITA is not expected to present a risk for operators, workers, bystanders and residents. No further refinement of the assessment is required.

### 3.6 Residues and consumer exposure (Part B, Section 7)

#### 3.6.1 Residues

##### Dicamba

Maize is the major crop in northern Europe (EU guideline Document SANCO 7525/VI/95 - rev.10.3 of 13 June 2017 and SANTE/2019/12752). A minimum of eight independent trials representative of the proposed growing area for outdoor are required.

Sufficient trials are available and provided to support the proposed uses. The critical EU GAP for maize is most critical than proposed GAP.

The trials conducted on maize (1 x 0.36 kg a.s./ha, post-emergence until BBCH 16, since the period between treatment and harvest is more than 100 days, no PHI is applicable, outdoor) have been evaluated at the EU level (EFSA Journal 2011;9(1):1965). No PHI is proposed in the critical EU GAP since the application is made early post-emergence and the maize grain is harvested at maturity. The samples were analysed for dicamba and 5-OH-dicamba, using an analytical method including a hydrolysis step in order to take into account the conjugates.

No residues were detected in maize grains, with all values being below the LOQs of 0.01 and 0.05 mg/kg mg/kg for both compounds.

These residue data are supported by the storage stability study showing dicamba and 5-OH-dicamba residues to be stable for up to 36 months in maize matrices (forage, fodder and grain), when stored frozen at c.a. -17°C.

The Applicant provided four reports covered a total of 8 field trials in Northern Europe conducted on maize. Summary:

E: 8x <0.01 mg/kg,

R: 8x <0.02 mg/kg.

Residues of dicamba and 5-OH-dicamba in maize grain were below the limit of quantification (<0.01 mg/kg).

Available results show that the in force MRL on maize/corn of 0.5 mg/kg (Reg. (EU) 2015/845) will not be exceeded. The current EU MRL for dicamba are sufficient to support the proposed use.

Applicant proposes to add tank-mixed adjuvant (Adigor, STYK, Olejan or Efica 960 EC) to product ADM.4651.H.1.A (Nikita). Some trials have been submitted with the tank-mixed adjuvant (Etolag 149 and Trend 90). Residues levels of dicamba in these studies were below the LOQ, so the addition of an adjuvant should not affect the residue level in this application. It could be expected that the use of an adjuvant will not lead to an exceedance of the MRL and will not lead to an unacceptable chronic risk for the consumer. Hence, at the intended GAP, the use of an adjuvant is considered to be supported for dicamba.

The use of A18032E on maize may result in residues of dicamba in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. The calculated dietary burdens for all livestock were found to exceed the trigger value of 0.1 mg/kg DM in feed of dairy and meat ruminants and pigs, using both, the EFSA PROFile calculator and EFSA Animal model 2017. Livestock feeding studies for dicamba were evaluated during the EU review (Denmark, 2007) and are considered acceptable. The requested uses modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

New studies for residues in succeeding crops have been submitted by the applicant in the framework of this application. This data is currently under evaluation for the renewal of approval of the active substance, dicamba (Commission Implementing Regulation (EU) No. 844/2012 of 18 September 2012). Considering the overdosing factor of the above study and the fact that dicamba was applied to a bare soil (interception of dicamba by the plants is expected in practice), it can be concluded that dicamba residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that dicamba is applied in compliance with the GAPs supported for this submission.

### **Mesotrione**

For the uses proposed for mesotrione in A18032E, all relevant residue data and assessments are provided and considered acceptable.

The critical EU GAP for maize is most critical than proposed GAP.

The trials conducted on maize (1 x 0.15 kg a.s./ha, BBCH 12-18, PHI not specified, outdoor) have been evaluated at the EU level in the original RAR (United Kingdom, 2015). No PHI is proposed in the critical EU GAP since the application is made pre- or early post-emergence and the maize grain is harvested at maturity.

Residues of mesotrione in all grain, silage and forage specimens were below the limit of quantification (<0.01 mg/kg).

Available results show that the in force MRL on maize/corn of 0.01\* mg/kg (Reg. (EU) 2017/626) will not be exceeded. Therefore the uses of A18032E (Nikita) can be considered as supported on maize in Central Europe.

The current EU MRLs for mesotrione are sufficient to support the proposed uses.

Applicant proposes to add tank-mixed adjuvant (Adigor, STYK, Olejan or Efica 960 EC) to product ADM.4651.H.1.A (Nikita). Nevertheless, neither trials have been submitted with the tank-mixed adjuvant (Adigor, STYK, Olejan or Efica 960 EC). Residues levels of mesotrione are expected to be below the LOQ at the intended GAP and the TMDI represents only 12% of the ADI. In our opinion, the addition of an adjuvant should not affect the residue level in this application. It could be expected that the use of an adjuvant will not lead to an exceedance of the MRL and will not lead to an unacceptable chronic risk for the consumer. Hence, at the intended GAP, the use of an adjuvant is considered to be supported for mesotrione.

No further data are required to support the proposed uses.

With relevance to the nature of residues in crops, new data have been submitted in the framework of this application to address further the toxicological profile of metabolite AMBA. Based on the available metabolism data on plants and the new toxicological data on AMBA, it can be concluded that the residue definition for risk assessment in food and feed commodities should include mesotrione parent compound only.

With relevance to the nature of residues in animals, new data have been submitted in the framework of this application to address further the toxicological profile of metabolite AMBA. A residue definition for animal commodities is not considered necessary.

Livestock animals are not exposed to residues *via* feed above the trigger value established in Reg. (EC) No 1107/2009. Feeding studies are therefore not required.

Field rotational crop studies are not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate and considering also the low to moderate persistence of mesotrione, MNBA and AMBA.

## Nicosulfuron

For the uses proposed for nicosulfuron in A18032E, all relevant residue data and assessments are provided and considered acceptable.

The active substance nicosulfuron is authorised for foliar outdoor applications on maize (grain and forage) in northern and southern Europe and on sweet corn in northern Europe. The critical EU GAP for maize is most critical than proposed GAP.

The trials conducted on maize (18 trials N-EU, 1 x 0.06 kg a.s./ha, at BBCH 12-20, no PHI is applicable, outdoor) have been evaluated at the EU level (EFSA Journal 2012;10(12):3048). No PHI is proposed in the critical EU GAP since the application is made early post-emergence and the maize grain is harvested at maturity.

No residues were detected in maize grains, with all values being below the LOQs of 0.01.

In EFSA Journal 2012;10(12):3048 it is stated that “*Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for maize and sweet corn (see also Table 3-2). Considering the lack of analytical data for enforcement, only tentative MRLs are derived. Tentative MRLs were also derived for maize forage in view of the future need to set MRLs in feed items.*”

The Applicant provided one report covered a total of 4 field trials in Northern Europe conducted on maize. Summary:

E: 4x <0.01 mg/kg,

R: 4x <0.01 mg/kg.

Residues of nicosulfuron in maize grain were below the limit of quantification (<0.01 mg/kg).

Available results show that the in force MRL on maize/corn of 0.01\* mg/kg (Reg. (EU) No 617/2014) will not be exceeded. The current EU MRL for nicosulfuron is sufficient to support the proposed use.

Applicant proposes to add tank-mixed adjuvant (Adigor, STYK, Olejan or Efica 960 EC) to product ADM.4651.H.1.A (Nikita). Although, no trials have been submitted with the tank-mixed adjuvant, in our opinion, it could be expected that the use of an adjuvant will not lead to an exceedance of the MRL and will not lead to an unacceptable chronic risk for the consumer.

New data regarding the stability of residues during storage of nicosulfuron has been investigated in high water and high starch commodities are submitted in the framework of this application, which have previously been submitted as part of the AIR process for nicosulfuron. Sufficient stability has been demonstrated to support the residue data presented in the submission.

With relevance to the nature of residues in crops, new data are submitted in the framework of this application, which have previously been submitted as part of the AIR process for nicosulfuron. The metabolism of nicosulfuron in plants following foliar application is sufficiently addressed to support the proposed uses of the product A18032E.

With relevance to the nature of residues in animals, new data are submitted in the framework of this application, which have previously been submitted as part of the AIR process for nicosulfuron. The metabolism of nicosulfuron in livestock is sufficiently addressed to support the proposed uses of the product A18032E.

The use of A18032E may result in residues of nicosulfuron in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. The calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues in commodities of animal origin is not necessary.

### 3.6.2 Consumer exposure

#### Dicamba

ADI	0.3 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	19% (based on GEMS/Food G11 diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.
ARfD	0.3 mg/kg bw



IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Unprocessed commodities: Maize / corn: 1% (based on UK infant diet)  Processed commodities: Maize / oil: 4% (based on NL toddler diet) Maize / processed (not specified): 0.4% (based on NL toddler diet)
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

The proposed uses of dicamba in the formulation A8032E do not represent unacceptable acute or chronic risks for the consumer.

### Mesotrione

ADI	0.01 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	12% (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.
ARfD	0.02 mg/kg bw/d
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	Unprocessed commodities: Maize / corn: 0.3% (based on UK infant diet)  Processed commodities: Maize / oil: 1% (based on NL toddler diet) Maize / processed (not specified): 0.1% (based on NL toddler diet)
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

The proposed uses of mesotrione in the formulation A18032E do not represent unacceptable acute or chronic risks for the consumer.

### Nicosulfuron

ADI	2 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	0.1% (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Not relevant. TMDI < 100%.
ARfD	Not relevant. ARfD was not deemed necessary.
IESTI (% ARfD) according to EFSA PRIMo rev. 3.*	Not relevant. ARfD was not deemed necessary.
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

The proposed uses of nicosulfuron in the formulation A18032E do not represent unacceptable acute or chronic risks for the consumer.

### Combined Exposure and Risk Assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to

multiple active substances; this approach is not mandatory at EU level.

### **3.7 Environmental fate and behaviour (Part B, Section 8)**

#### **3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)**

Soil exposure for dicamba, mesotrione, nicosulfuron and their relevant metabolites was calculated using approach described in respective FOCUS guidance for exaggerated application rate of 0.6 kg product/ha, covering application rate intended in Poland (0.4 kg product/ha). For all compounds, EU agreed data were taken into account. Where relevant, potential for accumulation in soil was considered. Soil exposure for the formulated product was also calculated. Obtained PEC<sub>SOIL</sub> values were used in the risk assessment for soil organisms.

#### **3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

The leaching behaviour of dicamba, mesotrione, nicosulfuron and their relevant metabolites was assessed using FOCUS leaching models FOCUS PEARL v. 4.4.4, FOCUS PELMO v. 5.5.3 and MACRO 5.5.4 on the basis of the EU agreed input parameters and intended use pattern of A18032E. For dicamba and mesotrione exaggerated rate was considered, while for nicosulfuron the intended rate was taken into account. Only scenarios relevant for Poland (Châteaudun, Hamburg, Kremsmünster) were taken into account since no other cMS is included in GAP table.

Calculations performed for dicamba, mesotrione and their relevant metabolites resulted with PEC<sub>GW</sub> values <0.1 µg/L in all relevant Polish scenarios, demonstrating that no unacceptable leaching of these compounds is expected when A18032E is used according to recommendations to maize at BBCH 12-14 at 1x0.4 kg/ha.

When simulations were performed for nicosulfuron and its metabolites, unacceptable leaching of the parent was observed in Hamburg scenario for annual and biennial application. No unacceptable leaching was observed when application every third year was assumed. For triennial application PEC<sub>GW</sub> of metabolites HMUD, AUSN, UCSN and ASDM were <0.75 µg/L and no further evaluation was deemed necessary since all nicosulfuron groundwater metabolites are toxicologically not relevant. PEC<sub>GW</sub> values for metabolites ADMP and MU-466 were <0.1 µg/L in all simulations (also for annual application).

Overall, in order to protect groundwater uses of A18032E must be restricted to one application every third year.

#### **3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)**

The surface water exposure was estimated using the respective FOCUS models. EU agreed endpoints and intended use pattern in Poland (the only cMS) were considered. The surface water exposure to the formulated product was calculated using Spray Drift Calculator. Obtained PEC<sub>sw</sub> values were used in the risk assessment for aquatic organisms.

#### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

Based on the available data contamination of the atmosphere with dicamba, mesotrione and nicosulfuron from the intended uses of A18032E is considered to be negligible.

## **3.8 Ecotoxicology (Part B, Section 9)**

### **3.8.1 Effects on terrestrial vertebrates**

#### **Birds**

The acute and long-term risks of A18032E to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with dicamba, mesotrione and nicosulfuron, and maximum residues occurring on food items following applications according to the proposed use pattern. The combined toxicity and risk assessment was also performed.

The risk to birds from exposure via drinking water has also been assessed. Risk of secondary poisoning has not been assessed, as dicamba, mesotrione, nicosulfuron and their relevant metabolites have  $\log P_{OW} < 3.0$ .

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds is acceptable following use of A18032E according to the proposed use pattern. Acceptable combined acute and long-term risk assessment could be concluded. The risk assessment for exposure via drinking water from puddles also showed acceptable risk.

#### **Mammals**

The acute and long-term risks of A18032E to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with A18032E, dicamba, mesotrione and nicosulfuron, and maximum residues occurring on food items following applications according to the proposed use pattern. The combined toxicity and risk assessment was also performed.

The risk to mammals from exposure via drinking water has also been assessed. Risk of secondary poisoning has not been assessed, as dicamba, mesotrione, nicosulfuron and their relevant metabolites have  $\log P_{OW} < 3.0$ .

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk, indicating that the acute risk to mammals is acceptable following use of A18032E according to the proposed use pattern. Acceptable combined acute risk could be concluded.

The long-term TER values for dicamba and nicosulfuron, calculated for recommended scenarios, exceed the trigger value of 5, indicating acceptable risk. However, the long-term TER values for mesotrione fall below the trigger of 5 and the combined long-term risk was also unacceptable at Tier 1.

Acceptable long-term risk to mammals from mesotrione could be demonstrated in a refined risk assessment by identifying the brown hare and wood mouse as relevant focal species for the intended use pattern, refining the residue decline of mesotrione in potential food items, and considering the realistic amount of time spent foraging in early maize fields (PT). Considered refinement options were also sufficient to resolve the combined long-term risk to the relevant focal species.

### **3.8.2 Effects on aquatic species**

The aquatic risk assessment for particular active compounds and their metabolites was performed in line with EFSA (2013) using EU agreed data. In case EU agreed data were not sufficient, additional studies submitted by the Applicant were taken into account. The studies performed with the formulation were also used in the mixture risk assessment.

Risk assessment was performed with consideration of the surface water exposure calculated for representative Polish scenarios (D3, D4 and R1). For the formulated product the formulation PECSW derived using Spray Drift Calculator was taken into account since the combined toxicity assessment demonstrated that at least two co-formulants significantly contribute to the formulation toxicity which would not be addressed when  $PEC_{SW,MIX}$  based on  $PEC_{SW}$  for individual active compounds was used.

Performed evaluation demonstrated that in order to protect aquatic organisms an vegetated filter strip to surface water bodies must be respected.

In case the A18032E is used as a tank mix with Efica 960 EC, in order to protect aquatic organisms 10 m unsprayed buffer zone (including 5 meters vegetated filter strip) must be respected. This risk mitigation measure results from combination of the outcome of the risk assessment for A18032E combined with indications provided on the label of Efica 960 EC.

### **3.8.3 Effects on bees**

The acute risk of A18032E posed to honeybees following the intended uses in maize was re-assessed by the zRMS in line with indications of SANCO/10329/2002 rev 2 final. Respective hazard quotients were calculated with consideration of acute oral and contact studies with A18032E, dicamba, mesotrione and nicosulfuron and the maximum single application rate of the product (0.4 kg/ha) and corresponding rates of active compounds.

All the calculated hazard quotients were less than the relevant trigger of 50, indicating that the acute oral and contact risk to bees is acceptable following use of A18032E according to the proposed use pattern.

### **3.8.4 Effects on other arthropod species other than bees**

At Tier I, the in-field and off-field HQ values for *Typhlodromus pyri* were below the trigger value for the worst-case use scenario (1 x 600 g A18032E/ha in maize) indicating that the risk to non-target arthropods is acceptable following the use of A18032E according to the proposed use pattern.

At Tier I the off-field HQ value for *Aphidius rhopalosiphi* was below the trigger value for the worst-case use scenario (1 x 600 g A18032E/ha in maize) indicating acceptable off-field risk to this species following the use of A18032E according to the proposed use pattern. However, the in-field HQ values for *Aphidius rhopalosiphi* were above the trigger value and required further refinement. The Tier II, extended laboratory studies showed acceptable foliar in-field and off-field effects from foliar applications of A18032E for *Aphidius rhopalosiphi* and *Aloechara bilineata* for the worst-case use scenario (1 x 600 g A18032E/ha in maize).

Overall, the risk to non-target arthropods is therefore acceptable following use of A18032E according to the proposed use pattern with no need for risk mitigation measures.

### **3.8.5 Effects on soil organisms**

#### **Soil meso- and macrofauna**

The long-term risk of A18032E, dicamba, mesotrione and nicosulfuron, and relevant metabolites was evaluated where relevant for earthworms, Collembola and *Hypoaspis*. The risk assessment demonstrated that the risk to non-target soil meso- and macrofauna is acceptable following use of A18032E according to the proposed use pattern.

#### **Soil micro-organisms**

All no-effect levels of A18032E, dicamba, mesotrione and nicosulfuron, and relevant metabolites exceeded the relevant PEC<sub>soil</sub> values, indicating that the risk to soil micro-organisms is acceptable following use of A18032E according to the proposed use pattern.

### 3.8.6 Effects on non-target terrestrial plants

The risk of A18032E to non-target terrestrial plants was assessed from toxicity exposure ratios (TERs) using the A18032E toxicity data from Tier II studies (performed with addition of adjuvant Adigor), and the maximum off-field predicted environmental residues (PERs). TER values, calculated from worst-case endpoints from seedling emergence and vegetative vigour studies with 10 species and a PER<sub>off-field</sub> value at 1 m from the treated crop, indicated a potential risk to off-field non-target plants. The risk was refined using a probabilistic risk assessment and considering mitigation with buffers and spray drift reduction technology.

For 1 x 400 g A18032E/ha it was concluded that the risk to non-target plants off-field was acceptable when **a non-spray buffer strip of 5 m is considered, or a 1 m buffer with 90% drift reducing nozzles is used.**

The risk to terrestrial non-target plants in off-crop areas is therefore acceptable following use of A18032E according to the proposed use pattern when the appropriate mitigation measures are used.

### 3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

### 3.9 Relevance of metabolites (Part B, Section 10)

PEC<sub>GW</sub> of the metabolites of dicamba (DCSA) and mesotrione (MNBA and AMBA) as well as the metabolite ADMP of nicosulfuron were all < 0.1 µg/L in the relevant application patterns (please see dRR Part B, Section 8, chapter 8.8.2 and below).

Both in terms of classification and labelling, and in terms of determination of the relevant NOAEL's, it was demonstrated that the metabolite MNBA was less toxic than the mother compound mesotrione. The metabolite does not share the same characteristics as mesotrione itself, and if found in the groundwater, is thus not considered a substance of higher concern than mesotrione.

No assessment is thus required for any metabolite of mesotrione or dicamba, nor for metabolite ADMP of nicosulfuron.

For annual applications, the nicosulfuron metabolites HMUD, AUSN, UCSN, ASDM and MU-466 are predicted to occur in groundwater at concentrations above 0.1 µg/L but (see chapter 8.8.2). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

The relevance of the groundwater metabolites HMUD, AUSN, UCSN, ASDM and MU-466 has already been assessed and the assessment agreed at EU level (see EFSA Scientific Report, 2007).

Groundwater metabolites HMUD, AUSN, UCSN, ASDM are considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

When the product is applied every third year (as required for nicosulfuron) PEC<sub>GW</sub> for all nicosulfuron metabolites is <0.75 µg/L and no specific consumer risk assessment is necessary since in line with EFSA conclusions presented in EFSA Scientific Report (22007) 120, all nicosulfuron metabolites are toxicologically not relevant.

## 4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

A18032E contains

- active substances dicamba and mesotrione which are not approved as candidates for substitution
- active substance nicosulfuron is classified as candidate for substitution in accordance to Regulation (UE) No 2015/408 of the European Parliament published 11<sup>th</sup> of March 2015 and Regulation no 1107/2009 published by the European Parliament and the Council of 21 October 2009.

Regarding major crops/major uses cultivated in Poland in 2016, according to data published by GUS, regarding structure of agriculture production in Poland in 2018, total corn (seeds and forage) growing area estimated as 750 -1,3 mln hectares.

**Table 1. The area of crop cultivating in Poland [thous. ha] (via Central Statistical Office of Poland 2017)**

Crop	In Poland / thous. ha	Major/minor
<b>Maize</b>	750-1 mln	Major

### Conclusions:

The conclusion of the comparative assessment is: not suitable for substitution.

ADM.4651.H.1.A contain dicamba which is the representative of O – group according to the Herbicide Resistance Action Committee (HRAC), mesotrione is representative of F2 – group according to Herbicide Resistance Action Committee (HRAC) and nicosulfuron is representative of B– group according to Herbicide Resistance Action Committee (HRAC).

ADM.4651.H.1.A is a unique sale formulation of three well-known actives, from its herbicidal activity, belong to 3 different groups according to the Herbicide Resistance Action Committee (HRAC).

ADM.4651.H.1.A is ready-mix formulation combines three complementary active substances, two of them at reduced rates in comparison to other commercial products.

Nicosulfuron contain in the formulation ADM.4651.H.1.A., applied in post-emergence, controls a wide spectrum of annual grasses, some perennial grasses and susceptible weeds.

Nicosulfuron is readily absorbed by both roots and foliage, and translocated in both the xylem and phloem to the site of action, at meristematic tissues.

The selectivity of nicosulfuron in maize is physiological: it is rapidly metabolized to inactive compounds due to the activity of the cytochrome P450; this process of detoxification is notably much more rapid in the maize than in the susceptible weeds

ADM.4651.H.1.A is recommended to be used as tank – mix with adjuvants: Adigor 440 EC and product: Efica 960 E (S-metolachlor).

ADM.4651.H.1.A is formulated as WG – water dispersible granules, which is a solid, non-dusty granular formulation dispersing quickly when added to water in the spray tank to give a fine particle suspension. WG formulation of ADM.4651.H.1.A is safer than most of nicosulfuron-based products which are mainly liquids, due to its physical properties reduces inhalation hazards.

Regarding environmental precautions, packaging does not pose the same environmental problem as liquid formulations whose containers have to be specially rinsed and recycled

Additional reasons for defending the product under the Regulation No 1107/2009:

- ADM.4651.H.1.A has a very broad-spectrum activity for the control of grasses and broadleaf weeds.
- broad-spectrum of effectiveness,
- greater crop profitability
- only one application in a growth season,
- safe windows of application and safe PHI,
- post emergence application,
- economical – good relation price vs efficacy
- environmental - package disposal easier to deal with than for liquid formulations

- health hazards - reduces inhalation hazards

### Proposed use of the product

ADM.4651.H.1.A is submitted for registration , to use in maize (ZEAMX) against annual/perennial grass and broadleaved weeds only.

<b>Crop</b>	<b>Corn maize</b>
<b>Pest</b>	<i>Weeds</i>
<b>Application Timing</b>	12-14 BBCH
<b>Max. Application rate Proposed use ; only in tank mix</b>	ADM.4651.H.1.A : 0,4 kg/ha + Efica 960 EC (S-metolachlor): 0,8 L/ha ADM.4651.H.1.A : 0,4 kg/ha + adjuvants (Adigor 440 EC and Olejan 85 EC)
<b>No. of applications</b>	1



**5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

None.

## **Appendix 1    Copy of the product authorization**

## Appendix 2 Copy of the product label

### Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem.

Zakres zmian jest następujący:

### Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodnie z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2-lata w opakowaniach wykonanych z HDPE.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu nazwy grupy chemicznej, do której przyporządkowano substancje czynną. Skorygowano zawartość substancji czynnej Dikamba.
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego potwierdzono zgodność łącznego stosowania środka ochrony roślin z adjuwantem ADIGOR (A12127R), Olejan 85 EC, Styk (Insert) oraz ze środkiem Efica 960 EC.

### Sekcja skuteczność:

1. Poprawiono nieznacznie, pod względem poprawności językowej, informacje o działaniu substancji aktywnych herbicydu.
2. Z uwagi na zalecenie stosowania środka wyłącznie z adiuwantami lub z herbicydem Efica 960 EC, zaproponowano zmianę położenia tabeli wrażliwości chwastów w tekście, tak aby informacja o stosowaniu w w/w mieszaninach **poprzedzała tabelę**.
3. Z uwagi na duże zróżnicowanie wrażliwości chwastów pomiędzy zastosowaniem środka z dwoma różnymi adiuwantami oraz w mieszaninie z Efica 960 EC, tabela wrażliwości chwastów została przedstawiona dla każdego zastosowania oddzielnie. Z tabeli usunięto następujące gatunki chwastów: zaśláz pospolity, komosa wielkolistna, bieluń dziedzierzawa, przytulia czepna, bodziszek drobny, rumianek pospolity oraz psianka czarna, ponieważ wystąpiły w zbyt niskiej liczbie badań (niezbędne jest przedłożenie 4 badań dla gatunków ważnych w uprawie kukurydzy, lub 2 dla gatunków mniej ważnych). Status chwastów w uprawie kukurydzy jest zgodny z: „METODYKA INTEGROWANEJ OCHRONY KUKURYDZY DLA DORADCÓW”, Poznań 2019.
4. Według kryterium zwiększania skuteczności w porównaniu do aplikacji NIKITA solo, adiuwant Adigor 440 EC został oceniony jako najlepszy spośród trzech badanych adiuwantów, a adiuwant Styk (Insert) - jako najgorszy. Adigor 440 EC nie jest jednak dostępny na rynku w Polsce, i zgodnie z deklaracją wnioskodawcy z tego powodu nie może być wpisany do etykiety. Nie mniej jednak, informację o wrażliwości chwastów przy aplikacji z tym adiuwantem zamieszczono poniżej. Poniższa klasyfikacja, podobnie jak te umieszczone w etykiecie, odzwierciedla wyniki badań przedłożonych wraz z niniejszym wnioskiem, **zgodnie z klasyfikacją przyjętą w Polsce**. Zdaniem eksperta może ona być wykorzystana w wypadku gdyby wnioskodawca złożył w przyszłości wniosek o rozszerzenie stosowania, na skutek udostępnienia Adigor 440 EC na polskim rynku.

#### **Aplikacja z adiuwantem Adigor 440 EC w dawce 1,0 l/ha**

Chwasty wrażliwe	szarłat szorstki, rzepak ozimy (samosiwy), słonecznik zwyczajny, tasznik pospolity, komosa biała, jasnota purpurowa, dymnica pospolita, gwiazdnica pospolita, tobołki polne,
Chwasty średnio wrażliwe	wyczyniec polny, chwastnica jednostronna, włośnica sina, rdest plamisty, przetacznik perski, fiołek polny
Chwasty średnio odporne	rdestówka powojowata

#### **Aplikacja z adiuwantem Adigor 440 EC w dawce 1,5 l/ha**

Chwasty wrażliwe	szarłat szorstki, rzepak ozimy (samosiwy), słonecznik zwyczajny, tasznik pospolity, komosa biała, jasnota purpurowa, dymnica pospolita, gwiazdnica pospolita, tobołki polne, rdest plamisty, przetacznik perski, fiołek polny
Chwasty średnio wrażliwe	wyczyniec polny, chwastnica jednostronna, włośnica sina, rdestówka powojowata,

5. Zmodyfikowano i uzupełniono rozdział dotyczący strategii antyodpornościowej, stosownie do wniosków z oceny skuteczności i ryzyka odporności zawartych w części B3 Raportu.

**Sekcja metody analityczne:**

1. Brak uwag.

**Sekcja toksykologia i istotność toksykologiczna metabolitów:**

1. W części dotyczącej klasyfikacji zagrożeń zmodyfikowano zwrot P280 oraz P260 zgodnie z wymaganiami CLP; dodano zwrot P308+P313 wynikający z klasyfikacji mesotrionu ze zwrotem H361d (1272/2008; ATP15).
2. W części dotyczącej klasyfikacji zagrożeń zmodyfikowano zwrot H373 zgodnie z wymaganiami CLP (wynikający z klasyfikacji mesotrionu; 1272/2008; ATP15).
3. W części dotyczącej zasad bezpieczeństwa dla osób stosujących środek, zapis zmodyfikowano tak aby stanowił wypadkową szacowania narażenia oraz klasyfikacji zagrożeń zgodnie z Ustaleniami dotyczącymi sporządzania oceny lub uwag w zakresie środków ochrony roślin przez podmioty upoważnione – Toksykologia (Min. Rol. 2018).

**Sekcja pozostałości:**

1. Na podstawie informacji przedstawionych w EFSA Journal 2012;10(12):3048 dla substancji nikosulfuron w zakresie upraw następczych należałoby ograniczyć sianie i sadzenie roślin następczych za wyjątkiem kukurydzy przy wcześniejszej likwidacji plantacji ze względu na możliwość wystąpienia efektu fitotoksycznego. Zapis dotyczący roślin następczych w etykiecie został odpowiednio skorygowany.

**Sekcja los i zachowanie w środowisku:**

1. Dodano informację o możliwości stosowania środka oraz innych środków zawierających nikosulfuron na tym samym polu jeden raz co trzy lata.

**Sekcja ekotoksykologia:**

1. Dodano zwrot P501.
2. Poprawiono zwroty dotyczące narzędzi zarządzania ryzykiem.
3. Wskazano jakie są wymagane narzędzie zarządzania ryzykiem, jeśli środek jest stosowany w mieszaninie ze środkiem Efica 960 EC.

Załącznik do zezwolenia MRiRW nr R - ..... z dnia ..... r.

**Posiadacz zezwolenia:**

ADAMA Polska Sp. z o.o. ul. Sienna 39, 00 - 121 Warszawa, tel.: +48 22 395 66 60, infolinia: +48 22 395 66 66, e-mail: biuro@adama.com, www.adama.com

**Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:**

.....


**NIKITA**

**Środek przeznaczony do stosowania przez użytkowników profesjonalnych**

**Zawartość substancji czynnej:**

Dikamba (związek z grupy pochodnych kwasu benzoowego) – 312,5 g/kg (31,3%)  
Mezotrion (związek z grupy pochodnych trójketonów) – 150 g/kg (15,0%)  
Nikosulfuron (związek z grupy pochodnych sulfonilomocznika) – 100 g/kg (10,0%)

**Zezwolenie MRiRW nr R-..... z dnia .....**

	
<b>Uwaga</b>	
H319	Działa drażniąco na oczy
H361d	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki
H373	Może powodować uszkodzenie narządów poprzez długotrwałe lub narażenie powtarzane (oczy, system nerwowy)
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia
EUH208	Zawiera disodium maleate. Może powodować wystąpienie reakcji alergicznej
P260	Nie wdychać pyłu/dymu/gazu/mgły/paru rozpylonej cieczy
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ <del>ochronę twarzy</del> .
P305 + P351 + P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P308+P313	W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach.

## OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany dolistnie, w formie granul do sporządzania zawiesiny wodnej (WG).

Zgodnie z klasyfikacją HRAC substancja czynna dikamba zaliczana jest do grupy O; substancja mezotrion do grupy F2, a substancja nikosulfuron do grupy B.

## DZIAŁANIE NA CHWASTY

Środek zawiera trzy substancje czynne należące do trzech różnych grup chemicznych o odmiennym sposobie działania na chwasty.

Dikamba zaliczana jest do inhibitorów wzrostu i rozwoju. W roślinie powoduje zakłócenia podziału komórek, co w efekcie prowadzi do deformacji liści i łodyg, zahamowania wzrostu, karłowacenia, a następnie chlorozy, nekrozy i zasychania roślin.

Mezotrion pobierany jest głównie przez liście oraz dodatkowo przez korzenie chwastów i szybko przemieszczany w roślinie, hamując jej wzrost i rozwój. Powoduje zahamowanie biosyntezy karotenoidów w roślinach chwastów, w następstwie czego następuje zniszczenie chlorofilu, objawiające się bieleciem liści.

Nikosulfuron pobierany jest głównie poprzez liście i szybko przemieszczany w roślinie. Wzrost i rozwój chwastów zostaje zahamowany wkrótce po zastosowaniu środka, po czym następuje stopniowe przebarwianie się roślin.

Pierwsze objawy działania środka można zaobserwować po 4-6 dni po zabiegu, natomiast pełne zamieranie chwastów następuje do 4 tygodni od zastosowania. Szybkość efektu chwastobójczego zależy od fazy rozwojowej zwalczanych chwastów i panujących warunków atmosferycznych (temperatura, wilgotność powietrza) oraz tempa wzrostu chwastów.

<b>Chwasty wrażliwe</b>	komosa biała, rzepak ozimy (samosiewy), fiołek polny, szarłat szorstki, rdestówka powojowata, jasnota purpurowa, rdest plamisty, przetacznik perski, tobołki polne, psianka czarna, gwiazdnica pospolita, tasznik pospolity, dymnica pospolita
<b>Chwasty średnio wrażliwe</b>	włośnica sina, włośnica zielona, wyczyniec polny, bodziszek drobny, chwastnica jednostronna

## STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

### Kukurydza

Maksymalna/zalecana dawka dla jednorazowego stosowania: 0,4 kg/ha

Termin stosowania : środek stosować po wschodach rośliny uprawnej, w fazie 2-4 liści (BBCH 12-14)

Środek NIKITA należy stosować wyłącznie w mieszaninie z adjuwantem

- Olejan 85 EC w dawce 1,5 L/ha,  
lub
- Styk (Insert) w dawce 0,2 L/ha  
lub
- łącznie ze środkiem Efica 960 EC w dawce 0,8 L/ha (obowiązują inne środki ostrożności związane z ochroną środowiska, wskazane poniżej)

Zalecana ilość wody: 200–300 L/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zalecane opryskiwanie: średniokropliste

Środek może być stosowany nie częściej niż co trzy lata na tym samym polu.

### Aplikacja z adjuwantem Olejan 85 EC w dawce 1,5 l/ha

<b>Chwasty wrażliwe</b>	rzepak ozimy (samosiewy), tasznik pospolity, komosa biała, jasnota purpurowa, dymnica pospolita, gwiazdnica pospolita, tobołki polne
<b>Chwasty średnio wrażliwe</b>	chwastnica jednostronna, rdest plamisty, fiołek polny, przetacznik perski
<b>Chwasty średnio odporne</b>	wyczyniec polny, włośnica sina
<b>Chwasty odporne</b>	rdestówka powojowata

### Aplikacja z adjuwantem Styk (Insert) w dawce 0,2 l/ha

<b>Chwasty wrażliwe</b>	rzepak ozimy (samosiewy), tasznik pospolity, komosa biała, jasnota purpurowa, gwiazdnica pospolita, tobołki polne
<b>Chwasty średnio wrażliwe</b>	dymnica pospolita, rdest plamisty, włośnica zielona
<b>Chwasty średnio odporne</b>	wyczyniec polny, włośnica sina, chwastnica jednostronna, przetacznik perski, fiołek polny

Chwasty odporne	rdestówka powojowata
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#### Aplikacja w mieszaniu zbiornikowej z herbicydem Efica 960 EC w dawce 0,8 l/ha

Chwasty wrażliwe	szarłat szorstki, rzepak ozimy (samosiewy), słonecznik zwyczajny, tasznik pospolity, komosa biała, jasnota purpurowa, dymnica pospolita, rdest plamisty, gwiazdnica pospolita, tobołki polne, fiołek polny, przetacznik perski, chwastnica jednostronna
Chwasty średnio wrażliwe	wyczyniec polny, włośnica sina
Chwasty średnio odporne	rdestówka powojowata

### NASTĘPSTWO ROŚLIN

W przypadku konieczności wcześniejszej likwidacji plantacji, jako roślinę następczą można uprawiać kukurydzę ~~lub zboża ozime~~ (przed siewem należy przeprowadzić orkę). ~~W roku, w którym wykonano zabieg nie można uprawiać pomidorów i tytoniu.~~

W przypadku uprawy roślin wrażliwych tj. buraka, strączkowych, rzepaku ozimego, słonecznika i warzyw oraz wcześniej sianych zbóż możliwe jest wystąpienie uszkodzeń.

### ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):**

Nie dotyczy

#### 1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

- postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin - stosować środek Nikita w zalecanej dawce, w zalecanej liczbie zabiegów, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów, oraz w mieszaninach zbiornikowych z zalecanymi w etykiecie adiuwantami lub herbicydem Efica 960 EC,
- dostosować dobór środka chwastobójczego oraz ~~decyzję~~ decyzję o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszaniu herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw, **zwalczania mechanicznego** (zalecane jest unikanie uproszczeń w uprawie gleby), itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

Appendix 3

#### 2. Środka nie stosować:

- w czasie opadu deszczu lub przed spodziewanym deszczem,
- na rośliny osłabione lub uszkodzone przez szkodniki, przymrozki, zalanie lub suszę,
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.

#### Appendix 4

### 3. Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

## SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. Podczas jazdy i podczas oprysku ciecz użytkową utrzymywać w ruchu za pomocą włączonego mieszadła.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

## POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- jeśli to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

## ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne oraz odzież ochronną, okulary i ochronę twarzy zabezpieczające przed oddziaływaniem środków ochrony roślin oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):**

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin



## **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO:**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 5 m.

W przypadku stosowania środka Nikita w mieszaninie ze środkiem Efica 960 EC, w celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 10 m (w tym 5 m zadarnionej strefy ochronnej) od zbiorników i cieków wodnych.

W celu ochrony stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

W celu ochrony roślin lądowych niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo lub redukcja znosu z chmurą oprysku o 90% za pomocą odpowiednich technik antyznoszeniowych.

W celu ochrony wód podziemnych nie stosować tego lub żadnego innego produktu zawierającego nikosulfuron nie częściej niż co trzy lata.

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości:~~

- ~~— 10 m od zbiorników i cieków wodnych lub~~
- ~~— 5 m od zbiorników i cieków wodnych z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%~~

~~W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości:~~

- ~~— 5 m od terenów nieużytkowanych rolniczo lub~~
- ~~— 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.~~

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

## **Appendix 5 Letter of Access**

Any necessary Letters of Access to support this authorisation are provided with the covering letter.

## Appendix 4 Lists of data considered for national authorization

### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Part C / 02	Syngenta	2017	A18032E Safety Data Sheet Document Syngenta Not GLP not published Syngenta File No A18032E_10382 <b><u>This is CONFIDENTIAL INFORMATION *</u></b>	N	N	Not relevant	SYN
KCP Section 2 / 01	Adolph S.	2012	A18032E - Chemical characterization of batch SMU2BP001 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 124460 GLP not published Syngenta File No A18032E_10026	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 2.1 / 01 & KCP 2.8.1 / 01 & KCP 2.8.2 / 01 & KCP 2.8.3 / 01 & KCP 2.8.5.1 / 02 & KCP 2.8.5.3 / 01 KCP 2.9.1/01	Fumeaux J.	2013	A18032E - Technical properties of batch SMU2BP001 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 125711 Not GLP not published Syngenta File No A18032E_10034	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 2.2 / 01 & KCP 2.3 / 01	Blessington K.	2012	A18032E - Safety Study Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT12/564 GLP not published Syngenta File No A18032E_10029	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 2.4 / 01 & KCP 2.6 / 01 & KCP 2.8.5.1 / 01 & KCP 2.8.5.2 / 01 KCP 2.9.1/02	Fumeaux J.	2013a	A18032E - Physical properties of batch SMU2BP001 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 125030 GLP not published Syngenta File No A18032E_10028	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 2.7 / 01	Kundel P.	2013	A18032E - Storage stability and shelf life statement (2 weeks 54 - C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10531055 Not GLP not published Syngenta File No A18032E_10033	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 2.7 / 02	Kundel P.	2015	A18032E - Storage Stability and Shelf Life Statement (2 Years 20 -C) in Packaging Made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 300045056 Not GLP not published Syngenta File No A18032E_10317	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 2.9.1/03	Hartmut T.	2021	Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of Nikita Adama BioChem project No.: 21 35 CRX 0016 Extranet code 218167-21 ADAMA trial code UK21HONOPLA044A GLP not published Report 21 35 CRX 0016	N	Y	Not relevant	ADAMA
KCP 2.11 / 01	Kundel P.	2013a	A18032E - The Effectiveness of the Spray Tank Cleaning Procedure Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 125696 Not GLP not published Syngenta File No A18032E_10031	N	N	Not relevant	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 / 01	Adolph S.	2012	Analytical Method SF-568/1 - mesotrione/dicamba/nicosulfuron WG (15731.25/10) in formulation, by HPLC Syngenta Syngenta Crop Protection, MÃ¼nchwilen, Switzerland, 10493506 Not GLP not published Syngenta File No A18032E_10062	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 5.1.1 / 02	De Benedictis S.	2013	A18032E - Validation of Analytical Method SF-568/1 Syngenta Syngenta Crop Protection, MÃ¼nchwilen, Switzerland, 10528232 GLP not published Syngenta File No A18032E_10063	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.1 / 03	Hager M.	2011	R287431 - Analytical Method SD-977/2 Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 10427012 Not GLP not published Syngenta File No R287431_10003	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN (ADAMA has LoA)
KCP 5.1.1 / 04	Hager M.	2011a	Validation of method SD-977/2 - R287431 in A14203B, A13789C, A14351BX, A12909Q, A15189G, A12738A, A15901A and A18219B Syngenta Syngenta Crop Protection, Inc., Greensboro, USA, 10427878 GLP not published Syngenta File No R287431_10001	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.1 / 05	Hager M.	2013	Mesotrione - Relevant Impurity in A18032E Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 10538107 Not GLP not published Syngenta File No A18032E_10061	N	N	Not relevant	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 / 06	Hager M.	2017	A18032E- Statement on Validation of Analytical Method SD-977 /2 for the Determination of R287431 (Xan-1) in Formulation A18032E Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300074792 Not GLP not published Syngenta File No A18032E_10366	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 5.1.1 / 07	Hager M., <i>et al</i>	2017	A18032E - Response to the Greek Regulatory Authority Concerning Relevant Impurity R287431, Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA Not GLP not published Syngenta File N.o. A18032E_10452	N	SYN (ADAMA has LOA)	KCP 5.1.1 / 07	Hager M., <i>et al</i>
KCP 5.1.1 / 08	Huang S.	2016	ZA1296 - SD-1990/1 - Determination of R287432 in Mesotrione Related Formulations by Liquid Chromatography/Mass Spectrometry (LC/MS) Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300068727 Not GLP not published Syngenta File No A13789C_50005	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 5.1.1 / 09	Huang S.	2016a	A13789C - Validation of Analytical Method SD-1990/1 Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, USGR160250 GLP not published Syngenta File No A13789C_50004	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1 / 10	Huang S.	2016b	A18032E - Statement on Validation of Analytical Method SD-1990/1 for Determination of R287432 in Formulation A18032E (SAN837/ZA1296/nicosulfuron WG (31.25/15/10)) Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300072567 Not GLP not published Syngenta File No A18032E_10347	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 5.1.1 / 11	Meyerhoffer W., Zhang Y., Patterson J.	2016	ZA1296 - SD-1973/1 - Determination of Impurity DCE (1,2-dichloroethane) in Mesotrione Related Formulations by Headspace Gas Chromatography Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300066025 Not GLP not published Syngenta File No A13789C_50002	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 5.1.1 / 12	Meyerhoffer W.	2016	A13789C - Validation of Analytical Method SD-1973/1 Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, USGR160249 GLP not published Syngenta File No A13789C_50001	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.1 / 13	Meyerhoffer W.	2016a	A18032E - Statement on Validation of Analytical Method SD-1973/1 for Determination of 1,2-Dichloroethane (DCE) in Formulation A18032E (SAN837/ZA1296/Nicosulfuron WG (31.25/15/10)) Syngenta Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300072403 Not GLP not published Syngenta File No A18032E_10346	N	N	Not relevant	SYN (ADAMA has LoA)



<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 5.1.2.1 / 01 & KCP 5.2.4 / 01	Braid S., Garcia-Alix M.	2013	Dicamba - Analytical Method GRM022.06A for the Determination of Dicamba and its Metabolite NOA414746 in Soil Syngenta CEMAS, North Ascot, United Kingdom, GRM022.06A Not GLP not published Syngenta File No SAN837_11434	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.1 / 02 & KCP 5.2.4 / 02	Garcia-Alix M.	2013	Dicamba - Analytical Method GRM022.06A for the Determination of Dicamba and its Metabolite NOA414746 in Soil Syngenta CEMAS, North Ascot, United Kingdom, CEMR-5791-REG GLP not published Syngenta File No SAN837_11433	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.1 / 03 & KCP 5.2.5 / 01	Hargreaves S.	2007	Dicamba - Residue Method for the Determination of Residues in Water Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.02A Not GLP not published Syngenta File No SAN837/6654	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.1 / 04 & KCP 5.2.5 / 02	Emburey S.	2007	Dicamba - Validation of an Analytical Method for the Determination of Residues of Dicamba in Water Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, T002102- 06-REG GLP not published Syngenta File No SAN837/6653	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.1 / 05 & KCP 5.2.5 / 03	Kotthoff M.	2016	Dicamba - Independent Laboratory Validation of Analytical Method GRM022.02A for the Determination of Residues of Dicamba (SAN837) in Water Syngenta Fraunhofer Institute, Schmallenberg, Germany, SYN-037/6-22 GLP not published Syngenta File No SAN837_11602	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.1 / 06 & KCP 5.2.6 / 01	Hargreaves S. L.	2007	Dicamba - Residue Method for the Determination of Residues in Air Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.01A GLP not published Syngenta File No SAN837/6677	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.1 / 07 & KCP 5.2.6 / 02	Emburey S.	2007a	Dicamba - Validation of an Analytical Method for the Determination of Residues of Dicamba Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, T010135-04-REG GLP not published Syngenta File No SAN837/6678	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.1/08 KCP 5.2.5 / 04	Allen, L. & Brooks S.	2017	Dicamba - Residue Method GRM022.09A for the Determination of the Metabolite NOA414746 (DCSA) in Water. Syngenta Analytical Method GRM022.09A. CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD UK. GLP Not published Syngenta File No. NOA414746_10010	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 5.1.2.1/09 & KCP 5.2.5 / 05	Allen, L.	2017	Dicamba - Validation of Draft Residue Method GRM022.09A for the Determination of Dicamba Metabolite NOA414746 (DCSA) in Water. CEMAS Report Number CEMR-7878. CEM Analytical Services Ltd (CEMAS), Imperial House, Oaklands Business Centre, Oaklands Park, Wokingham, Berkshire, RG41 2FD UK. GLP Not published Syngenta File No. NOA414746_10011	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.1 / 08 & KCP 5.2.4 / 03	Williams R.	2004	Analytical Method 1200-03 for the Determination of Mesotrione and its Metabolites AMBA and MNBA, in Soil, Using Liquid Chromatography - Electrospray Ionization Tandem Mass Spectrometry (Including Validation Data) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001200-03 GLP not published Syngenta File No ZA1296/1567	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.1 (report available from data owner)	Schneider M. Holzer S.	2016	Groundwater Monitoring for Nicosulfuron and Six Metabolites in Four Representative Regions in Germany SGS INSTITUT FRESENIUS GmbH Report: DuPont-28685 GLP Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	DuPont (ADAMA is co-owner)
KCP 5.1.2.1 (report available from data owner)	Ferrari F	2016	Groundwater Monitoring for nicosulfuron and 6 Metabolites in Maize Growing Regions of Italy LABCAM s.r.l. Report: DuPont-40798 (Interim Report) GLP Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	E.I. du Pont de Nemours and Company, Cheminova, (ADAMA has LoA from Dupont (1 LoA))

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.4 / 01	Bachelor B.	2014	Analytical Method Transfer and Partial Validation for the Determination of CA3511 in Dosing Formulations Syngenta Xenometrics, LLC, Stilwell, KS, USA, 11070 GLP not published Syngenta File No CA3511_50013	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.4 / 02	Faulkner L., Heap C.	2013	CA3511 - Feasibility of the Assay for the Determination of CA3511 in 1 % w/v Aqueous Carboxymethylcellulose Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0147 Not GLP not published Syngenta File No CA3511_10006	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 5.1.2.4 / 03	Faulkner L., Heap C.	2013a	CA3511 - Validation of the Assay for the Determination of CA3511 in 1 % w/v Aqueous Carboxymethylcellulose Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0148 GLP not published Syngenta File No CA3511_10007	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.4 / 04	Faulkner L., Heap C.	2013b	CA3511 - Validation of the Formulation Procedure for CA3511 in 1 % w/v Aqueous Carboxymethylcellulose and Assessment of Formulation Stability Syngenta Sequani Limited, Ledbury, United Kingdom, BFI0149 GLP not published Syngenta File No CA3511_10009	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.4 / 05	xxxxxxx	2016	AMBA - Single Dose Oral (Gavage) Proof of Exposure Study in the Rat Syngenta xxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No R044276_10012	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.5 / 01	Richards S., Mackenzie R.	2006	Residue analytical method for the determination of residues of dicamba (SAN837) and 5-hydroxy dicamba (NOA405873) in barley (grain, straw, whole plant) and barley processed fractions (malt, wort, spent hops and spent yeast) Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, REM 193.05 Not GLP not published Syngenta File No SAN837/6535	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.5 / 02	Richards SJ., Mackenzie R., Crook SJ.	2008	Residue analytical method for the determination of Dicamba (SAN837) and 5-Hydroxy Dicamba (NOA405873) in barley (grain, straw, whole plant) and barley processed fractions (malt, wort, spent hops and spent yeast) Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, REM193.05B Not GLP not published Syngenta File No SAN837/6686	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.5 / 03	Richards S., Mackenzie R.	2004	Residue Study with Dicamba (SAN837) in or on Winter Barley in France (South) Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7009 GLP not published Syngenta File No SAN837/6191	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.5 / 04	Richards S.	2004	Residue Study with Triasulfuron (CGA131036) and Dicamba (SAN837) in or on Winter Barley in The United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7013 GLP not published Syngenta File No CGA131036/1358	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 5.1.2.5 / 05	Richards S., Mackenzie R.	2004a	Residue Study with Dicamba (SAN837) in or on Winter Barley and Brewing Fractions in The United Kingdom Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, 03-7017 GLP not published Syngenta File No SAN837/6359	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.5 / 06	Braid S., Kennedy S.	2017	Dicamba - Analytical Method GRM022.07A for the Determination of Dicamba and its Metabolite NOA405873 in Crops Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM022.07A Not GLP not published Syngenta File No SAN837_11703	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.5 / 07	Kennedy S.	2016	Dicamba - Validation of Analytical Method GRM022.07A for the Determination of Dicamba and its metabolite NOA405873 in Plant Matrices by LC-MS/MS Syngenta CEM Analytical Services Ltd (CEMAS) - Berkshire, UK, CEMR-7414 GLP not published Syngenta File No SAN837_11691	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.1.2.5 / 08	Crook S., Andrews G.	2016	Nicosulfuron - Analytical Method GRM074.01A for the Determination of Nicosulfuron in Plant Matrices Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM074.01A Not GLP not published Syngenta File No ASF628_11278	N	N	Not relevant	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.5 / 09	Andrews G.	2016	Nicosulfuron and Dicamba - Residue Validation and Study on Maize in Northern France, Germany and Poland in 2015 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0258007-REG GLP not published Syngenta File No A19658H_10060	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 01	Weber K.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Assessment of Toxic Effects on Daphnia magna using the 48 h Acute Immobilisation Test Syngenta Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S12-02294 GLP not published Syngenta File No A18032E_10008	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 02	Falk S.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Testing of Effects on the Single Cell Green Alga Pseudokirchneriella subcapitata Syngenta Eurofins Agrosience Services GmbH, Niefern-Äschel., Germany, S12-02296 GLP not published Syngenta File No A18032E_10002	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 03	xxxxxxx	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Acute Toxicity Testing in Rainbow Trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10001	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.6 / 04	xxxxxxx	2012a	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor(A12127R) - Assessment of Toxic Effects on the duckweed Lemna gibba in a Semi-Static Test Syngenta xx GLP not published Syngenta File No A18032E_10009	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 05	Bramby- Gunary J.	2013	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, David Norris Analytical Labs Ltd., Dartford, UK, ACE-12-149 GLP not published Syngenta File No A18032E_10025	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 06	Bramby- Gunary J.	2013a	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, David Norris Analytical Labs Ltd., Dartford, UK, ACE-12-148 GLP not published Syngenta File No A18032E_10024	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 07	Hengsberger A., Wydra V.	2015	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a reciprocal growth inhibition test Syngenta IBACON GmbH, Rossdorf, Germany, 105731240 GLP not published Syngenta File No ZA1296_10436	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2.6 / 08	Kosak L., Wydra V.	2016	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a semi-static growth inhibition test with a subsequent recovery period Syngenta IBACON GmbH, Rossdorf, Germany, 105732240 GLP not published Syngenta File No ZA1296_10438	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 09	Gonsior G.	2017	Mesotrione - Growth inhibition of Myriophyllum spicatum in a water/sediment system Syngenta Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S16-06273 GLP not published Syngenta File No ZA1296_10504	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 / 10	North L.	2016	Mesotrione - Foliage Decline with A12739A on Maize in Northern France and the United Kingdom in 2015 Syngenta Eurofins Agrosience Services Ltd, Wilson, UK, S15-02057 GLP not published Syngenta File No A12739A_11065	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 5.1.2.6 (report available from data owner)	Obert-Rausser P.	2016	MU-466: Toxicity to the Duckweed Lemna gibba under Laboratory Conditions Eurofins Agrosience Services Report: S15-05478 GLP: yes Published: No	N	Y	Data protection is claimed for this study starting with this submission in Poland. Study is owned by multiple parties and data protection could have started with earlier submission not know to ADAMA.	Nicosulfuron Task Force (ADAMA is member)
KCP 5.1.2.6 (report available from data owner)	Dengler D.	2009	Assessment of Toxic Effects of HMUD on the Duckweed Lemna gibba in a Semi Static Test Eurofins-GAB GmbH Report: GAB S08-00827 GLP: yes Published: No	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	Nufarm S.A.S (ADAMA has LoA from Nufarm (2 LoA))

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 5.2.1 / 01	Swales S.	2016	SAN837 - Uptake and Metabolism of [14C]-SAN837 in Confined Rotational Crops Syngenta, BASF Corporation, Research Triangle Park, NC, USA Smithers Viscient (ESG) Ltd, Harrogate, UK, AgroChemex Ltd, Manningtree, United Kingdom, 3200368 GLP not published Syngenta File No SAN837_11645	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.2.1 (report available from data owner)	Steinhilper D	2008	Validation of a Multiresidue method for the determination of Nicosulfuron in maize, Cheminova A/S. Report No.: 107 NIS GLP Unpublished	N	Y	Study is owned by multiple parties and data protection could have started with earlier submission not know to ADAMA	Cheminova
KCP 5.2.1 (report available from data owner)	Schwarz T.	2008	Independent Laboratory Validation (ILV) of a residue analytical method for the determination of residue of nicosulfuron in maize plant, straw and grain, using LC/MS/MS, Cheminova A/S. Report No.: 119 NIS GLP Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	Cheminova
KCP 5.2.1 (report available from data owner)	Cabusas, M.E. Pentz, A.	2012	Analytical Method for the Determination of Nicosulfuron and Rimsulfuron in Corn, Cherry, Lemon and Soybean Matrices using HPLC/ESI-MS/MS, Non GLP Unpublished	N	N	Not relevant	E.I. du Pont de Nemours and Company (Study not protected, non-GLP)
KCP 5.2.1 (report available from data owner))	McInerney K.	2016	Validation report DuPont-11776 RV2: Extension of the Linearity Range for Nicosulfuron in Oily and Acidic Crop Report No.: 100077587-03 Non GLP Unpublished	N	N	Not relevant	Nicosulfuron Task Force (ADAMA is member)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.1 (report available from data owner)	Ducat, N., Pigeon O.	2004	Independent Laboratory validation of DuPont-11776, “Analytical Enforcement Method for the Determination of Nicosulfuron in Corn Matrices using HPLC/ESI-MS/MS Report No.: DuPont-12347 GLP Unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (Study should not attract data protection)
KCP 5.2.2 / 01	Richardson M., Braid S.	2012	Dicamba - Analytical Method for the Determination of Residues of Dicamba (SAN837) in Animal Matrices Final Determination by GC-MSD Syngenta Syngenta - Jealott’s Hill, Bracknell, United Kingdom, GRM022.05A Not GLP not published Syngenta File No SAN837_11414	N	N	Not relevant	SYN/ BASF (ADAMA has LoA)
KCP 5.2.2 / 02	Heillaut C	2008	Dicamba - Validation of Residue Method GRM022.03A for Dicamba (SAN837) and NOA414746 Metabolite in Animal Matrices (milk, eggs, muscle, fat, liver and kidney) SynTech Research France SAS, La Chapelle de Guinchay, France ADME - Bioanalyses, Vergeze, France, T010322-04-REG GLP not published Syngenta File No SAN837_10997	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF (ADAMA has LoA)
KCP 5.2.2 / 03	Class T, Kuhn T	2010	Dicamba - Independent Laboratory Validation of Analytical Method GRM022.03A for the Determination of Residues of Dicamba and its Metabolite NOA414746 in Animal Materials by GC/MS (NCI) Syngenta - Jealott’s Hill, Bracknell, United Kingdom PTRL Europe, Ulm, Germany, B 1836 G GLP not published Syngenta File No SAN837_11330	N	Y	ADAMA reached agreement to access the study from Syngenta. The data owner can provide further data on data protection if required.	SYN/ BASF(ADAMA has LoA)
KCP 5.2.2 (report available from data owner)	Wolf, S.	2009	Development and Validation of a Residue Analytical Method for Nicosulfuron in Animal Tissues (Milk, Egg, Muscle and Liver) Report No.: 90011604 Non GLP Unpublished	N	N	Not relevant	Agan Chemical Manufacturerers Ltd

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.3 (report available from data owner)	xxxxxxxxxxxx xxxx.	2016a	Method Validation for the Determination of Nicosulfuron in Mouse Plasma Report No.: 100077587-04 GLP Unpublished	Y	Y	Data protection is claimed for this study starting with this application in Poland. Study is owned by multiple parties and data protection could have started with earlier submission not know to ADAMA.	Nicosulfuron Task Force (ADAMA is member)
KCP 7.1.1 / 01	xxxxxxxxxxxx xxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta xxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10018	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 7.1.2 / 01	xxxxxxxxxxxx xxxxx	2012	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Dermal Toxicity Study in Rats Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10006	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 7.1.3 / 01	xxxxxxxxxxxx xx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Inhalation Toxicity Study (Nose-Only) in the Rat Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10019	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 7.1.4 / 01	xxxxxxxxxxxx xxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Primary Skin Irritation Study in Rabbits Syngenta xx GLP not published Syngenta File No A18032E_10016	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5 / 01	xxxxxxxxxxxx xxxx	2012	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Acute Eye Irritation Study in Rabbits Syngenta xxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10013	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 7.1.6 / 01	xxxxxxxxxxxx xxxxxxxxxx	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) - Local Lymph Node Assay in the Mouse Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10023	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 7.3 / 01	Blackstock C., Vinall J.	2013	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) - The In Vitro Percutaneous Absorption of Radiolabelled Dicamba in Concentrate Formulation and Two In-Use Dilutions Through Human Split-Thickness Skin Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 34224 GLP not published Syngenta File No A18032E_10281	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 7.3 / 02	Blackstock C., Haldane C.	2015	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) - The In Vitro Percutaneous Absorption of Radiolabelled Mesotrione in Concentrate Formulation and Two In-Use Dilutions Through Human Split-Thickness Skin Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 36743 GLP not published Syngenta File No A18032E_10320	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.3 / 03	Kerin T., Wilinska I.	2017	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) - The In Vitro Percutaneous Absorption of Radiolabelled Mesotrione in Two In Use Dilutions Through Human Skin Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 38101 GLP not published Syngenta File No A18032E_10373	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA2 5.8.1 / 01	xxxxxxxxxxxx xx	2016	CA3511 - Oral (Gavage) Prenatal Developmental Toxicity Study in the Rat Syngenta xxxxxxxxxxxx not published Syngenta File No CA3511_10024	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA2 5.8.1 / 02	xxxxxxxxxxxx xxx	2016	CA3511 - Oral (Gavage) Two-Generation Reproduction Toxicity Study in the Rat Syngenta xxxxxxxxxxxx GLP not published Syngenta File No CA3511_10030	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA2 5.8.1 / 03	xxxxxxxxxxxx xxx	2016	AMBA - Oral (Gavage) Rat Micronucleus Test Syngenta xx GLP not published Syngenta File No R044276_10010	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.3.1 / 01	Hertl P.	1995	Determination of Residues of DICAMBA in CORN (Zea mais) after Application of BANVEL 4S or SAN 845 H 70 WG under Field Conditions in the FEDERAL REPUBLIC of GERMANY, 1993. Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Ltd., Huningue, France, R10280 GLP not published Syngenta File No SAN837/5434	N	N	Not relevant	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA1 6.3.1 / 02	Andrews G.	2016	Nicosulfuron and Dicamba - Residue Validation and Study on Maize in Northern France, Germany and Poland in 2015 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0258007-REG GLP not published Syngenta File No A19658H_10060	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.3.1 / 03	Mound L., Gardinal P., Kwiatkowski A.	2006	Prosulfuron (CGA152005) and Dicamba (SAN837): Residue Study in or on Maize In Switzerland Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, 04-7016 GLP not published Syngenta File No SAN837/6543	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.3.1 / 04	Simon P.	2006	Prosulfuron and Dicamba: Residue study in or on maize in Germany 2004 (Test product: A14031B) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Agro GmbH, Maintal, Germany, gmz043004 GLP not published Syngenta File No SAN837/6545	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.3.1 / 05	Oppiliart S	2009	Dicamba (CGA57706) and Prosulfuron (CGA152005) - Residue Study on Corn in France (North) in 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - ADME Bioanalyses, Vergeze, France, T001033-07-REG GLP not published Syngenta File No A14031E_10809	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.5.1 / 01	Yeomans P.	2015	NOA405873 - Simulated Processing Practices: Aqueous Hydrolysis of [14C] 5-Hydroxy-Dicamba at 90, 100 and 120 -C Syngenta, BASF Corporation, Research Triangle Park, NC, USA Smithers Viscient (ESG) Ltd, Harrogate, UK, 3200933 GLP not published Syngenta File No NOA405873_10000	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA1 6.6.1 / 01	Swales S.	2016	SAN837 - Uptake and Metabolism of [14C]-SAN837 in Confined Rotational Crops Syngenta, BASF Corporation, Research Triangle Park, NC, USA Smithers Viscient (ESG) Ltd, Harrogate, UK, AgroChemex Ltd, Manningtree, United Kingdom, 3200368 GLP not published Syngenta File No SAN837_11645	N	Y	D Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.6.2 / 01	Andrews G.	2016a	Dicamba- Residue Study on Rotational Crops in Southern France and Spain in 2014 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0223573-REG GLP not published Syngenta File No A7254B_10456	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA1 6.6.2 / 02	Austin R., Andrews G.	2016	Dicamba - Residue Study on Rotational Crops in the United Kingdom and Northern France in 2014 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, NC14032 GLP not published Syngenta File No A7254B_10460	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA3 6.1 (report available from data owner)	Peatman M. H.	2007	Nicosulfuron: Storage Stability of Residues in Corn Matrices Stored Deep Frozen Report No. 0676/032-D2149 (NIS-42) GLP, unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	Cheminova A/S (ADAMA has access (3 LoA))
KCA3 6.2.1 (report available from data owner)	Scott M.T.	1989	Plant metabolism study of <sup>14</sup> C-DPX-V9360 in corn. Report No. AMR 861-87 GLP, unpublished	N	Y	Out of data protection	E.I. du Pont de Nemours and Company (study no longer has data protection)



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA3 6.3.1 / 01	Andrews G.	2016	Nicosulfuron and Dicamba - Residue Validation and Study on Maize in Northern France, Germany and Poland in 2015 Syngenta Battelle UK Ltd, Chelmsford, Essex, UK, TK0258007-REG GLP not published Syngenta File No A19658H_10060	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCA3 6.6.1 (report available from data owner)	Dietrich R.F.	1989	Confined accumulation study of 14C-DPX-V9360 on rotational crops Report No. AMR 874-87 Non-GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (study no longer has data protection)
KCA3 6.2.3 (report available from data owner)	Lin P.T., Scott M.T.,	1989	Metabolism of [pyrimidine-2-14C]DPX-V9360 and [pyridine 2 14C]DPX-V9360 in lactating goats Syngenta Report No. AMR 947-87 GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (Study no longer has data protection)
KCA3 6.6.1 (report available from data owner)	Scott M.T.	2004	Confined accumulation study of 14C-DPX-V9360 on rotational crops. Report No. AMR 874-87, Supplement No. 1 Non-GLP, unpublished	N	N	Out of data protection	E.I. du Pont de Nemours and Company (study no longer has data protection)
KCP 8.5.3	Hardy I., Agostini F.	2021	Organic carbon and clay dependency of nicosulfuron adsorption in soils: correlation analyses based on three adsorption studies Battelle UK Ltd., UK, TH/19/001A ADAMA Doc ID 000109197 Not GLP not published	N	N		ADAMA

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.4.1/01	Llanderal J.	2015	Dicamba - A Leaching Assessment for Parent and One Soil Metabolite (DCSA) Using the FOCUS Groundwater Scenarios Following Spray Application to Maize in the EU Syngenta RIFCON GmbH, Hirschberg, Germany, R1520411-1 Not GLP not published Syngenta File No SAN837_11572 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAM has LoA)
KCP 9.2.4.1 /02	Ibrahim L.	2017	Mesotrione—A Leaching Assessment for Parent and Metabolites MNBA and AMBA Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Maize Syngenta RIFCON GmbH, Hirschberg, Germany, R1520528-1 Not GLP not published Syngenta File No ZA1296_10472 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 9.2.4.1 /03	Nicolaisen	2017	Mesotrione—A Leaching Assessment for Parent and Metabolites MNBA and AMBA Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Spray Application to Maize (Simulations for Neutral Soil) Syngenta Crop Protection AG, Basel, Switzerland RIFCON GmbH, Hirschberg, Germany, R1760183-1 Not GLP not published Syngenta File No ZA1296_10590 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.4.1 / 04	Carnall J.	2017	Nicosulfuron – A Leaching Assessment for Parent and Soil Metabolites HMUD, AUSN, UCSN, ASDM, MU 466 and ADMP Using the FOCUS Groundwater Scenarios Following Spray Application to Maize in the EU Syngenta, Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1865 Not GLP not published Syngenta File No ASF628_11313 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 9.2.5 / 01	Llanderal J.	2016	Dicamba - A Surface Water Assessment for Parent and Metabolite DCSA Using the FOCUS Surface Water Scenarios at Step 1 and 2 Following Spray Applications to Maize in Europe Syngenta RIFCON GmbH, Hirschberg, Germany, R1520411-2 Not GLP not published Syngenta File No SAN837_11574 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 9.2.5 / 02	Ibrahim L.	2017a	Mesotrione - A European Environmental Fate Assessment for Parent Using the FOCUS Surface Water Models at Steps 3 to 4 Following Spray Application to Maize and an Analysis of its FOCUS Step 3 and 4 Exposure Patterns Using the EPAT Tool Syngenta RIFCON GmbH, Hirschberg, Germany, R1520528-2 Not GLP not published Syngenta File No ZA1296_10482 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5 / 03	Carnall J.	2017a	Nicosulfuron - A European Fate Assessment Using the FOCUS Surface Water Step 1-2 Tool Following Spray Application to Maize Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1863 Not GLP not published Syngenta File No ASF628_11334 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 9.2.5 / 04	Carnall J.	2017b	Nicosulfuron - A European Fate Assessment Using the FOCUS Surface Water Scenarios at Step 3 and Step 4 Following Spray Application to Maize Syngenta Cambridge Environmental Assessments, United Kingdom, CEA.1864 Not GLP not published Syngenta File No ASF628_11312 This is CONFIDENTIAL INFORMATION *	N	N	Not relevant	SYN (ADAMA has LoA)
<del>KCA3 7.1.3.1</del>	<del>Graham, R. &amp; Strachan, K.</del>	<del>2008</del>	<del>[14C] Nicosulfuron: Adsorption / Desorption in Soil. Report No.: 79 NIS Cheminova A/S GLP Unpublished Report No. 79 NIS is not submitted with this dossier but is available via Letter of Access from Cheminova.</del>	<del>N</del>	<del>Y</del>	<del>ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.</del>	<del>Cheminova (ADAMA has access (3-LoA))</del>
<del>KCA3 7.5</del>	<del>Schneider, M. &amp; Holzer, S.</del>	<del>2014</del>	<del>Groundwater monitoring for nicosulfuron and six metabolites in four representative regions in Germany. DuPont 28685 SGS Institut Fresenius GLP Unpublished Report DuPont 28685 is not submitted with this dossier but is available via Letter of Access from DuPont.</del>	<del>N</del>	<del>Y</del>	<del>ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.</del>	<del>DuPont (ADAMA is co-owner)</del>

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA3.7.5/01	Ferrari, F.	2016	Groundwater Monitoring for Nicosulfuron and 6 Metabolites in Maize Growing Regions of Italy Syngenta, CHEMINOVA A/S, Lemvig, Denmark, E.I. Dupont Nemours & Co., Inc., Wilmington, USA LABCAM s.r.l. Centro di Saggio, Albenga, Italy, DuPont 40798 IM GLP not published Syngenta File No ASF628_11279	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	E.I. du Pont de Nemours and Company; Cheminova; (ADAMA has access (1 LoA))
KCP 10.1.1 / 01	xxxxxxxxxxxx xxxxx	2018	Mesotrione—An Acute Oral Toxicity Study with the Mallard Using a Sequential Testing Procedure Syngenta Crop Protection AG, Basel, Switzerland xx GLP not published Syngenta File No ZA1296/10605	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.1.2 / 01	Haaf S., Alvarez T.	2017	A18032E Mesotrione Refined risk assessment for mammals (Central Zone) Syngenta European Product Registration, Basel, Switzerland Not GLP not published Syngenta File No A18032E_10335 <u>This is CONFIDENTIAL INFORMATION*</u>	N	N	Not relevant	SYN
KCP 10.1.2	Alvarez T.	2019	Mesotrione: refined risk assessments for mammals. Syngenta, Jealott's Hill, Bracknell, United Kingdom. Syngenta Unpublished Report (Syngenta File No. A18032E_10335) <u>This is CONFIDENTIAL INFORMATION*</u>	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.1.2.2 / 01	xxxxxxxxxxxx xxxxxxxxx	2015	Generic field study on the presence and abundance of common voles in maize fields in Northern France xxxxxxxxxxxxxxxx 774934 GLP not published Syngenta File No NA_13749	Y	Y	Syngenta to provide further information on data protection if required.	BASF (SYN access)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.1.2.2 / 02	Prescott C.	2004	The assessment of Wood mouse acceptance /avoidance of different crop seeds when presented in free feeding conditions to individually caged animals in a six hour no choice situation; and to monitor the incidence of de husking for each seed type. Syngenta Crop Protection AG, Basel, Switzerland University of Reading, Reading, United Kingdom, VPU/04/026 2033623 Not GLP not published Syngenta File No N/1014	N	N	Not relevant	SYN (ADAMA has LoA)
KCP 10.1.2.2 / 03	xxxxxxxxxxxx xxxxxxxxxx	2013	Generic field monitoring of hares in a mixed landscape in Germany Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx Not GLP not published Syngenta File No NA_13449	Y	Y	Data/study never submitted before to Poland	BCS (SYN access)
KCP 10.1.2.2 / 04	Voigt U., Zaccaroni M.	2015	Generic field monitoring of hares in a mixed landscape in Germany—Jacobs index Bayer Crop Science AG, Monheim, Germany BAR/FS069 Not GLP not published Syngenta File No NA_13997	N	N	Not relevant	BCS (Data protection not claimed)
KCP 10.1.2.2 / 05	Dittrich R., Benito M.	2016	Occurrence and PT of Wood mice in pre and post emergence maize fields in France, southern zone. Syngenta tier3 solutions GmbH, Leverkusen, Germany, NA_14235, B15064 Not GLP not published Syngenta File No NA_14237	N	Y	Syngenta to provide further information on data protection if required.	BCS

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 10.1.2.2 / 06	North L.	2016	Mesotrione - Foliage Decline with A12739A on Maize in Northern France and the United Kingdom in 2015 Syngenta Eurofins Agrosience Services Ltd, Wilson, UK, S15-02057 GLP not published Syngenta File No A12739A_11065	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.1.2.2/07	Grimm T & Katzschner I	2019	Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, Germany Report No. R1740045 GLP, Unpublished Syngenta File No. NA_14950	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.1.2.2/12	Allen L.	2019	Mesotrione – Mesotrione – Study on Clover in Hungary, Germany, United Kingdom, Northern France and Belgium in 2018. CEMAS, Imperial House, Oaklands Park, Wokingham, Berkshire, RG41 2FD, , UK Report No. CEMR-8397 GLP, Unpublished Syngenta File No. A12738A_10535	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.2.1 / 01	Falk S.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Testing of Effects on the Single Cell Green Alga Pseudokirchneriella subcapitata Syngenta Eurofins Agrosience Services GmbH, Niefern-Äschel., Germany, S12-02296 GLP not published Syngenta File No A18032E_10002	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1 / 02	Gonsior G.	2017	Mesotrione - Growth inhibition of Myriophyllum spicatum in a water/sediment system Syngenta Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S16-06273 GLP not published Syngenta File No ZA1296_10504	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.2.1 / 03	Kosak L., Wydra V.	2016	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a semi-static growth inhibition test with a subsequent recovery period Syngenta IBACON GmbH, Rossdorf, Germany, 105732240 GLP not published Syngenta File No ZA1296_10438	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
<del>KCP 10.2.1 / 04</del>	<del>Hengsberger A., Wydra V.</del>	<del>2015a</del>	<del>Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a reciprocal growth inhibition test Syngenta IBACON GmbH, Rossdorf, Germany, 105731240 GLP not published Syngenta File No ZA1296_10436</del>	<del>N</del>	<del>Y</del>	<del>Data/study never submitted before to Poland</del>	<del>SYN (ADAMA has LoA)</del>
KCP 10.2.1	Hengsberger A., Wydra V. (amendment 2; Kosak L., Wydra V.	2015 (amend.2 2016)	Mesotrione Wet Paste (ZA1296) - Toxicity to the Aquatic Plant Lemna gibba in a Semi-Static Growth Inhibition Test with a Subsequent Recovery Period. Ibacon GmbH Arheilger Weg 17 64380 Rossdorf Germany. Report No. 105732240 GLP, Unpublished Syngenta File No. ZA1296_10438	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2.1 / 05	Weber K.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Assessment of Toxic Effects on Daphnia magna using the 48 h Acute Immobilisation Test Syngenta Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S12-02294 GLP not published Syngenta File No A18032E_10008	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.2.1 / 06	Weber K.	2012a	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor(A12127R) - Assessment of Toxic Effects on the duckweed Lemna gibba in a Semi-Static Test Syngenta Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S12-02297 GLP not published Syngenta File No A18032E_10009	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.2.1 / 07	xxxxxxxxxxxx	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Acute Toxicity Testing in Rainbow Trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) Syngenta xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No A18032E_10001	Y	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.2 (report available from data owner)	Wenzel, A.	2010	Macrophyte Growth Test with Nicosulfuron Technical. Test with a subsequent Recovery Period. Fraunhofer IME study No. CHE-009/4-80 Report No. 185 NIS GLP, Unpublished	N	No information provided	No information provided	Cheminova (ADAMA has LoA from FMC, owner of Cheminova)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1.1 / 01 & KCP 10.3.1.1.2 / 01	Kling A.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus Adigor (A12127R) - Acute Oral and Contact Toxicity to the Honeybee Apis mellifera L. in the Laboratory Syngenta Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-02293 GLP not published Syngenta File No A18032E_10005	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.3.1.2 / 01	Ruhland S.	2015	Dicamba SL (A7254B) —Chronic toxicity to the Honeybee Apis mellifera L. in a 10-Day Continuous Laboratory Feeding Study Syngenta BioChem Agrar, Gerichshain, Germany, 14 10 48 057 B GLP not published Syngenta File No A7254B_10378	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.3.1.2/02	xxxxxxxxxxxx xxxxxxx	2018	Mesotrione — Honey Bee (Apis mellifera L.) Chronic Oral Toxicity Test 10-Day Feeding Test in the Laboratory; xxxxxxxxxxxxxxxxxxxxxxxxxxxx Report Number S18-03658 GLP, Unpublished Syngenta file No. ZA1296_10608	Y	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.3.1.2/03 (report available from data owner)	Schmitt, H.	2014	Nicosulfuron (DPX V9360) Technical: Assessment of Effects to the Honeybee, Apis mellifera L., in a 10-Days Chronic Feeding Test under Laboratory Conditions Eurofins Agroscience Services EcoChem GmbH, D-75223 Niefern-Öschelbronn, Germany Report No. S 14-00413 GLP, Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	DuPont (ADAMA has access (1 LOA))
KCP 10.3.1.3 / 01	Kleebaum K.	2015	Dicamba SL (A7254B) —Chronic toxicity to the honeybee larvae Apis mellifera L. under laboratory conditions (in vitro) Syngenta, BASF BioChem Agrar, Gerichshain, Germany, 14 10 48 072 B GLP not published Syngenta File No A7254B_10377	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.3/02	xxxxxxxxxxx	2016	Mesotrione – Honey bee ( <i>Apis mellifera</i> L.) Larval Toxicity Test (Repeated Exposure through to Adult Emergence); xxxxxxxxxxxxxxxxxxxxxx Report Number S16-00332 GLP, Unpublished Syngenta file No. ZA1296_10465	Y	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.3.1.3/03 (report available from data owner)	Klank, C.	2014	Nicosulfuron (DPX V9360) Technical: Honey Bee ( <i>Apis mellifera</i> L.) Larval Toxicity Test (Single Feeding Exposure) Eurofins Agroscience Services EcoChem GmbH, D-75223 Niefern-Öschelbronn, Germany Report No. S14-00341 GLP, Unpublished	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	DuPont (ADAMA has access (1 LoA))
KCP 10.3.2.1 / 01	Fallowfield L.	2012	Mesotrione/nicosulfuron/dicamba WG (A18032E) plus A12127R (Adigor adjuvant) - A rate-response laboratory bioassay of the effects of fresh residues on the predatory mite, Typhlodromus pyri (Acari: phytoseiidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-28 GLP not published Syngenta File No A18032E_10003	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.3.2.1 / 02	Stevens J.	2012	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus A12127R (Adigor adjuvant) - A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-29 GLP not published Syngenta File No A18032E_10000	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.2 / 01	Stevens J.	2012a	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) - A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-45 GLP not published Syngenta File No A18032E_10010	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.3.2.2 / 02	Tew G.	2013	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) - A rate-response extended laboratory bioassay of the effects of fresh residues on the rove beetle <i>Aleochara bilineata</i> (Coleoptera; Staphylinidae) Syngenta Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-46 GLP not published Syngenta File No A18032E_10015	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.4.1.1 / 01	Friedrich S.	2012	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) plus Adigor (A12127R) - Sublethal Toxicity to the Earthworm <i>Eisenia fetida</i> in Artificial Soil Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 147 S GLP not published Syngenta File No A18032E_10007	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.4.2.1 / 01	Dickinson R.	2015	R169649 - Collembola ( <i>Folsomia candida</i> ) Reproduction Test in Soil Syngenta AgroChemex Ltd, Manningtree, United Kingdom, ENV-14-015 GLP not published Syngenta File No CA3511_10011	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 10.4.2.1 / 02	Friedrich S.	2013	Mesotrione/Dicamba/Nicosulfuron WG (A18032E) plus Adigor (A12127R) - Effects on the Reproduction of the Collembolan Folsomia candida Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 090 S GLP not published Syngenta File No A18032E_10011	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.4.2.1 / 03	Ramsden C.	2015	R169649 - Predatory Mite (Hypoaspis (Geolaelaps) aculeifer) Reproduction Test in Soil Syngenta AgroChemex Ltd, Manningtree, United Kingdom, ENV-14-012 GLP not published Syngenta File No CA3511_10010	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.4.2.1 / 04	Schulz L.	2013	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) - Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 148 S GLP not published Syngenta File No A18032E_10012	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.5 / 01	Schulz L.	2012	Mesotrione/Nicosulfuron/Dicamba WG (A18032E) plus Adigor (A12127R) - Effects on the activity of soil microflora (nitrogen and carbon transformation tests) Syngenta BioChem Agrar, Gerichshain, Germany, 12 10 48 048 C/N GLP not published Syngenta File No A18032E_10004	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

<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>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 10.6.2 / 01	Bramby- Gunary J.	2013	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Vegetative Vigour Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, David Norris Analytical Labs Ltd., Dartford, UK, ACE-12-149 GLP not published Syngenta File No A18032E_10025	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)
KCP 10.6.2 / 02	Bramby- Gunary J.	2013a	Mesotrione/dicamba/nicosulfuron WG (A18032E) plus A12127R (Adigor adjuvant) - Evaluation of the Phytotoxicity to Non Target Terrestrial Plant Seedling Emergence and Seedling Growth Test Syngenta AgroChemex Ltd, Manningtree, United Kingdom, David Norris Analytical Labs Ltd., Dartford, UK, ACE-12-148 GLP not published Syngenta File No A18032E_10024	N	Y	Data/study never submitted before to Poland	SYN (ADAMA has LoA)

\* MS to complete as used by multiple applicants

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

**Dicamba** (Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011); active substance data submitted with an application considered under Article 80 (2) b attracted 5 years data protection from re-approval of the active substance. Active substance approval was 1<sup>st</sup> January 2009, therefore data protection for the active substance data relied on for Annex 1 renewal expired on 1 January 2014.

**Mesotrione** (Commission Implementing Regulation (EU) 2017/725 of 24 April 2017) '[List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to the approval of the active](#)' contains the complete list of data relied on for Mesotrione renewal. Syngenta claims 30 months of data protection for this data from the date the first authorisation decision taken in this member state.

**Nicosulfuron** (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011); active substance data submitted with an application considered under Article 80 (2) b attracted 5 years data protection from re-approval of the active substance. Active substance approval was 1st January 2009, therefore data protection for the active substance data relied on for Annex 1 renewal expired on 1 January 2014.

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA1 6.3.1 / 01	Hertl P.	1995	Determination of Residues of DICAMBA in CORN (Zea mais) after Application of BANVEL 4S or SAN 845 H 70 WG under Field Conditions in the FEDERAL REPUBLIC of GERMANY, 1993. Novartis Crop Protection AG, Basel, Switzerland Sandoz Agro Ltd., Huningue, France, R10280 GLP not published Syngenta File No SAN837/5434	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCA2 6.3.1 / 01	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP not published Syngenta File No ZA1296/0409	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCA2 6.3.1 / 02	Heillaut C	2009	Glyphosate (ASF71), Mesotrione (ZA1296) and S-Metolachlor (CGA77102) - Residue Study on GA21 (MON----21-9) Corn in France (North) and Slovakia in 2007 Syngenta ADME - Bioanalyses, Vergeze, France, T011085-06 GLP not published Syngenta File No A15189G_10009	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA2 6.3.1 / 03	Heillaut C	2009a	Glyphosate, Mesotrione and S-Metolachlor - Residue Study on GA21 (MON-00021-9) Corn in Denmark and Sweden in 2008 Syngenta ADME - Bioanalyses, Vergeze, France, T009533-07-REG GLP not published Syngenta File No A15189G_10014	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCA2 6.3.1 / 04	Meyer M	2011	Mesotrione - Residue Study on Field Corn in Germany and the United Kingdom in 2009 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T000920-09-REG GLP not published Syngenta File No A14203B_10105	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCA2 6.3.1 / 05	Klimmek S., Gizler A.	2008	Mesotrione and Nicosulfuron: Residue Study on Maize in Northern France in 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-06-REG GLP not published Syngenta File No A14351BX_10613	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCA2 6.3.1 / 06	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07-REG GLP not published Syngenta File No ZA1296_10049	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)
KCP 10.1.2.2 / 07	Funkenhaus A, Giessing B	2010	Exposure of mammals in maize fields in France - Attractiveness of maize fields and relevant species Syngenta - Jealott's Hill, Bracknell, United Kingdom Rifcon, Heidelberg, Germany, R09012-2 GLP not published Syngenta File No NA_11991	N	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	SYN (ADAMA has LoA)



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.1.2.2 / 08	xxxxxxxxxxxxxx	2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No N/1155	Y	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	BCS (ADAMA has access (4 LoA))
KCP 10.1.2.2 / 09	xxxxxxxxxxxxxx	2014	Generic field study on small mammals - focal species and wood mouse (Apodemus sylvaticus) PT in maize fields in Germany Oxon Italia S.p.A., Pero, Italy xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx GLP not published Syngenta File No NA_13410	Y	Y	ADAMA reached agreement to access the study. Data owner to provide further information on data protection if required.	OXN (ADAMA has access (5 LoA))

\* MS to complete as used by multiple applicants

#### List of data submitted by the applicant and not 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

#### List of data relied on and not submitted by the applicant but necessary for evaluation

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-