

# REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

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

Product name: NIKITA

Chemical active substances:

Dicamba: 312.5 g/kg

Mesotrione: 150 g/kg

Nicosulfuron: 100 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

Sponsor: ADAMA

Applicant: ADAMA

Submission date: June 2020

MS Finalisation date: 22/12/2021(initial Core Assessment)

June 2022 (final Core Assessment)

### Version history

When	What
June 2020	Applicant initial dRR
December 2021	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are <del>struck through and shaded for transparency</del> .
June 2022	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

## 1 Section 1: Identity of the plant protection product

### 1.1 Applicant (KCP 1.1)

Name: ADAMA Agan

Refer to Part A for national applicant details

### 1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

#### 1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

#### 1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

### 1.2.3 Statement of purity (and detailed information on impurities) of the active substances

#### 1.2.3.1 Dicamba

	EU agreed minimum purity Reference: Commission Implementing Regulation (EU) No. 1100/2011	EU minimum purity – included in Confidential Volume 4 Annex C (Revision, October 2010) and Annex I Renewal dossier submitted June 2016
Dicamba	850 g/kg	880 g/kg*

\*Commission Directive 2008/69/EC, Commission Implementing Regulation (EU) 540/2011 of 25 May 2011 and subsequent amendment in Commission Implementing Regulation (EU) No. 1100/2011 of 31 October 2011 specifies the minimum purity of dicamba technical material as 850 g/kg, but as agreed between the notifiers during the EU Review in 2010, a revised specification of 880 g/kg was proposed and accepted by the RMS as part of a revised Document J (September 2009). The change in specification was formally published in the Confidential Volume 4 Annex C (Revision, October 2010).

#### Pure dicamba in A18032E

content of pure active substance:	313 g/kg	31.3 % w/w
limits :	297 – 328 g/kg	27.9 – 32.8 % w/w

#### Technical dicamba in A18032E

at a minimum purity of the technical active substance of 85.0 % w/w.		
content of technical active substance:	368 g/kg	36.8 % w/w
limits :	349 – 386 g/kg	34.9 – 38.6 % w/w

During the manufacturing process for A18032E, the first stage involves the neutralisation of dicamba technical material with sodium hydroxide to form the sodium salt of dicamba *in-situ*. This non-isolated intermediate is then processed through to the final product. For the purpose of demonstrating the full formulation composition the amount of the sodium salt of dicamba, formed as an intermediate, based on minimum and typical dicamba purities are given below.

Dicamba sodium salt (at a minimum purity of the technical active substance of 85 % w/w)	404 g/kg (40.4 % w/w)
Dicamba sodium salt (pure active substance)	343.4 g/kg (34.3 % w/w)
Neutralised technical dicamba (at a typical purity of the technical active substance of 95 % w/w)	362 g/kg (36.2 % w/w)

Chemical equivalence: see Part C of this dossier.

### 1.2.3.2 Mesotrione

	<b>EU agreed minimum purity</b> <b>Reference: COMMISSION IMPLEMENTING REGULATION (EU) 2017/725</b>
<b>Mesotrione</b>	920 g/kg*
R287431, 6-(methylsulfonyl)-7-nitro-9-oxo-9H-xanthene-1-carbonitrile (relevant impurity)	< 0.002 g/kg
R287432, 6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile (relevant impurity)	< 2 g/kg
1,2-dichloroethane (relevant impurity)	< 1 g/kg

\* In the RAR Volume 4 (11 November 15) and the EFSA Conclusions (EFSA Journal 2016;14(3):4419), the minimum purity is given as 930 g/kg, however this is superseded by the **COMMISSION IMPLEMENTING REGULATION (EU) 2017/725** which states 920 g/kg

#### Pure mesotrione in A18032E

<b>content of pure active substance:</b>	<b>150 g/kg</b>	<b>15.0 % w/w</b>
limits :	141 – 159 g/kg	14.1 – 15.9 % w/w

#### Technical mesotrione in A18032E

<b>at a minimum purity of the technical active substance of 92.0 % w/w.</b>		
<b>content of technical active substance:</b>	<b>163 g/kg</b>	<b>16.3 % w/w</b>
limits :	153 – 173 g/kg	15.3 – 17.3 % w/w

Chemical equivalence: see Part C of this dossier.

### 1.2.3.3 Nicosulfuron

	<b>EU agreed minimum purity</b> <b>Reference: COMMISSION DIRECTIVE 2009/51/EC and Commission Implementing Regulation (EU) No. 540/2011</b>	<b>Proposed EU minimum purity – pending June 2016 Annex I Renewal</b>
<b>Nicosulfuron</b>	910 g/kg	938 g/kg*

\*The Syngenta/Cheminova joint source of nicosulfuron, with minimum purity 938 g/kg has been declared equivalent after evaluation by the former RMS; CRD (UK) in May 2013. The equivalence report is available on CIRCA. The confirmatory data required was submitted to UK CRD in June 2016. The min. purity of 938 g/kg has also been proposed in AIR3 dossier submitted to the current RMS LV in June 2016.

#### Pure nicosulfuron in A18032E

<b>content of pure active substance:</b>	<b>100 g/kg</b>	<b>10.0 % w/w</b>
limits :	90 – 110 g/kg	9 – 11 % w/w

#### Technical nicosulfuron in A18032E

<b>at a minimum purity of the technical active substance of 93 % w/w.</b>		
<b>content of technical active substance:</b>	<b>108 g/kg</b>	<b>10.8 % w/w</b>
limits :	101 – 114 g/kg	10.1 – 11.4 % w/w

Chemical equivalence: see Part C of this dossier.

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: NIKITA

Company code number: ADM.4651.H.1.A

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

The product A18032E was not evaluated previously as a representative formulation (same uses and same GAPs) during the EU review of the active substances mesotrione, dicamba and nicosulfuron.

The content of dicamba, mesotrione and nicosulfuron in A18032E is given under point 1.2.3.

The maximum amount of relevant impurities has been addressed in point 1.2.3.

Information on the variants is addressed under point 1.4.2.

Information on the formulants including safeners and synergists is confidential and is included in **Part C (Confidential information)**.

The product A18032E does not contain safeners or synergists.

The product A18032E does contain relevant impurities.

Information on the formulants is confidential and is included in **Part C (Confidential information)**.

#### 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-1: Information on dicamba**

Type	Name/Code Number	
ISO common name	Dicamba (SAN837)	Variant: not relevant
CAS No.	1918-00-9	
EC No.	217-635-6	
CIPAC No.	85	

**Table 1.4-2: Information on mesotrione**

Type	Name/Code Number	
ISO common name	Mesotrione (ZA1296)	Variant: not relevant
CAS No.	104206-82-8	
EC No.	not available	
CIPAC No.	625	

**Table 1.4-3: Information on nicosulfuron**

Type	Name/Code Number	
ISO common name	Nicosulfuron (ASF628)	Variant: not relevant
CAS No.	111991-09-4	-
EC No.	not available	-
CIPAC No.	709	-

#### 1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

The product A18032E does not contain safeners or synergists.

**CONFIDENTIAL** information on co-formulants is provided separately (**Part C**).

**1.5                    Type and code of the plant protection product (KCP 1.5)**

Type: Water dispersible granule                    [Code: WG]

**1.6                    Function (KCP 1.6)**

Herbicide.

## **2 Section 2: Physical, chemical and technical properties of the plant protection product**

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, however this dRR and studies are based on the worst case GAP for C-EU with a higher application rate. The data is applicable to the Polish GAP.

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%.

A tank mixed oil-based adjuvant needed (e.g. Adigor: 1.0-1.5L/ha, STYK/INSERT with 0.2L/ha, Efica 960 EC with 0.8L/ha).

The dossier does not include recommendations for specific mixing of the preparation with any other plant protection product and adjuvant please refer point 2.9.1.

### **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.



**Table 2-1: Physical, chemical and technical properties of the plant protection product**

All tests have been performed under GLP, except where mentioned.

A18032E test material batches used in studies were:

GLP-certified laboratories have performed the studies using batch SMU2BP001 containing 156 g/kg mesotrione, 313 g/kg dicamba, and 101 g/kg nicosulfuron (*Adolph S., 2012, Syngenta File No. A18032E\_10026*).

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and organoleptic test	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Beige solid with a weak odour.	N	<i>Fumeaux J. 2013 A18032E_10034</i>	Accepted.
Explosive properties (KCP 2.2.1)	Theoretical assessment	-	Not an explosive substance	Y	<i>Blessington K. 2012 A18032E_10029</i>	Accepted.
Oxidizing properties (KCP 2.2.2)	Theoretical assessment	-	Not an oxidising substance	Y	<i>Blessington K. 2012 A18032E_10029</i>	Accepted.
Flash point (KCP 2.3.1)	-	-	Not applicable. Formulation is a solid.	-	-	-
Flammability (KCP 2.3.2)	EEC A.10	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Not classified as highly flammable in terms of its burning characteristics	Y	<i>Blessington K. 2012 A18032E_10029</i>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Self-heating (KCP 2.3.3)	EEC A.16	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Relative Self-Ignition Temperature: $294 \pm 5$ °C	Y	<i>Blessington K. 2012</i> <i>A18032E_100 29</i>	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Acidity: 3.21 % (calculated as H <sub>2</sub> SO <sub>4</sub> )	Y	<i>Fumeaux J. 2013a</i> <i>A18032E_100 28</i>	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	1 % suspension in water: 4.5 at 25°C 1 % suspension in water with addition of 0.25 % v/v adjuvant <sup>1)</sup> at 25°C: 4.1 1 % suspension in water with addition of 1.9 % v/v adjuvant <sup>1)</sup> at 25°C: 4.2 <sup>1)</sup> Adjuvant is ADIGOR (A12127R): mixture of fatty acid esters	Y	<i>Fumeaux J. 2013a</i> <i>A18032E_100 28</i>	Accepted.
Kinematic viscosity (KCP 2.5.1)	-	-	Not applicable. Formulation is a solid.	-	-	-
Dynamic Viscosity (KCP 2.5.2)	-	-	Not applicable. Formulation is a solid.	-	-	-
Surface tension (KCP 2.5.3)	-	-	Not applicable. Formulation is a solid.	-	-	-
Relative density (KCP 2.6.1)	-	-	Not applicable. Formulation is a solid.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Bulk density (KCP 2.6.2)	CIPAC MT 186	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	- Pour density: 0.629 g/mL - Tap density: 0.646 g/mL	Y	<i>Fumeaux J. 2013a A18032E_100 28</i>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 Content of mesotrione, dicamba and nicosulfuron, was determined by HPLC (SF-568/1, external standard); For full validation details please refer to the dRR Section 5.	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	The formulation undergoes no significant physical or chemical degradation during storage at 54 ± 2°C for 14 days in the following packaging material: <ul style="list-style-type: none"> <li>High density polyethylene (HDPE)</li> </ul> A summary of the data generated before and after storage is given in Appendix 3.	N	<b>Kundel P. 2013</b> <b>A18032E_10033</b>	The product showed no significant physical changes after accelerated storage in HDPE packaging and all performance properties were within acceptable limits.  The active ingredient content after two weeks of 54°C storage conditions did not significantly change. R287431, R287432, 1,2-dichloroethane cannot be formed during manufacturing or storage of formulations. Storage stability study for the above mentioned impurities in formulations is not necessary. The formulation is expected to be stable for at least 2 years at ambient conditions, based on the accelerated storage study results.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required as there is no decomposition.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not applicable. Formulation is a solid.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)	<p>GIFAP monograph 17;</p> <p>Content of mesotri-one, dicamba and nicosulfuron, was determined by HPLC (SF-568/1, external standard);</p> <p>For full validation details please refer to the dRR Section 5.</p>	<p>Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)</p>	<p>The formulation undergoes no significant physical or chemical degradation during storage at ambient temperature for two years in the following packaging material:</p> <ul style="list-style-type: none"> <li>High density polyethylene (HDPE)</li> </ul> <p>A summary of the data generated before and after storage is given in Appendix 4.</p>	N	<b>Kundel P. 2015 A18032E_103 17</b>	<p>The formulation is stable for 2 years at 20°C in HDPE packaging. No significant changes of physical-chemical properties and packaging stability occurred during the tests.</p> <p>The HDPE container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product. No toxicologically, ecotox-icologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p> <p>Period of validity: 2 years</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant	-	-	-
Wettability (KCP 2.8.1)	CIPAC MT 53.3	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	CIPAC water D: 1 sec CIPAC water D with addition of 0.25 % v/v adjuvant <sup>1)</sup> : 1 sec CIPAC water D with addition of 1.9 % v/v adjuvant <sup>1)</sup> : 1 sec <sup>1)</sup> Adjuvant is ADIGOR (A12127R): mixture of fatty acid esters	N	<i>Fumeaux J. 2013 A18032E_100 34</i>	Accepted.
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Concentration 0.1 % in CIPAC water D: after 10 s 35 mL after 1 min 30 mL after 3 min 30 mL after 12 min 24 mL Concentration 0.75 % in CIPAC water D: after 10 s 50 mL after 1 min 50 mL after 3 min 48 mL after 12 min 32 mL  Concentration 0.1 % in CIPAC water D with addition of 0.25 % v/v adjuvant <sup>1)</sup> : after 10 s 0 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL Concentration 0.75% in CIPAC water D with addition of 1.9 % v/v adjuvant <sup>1)</sup> : after 10 s 0 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL <sup>1)</sup> Adjuvant is ADIGOR (A12127R): mixture of fatty acid esters	N	<i>Fumeaux J. 2013 A18032E_100 34</i>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	<b><u>Gravimetric Assay</u></b> - 0.1 % in CIPAC water D at 30°C after 30 min: 93 % - 0.75 % in CIPAC water D at 30°C after 30 min: 93 % - 0.1 % in CIPAC water D with addition of 0.25 % v/v adjuvant <sup>1)</sup> at 30°C after 30 min: 97 % - 0.75 % in CIPAC water D with addition of 1.9 % v/v adjuvant <sup>1)</sup> at 30°C after 30 min: 97 % <sup>1)</sup> Adjuvant is ADIGOR (A12127R): mixture of fatty acid esters <b><u>A.I. Suspensibility</u></b> 0.1 % in CIPAC water D at 30°C after 30 min: - mesotrione: 97 % - dicamba: 100 % - nicosulfuron: 92 % 0.75 % in CIPAC water D at 30°C after 30 min: - mesotrione: 93 % - dicamba: 101 % - nicosulfuron: 92 %	N	<i>Fumeaux J. 2013 A18032E_100 34</i>	Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	<b><u>Gravimetric Assay</u></b> in CIPAC water D: 92 % 1% in CIPAC water D with addition of 0.25 % adjuvant <sup>1)</sup> : 100 % 1% in CIPAC water D with addition of 1.9 % adjuvant <sup>1)</sup> : 92 % <sup>1)</sup> Adjuvant is ADIGOR (A12127R): mixture of fatty acid esters	N	<i>Fumeaux J. 2013 A18032E_100 34</i>	Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	Not applicable for WG formulation.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not applicable (not an SL formulation)	-	-	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	≥ 90 % was retained on the 800 µm sieve ≤ 10 % was retained on the 1250 µm sieve	Y	<i>Fumeaux J. 2013a A18032E_100 28</i>	Accepted.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Material retained on a 75 µm test sieve: In tap water: <0.01 % In tap water with addition of 0.25 % v/v of the adjuvant <sup>1)</sup> : < 0.01 % In tap water with addition of 1.9 % v/v of the adjuvant <sup>1)</sup> : < 0.01 % <sup>1)</sup> Adjuvant is ADIGOR (A12127R): mixture of fatty acid esters	N	<i>Fumeaux J. 2013 A18032E_100 34</i>	Accepted.
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Collected dust: 1.3 mg	Y	<i>Fumeaux J. 2013a A18032E_100 28</i>	Accepted.
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not applicable.	-	-	-
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Attrition resistance: 100 %	N	<i>Fumeaux J. 2013 A18032E_100 34</i>	Accepted.
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable.	-	-	-
Emulsion stability (KCP 2.8.6.1)	-	-	Not applicable.	-	-	-
Re-emulsifiability (KCP 2.8.6.1)	-	-	Not applicable.	-	-	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Stability of dilute emulsions (KCP 2.8.6.2)	-	-	Not applicable.	-	-	-
Flowability (KCP 2.8.7.1)	-	-	Not applicable.	-	-	-
Pourability (KCP 2.8.7.2)	-	-	Not applicable.	-	-	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	A18032E will be used with a tank mix adjuvant e.g. ADIGOR (A12127R). Please refer to GAP document for details of application rates and use pattern. The dilution properties i.e. physical compatibility of tank mixes of A18032E and ADIGOR as a representative adjuvant, have been described under Annex points KCP 2.8.1, 2.8.2, 2.8.3.1, 2.8.3.2 and 2.8.5.1.2 of this submission. These data demonstrate that tank mixes of A18203E and ADIGOR are physically compatible.	-	<b>Fumeaux J. 2013</b> <b>A18032E_100 34</b> <b>Fumeaux J. 2013a</b> <b>A18032E_100 28</b>	Accepted. Compatibility is confirmed.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																								
	ASTM E1518-05	<p>Nikita: Mesotrione (15 %) + dicamba (31.3 %) + nicosulfuron (10%);</p> <p>Oljean 85 EC: Rapeseed oil (85%)</p> <p>Insert: Fatty alcohol ethoxylate (81%)</p> <p>Efica 960 EC: S-metolachlor 960 g/L</p>	<p>An evaluation of the physical compatibility and stability of pesticide tank mixtures diluted for aqueous application was performed.</p> <p>The pesticides were diluted in water and tank mixed at specific application rates. Evaluations were conducted under dynamic conditions. Pesticides were mixed and kept under agitation by a mechanical shaker. Evaluations were conducted at chosen water hardnesses and temperatures. Compatibility was measured in terms of the dispersion stability and screen residue.</p> <p>Pesticides that were examined for mixing compatibility were evaluated individually as controls.</p> <p>Order of Addition: Pesticides were tank mixed as recommended on the product label. If the order of the addition was not specified, the following order was used: water soluble concentrates, water dispersible granules (dry flowables), wettable powders, liquid flowables, and emulsifiable concentrates.</p> <table><caption>Table 1: Physical compatibility results, tank mixtures</caption><thead><tr><th>No.</th><th>Product</th><th>Application rate</th><th>Water</th><th>Test application per 100 mL water</th><th>Dispersion stability</th><th>Nonrinsable residue on flask walls</th><th>Residue on sieve</th><th>Result: compatible?</th><th>pH</th></tr></thead><tbody><tr><td>M1</td><td>NIKITA Olejan 85 EC</td><td>0.4 kg/ha 1.50 L/ha</td><td>80 L/ha</td><td>0.500 g 1.875 mL</td><td>yes</td><td>no</td><td>no</td><td>yes</td><td>3.91</td></tr><tr><td>M2</td><td>NIKITA Insert</td><td>0.4 kg/ha 0.2 L/ha</td><td>80 L/ha</td><td>0.500 g 0.250 mL</td><td>yes</td><td>no</td><td>no</td><td>yes</td><td>3.90</td></tr><tr><td>M3</td><td>Nikita Efica 960 EC</td><td>0.4 kg/ha 0.8 L/ha</td><td>80 L/ha</td><td>0.500 g 1.00 mL</td><td>yes</td><td>no</td><td>no</td><td>yes</td><td>4.18</td></tr></tbody></table> <p>Test temperature: 25 °C</p> <p>No chemical reactions were observed in the tested mixtures.</p> <p>From the chemical data of the active substances (see appendix) the following conclusions can be drawn:</p> <ul style="list-style-type: none"><li>- All mixtures are acidic (pH in the range of 3.9 - 4.2)</li><li>- All active substances are hydrolytically sufficiently stable at the pH of the mixtures</li><li>- No cationic and anionic actives are combined in the mixes</li></ul> <p>Based on the individual chemistries of the active substances, tank mixing of Nikita with all products should be possible.</p> <p>All mixtures reported in Table 1 above gave well-dispersed mixtures in water. No separation, flocculation, coagulation, gel or curd were noticed. There were no residues on the wall of the flasks and no residues remaining on a 0.3 mm sieve.</p>	No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve	Result: compatible?	pH	M1	NIKITA Olejan 85 EC	0.4 kg/ha 1.50 L/ha	80 L/ha	0.500 g 1.875 mL	yes	no	no	yes	3.91	M2	NIKITA Insert	0.4 kg/ha 0.2 L/ha	80 L/ha	0.500 g 0.250 mL	yes	no	no	yes	3.90	M3	Nikita Efica 960 EC	0.4 kg/ha 0.8 L/ha	80 L/ha	0.500 g 1.00 mL	yes	no	no	yes	4.18	Y	Hartmut T. 2021 21 35 CRX 0016	Accepted. Compatibility is confirmed.
No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve	Result: compatible?	pH																																					
M1	NIKITA Olejan 85 EC	0.4 kg/ha 1.50 L/ha	80 L/ha	0.500 g 1.875 mL	yes	no	no	yes	3.91																																					
M2	NIKITA Insert	0.4 kg/ha 0.2 L/ha	80 L/ha	0.500 g 0.250 mL	yes	no	no	yes	3.90																																					
M3	Nikita Efica 960 EC	0.4 kg/ha 0.8 L/ha	80 L/ha	0.500 g 1.00 mL	yes	no	no	yes	4.18																																					
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	<del>This dossier does not include the authorization of the combined use of the preparation with any other product.</del> Data on compatibility please refer to the KCP 2.9.1.	-	-	Data on compatibility please refer to the KCP 2.9.1.																																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant (not intended for use as a seed dressing)	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not relevant (not intended for use as a seed dressing)	-	-	-
Other/special studies (KCP 2.11) Equipment cleaning	Proprietary method	Mesotrione 156 g/kg, dicamba 313 g/kg, nicosulfuron 101 g/kg (A18032E)	Tests have been carried out to determine the effectiveness of the tank cleaning procedure for A18032E (mesotrione/dicamba/nicosulfuron WG (15/31.25/10)). After applying the cleaning procedure 0.01 % mesotrione, 0.01 % dicamba and 0.06 % nicosulfuron residues were found in the refilled spray tank. Therefore, the applied rinsing procedure can be considered as sufficient.	N	<b>Kundel P. 2013a A18032E_100 31</b>	The applied rinsing procedure can be considered as sufficient.

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

Packaging proposed for A18032B is described. Information/data on packaging type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and are considered to be acceptable.

Study Comments: KCP 4.1/01	The formulation is stable for 2 years at 20°C in HDPE packaging. No significant changes of physical-chemical properties and packaging stability occurred during the tests.
Agreed endpoint: KCP 4.1/01	The HDPE container showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product.

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

<b>250g canister</b>	Material	:	HDPE
	Height	:	187 mm
	Diameter	:	75 mm
	Capacity	:	250g (nominal)
	Opening	:	45 mm screw cap with induction heat seal, or compression wad plus tamper evidence
	Seals	:	Induction Heat Seal
<b>500g canister</b>	Material	:	HDPE
	Height	:	224 mm
	Diameter	:	92 mm
	Capacity	:	500g (nominal)
	Closure	:	63 mm screw cap with induction heat seal, or compression wad plus tamper evidence
	Seals	:	Induction Heat Seal
<b>1kg canister</b>	Material	:	HDPE
	Height	:	244 mm
	Length	:	158 mm
	Width	:	90 mm
	Capacity	:	1kg (nominal)
	Opening	:	63 mm screw cap with induction heat seal, or compression wad plus tamper evidence
<b>5kg canister</b>	Material	:	HDPE
	Size height	:	307 mm
	Length	:	237 mm
	Width	:	233 mm
	Capacity	:	5kg (nominal)
	Closure	:	85 mm screw cap with induction heat seal, or compression wad plus tamper evidence
<b>5kg canister</b>	Seals	:	Induction Heat Seal

The packaging for the product A18032E is in compliance with all relevant UN and ADR requirements.

Stability of the packaging material has been tested during the storage stability study done according to GIFAP monograph 17.

No significant adverse effects of the product to the stability of the packaging material have been noticed.

It is concluded the packaging material will be fully resistant to the product A18032E for up to two years under normal storage conditions. For details please see Appendix 4.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2 / 01	Adolph S.	2012	A18032E - Chemical characterization of batch SMU2BP001 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 124460 GLP not published Syngenta File No A18032E_10026	N	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, Munchwilen, Switzerland, 125711 Not GLP not published Syngenta File No A18032E_10034	N	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	SYN (ADAMA has LOA)
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, Munchwilen, Switzerland, 125030 GLP not published Syngenta File No A18032E_10028	N	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, Munchwilen, Switzerland, 10531055 Not GLP not published Syngenta File No A18032E_10033	N	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>Owner</b>
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, Munchwilen, Switzerland, 300045056 Not GLP not published Syngenta File No A18032E_10317	N	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	ADAMA
KCP 2.11 / 01	Kundel P.	2013a	A18032E - The Effectiveness of the Spray Tank Cleaning Procedure Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 125696 Not GLP not published Syngenta File No A18032E_10031	N	SYN (ADAMA has LOA)

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-



## **Appendix 2      Additional data on the physical, chemical and technical properties of the active substance**

No additional data have been generated on the active substances.

### Appendix 3 Content of active ingredients and properties before and after storage for two weeks at 54°C in HDPE packaging

#### Content of active ingredient before and after storage for two weeks at 54°C in HDPE packaging

Active Substance	Storage Conditions	Content of control sample	Content of test sample
mesotrione	Initial	15.6 %	- -
mesotrione	2 weeks below -10 °C	15.6 %	- -
mesotrione	2 weeks 54 °C	- -	15.0 %
dicamba	Initial	31.3 %	- -
dicamba	2 weeks below -10 °C	31.3 %	- -
dicamba	2 weeks 54 °C	- -	31.4 %
nicosulfuron	Initial	10.1 %	- -
nicosulfuron	2 weeks below -10 °C	10.1 %	- -
nicosulfuron	2 weeks 54 °C	- -	9.84 %

#### Observations and Conclusion

The values for mesotrione show 3.8 % relative decomposition after storage.

The values for dicamba are within the analytical error and show no decomposition after storage.

The values for nicosulfuron show 2.6 % relative decomposition after storage.

#### Physical and technical properties before and after storage for two weeks at 54°C in HDPE packaging

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
<b>Color</b>	Visual	beige	beige
<b>Odor</b>	Organoleptic	weak	weak
<b>Physical State</b>	Visual	solid	solid
<b>Appearance</b>	Visual	- - -	free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1 % Deionized Water at 25°C	CIPAC MT 75.3	4.5	4.6
<b>Dust Content</b>	CIPAC MT 171	1.3 mg	1.1 mg
<b>Wettability</b> CIPAC Water D	CIPAC MT 53.3	1 sec	3 sec
<b>Wet Sieve Test</b> Sieve Size: 75 µm	CIPAC MT 185	<0.01 %	<0.01 %
<b>Persistent Foaming</b> CIPAC Water D Waiting Period: 1 min. Concentration: 0.1 % w/v Concentration: 0.75 % w/v	CIPAC MT 47.2	30 ml 50 ml	36 ml 45 ml

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C
<b>Suspensibility</b> Concentration: 0.1 % w/v CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione dicamba nicosulfuron	CIPAC MT 184 (chemical assay)	97 % 100 % 92 %	98 % 100 % 88 %
<b>Suspensibility</b> Concentration: 0.75 % w/v CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione dicamba nicosulfuron	CIPAC MT 184 (chemical assay)	93 % 101 % 92 %	93 % 102 % 91 %
<b>Spontaneity of Dispersion</b> CIPAC Water D Temperature: 20 °C	CIPAC MT 174 (gravimetrically)	92 %	82 %
<b>Friability and Attrition</b>	CIPAC MT 178.2	100 %	100 %

### Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

### Packaging Evaluation after storage for two weeks at 54°C in HDPE packaging

Evaluation Criteria	Results after 2 weeks at 54 °C
Color change of the packaging	none
Odor (noticeable before opening the packaging)	none
Panelling of the test container	none
Ballooning of the test container	none
Pimples on the test container	none
Cracks in the test container	none
Tightness of the test container	tight
Reclosability of closure	reclosable
Tightness of closure	tight
Weight change (gross weight)	0.04 % weight loss

### Observations and Conclusion

The packaging material proved to be resistant to its content.

## Appendix 4 Content of active ingredients and properties before and after storage for two years at 20°C in HDPE packaging

### Content of active ingredient before and after storage for two years at 20°C in HDPE packaging

Active Ingredient	Initial	2 years below -10 °C (control sample)	2 years 20 °C (test sample)
mesotrione	156 g/kg	158 g/kg	157 g/kg
dicamba	313 g/kg	313 g/kg	312 g/kg
nicosulfuron	101 g/kg	99.9 g/kg	99.4 g/kg

### Observations and Conclusion

All the values are well within analytical error and show no decomposition.

### Physical and technical properties before and after storage for two years at 20°C in HDPE packaging

Test Description	Method	Initial Results	Results after 2 years 20 °C
<b>Color</b>	Visual	beige	beige
<b>Odor</b>	Organoleptic	weak	weak
<b>Physical State</b>	Visual	solid	solid
<b>Appearance</b>	Visual	- - -	free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1 % Deionized Water at 25°C	CIPAC MT 75.3	4.5	4.5
<b>Dust Content</b>	CIPAC MT 171	1.3 mg	0.4 mg
<b>Wet Sieve Test</b> Sieve Size: 75 µm	CIPAC MT 185	< 0.01 %	0.01 %
<b>Suspensibility</b> Concentration: 0.75 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione dicamba nicosulfuron	CIPAC MT 184 (chemical assay)	93 % 101 % 92 %	93 % 101 % 91 %
<b>Suspensibility</b> Concentration: 0.1 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. mesotrione dicamba nicosulfuron	CIPAC MT 184 (chemical assay)	97 % 100 % 92 %	98 % 100 % 93 %
<b>Spontaneity of Dispersion</b> CIPAC Water D Temperature: 20 °C	CIPAC MT 174 (gravimetrically)	92 %	90 %
<b>Friability and Attrition</b> Attrition Resistance	CIPAC MT 178.2	100 %	100 %

## Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

### Packaging Evaluation after storage for two years at 20°C in HDPE packaging

Evaluation Criteria	Results after 2 years 20 °C
Color change of the packaging	none
Odor (noticeable before opening the packaging)	none
Panelling of the test container	none
Ballooning of the test container	none
Pimples on the test container	none
Cracks in the test container	none
Tightness of the test container	tight
Reclosability of closure	reclosable
Tightness of closure	tight
Weight change (gross weight)	0.08 % weight gain

## Observations and Conclusion

The packaging material proved to be resistant to its content.