

# FINAL 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: A18385B

Product name: Spandis 54 WG

Chemical active substances:

Dicamba, 400 g/kg

Nicosulfuron, 100 g/kg

Prosulfuron, 40 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(new authorization)

Applicant: Syngenta

Submission date: 26/11/2020

MS Finalisation date: 19/12/2022

## Version history

When	What
February 2021	Dossier sent for evaluation
April 2022	zRMS evaluation of dRR
July 2022	Final version prepared by zRMS after Commenting period
December 2022	zRMS updated finalised evaluation

## Table of Contents

<b>1</b>	<b>Section 1: Identity of the plant protection product.....</b>	<b>4</b>
1.1	Applicant (KCP 1.1) .....	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2) .....	4
1.2.1	Producer(s) of the preparation .....	4
1.2.2	Producer(s) of the active substance(s) .....	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s) .....	4
1.2.3.1	Prosulfuron.....	4
1.2.3.2	Dicamba .....	4
1.2.3.3	Nicosulfuron .....	5
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3) .....	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4) .....	5
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	5
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	6
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	6
1.5	Type and code of the plant protection product (KCP 1.5) .....	6
1.6	Function (KCP 1.6) .....	6
<b>2</b>	<b>Section 2: Physical, chemical and technical properties of the plant protection product .....</b>	<b>7</b>
<b>3</b>	<b>Section 3 is presented as a separate document.....</b>	<b>20</b>
<b>4</b>	<b>Section 4: Further information on the plant protection product .....</b>	<b>22</b>
4.1	Packaging and Compatibility with the Preparation (KCP 4.4) .....	22
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>28</b>
<b>Appendix 2</b>	<b>Additional data on the physical, chemical and technical properties of the active substance.....</b>	<b>30</b>

**zRMS comments:**

The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance.

Following data gaps are identified: **none**

- ~~When adjuvant is used in combination with the PPP is in tank mixture as stated in the label, following ASTM E1518-05 test has to be done to confirm physical compatibility (with the target adjuvant /product – not with the whole group) . Please provide the information.~~

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

### **1.1 Applicant (KCP 1.1)**

See covering letter

### **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 substance(s)**

#### **1.2.3.1 Prosulfuron**

	<b>EU agreed minimum purity Reference: 2017/375</b>
<b>Prosulfuron</b>	min. 950 g/kg
Relevant impurity CGA159902	max. 10 g/kg

#### **Pure Prosulfuron in A18385B**

<b>content of pure active substance:</b>	<b>40 g/kg</b>	<b>4 % w/w</b>
limits:	36 – 44 g/kg	3.6 – 4.4 % w/w

#### **Technical Prosulfuron in A18385B**

<b>at the EU agreed minimum purity of technical active substance of 95.0 % w/w.</b>		
<b>content of technical active substance:</b>	<b>42.1 g/kg</b>	<b>4.21 % w/w</b>
limits:	37.9 – 46.3 g/kg	3.79 – 4.63% w/w

#### **1.2.3.2 Dicamba**

	<b>EU agreed minimum purity Reference: 2008/69</b>
<b>Dicamba</b>	850 g/kg

### Pure Dicamba in A18385B

content of pure active substance:	400 g/kg	40 % w/w
limits:	380 – 420 g/kg	38 – 42 % w/w

### Technical Dicamba in A18385B

at the EU agreed minimum purity of technical active substance of 85.0 % w/w.		
content of technical active substance:	471 g/kg	47.1 % w/w
limits:	447 – 495 g/kg	44.7 – 49.5% w/w

### 1.2.3.3 Nicosulfuron

	EU agreed minimum purity Reference: 2008/40
Nicosulfuron	910 g/kg

### Pure Nicosulfuron in A18385B

content of pure active substance:	100 g/kg	10 % w/w
limits:	90 – 110 g/kg	9 – 11.0 % w/w

### Technical Nicosulfuron in A18385B

at the EU agreed minimum purity of technical active substance of 91.0 % w/w.		
content of technical active substance:	110 g/kg	11 % w/w
limits:	99 – 121 g/kg	9.9 – 12.1% w/w

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

Trade names: Please refer to **Registration Report, Part A** for the relevant country  
SPANDIS

Company code number: A18385B

## 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 A18385B was not evaluated previously as the representative formulation during the EU review of prosulfuron, dicamba and nicosulfuron.

The content of prosulfuron, dicamba and nicosulfuron and in A18385B 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)**.

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

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

Type	Name/Code Number
ISO common name	Prosulfuron (CGA152005)
CAS No.	94125-34-5
EC No.	Not available
CIPAC No.	579

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

Type	Name/Code Number
ISO common name	Dicamba (SAN837)
CAS No.	1918-00-9
EC No.	217-635-6
CIPAC No.	85

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

Type	Name/Code Number
ISO common name	Nicosulfuron (ASF628)
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)

**Table 1.4-4: Information on co-formulant**

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

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

Type: (Water Dispersible Granules) [Code: WG]

## 1.6 Function (KCP 1.6)

Herbicide

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

The product A18385B is a water dispersible granule formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of brown solid with a weak odour. It is not explosive, has no oxidising properties and has a self-ignition temperature of 206°C. The pH in 1% aqueous dispersion is 7.7. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE bottles. Its technical characteristics are acceptable for a water dispersible granules formulation.

The intended concentration of use is 0.1% w/v – 0.25% w/v

Conditional approval on combined use of the PPP with Adigor 440 EC (Adigor adjuvant) oil-based adjuvant in tank mixture. Applicant has to provide the missing ASTM E1518-05 test in post registration.

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

Classification and labelling based on physical chemical properties of A18385B is not triggered according to criteria set out in Regulation (EC) 1272/2008.

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

None

### Compliance with FAO specifications:

The product A18385B complies with FAO specifications.

### Formulation used for tests

The product used in the tests submitted in Part B of this Dossier has the same composition as the one cited in Part C.

Where studies have been conducted GLP-certified laboratories have performed all tests using material from batch:

- SMU2BP004 containing a mean of 43.2 g/kg prosulfuron, 410.0 g/kg dicamba and 105 g/kg nicosulfuron (Dos Santos A.M., 2012, Syngenta File No A18385B\_10064).

Physical, chemical and technical properties of A18385B have not been evaluated as part of the EU review of prosulfuron, dicamba nor nicosulfuron. Therefore, all relevant data are provided.

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

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	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	Physical state: solid Colour: Brown Odour: weak odour	N	Fumeaux J., 2013 Syngenta File No. A18385B_10062	Accepted
Explosive properties (KCP 2.2.1)	Theoretical assessment	-	Not an explosive substance	Y	Jackson W.A., 2013 Syngenta File No A18385B_10059	Accepted
Oxidizing properties (KCP 2.2.2)	Theoretical assessment	-	Not an oxidising substance	Y	Jackson W.A., 2013 Syngenta File No A18385B_10059	Accepted
Flash point (KCP 2.3.1)	Not applicable as the product is not a liquid					
Flammability (KCP 2.3.2)	EEC A.10	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)	Not classified in terms of its burning characteristics	Y	Jackson W.A., 2013 Syngenta File No A18385B_10059	Accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No. SMU2BP004				
Self-heating (KCP 2.3.3)	EEC A.16	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	Relative Self-Ignition Temperature: $206 \pm 5$ °C	Y	Jackson W.A., 2013 Syngenta File No A18385B_10059	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	Alkalinity: 0.05 % (calculated as NaOH)	Y	Fumeaux J., 2013a Syngenta File No. A18385B_10067	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	1 % suspension in water : 7.7 1 % suspension in water with addition of 0.25 % v/v adjuvant <sup>1</sup> : 7.7 1 % suspension in water with addition of 0.75 % v/v adjuvant <sup>1</sup> : 7.7 <sup>1</sup> Adjuvant is A12127R: Mixture of fatty acid esters	Y	Fumeaux J., 2013a Syngenta File No. A18385B_10067	Accepted
Viscosity (KCP 2.5.1)	Not relevant since the formulation is a water dispersible granule					
Surface tension (KCP 2.5.2)	Not relevant since the formulation is a water dispersible granule					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Relative density (KCP 2.6.1)	Not relevant since the formulation is a water dispersible granule					
Bulk density (KCP 2.6.2)	CIPAC MT 186	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	- Pour density: 0.547 g/ml - Tap density: 0.618 g/ml	Y	Fumeaux J., 2013a Syngenta File No. A18385B_10067	Accepted
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3  AF-1047/1  Visual  CIPAC MT 75.3 CIPAC MT 178.2	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	The formulation is physically and chemically stable after storage for two weeks at 54°C in the following packaging materials: - High density polyethylene pack (HDPE) A shelf life of at least 2 years can be expected. <u>Result after 2 weeks at 54 °C:</u> <ul style="list-style-type: none"> <li>Active substance content: Prosulfuron: 41.4 g/kg Dicamba: 403 g/kg Nicosulfuron: 103 g/kg</li> <li>Colour: light brown</li> <li>Odour: weak</li> <li>Appearance: free flowing, no compaction, granule integrity unchanged</li> <li>pH of a 1% dispersion : 7.8</li> <li>Attrition resistance: 100 %</li> </ul>	N	Fumeaux J., 2013b Syngenta File No. A18385B_10061	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 53.3 CIPAC MT 185 CIPAC MT 47.2  CIPAC MT 171 CIPAC MT 184  CIPAC MT 174 -		<ul style="list-style-type: none"> <li>• Wettability: 3 sec.</li> <li>• Wet sieve residue. Sieve size 75 µm: &lt; 0.01 %</li> <li>• Persistent foaming:  Concentration 0.1 % in CIPAC water D: 0 ml after 1 minute  Concentration 0.25 % in CIPAC water D: 0 ml after 1 minute</li> <li>• Dust: 0.4 mg</li> <li>• Suspensibility:  Concentration 0.25 % in CIPAC water D, after 30 min, 30 °C  Prosulfuron: 100 %  Dicamba: 100 %  Nicosulfuron: 100 %  Concentration 0.1 % in CIPAC water D, after 30 min, 30 °C  Prosulfuron: 100 %  Dicamba: 100 %  Nicosulfuron: 100 %</li> <li>• Spontaneity of dispersion: 99 % in CIPAC water D, 20 °C</li> <li>• Significant changes of the packaging material(HDPE pack): None</li> </ul> Weight change of the packaging (HDPE pack) :			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			0.01 % weight loss			
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 relevant as the formulation is stable at 54 °C for two weeks.					
Effect of low temperatures on stability (KCP 2.7.4)	Not relevant since the formulation is a solid					
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Monograph 17  AF-1047/1	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	No relative decomposition of the active ingredients was found during storage. No significant changes of the physical and technical properties were found after storage.  During storage, the packaging material proved to be resistant to its content.  Based on this finding a shelf life of at least 2 years is assigned.  <u>Result after 2 years at 20 °C:</u> <ul style="list-style-type: none"> <li>Active substance content: Prosulfuron: 43.8 g/kg  Dicamba: 413 g/kg  Nicosulfuron: 207 g/kg </li> <li>Colour: brown</li> </ul>	N	Wochner, F. 2015  Syngenta File No. A18385B_10383	Accepted.  The packaging remained intact after storage. All physico-chemical parameters before and after storage are accepted. For full details please refer to the Table 2-2 below.  Summarising, the two-year shelf-life can be granted for the PPP.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Visual		<ul style="list-style-type: none"> <li>• Odour: weak</li> <li>• Appearance: free flowing, no compaction, granule integrity unchanged</li> <li>• pH 7.7</li> <li>• Dust content: 0.2 mg</li> <li>• Attrition resistance: 100 %</li> <li>• Wettability: 3 sec.</li> <li>• Wet sieve residue. Sieve size 75 µm: 0.03 %</li> <li>• Suspensibility: Concentration 0.25 % in CIPAC water D, after 30 min, 30 °C Prosulfuron: 101 % Dicamba: 100 % Nicosulfuron: 101 % Concentration 0.1 % in CIPAC water D, after 30 min, 30 °C Prosulfuron: 100 % Dicamba: 100 % Nicosulfuron: 100 %</li> </ul>			
	CIPAC MT 75.3					
	CIPAC MT 171					
	CIPAC MT 178.2					
	CIPAC MT 53.3					
	CIPAC MT 185					
	CIPAC MT 184					
	CIPAC MT 174		<ul style="list-style-type: none"> <li>• Spontaneity of dispersion: 98 % in CIPAC water D, 20 °C</li> <li>• Significant changes of the packaging material(HDPE pack): None</li> </ul>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	-		Weight change of the packaging (HDPE pack) : 0.09 % weight gain			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not relevant					
Wettability (KCP 2.8.1)	CIPAC MT 53.3	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	in CIPAC water D: 2 sec  in CIPAC water D with addition of 0.25 % v/v adjuvant <sup>1</sup> : 2 sec  in CIPAC water D with addition of 0.75 % v/v adjuvant <sup>1</sup> : 2 sec  <sup>1</sup> Adjuvant is A12127R: Mixture of fatty acid esters	N	Fumeaux J., 2013  Syngenta File No. A18385B_10062	Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	Concentration 0.1 % in CIPAC water D: after 10 s 0 ml after 1 min 0 ml after 3 min 0 ml after 12 min 0 ml  Concentration 0.25 % in CIPAC water D: after 10 s 0 ml after 1 min 0 ml after 3 min 0 ml after 12 min 0 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	N	Fumeaux J., 2013  Syngenta File No. A18385B_10062	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			after 12 min      0 ml Concentration 0.25% in CIPAC water D with addition of 0.75 % 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 A12127R: Mixture of fatty acid esters			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B) Batch No. SMU2BP004	<u>Gravimetrically</u> - 0.1 % in CIPAC water D at 30°C after 30 min: 92 % - 0.25 % in CIPAC water D at 30°C after 30 min: 98 % - 0.1 % in CIPAC water D with addition of 0.25 % v/v adjuvant <sup>1</sup> at 30°C after 30 min: 99 % - 0.25 % in CIPAC water D with addition of 0.75 % v/v adjuvant <sup>1</sup> at 30°C after 30 min: 92 % <sup>1</sup> Adjuvant is A12127R: Mixture of fatty acid esters <u>Chemical Assay</u> 0.1 % in CIPAC water D at 30°C after 30 min: - prosulfuron: 100 % - dicamba 99 % - nicosulfuron 100 % 0.25 % in CIPAC water D at 30°C after 30 min: - prosulfuron: 100 % - dicamba 100 %	N	Fumeaux J., 2013 Syngenta File No. A18385B_10062	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			- nicosulfuron 100 %			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B) Batch No. SMU2BP004	<u>Gravimetrically</u> in CIPAC water D: 98 % in CIPAC water D with addition of 0.25 % adjuvant <sup>1</sup> : 99 % in CIPAC water D with addition of 0.75 % adjuvant <sup>1</sup> : 98 % <sup>1</sup> Adjuvant is A12127R: Mixture of fatty acid esters	N	Fumeaux J., 2013 Syngenta File No. A18385B_10062	Accepted
Dispersion stability (KCP 2.8.3.3)	Not relevant since the formulation is a water dispersible granule					
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable as the product is not water soluble					
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B) Batch No. SMU2BP004	≥ 90 % was retained on the 1000 µm sieve ≤ 10 % was retained on the 250 µm sieve	Y	Fumeaux J., 2013a Syngenta File No. A18385B_10067	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron	Material retained on a 75 µm test sieve: In tap water: <0.01 %	N	Fumeaux J., 2013 Syngenta File No. A18385B_10062	Accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		WG (A18385B) Batch No. SMU2BP004	In tap water with addition of 0.25 % v/v of the adjuvant <sup>1</sup> : < 0.01 % In tap water with addition of 0.75 % v/v of the adjuvant <sup>1</sup> : < 0.01 % <sup>1</sup> Adjuvant is A12127R: Mixture of fatty acid esters			
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B) Batch No. SMU2BP004	Collected dust: 0.3 mg	Y	Fumeaux J., 2013a Syngenta File No. A18385B_10067	Accepted
Particle size of dust (KCP 2.8.5.2.2)			Not required because of low dust content (KCP 2.8.5.2.1)			
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B) Batch No. SMU2BP004	Attrition resistance: 100 % 4500 revolutions with a rotational speed of 75 to 125 rpm	N	Fumeaux J., 2013 Syngenta File No. A18385B_10062	Accepted
Hardness and integrity (KCP 2.8.5.4)	Not relevant since the formulation is a water dispersible granule					
Emulsifiability (KCP 2.8.6.1)	Not applicable as the product is not an emulsion					
Emulsion stability (KCP 2.8.6.2)	Not applicable as the product is not an emulsion					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	Not applicable as the product is not an emulsion					
Flowability (KCP 2.8.7.1)	CIPAC MT 172	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	The item dropped spontaneously through the 5mm test sieve.	N	Fumeaux J., 2013  Syngenta File No. A18385B_10062	Accepted
Pourability (KCP 2.8.7.2)	Not applicable as the product is not a suspension					
Dustability following accelerated storage (KCP 2.8.7.3)	Not applicable as the product is not a dustable powder					
Physical compatibility of tank mixes (KCP 2.9.1)	Not applicable					<p>Data Gap Accepted</p> <p>When adjuvant is used in combination with the PPP is in tank mixture as stated in the label, following ASTM E1518-05 test has to be done to confirm physical compatibility. It's a procedural requirement.</p> <p>Nevertheless, all the physicochemical tests were done using adjuvant A12127R</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						(Adigor). In Poland it is known as Adigor 440 EC. Taking into consideration the efficacy data conditional agreement for combined use of the PPP with Adigor 440 EC in tank mixture is accepted.  Yet, applicant is requested to provide the ASTM E1518-05 study to cover the requirements in post registration
Chemical compatibility of tank mixes (KCP 2.9.2)	Not applicable					
Adhesion to seeds (KCP 2.10.1)	Not applicable (not for seed treatment)					
Distribution to seed (KCP 2.10.2)	Not applicable (not for seed treatment)					
Other/special studies (KCP 2.11)  KCP 2.11/01 The effectiveness of cleaning procedures for the application equipment	-	40 g/kg prosulfuron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B) Batch No. SMU2BP004	After applying the cleaning procedure, less than 0.01 % prosulfuron, 0.01 % dicamba and 0.05 % nicosulfuron residues were found in the re-filled spray tank; the tank cleaning procedure is therefore deemed effective.	N	Fumeaux, J. 2013c Syngenta File No. A18385B_10060	Accepted
Other/special studies	-	40 g/kg prosulfu-	SMU2BP004 contains a mean of 43.2 g/kg prosul-	Y	Dos Santos A.M., 2012	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.11)  KCP 2.11/02 Chemical characterization (batch SEZ4BP001/1)		ron, 400 g/kg dicamba, 100 g/kg nicosulfuron WG (A18385B)  Batch No. SMU2BP004	furon, 410.0 g/kg dicamba and 105 g/kg nicosulfuron		Syngenta File No. A18385B_10064	

Table 2-2. The two-year study in HDPE

Test Description	Method	Initial Results	Results after 2 years 20 °C
<b>Color</b>	Visual	brown	brown
<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	CIPAC MT 75.3	7.7	7.7
<b>Dust Content</b>	CIPAC MT 171	0.3 mg	0.2 mg
<b>Wet Sieve Test</b> Sieve Size: 75 µm	CIPAC MT 185	< 0.01 %	0.03 %q
<b>Wettability</b> CIPAC Water D	CIPAC MT 53.3	2 sec.	3 sec.

<b>Suspensibility</b> Concentration: 0.25 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. prosulfuron dicamba nicosulfuron	CIPAC MT 184 (chemical assay)	100 % 100 % 100 %	101 % 100 % 101 %
<b>Suspensibility</b> Concentration: 0.1 % CIPAC Water D Temperature: 30 °C Waiting Period: 30 min. prosulfuron dicamba nicosulfuron	CIPAC MT 184 (chemical assay)	100 % 99 % 100 %	100 % 100 % 100 %
<b>Spontaneity of Dispersion</b> CIPAC Water D Tempera- ture: 20 °C	CIPAC MT 174 (gravimetrically)	98 %	98 %
<b>Friability and Attrition</b> Attrition Resistance	CIPAC MT 178.2	100 %	100 %

### 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

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

As part of the storage stability study, packs were examined to ensure that no significant interaction with the formulation, affecting the stability of the packaging material, had taken place during storage in HDPE bottles. The studies have been carried out according to GIFAP Monograph 17.

It can therefore be concluded that the packaging will be resistant to its contents for up to two years under normal storage conditions.

#### **RMS comment**

Taking into consideration the two-year storage stability study in all the packs presented below are accepted for this WG formulation in Poland.

#### **Packing for product marketed by Syngenta:**

**Table 4.1-1: Packaging information for 50 g HDPE canister**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	Diameter 48mm x Height 106mm
Opening:	50 g
Closure:	Screw cap closure (36 mm diameter) with compression wad and tamper evident ring
Seal:	See above
Manner of construction	-
UN/ADR	Compliant

**Table 4.1-2: Packaging information for 100 g HDPE canister**

Type	Description
Material:	HDPE
Shape/size:	Diameter 62mm x Height 128mm
Opening:	-
Closure:	Screw cap closure (45 mm diameter) with compression wad and tamper evident ring
Seal:	See above
Manner of construction	-
UN/ADR	Compliant

**Table 4.1-3: Packaging information for 250 g HDPE canister**

Type	Description
Material:	HDPE
Shape/size:	Diameter 75mm x Height 187mm
Opening:	-
Closure:	Screw cap closure (45 mm diameter) with compression wad and tamper evident ring
Seal:	See above
Manner of construction	-

Type	Description
UN/ADR	Compliant

**Table 4.1-4: Packaging information for 0.5 kg HDPE canister**

Type	Description
Material:	HDPE
Shape/size:	Diameter 92mm x Height 224mm
Opening:	-
Closure:	Screw cap closure (63 mm diameter) with compression wad and tamper evident ring
Seal:	See above
Manner of construction	-
UN/ADR	Compliant

**Table 4.1-5: Packaging information for 1 kg HDPE canister**

Type	Description
Material:	HDPE
Shape/size:	158mm x 90mm x 244mm (Length x Width x Height)
Opening:	-
Closure:	Screw cap closure (63 mm diameter) with compression wad and tamper evident ring
Seal:	See above
Manner of construction	-
UN/ADR	Compliant

**Table 4.1-6: Packaging information for 5 kg HDPE canister**

Type	Description
Material:	HDPE
Shape/size:	237mm x 233mm x 307mm (Length x Width x Height)
Opening:	-
Closure:	Screw cap closure (85 mm diameter) with compression wad and tamper evident ring
Seal:	See above
Manner of construction	-
UN/ADR	Compliant

**Table 4.1-7: Packaging information for 10 kg HDPE canister**

Type	Description
Material:	HDPE
Shape/size:	239mm x 235mm x 491mm (Length x Width x Height)
Opening:	-
Closure:	Screw cap closure (85 mm diameter) with compression wad and tamper evident ring
Seal:	See above

Type	Description
Manner of construction	-
UN/ADR	Compliant

**Packing for product marketed by Cheminova:**

**Table 4.1-8: Packaging information for 500 g plastic bottle**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle. Capacity (nominal) 1L rectangular bottle. 70 x 85 x 234.5 mm
Opening:	42 mm
Closure:	Screw cap closure, 50 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-9: Packaging information for 500 g plastic bottle**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle. Capacity (nominal) 1L External diameter: 65-100 mm, normal 89 mm Overall height: 200-260 mm, normal 234 mm
Opening:	32-42-48-54.7 mm, normal 42 mm
Closure:	Screw cap closure, 40-50-60-63 mm, normal 50 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-10: Packaging information for 1 kg plastic bottle**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 2L 190-250 mm (height) 100-140 (depth) 90-130 (width)
Opening:	42-48-54.7-68.5 mm
Closure:	Screw cap closure, 50-60-63-80 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant



**Table 4.1-11: Packaging information for 1 kg plastic bottle**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 2 L External diameter (possible slow rectangular): 65-180 mm, normal 108 mm Overall height: 200-260 mm, normal 209 mm
Opening:	42-48-54,7-68.5 mm
Closure:	Screw cap closure, 50-60-63-80 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-12: Packaging information for 1 kg plastic bottle**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 2.5 L 245-260 mm (height, bottom – neck rim) normal 255 mm 130-150 (depth), normal 140 mm 85-100 (width), normal 94 mm
Opening:	42-48-54,7 mm, normal 54,7 mm
Closure:	Screw cap closure, 50-60-63 mm, normal 63 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-13: Packaging information for 1.8 kg and 2 kg plastic bottles**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 4 L 260-300 mm (height), normal 255 mm 130-160 mm (depth), normal 142 mm 130-160 mm (width), normal 142 mm
Opening:	42-48-54,7-ca.67 mm, normal 54,7 mm and ca. 67 mm
Closure:	Screw cap closure, 50-60-63-80 mm, normal 63 mm and 80 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-14: Packaging information for 2 kg and 2.4 kg plastic bottles**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 5 L 260-350 mm (height), normal 298 mm

Type	Description
	170-210 mm (depth), normal 193 mm 120-160 mm (width), normal 142 mm
Opening:	42-48-54.7-ca.67 mm, normal 54.7 mm
Closure:	Screw cap closure, 50-60-63-80 mm, normal 63 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-15: Packaging information for 3 kg plastic bottle**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE, PET
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 6 L 270-340 mm (height), normal 298 mm 140-190 mm (depth), normal 170 mm 140-190 mm (width), normal 170 mm
Opening:	42-48-54.7-ca.67 mm, normal 54.7 and ca. 67 mm
Closure:	Screw cap closure, 50-60-63-80 mm, normal 63 mm and 80 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-16: Packaging information for 4.8 kg and 5 kg plastic bottles**

Type	Description
Material:	HDPE, COEX HDPE/PA, fluorinated HDPE
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 10 L 310-400 mm (height), normal 371 mm 190-260 mm (depth), normal 240 mm 150-200 mm (width), normal 179 mm
Opening:	42-48-54.7-ca.67 mm, normal 54.7
Closure:	Screw cap closure, 50-60-63-80 mm, normal 63 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

**Table 4.1-17: Packaging information for 9.6 kg and 10 kg plastic bottle**

Type	Description
Material:	HDPE, HDPE/PA, fluorinated HDPE
Shape/size:	Blow moulded plastics bottle or can. Capacity (nominal) 20 L 350-450 mm (height), normal 386 mm 250-320 mm (depth), normal 292 mm 180-270 mm (width), normal 247 mm

Type	Description
Opening:	42-48-54.7-ca.67 mm, normal 48.0 mm
Closure:	Screw cap closure, 50-61-63-80 mm
Seal:	-
Manner of construction	Blow moulded
UN/ADR	Compliant

## 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 2.1 / 01 & KCP 2.8.1 / 01 & KCP 2.8.2 / 01 & KCP 2.8.3 / 01 & KCP 2.8.5.1 / 02 & KCP 2.8.5.2 / 02 & KCP 2.8.7 / 01	Fumeaux J.	2013	A18385B - Technical Properties of Batch SMU2BP004 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 125738 Not GLP not published Syngenta File No A18385B_10062; VV-406869	N	Syngenta
KCP 2.2 / 01 & KCP 2.3 / 01	Jackson W.	2013	A18385B - Safety Study Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT12/584 GLP not published Syngenta File No A18385B_10059; VV-406760	N	Syngenta
KCP 2.4 / 01 & KCP 2.6 / 01 & KCP 2.8.5.1 / 01 & KCP 2.8.5.2 / 01	Fumeaux J.	2013a	A18385B - Physical properties of batch SMU2BP004 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 10526086 GLP not published Syngenta File No A18385B_10067; VV-406871	N	Syngenta

<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 / 01	Fumeaux J.	2013b	A18385B - Storage Stability and Shelf Life Statement (2 Weeks 54-C) in Packaging Made of HDPE according to CIPAC MT 46.3 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 300009718 Not GLP not published Syngenta File No A18385B_10061; VV-406868	N	Syngenta
KCP 2.7 / 02	Wochner F.	2015	A18385B - Storage Stability and Shelf Life Statement (2 Years 20 -C) in Packaging Made of HDPE Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 300046482 Not GLP not published Syngenta File No A18385B_10383; VV-413978	N	Syngenta
KCP 2.11 / 01	Fumeaux J.	2013c	A18385B - The Effectiveness of the Spray Tank Cleaning Procedure Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 126304 Not GLP not published Syngenta File No A18385B_10060; VV-406761	N	Syngenta
KCP 2.11 / 02	Dos Santos A-M.	2012	A18385B - Chemical Characterization of Batch SMU2BP004 Syngenta Syngenta Crop Protection, Munchwilen, Switzerland, 10498610 GLP not published Syngenta File No A18385B_10064; VV-406870	N	Syngenta

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

No additional data on the physical, chemical and technical properties of the active substance are submitted.